Re: [EXTERNAL] Re: Public launch of Google/Apple Exposure Notifications API on Wed., May 20

From: Yul Kwon (b) (6)

To: "Koizumi, Kei EOP/OSTP" (b) (6)

Date: Fri, 22 Jan 2021 14:37:53 -0500

Kei!

It's so good to hear from you! My gosh, it's been like ... I don't know many years, but it's been way too long. First, congratulations on rejoining the Administration, I'm super excited for you and super excited for OSTP. Second, I'd love to catch up on our own (and if you'd like, I'd be happy to give you context on the Exposure Notifications stuff, or we can punt that for another day).

I know you must be swamped, but let me know if you'd be up for a call/video meet sometime. I think you already have my cell, but just in case, it's (b) (6)

I wish you the best of luck as you settle in -- OSTP is lucky to have you back. I'm looking forward to reconnecting!

Yul

On Fri, Jan 22, 2021 at 6:15 AM Koizumi, Kei EOP/OSTP (b) (6) wrote:

> Yul, Hi there! Good morning! Sorry for barging into the conversation but now that I am the Chief of Staff and Acting Director of OSTP, Eric's new federal home, I have to tell you that Dr. Lander will not be able to meet with you about your topic nor talk about this Administration's S&T priorities until after he is confirmed by the Senate. I hope that will be soon. I hope you're well and safe. I am, back again in Washington, DC, after a year away. I hope we can catch up soon.

Kei

Kei Koizumi
(he/him)

Acting Director and Chief of Staff

Office of Science and Technology Policy

(b) (6)

Begin forwarded message:

From: Yul Kwon (b) (6)

Subject: Re: Public launch of Google/Apple Exposure Notifications API on Wed., May 20

Date: January 21, 2021 at 10:56:37 PM EST

To: Eric S Lander (b) (6)

Eric,

I want to express how excited I was to hear the news that you'll be President Biden's Science Advisor -- congratulations! I worked closely with OSTP many years ago when I was Senator Joe Lieberman's legislative aide on S&T issues, and I'm deeply gratified to see the new Administration elevate S&T as a national priority.

I also wanted to thank you for your early support for the Exposure Notification technology that Google and Apple developed to help curb the spread of COVID-19. It's been a long road, but over 30 countries have now launched Exposure Notification apps, and 21 U.S. states have done so as well, including California, New York, Pennsylvania, Virginia, and

Washington, DC. We're seeing promising evidence that this technology is working -- it's proving to be an effective tool in augmenting traditional contact tracing efforts without compromising user privacy.

As you transition into your new role, I was wondering if you would be open to discussing how the Administration could potentially leverage this tool in the fight against the virus. Notwithstanding significant interest from states, the prior Administration had no interest in assessing this technology or helping states leverage it themselves. The absence of federal leadership has hampered adoption on a national level, as states have had to shoulder the burden of deploying the technology and encouraging their citizens to adopt it.

The good news is that quite a few states have successfully launched Exposure Notification apps on their own (California has had over 25% of adults opt-in, while over 50% of Washington DC's entire population has opt-in). Nonetheless, it's clear that overall adoption in the US will continue to lag in the absence of any federal messaging and guidance. Given that the technology already exists and is currently available to 60% of all Americans, we believe that simply encouraging people to use the technology is one step the Administration could take that would have broad, immediate impact for little cost.

My colleagues and I would love to give you an update and discuss whether there might be an opportunity to explore this further. Apart from Exposure Notifications, we'd also be excited to chat with you about a number of areas we've been investing in, including artificial intelligence, quantum computing, internet connectivity and radio spectrum, and the reduction of carbon emissions. We're thrilled by the Administration's laser focus on the pandemic and its broader support for S&T issues, and we want to do whatever we can to help.

Thanks again, and congratulations!

Yul

On Mon, May 18, 2020 at 12:50 PM Yul Kwon (b) (6) wrote:

Hi Eric,

No worries at all, I completely understand. We appreciate your continued nudging in the background and would love your support when Massachusetts launches an app (which I hope will be not too far away :)

Thanks.

Yul

On Mon, May 18, 2020 at 5:10 AM Eric S Lander (b) (6) wrote:

Yul:

In principle, I would be glad to, as I am hugely supportive.

In practice, however, I think I may be more effective in nudging along Massachusetts if I'm not out there publicly endorsing the API until Massachusetts has come on board.

Would that be OK?

Best,

Eric

BROAD INSTITUTE

Eric Lander

President and Director

415 Main Street

Cambridge MA 02142

(b) (6)

On May 17, 2020, at 10:43 PM, Yul Kwon (b) (6) > wrote:

Eric,

We're planning to publicly launch our Exposure Notifications API this Wednesday, which means that contact tracing apps will be able to start using the API once they've been reviewed and approved for compliance with our requirements. We're still hoping that an app for Massachusetts will be developed soon (things are definitely moving forward), but in the meantime, we expect that apps from several countries and a couple of states will start using the API within the next few weeks.

We'll be holding a press briefing (background only) on Wednesday and are hoping to share a sense of the breadth of organizations and experts we've engaged with over the last few weeks. To that end, would you be open to any one or more of the following:

1. Letting us share that we've solicited feedback from you and the Broad Institute about our exposure notifications effort?
2. Sharing your name and contact information to reporters who may want to reach out to third-parties for additional perspectives on this effort?
3. Providing a quote or brief statement of support/encouragement that we can share with press? We'd be happy with any statement you'd feel comfortable giving, even if it's just acknowledging our willingness to engage with experts such as yourself.

Please don't feel any pressure at all, you've already been tremendously helpful and we're grateful for continued support behind the scenes.

Thanks!

Yul

[EXTERNAL] Communications Requests for Eric Lander

From: Megan Mandosa-Hayes (b) (6)

To: "Koizumi, Kei EOP/OSTP" (b) (6)

Date: Thu, 28 Jan 2021 18:01:24 -0500

Hi,

We got two communications related requests for Eric today that I wanted to pass along.

- **Invitation to Speak on EverythingALS Platform from Lisa Deegan**
  (b) (6) >: My name is Lisa Deegan, I am a co-founder in charge of strategic partnerships for a grassroots organization called EverythingALS.org. (b) (6) and all of our team members have been affected by ALS as well.

  I know that Eric Lander (b) (6) and was wondering if any of his work with The Human Genome Project and The Brode Institute have involved any research on ALS, especially involving CRISPR.

  Our organization also collaborates with MIT, Johns Hopkins, Mass General Harvard, IBM and several start ups. We have an IRB voice project with 1000 participants that we share data on. We host bi-monthly webinars to educate our 2000+ ALS patient and caregiver community. If Eric has any research he can share with us please contact me. I heard his podcast on Armchair Expert and loved it!

  Here is a video of one of our webinars with Dr. Richard Bedlack from Duke:
  >https://www.youtube.com/watch?v=Lhs4T5NhdUc&t=3s<

- **Association of Government Health and Environmental Scientists from Jim Laurenson** (b) (6) >: We would like to invite Dr Lander to a webinar where our group, and possibly partnering with other similar groups, will explore the goals of this new administration with regard to government health and environmental science, and in particular how we can help. We understand that Dr Lander is going to be more than busy in the coming months, so perhaps he could at least give a 10 or so minute intro, and or provide a deputy who could get into the weeds with us during the webinar. Thanks!

Let me know if you have any questions! Thank you!

Megan

--

Megan Mandosa-Hayes
Senior Administrative Assistant
Broad Institute of MIT and Harvard
75 Ames Street, Cambridge, MA 02142
(b) (6)
(b) (6)
Pronouns: she/her



RE: [EXTERNAL] my thoughts on the process/questions

From: Jonathan Gruber (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Cc: "Zarrelli, Kristen M. EOP/OSTP" <(b) (6)

Date: Thu, 04 Feb 2021 12:20:07 -0500

Eric –

It is my pleasure. I would be delighted to serve as a sounding board in any way as you flesh out how to approach the assignment. Call on me anytime! Its time for the long-overdue marriage between science and economics.

Best

Jon

Jonathan Gruber
Ford Professor of Economics
MIT Department of Economics
50 Memorial Drive, E52-434
Cambridge, MA 02142
phone (b) (6)
fax: 617-253-1330
e-mail: (b) (6)
web: >http://econ-www.mit.edu/faculty/gruberj/<
>https://www.jump-startingamerica.com/<

From: Lander, Eric S. EOP/OSTP [mailto(b) (6)

Sent: Thursday, February 4, 2021 12:17 PM

To: Jonathan Gruber (b) (6)

Cc: Zarrelli, Kristen M. EOP/OSTP (b) (6) >

Subject: Re: [EXTERNAL] my thoughts on the process/questions

Jon:

Thanks for this input!

I'm just starting to think about how best to approach the President's assignment, to ensure that we get the broadest range of engagement.

So, I really appreciate your taking the time to lay out your thoughts.

Best,
Eric

From: Jonathan Gruber (b) (6)

Date: Thursday, February 4, 2021 at 9:17 AM

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Subject: [EXTERNAL] my thoughts on the process/questions

Eric –

Thanks again for talking this past weekend. I am thrilled to help you design a process that leads to a report that experts will be citing 75 years from now!

Attached is a memo that lays out my thoughts on process (which largely mirror yours), membership, and topics.

I would be delighted to discuss this further at your convenience

Best

Jon

Jonathan Gruber
Ford Professor of Economics
MIT Department of Economics
50 Memorial Drive, E52-434
Cambridge, MA 02142
phone (b) (6)
fax: 617-253-1330
e-mail: (b) (6)
web: >>http://econ-www.mit.edu/faculty/gruberj/<<;
>>https://www.jump-startingamerica.com/<<;

[EXTERNAL] Table

From: Eric S Lander (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Date: Fri, 05 Feb 2021 09:57:38 -0500

Attachments: Lander.xlsx (11.22 kB)

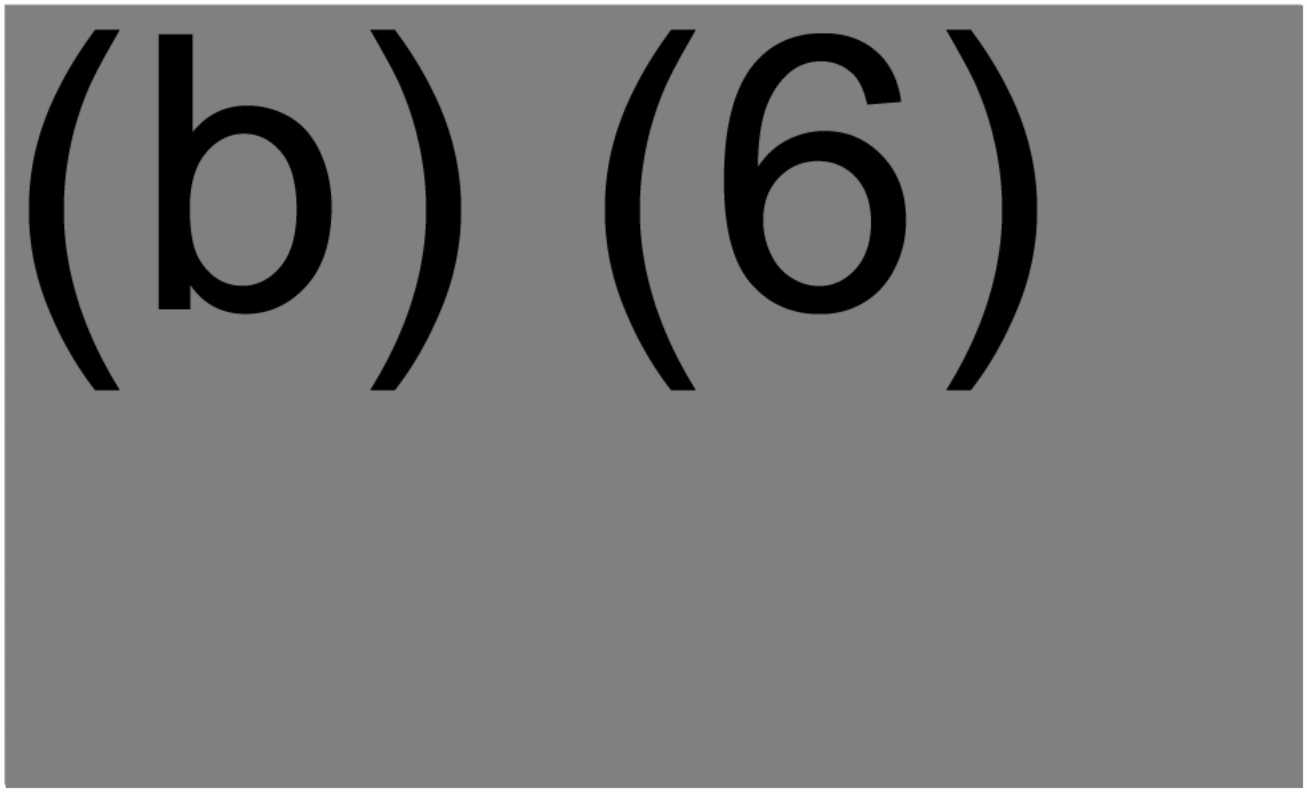
Begin forwarded message:

From: Sascha Rosebush (b) (6)

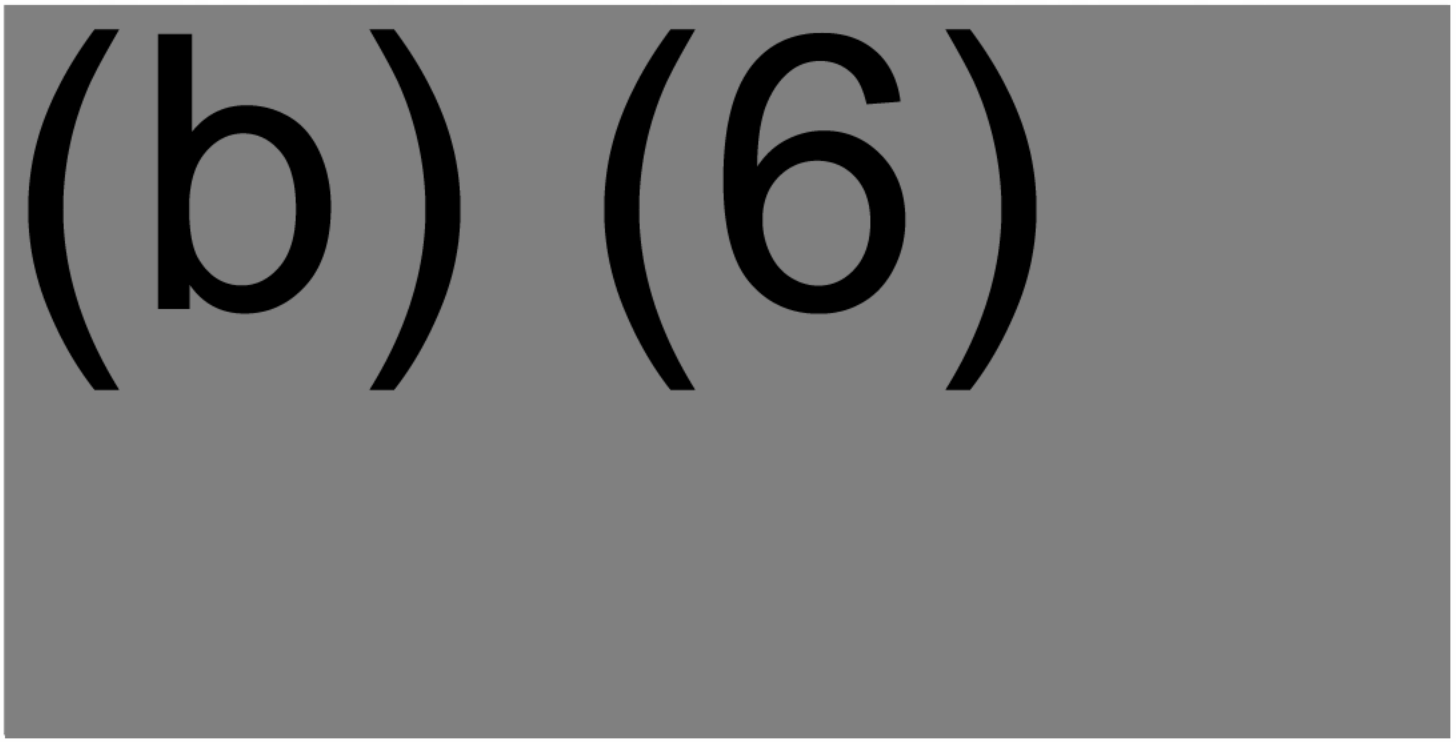
Subject: RE: Important: Can we talk this morning?

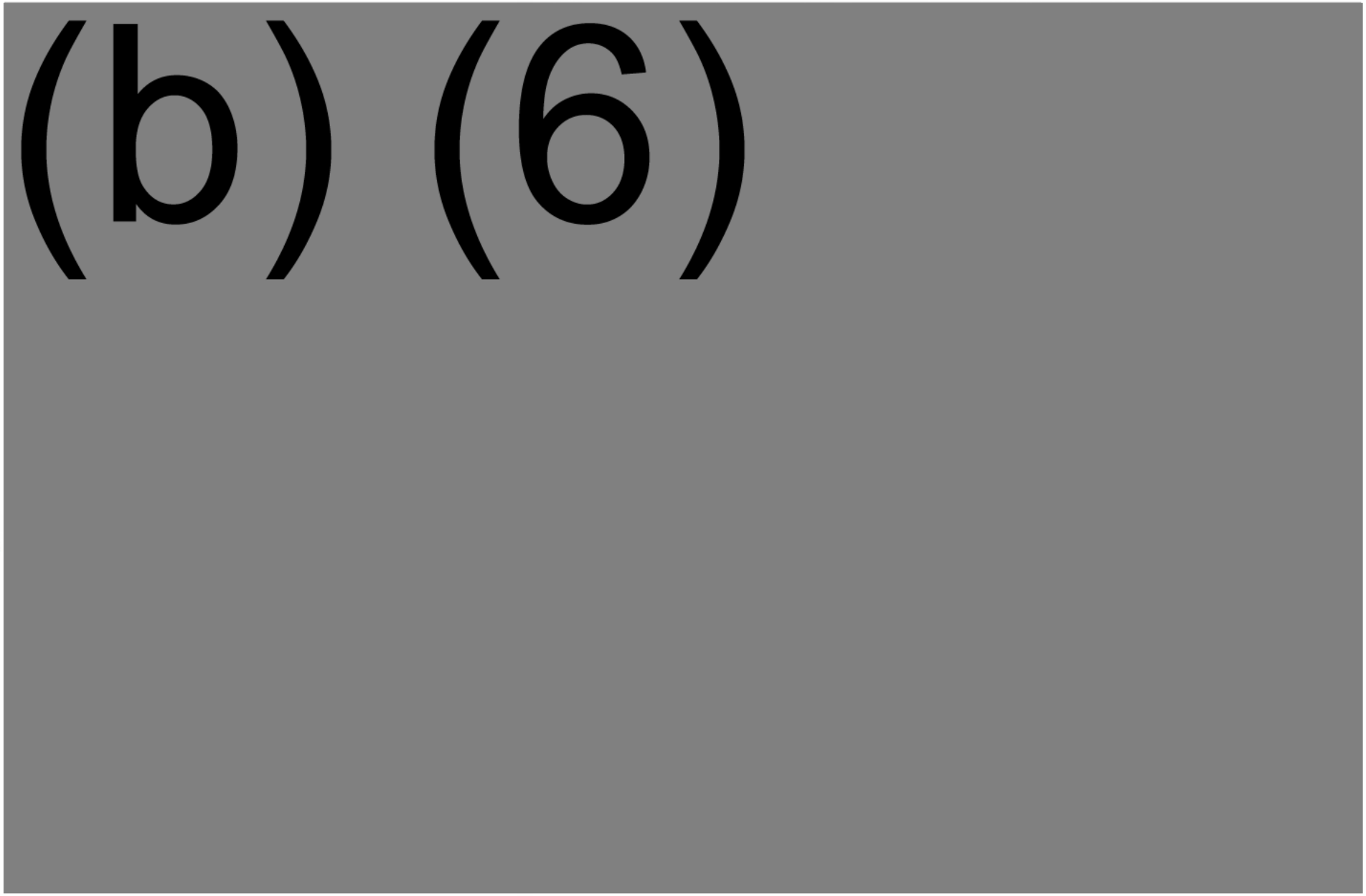
Date: February 5, 2021 at 9:25:12 AM EST

To: Eric S Lander (b) (6)


(b) (6)

(b) (6)


(b) (6)


(b) (6)

[EXTERNAL] Re: Introductions

From: Eric S Lander (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Date: Sat, 13 Feb 2021 11:29:40 -0500

Forwarding to my OSTP account.

On Mon, Feb 8, 2021 at 12:29 PM Michael Wagner (b) (6) > wrote:

Rochelle and Eric,
I would like to introduce you to Dr. Chris Witty, Chief Medical Officer for the United Kingdom. I had the great opportunity to meet Dr. Whitty and in your new roles with the Biden administration I thought you all being introduced might help to accelerate opportunities for collaboration between the US and the UK.
Dr. Whitty,
As mentioned in my previous email, Rochelle and Eric have taken on key roles in the Biden administration - Rochelle is heading up the CDC and Eric is the Science Advisor on President Biden's Cabinet. Both are incredible public servants and experts - we are very fortunate to have them in these roles.
Hope you all have a chance to connect,
Mike

Michael Wagner, MD FACP

Chief Physician Executive

Wellforce

Boston MA

From: Chris Whitty (b) (6)

Sent: Sunday, February 7, 2021 3:51 PM

To: Michael Wagner (b) (6)

Cc: Whitty, Chris (b) (6)

Subject: RE: Introductions

EXTERNAL EMAIL - Treat Links and Files with Caution

Dear Michael

Many thanks for reaching out, and apologies for the delay, I only check this email intermittently.

It would be great to have the introduction. I am ccing my government address as that is the best one to use.

Very many thanks again, really appreciated.

Best wishes

Chris

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--



Eric Lander

Founding Director, Broad Institute of MIT and Harvard (on leave)

415 Main Street

Cambridge MA 02142

(b) (6)

[EXTERNAL] Clean energy innovation ideas for the next recovery bill

From: Doug Rand (b) (6)

To: "Koizumi, Kei EOP/OSTP" (b) (6)

Date: Tue, 16 Feb 2021 21:49:07 -0500

Hi Kei,

I hope you're staying healthy and sane with your three big hats on!

Something tells me that with a quasi-SOTU speech coming up, plus a FY22 budget reconciliation opportunity, there must be a lot of ideas floating around.

Just in case OSTP is looking for a menu of legislative provisions that would help clean energy startups, I wrote a paper!
https://www.thirdway.org/memo/rescue-rebuild-and-reinvest-how-to-save-clean-energy-startups

Happy to drill down on any of this, at any time.

Take care,
Doug

Doug Rand
Senior Fellow
Federation of American Scientists
(b) (6)
Bio / LinkedIn / Twitter

RE: [EXTERNAL] Office of Eric Schmidt (Dinner Feb 22)

To: ES Team <(b) (6)

Date: Fri, 19 Feb 2021 17:47:43 -0500

Hi Tracy,

Address (b) (6)

Kevin Lo *(he/him)*
Special Assistant
Office of Science and Technology Policy
Executive Office of the President
(b) (6)
Cell: (b) (6)

From: ES Team(b) (6) >
Sent: Friday, February 19, 2021 1:51 PM
To: Lo, Kevin C. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] Office of Eric Schmidt (Dinner Feb 22)

7:30pm next Mon., Feb 22 confirmed. Let me know best address.

Eric Schmidt - no seafood

Michelle Ritter - no pork

On Wed, Feb 17, 2021 at 6:22 PM Lo, Kevin C. EOP/OSTP <(b) (6) wrote:

> Sounds good!
>
> Kevin Lo *(he/him)*
> Special Assistant
> Office of Science and Technology Policy
> Executive Office of the President
> (b) (6)

Cell: (b) (6)

From: ES Team <(b) (6)
Sent: Wednesday, February 17, 2021 6:05 PM
To: Lo, Kevin C. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] Office of Eric Schmidt (Dinner Feb 22)

Wow, thanks for taking care of restaurant! :-)

Eric will probably be bringing another person, so reservation for 3 please.

On Wed, Feb 17, 2021 at 5:58 PM Lo, Kevin C. EOP/OSTP (b) (6) > wrote:

> I'll circle back tomorrow with restaurant/location! And noted.
>
> Thanks so much,
> Kevin
>
> Kevin Lo *(he/him)*
> Special Assistant
> Office of Science and Technology Policy
> Executive Office of the President
> (b) (6)
> Cell (b) (6)
>
> **From:** ES Team (b) (6) >
> **Sent:** Wednesday, February 17, 2021 5:45 PM
> **To:** Lo, Kevin C. EOP/OSTP (b) (6)
> **Subject:** Re: [EXTERNAL] Office of Eric Schmidt (Dinner Feb 22)
>
> Hi Kevin,
>
> I think I can get Eric S to DC in time for a 7:30pm EST dinner next Mon., Feb 22. He'll be flying into IAD.
>
> Can you recommend a restaurant or location to meet? I'll be booking him a hotel in DC.

By the way, my cell is (b) (6) in case of any last minute changes.

Thank you,
Tracy

On Wed, Feb 17, 2021 at 12:24 PM Lo, Kevin C. EOP/OSTP (b) (6) wrote:

> Yup, done!
>
> Kevin Lo *(he/him)*
> Special Assistant
> Office of Science and Technology Policy
> Executive Office of the President
> (b) (6)
> Cell: (b) (6)
>
> **From:** ES Team (b) (6)
> **Sent:** Wednesday, February 17, 2021 12:05 PM
> **To:** Lo, Kevin C. EOP/OSTP (b) (6)
> **Subject:** Re: [EXTERNAL] Office of Eric Schmidt (Dinner Feb 22)
>
> Great! Can you block in his calendar for now until I can work on logistics on my end?
>
> On Wed, Feb 17, 2021 at 11:52 AM Lo, Kevin C. EOP/OSTP (b) (6) wrote:
>
> > Hi Tracy,
> >
> > Eric L. would be happy to meet for dinner. He should be available starting at 6:45pm et. Please let me know when you have more information and I'll pass along.
> >
> > Thanks so much,
> > Kevin
> >
> > Kevin Lo *(he/him)*
> > Special Assistant
> > Office of Science and Technology Policy

Executive Office of the President
(b) (6)
Cell: (b) (6)

From: Lo, Kevin C. EOP/OSTP
Sent: Tuesday, February 16, 2021 6:16 PM
To: 'ES Team' (b) (6)
Subject: RE: [EXTERNAL] Office of Eric Schmidt (Dinner Feb 22)

Hi Tracy,

Thanks so much for reaching out. I'll circle back tomorrow and let you know!

Best,
Kevin

Kevin Lo *(he/him)*
Special Assistant
Office of Science and Technology Policy
Executive Office of the President
(b) (6)
Cell: (b) (6)

From: ES Team (b) (6)
Sent: Tuesday, February 16, 2021 6:10 PM
To: Lo, Kevin C. EOP/OSTP (b) (6)
Subject: [EXTERNAL] Office of Eric Schmidt (Dinner Feb 22)

Hi Kevin,

First and foremost, nice to "meet" you.

Eric Schmidt, whom Dr. Lander knows as a friend and through the Broad Institute, may be in DC the evening of Monday, February 22 and wondered if Dr. Lander might be available for dinner anytime after 6:30pm ET?

Thank you,

Tracy

[EXTERNAL] update on ancient DNA ethics / a suggestion

From: "Reich, David Emil" (b) (6)

To: eric (b) (6) Eric S Lander (b) (6), "Lander, Eric S. EOP/OSTP" (b) (6) >

Date: Fri, 19 Feb 2021 19:31:52 -0500

Attachments: 2-19-21_AncientDNAEthics for Eric.docx (54.94 kB); (b)(6) PII -cv-3 pages 20210119.docx (49.96 kB)

Eric:
I'm writing first of all to thank you for the advice you gave me in September about how to handle the ongoing discussions about ancient DNA ethics. Following that call (in November) we organized a Zoom conference with 69 people from 24 countries, and we have now followed that by drafting an article signed by all those participants. The article makes clear that North American-specific perspective are valuable but not fully generalizable to international contexts, and suggests a more general set of principles. I attach the final version.
On another matter, I wanted to ask if you are looking to recruit people with deep background in both science and public service to your team in Washington. If so, I wanted to let you know about the strong interest in such a position (b)(6) PII He is also deeply interested in public service, (b)(6) PII When he heard about the Biden administrator's new science team, he wrote to (b)(6) PII) asking whether there would be a possibility of him being detailed to the Office of Science and Technology Policy, and Francis was positive in principle. (b)(6) PII a topic about which he is passionate and in which he has had great success in the past years. In addition to forwarding the thread, I attach his CV.
Yours,
David

***

On Sep 13, 2020, at 3:22 PM, Eric S Lander (b) (6) wrote:

David

I'm in New Hampshire and our internet went out. (Very rare occurrence!)

Could you call my cell (b) (6)

Thanks
Eric

Sent from my iPhone
***

From: Francis Collins <collinsf@od.nih.gov>

Date: Wednesday, January 20, 2021 at 6:46 AM

To: "(b)(6) PII

Subject: RE: Congratulations and request

Hi Danny,

Thanks for your note, it's a privilege to be able to continue as NIH Director with the new administration.

With Eric Lander's arrival (though he will have to be confirmed by the Senate, which might take a while), OSTP is likely to be a much more interesting place. I've had a couple of preliminary discussions with Eric about possible NIII details to fill out his scientific staff, but the exact skill sets he is looking for have not quite emerged yet. I take note of your interest with enthusiasm! Let's see how this evolves over the next few weeks.

All the best, Francis

(b)(6) PII

From: (b)(6) PII

Sent: Tuesday, January 19, 2021 9:38 AM

To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>

Subject: Congratulations and request

Dear Francis,

Congratulations on your reappointment and thank you for your exemplary leadership, particularly during COVID-19.

Following Saturday's announcement of the incoming administration's centering of science in its policymaking, I'm writing to express my interest in discussing with you the possibility of a detail to the White House Office of Science and Technology Policy.

I'm particularly interested in developing policy to expand public-private partnerships, in which I have long believed deeply — a belief cemented through observation of COVID-related initiatives like ACTIV. Such an expansion also seems to me a critical component of successfully meeting the 5 challenges outlined in President-Elect Biden's letter.

I bring to the table:

(b)(6) PII

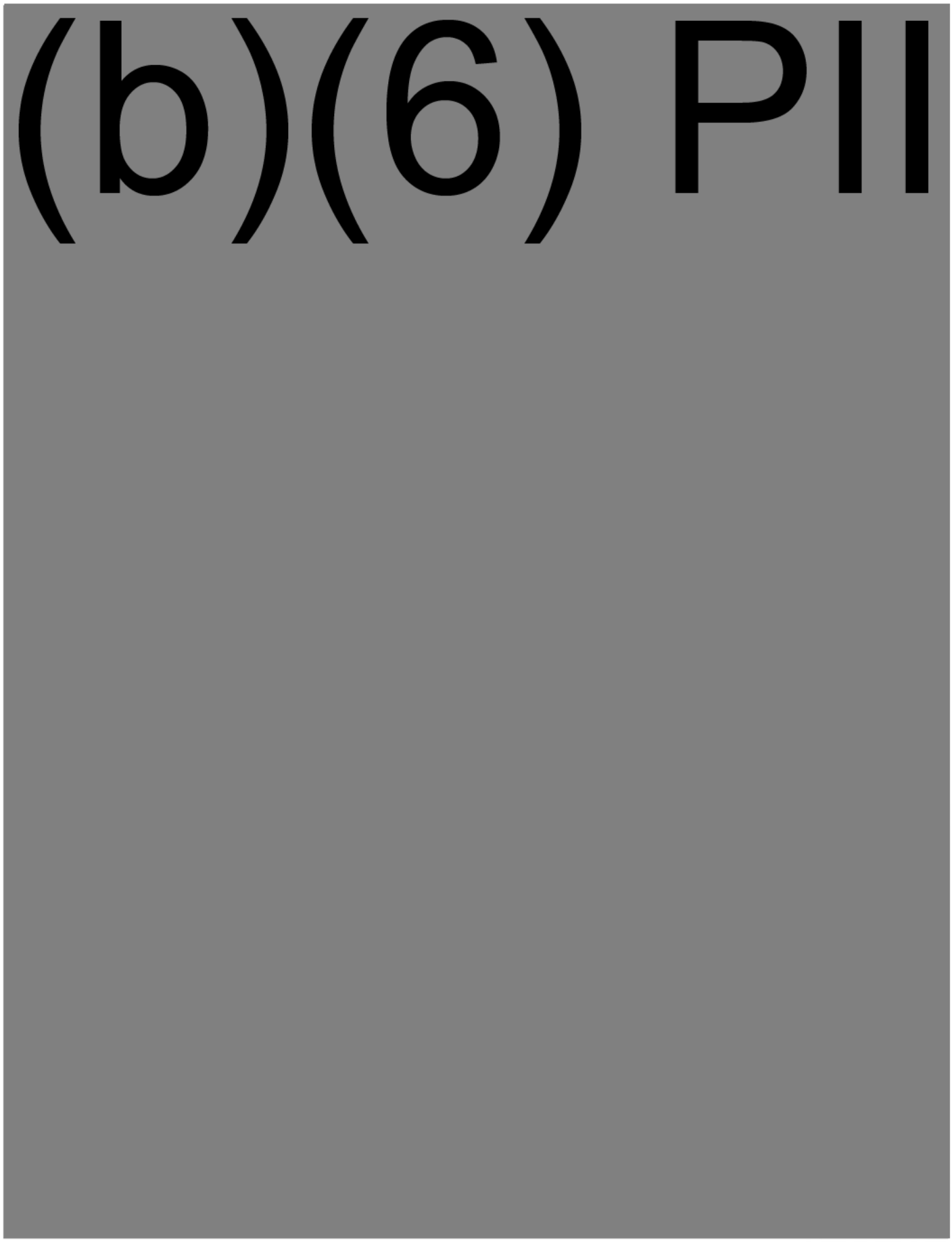
(b)(6) PII

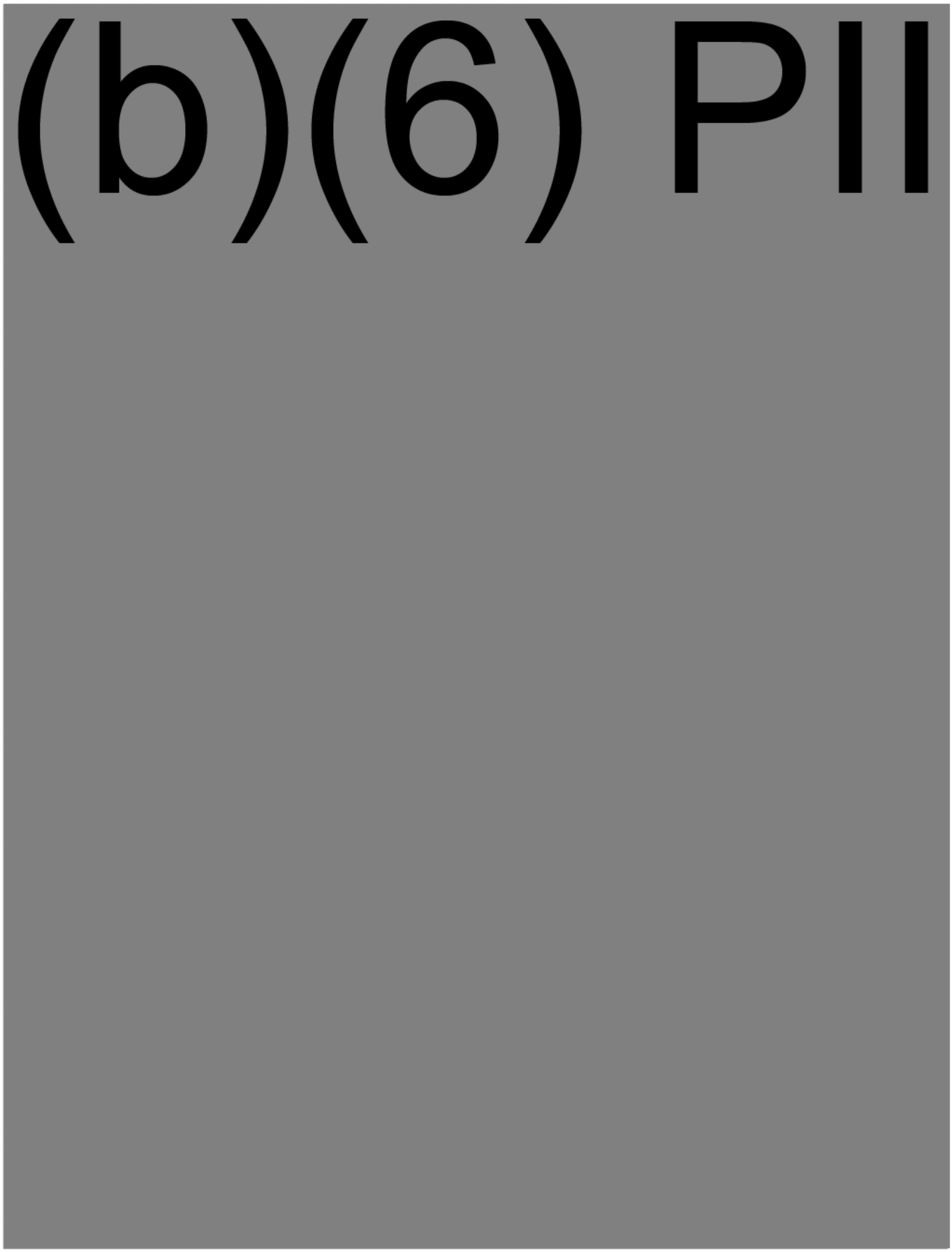
I'm as energized about the next five years of science in my lab as I've ever been, not least on account of my collaborations with both industry and academia. But my interest in policy is not new: (b)(6) PII then foregoing a chance to work in the White House in order to finish college and pursue (b)(6) PII I've thought that someday I might turn my skills and experience in science, medicine, and management toward policy. I believe that now may be the right moment — and this the right opportunity — to grow and contribute in new ways while continuing to serve (b)(6) PII and the country's shared purpose.

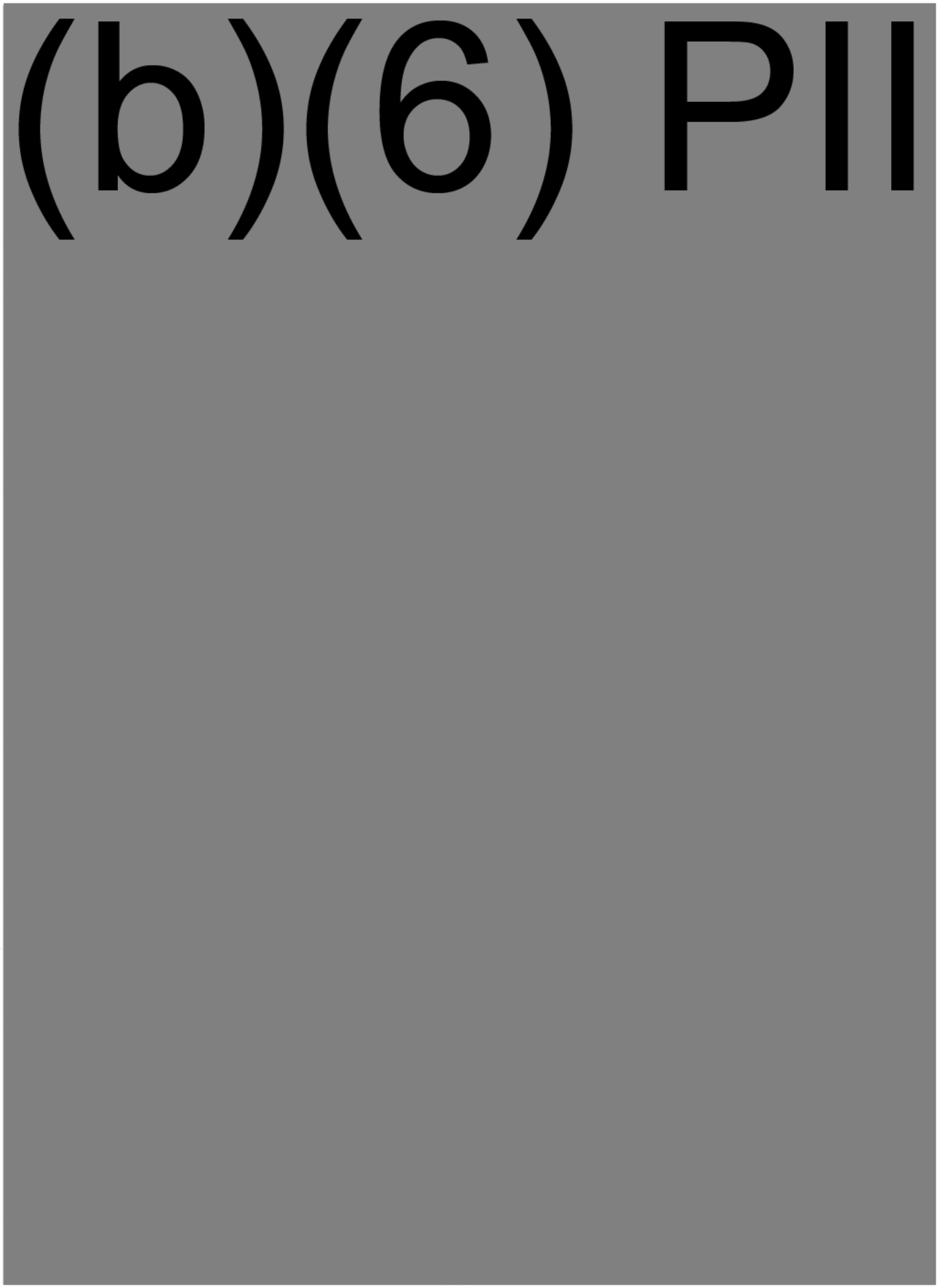
Thanks for considering this possibility, which I would love to discuss further with you.

All the best,
(b)(6) PII

(b)(6) PII


(b)(6) PII


(b)(6) PII


(b)(6) PII

Five Principles for Ethical Ancient DNA Research

Songul Alpaslan-Roodenberg[1], David Anthony[2], Hiba Babiker[3], Eszter Bánffy[4], Thomas Booth[5], Patricia Capone[6], José M. Capriles[7,8], Arati Deshpande-Mukherjee[9], Stefanie Eisenmann[3], Lars Fehren-Schmitz[10], Michael Frachetti[11], Catherine Frieman[12], Qiaomei Fu[13], Ricardo Fujita[14], Henry Louis Gates, Jr.[6], Victoria Gibbon[15], Wolfgang Haak[3], Mateja Hajdinjak[16], Kerstin P. Hofmann[17], Brian Holguin[18], Takeshi Inomata[19], Hideaki Kanzawa[20], William Keegan[21], Janet Kelso[22], Logan Kistler[23], Johannes Krause[3], Ganesan Kumaresan[24], Chapurukha Kusimba[25], Sibel Kusimba[25], Carles Lalueza-Fox[26], Bastien Llamas[12,27], Jose Luis Punzo[28], Scott MacEachern[29], Swapan Mallick[6], Hirofumi Matsumura[30], Janet Monge[31], Anna Morales Arce[32], Giedre Motuzaite Matuzeviciute[33], Nathan Nakatsuka[6], Veena Mushrif-Tripathy[34], Rodrigo Nores[35], Christine Ogola[36], Mercedes Okumura[37], Nick Patterson[6], George Perry[7], Ron Pinhasi[38], S.P.R. Prasad[39], Mary E. Prendergast[40], David Reich[6], Rikai Sawafuji[41], Elizabeth Sawchuk[42], Jakob Sedig[6], Sveta Shnayder[43], Kendra Sirak[6], Pontus Skoglund[5], Vivianc Slon[44], Mcradeth Snow[45], Marie Soressi[46], Matthew Spriggs[47], Philipp W. Stockhammer[48], Anna Szécsényi-Nagy[49], K. Thangaraj[50], Vera Tiesler[51], Ray Tobler[27], Chuan-Chao Wang[52], Christina Warinner[3,6], Surangi Yaswardene[53], Muhammed Zahir[54]

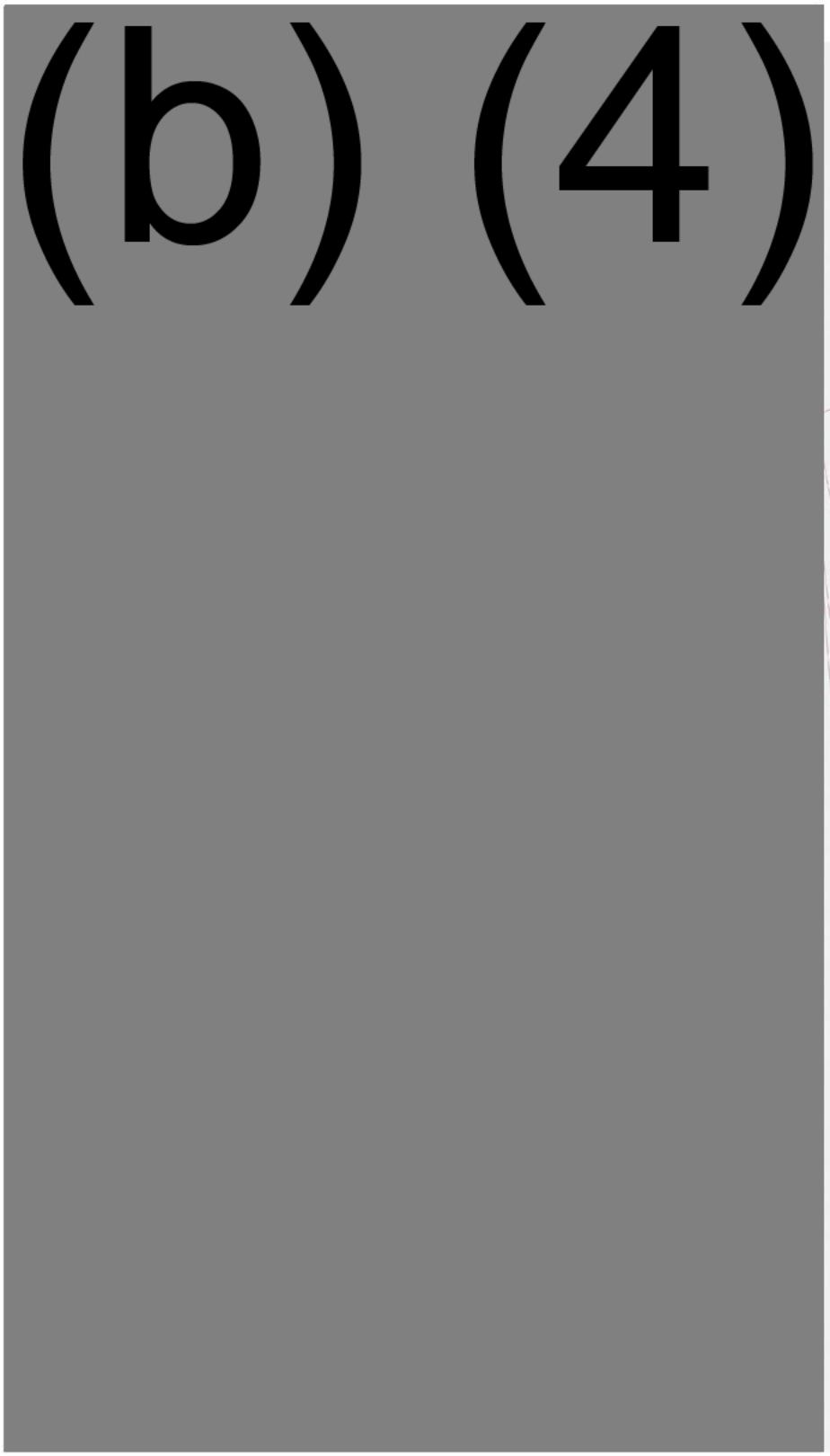
[authors will be added (and sometimes removed) as development of this essay proceeds]

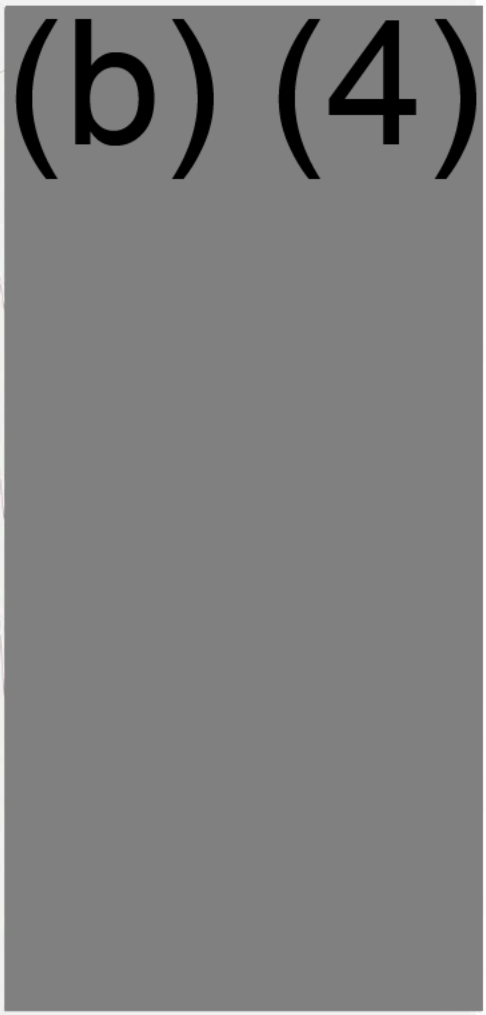
1: Independent Researcher, Netherlands
2: Hartwick College, Oneonta, NY, USA
3: Max Planck Institute for the Science of Human History, Jena, Germany
4: German Archaeological Institute, Frankfurt, Germany
5: Francis Crick Institute, London, UK
6: Harvard University, Cambridge, USA
7: The Pennsylvania State University, University Park, USA
8: Instituto de Investigaciones Antropológicas y Arqueológicas, Universidad Mayor de San Andrés, La Paz, Bolivia
9: Deccan College, Pune, India
10: University of California, Santa Cruz, USA
11: University of Washington, St. Louis, USA
12: Australian National University, Canberra, Australia
13: Inst. Vertebrate Palaeontology and Palaeoanthropology, Beijing, China
14: Universidad de San Martín de Porres, Peru
15: University of Cape Town, South Africa
16: Francis Crick Institute, London, UK
17: German Archaeological Institute
18: University of California, Santa Barbara, USA
19: The University of Arizona, Tucson, USA
20: National Museum of Nature and Science, Tokyo, Japan
21: Florida Museum of Natural History, USA
22: Max Planck Institute for Evolutionary Anthropology, Leipzig, Germany
23: Smithsonian Institution, Washington DC, USA
24: Madurai Kamaraj University, India

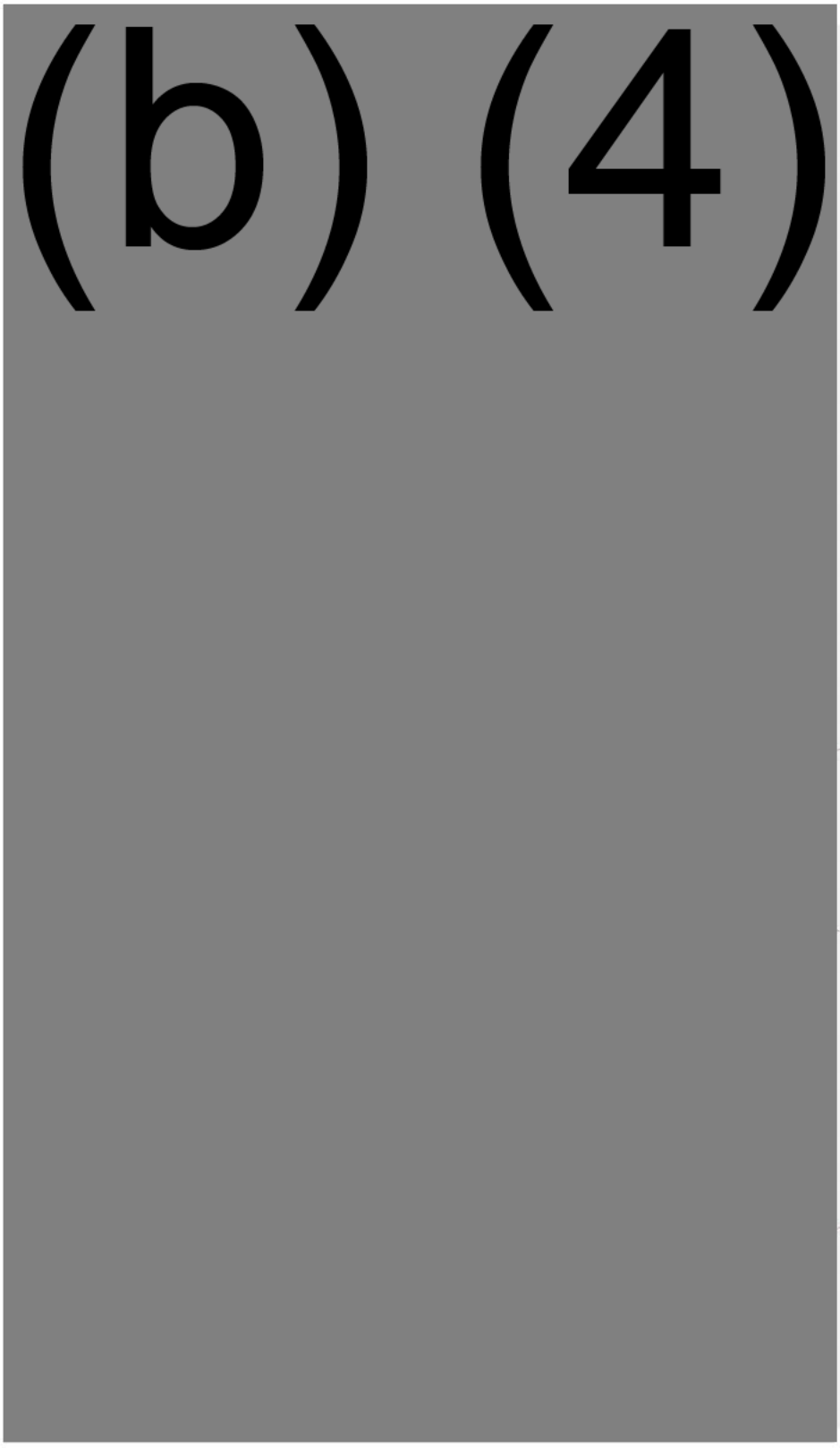
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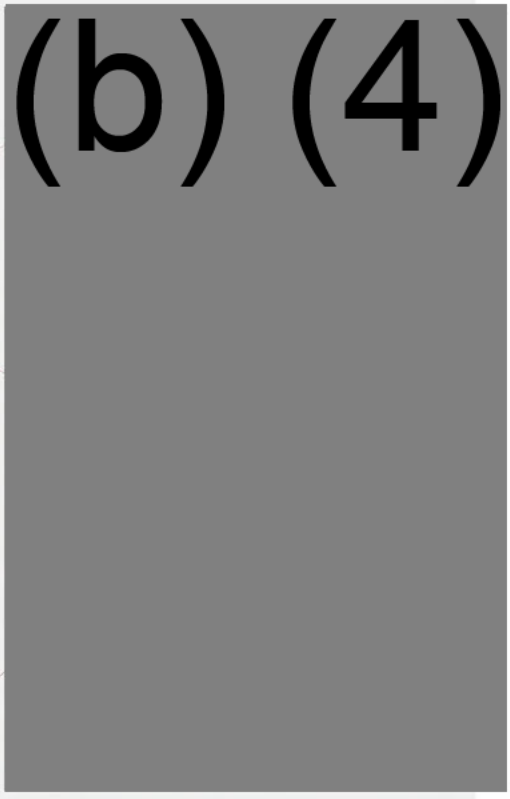
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26: University of Pompeu Fabra, Barcelona, Spain
27: University of Adelaide, Australia
28: Instituto Nacional de Antropología e Historia, Michoacán, Mexico
29: Duke Kunshan University, Jiangsu, China
30: Sapporo Medical University, Japan
31: Penn Museum, Philadelphia, USA
32: Instituto Gulbenkian de Ciência, Oeiras, Portugal
33: Vilnius University, Lithuania
34: Deccan College, Pune, India
35: Museo de Antropología, Córdoba, Argentina
36: National Museum of Kenya, Nairobi, Kenya
37: University of Sao Paulo, Brazil
38: University of Vienna, Austria
39: Centre for DNA Fingerprinting and Diagnostics, India
40: Rice University, USA
41: University of the Ryukyus, Okinawa, Japan
42: University of Alberta, Canada
43: Institute of Archaeology and Ethnography, Novosibirsk, Russia
44: Tel Aviv University, Israel
45: University of Montana, Missoula, USA
46: Leiden University, Netherlands
47: The Australian National University, Australia and Vanuatu Culture Centre, Vanuatu
48: Ludwig Maximilian University, Munich, Germany
49: Institute of Archaeology, Research Centre for the Humanities, Eötvös Loránd Research Network, Budapest, Hungary
50: Centre for Cellular and Molecular Biology, Hyderabad, India
51: Universidad Autónoma de Yucatán, Mérida, Mexico
52: Department of Anthropology and Ethnology, Institute of Anthropology, School of Sociology and Anthropology, and State Key Laboratory of Cellular Stress Biology, School of Life Sciences, Xiamen University, Xiamen 361005, China
53: University of Sri Jayewardenepura, Nugegoda, Sri Lanka
54: Hazara University, Pakistan

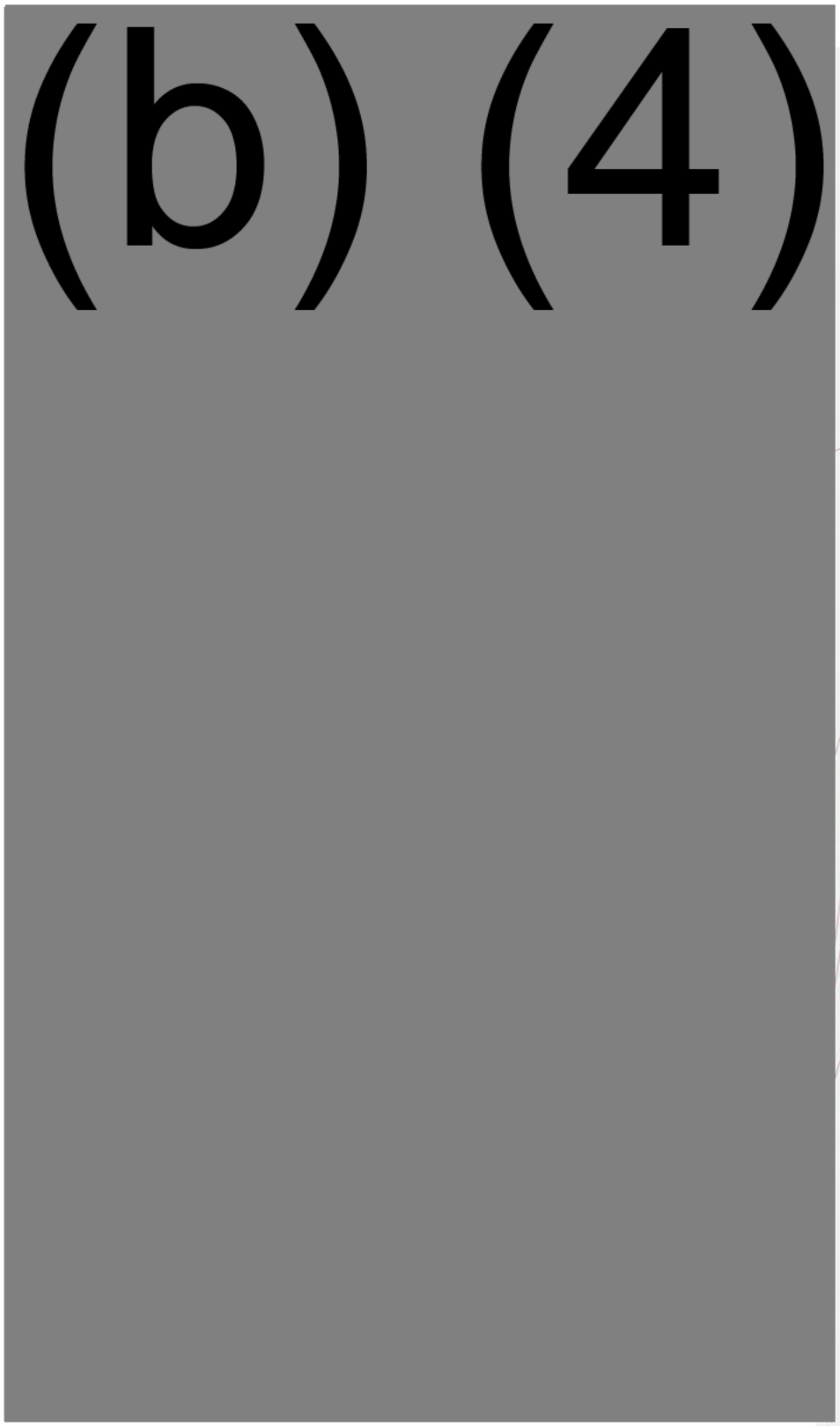
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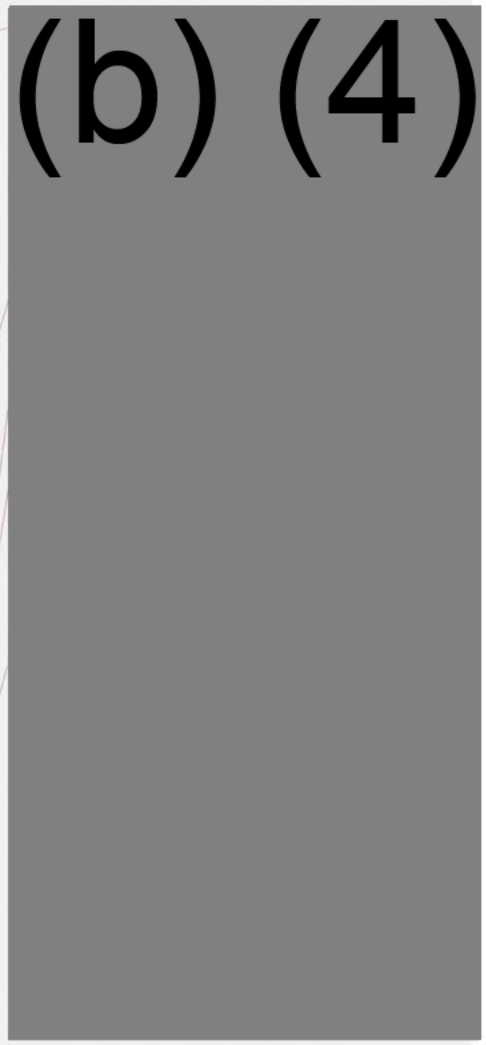

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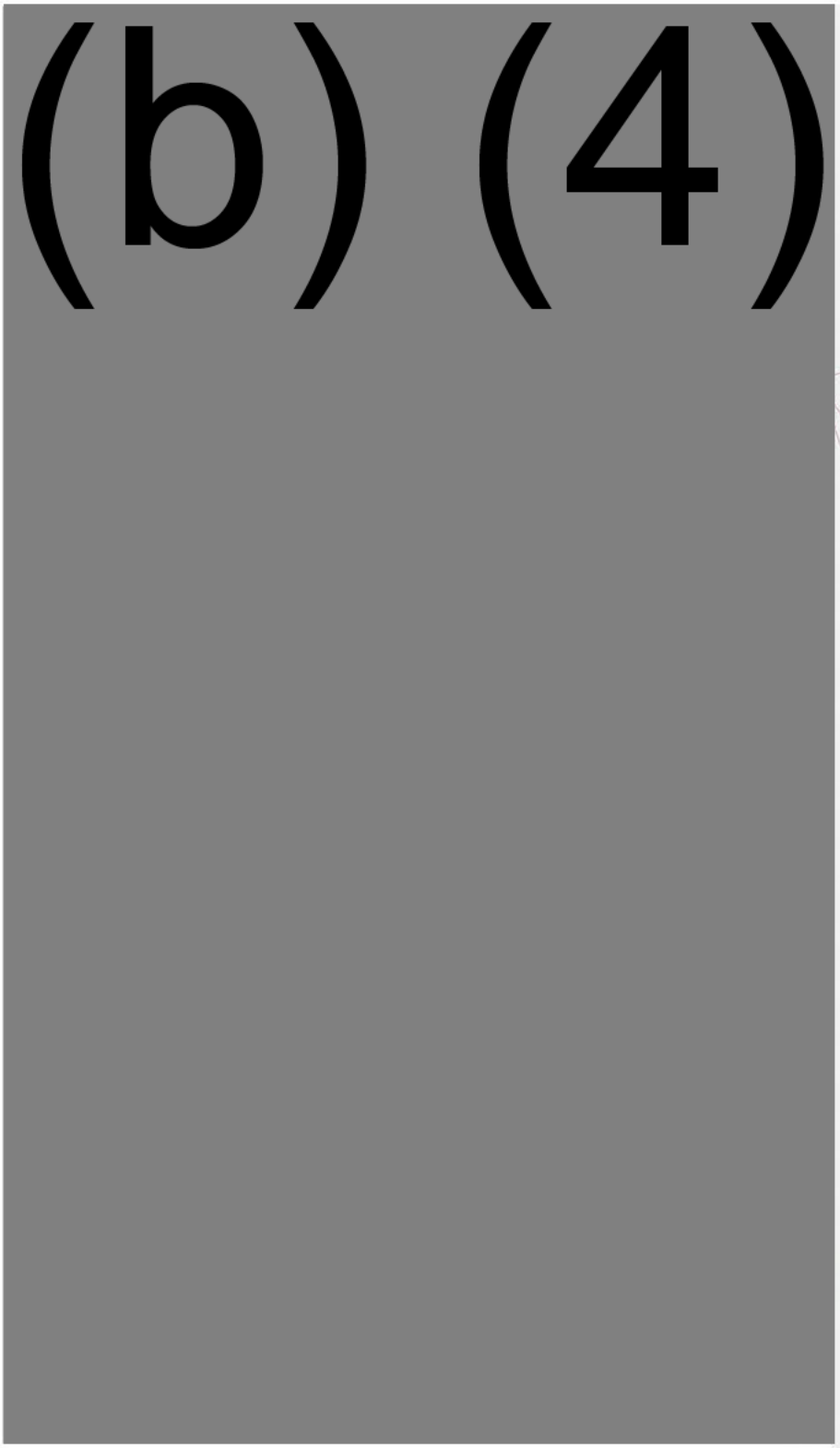

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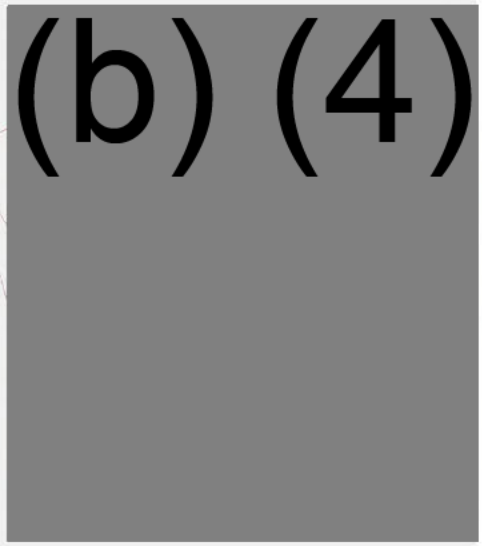

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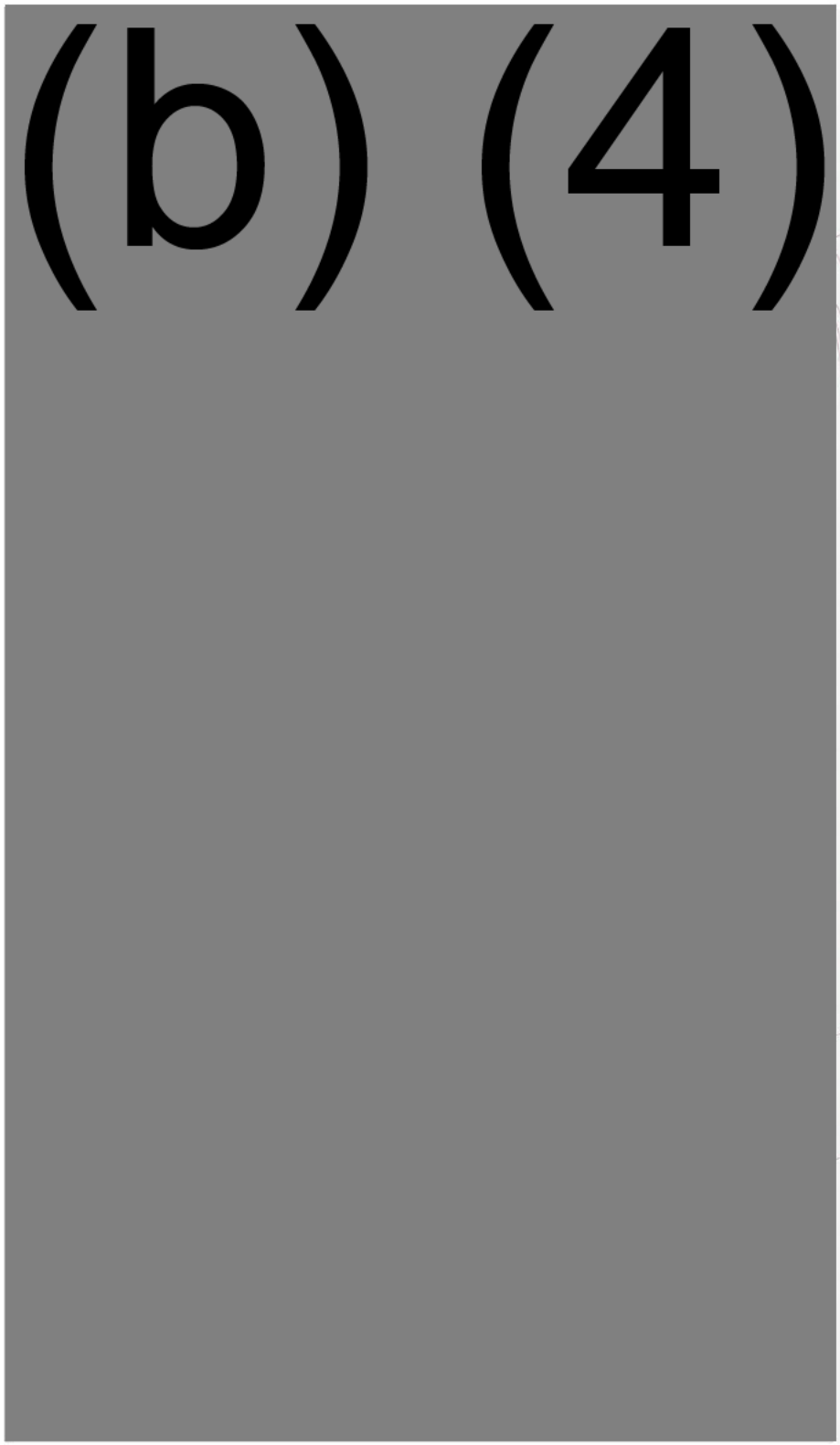

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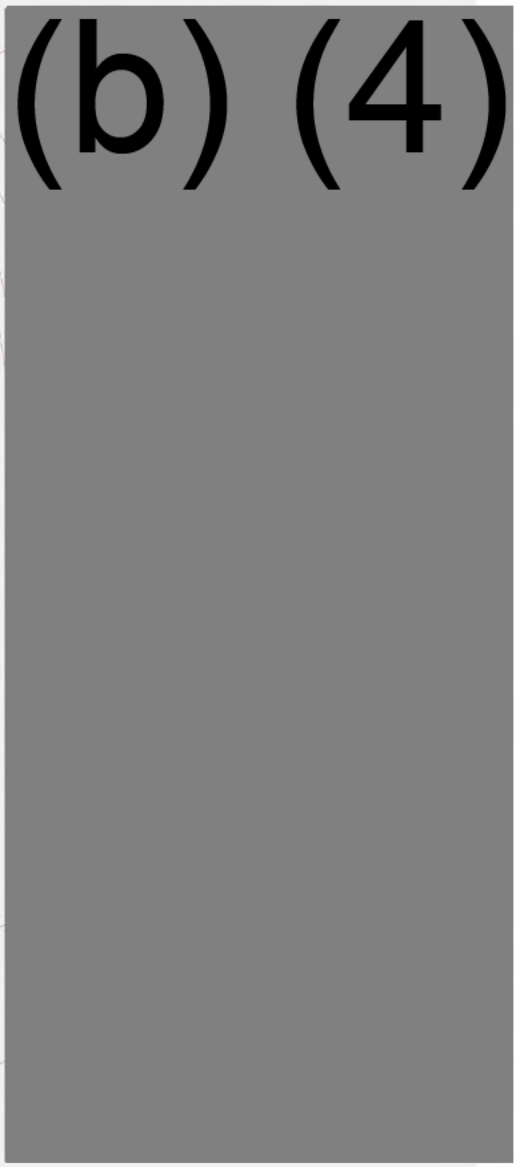

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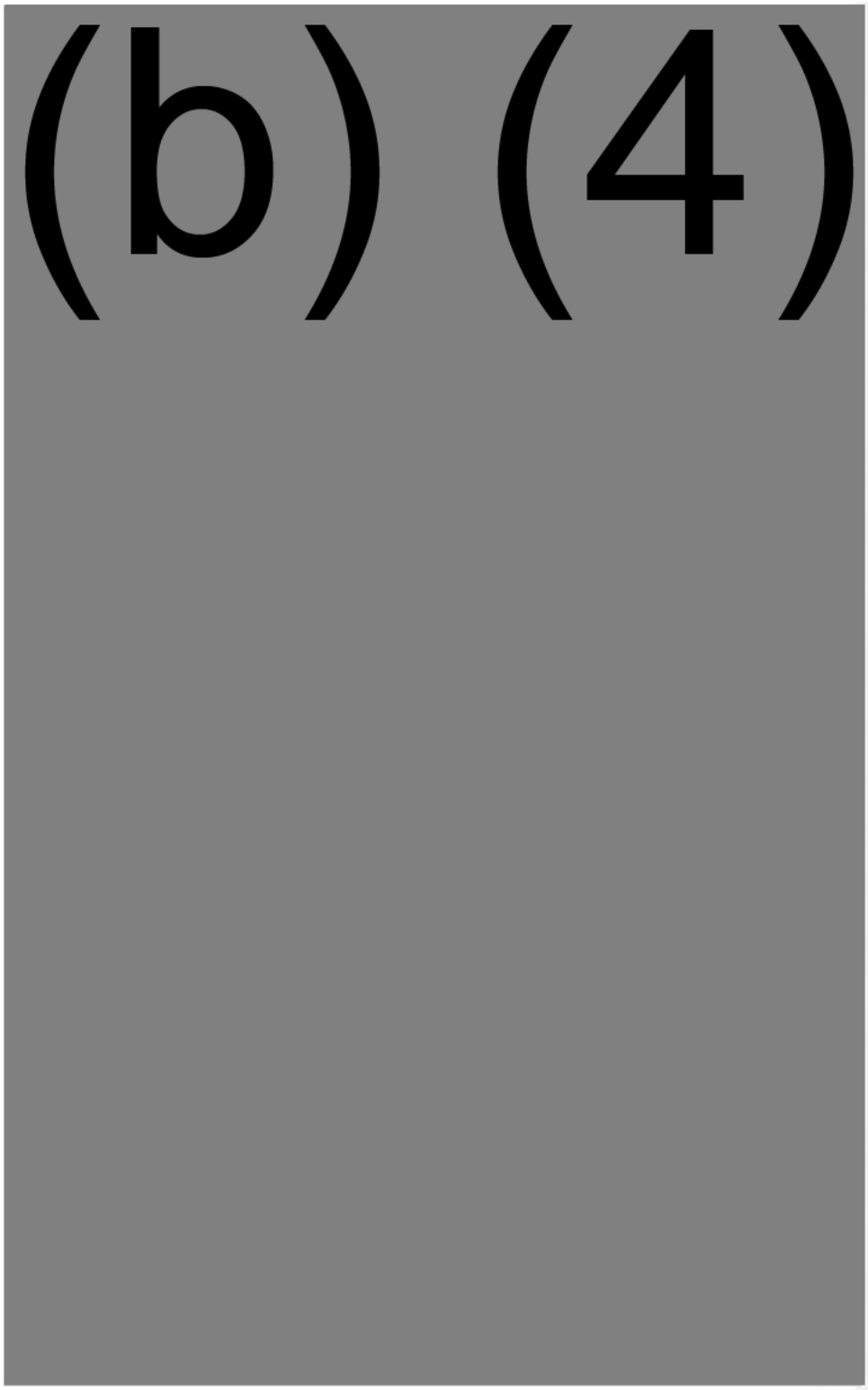

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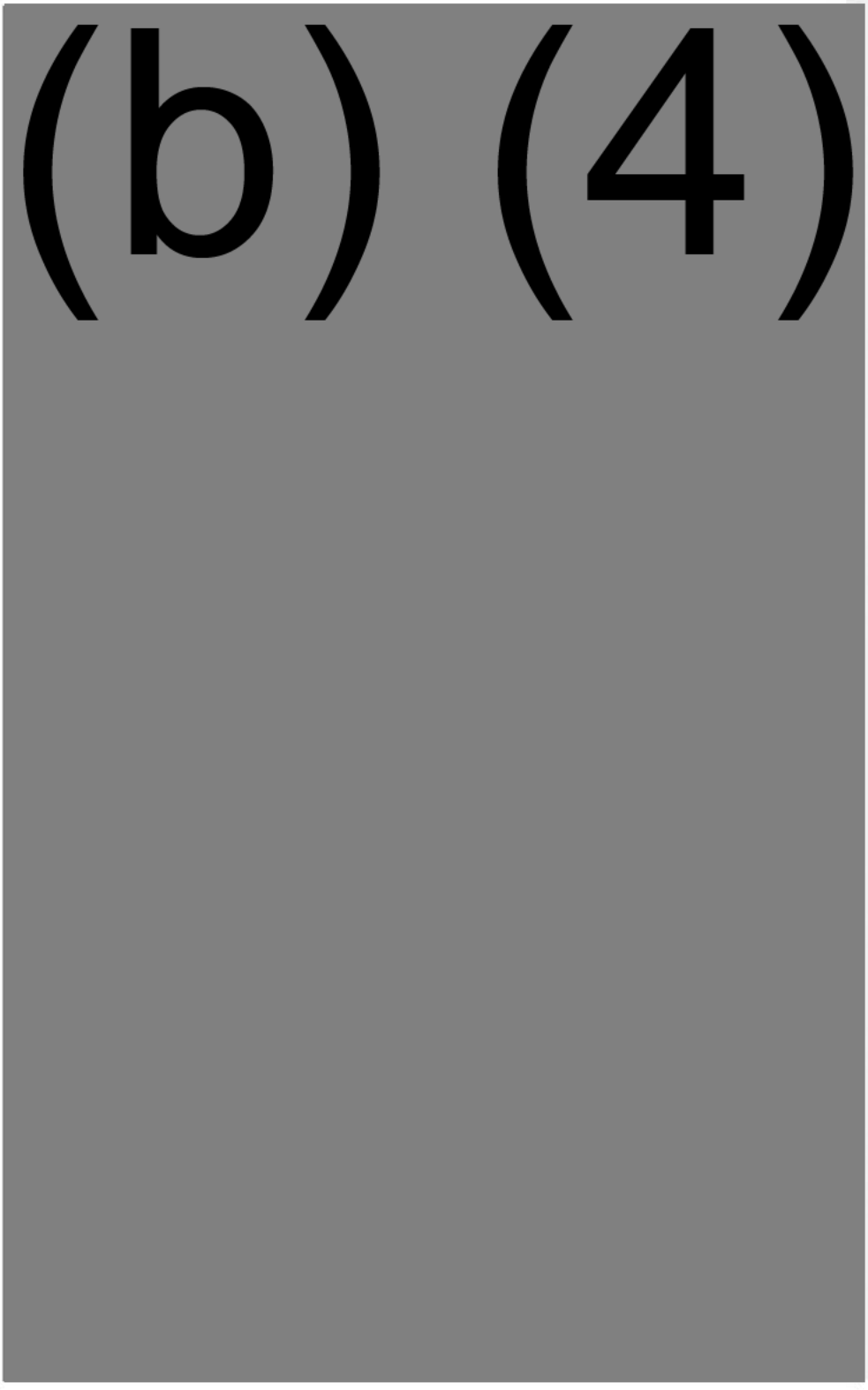

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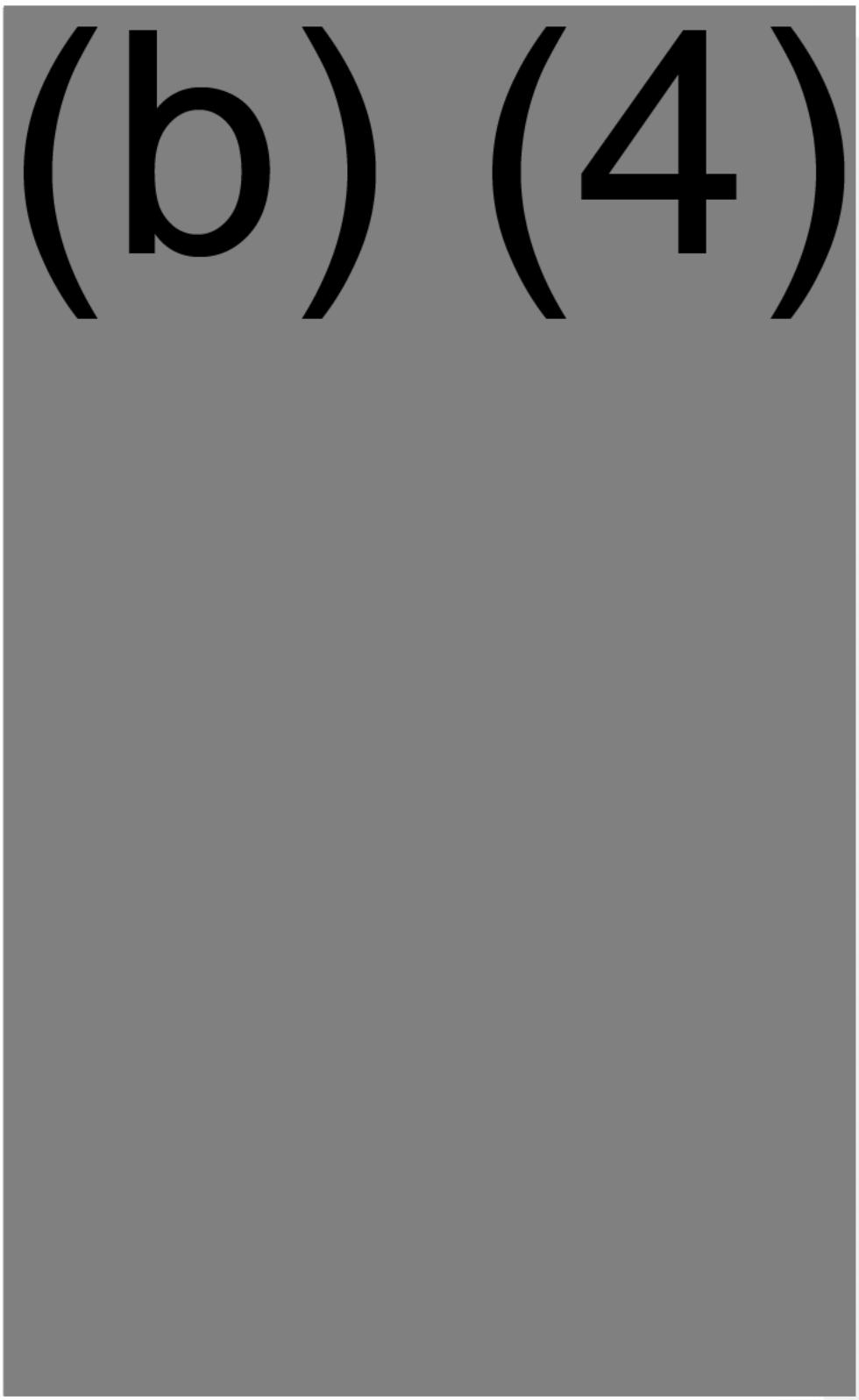

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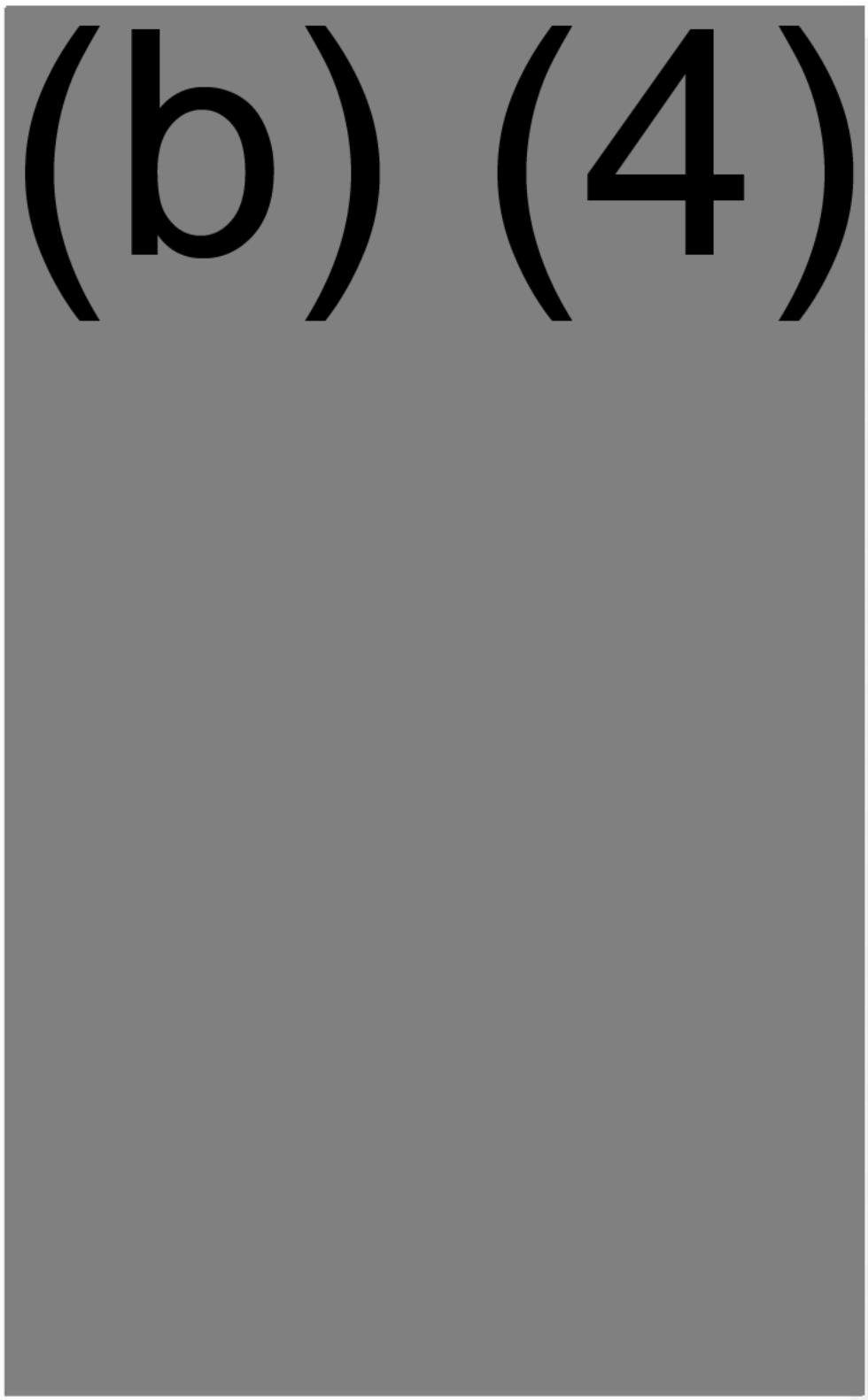

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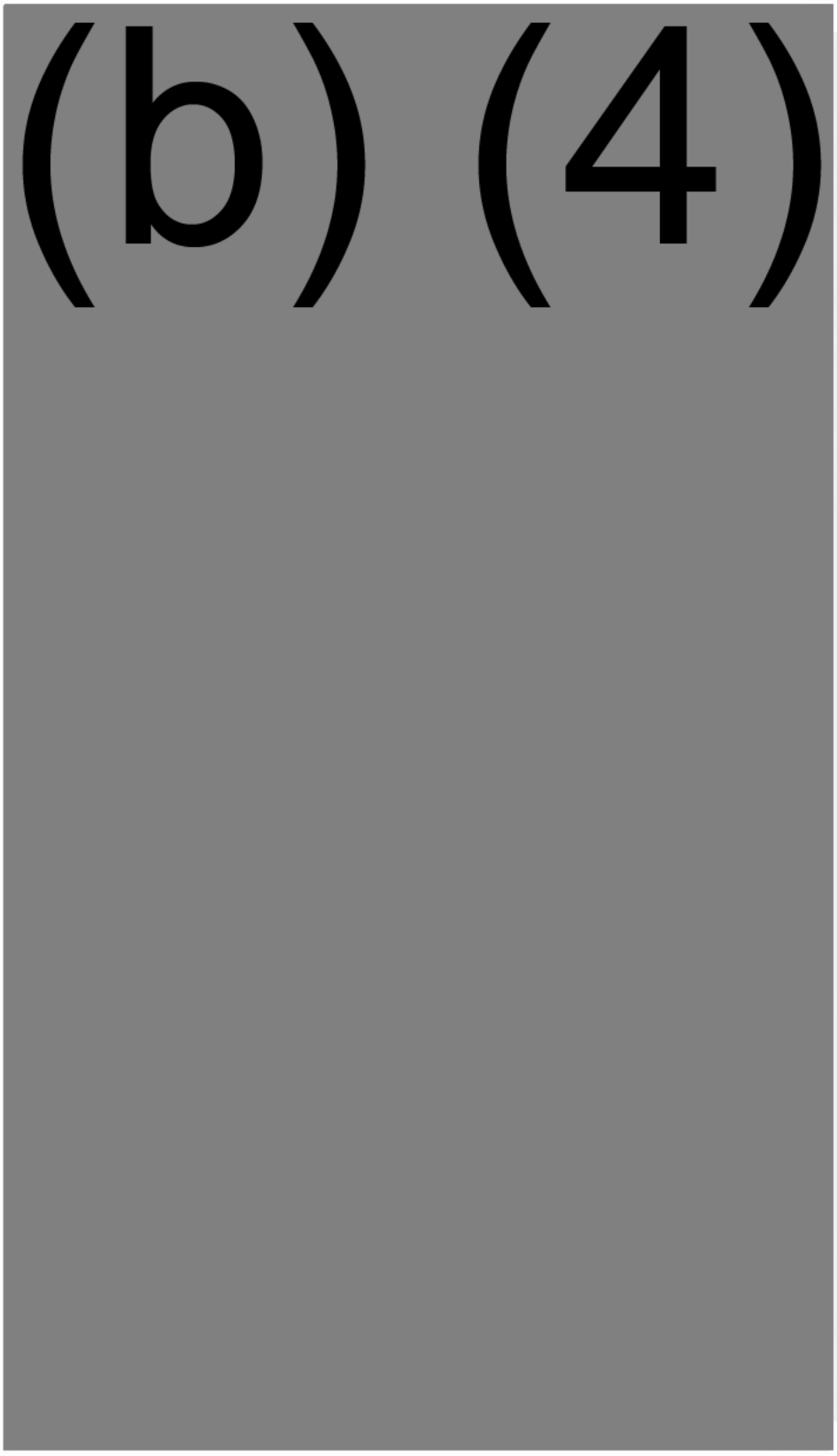

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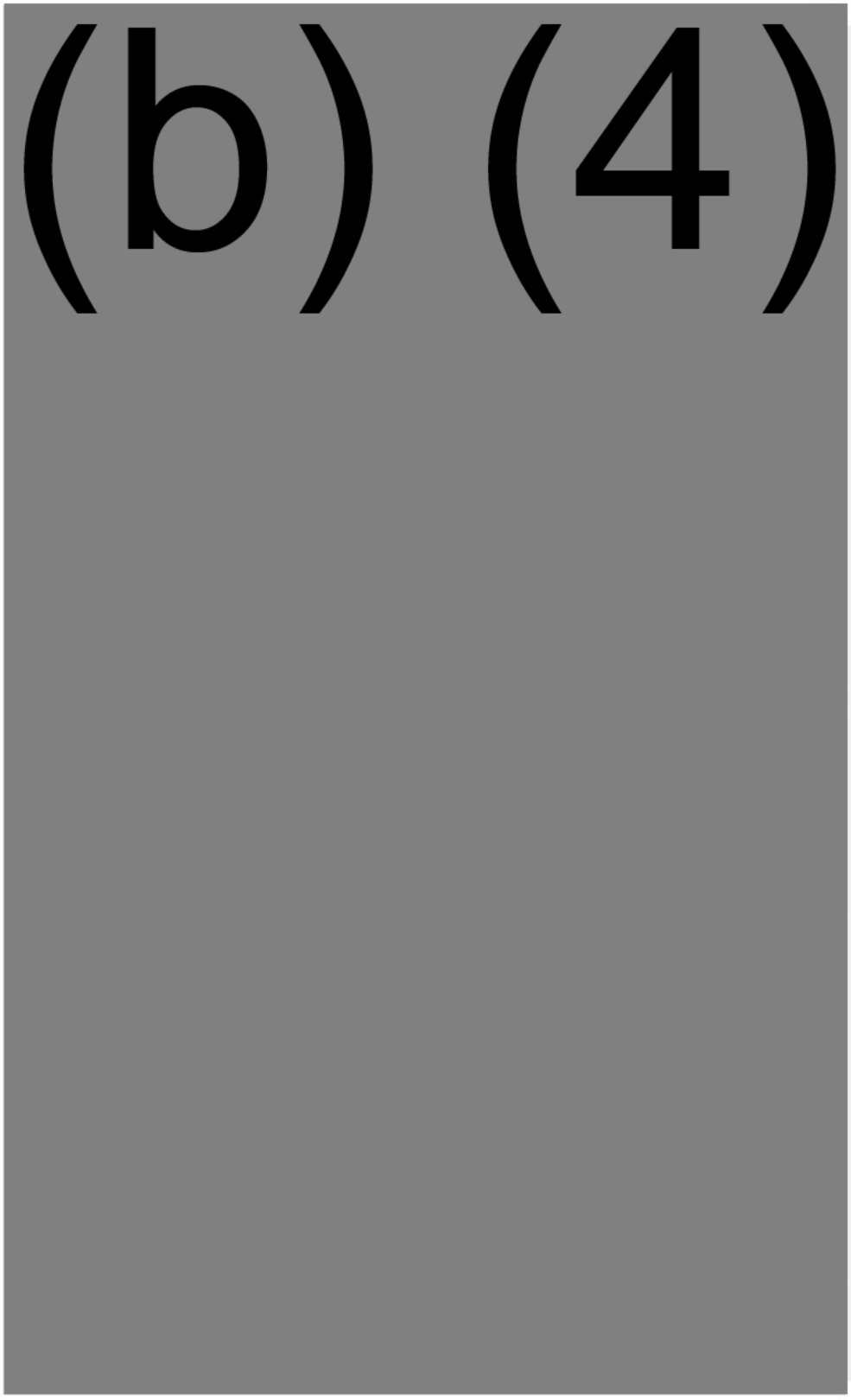

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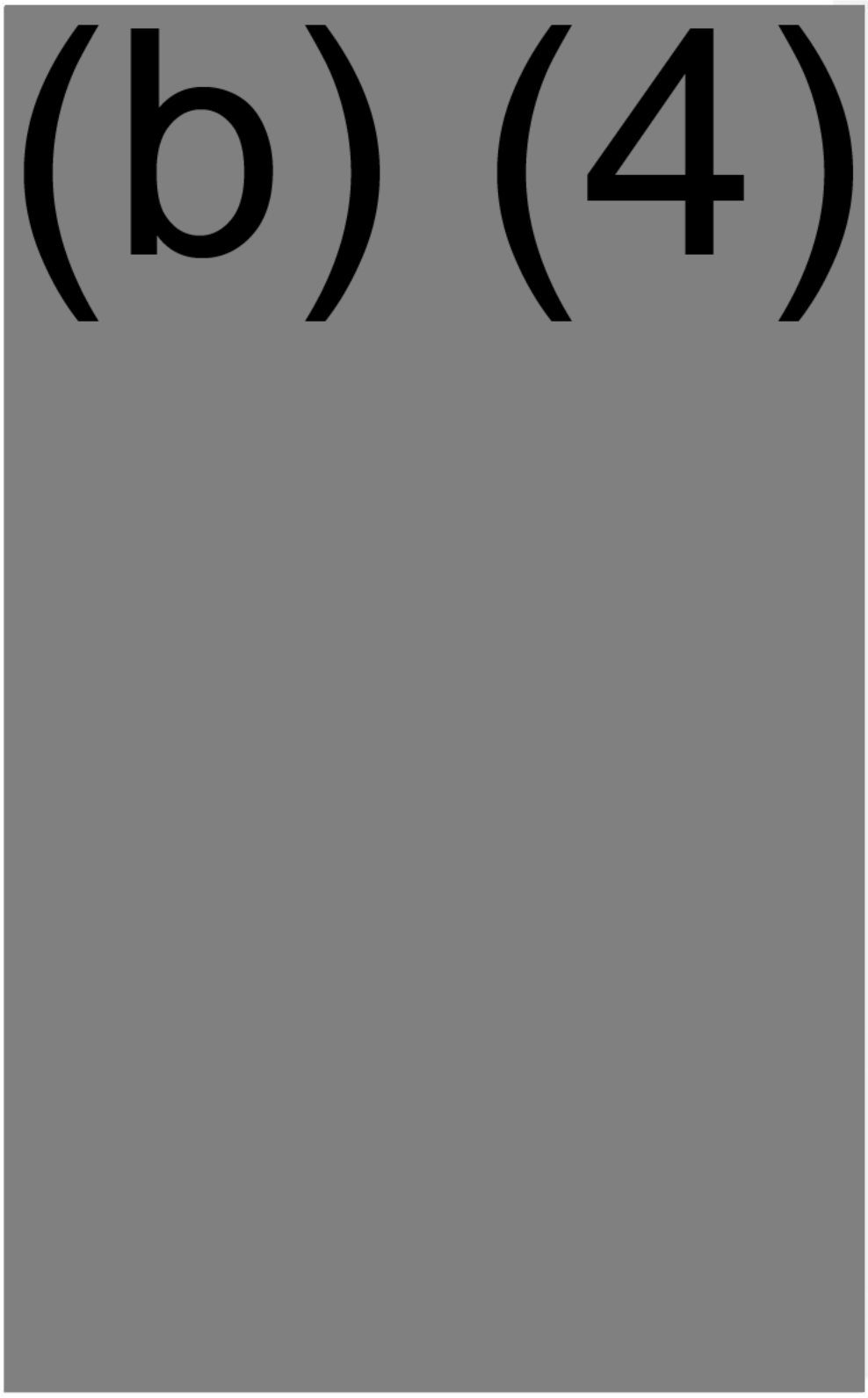

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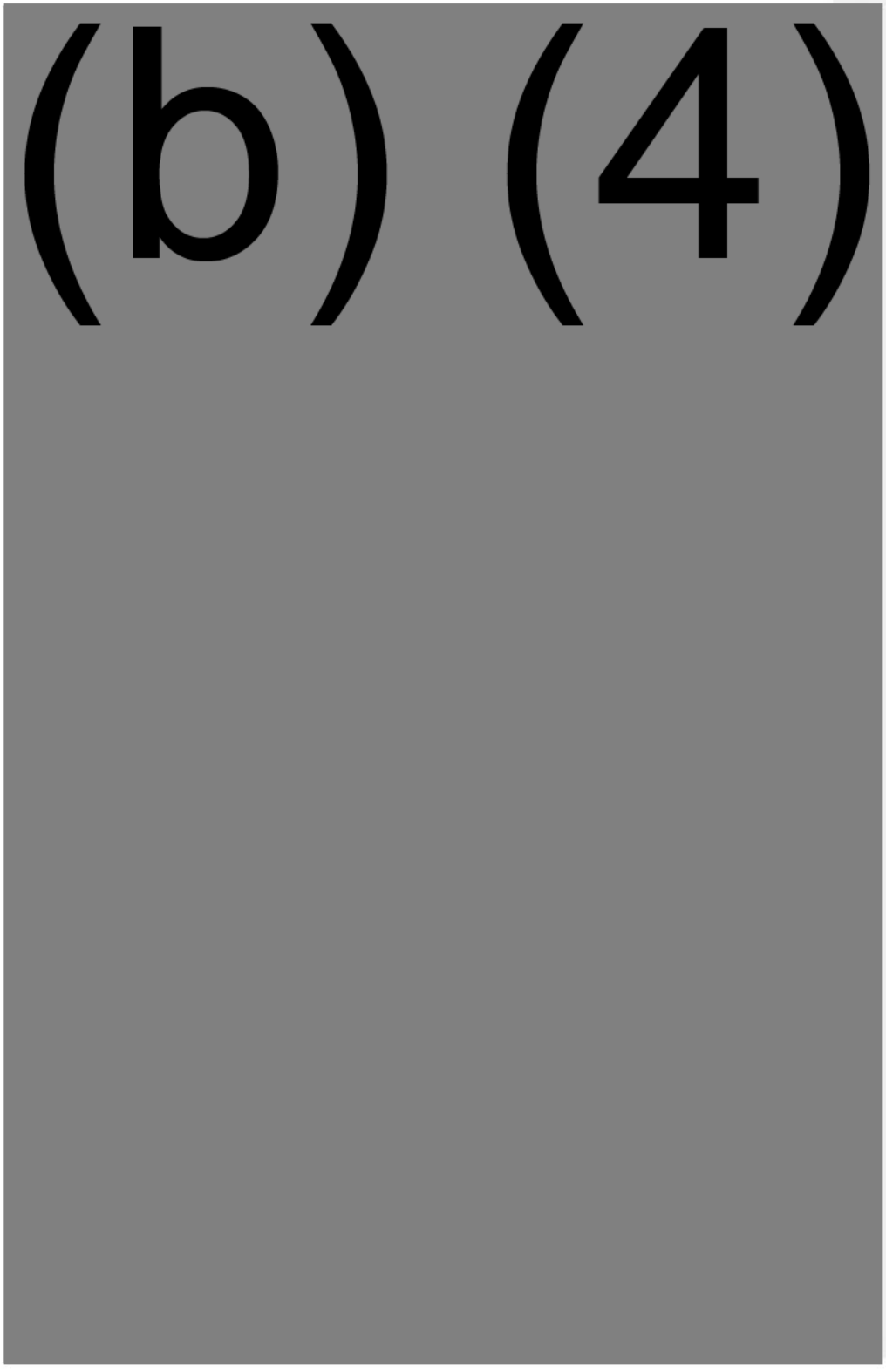

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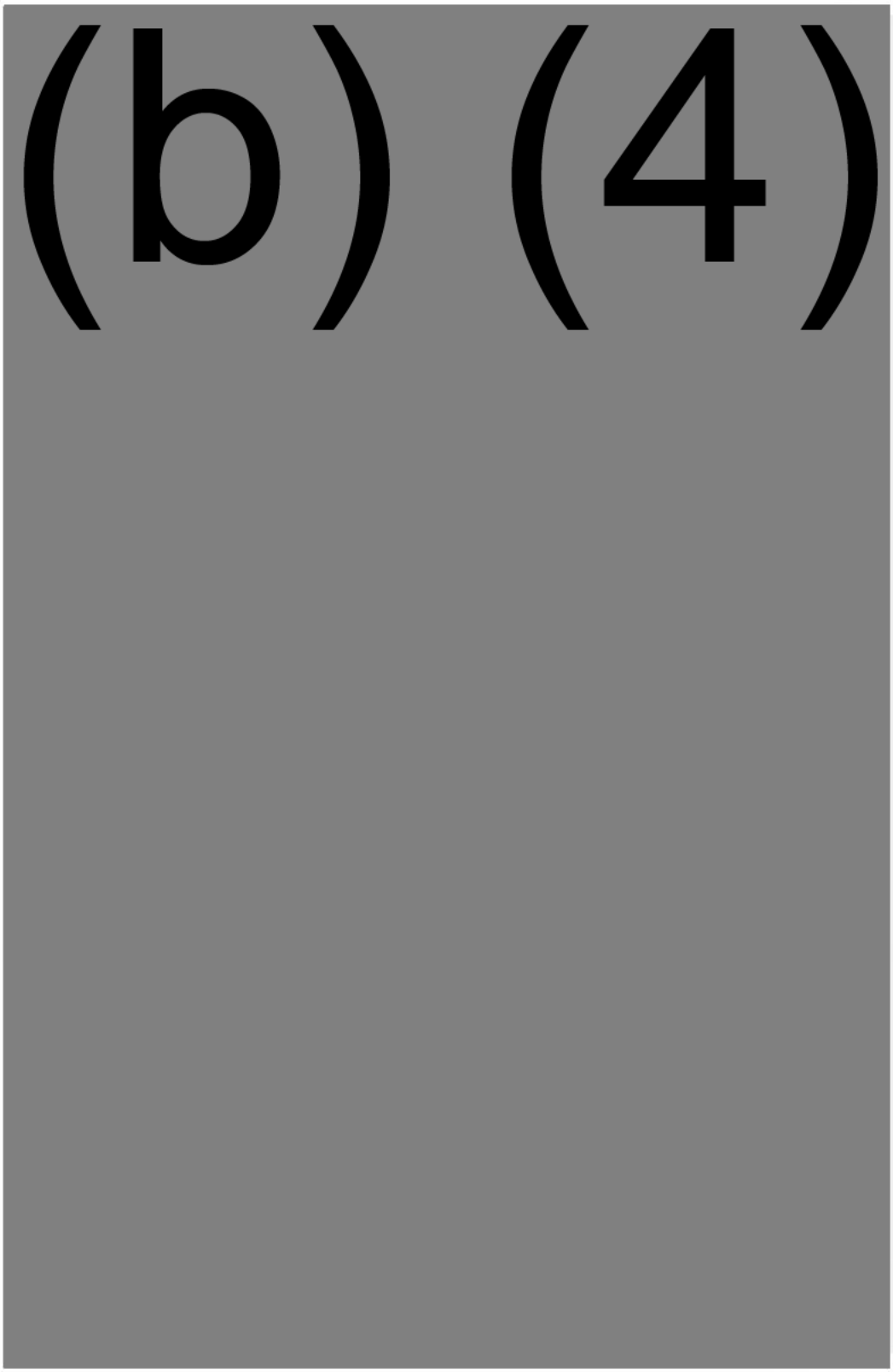

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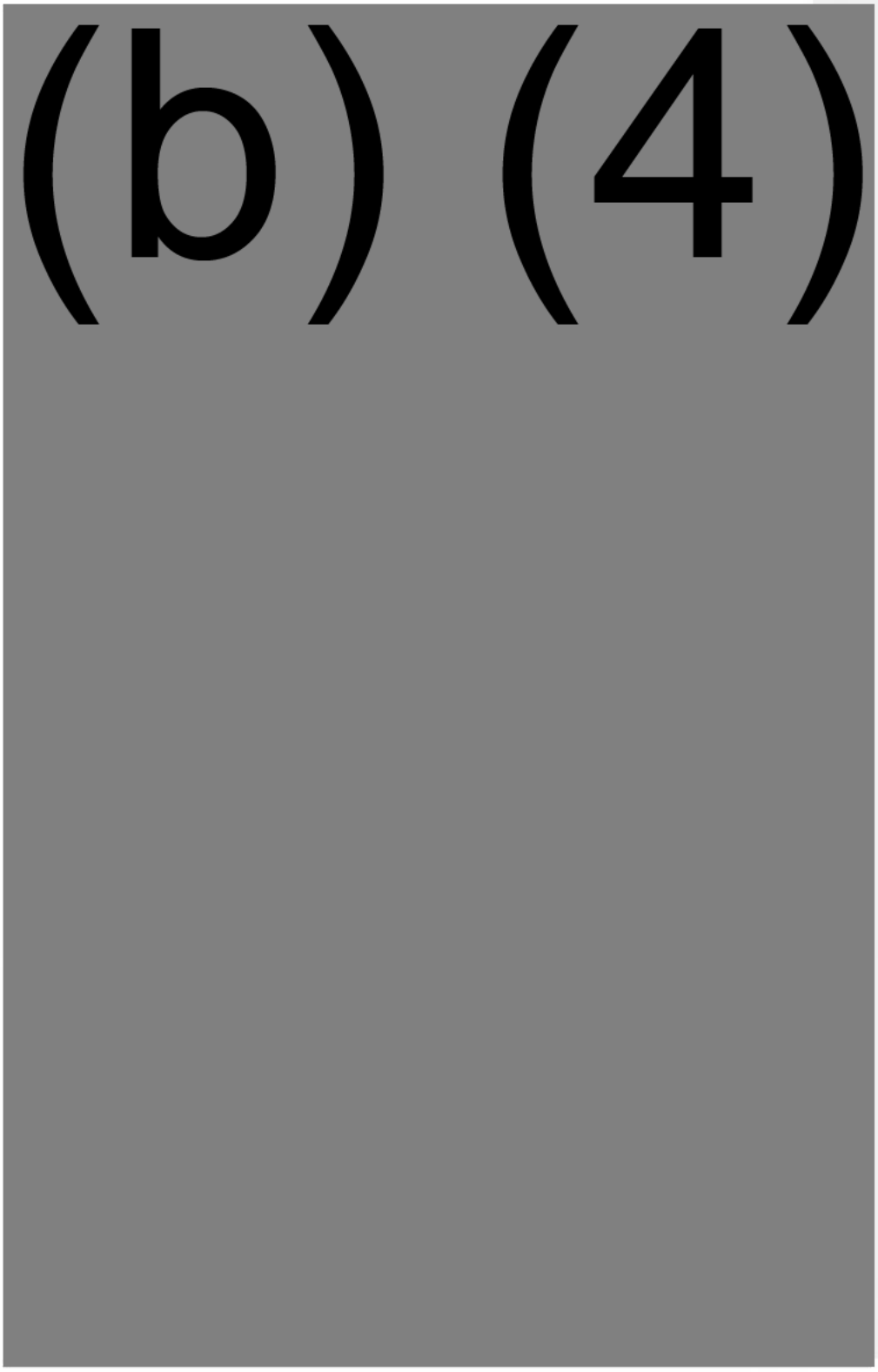

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[APG]

[EXTERNAL] Harvard course conversation on science advocacy

From: Shannon Miller (b) (6) >

To: "Lander, Eric S. EOP/OSTP" <(b) (6)

Date: Mon, 22 Feb 2021 21:14:05 -0500

Hi Eric,

I sent a message to your Broad email and got the automated response, so I figured I would try your new email as well. I contacted about a month ago about speaking with our Harvard class, CHEM100R, about your experience with science advocacy and how you plan to communicate important scientific problems with members of government and to the American People. I wanted to circle back to check if you know more about your schedule and if you would have a moment to talk with our class. We'd love to hear from you at any point during the semester! The class takes place Monday/Wednesday 12-2pm EST, but if you have any time at all we can set up a special session.

Best,
Shannon Miller

Harvard University, Ph.D. Candidate in Chemistry and Chemical Biology
David R. Liu lab, Broad Institute

RE: three follow ups

From: "Lo, Kevin C. EOP/OSTP" (b) (6)

To: Jonathan Gruber (b) (6) u>

Date: Wed, 24 Feb 2021 16:20:41 -0500

Jon:

Thanks so much for following up. We're in the process of planning a general strategy for engagement around the President's letter. Let's circle back when we've made a bit more progress on that.

With respect to the economics event, the issue will be the timing of my Senate confirmation. Again, let's circle back when I have greater clarity on that.

With all best wishes,
Eric

From: Jonathan Gruber (b) (6)

Sent: Monday, February 15, 2021 11:35 AM

To: Lander, Eric S. EOP/OSTP <(b) (6)

Subject: [EXTERNAL] three follow ups

Eric –

Hope you are keeping your head above water! Wanted to follow up on three things

1. any follow ups to my thoughts on the report process ? any ways I can help you and your staff to move forward on this?
2. I am working with some colleagues and congressional leadership on a plan to reinvest some of the savigns from drug price regulation into promoting innovation in biopharma – not just more NIH, but more downstream funding as well. We think that OSTP could play an important convening/organizing role here. is there someone on your staff I could talk to about this?
3. Any willingness to speak at that economics event I emailed about?

Thanks!

Jon

Jonathan Gruber
Ford Professor of Economics
MIT Department of Economics
50 Memorial Drive, E52-434
Cambridge, MA 02142
phone: (b) (6)
fax: 617-253-1330
e-mail: (b) (6)
web: >http://econ-www.mit.edu/faculty/gruberj/<
>https://www.jump-startingamerica.com/<

[EXTERNAL] NYT -Wbat My Parents Taught Me

From: Debra Weiner (b) (6)

To: Eric Lander (b) (6) "Lander, Eric S. EOP/OSTP"
(b) (6)

Date: Thu, 25 Feb 2021 09:36:20 -0500

Attachments: ERIC LANDER - sent out.docx (43.07 kB)

Hi Eric,

Hope you've been doing well. I imagine you're finding things interesting!

So here's your story. I've attached it below. If you can fact-check all, that'd be great. Some people prefer to talk over fact-check changes. Phone if that's the case for you. I've titled your piece "The Wonders of the World." Does that capture what you wanted to convey?

As far as bio line, feel free to change. It needs to be very short, but best that you decide what you'd like to highlight rather than me.

I will need several childhood photos. You and your mom definitely need to be in them, but they can also include your brother and dad. Be sure to ID everyone with full names. They'll be included in the photo caption.

Thanks and all my best,
Debra
(b) (6)

ERIC LANDER

(b) (4), (b) (6)

(b) (4)

[EXTERNAL] [WARNING: MESSAGE ENCRYPTED]Meeting Request: American Society of Human Genetics

From: Derek Scholes (b) (6) >
To: (b) (6) "Koizumi, Kei EOP/OSTP" (b) (6)
Cc: Mona Miller (b) (6)
Date: Fri, 26 Feb 2021 18:39:27 -0500
Attachments: 2021-02-18-ASHGLettertoOSTPleadership.pdf (266.38 kB)

Dear Dr. Lander and Mr. Koizumi,

Please find attached a letter to Dr. Lander and Dr. Nelson from ASHG President Dr. Gail Jarvik and CEO Ms. Mona Miller. ASHG would like to congratulate you, Dr. Lander, on being chosen by President Biden to lead the Office of Science and Technology Policy. Dr. Jarvik and Ms. Miller would like to request a meeting to discuss how ASHG might be of assistance to OSTP in the new Administration.

The Society looks forward to working with you all at OSTP. Thank you for considering our request for a meeting.

Best regards,

Derek Scholes

Derek T. Scholes, PhD
Senior Director, Policy & Advocacy
American Society of Human Genetics

ASHG
American Society of Human Genetics

tel: (b) (6) | (b) (6)
6120 Executive Blvd., Suite 500 | Rockville, MD 20852
>www.ashg.org<

Join ASHG, the world's largest community of human genetics and genomics specialists! >www.ashg.org/membership<

ASHG
American Society of Human Genetics
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6120 Executive Boulevard, Suite 500
Rockville, MD 20852

tel: 301.634.7300
email: society@ashg.org
web: http://www.ashg.org

February 18, 2021

Eric S. Lander, PhD, Director (nominated)
Alondra Nelson, PhD, Deputy Director for Science & Society
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Dear Drs. Lander and Nelson,

On behalf of the nearly 8,000 members of the American Society of Human Genetics (ASHG), we congratulate you on your recent appointments by President Biden to lead the Office of Science and Technology Policy in the new Administration as Director and Deputy Director for Science and Society, respectively. ASHG applauds your commitment to public service and to ensuring that all Americans and people worldwide can benefit from the power and innovation of science and technology.

ASHG is the primary professional membership organization for human genetics specialists worldwide and is dedicated to advancing human genetics and genomics in science, health, and society, and the Society is proud to count you both among our broad community. As you embark on your important leadership of America's scientific agenda, ASHG would like to be a partner with you in addressing many of important questions President Biden has asked of you in his recent letter, and we would like to meet with you to explore how we can assist. In advance of that opportunity, we offer here two of ASHG's key priorities that would also advance President Biden's call:

1. **Supporting Genetics and Genomics Research & Application, and the American Research Enterprise:** Thanks to decades of leadership and scientific investigation spanning the life, physical and social sciences, the genetics and genomics community is revolutionizing biomedicine by elucidating the structure and function of the human genome and the genetic underpinnings of disease. Today, we are applying that knowledge widely across research, medicine, and health to prevent, diagnose, and treat disease. Genetics-based research and technology is improving our knowledge across all areas of life science research, including cancer, cardiovascular diseases, mental health, and infectious diseases. For example, the deployment of genome sequencing technologies developed by the human genetics community has been fundamental for responding to the COVID-19 pandemic, and ongoing research in the human genetics and genomics research community is helping elucidate why some people develop more serious symptoms than others and how we can more effectively treat COVID-19 infections.

   The remarkable progress of genetics and genomics research has been possible only because of sustained federal investment in biomedical research and its application. We know you appreciate that the nation must continue this robust support for scientific inquiry if the U.S. is to continue to be a world leader. We stand ready to be a vocal partner to OSTP as it articulates why we must continue strong investment in genetics and

genomics research at the National Institutes of Health and how other scientific agencies like the National Science Foundation play a vital role in its success. In support of our mission, ASHG also prioritizes public policies to protect research participant privacy; encourage research participation; foster data sharing strategies in our research community; support and encourage the next generation of scientific leaders; and continue America's leadership role in the international scientific community as a welcoming place for scholars from around the world.

2. **Diversity, Equity and Inclusion in Genetics and Genomics Research:** To fully leverage the extraordinary gift of humanity's genetic diversity, the entire genetics and genomics ecosystem needs to become much more diverse to determine the health risks and resiliencies we share in common and the unique evolutionary heritage of our diverse individual genomes, applying this knowledge to improve health care. Only then can we apply that knowledge to improve health for all. The genetics and genomics community has been increasingly outspoken that diversity, equity and inclusion are scientific and societal imperatives and the Society is championing efforts to educate our members about the importance and impact of cohort diversity as well as public research participation through programs like *All of Us*. Additionally, ASHG has begun a range of efforts within our own research community, which must be much more diverse itself to provide new perspectives and emphasis on research agendas that meet the needs of all populations. The Society is deeply engaged in program development as well as policy and system change to achieve diversity, equity, and inclusion within our leadership and membership, the broader human genetics and genomics field, and STEM communities. We aim to ensure that research cohorts fully reflect humanity's diversity; that the scientific workforce has broad inclusion of individuals from different backgrounds and experiences, particularly those who have traditionally been underrepresented; and that sound policies are in place to enable equitable access to the societal gains that emerge from scientific discovery. We also speak out when genetic knowledge is twisted to support discredited views or racist ideologies, and we are helping to build field understanding of the particular concerns of indigenous, marginalized and vulnerable populations.

As ASHG approaches its 75th anniversary, we are committed to pursuing our vision that people everywhere realize the benefits of human genetics and genomics research. We whole-heartedly share President Biden's call to ensure America remains a scientific leader and that we "guarantee that the fruits of science and technology are fully shared across America and among all Americans." ASHG looks forward to working with you and welcomes the opportunity to meet and discuss how we can serve as a resource to you and your staff. In the meantime, we attach our most recent annual report, which provides an overview of our current activities. Please ask your staff to reach out to Derek Scholes (dscholes@ashg.org), Senior Director of Policy and Advocacy, if we can be of assistance.

Sincerely,

Gail Jarvik

Gail P. Jarvik, M.D., PhD
2021 President

Mona V. Miller
Chief Executive Officer

[EXTERNAL] Re: Follow up

From: Tyler E Jacks (b) (6)

To: "Lo, Kevin C. EOP/OSTP" (b) (6)

Date: Fri, 26 Feb 2021 13:40:16 -0500

Attachments: smime.p7s (1.86 kB)

Yes, that's the best number.

Tyler

On Feb 26, 2021, at 10:37 AM, Lo, Kevin C. EOP/OSTP <(b) (6) wrote:

Hi Tyler,

I'll have Eric plan on giving you a call at 2:15pm. I know Eric has it, but confirming that (b) (6) is the best number to reach you?

Kevin Lo *(he/him)*
Special Assistant
Office of Science and Technology Policy
Executive Office of the President
(b) (6)
Cell: (b) (6)

From: Tyler E Jacks <(b) (6)

Sent: Friday, February 26, 2021 10:29 AM

To: Lander, Eric S. EOP/OSTP (b) (6)

Cc: Lo, Kevin C. EOP/OSTP <(b) (6)

Subject: [EXTERNAL] Re: Follow up

Hi-

I have an open window between 2 and 3 today, if that might work. Otherwise, I would have to wait to 5:15 or later. This weekend can work as well.

Let me know.

Best,

Tyler

On Feb 26, 2021, at 10:02 AM, Lander, Eric S. EOP/OSTP (b) (6) wrote:

Hi Tyler:

Following up on our last conversation, would you have time to talk for 15 min later today?

Best,
Eric

[EXTERNAL] Re: Harvard course conversation on science advocacy

From: Shannon Miller (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Date: Wed, 03 Mar 2021 13:24:13 -0500

Hi Eric,

I just wanted to follow up on this email to see if you would have any time to talk with our CHEM100R class. Hoping to hear back!

Best,
Shannon

> On Feb 22, 2021, at 9:14 PM, Shannon Miller (b) (6) wrote:
>
> Hi Eric,
>
> I sent a message to your Broad email and got the automated response, so I figured I would try your new email as well. I contacted about a month ago about speaking with our Harvard class, CHEM100R, about your experience with science advocacy and how you plan to communicate important scientific problems with members of government and to the American People. I wanted to circle back to check if you know more about your schedule and if you would have a moment to talk with our class. We'd love to hear from you at any point during the semester! The class takes place Monday/Wednesday 12-2pm EST, but if you have any time at all we can set up a special session.
>
> Best,
> Shannon Miller
>
> Harvard University, Ph.D. Candidate in Chemistry and Chemical Biology
> David R. Liu lab, Broad Institute

[EXTERNAL] Fwd: Post-Apex March 8

From: Eric S Lander <(b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6) >

Date: Fri, 12 Mar 2021 03:47:41 -0500

Sent from my iPhone

Begin forwarded message:

From: Thomas Kalil (b) (6)
Date: March 12, 2021 at 12:47:26 AM EST
To: Zoe Weinberg (b) (6)
Cc: Post-Apex (b) (6)
Subject: Re: Post-Apex March 8

Here's the CEPI $3.5 billion plan to reduce the time to vaccines to 100 days that Rajeev mentioned.
>https://cepi.net/wp-content/uploads/2021/03/CEPI_3.5_billion_investment_case_10032021.pdf<

On Sun, Mar 7, 2021 at 2:34 PM Zoe Weinberg (b) (6) > wrote:

All,

Tomorrow we'll be joined by Rajeev Venkayya, head of vaccines for Takeda and former special assistant to the president for biodefense, where he oversaw the National Strategy for Pandemic Influenza. Rajeev will be discussing long-term strategy for combatting pandemic threats, and has asked that I pass along the below background & attached materials. We'll also have our regular briefing from Chris & Ronit (slides attached).

See you tomorrow—
Zoe

Topic: Taking the pandemic threat off the table

Background: CEPI (Coalition of Epidemic Preparedness Innovations) has played a key role in pandemic vaccine development and the creation of COVAX to support equitable access to pandemic vaccines. This week, CEPI will release its strategy for the next five years, which will have a significant focus on pandemic preparedness. This discussion will focus on the ambitions of that strategy and the concepts and technologies underpinning it.

Readaheads (optional):

1. Another Pandemic Need Never Happen: Richard Hatchett in FT (attached)
2. Concepts to be captured CEPI's new strategy (and for more background on CEPI): >https://cepi.net/covid-19-what-next/<
3. Promoting versatile vaccine development for emerging pandemics: Barney Graham & Nancy Sullivan in Nature Vaccines (attached). Note - this is a technical article that was published two years before the start of the pandemic. I'm providing it for those who are interested in the scientific basis of the prototype pathogen approach that we'll discuss.

--
You received this message because you are subscribed to the Google Groups "Post-Apex" group.
To unsubscribe from this group and stop receiving emails from it, send an email to post-apex+unsubscribe@schmidtfutures.com.
To view this discussion on the web visit >https://groups.google.com/a/schmidtfutures.com/(b) (6) [redacted]

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You received this message because you are subscribed to the Google Groups "Post-Apex" group.
To unsubscribe from this group and stop receiving emails from it, send an email to post-apex+unsubscribe@schmidtfutures.com.

To view this discussion on the web visit
>https://groups.google.com/a/schmidtfutures.com/d/msgid/post-apex/CAPmd_bbxHBsExw-k-jVfVy8ZqUOWL1ogF%2BiY%3DYoYVQi4T-uXkw%40mail.gmail.com<.

[EXTERNAL] Fwd: Invitation

From: Sira Dooley Fairchild (b) (6)

To: "Lo, Kevin C. EOP/OSTP" (b) (6)

Date: Tue, 23 Mar 2021 10:38:21 -0400

Attachments: Invitation Eric Lander.pdf (423.31 kB); FoGip_Concept Note.pdf (596.38 kB)

Hi Kevin,

Is this one already on the engagements tracking list/has it been discussed?

Best,
Sira

---------- Forwarded message ---------
From: **Schütte, Georg** (b) (6) >
Date: Tue, Mar 16, 2021 at 11:47 AM
Subject: Invitation
To: (b)(6) Eric Lander (b)(6) Eric Lander
Cc: (b)(6) Kei Koizumi (b)(6) Kei Koizumi , (b)(6) Eric Lander
<(b)(6) Eric Lander

Dear Professor Lander,

on behalf of my colleagues at the Stifterverband, the German National Academy of Sciences Leopoldina, the Commission of Experts for Research and Innovation (EFI), and the VolkswagenStiftung/Volkswagen Foundation I would like to cordially invite you to be the Distinguished Speaker of our Research Summit – the Forschungsgipfel.

This year's Forschungsgipfel, entitled ‚The Next Generation Innovation System,' aims to provide input for the new legislative period. We will discuss the innovative potential of future key technologies and we will ask high-profile business, political, and academic leaders for their priorities in research and innovation. In addition, the discussion will tackle the issue of who should steer the innovation system – what role should the Federal Government adopt and to which extent should it be steering the innovation agenda. We would be delighted if you would share your expertise, expectations, and

demands for an innovation system of the future.

Due to the ongoing challenges by the Covid-19 pandemic, this year's summit will be held in a hybrid format, enabling your participation digitally. About 500 participants are expected to follow the online program of the Forschungsgipfel. Please find further details in the attached invitation and concept note. Of course, I would be happy to answer any further questions of yours directly.

Please consider this invition as an advance notice. The invitation will officially be extended by the German Embassy in due course.

Sincerely,

Georg Schütte

Dr. Georg Schütte
Generalsekretär/Secretary General
VolkswagenStiftung
Kastanienallee 35
30519 Hannover
Germany
Tel.: (b) (6)
Fax: +(b) (6)
mailto(b) (6)
>http://www.volkswagenstiftung.de<<>http://www.volkswagenstiftung.de/<>

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Sira Dooley Fairchild
Pronouns: she/her/hers



2021 FORSCHUNGS GIPFEL Perspektiven für Wirtschaft, Wissenschaft und Innovation

STIFTERVERBAND . Berlin Office . Pariser Platz 6 . D-10117 Berlin

Office of Science and Technology Policy
Executive Office of the President
c/o: Prof. Dr. Eric Lander
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Stifterverband für die
Deutsche Wissenschaft e.V.

Pariser Platz 6 . D-10117 Berlin

Contact
Sonja Kaufmann
Project Lead Research Summit

P (b) (6)

(b) (6)

www.forschungsgipfel.de

Our reference
ska

Date
March 15, 2021

Invitation: Distinguished Speaker at the Forschungsgipfel 2021

Dear Professor Lander,

On May 19, 2021, the *Forschungsgipfel (Research Summit) 2021* will bring together decision-makers, experts, and innovators from the fields of business, science, civil society, and politics in Germany in order to discuss current questions and challenges in research and innovation policy. On behalf of the Stifterverband, the German National Academy of Sciences Leopoldina, the Commission of Experts for Research and Innovation (EFI), and the VolkswagenStiftung/Volkswagen Foundation we cordially invite you to be the Distinguished Speaker of our Reseach Summit and to join our discussion online.

Entitled ‚The Next Generation Innovation System' and taking into account the upcoming elections for the German Bundestag, this year's *Forschungsgipfel* aims to provide input for the new legislative period. A special point of reference is the Covid-19 pandemic. It has demonstrated the innovation potential of the German and European research sector, both in life science and vaccine research as well as in its digitalization capabilities. At the same time, it has highlighted the strategic challenges such as the transfer of research results to commercial applications. Therefore, we will discuss the innovative potential of future key technologies and we will ask high-profile business, political, and academic leaders for their priorities in research and innovation. In addition, the discussion will tackle the issue of who should steer the innovation system – what role should the Federal Government adopt and to which extent should it be steering the innovation agenda.

For decades, the transatlantic cooperation in research and innovation has been a cornerstone of German-American relations. We would be honored if you were to join our meeting with a keynote address to explain how the U.S. is approaching the topics of key technologies and managing innovation.

Initiated by:

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Leopoldina
Nationale Akademie der Wissenschaften

EXPERTENKOMMISSION FORSCHUNG UND INNOVATION
EFI

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International cooperation and division of labor have strongly shaped the German innovation system. How the US is approaching the topics of key technologies and managing innovation research is therefore of great interest to the German discussion.

We would be delighted if you would share your expertise, expectations, and demands for an innovation system of the future and contribute to an expectedly lively and fruitful *Forschungsgipfel 2021*. Due to the Covid-19 pandemic, the conference will be held in a hybrid format. We expect an audience of approximately 500 participants in the video stream. Please find the concept note for the event in the attachment.

For any questions regarding the conference or your potential participation, please feel free to contact Dr. Georg Schütte at the VolkswagenStiftung (schuette@volkswagenstiftung.de) on behalf of the undersigned partners.

We look forward to hearing from you!

Sincerely,

Prof. Dr. Dr.
Andreas Barner
Stifterverband

Prof. Dr.
Uwe Cantner
EFI

Prof. Dr.
Gerald H. Haug
Leopoldina

Dr.
Georg Schütte
VolkswagenStiftung

2021
FORSCHUNGS
GIPFEL

Perspektiven für Wirtschaft,
Wissenschaft und Innovation

Concept Note

The Next Generation Innovation System

Wednesday, May 19, 2021

As of March 12, 2021

Initiiert von:

STIFTERVERBAND
Bildung. Wissenschaft. Innovation.

Leopoldina
Nationale Akademie
der Wissenschaften

EXPERTENKOMMISSION
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VolkswagenStiftung

The 2021 Research Summit (*Forschungsgipfel*): The Next Generation Innovation System

The 2021 German federal election marks the beginning of a new legislative period in which directions for research and innovation policy will have to be set anew. Much has already been achieved in recent years - from an increase in funding for R&D and start-up activities, to setting technological priorities, to intensifying competition in the science sector, to coordinated action within the framework of the High-Tech Strategy. Today, Germany is in a good position internationally with its above-average investments in research and innovation. At the same time, it faces a number of serious challenges. These include, for example, a more extensive transfer of research results into commercial applications, the development and realization of digital business models, increasing e-government offerings or boosting start-up rates.

Two factors - technology profile and governance model - must be adjusted during the coming legislative term if Germany wants to continue to keep pace with the global competition among high-tech nations. External shocks, such as the Corona pandemic, can be used for a positive development of the innovation system by strengthening resilience and thus increasing competitiveness.

The following key topics and guiding questions will be the focus of the 2021 Research Summit:

Key Topic 1: Technology Profile and Technological Sovereignty - in Germany and Europe

Germany has long been the global technology leader in many segments of production, materials and mobility technologies. However, the deficit in artificial intelligence and information and communications technology, combined with a comparatively low level of digitization, is becoming a development risk. The German innovation system is not able to provide to a satisfying degree the necessary information and communications technologies which are crucial for growth, quality of life and competitiveness. It has thus lost its technological sovereignty and is dependent on technology supplies and innovations from other countries.

At the same time, complementary competencies and the international division of labor in economic and innovation policy that havsbeen practiced for decades reduce dependency on individual providers. Efforts to achieve technological independence therefore need to find a balance between cooperation and going it alone. Developing focal points within the innovation system also requires new or expanded foresight methods to sound out potentials and societal needs for action and to identify and compensate for backlogs.

Guiding questions: Which key technologies and infrastructures need to be strengthened or developed in the future, how are they identified and built up?

- What does technological sovereignty mean, and should German or European research and innovation (R&I) policy be geared towards achieving technological sovereignty?
- How can technological sovereignty be achieved for Germany and Europe in concrete terms, which technologies and areas of competence would be affected, which decision-making bodies would have to be changed?

- According to the political parties represented in the Bundestag, which previous R&I policy priorities should be urgently redefined, changed or abandoned in the new legislative period?

- How can and should the development of a defined technology portfolio be linked with strategies and measures to increase resilience? Which measures should be taken, and which actors would be required?

Key Topic 2: Governance of the Innovation System

Who guides the development of an innovation system? Voices calling for a more active role of the state are currently growing louder in Germany. Advocates of an entrepreneurial state go even further, leaving all steering activities along the innovation process and distribution of resulting profits to the government. At this point, the role that government, civil society and private actors should play in this remains open to discussion.

In addition, the question arises as to which instruments and measures the state, but also other actors in the innovation system, can use to achieve intended effects. At present, there are increasing calls for more experimental approaches that move away from traditional project funding. Establishing the Federal Agency for Disruptive Innovation, the German government has already shown that there is a desire to leverage disruptive potential to a much greater extent than before.

Guiding questions: Should German research and innovation policy be more proactive, strategic and normative and specifically initiate and steer transformation processes? How can this succeed?

- Do we need a new mission orientation in Germany and Europe? Which missions would be of central importance and how can they be achieved?

- Should policy interventions be limited to the pre-market sphere or are market interventions appropriate in specific situations and selected sectors?

- Does the state need new instruments for its R&I policy action? Should the industrial policy dimension of German R&I policy also be strengthened?

- What are the lessons learned from the Corona pandemic in science, business, politics and civil society and what specific measures can be derived from them?

The Initiators

The **Stifterverband für die Deutsche Wissenschaft** is a joint initiative of the German economy. The organization is interested in sustainably improving the German education and research environment. In order to achieve this goal, the Stifterverband supports universities and research institutes, talented individuals, and analyses the economic system, which serves as a basis for formulating recommendations for public policy and economic practice.
www.stifterverband.org

Originating in 1652, the **Leopoldina** has been committed to the advancement of free science for the benefit of humankind. With its base of about 1,600 members, it brings together outstanding scientists from Germany and numerous other countries. Appointed as Germany's National Academy of Sciences in 2008, the Leopoldina represents the German scientific community in international bodies and provides policymakers and the public with science-based advice.
www.leopoldina.org

The **Commission of Experts for Research and Innovation** (EFI) advises the Federal Government from a scientific perspective and submits an annual report on research, innovation and technological performance in Germany. The EFI's key task is to analyse the strengths and weaknesses of the German innovation system based on international comparisons, and to assess Germany's prospects as a location for research and innovation. On this basis, the EFI develops recommendations for national research and innovation policy.
www.e-fi.de

With special support from the VolkswagenStiftung.
The foundation is an independent, non-profit organization that funds research projects in all disciplines. Within the framework of changing funding initiatives, it provides impetus for the development of research and higher education. The foundation perceives a special mission in providing support for junior researchers, in fostering cooperation between researchers across the borders of disciplines, cultures, and national states, and in facilitating structural improvements to education and research in Germany.
www.volkswagenstiftung.de

Contact

Sonja Kaufmann
Project Lead Forschungsgipfel
T +49 (0)201 8401-499
forschungsgipfel@stifterverband.de
www.forschungsgipfel.de · www.stifterverband.org

RE: [EXTERNAL] Proposal for Dr. Nelson from the Innocence Project

From "Nelson, Alondra R. EOP/OSTP" (b) (6) >
:
To: Peter Neufeld (b) (6) >
Cc: "Lander, Eric S. EOP/OSTP" (b) (6) >, "Ochoa, Jorge A. EOP/OSTP" (b) (6)
Date: Thu, 25 Mar 2021 20:57:12 -0400

Dear Peter, (if I may)
Thank you for writing. I hope you will pardon me for being delayed in replying as I got settled into my new work at OSTP. I welcome the opportunity to meet with you and Ms. Swarns to discuss the ideas you raised in your letter of last month. I've copied my colleague Jorge Ochoa who can help us find a time to meet. I look forward to the discussion.
With best wishes,
Alondra

Alondra Nelson
Deputy Director for Science and Society
Office of Science and Technology Policy
Executive Office of the President

This email exchange is subject to the Freedom of Information Act.

From: Peter Neufeld (b) (6)
Sent: Saturday, February 27, 2021 3:38 PM
To: Nelson, Alondra R. EOP/OSTP (b) (6)
Cc: Lander, Eric S. EOP/OSTP (b) (6)
Subject: [EXTERNAL] Proposal for Dr. Nelson from the Innocence Project

NOTICE
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RE: Portman -- confirming?

From: "Koizumi, Kei EOP/OSTP" (b) (6) >

To: David Goldston (b) (6)

Date: Wed, 31 Mar 2021 09:04:07 -0400

Attachments: American Jobs Plan Fact Sheet 3-30-21 FINAL.pdf (309.34 kB)

David,

Thank you for noticing! I know, this is a big day. And thank you for the material on the bill.

Kei

Kei Koizumi
(he/him)
Acting Director and Chief of Staff
Office of Science and Technology Policy
(b) (6)

From: David Goldston (b) (6)

Sent: Wednesday, March 31, 2021 8:51 AM

To: Koizumi, Kei EOP/OSTP (b) (6)

Subject: [EXTERNAL] Portman -- confirming?

Kei,

Just want to be sure you saw the material I sent on Portman yesterday and that you have what you need. I understand you spoke with AAU on this late last week, which is good. As you know, this is a major issue for all of us and moving fast.

Congrats on getting the Infrastructure package out, and thanks for including the new directorate! We've come a long way.

David

The American Jobs Plan

While the American Rescue Plan is changing the course of the pandemic and delivering relief for working families, this is no time to build back to the way things were. This is the moment to reimagine and rebuild a new economy. The American Jobs Plan is an investment in America that will create millions of good jobs, rebuild our country's infrastructure, and position the United States to out-compete China. Public domestic investment as a share of the economy has fallen by more than 40 percent since the 1960s. The American Jobs Plan will invest in America in a way we have not invested since we built the interstate highways and won the Space Race.

The United States of America is the wealthiest country in the world, yet we rank 13th when it comes to the overall quality of our infrastructure. After decades of disinvestment, our roads, bridges, and water systems are crumbling. Our electric grid is vulnerable to catastrophic outages. Too many lack access to affordable, high-speed Internet and to quality housing. The past year has led to job losses and threatened economic security, eroding more than 30 years of progress in women's labor force participation. It has unmasked the fragility of our caregiving infrastructure. And, our nation is falling behind its biggest competitors on research and development (R&D), manufacturing, and training. It has never been more important for us to invest in strengthening our infrastructure and competitiveness, and in creating the good-paying, union jobs of the future.

Like great projects of the past, the President's plan will unify and mobilize the country to meet the great challenges of our time: the climate crisis and the ambitions of an autocratic China. It will invest in Americans and deliver the jobs and opportunities they deserve. But unlike past major investments, the plan prioritizes addressing long-standing and persistent racial injustice. The plan targets 40 percent of the benefits of climate and clean infrastructure investments to disadvantaged communities. And, the plan invests in rural communities and communities impacted by the market-based transition to clean energy. Specifically, President Biden's plan will:

Fix highways, rebuild bridges, upgrade ports, airports and transit systems. The President's plan will modernize 20,000 miles of highways, roads, and main-streets. It will fix the ten most economically significant bridges in the country in need of reconstruction. It also will repair the worst 10,000 smaller bridges, providing critical linkages to communities. And, it will replace thousands of buses and rail cars, repair hundreds of stations, renew airports, and expand transit and rail into new communities.

Deliver clean drinking water, a renewed electric grid, and high-speed broadband to all Americans. President Biden's plan will eliminate all lead pipes and service lines in our drinking water systems, improving the health of our country's children and communities of color. It will put hundreds of thousands of people to work laying thousands of miles of transmission lines and capping hundreds of thousands of orphan oil and gas wells and abandoned mines. And, it will bring affordable, reliable, high-speed broadband to every American, including the more than 35 percent of rural Americans who lack access to broadband at minimally acceptable speeds.

Build, preserve, and retrofit more than two million homes and commercial buildings, modernize our nation's schools and child care facilities, and upgrade veterans' hospitals and federal buildings. President Biden's plan will create good jobs building, rehabilitating, and retrofitting affordable, accessible, energy efficient, and resilient housing, commercial buildings, schools, and child care facilities all over the country, while also vastly improving our nation's federal facilities, especially those that serve veterans.

Solidify the infrastructure of our care economy by creating jobs and raising wages and benefits for essential home care workers. These workers – the majority of whom are women of color – have been underpaid and undervalued for too long. The President's plan makes substantial investments in the infrastructure of our care economy, starting by creating new and better jobs for caregiving workers. His plan will provide home and community-based care for individuals who otherwise would need to wait as many as five years to get the services they badly need.

Revitalize manufacturing, secure U.S. supply chains, invest in R&D, and train Americans for the jobs of the future. President Biden's plan will ensure that the best, diverse minds in America are put to work creating the innovations of the future while creating hundreds of thousands of quality jobs today. Our workers will build and make things in every part of America, and they will be trained for well-paying, middle-class jobs.

Create good-quality jobs that pay prevailing wages in safe and healthy workplaces while ensuring workers have a free and fair choice to organize, join a union, and bargain collectively with their employers. By ensuring that American taxpayers' dollars benefit working families and their communities, and not multinational corporations or foreign governments, the plan will require that goods and materials are made in America and shipped on U.S.-flag, U.S.-crewed vessels. The plan also will ensure that Americans who have endured systemic discrimination and exclusion for generations finally have a fair shot at obtaining good paying jobs and being part of a union.

Alongside his American Jobs Plan, President Biden is releasing a Made in America Tax Plan to make sure corporations pay their fair share in taxes and encourage job creation at home. A recent study found that 91 Fortune 500 companies paid $0 in federal taxes on U.S. income in 2018. Another study found that the average corporation paid just 8 percent in taxes. President Biden believes that profitable corporations should not be able to get away with paying little or no tax by shifting jobs and profits overseas. President Biden's plan will reward investment at home, stop profit shifting, and ensure other nations won't gain a competitive edge by becoming tax havens.

The President's American Jobs Plan is a historic public investment – consisting principally of one-time capital investments in our nation's productivity and long-term growth. It will invest about 1 percent of GDP per year over eight years to upgrade our nation's infrastructure, revitalize manufacturing, invest in basic research and science, shore up supply chains, and solidify our care infrastructure. These are investments that leading economists agree will give Americans good jobs now and will pay off for future generations by leaving the country more competitive and our communities stronger. In total, the plan will invest about $2 trillion this

decade. If passed alongside President Biden's Made in America corporate tax plan, it will be fully paid for within the next 15 years and reduce deficits in the years after.

BUILD WORLD-CLASS TRANSPORTATION INFRASTRUCTURE: FIX HIGHWAYS, REBUILD BRIDGES, AND UPGRADE PORTS, AIRPORTS AND TRANSIT SYSTEMS

President Biden is calling on Congress to make a historic and overdue investment in our roads, bridges, rail, ports, airports, and transit systems. The President's plan will ensure that these investments produce good-quality jobs with strong labor standards, prevailing wages, and a free and fair choice to join a union and bargain collectively. These investments will advance racial equity by providing better jobs and better transportation options to underserved communities. These investments also will extend opportunities to small businesses to participate in the design, construction, and manufacturing of new infrastructure and component parts. President Biden's plan will deliver infrastructure Americans can trust, because it will be resilient to floods, fires, storms, and other threats, and not fragile in the face of these increasing risks. President Biden is calling on Congress to:

Transform our crumbling transportation infrastructure:

Decades of declining public investment has left our roads, bridges, rail, and transit systems in poor condition, with a trillion-dollar backlog of needed repairs. More than 35,000 people die in traffic crashes on U.S. roads each year, and millions more are seriously and often permanently injured. The United States has one of the highest traffic fatality rates in the industrialized world, double the rate in Canada and quadruple that in Europe. Across cities, suburbs, and rural areas, President Biden's plan will help parents get to work reliably and affordably, reduce the impacts of climate change for our kids, and make sure fewer families mourn the loss of a loved one to road crashes. His investments will use more sustainable and innovative materials, including cleaner steel and cement, and component parts Made in America and shipped on U.S.-flag vessels with American crews under U.S. laws. And, his infrastructure investments will mitigate socio-economic disparities, advance racial equity, and promote affordable access to opportunity.

The President's plan invests an additional $621 billion in transportation infrastructure and resilience. It will:

- **Repair American roads and bridges**. One in five miles, or 173,000 total miles, of our highways and major roads are in poor condition, as well as 45,000 bridges. Delays caused by traffic congestion alone cost over $160 billion per year, and motorists are forced to pay over $1,000 every year in wasted time and fuel. The President is proposing a total increase of $115 billion to modernize the bridges, highways, roads, and main streets that are in most critical need of repair. This includes funding to improve air quality, limit greenhouse gas emissions, and reduce congestion. His plan will modernize 20,000 miles of highways, roads, and main streets, not only "fixing them first" but "fixing them right," with safety, resilience, and all users in mind. It will fix the most economically significant

large bridges in the country in need of reconstruction, and it will repair the worst 10,000 smaller bridges, including bridges that provide critical connections to rural and tribal communities. The plan includes $20 billion to improve road safety for all users, including increases to existing safety programs and a new Safe Streets for All program to fund state and local "vision zero" plans and other improvements to reduce crashes and fatalities, especially for cyclists and pedestrians.

- **Modernize public transit**. Households that take public transportation to work have twice the commute time, and households of color are twice as likely to take public transportation. Our current transit infrastructure is inadequate – the Department of Transportation estimates a repair backlog of over $105 billion, representing more than 24,000 buses, 5,000 rail cars, 200 stations, and thousands of miles of track, signals, and power systems in need of replacement. This translates to service delays and disruptions that leave riders stranded and discourage transit use. President Biden is calling on Congress to invest $85 billion to modernize existing transit and help agencies expand their systems to meet rider demand. This investment will double federal funding for public transit, spend down the repair backlog, and bring bus, bus rapid transit, and rail service to communities and neighborhoods across the country. It will ultimately reduce traffic congestion for everyone.

- **Invest in reliable passenger and freight rail service**. The nation's rail networks have the potential to offer safe, reliable, efficient, and climate-friendly alternatives for moving people and freight. However, unlike highways and transit, rail lacks a multi-year funding stream to address deferred maintenance, enhance existing corridors, and build new lines in high-potential locations. There are currently projects just waiting to be funded that will give millions more Americans reliable and fast inter-city train service. President Biden is calling on Congress to invest $80 billion to address Amtrak's repair backlog; modernize the high traffic Northeast Corridor; improve existing corridors and connect new city pairs; and enhance grant and loan programs that support passenger and freight rail safety, efficiency, and electrification.

- **Create good jobs electrifying vehicles**. U.S. market share of plug-in electric vehicle (EV) sales is only one-third the size of the Chinese EV market. The President believes that must change. He is proposing a $174 billion investment to win the EV market. His plan will enable automakers to spur domestic supply chains from raw materials to parts, retool factories to compete globally, and support American workers to make batteries and EVs. It will give consumers point of sale rebates and tax incentives to buy American-made EVs, while ensuring that these vehicles are affordable for all families and manufactured by workers with good jobs. It will establish grant and incentive programs for state and local governments and the private sector to build a national network of 500,000 EV chargers by 2030, while promoting strong labor, training, and installation standards. His plan also will replace 50,000 diesel transit vehicles and electrify at least 20 percent of our yellow school bus fleet through a new Clean Buses for Kids Program at the

Environmental Protection Agency, with support from the Department of Energy. These investments will set us on a path to 100 percent clean buses, while ensuring that the American workforce is trained to operate and maintain this 21st century infrastructure. Finally, it will utilize the vast tools of federal procurement to electrify the federal fleet, including the United States Postal Service.

- **Improve ports, waterways, and airports.** The United States built modern aviation, but our airports lag far behind our competitors. According to some rankings, no U.S. airports rank in the top 25 of airports worldwide. Our ports and waterways need repair and reimagination too. President Biden is calling on Congress to invest $25 billion in our airports, including funding for the Airport Improvement Program, upgrades to FAA assets that ensure safe and efficient air travel, and a new program to support terminal renovations and multimodal connections for affordable, convenient, car-free access to air travel. President Biden is calling on Congress to invest an additional $17 billion in inland waterways, coastal ports, land ports of entry, and ferries, which are all essential to our nation's freight. This includes a Healthy Ports program to mitigate the cumulative impacts of air pollution on neighborhoods near ports, often communities of color. These investments will position the United States as a global leader in clean freight and aviation.

- **Redress historic inequities and build the future of transportation infrastructure.** The President's plan for transportation is not just ambitious in scale, it is designed with equity in mind and to set up America for the future. Too often, past transportation investments divided communities – like the Claiborne Expressway in New Orleans or I-81 in Syracuse – or it left out the people most in need of affordable transportation options. The President's plan includes $20 billion for a new program that will reconnect neighborhoods cut off by historic investments and ensure new projects increase opportunity, advance racial equity and environmental justice, and promote affordable access. The President's plan will inspire basic research, like advanced pavements that recycle carbon dioxide, and "future proof" investments that will last decades to leave coming generations with a safe, equitable, and sustainable transportation system. And, the President's plan will accelerate transformative investments, from pre-development through construction, turning "shovel worthy" ideas into "shovel ready" projects. This includes $25 billion for a dedicated fund to support ambitious projects that have tangible benefits to the regional or national economy but are too large or complex for existing funding programs.

- **Invest resources wisely to deliver infrastructure projects that produce real results.** America lags its peers – including Canada, the U.K., and Australia – in the on-time and on-budget delivery of infrastructure, and is falling behind countries like China on overall investment. Delivering this historic investment will require partnership across government, unions, and industry, to produce meaningful outcomes for the American people – reliable transportation, safe water, affordable housing, healthy schools, clean

electricity, and broadband for all. When President Biden managed the implementation of the Recovery Act, he insisted on the strongest possible accountability and transparency measures to ensure public dollars were invested efficiently and effectively. When Congress enacts the American Jobs Plan, the President will bring the best practices from the Recovery Act and models from around the world to break down barriers and drive implementation of infrastructure investments across all levels of government to realize the President's vision of safe, reliable, and resilient infrastructure. Critically, in order to achieve the best outcomes on cost and performance for the American people, the Administration will support the state, local, and tribal governments delivering these projects through world-class training, technical assistance, and procurement best practices. In addition, the President's plan will use smart, coordinated infrastructure permitting to expedite federal decisions while prioritizing stakeholder engagement, community consultation, and maximizing equity, health, and environmental benefits.

Make our infrastructure more resilient:

Millions of Americans feel the effects of climate change each year when their roads wash out, airport power goes down, or schools get flooded. Last year alone, the United States faced 22 extreme weather and climate-related disaster events with losses exceeding $1 billion each – a cumulative price tag of nearly $100 billion. Chronic underinvestment in resilience has harmed American transportation infrastructure, disrupting service, making travel conditions unsafe, causing severe damage, and increasing maintenance and operating costs.

In 2020, the United States endured 22 separate billion-dollar weather and climate disasters, costing $95 billion in damages to homes, businesses, and public infrastructure. In Louisiana, Hurricane Laura caused $19 billion of damage, resulting in broken water systems and a severely damaged electrical grid that impeded a quick recovery. Building back better requires that the investments in this historic plan make our infrastructure more resilient in the face of increasingly severe floods, wildfires, hurricanes, and other risks. Every dollar spent on rebuilding our infrastructure during the Biden administration will be used to prevent, reduce, and withstand the impacts of the climate crisis. Additionally, the President is calling for $50 billion in dedicated investments to improve infrastructure resilience and:

- **Safeguard critical infrastructure and services, and defend vulnerable communities.** People of color and low-income people are more likely to live in areas most vulnerable to flooding and other climate change-related weather events. They also are less likely to have the funds to prepare for and recover from extreme weather events. In the wake of Hurricane Harvey, Black and Hispanic residents were twice as likely as white residents to report experiencing an income shock with no recovery support. President Biden's plan increases resilience in the most essential services, including the electric grid; food systems; urban infrastructure; community health and hospitals; and our roads, rail, and other transportation assets. His plan also targets investments to support infrastructure in those communities most vulnerable physically and financially to climate-driven disasters and to build back above existing codes and standards. The President's plan will invest in

vulnerable communities through a range of programs, including FEMA's Building Resilient Infrastructure and Communities program, HUD's Community Development Block Grant program, new initiatives at the Department of Transportation, a bipartisan tax credit to provide incentives to low- and middle-income families and to small businesses to invest in disaster resilience, and transition and relocation assistance to support community-led transitions for the most vulnerable tribal communities.

- **Maximize the resilience of land and water resources to protect communities and the environment.** President Biden's plan will protect and, where necessary, restore nature-based infrastructure – our lands, forests, wetlands, watersheds, and coastal and ocean resources. Families and businesses throughout the United States rely on this infrastructure for their lives and livelihoods. President Biden is calling on Congress to invest in protection from extreme wildfires, coastal resilience to sea-level rise and hurricanes, support for agricultural resources management and climate-smart technologies, and the protection and restoration of major land and water resources like Florida's Everglades and the Great Lakes. Additionally, the President's plan provides funding for the western drought crisis by investing in water efficiency and recycling programs, Tribal Water Settlements, and dam safety. President Biden's plan will empower local leaders to shape these restoration and resilience project funds in line with the Outdoor Restoration Force Act.

REBUILD CLEAN DRINKING WATER INFRASTRUCTURE, A RENEWED ELECTRIC GRID, AND HIGH-SPEED BROADBAND TO ALL AMERICANS

Too many American families drink polluted water, lack access to affordable, high-speed internet, or experience power outages too often – all while paying more for those services. President Biden's plan invests in the infrastructure necessary to finally deliver the water, broadband, and electricity service that Americans deserve. Specifically, his plan will:

Ensure clean, safe drinking water is a right in all communities:

Across the country, pipes and treatment plants are aging and polluted drinking water is endangering public health. An estimated six to ten million homes still receive drinking water through lead pipes and service lines. The President's investments in improving water infrastructure and replacing lead service lines will create good jobs, including union and prevailing wage jobs. President Biden's plan invests $111 billion to:

- **Replace 100 percent of the nation's lead pipes and service lines.** According to the CDC, there is no safe level of lead exposure for children. Lead can slow development and cause learning, behavior, and hearing problems in children, as well as lasting kidney and brain damage. President Biden believes that no American family should still be receiving drinking water through lead pipes and service lines. To eliminate all lead pipes and service lines in the country, he is calling on Congress to invest $45 billion in the

Environmental Protection Agency's Drinking Water State Revolving Fund and in Water Infrastructure Improvements for the Nation Act (WIIN) grants. In addition to reducing lead exposure in homes, this investment also will reduce lead exposure in 400,000 schools and childcare facilities.

- **Upgrade and modernize America's drinking water, wastewater, and stormwater systems, tackle new contaminants, and support clean water infrastructure across rural America.** Aging water systems threaten public health in thousands of communities nationwide. President Biden will modernize these systems by scaling up existing, successful programs, including by providing $56 billion in grants and low-cost flexible loans to states, Tribes, territories, and disadvantaged communities across the country. President Biden's plan also provides $10 billion in funding to monitor and remediate PFAS (per- and polyfluoroalkyl substances) in drinking water and to invest in rural small water systems and household well and wastewater systems, including drainage fields.

Revitalize America's digital infrastructure:

Generations ago, the federal government recognized that without affordable access to electricity, Americans couldn't fully participate in modern society and the modern economy. With the 1936 Rural Electrification Act, the federal government made a historic investment in bringing electricity to nearly every home and farm in America, and millions of families and our economy reaped the benefits.

Broadband internet is the new electricity. It is necessary for Americans to do their jobs, to participate equally in school learning, health care, and to stay connected. Yet, by one definition, more than 30 million Americans live in areas where there is no broadband infrastructure that provides minimally acceptable speeds. Americans in rural areas and on tribal lands particularly lack adequate access. And, in part because the United States has some of the highest broadband prices among OECD countries, millions of Americans can't use broadband internet even if the infrastructure exists where they live. In urban areas as well, there is a stark digital divide: a much higher percentage of White families use home broadband internet than Black or Latino families. The last year made painfully clear the cost of these disparities, particularly for students who struggled to connect while learning remotely, compounding learning loss and social isolation for those students.

The President believes we can bring affordable, reliable, high-speed broadband to every American through a historic investment of $100 billion. That investment will:

- **Build high-speed broadband infrastructure to reach 100 percent coverage.** The President's plan prioritizes building "future proof" broadband infrastructure in unserved and underserved areas so that we finally reach 100 percent high-speed broadband coverage. It also prioritizes support for broadband networks owned, operated by, or affiliated with local governments, non-profits, and co-operatives—providers with less pressure to turn profits and with a commitment to serving entire communities. Moreover,

it ensures funds are set aside for infrastructure on tribal lands and that tribal nations are consulted in program administration. Along the way, it will create good-paying jobs with labor protections and the right to organize and bargain collectively.

- **Promote transparency and competition.** President Biden's plan will promote price transparency and competition among internet providers, including by lifting barriers that prevent municipally-owned or affiliated providers and rural electric co-ops from competing on an even playing field with private providers, and requiring internet providers to clearly disclose the prices they charge.

- **Reduce the cost of broadband internet service and promote more widespread adoption.** President Biden believes that building out broadband infrastructure isn't enough. We also must ensure that every American who wants to can afford high-quality and reliable broadband internet. While the President recognizes that individual subsidies to cover internet costs may be needed in the short term, he believes continually providing subsidies to cover the cost of overpriced internet service is not the right long-term solution for consumers or taxpayers. Americans pay too much for the internet – much more than people in many other countries – and the President is committed to working with Congress to find a solution to reduce internet prices for all Americans, increase adoption in both rural and urban areas, hold providers accountable, and save taxpayer money.

Reenergize America's power infrastructure:

As the recent Texas power outages demonstrated, our aging electric grid needs urgent modernization. A Department of Energy study found that power outages cost the U.S. economy up to $70 billion annually. The President's plan will create a more resilient grid, lower energy bills for middle class Americans, improve air quality and public health outcomes, and create good jobs, with a choice to join a union, on the path to achieving 100 percent carbon-free electricity by 2035. President Biden is calling on Congress to invest $100 billion to:

- **Build a more resilient electric transmission system.** Through investments in the grid, we can move cheaper, cleaner electricity to where it is needed most. This starts with the creation of a targeted investment tax credit that incentivizes the buildout of at least 20 gigawatts of high-voltage capacity power lines and mobilizes tens of billions in private capital off the sidelines – right away. In addition, President Biden's plan will establish a new Grid Deployment Authority at the Department of Energy that allows for better leverage of existing rights-of-way – along roads and railways – and supports creative financing tools to spur additional high priority, high-voltage transmission lines. These efforts will create good-paying jobs for union laborers, line workers, and electricians, in addition to creating demand for American-made building materials and parts.

- **Spur jobs modernizing power generation and delivering clean electricity.** President Biden is proposing a ten-year extension and phase down of an expanded direct-pay

investment tax credit and production tax credit for clean energy generation and storage. These credits will be paired with strong labor standards to ensure the jobs created are good-quality jobs with a free and fair choice to join a union and bargain collectively. President Biden's plan will mobilize private investment to modernize our power sector. It also will support state, local, and tribal governments choosing to accelerate this modernization through complementary policies – like clean energy block grants that can be used to support clean energy, worker empowerment, and environmental justice. And, it will use the federal government's incredible purchasing power to drive clean energy deployment across the market by purchasing 24/7 clean power for federal buildings. To ensure that we fully take advantage of the opportunity that modernizing our power sector presents, President Biden will establish an Energy Efficiency and Clean Electricity Standard (EECES) aimed at cutting electricity bills and electricity pollution, increasing competition in the market, incentivizing more efficient use of existing infrastructure, and continuing to leverage the carbon pollution-free energy provided by existing sources like nuclear and hydropower. All of this will be done while ensuring those facilities meet robust and rigorous standards for worker, public, and environmental safety as well as environmental justice – and all while moving toward 100 percent carbon-pollution free power by 2035.

- **Put the energy industry to work plugging orphan oil and gas wells and cleaning up abandoned mines.** Hundreds of thousands of former orphan oil and gas wells and abandoned mines pose serious safety hazards, while also causing ongoing air, water, and other environmental damage. Many of these old wells and mines are located in rural communities that have suffered from years of disinvestment. President Biden's plan includes an immediate up-front investment of $16 billion that will put hundreds of thousands to work in union jobs plugging oil and gas wells and restoring and reclaiming abandoned coal, hardrock, and uranium mines. In addition to creating good jobs in hard-hit communities, this investment will reduce the methane and brine that leaks from these wells, just as we invest in reducing leaks from other sources like aging pipes and distribution systems.

- **Remediate and redevelop idle real property, and spur the buildout of critical physical, social, and civic infrastructure in distressed and disadvantaged communities.** In thousands of rural and urban communities around the country, hundreds of thousands of former industrial and energy sites are now idle – sources of blight and pollution. Through a $5 billion investment in the remediation and redevelopment of these Brownfield and Superfund sites, as well as related economic and workforce development, President Biden's plan will turn this idle real property into new hubs of economic growth and job creation. But it's not enough to redevelop old infrastructure. President Biden's plan also will bring these communities new critical physical, social, and civic infrastructure. This means investing in the Economic Development Agency's Public Works program (while lifting the cap of $3 million on projects) and in "Main Street" revitalization efforts through HUD and USDA. President Biden's plan also will spur

targeted sustainable, economic development efforts through the Appalachian Regional Commission's POWER grant program, Department of Energy retooling grants for idled factories (through the Section 132 program), and dedicated funding to support community-driven environmental justice efforts – such as capacity and project grants to address legacy pollution and the cumulative impacts experienced by frontline and fenceline communities.

- **Build next generation industries in distressed communities.** President Biden believes that the market-based shift toward clean energy presents enormous opportunities for the development of new markets and new industries. For example, by pairing an investment in 15 decarbonized hydrogen demonstration projects in distressed communities with a new production tax credit, we can spur capital-project retrofits and installations that bolster and decarbonize our industry. The President's plan also will establish ten pioneer facilities that demonstrate carbon capture retrofits for large steel, cement, and chemical production facilities, all while ensuring that overburdened communities are protected from increases in cumulative pollution. In addition, in line with the bipartisan SCALE Act, his plan will support large-scale sequestration efforts that leverage the best science and prioritize community engagement. And to accelerate responsible carbon capture deployment and ensure permanent storage, President Biden's plan reforms and expands the bipartisan Section 45Q tax credit, making it direct pay and easier to use for hard-to-decarbonize industrial applications, direct air capture, and retrofits of existing power plants.
- **Mobilize the next generation of conservation and resilience workers.** This $10 billion investment will put a new, diverse generation of Americans to work conserving our public lands and waters, bolstering community resilience, and advancing environmental justice through a new Civilian Climate Corps, all while placing good-paying union jobs within reach for more Americans.

BUILD, PRESERVE, AND RETROFIT MORE THAN TWO MILLION HOMES AND COMMERCIAL BUILDINGS; MODERNIZE OUR NATION'S SCHOOLS, COMMUNITY COLLEGES, AND EARLY LEARNING FACILITIES; AND UPGRADE VETERANS' HOSPITALS AND FEDERAL BUILDINGS

There is a severe shortage of affordable housing options in America, and the American Society of Civil Engineers gives our school infrastructure a "D+." President Biden believes we must invest in building and upgrading modern, resilient, and energy-efficient homes and buildings, including our nation's schools, early learning facilities, veterans' hospitals and other federal buildings, and in the process, employ American workers in jobs with good wages and benefits. President Biden's plan will:

Build, preserve, and retrofit more than two million homes and commercial buildings to address the affordable housing crisis:

There is a severe shortage of affordable housing options in America. Millions of families pay more than half their income on rent, and home energy costs are a significant concern for American renters as well. And, across the country, people are struggling to purchase their first home.

The President's plan invests $213 billion to produce, preserve, and retrofit more than two million affordable and sustainable places to live. It pairs this investment with an innovative new approach to eliminate state and local exclusionary zoning laws, which drive up the cost of construction and keep families from moving to neighborhoods with more opportunities for them and their kids. The President's plan will help address the growing cost of rent and create jobs that pay prevailing wages, including through project labor agreements with a free and fair choice to join a union and bargain collectively.

President Biden is calling on Congress to:

- **Produce, preserve, and retrofit more than a million affordable, resilient, accessible, energy efficient, and electrified housing units.** Through targeted tax credits, formula funding, grants, and project-based rental assistance, President Biden's plan will extend affordable housing rental opportunities to underserved communities nationwide, including rural and tribal areas.

- **Build and rehabilitate more than 500,000 homes for low- and middle-income homebuyers.** President Biden is calling on Congress to take immediate steps to spur the construction and rehabilitation of homes for underserved communities. Specifically, he is calling on Congress to pass the innovative, bipartisan Neighborhood Homes Investment Act (NHIA). Offering $20 billion worth of NHIA tax credits over the next five years will result in approximately 500,000 homes built or rehabilitated, creating a pathway for more families to buy a home and start building wealth.

- **Eliminate exclusionary zoning and harmful land use policies.** For decades, exclusionary zoning laws – like minimum lot sizes, mandatory parking requirements, and prohibitions on multifamily housing – have inflated housing and construction costs and locked families out of areas with more opportunities. President Biden is calling on Congress to enact an innovative, new competitive grant program that awards flexible and attractive funding to jurisdictions that take concrete steps to eliminate such needless barriers to producing affordable housing.

- **Address longstanding public housing capital needs.** Years of disinvestment have left our public housing in disrepair. President Biden is calling on Congress to invest $40 billion to improve the infrastructure of the public housing system in America. This funding will address critical life-safety concerns, mitigate imminent hazards to residents, and undertake energy efficiency measures which will significantly reduce ongoing

operating expenses. These improvements will disproportionately benefit women, people of color, and people with disabilities.

- **Put union building trade workers to work upgrading homes and businesses to save families money.** President Biden's plan will upgrade homes through block grant programs, the Weatherization Assistance Program, and by extending and expanding home and commercial efficiency tax credits. President Biden's plan also will establish a $27 billion Clean Energy and Sustainability Accelerator to mobilize private investment into distributed energy resources; retrofits of residential, commercial and municipal buildings; and clean transportation. These investments have a particular focus on disadvantaged communities that have not yet benefited from clean energy investments.

Modernize our nation's schools and early learning facilities:

Too many students attend schools and child care centers that are run-down, unsafe, and pose health risks. These conditions are dangerous for our kids and exist disproportionately in schools with a high percentage of low-income students and students of color. And even before COVID-19, 43 percent of parents reported struggling to find an adequate child care facility for their children. President Biden is calling on Congress to:

- **Modernize our public schools.** President Biden believes we can't close the opportunity gap if low-income kids go to schools in buildings that undermine health and safety, while wealthier students get access to safe buildings with labs and technology that prepare them for the jobs of the future. The President's plan invests $100 billion to upgrade and build new public schools, through $50 billion in direct grants and an additional $50 billion leveraged through bonds. These funds will first go toward making sure our schools are safe and healthy places of learning for our kids and work for teachers and other education professionals, for example by improving indoor air quality and ventilation. As we make our schools safer, we also will invest in cutting-edge, energy-efficient and electrified, resilient, and innovative school buildings with technology and labs that will help our educators prepare students to be productive workers and valued students. Under the President's plan, better operating school facilities will reduce their greenhouse gas emissions and also will become environments of community resilience with green space, clean air, and safe places to gather, especially during emergencies. Funds also will be provided to improve our school kitchens, so they can be used to better prepare nutritious meals for our students and go green by reducing or eliminating the use of paper plates and other disposable materials.

- **Investing in community college infrastructure**. Investing in community college facilities and technology helps protect the health and safety of students and faculty, address education deserts (particularly for rural communities), grow local economies, improve energy efficiency and resilience, and narrow funding inequities in the short-term, as we rebuild our higher education finance system for the long-run. President Biden

is calling on Congress to invest $12 billion to address these needs. States will be responsible for using the dollars to address both existing physical and technological infrastructure needs at community colleges and identifying strategies to address access to community college in education deserts.

- **Upgrade child care facilities and build new supply in high need areas.** Lack of access to child care makes it harder for parents, especially mothers, to fully participate in the workforce. In areas with the greatest shortage of child care slots, women's labor force participation is about three percentage points less than in areas with a high capacity of child care slots, hurting families and hindering U.S. growth and competitiveness. President Biden is calling on Congress to provide $25 billion to help upgrade child care facilities and increase the supply of child care in areas that need it most. Funding would be provided through a Child Care Growth and Innovation Fund for states to build a supply of infant and toddler care in high-need areas. President Biden also is calling for an expanded tax credit to encourage businesses to build child care facilities at places of work. Employers will receive 50 percent of the first $1 million of construction costs per facility so that employees can enjoy the peace of mind and convenience that comes with on-site child care. These investments will provide safe, accessible, energy efficient, high-quality learning environments for providers to teach and care for children. Public investments in schools and childcare improves children's outcomes—the foundation for future productivity gains. In classrooms with poor ventilation, for example, student absences are 10 to 20 percent higher.

Upgrade VA hospitals and federal buildings:

The federal government operates office buildings, courthouses, and other facilities in every state, where millions of workers serve the public from outdated, inefficient, and sometimes unsafe working conditions. While the median age of U.S. private sector hospitals is roughly 11 years, the Veterans Affairs' hospital portfolio has a median age of 58. The President believes our veterans deserve state-of-the-art hospitals and care. President Biden's plan provides $18 billion for the modernization of Veterans Affairs hospitals and clinics. President Biden's plan also invests $10 billion in the modernization, sustainability, and resilience of federal buildings, including through a bipartisan Federal Capital Revolving Fund to support investment in a major purchase, construction or renovation of Federal facilities. And, President Biden's plan utilizes the vast tools of federal procurement to purchase low carbon materials for construction and clean power for these newly constructed VA hospitals and federal buildings.

SOLIDIFY THE INFRASTRUCTURE OF OUR CARE ECONOMY BY CREATING JOBS AND RAISING WAGES AND BENEFITS FOR ESSENTIAL HOME CARE WORKERS

Even before COVID-19, our country was in the midst of a caregiving crisis. In addition to caring for children, families feel the financial burden of caring for aging relatives and family members with disabilities, and there is a financial strain for people with disabilities living independently to

ensure that they are getting care in their homes. At the same time, hundreds of thousands of people who need better care are unable to access it, even though they qualify under Medicaid. In fact, it can take years for these individuals to get the services they badly need. Aging relatives and people with disabilities deserve better. They deserve high-quality services and support that meet their unique needs and personal choices.

Caregivers – who are disproportionally women of color – have been underpaid and undervalued for far too long. Wages for essential home care workers are approximately $12 per hour, putting them among the lowest paid workers in our economy. In fact, one in six workers in this sector live in poverty. President Biden is calling on Congress to make substantial investments in the infrastructure of care in our country. Specifically, he is calling on Congress to put $400 billion toward expanding access to quality, affordable home- or community-based care for aging relatives and people with disabilities. These investments will help hundreds of thousands of Americans finally obtain the long-term services and support they need, while creating new jobs and offering caregiving workers a long-overdue raise, stronger benefits, and an opportunity to organize or join a union and collectively bargain. Research shows that increasing the pay of direct care workers greatly enhances workers' financial security, improves productivity, and increases the quality of care offered. Another study showed that increased pay for care workers prevented deaths, reduced the number of health violations, and lowered the cost of preventative care.

President Biden's plan will:

- **Expand access to long-term care services under Medicaid.** President Biden believes more people should have the opportunity to receive care at home, in a supportive community, or from a loved one. President Biden's plan will expand access to home and community-based services (HCBS) and extend the longstanding Money Follows the Person program that supports innovations in the delivery of long-term care.

- **Put in place an infrastructure to create good middle-class jobs with a free and fair choice to join a union.** The HCBS expansion under Medicaid can support well-paying caregiving jobs that include benefits and the ability to collectively bargain, building state infrastructure to improve the quality of services and to support workers. This will improve wages and quality of life for essential home health workers and yield significant economic benefits for low-income communities and communities of color.

INVEST IN R&D, REVITALIZE MANUFACTURING AND SMALL BUSINESSES, AND TRAIN AMERICANS FOR THE JOBS OF THE FUTURE

Half the jobs in our high growth, high wage sectors are concentrated in just 41 counties, locking millions of Americans out of a shot at a middle-class job. President Biden believes that, even in the face of automation and globalization, America can and must retain well-paid union jobs and create more of them all across the country. U.S. manufacturing was the Arsenal of Democracy in World War II and must be part of the Arsenal of American Prosperity today, helping fuel an economic recovery for working families. From the invention of the semiconductor to the creation

of the Internet, new engines of economic growth have emerged due to public investments that support research, commercialization, and strong supply chains. President Biden is calling on Congress to make smart investments in research and development, manufacturing and regional economic development, and in workforce development to give our workers and companies the tools and training they need to compete on the global stage. Specifically, President Biden is calling on Congress to:

Invest in R&D and the technologies of the future:

Public investments in R&D lay the foundation for the future breakthroughs that over time yield new businesses, new jobs, and more exports. However, we need more investment if we want to maintain our economic edge in today's global economy. We are one of the few major economies whose public investments in research and development have declined as a percent of GDP in the past 25 years. Countries like China are investing aggressively in R&D, and China now ranks number two in the world in R&D expenditures. In addition, barriers to careers in high-innovation sectors remain significant. We must do more to improve access to the higher wage sectors of our economy. In order to win the 21st century economy, President Biden believes America must get back to investing in the researchers, laboratories, and universities across our nation. But this time, we must do so with a commitment to lifting up workers and regions who were left out of past investments. He is calling on Congress to make an $180 billion investment that will:

- **Advance U.S. leadership in critical technologies and upgrade America's research infrastructure.** U.S. leadership in new technologies—from artificial intelligence to biotechnology to computing—is critical to both our future economic competitiveness and our national security. Based on bipartisan proposals, President Biden is calling on Congress to invest $50 billion in the National Science Foundation (NSF), creating a technology directorate that will collaborate with and build on existing programs across the government. It will focus on fields like semiconductors and advanced computing, advanced communications technology, advanced energy technologies, and biotechnology. He also is calling on Congress to provide $30 billion in additional funding for R&D that spurs innovation and job creation, including in rural areas. His plan also will invest $40 billion in upgrading research infrastructure in laboratories across the country, including brick-and-mortar facilities and computing capabilities and networks. These funds would be allocated across the federal R&D agencies, including at the Department of Energy. Half of those funds will be reserved for Historically Black College and Universities (HBCUs) and other Minority Serving Institutions, including the creation of a new national lab focused on climate that will be affiliated with an HBCU.

- **Establish the United States as a leader in climate science, innovation, and R&D**. The President is calling on Congress to invest $35 billion in the full range of solutions needed to achieve technology breakthroughs that address the climate crisis and position America as the global leader in clean energy technology and clean energy jobs. This includes launching ARPA-C to develop new methods for reducing emissions and building climate resilience, as well as expanding across-the-board funding for climate research. In addition

to a $5 billion increase in funding for other climate-focused research, his plan will invest $15 billion in demonstration projects for climate R&D priorities, including utility-scale energy storage, carbon capture and storage, hydrogen, advanced nuclear, rare earth element separations, floating offshore wind, biofuel/bioproducts, quantum computing, and electric vehicles, as well as strengthening U.S. technological leadership in these areas in global markets.

- **Eliminate racial and gender inequities in research and development and science, technology, engineering, and math.** Discrimination leads to less innovation: one study found that innovation in the United States will quadruple if women, people of color, and children from low-income families invented at the rate of groups who are not held back by discrimination and structural barriers. Persistent inequities in access to R&D dollars and to careers in innovation industries prevents the U.S. economy from reaching its full potential. President Biden is calling on Congress to make a $10 billion R&D investment at HBCUs and other MSIs. He also is calling on Congress to invest $15 billion in creating up to 200 centers of excellence that serve as research incubators at HBCUs and other MSIs to provide graduate fellowships and other opportunities for underserved populations, including through pre-college programs.

Retool and revitalize American manufacturers and small businesses:

The U.S. manufacturing sector accounts for 70 percent of business R&D expenditure, 30 percent of productivity growth, and 60 percent of exports. Manufacturing is a critical node that helps convert research and innovation into sustained economic growth. Workers on the factory floor work hand-in-hand with engineers and scientists to sharpen and maintain our competitive edge. While manufacturing jobs have been a ladder to middle-class life, we have let our industrial heartland be hollowed out, with quality jobs moving abroad or to regions with lower wages and fewer protections for workers. President Biden is calling on Congress to invest $300 billion in order to:

- **Strengthen manufacturing supply chains for critical goods.** President Biden believes we must produce, here at home, the technologies and goods that meet today's challenges and seize tomorrow's opportunities. President Biden is calling on Congress to invest $50 billion to create a new office at the Department of Commerce dedicated to monitoring domestic industrial capacity and funding investments to support production of critical goods. The President also is calling on Congress to invest $50 billion in semiconductor manufacturing and research, as called for in the bipartisan CHIPS Act.

- **Protect Americans from future pandemics.** This funding provides $30 billion over 4 years to create U.S. jobs and prevent the severe job losses caused by pandemics through major new investments in medical countermeasures manufacturing; research and development; and related biopreparedness and biosecurity. This includes investments to shore up our nation's strategic national stockpile; accelerate the timeline to research, develop and field tests and therapeutics for emerging and future outbreaks; accelerate

response time by developing prototype vaccines through Phase I and II trials, test technologies for the rapid scaling of vaccine production, and ensure sufficient production capacity in an emergency; enhance U.S. infrastructure for biopreparedness and investments in biosafety and biosecurity; train personnel for epidemic and pandemic response; and onshore active pharmaceutical ingredients. COVID-19 has claimed over 500,000 American lives and cost trillions of dollars, demonstrating the devastating and increasing risk of pandemics and other biological threats. Over the past two decades, outbreaks of SARS, Ebola, influenza, Zika and others have cost billions in lost productivity. The risk of catastrophic biological threats is increasing due to our interconnected world, heightened risk of spillover from animals to humans, ease of making and modifying pandemic agents, and an eroding norm against the development and use of biological weapons. The American Rescue Plan serves as an initial investment of $10 billion. With this new major investment in preventing future pandemics, the United States will build on the momentum from the American Rescue Plan, bolster scientific leadership, create jobs, markedly decrease the time from discovering a new threat to putting shots in arms, and prevent future biological catastrophes.

- **Jumpstart clean energy manufacturing through federal procurement.** The federal government spends more than a half-a-trillion dollars buying goods and services each year. As a result, it has the ability to be a first-mover in markets. This incredible purchasing power can be used to drive innovation and clean energy production, as well as to support high quality jobs. To meet the President's goals of achieving net-zero emissions by 2050, the United States will need more electric vehicles, charging ports, and electric heat pumps for residential heating and commercial buildings. The President is calling on Congress to enable the manufacture of those cars, ports, pumps, and clean materials, as well as critical technologies like advanced nuclear reactors and fuel, here at home through a $46 billion investment in federal buying power, creating good-paying jobs and reinvigorating local economies, especially in rural areas.

- **Make it in ALL of America.** The President believes we must build social infrastructure to support innovation and productivity across the country. He is calling on Congress to invest $20 billion in regional innovation hubs and a Community Revitalization Fund. At least ten regional innovation hubs will leverage private investment to fuel technology development, link urban and rural economies, and create new businesses in regions beyond the current handful of high-growth centers. The Community Revitalization Fund will support innovative, community-led redevelopment projects that can spark new economic activity, provide services and amenities, build community wealth, and close the current gaps in access to the innovation economy for communities of color and rural communities that have suffered from years of disinvestment. And, President Biden is calling on Congress to invest $14 billion in NIST to bring together industry, academia, and government to advance technologies and capabilities critical to future competitiveness. He is calling on Congress to quadruple support for the Manufacturing

Extensions Partnership —increasing the involvement of minority-owned and rurally-located small- and-medium-sized enterprises in technological advancement.

- **Increase access to capital for domestic manufacturers.** America's manufacturing industry needs to innovate, adapt, and scale to win the industries of the future. President Biden is calling on Congress to invest more than $52 billion in domestic manufacturers. The President is calling on Congress to invest in existing capital access programs with a proven track record of success, with a focus on supporting rural manufacturing and clean energy. The President's plan also includes specific supports for modernizing supply chains, including in the auto sector, like extending the 48C tax credit program. He also will call for the creation of a new financing program to support debt and equity investments for manufacturing to strengthen the resilience of America's supply chains.

- **Create a national network of small business incubators and innovation hubs**. Almost all manufacturers (98 percent) are small- and medium-sized firms. Furthermore, small business ownership is a cornerstone of job creation and wealth building. However, even before the pandemic, many entrepreneurs struggled to compete in a system that is so often tilted in favor of large corporations and wealthy individuals. President Biden is calling on Congress to invest $31 billion in programs that give small businesses access to credit, venture capital, and R&D dollars. The proposal includes funding for community-based small business incubators and innovation hubs to support the growth of entrepreneurship in communities of color and underserved communities.

- **Partner with rural and Tribal communities to create jobs and economic growth in rural America.** Today, despite the fact that rural and Tribal communities across the country are asset-rich, more than 8 in 10 persistent poverty counties fall outside of a metropolitan area. President Biden's plan invests in rural and Tribal communities, including by providing 100 percent broadband coverage, rebuilding crumbling infrastructure like roads, bridges, and water systems, providing research and development funding to land grant universities, and positioning the U.S. agricultural sector to lead the shift to net-zero emissions while providing new economic opportunities for farmers. President Biden also is proposing to transform the way the federal government partners with rural and Tribal communities to create jobs and spur inclusive economic growth. Rural communities often don't have the same budget as big cities to hire staff needed to navigate and access federal programs. On top of that, they have to navigate a myriad of programs all with different purposes and requirements. As part of his plan to ensure that all communities recover – regardless of geography – President Biden is proposing a $5 billion for a new Rural Partnership Program to help rural regions, including Tribal Nations, build on their unique assets and realize their vision for inclusive community and economic development. This program will empower rural regions by supporting locally-led planning and capacity building efforts, and providing flexible funding to meet critical needs.

Invest in Workforce Development:

As more Americans rejoin the workforce or seek out new opportunities in a changing economy, there is a greater need for skills development opportunities for workers of all kind. In order to ensure workers have ready access to the skills they will need to succeed, and to improve racial and gender equity, President Biden is calling on Congress to invest $100 billion in proven workforce development programs targeted at underserved groups and getting our students on paths to careers before they graduate from high school. His plan will:

- **Pair job creation efforts with next generation training programs.** President Biden is calling on Congress to invest in evidence-based approaches to supporting workers. This includes wraparound services, income supports, counseling, and case management, paired with high-quality training and effective partnerships between educational institutions, unions, and employers. Specifically, he is calling for a $40 billion investment in a new Dislocated Workers Program and sector-based training. This funding will ensure comprehensive services for workers, who have lost jobs through no fault of their own, to gain new skills and to get career services they need with in-demand jobs. Sector-based training programs will be focused on growing, high demand sectors such as clean energy, manufacturing, and caregiving, helping workers of all kinds to find good-quality jobs in an ever-changing economy.

- **Target workforce development opportunities in underserved communities**. Structural racism and persistent economic inequities have undermined opportunity for millions of workers. All of the investments in workforce training will prioritize underserved communities and communities hit hard by a transforming economy. President Biden also will call upon Congress to ensure that new jobs created in clean energy, manufacturing, and infrastructure are open and accessible to women and people of color. President Biden is calling on Congress to also specifically target funding to workers facing some of the greatest challenges, with a $12 billion investment. This includes $5 billion over eight years in support of evidence-based community violence prevention programs. He is calling on Congress to invest in job training for formerly incarcerated individuals and justice-involved youth and in improving public safety. He also is calling on Congress to tackle long-term unemployment and underemployment through a new subsidized jobs program. And, he is calling on Congress to eliminate sub-minimum wage provisions in section 14(c) of the Fair Labor Standards Act and expand access to competitive, integrated employment opportunities and fair wages for workers with disabilities.

- **Build the capacity of the existing workforce development and worker protection systems**. The United States has underinvested in the workforce development system for decades. In fact, we currently spend just one-fifth of the average that other advanced economies spend on workforce and labor market programs. This lack of investment impacts all of us: better educated workers create spillover effects for other workers and lack of employment has negative social impacts on communities. President Biden is

calling on Congress to invest a combined $48 billion in American workforce development infrastructure and worker protection. This includes registered apprenticeships and pre-apprenticeships, creating one to two million new registered apprenticeships slots, and strengthening the pipeline for more women and people of color to access these opportunities through successful pre-apprenticeship programs such as the Women in Apprenticeships in Non-Traditional Occupations. This will ensure these underserved groups have greater access to new infrastructure jobs. These investments include the creation of career pathway programs in middle and high schools, prioritizing increased access to computer science and high-quality career and technical programs that connect underrepresented students to STEM and in-demand sectors through partnerships with both institutions of higher education and employers. The President's plan also will support community college partnerships that build capacity to deliver job training programs based on in-demand skills. His plan will better tailor services to workers' job seeking and career development needs through investments in Expanded Career Services and the Title II adult literacy program.The President's plan includes funding to strengthen the capacity of our labor enforcement agencies to protect against discrimination, protect wages and benefits, enforce health and safety safeguards, strengthen health care and pensions plans, and promote union organizing and collective bargaining.

CREATE GOOD-QUALITY JOBS THAT PAY PREVAILING WAGES IN SAFE AND HEALTHY WORKPLACES WHILE ENSURING WORKERS HAVE A FREE AND FAIR CHOICE TO ORGANIZE, JOIN A UNION, AND BARGAIN COLLECTIVELY WITH THEIR EMPLOYERS

As America works to recover from the devastating challenges of a deadly pandemic, an economic crisis, and a reckoning on race that reveals deep disparities, we need to summon a new wave of worker power to create an economy that works for everyone. We owe it not only to those who have put in a lifetime of work, but to the next generation of workers who have only known an America of rising inequality and shrinking opportunity. This is especially important for workers of color and for women, who have endured discrimination and systematic exclusion from economic opportunities for generations. All of us deserve to enjoy America's promise in full — and our nation's leaders have a responsibility to overcome racial, gender, and other inequalities to make it happen. To that end, the President is calling on Congress to create new, good-quality union jobs for American workers by leveraging their grit and ingenuity to address the climate crisis and build a sustainable infrastructure. Increased unionization can also impact our economic growth overall by improving productivity. President Biden's plan will:

- **Empower Workers**. President Biden is calling on Congress to update the social contract that provides workers with a fair shot to get ahead, overcome racial and other inequalities that have been barriers for too many Americans, expand the middle class, and strengthen communities. He is calling on Congress to ensure all workers have a free and fair choice to join a union by passing the Protecting the Right to Organize (PRO) Act, and guarantee union and bargaining rights for public service workers. His plan also ensures domestic

workers receive the legal benefits and protections they deserve and tackles pay inequities based on gender.

- **Create good jobs**. The President's plan demands that employers benefitting from these investments follow strong labor standards and remain neutral when their employees seek to organize a union and bargain collectively. He is asking Congress to tie federal investments in clean energy and infrastructure to prevailing wages and require transportation investments to meet existing transit labor protections. He also is calling for investments tied to Project Labor, Community Workforce, local hire, and registered apprenticeships and other labor or labor-management training programs so that federal investments support good jobs and pathways to the middle class. Finally, he is asking Congress to include a commitment to increasing American jobs through Buy America and Ship American provisions.

- **Protect workers**. President Biden is calling on Congress to provide the federal government with the tools it needs to ensure employers are providing workers with good jobs – including jobs with fair and equal pay, safe and healthy workplaces, and workplaces free from racial, gender, and other forms of discrimination and harassment. In addition to a $10 billion investment in enforcement as part of the plan's workforce proposals, the President is calling for increased penalties when employers violate workplace safety and health rules.

THE MADE IN AMERICA TAX PLAN

Alongside the American Jobs Plan, the President is proposing to fix the corporate tax code so that it incentivizes job creation and investment here in the United States, stops unfair and wasteful profit shifting to tax havens, and ensures that large corporations are paying their fair share.

The 2017 tax law only made an unfair system worse. A recent independent study found that 91 Fortune 500 companies paid $0 in federal corporate taxes on U.S. income in 2018. In fact, according to recent analysis by the Joint Committee on Taxation, the 2017 tax bill cut the average rate that corporations paid in half from 16 percent to less than 8 percent in 2018. A number of the provisions in the 2017 law also created new incentives to shift profits and jobs overseas. President Biden's reform will reverse this damage and fundamentally reform the way the tax code treats the largest corporations.

President Biden's reform will also make the United States a leader again in the world and help bring an end to the race-to-the-bottom on corporate tax rates that allows countries to gain a competitive advantage by becoming tax havens. This is a generational opportunity to fundamentally shift how countries around the world tax corporations so that big corporations can't escape or eliminate the taxes they owe by offshoring jobs and profits from the United States.

Together these corporate tax changes will raise over $2 trillion over the next 15 years and more than pay for the mostly one-time investments in the American Jobs Plan and then reduce deficits on a permanent basis:

- **Set the Corporate Tax Rate at 28 percent.** The President's tax plan will ensure that corporations pay their fair share of taxes by increasing the corporate tax rate to 28 percent. His plan will return corporate tax revenue as a share of the economy to around its 21st century average from before the 2017 tax law and well below where it stood before the 1980s. This will help fund critical investments in infrastructure, clean energy, R&D, and more to maintain the competitiveness of the United States and grow the economy.

- **Discourage Offshoring by Strengthening the Global Minimum Tax for U.S. Multinational Corporations.** Right now, the tax code rewards U.S. multinational corporations that shift profits and jobs overseas with a tax exemption for the first ten percent return on foreign assets, and the rest is taxed at half the domestic tax rate. Moreover, the 2017 tax law allows companies to use the taxes they pay in high-tax countries to shield profits in tax havens, encouraging offshoring of jobs. The President's tax reform proposal will increase the minimum tax on U.S. corporations to 21 percent and calculate it on a country-by-country basis so it hits profits in tax havens. It will also eliminate the rule that allows U.S. companies to pay zero taxes on the first 10 percent of return when they locate investments in foreign countries. By creating incentives for investment here in the United States, we can reward companies that help to grow the U.S. economy and create a more level playing field between domestic companies and multinationals.

- **End the Race to the Bottom Around the World.** The United States can lead the world to end the race to the bottom on corporate tax rates. A minimum tax on U.S. corporations alone is insufficient. That can still allow foreign corporations to strip profits out of the United States, and U.S. corporations can potentially escape U.S. tax by inverting and switching their headquarters to foreign countries. This practice must end. President Biden is also proposing to encourage other countries to adopt strong minimum taxes on corporations, just like the United States, so that foreign corporations aren't advantaged and foreign countries can't try to get a competitive edge by serving as tax havens. This plan also denies deductions to foreign corporations on payments that could allow them to strip profits out of the United States if they are based in a country that does not adopt a strong minimum tax. It further replaces an ineffective provision in the 2017 tax law that tried to stop foreign corporations from stripping profits out of the United States. The United States is now seeking a global agreement on a strong minimum tax through multilateral negotiations. This provision makes our commitment to a global minimum tax clear. The time has come to level the playing field and no longer allow countries to gain a competitive edge by slashing corporate tax rates.

- **Prevent U.S. Corporations from inverting or claiming tax havens as their residence.** Under current law, U.S. corporations can acquire or merge with a foreign company to avoid U.S. taxes by claiming to be a foreign company, even though their place of management and operations are in the United States. President Biden is proposing to make it harder for U.S. corporations to invert. This will backstop the other reforms which should address the incentive to do so in the first place.

- **Deny Companies Expense Deductions for Offshoring Jobs and Credit Expenses for Onshoring.** President Biden's reform proposal will also make sure that companies can no longer write off expenses that come from offshoring jobs. This is a matter of fairness. U.S. taxpayers shouldn't subsidize companies shipping jobs abroad. Instead, President Biden is also proposing to provide a tax credit to support onshoring jobs.

- **Eliminate a Loophole for Intellectual Property that Encourages Offshoring Jobs and Invest in Effective R&D Incentives.** The President's ambitious reform of the tax code also includes reforming the way it promotes research and development. This starts with a complete elimination of the tax incentives in the Trump tax law for "Foreign Derived Intangible Income" (FDII), which gave corporations a tax break for shifting assets abroad and is ineffective at encouraging corporations to invest in R&D. All of the revenue from repealing the FDII deduction will be used to expand more effective R&D investment incentives.

- **Enact A Minimum Tax on Large Corporations' Book Income.** The President's tax reform will also ensure that large, profitable corporations cannot exploit loopholes in the tax code to get by without paying U.S. corporate taxes. A 15 percent minimum tax on the income corporations use to report their profits to investors—known as "book income"—will backstop the tax plan's other ambitious reforms and apply only to the very largest corporations.

- **Eliminate Tax Preferences for Fossil Fuels and Make Sure Polluting Industries Pay for Environmental Clean Up**. The current tax code includes billions of dollars in subsidies, loopholes, and special foreign tax credits for the fossil fuel industry. As part of the President's commitment to put the country on a path to net-zero emissions by 2050, his tax reform proposal will eliminate all these special preferences. The President is also proposing to restore payments from polluters into the Superfund Trust Fund so that polluting industries help fairly cover the cost of cleanups.

- **Ramping Up Enforcement Against Corporations.** All of these measures will make it much harder for the largest corporations to avoid or evade taxes by eliminating parts of the tax code that are too easily abused. This will be paired with an investment in enforcement to make sure corporations pay their fair share. Typical workers' wages are reported to the IRS and their employer withholds, so they pay all the taxes they owe. By contrast, large corporations have at their disposal loopholes they exploit to avoid or evade tax liabilities, and an army of high-paid tax advisors and accountants who help them get away with this. At the same time, an under-funded IRS lacks the capacity to scrutinize these suspect tax maneuvers: A decade ago, essentially all large corporations were audited annually by the IRS; today, audit rates are less than 50 percent. This plan will reverse these trends, and make sure that the Internal Revenue Service has the resources it needs to effectively enforce the tax laws against corporations. This will be paired with a broader enforcement initiative to be announced in the coming weeks that will address tax evasion among corporations and high-income Americans.

These are key steps toward a fairer tax code that encourages investment in the United States, stops shifting of jobs and profits abroad, and makes sure that corporations pay their fair share. The President looks forward to working with Congress, and will be putting forward additional ideas in the coming weeks for reforming our tax code so that it rewards work and not wealth, and makes sure the highest income individuals pay their fair share.

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[EXTERNAL] FW: MIT speaking invitation for Buttigieg

From: David Goldston (b) (6)
To: "Koizumi, Kei EOP/OSTP" (b) (6)
Date: Sun, 04 Apr 2021 08:10:41 -0400
Attachments: BUTTIGIEG Pete 2021 04 02.pdf (125.04 kB)

Fyi, in case you can help with this, per our prior exchange. Thanks.

David

From: L. Rafael Reif (b) (6)
Sent: Friday, April 2, 2021 4:50 PM
To: secretary (b) (6)
Cc: deva.tucker@dot.gov; R. David Edelman (b) (6) ; David Goldston (b) (6) >
Subject: MIT speaking invitation

Dear Secretary Buttigieg,

Please find attached an invitation to speak at a symposium on Artificial Intelligence on May 6. We look forward to your response. Thank you.

Warm regards,

Rafael Reif
President, MIT

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

L. Rafael Reif, *President*

77 Massachusetts Avenue, Building 3-208
Cambridge, Massachusetts 02139-4307 U.S.A.
Phone (b) (6)

April 2, 2021

The Honorable Pete Buttigieg
Secretary of Transportation
US Department of Transportation
West Building, 1200 New Jersey Avenue, SE. 9th Floor
Washington, DC 20590

Dear Mr. Secretary:

I am writing to invite you to be a keynote speaker at the inaugural Symposium of MIT's Artificial Intelligence Policy Forum (AIPF). The event will take place on May 6 and 7, and we would be honored if you could speak on May 6. The event will be virtual and, if necessary, you could record your remarks.

The AIPF is a new undertaking by MIT to bring together leaders in government, industry, academia and civil society from around the world to develop approaches to deal with the societal challenges posed by AI. The AIPF is kicking off the effort by focusing on issues in three areas – mobility, finance and health. We may add climate change as a fourth initial focus area.

The goal of the AIPF is to bridge high-level principles of AI policy with the practice and tradeoffs of governing – taking the next step toward designing the public policies that will shape the specific uses of AI in our lives, and the AI systems that will deliver a more equitable, just, sustainable and innovative future.

The May Symposium will bring together some of the world's leading AI, robotics, and public policy scholars; high-level government officials and regulators from cities, states, countries, and international organizations; and civil society leaders and advocates to dig into the issues in the three focus areas.

The Symposium would greatly benefit from hearing your sense of how the U.S. government is considering dealing with AI issues, especially in the realm of mobility. Your perspective as a former mayor, as well as from your current role would be enormously valuable to the varied group of experts attending the Symposium.

We know how demanding your schedule is, but we hope you will be able to find time for this event. If you have questions or would like further detail, please reach out to R. David Edelman who is managing this event, at (b) (6) Of course, feel free to contact me directly if you would like to discuss this invitation or the AIPF more broadly.

Thank you for the many ways you have served our nation from your time in the military through to the current day, and congratulations on becoming Secretary of Transportation.

Sincerely,

L. Rafael Reif
LRR/gac

AI Training Resource Introduction

From: "Lynch, Justin R. EOP/OSTP" (b) (6)

To: (b) (6), (b) (6), (b) (6)

Cc: "DeBlanc-Knowles, Tess K. EOP/OSTP" (b) (6)

Date: Wed, 07 Apr 2021 14:33:49 -0400

John,
I would like to introduce you to Roxanne Heston and Tara Maria. They both work at the State Department Office of Science and Technology Adviser. Among their many other projects, they are looking for resources to help educate the State Department's workforce about AI. I mentioned that some of the work you're doing at the AI Accelerator might be helpful.

Roxanne and Tara,
John is at the forefront of the DoD's AI education initiatives. His advice was incredibly helpful for NSCAI, and I'm betting you all will find areas to collaborate on as well.

Best,
Justin

Justin Lynch
Policy Advisor
Office of Science and Technology Policy
Executive Office of the President
(b) (6)
Cel (b) (6)

[EXTERNAL] Fwd: Upcoming paper in Science (4/22/21) on papillary thyroid cancers from the Chernobyl accident

From:	Gad Getz (b) (6)
To:	"Lander, Eric S. EOP/OSTP" (b) (6)
Cc:	"Chanock, Stephen (NIH/NCI) [E]" <chanocks@mail.nih.gov>, "Sharpless, Norman (NIH/NCI) [E]" <norman.sharpless@nih.gov>
Date:	Tue, 20 Apr 2021 08:24:24 -0400
Attachments:	abg2538_combinedPDF_20210317-printsum-article-figs-compressed.pdf (16.56 MB); abg2538_Suppl_20210317.pdf (6.97 MB)

Dear Eric,

Hope all is well with you!

I am sure that you are extremely busy in your new role.

I wanted to give you a heads up about a paper that will appear in *Science* on Thursday Apr 22 (in two days) on papillary thyroid cancers caused by the 1986 Chernobyl accident.

Since this may be a politically important paper -- we thought it would be good to give you a heads up.

This project was initiated and led by Stephen Chanock (from NCI; CC'd) and we worked together on the analysis of 440 whole genomes tumor/normal pairs -- by far the most comprehensive analysis thus far.

In general, there weren't many differences between the Chernobyl-related thyroid cancers and sporadic ones. We did, however, find an increase in fusion-drivers, deletions and structural variations.

I've attached the manuscript (and supplementary data).

The NCI is planning a press release on Thursday.

Perhaps you already heard about it and a co-published related paper from Ned Sharpless (CC'd). The other co-published paper is on the trans-generational effects of the Chernobyl accident (also led by Stephen Chanok).

Please let us know if you have any questions about the paper.

Best wishes,

Gaddy (on behalf of the team)

For administrative assistance please contact Serene King

(b) (6) or (b) (6)

Introduction

The 1986 Chernobyl (Chornobyl in Ukrainian) nuclear power plant accident exposed millions of individuals in the surrounding region to radioactive contaminants, resulting in increased papillary thyroid cancer (PTC) incidence in ^{131}I-exposed children. Currently, no reliable biomarkers for radiation-induced cancers have been identified, and large-scale genomic characterizations of human tumors following radiation exposure are lacking.

Rationale

To investigate the contribution of environmental radiation to the genomic characteristics of PTC and gain further insight into radiation-induced carcinogenesis, we analyzed 440 pathologically-confirmed fresh-frozen PTCs from Ukraine (359 with estimated childhood or *in utero* ^{131}I exposure, 81 from unexposed children born after March 1987; mean age at PTC=28.0 years, range 10.0-45.6) and matched normal tissue (non-tumor thyroid tissue and/or blood). Our genomic characterization included whole genome, mRNA, and microRNA sequencing, DNA methylation profiling, and genotyping arrays.

Results

Mean estimated radiation dose among ^{131}I-exposed individuals was 250 mGy (range: 11.0-8,800). In multivariable models adjusted for age at PTC and sex, we observed radiation dose-dependent increases in small deletions ($P=8.0\times10^{-9}$) and simple/balanced structural variants ($P=1.2\times10^{-14}$), but no association with single nucleotide variants or insertions. Further analyses demonstrated stronger radiation-related associations for clonal small deletions and simple/balanced structural variants that bore hallmarks of non-homologous end-joining repair

(deletions: $P=4.9\times10^{-31}$; simple/balanced structural variants: $P=5.5\times10^{-19}$). In contrast, radiation dose was not associated with locally templated insertions, characteristic of alt-end-joining repair.

Candidate drivers were identified for 433 (98.4%) tumors, of which 401 had only a single candidate driver, illustrating the parsimonious nature of PTC carcinogenesis. Over half the drivers (n=253) were mutations, occurring commonly (n=194) in *BRAF*. Fusions accounted for the remaining drivers, frequently involving *RET* (n=73) or other receptor tyrosine kinase genes (n=64). In total, 401 PTCs had drivers in the mitogen-activated protein kinase (MAPK) pathway. In multivariable models adjusted for age at PTC and sex, we observed radiation dose-dependent enrichment of fusion versus mutation drivers ($P=6.6\times10^{-8}$), whereas the radiation dose distribution did not differ substantially by driver.

The effects of radiation on genomic alterations (fusion drivers, deletions, structural variants) were more pronounced for those younger at exposure. Analyses were consistent with a linear radiation dose-response for most molecular characteristics. Individuals who were unexposed to ^{131}I or had lower doses had higher genetic risk ($P=4.7\times10^{-4}$), based on a 12-locus polygenic risk score. Analyses of transcriptomic and epigenomic features demonstrated strong associations with the PTC driver gene but not radiation dose.

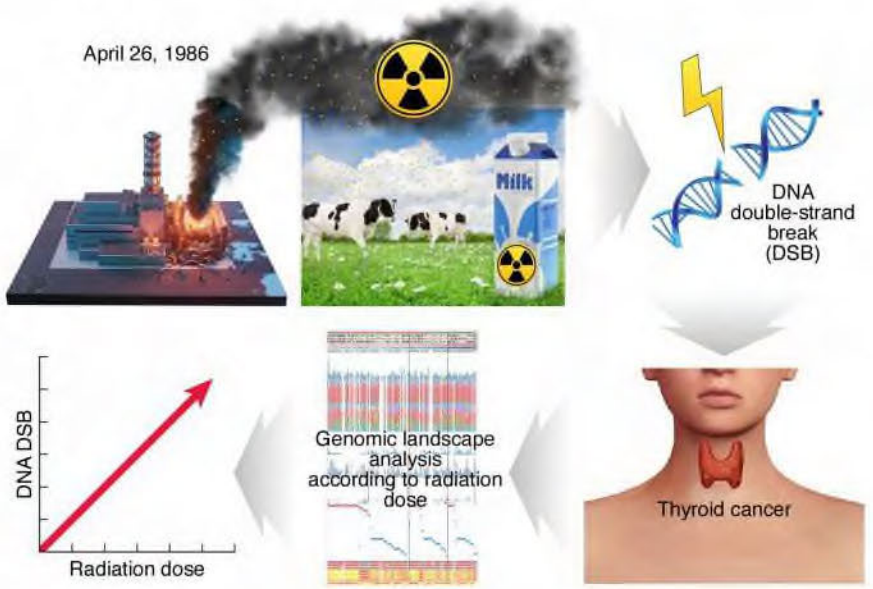
Conclusions

Our large-scale integrated genomic landscape analysis of PTCs after the Chernobyl accident with detailed dose estimation points to DNA double-strand breaks as early carcinogenic events that subsequently enable PTC growth following environmental radiation exposure. Tumor epigenomic and transcriptomic profiles reflected the PTC driver and did not identify a reliable set of biomarkers for radiation-induced carcinogenesis. Non-homologous end-joining was

consistently implicated as the key repair mechanism for the observed radiation dose-associated DNA double-strand breaks, leading to more fusion drivers as a result of increasing radiation dose. Linear increases in radiation-associated damage, especially for exposure at younger ages, emphasize the potential deleterious consequences of ionizing radiation exposure.

Figure caption:

Genomic profiling of post-Chernobyl thyroid cancers reveals clonal DNA double-strand breaks repaired by non-homologous end-joining. Radioactive iodine deposited on surrounding pastures after the Chernobyl nuclear power plant explosion increased thyroid cancer risk, particularly for childhood exposure. Comprehensive genomic profiling of post-Chernobyl thyroid tumors revealed radiation dose-dependent increases in clonal DNA double-strand breaks but no dose relationship with transcriptomic/epigenomic characteristics, highlighting environmental radiation exposure as an early carcinogenic event.


April 26, 1986
Milk
DNA
double-strand
break
(DSB)
Thyroid cancer
Genomic landscape
analysis
according to radiation
dose
DNA DSB
Radiation dose

Radiation-related genomic profile of papillary thyroid cancer after the Chernobyl accident

One Sentence Summary (125 character maximum): Post-Chernobyl papillary thyroid cancers demonstrate radiation dose-dependent increases in clonal DNA double-strand breaks.

Lindsay M. Morton[1,*], Danielle M. Karyadi[2,*], Chip Stewart[3,*], Tetiana I. Bogdanova[4,†], Eric T. Dawson[2,5,†], Mia K. Steinberg[6,†], Jieqiong Dai[6], Stephen W. Hartley[2], Sara J. Schonfeld[1], Joshua N. Sampson[7], Yosi Maruvka[3], Vidushi Kapoor[6], Dale A. Ramsden[8], Juan Carvajal-Garcia[9], Charles M. Perou[10,11], Joel S. Parker[11], Marko Krznaric[12], Meredith Yeager[6], Joseph F. Boland[6], Amy Hutchinson[6], Belynda D. Hicks[6], Casey L. Dagnall[6], Julie M. Gastier-Foster[13,14], Jay Bowen[13], Olivia Lee[2], Mitchell J. Machiela[15], Elizabeth K. Cahoon[1], Alina V. Brenner[16], Kiyohiko Mabuchi[1], Vladimir Drozdovitch[1], Sergii Masiuk[17], Mykola Chepurny[17], Liudmyla Yu. Zurnadzhy[4], Maureen Hatch[1], Amy Berrington de Gonzalez[1], Gerry A. Thomas[12,‡], Mykola D. Tronko[18,‡], Gad Getz[3,19,20,‡], Stephen J. Chanock[2,‡]

[1]Radiation Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 20892, United States

[2]Laboratory of Genetic Susceptibility, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 20892, United States

[3]Broad Institute of MIT and Harvard, Cambridge, Massachusetts, 02142, United States

[4]Laboratory of Morphology of the Endocrine System, V.P.Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine, Kyiv, 04114, Ukraine

[5]Nvidia Corporation, Santa Clara, California, 95051, United States

[6]Cancer Genomics Research Laboratory, Leidos Biomedical Research, Inc., Frederick National Laboratory for Cancer Research, Bethesda, Maryland, 20892, United States

[7]Biostatistics Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 20892, United States

[8]Department of Biochemistry and Biophysics, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, 27599, United States

[9]Curriculum in Genetics and Molecular Biology, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, 27599, United States

[10]Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, 27599, United States

[11]Department of Genetics, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, 27599, United States

[12]Department of Surgery and Cancer, Imperial College London, Charing Cross Hospital, London, W6 8RF, United Kingdom

[13]Nationwide Children's Hospital, Biospecimen Core Resource, Columbus, Ohio, 43205, United States

[14]Departments of Pathology and Pediatrics, Ohio State University College of Medicine, Columbus, Ohio, 43210, United States

[15]Integrative Tumor Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 20892, United States

[16]Radiation Effects Research Foundation, Hiroshima, 732-0815, Japan

[17]Radiological Protection Laboratory, Institute of Radiation Hygiene and Epidemiology,

National Research Center for Radiation Medicine of the National Academy of Medical Sciences of Ukraine, Kyiv, 04050, Ukraine

[18]Department of Fundamental and Applied Problems of Endocrinology, V.P.Komisarenko Institute of Endocrinology and Metabolism of the National Academy of Medical Sciences of Ukraine, Kyiv, 04114, Ukraine

[19]Center for Cancer Research and Department of Pathology, Massachusetts General Hospital, Boston, Massachusetts, 02114, United States

[20]Harvard Medical School, Boston, Massachusetts, 02115, United States

[*]These authors contributed equally to this work.

[†]These authors contributed equally to this work.

[‡]These authors jointly directed this work.

Correspondence to: chanocks@mail.nih.gov, mortonli@mail.nih.gov

Abstract (125 word maximum):

The 1986 Chernobyl nuclear power plant accident increased papillary thyroid cancer (PTC) incidence in surrounding regions, particularly for ^{131}I-exposed children. We analyzed genomic, transcriptomic, and epigenomic characteristics of 440 PTCs from Ukraine (359 with estimated childhood ^{131}I exposure and 81 unexposed children born after 1986). PTCs displayed radiation dose-dependent enrichment of fusion drivers, nearly all in the mitogen-activated protein kinase pathway, and increases in small deletions and simple/balanced structural variants that were clonal and bore hallmarks of non-homologous end-joining repair. Radiation-related genomic alterations were more pronounced for those younger at exposure. Transcriptomic and epigenomic features were strongly associated with driver events but not radiation dose. Our results point to DNA double-strand breaks as early carcinogenic events that subsequently enable PTC growth following environmental radiation exposure.

The accidental explosion in reactor 4 at the Chernobyl (Chornobyl in Ukrainian) nuclear power plant in April 1986 resulted in the exposure of millions of inhabitants of the surrounding areas of Ukraine, Belarus, and the Russian Federation to radioactive contaminants (*1*). Epidemiologic and clinical research in the ensuing decades has demonstrated increased risk of papillary thyroid carcinoma (PTC) with increasing thyroid gland exposure to radioactive iodine (^{131}I) from fallout, which was deposited on pastures with grazing cows and ingested through milk and leafy greens, particularly during early childhood (*2*). Together with data from populations exposed to other types of radiation, compelling evidence indicates that PTC risk increases following childhood exposure to ionizing radiation, a recognized carcinogen (*2-5*).

Currently, there are no established molecular biomarkers for cancers induced by radiation, nor have there been large-scale analyses of the genomic landscape of human cancers occurring after a well-quantified radiation exposure. Classical cytogenetic studies have demonstrated radiation dose-associated increases in large chromosomal aberrations (such as inversions and translocations) that reflect DNA double-strand breaks and are the current standard for biodosimetry; however, these assays are typically performed in peripheral blood lymphocytes from individuals exposed to whole body irradiation and have not been directly linked to tumor characteristics (*6, 7*). Next-generation sequencing of 12 second primary tumors of various types that occurred within the field of previous therapeutic ionizing radiation suggested an excess of small deletions and balanced inversions (*8*), but radiation dose estimates were not available. RNA sequencing (RNA-seq) analyses of 65 PTCs (mean age at diagnosis=24.7 years) occurring after the Chernobyl accident identified that higher doses were associated with an increased likelihood of gene fusion drivers (*9*). In a genomic landscape analysis of 496 primarily unexposed PTCs (mean age at diagnosis=46.8 years; 16 patients with known prior radiation

exposure), The Cancer Genome Atlas (TCGA) reported a low density of somatic point mutations, especially for PTCs in younger patients, and a high frequency of activating somatic alterations in the mitogen-activated protein kinase (MAPK) pathway, including point mutations in *BRAF* (61.7%) and *NRAS/HRAS/KRAS* (12.9%) as well as fusions with *RET* (6.8%), *BRAF* (2.7%) and other MAPK-related genes (5.0%) (*10*).

Here, we report a comprehensive characterization of the genomic, transcriptomic, and epigenomic profile of PTC as well as non-tumor thyroid tissue and/or blood for 440 individuals from Ukraine who developed PTC after the Chernobyl accident (mean age at PTC=28.0 years), affording an opportunity to investigate the contribution of environmental radiation to PTC characteristics. The study analyzed a collection of pre-treatment fresh frozen tumor tissues with pathological confirmation of first primary PTC by an international panel of experts through the Chernobyl Tissue Bank (CTB) (*11, 12*). Our study included 359 individuals with PTC with well-quantified ^{131}I-exposure before adulthood (≤18 years of age; mean=7.3 years) and, as controls, 81 ^{131}I-unexposed individuals with PTC born >9 months after the Chernobyl accident (all were born after March 1, 1987) (*13*).

RESULTS

Samples, Clinical Data, and Analytic Approach

Based on the availability of sufficient DNA and RNA extracted from CTB samples, we analyzed up to 440 individuals with whole genome sequencing (WGS) and/or mRNA-seq of pathologically confirmed tumor (374 both, 57 mRNA-seq only, 9 WGS only) (**Fig. S1-2**) (*13*). Matched normal tissue with WGS and/or mRNA-seq included non-tumor thyroid tissue and/or blood (233 both, 182 non-tumor tissue only, 16 blood only, 9 normal tissue not available). The

genomic landscape characterization was augmented by single nucleotide polymorphism (SNP) microarray genotyping (Illumina Infinium HumanOmniExpress-24 array) and relative telomere length quantification on all samples, and DNA methylation profiling (Illumina Infinium MethylationEPIC array) and microRNA (miRNA)-seq for PTC and non-tumor thyroid tissue (**Fig. S3**). A total of 357 individuals had tumor sample data across all platforms.

The majority of individuals with PTC were female (n=335, 76.1%), resided in the Kiev (Kyiv in Ukrainian) region at the time of the accident (n=286, 65.0%), and were diagnosed during young adulthood (mean=28.0 years, range: 10.0-45.6); ^{131}I-unexposed individuals with PTC were born at least 9 months after the accident and thus had a younger average age than the exposed individuals (mean: unexposed=20.7 years, exposed=29.7 years) (**Table S1, Fig. S4**). For ^{131}I-exposed individuals, mean age at exposure was 7.3 years (range: in utero to 18.9 years) and mean time from the accident to PTC diagnosis was 22.4 years (range: 12.5-29.9). Radiation doses to the thyroid were reconstructed by an international team of dosimetry experts (*14-16*). For 53 individuals, doses were estimated using detailed information derived from individual direct thyroid radioactivity measurements taken within 8 weeks of the accident, with (n=49) or without (n=4) personal interviews regarding residential history and dietary patterns. For the remaining individuals, dose estimates were derived from direct measurements taken for other individuals who lived in the same residential area (n=249), neighboring area (n=9), or other areas (n=39), or based on dose estimates to the mother for individuals who were in utero at the time of the accident (n=9). Mean estimated radiation dose was 250 mGy (range: 11-8,800) (**Fig. S4-S5**).

Our primary analyses investigated the relationship between ^{131}I dose and 68 PTC molecular characteristics derived from a comprehensive genomic landscape analysis (**Fig. 1**) using multivariable linear, proportional odds, or logistic regression models adjusted for sex and

age at PTC diagnosis (*13*). For associated variables (defined as $P<7.4\times10^{-4}$ based on a Bonferroni correction for 68 tests), further analyses were conducted by specific molecular characteristics, as well as by age at PTC, age at exposure, and time since exposure (latency) because these factors influence radiation-related thyroid cancer risk (*17*). In addition, we conducted sensitivity analyses to assess whether the results were consistent when we restricted the population to ^{131}I-exposed individuals with lower radiation dose (<500 mGy, resulting in n=326 with mean dose=110 mGy) (*18, 19*).

Simple somatic variants

WGS analysis of tumor/normal pairs (n=383; mean sequencing depth, tumor=89X, non-tumor thyroid tissue=33X, blood=33X; **Table S2**) revealed a low burden of simple somatic variants (SSV) (mean=0.27 nonsynonymous mutations per Mb) (**Fig. 1, Fig. S6-S7**), which was lower than in older TCGA PTC cases (0.41 nonsynonymous mutations per Mb) (*10*) and comparable to mutationally quiet tumors typically reported for pediatric cancers (*20*). A total of 318,956 SSVs were identified, the majority (93.3%) of which were single nucleotide variants (SNVs) (n=297,512 in 383 tumors; mean per tumor=776.8), whereas small insertions and deletions (indels) were less common (insertions: n=5,842, 1.8%, mean=37.2; deletions: n=14,231, 4.5%, mean=15.3), and doublet and triplet base substitutions were rare (dinucleotide polymorphism [DNP] or doublet: n=1,351, 0.4%, mean=3.5; trinucleotide polymorphism [TNP] or triplet: n=20, 0.006%) (**Table S3**). Among the 3,886 coding mutations (1.2% of total; 0.35/Mb), most were nonsynonymous (3,023/3,886=77.8%). Approximately one-third of mutations (n=114,898, 36.0%) were clonal (cancer cell fraction ≥0.9), regardless of mutation type (SNV=35.9%, insertions=36.7%, deletions=38.0%) (**Table S3, Fig. S8**) (*13*).

In multivariable analyses restricted to n=356 samples with both high tumor and normal tissue purity (**Fig. 1**, **Fig. S9**) (*13*), increased radiation dose was associated with an increase in small deletions ($P=8.0\times10^{-9}$) as well as the deletion:SNV ratio ($P=4.9\times10^{-21}$), but not other SSV types (**Fig. 2, Table S4**). In addition, we observed the expected increase in the burden of SNVs ($P=3.2\times10^{-6}$), doublet mutations ($P=2.7\times10^{-5}$), insertions ($P=1.5\times10^{-6}$), and deletions ($P=7.4\times10^{-16}$) with increasing age at PTC diagnosis (**Table S4**) (*10*). Few of these mutations were clustered (22 clusters [>2 mutations within 150 base pairs (bp)] in 18 cases; 83 clusters [>2 mutations within 1 kb] in 36 cases) and were not associated with radiation dose (P>0.3). In an analysis of the frequency and types of microsatellite indels in the tumors, detected using MSMuTect (*21*), all tumors were microsatellite stable (mean [range] per tumor, insertions=1.8 [0-7], deletions=7.3 [0-24]), and radiation dose was not significantly associated with the number of microsatellite insertions or deletions (**Table S4**).

An investigation of mutational processes in PTC was conducted using SigProfiler to determine both single base substitution (SBS) and small indel (ID) mutational signatures (*20, 22*). Comparing the PTC mutations with known signatures from the Catalogue of Somatic Mutations in Cancer (COSMIC v3, https://cancer.sanger.ac.uk/cosmic/signatures) (*20*), the majority of the SBS signatures (69.9%) were attributable to clock-like signatures (SBS1=9.8%, SBS5=60.2%), with smaller fractions due to APOBEC (apolipoprotein B mRNA editing enzyme, catalytic polypeptide-like) cytidine deaminase DNA-editing activity (SBS2=6.2%, SBS13=6.4%), damage from reactive oxygen species (SBS18=0.9%), and two signatures of unknown etiology (SBS8=15.1%, SBS23=1.6%) (mean cosine similarity between actual mutations and attributed patterns=0.94) (**Fig. 1**, **Table S5, Fig. S10-S12**). In multivariable analyses, no SBS signatures were significantly associated with radiation dose, whereas increased

age at PTC diagnosis was associated with an increase in clock-like SBS mutations ($P_{SBS1}=1.9\times10^{-7}$; $P_{SBS5}=6.8\times10^{-17}$) as well as SBS8 ($P=4.3\times10^{-11}$) and SBS18 ($P=2.0\times10^{-8}$) (**Table S4**).

The majority (54.0%) of indels were attributed to clock-like signatures (ID1=14.2%, ID5=39.8%), 21.2% to ID3 (tobacco smoking, which is not a major risk factor for PTC), 19.0% to repair of DNA double-strand breaks by end-joining mechanisms (ID6=3.3%, ID8=15.8%), and 5.8% to ID4 (unknown etiology) (mean cosine similarity=0.77) (**Fig. 1, Table S5, Fig. S10-S12**). In multivariable analyses, radiation dose was strongly associated with end-joining-related indel mutational patterns ($P=1.5\times10^{-10}$), particularly ID8 ($P=7.3\times10^{-9}$), and more weakly with the clock signature ID5 ($P=1.3\times10^{-4}$) (**Fig. 2**, **Table S4**). In comparison, increased age at PTC diagnosis was associated with significantly increased numbers of ID3 ($P=1.9\times10^{-7}$), ID5 ($P=1.9\times10^{-9}$), and ID8 ($P=6.6\times10^{-4}$) mutational patterns (**Table S4**). *De novo* signature extraction did not reveal a novel signature related to environmental exposure to ionizing radiation but identified 4 SBS (mean cosine similarity=0.96) and 2 ID (mean cosine similarity=0.83) signatures highly correlated with COSMIC signatures described above (**Table S4**, **Table S6, Fig. S10-S12**). Similarly, no novel signature was identified when we restricted the analysis to PTCs in individuals who received ≥200 mGy (**Table S5**).

Structural variation

Overall, 479 structural variants (SV) were identified in 356 tumors; approximately one-quarter of SVs (n=132, 27.6%) were simple/balanced events (balanced interchromosomal translocations and inversions), one-half (n=253, 52.8%) were simple/unbalanced (such as deletions, unbalanced interchromosomal translocations), and the remaining (n=94, 19.6%) were

complex (such as >2 breaks repaired together in a cluster) (**Fig. S13-14, Table S6**) (*13*). Approximately one-third of tumors (n=113, 31.7%) had no SV, one-third (n=126, 35.4%) had one SV, and the remaining third had two (n=61, 17.1%) or more (n=56, 15.7%) SVs. Two tumors had >10 SV events (**Fig. S15**), one of which was the only tumor with evidence for chromothripsis (age at PTC=30.2 years, age at exposure=1.3 years, dose=1000 mGy).

Multivariable analyses (n=354, excluding the 2 outliers) demonstrated that increasing radiation dose was significantly associated with increased SV count ($P=1.4\times10^{-8}$), particularly simple/balanced SVs ($P=1.2\times10^{-14}$) but not those classified as complex (P=0.52) or simple/unbalanced ($P=5.6\times10^{-3}$) (**Fig. 3A**, **Table S4**). Increasing radiation dose also was not associated with occurrence of chromoplexy (P=0.70) (**Table S4**), which was identified in 19 tumors (n=15 single event, n=4 two events) (*13, 23*), nearly all unexposed or in the lower dose groups ($n_{unexposed}=7$, $n_{1\text{-}99\ mGy}=8$, $n_{100\text{-}199\ mGy}=2$, $n_{\geq500\ mGy}=2$).

Somatic copy number alteration

A total of 40.3% (n=143/355) of the tumors evaluated for somatic copy number alterations (SCNA) had one (n=96, 27.0%) or more (n=47, 13.2%) such events (**Fig. S16**) (*13*). Four tumors had ≥20 SCNAs each (**Fig. S17**): the tumor with chromothripsis and three additional tumors (age at PTC=19.0-29.3 years, age at exposure=1.3-2.3 years, dose=125-175 mGy). Those three tumors predominantly had gains or copy neutral loss of heterozygosity (CNLOH) and were the only tumors with ploidy>2.5, with one of the three displaying extensive CNLOH (>20 arms), similar to previous reports for the rare thyroid Hürthle cell carcinoma (*24, 25*). Exclusion of the four tumors with ≥20 SCNAs each yielded 239 total SCNAs: 69 (28.9%) at

the chromosome level, of which 48 were deletions, and 170 (71.1%) sub-chromosomal, of which 106 were deletions (**Table S6**).

In multivariable models, radiation dose was related to the number of sub-chromosomal SCNAs ($P=3.5\times10^{-5}$), particularly deletions ($P=7.0\times10^{-4}$) but not gains (P=0.32) or CNLOH (P=0.52); radiation dose also was not related to the number of chromosomal SCNAs (P=0.20) (**Table S4**). The most frequent recurrent event was loss of 22q (n=47/353, 13.3%) (**Fig. S18-S19**), but occurrence of 22q deletions was not associated with radiation dose (P=0.37) (**Table S4**).

Drivers of PTC

We identified at least one candidate driver for 433 of 440 (98.4%) tumors (**Fig. S20, Table S7**) (*13*), with the majority (n=401; 92.6%) having a single candidate driver, underscoring the parsimony of events driving PTC carcinogenesis. We designated 429 (97.5%) drivers for analysis (**Fig. 1**). Over half the designated driver events (n=253, 59.0%) were mutations (SSVs; **Table S8**), predominantly activating point mutations in genes previously implicated in PTC. The most commonly mutated gene was *BRAF* (n=194, 45.2%), where all the mutations either were canonical $BRAF^{V600E}$ substitutions (n=190) or disrupted the V600 sequence context (n=4). *RAS* genes were the next most commonly mutated (n=44, 10.3%), specifically *NRAS* (n=20, 4.7%), *HRAS* (n=15, 3.5%), and *KRAS* (n=9, 2.1%). Additional mutation drivers were identified in *TSHR* (n=6, 1.4%), *DICER1* (n=3, 0.7%), *APC* (n=2, 0.5%), *TSC1/TSC2* (n=2, 0.5%), and *NFE2L2* (n=2, 0.5%). In TCGA, 9.4% of PTC harbored *TERT* promoter mutations, often in older individuals (*8*), but only one individual with a *TERT* promoter mutation was observed in our study (age at PTC diagnosis=40.7 years, designated driver=$BRAF^{V600E}$).

Fusion drivers accounted for 176 (41.0%) PTC cases (**Table S9**). The most frequently involved genes were *RET* (n=73, 17.0%) as well as other receptor tyrosine kinase (RTK) genes, specifically *NTRK3* (n=36, 8.4%), *NTRK1* (n=13, 3.0%), *ALK* (n=12, 2.8%), and *LTK* (n=3, 0.7%). Additional fusion drivers included *BRAF* (n=20, 4.7%) and *PPARG* (n=13, 3.0%), as well as SVs that resulted in overexpression of *IGF2* or *IGF2BP3* (n=6, 1.4%). Of the 23 chromoplexy events described above, 16 generated driver fusions. All 22q deletions co-occurred with known driver mutations, most frequently *RAS* mutations ($P_{heterogeneity}=2.8\times10^{-10}$; n=22/38, 56.4%) (**Table S10**).

In multivariable analyses, fusion drivers in PTC were more common in individuals exposed to higher radiation dose ($P=6.6\times10^{-8}$) and in those diagnosed at younger ages ($P=5.4\times10^{-9}$) relative to those with mutation drivers (**Fig. 3B, Table S4**). There was a suggestion of a heterogeneous effect of dose by specific gene fusion ($P_{heterogeneity}=0.020$), with higher doses on average for PTCs with *IGF2/IGF2BP3* or *BRAF* fusion drivers, whereas the dose distribution did not differ significantly among mutation drivers (*BRAF*, *RAS*, other; $P_{heterogeneity}=0.17$) (**Fig. 4**). We extended our observations by inclusion of 45 non-overlapping individuals with PTC (excluding the 20 individuals already in our analyses) drawn from a previous Chernobyl study with known drivers identified with RNAseq (*7*); over half had doses ≥500 mGy (mean age at PTC=24.2 years, mean age at exposure=7.2 years, mean dose=1050 mGy) (**Table S1**). That smaller sample set also suggested a radiation dose-related increase in fusion drivers (P=0.069), which was consistent with the results from our study ($P_{heterogeneity}=0.90$; pooled analysis of fusion vs. mutation driver, adjusting for age at PTC, sex, and study: $P=4.6\times10^{-9}$).

Gene expression and methylation patterns

We conducted several analyses to assess whether gene expression and methylation patterns were related to radiation dose. First, unsupervised clustering analyses restricted to PTC tumor tissue yielded 5 mRNA clusters, 5 miRNA clusters, and 3 methylation clusters (**Fig. S21-S22**) (*13*). None of these clusterings were associated with radiation dose (P_{mRNA}=0.85; P_{miRNA}=0.38; $P_{methylation}$=0.10), but each closely correlated with the driver gene pathway (P_{mRNA} =1.6×10^{-64}; P_{miRNA}=1.0×10^{-9}; $P_{methylation}$=6.4×10^{-43}) (**Fig. 5A, Table S4, Table S11**, **Fig. S23**), supporting the overriding importance of the driver for RNA expression patterns (*10*). Second, we identified three transcriptional patterns important in PTC based on the TCGA analysis (*10*): the *BRAF*^{V600E}-*RAS* score (BRS), estimating the degree to which the mRNA, miRNA, and methylation profiles resemble either *BRAF*^{V600E} or *RAS*-mutated PTC; the thyroid differentiation score (TDS), based on expression of 16 thyroid metabolism and function genes; and the ERK-activity score of 52 expressed genes responsive to MEK inhibition (*13*). As expected, the mRNA, miRNA, and methylation BRS scores were highly correlated with one another (r=0.78-0.92) (**Table S12**). Consistent with TCGA (*10*), the three different mRNA-based scores also were significantly correlated, particularly the BRS with both the TDS (r=0.69) and the ERK score (r=-0.66). None of the scores were associated with radiation dose after correction for multiple testing ($P_{mRNA\text{-}BRS}$=2.1×10^{-3}; $P_{miRNA\text{-}BRS}$=5.5×10^{-3}; $P_{methylation\text{-}BRS}$=0.082; P_{ERK}=0.011, P_{TDS}=7.8×10^{-3}) (**Table S4, Fig. S24A**), whereas each was strongly related to driver gene pathway ($P<1.0\times10^{-30}$ for all scores) (**Fig. S24B**).

To confirm the lack of association between radiation exposure and gene expression patterns, we conducted exploratory analyses of the differential expression of specific genes and gene sets by dose (*13*). In multivariable linear regression models adjusted for age at PTC, sex,

and batch, the $P_{adjusted}$ for dose was <0.05 for five genes (**Fig. 5B, Table S13**), with the smallest P-value ($P_{adjusted}=8.0\times10^{-3}$; $\log_{10}$-fold expression change/100 mGy=0.059) for transfer RNA asparagine (anticodon GUU) (*TRNAN-GUU-2*), which is a target of the transcription factor *MYBL2*, a key regulator of cell cycle progression and apoptosis (*26, 27*). However, each of these associations were attenuated when the model was further adjusted for the driver gene pathway (**Table S13**). In contrast, over half the genes were differentially expressed ($P_{adjusted}<0.05$) among the different driver gene pathways (**Table S13**). Despite previous reports suggesting radiation dose could be linked to *CLIP2* expression (*28-30*), no such relationship was observed in our substantively larger study, which included 33 overlapping samples from the previously-published analyses (*29*) (**Fig. S25**), either in the overall set of PTC cases (P=0.42, **Fig. 5C**) or in subsets defined by early age at radiation exposure (**Fig. S26**). An exploration of expression signatures through gene set enrichment analyses was pursued in the Molecular Signatures Database (MSigDB; https://www.gsea-msigdb.org/gsea/msigdb) (*31*). For 3,213 gene sets (those related to hallmark biological processes, thyroid, radiation, and the genes included in germline analyses below) (*13*), multivariable regression models adjusting for age at PTC, sex, and batch revealed similar results as those above for single gene differential expression analyses, namely no gene set expression patterns were significantly associated with radiation dose ($P_{adjusted}<0.05$), whereas over half were strongly associated with the driver gene pathway (**Fig. S27, Table S14**).

Germline genetic variation

Possible contribution of germline genetic variation to radiation-related PTC was investigated in individuals of comparable Ukrainian ancestry (n=383 individuals, including 305 exposed, 78 unexposed) (**Fig. S28**). Twelve previously reported risk SNPs for sporadic PTC

were used to generate a polygenic risk score (PRS) (*32*). Multivariable analyses adjusting for population substructure revealed that unexposed individuals with PTC and those who received lower radiation doses were more likely to have higher genetic risk ($P=4.7\times10^{-4}$) (**Fig. 6**, **Table S4**). Analyses of the 12 individual SNPs, albeit underpowered, yielded three possible associations with radiation dose: rs1588635 (9q22.33; P=0.012), rs2289261 (15q22.33, *SMAD3*; P=0.030) and rs10069690 (5p15.33, *TERT*; P=0.054) (**Table S15**).

Investigation of rare potentially protein-damaging variants in genes and pathways related to thyroid or other cancer predisposition, clinical radiation sensitivity syndromes, and DNA damage response revealed no major differences in the burden of these variants among individuals who developed PTC after different radiation doses (**Table S4, Table S16-S17**). Only four individuals (n=2, 2.6% unexposed; n=2, 1.2% <100 mGy; 0, 0% ≥100 mGy) carried potentially protein-damaging variants in known thyroid cancer susceptibility genes (**Table S16-S17**).

Detailed analyses of molecular characteristics associated with radiation dose

Analyses by clonality for each of the deletion metrics (total deletion count, deletion:SNV ratio, and ID5 and ID8 mutational patterns) revealed that the radiation dose-related associations were restricted consistently to clonal rather than subclonal deletions (**Fig. 2, Table S18**). Similarly, analyses of SCNAs also demonstrated associations only with clonal but not subclonal sub-chromosomal deletions (**Table S18**). Because distinct repair mechanisms can generate deletions of different lengths (*33-35*), we further stratified the clonal deletion count by length (**Fig. S29**) and found the strongest association between radiation dose and ≥5 bp clonal deletions with patterns characteristic of end-joining repair ($P=4.9\times10^{-31}$) (**Fig. 3C, Table S18**). These

results are consistent with the ID8 mutational association and suggest a key role for end-joining mechanisms in repairing radiation-induced DNA double-strand breaks. Analyses of the ≥5 bp clonal deletions by the amount of microhomology at the deletion boundary revealed consistent associations between radiation dose and deletions with 0-1 bp microhomology as well as those with ≥2 bp microhomology (**Table S18**). These results implicate non-homologous end-joining (NHEJ) repair mechanisms, which are employed regardless of the amount of microhomology, whereas alternative end-joining (alt-EJ) repair mechanisms such as theta-mediated end-joining (TMEJ) typically generate deletions with ≥2 bp microhomology (*33-35*). In an ancillary analysis, we quantified in the small insertions the number of TINS (locally templated insertions), which are characteristic of TMEJ repair (*34*), and found that TINS were not associated with radiation dose (P=0.69) (**Fig. S30**). Further exploration of insertions and deletions by genomic sequence context (*8*) revealed only weak correlations for radiation dose with occurrence of deletions classified by flanking GC content (P=0.015), proximity to CPG islands (P=0.014), and the mean replication timing at the variant locus (P=0.010); in each case deletions in the higher radiation dose groups were more similar to a random background distribution (**Table S19)** (*13*). No such correlations between radiation dose and genomic sequence context were observed for insertions.

We undertook similar analyses of SVs after confirming each event (**Table S6**) (*13*), identifying those SVs with <20 bp of intervening loss/gain at the breakpoint, which indicates repair by end-joining mechanisms (*33-35*). Increased radiation dose was strongly associated with simple/balanced SVs that were clonal ($P=1.4\times10^{-16}$) but not subclonal (P=0.91), with a pronounced association for clonal simple/balanced SVs enriched for patterns characteristic of end-joining mechanisms ($P=5.5\times10^{-19}$) (**Fig. 3D**) versus other clonal SVs (P=0.41, **Fig. 3E**)

(**Table S18**). Further analyses demonstrated consistent associations for radiation dose with clonal simple/balanced/end-joining SVs with <4 bp and 4-<20 bp of intervening loss/gain (**Table S18**). Similar to our observations for small deletions, these results specifically implicate the importance of NHEJ repair, which accounts for almost all <4 bp events but which could contribute regardless of the amount of intervening loss/gain. By comparison, alt-EJ repair mechanisms primarily give rise to events with ≥4 bp of intervening loss/gain (*33-35*). Additional analyses of clonal simple/balanced/end-joining SVs by type revealed a strong association between radiation dose and inversions ($P=3.6\times10^{-14}$), consistent with a previous report (*8*), but also an association with translocations ($P=4.4\times10^{-4}$) (**Table S18**).

For each of the radiation dose-associated variables, the results were similar when we restricted the study population to exposed individuals (**Table S20**). Albeit based on limited statistical power, further restriction to individuals with exposures 1-<500 mGy revealed consistent associations for dose only with the clonal deletion:SNV ratio, enrichment of fusion drivers, and presence of clonal simple/balanced/EJ SVs (**Table S20**). Linear-quadratic and linear-exponential models of radiation dose generally did not improve the model fit compared with a linear model for any of the variables, except for clonal small deletions (total and restricted to ≥5 bp EJ deletions) (**Table S20**).

Notably, radiation dose-related increases in clonal deletions (particularly the deletion:SNV ratio, ID8, and the number of clonal ≥5 bp EJ small deletions), as well as fusion PTC drivers were substantially more pronounced for individuals exposed at younger ages (**Fig. 7, Table S21-S22**), albeit based on small numbers for certain analyses. In contrast, the radiation dose-related increase in SCNA clonal sub-chromosomal deletions was most pronounced at longer latencies (**Table S21**).

Radiation-related acceleration of PTC development

Exploratory analyses to address previous reports that ionizing radiation exposure accelerates aging and cancer development (*36, 37*) revealed no such evidence in our study population. First, we stratified analyses of the relationship of clock-like SBS and ID signatures with age at PTC and latency but found no effect modification by radiation dose (age at PTC: P_{SBS}=0.63, P_{ID}=0.93; latency: P_{SBS}=0.28, P_{ID}=0.21) (**Fig. S31-S32**). Additionally, radiation dose-dependent associations with key molecular characteristics did not appear to be strongly modified by latency, after accounting for age at exposure and age at PTC (**Table S21**). Analyses of relative telomere length demonstrated the expected association between decreased telomere length and increased age at PTC in blood ($P=3.2x10^{-5}$) but not in normal thyroid tissue (P=0.99) or PTC (P=0.81), and there was no association between relative telomere length and thyroid radiation dose (P>0.4 for all tissues). Methylation profiles were evaluated to estimate epigenetic age acceleration using two established metrics (*38, 39*). Regressing epigenetic age against chronological age in the non-tumor thyroid tissue and then comparing the residuals from this predicted age in the PTC tissue (*13*) revealed no association between age acceleration and radiation dose using either metric (P>0.1).

Discussion

Our large-scale integrated analyses of the genomic landscape of PTC that developed following the 1986 Chernobyl nuclear power plant accident provide consistent evidence that ionizing radiation-induced DNA damage, particularly double-strand breaks, represents an early carcinogenic event in thyroid tumorigenesis following radiation exposure. These findings

substantially extend preliminary reports of radiation-related human tumor characteristics (*8, 9*) by integrating data from multiple platforms with large sample size and detailed radiation dose data. Increasing radiation dose was strongly associated with increased likelihood of fusion versus point mutation drivers, simple/balanced SVs, and small deletions, with the strongest associations observed for those that bore hallmarks of NHEJ repair and were clonal, particularly for individuals exposed at a young age. However, no unique radiation-related biomarker was identified. Together, our results indicate that thyroid tumorigenesis following radiation exposure results from DNA double-strand breaks in the genome that have an impact on key thyroid cell growth and differentiation genes, which in turn drive the expression and epigenetic characteristics of individual PTCs.

Most tumors had evidence for only a single, known oncogenic driver, which involved the MAPK pathway in nearly all cases, which is consistent with previously published studies of sporadic PTCs (*10, 40, 41*). These findings combined with the low mutational burden in thyroid tumors emphasize the efficiency of driver mutations in thyroid tumorigenesis even following ionizing radiation exposure, in contrast to other environmentally-driven cancers, such as cigarette smoking and lung adenocarcinoma or ultraviolet light and melanoma, that often require multiple drivers and have multiple subclones together with substantial somatic burden (*23*).

Based on multiple lines of evidence, our study demonstrates striking radiation dose-related increases in DNA double-strand breaks in human thyroid cancers developing after the Chernobyl accident, extending results from in vitro and animal radiobiological experiments (*33-35*). In contrast, the PTCs did not have evidence of radiation-related specific base mutations or clustered mutations (*42*). Cells with DNA double-strand breaks can recruit various repair mechanisms, each of which leaves characteristic evidence in the repaired sequence. A series of

analyses consistently implicated NHEJ as the most important repair mechanism for the radiation dose-associated DNA double-strand breaks observed in the PTCs. While the importance of end-joining repair in human tumors has been reported previously (*8*), our detailed examination of the local sequence context for the SVs (including fusion drivers) and small deletions enabled us to identify that radiation dose was most clearly associated with NHEJ rather than alt-EJ or other repair mechanisms. The lack of association between radiation dose and TINS further demonstrated the lack of importance of alt-EJ mechanisms. The importance of NHEJ repair also was supported by the lack of significant association between radiation dose and mutation signatures associated with APOBEC, which preferentially targets intermediates in replication and repair by homologous recombination (*43*). Our results necessitate further research such as using genetically modified organoids (*44, 45*) to establish the causal role of radiation-related DNA double-strand breaks predominantly repaired by NHEJ in human carcinogenesis.

The role of radiation-related DNA damage as an early step in PTC carcinogenesis following the Chernobyl accident is further supported by the lack of association between radiation dose and PTC transcriptomic and epigenomic features, despite the use of various analytic approaches, including clustering, differential expression by gene or miRNA, and gene set enrichment analyses. With our large sample size, we did not confirm the previously reported association between radiation dose and *CLIP2* expression (*28-30*), even when we restricted our analyses to individuals exposed at younger ages. Notably, however, the PTC transcriptomic and epigenomic features differed strikingly by driver gene/pathway, supporting the importance of the specific driver in shaping the tumor profile (*10, 40, 41*). Utilization of both WGS and RNA-seq enabled us to identify a driver in 98% of the PTCs in our study. Deletion of chromosome 22q has been suggested as a driver for PTC, but all cases in our study with 22q deletions also had other

known PTC drivers, suggesting that 22q did not act independently in our set of individuals who developed PTC during young adulthood. Intriguingly, however, 22q deletions were strongly related to the driver pathway, occurring most commonly in *RAS*-mutated PTCs, suggesting that 22q deletion could provide a growth advantage or otherwise enhance the effect of certain MAPK drivers.

With our large sample size, we were able to explore the independent effects of radiation dose, age at PTC, age at exposure, and latency on PTC molecular characteristics. The pronounced evidence of radiation-related damage that we observed for individuals exposed at younger ages is consistent with epidemiologic analyses that have identified higher thyroid cancer risks with radiation exposure at younger ages (*17*). The relationship of a number of molecular characteristics, particularly total mutational burden and driver type, with age at PTC warrants further investigation across a broader age range (*10*). Additional research with detailed dose data is needed to understand whether our findings extend across a broader dose range, to other types of radiation, as well as to other tumor types, and whether radiation-related genomic characteristics have an impact on histopathological parameters (*46-48*). It has been hypothesized that ionizing radiation exposure could accelerate tumor development, and substantial evidence demonstrates that cancer survivors exposed to high-dose radiotherapy exhibit an aging phenotype (*36, 37*). However, exploratory analyses within our data did not support this hypothesis.

Our results have important implications for radiation protection and public health, particularly for low dose exposure, from two perspectives. First, the lack of a unique radiation-related pattern of molecular characteristics in the PTCs in our study, due in part to the random nature of ionizing radiation-related damage across the genome as well as the fact that other

mutagens can cause DNA double-strand breaks, suggests that we are yet to establish a reliable biomarker to distinguish tumors induced by radiation versus other causes. Nevertheless, further investigation is warranted to consider how the radiation dose-associated characteristics we identified could be incorporated into estimates of the probability that a specific papillary thyroid tumor was caused by ^{131}I exposure (probability of causation [POC] (**Fig. S5**) (*49, 50*)), which is currently based on prior epidemiologic studies (*17*). Second, our data are consistent with a linear dose-response for the key molecular characteristics associated with radiation dose in the range examined in our analysis (≤1 Gy), which aligns with the extensive radiobiological literature and other epidemiologic evidence regarding DNA damage and cancer risk following ionizing radiation exposure (*51, 52*).

Our study population included a substantial number of PTCs occurring after <100 mGy exposure, likely reflecting both the availability of samples from the Chernobyl Tissue Bank as well as the increased detection of pre-existing PTC in the population that may not become clinically evident until later, if at all, due to intensive screening and heightened awareness of thyroid cancer risk in Ukraine. The increased genetic risk based on the PRS was notable among PTCs that occurred after lower doses despite limited statistical power to investigate germline genetic variants. The low overall mutational burden of early adulthood PTC, small sample sizes in certain population subgroups, and uncertainties in radiation dose estimates also limited our statistical power to thoroughly investigate the shape of the dose-response curve, precisely identify the magnitude of radiation-related effects (as reflected by the wide confidence intervals for many effect estimates), or reliably identify new radiation signatures.

In conclusion, we have characterized the genomic landscape of PTC, the most frequent cancer observed after the Chernobyl nuclear accident. Our results demonstrate a dose-dependent

carcinogenic effect of radiation derived primarily from DNA double-strand breaks repaired by NHEJ that initiate subsequent thyroid tumor growth, the patterns of which are shaped not by radiation exposure but rather by the specific driver gene. The consistency of the spectrum of PTC drivers in our study population compared with previous PTC series suggests that current therapeutic approaches for PTC are appropriate even for tumors that arise following radiation exposure (*53*). Our work provides a foundation for further investigation of radiation-induced cancer, particularly with respect to differences in risk as a function of both dose and age, and underscores the deleterious consequences of ionizing radiation exposure.

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Data and materials availability: Analytic data are available in Data S1-S3. The Materials and Methods text specifies code that has been posted to GitHub and is archived on Zenodo (*13*). Raw molecular data are available from the Genomic Data Commons, accessed through the database of Genotypes and Phenotypes (dbGaP, accession phs001134; https://www.ncbi.nlm.nih.gov/gap/).

SUPPLEMENTARY MATERIALS

Materials and Methods

Figs. S1 to S32

Tables S1 to S22

References 54 to 124

Data S1 to S3

MDAR Reproducibility Checklist

FIGURE TITLES AND LEGENDS:

Fig. 1. Landscape of somatic alterations in 440 papillary thyroid carcinomas, by radiation dose from ^{131}I exposure. Blank (white) spaces represent unavailable data due to lack of data from a specific platform (**Figs. S1-S3**). Signature analyses were restricted to high purity samples, defined as those with tumor purity >20% and no evidence of tumor contamination in the normal tissue. Abbreviations: *BRAF^{V600E}-RAS* score (BRS), copy neutral loss of heterozygosity (CNLOH), deletion (DEL), dinucleotide polymorphism (DNP, i.e., doublet), ERK-activity score (ERK), indel (ID), insertion (INS), microsatellite (ms), papillary thyroid carcinoma (PTC), probability of causation (POC), single nucleotide variant (SNV), somatic copy number alteration (SCNA), single nucleotide variant (SNV), structural variant (SV), thyroid differentiation score (TDS), trinucleotide polymorphism (TNP, i.e., triplet).

Fig. 2. Relationship between radiation dose from ^{131}I exposure and small deletions. (**A**) Total small deletion count and restricted to (**B**) clonal and (**C**) subclonal small deletions. (**D**) Total deletion:SNV ratio and restricted to (**E**) clonal and (**F**) subclonal deletions and SNVs. (**G**) Total ID5 count and restricted to (**H**) clonal and (**I**) subclonal ID5. (**J**) Total ID8 count and restricted to (**K**) clonal and (**L**) subclonal ID8. β per 100 mGy and P-value were derived from multivariable linear regression models adjusting for age at PTC and sex. Gray shading indicates 95% confidence interval (CI). Full model results are provided in **Table S18**.

Fig. 3. Relationship between radiation dose from ^{131}I exposure and selected SV metrics. (**A**) Number of simple/balanced SVs. (**B**) Likelihood of having a fusion versus mutation driver. (**C**)

Number of clonal ≥5 bp EJ small deletions. (**D**) Number of confirmed clonal simple/balanced/end-joining SVs. (**E**) Number of confirmed clonal other SVs (E). Different scales are used for each panel to reflect the distributions and uncertainties of the excess odds ratio (EOR) estimates. Referent group for categorical analyses: EOR=0 (which is equivalent to odds ratio=1). EOR per 100 mGy and P-value were derived from multivariable proportional odds or logistic regression models adjusting for age at PTC and sex. Full model results are provided in **Table S18**.

Fig. 4. Distribution of radiation dose from ^{131}I exposure by driver type and pathway.

Fig. 5. Selected RNA-seq results. (**A**) Differential expression by driver and cluster. (**B**) Differential expression for all genes by radiation dose from ^{131}I exposure. (**C**) Differential expression of *CLIP2* by radiation dose from ^{131}I exposure.

Abbreviation: principal component (PC).

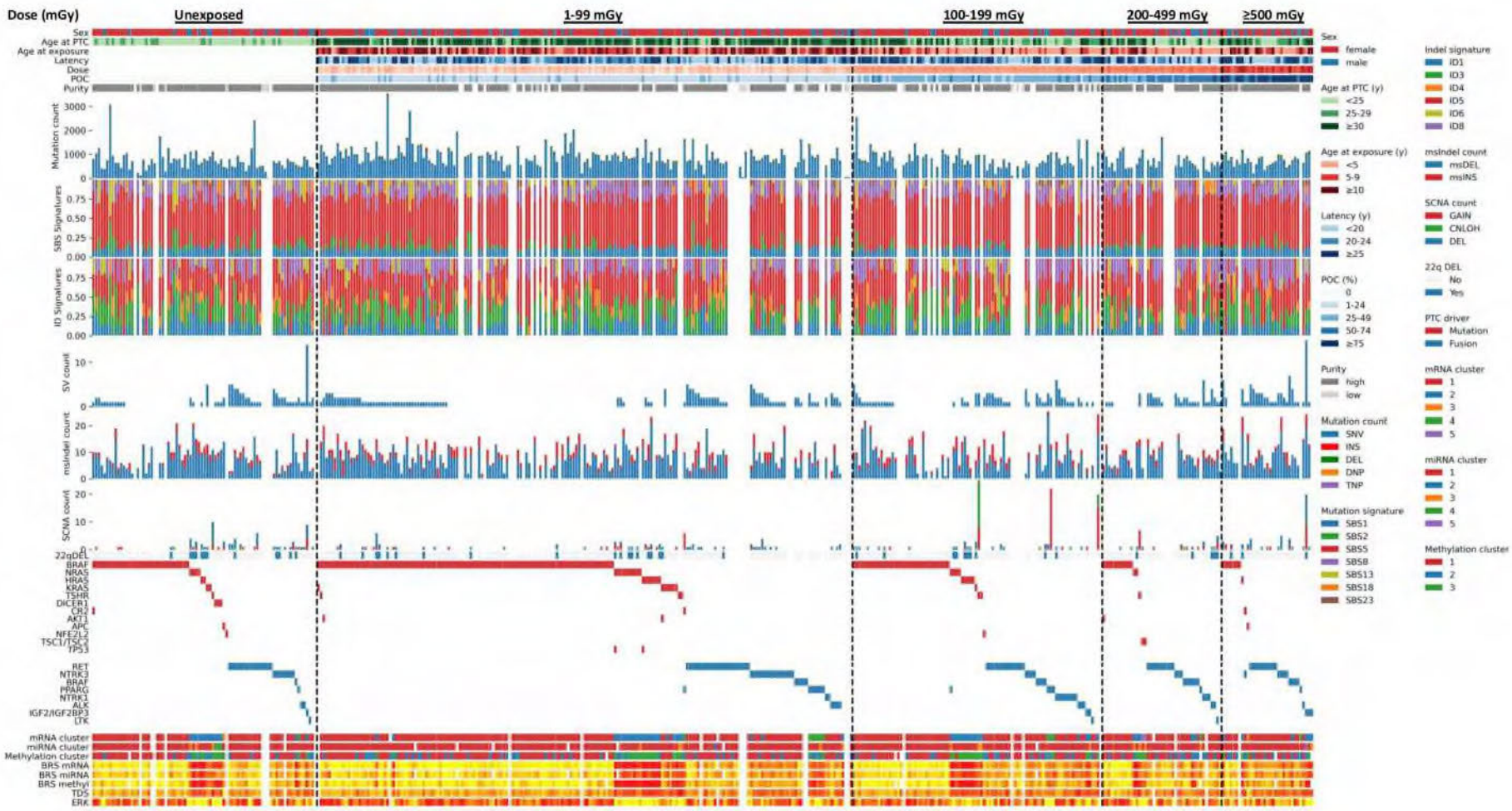
Fig. 6. Relationship between radiation dose from ^{131}I exposure and PRS. Data for the 12 single nucleotide polymorphisms that comprise the PRS are provided in **Table S15**.

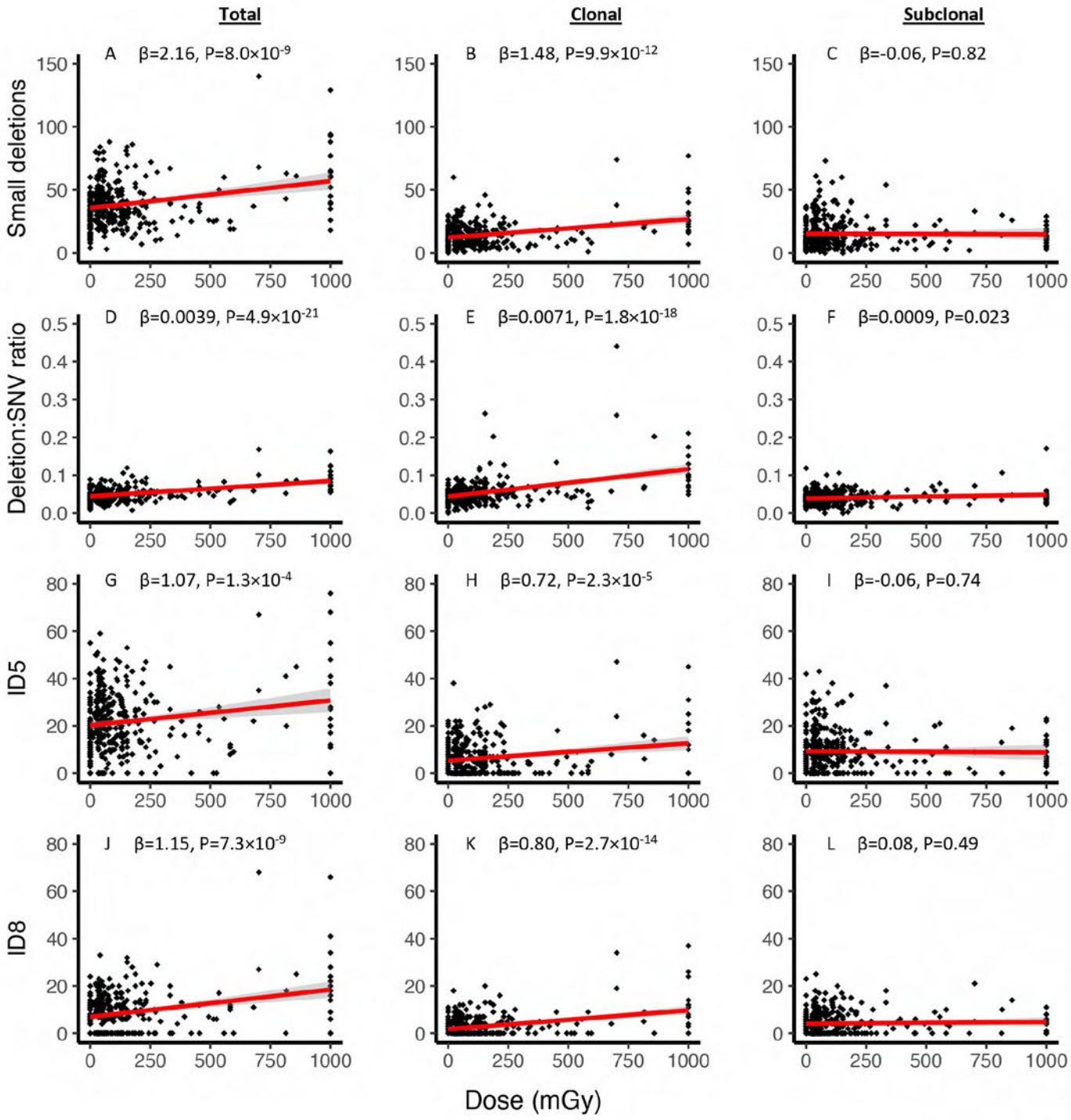
Fig. 7. Relationship between radiation dose from ^{131}I exposure and selected genomic characteristics by age at exposure. Clonal deletion:SNV ratio for (**A**) <5 years at exposure, (**B**) 5-9 years at exposure, and (**C**) ≥10 years at exposure. Number of clonal ID8 mtuations for (**D**) <5 years at exposure, (**E**) 5-9 years at exposure, and (**F**) ≥10 years at exposure. Number of clonal ≥5 bp EJ small deletions for (**G**) <5 years at exposure, (**H**) 5-9 years at exposure, and (**I**) ≥10

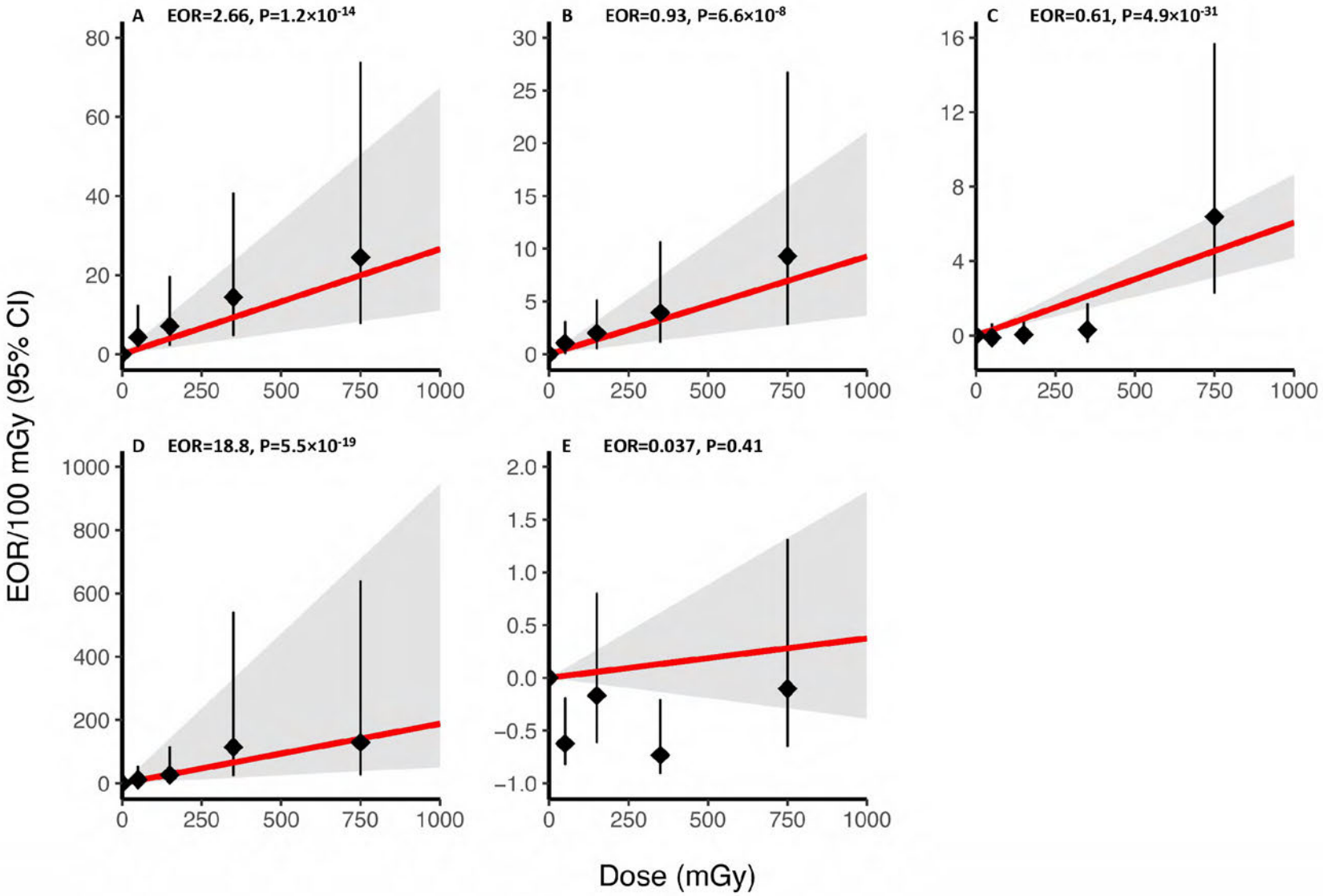
years at exposure. Likelihood of having a fusion versus mutation driver for (**J**) <10 years at exposure and (**K**) ≥10 years at exposure. All analyses exclude ^{131}I-unexposed individuals. β or EOR per 100 mGy and P-value were derived from multivariable linear, proportional odds, or logistic regression models adjusting for age at PTC and sex. Full model results are provided in **Table S22**.

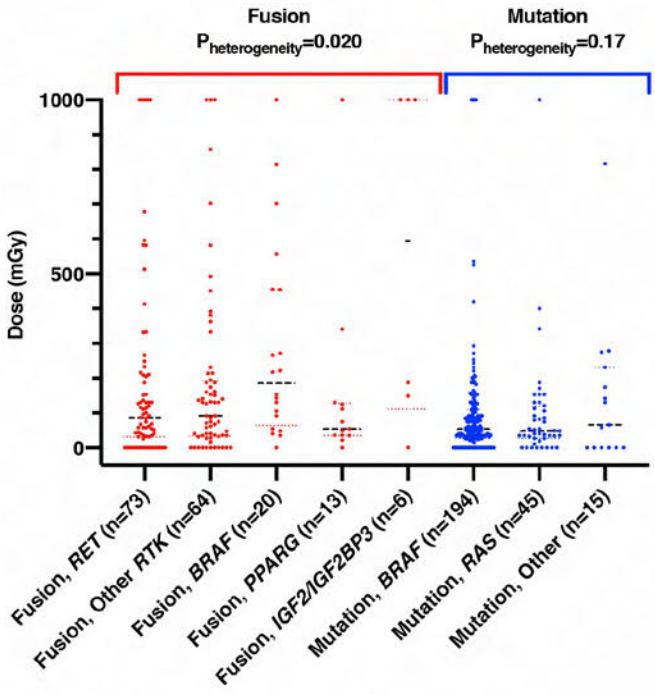
* Models evaluating the effect of dose on driver type restricted to <5 years of age at exposure did not converge, so individuals exposed at <5 and 5-9 years were combined in panel J. EOR/100 mGy for 5-9 years alone=1.78, 95%CI=0.12-226.

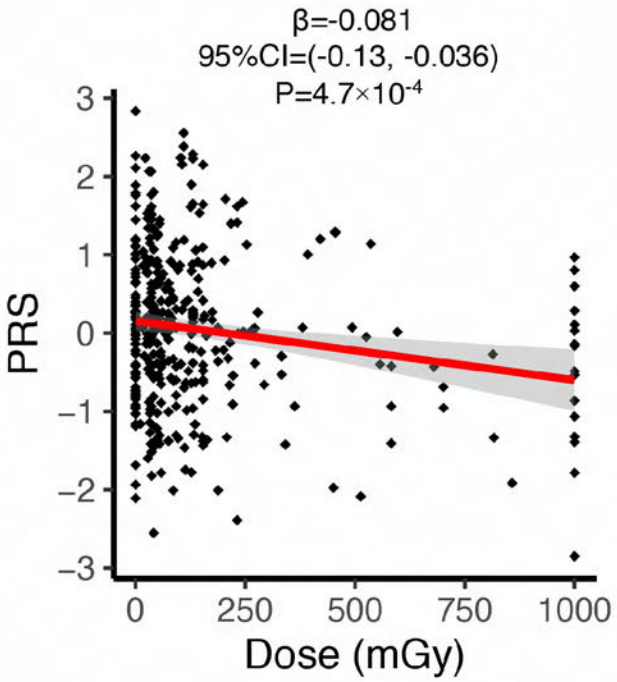
^^ in Panel H indicates that the upper 95% CI exceeds the y-axis maximum value.

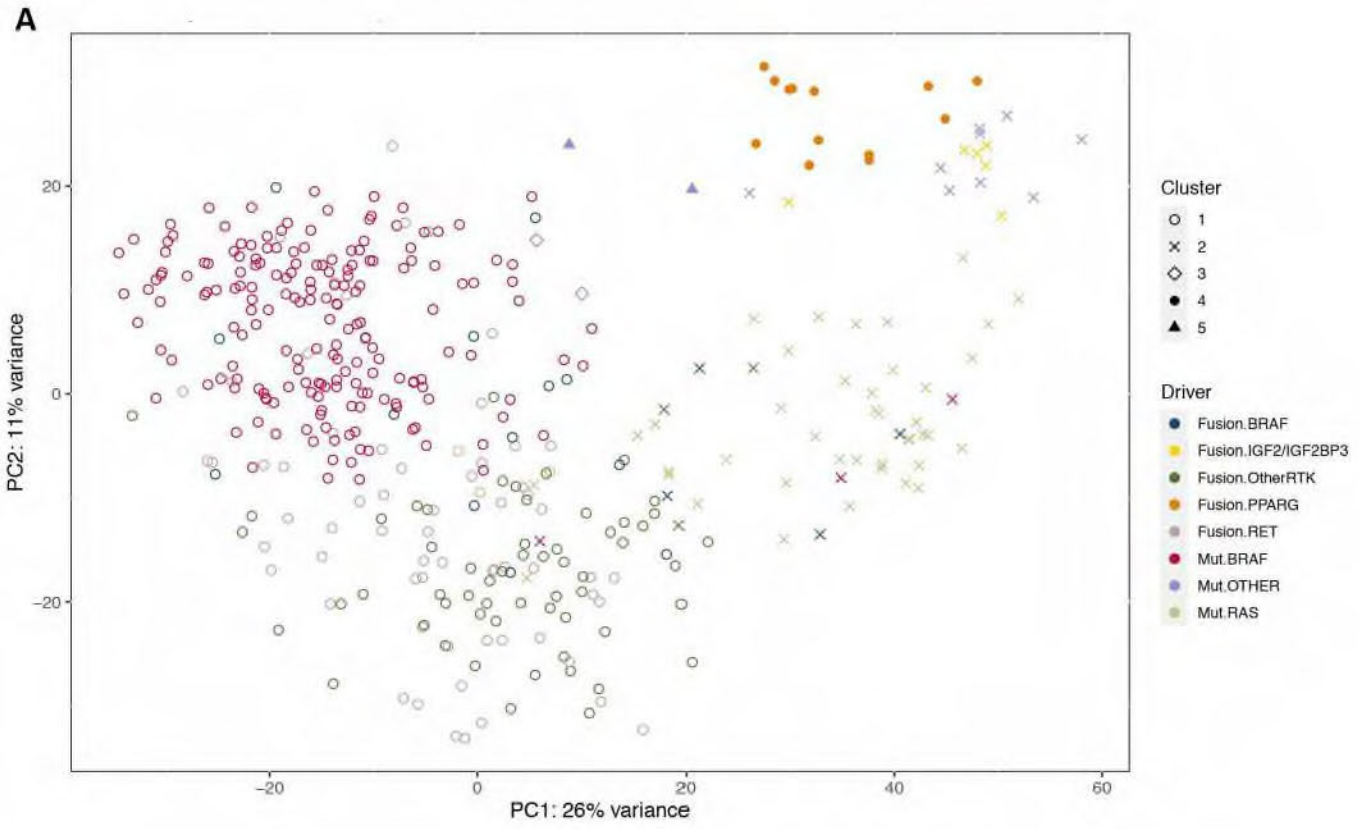

Dose (mGy)
Unexposed
1-99 mGy
100-199 mGy
200-499 mGy
≥500 mGy
Sex
Age at PTC
Age at exposure
Latency
Dose
POC
Purity
Mutation count
SBS Signatures
ID Signatures
SV count
msIndel count
SCNA count
22qDEL
BRAF
NRAS
HRAS
KRAS
TSHR
DICER1
CHD2
AKT1
APC
NFE2L2
TSC1/TSC2
TP53
RET
NTRK3
BRAF
PPARG
NTRK1
ALK
IGF2/IGF2BP3
LTK
mRNA cluster
miRNA cluster
Methylation cluster
BRS mRNA
BRS miRNA
BRS methyl
TDS
ERK
Sex
female
male
Age at PTC (y)
<25
25-29
≥30
Age at exposure (y)
<5
5-9
≥10
Latency (y)
<20
20-24
≥25
POC (%)
0
1-24
25-49
50-74
≥75
Purity
high
low
Mutation count
SNV
INS
DEL
DNP
TNP
Mutation signature
SBS1
SBS2
SBS5
SBS8
SBS13
SBS18
SBS23
Indel signature
ID1
ID3
ID4
ID5
ID6
ID8
msIndel count
msDEL
msINS
SCNA count
GAIN
CNLOH
DEL
22q DEL
No
Yes
PTC driver
Mutation
Fusion
mRNA cluster
1
2
3
4
5
miRNA cluster
1
2
3
4
5
Methylation cluster
1
2
3

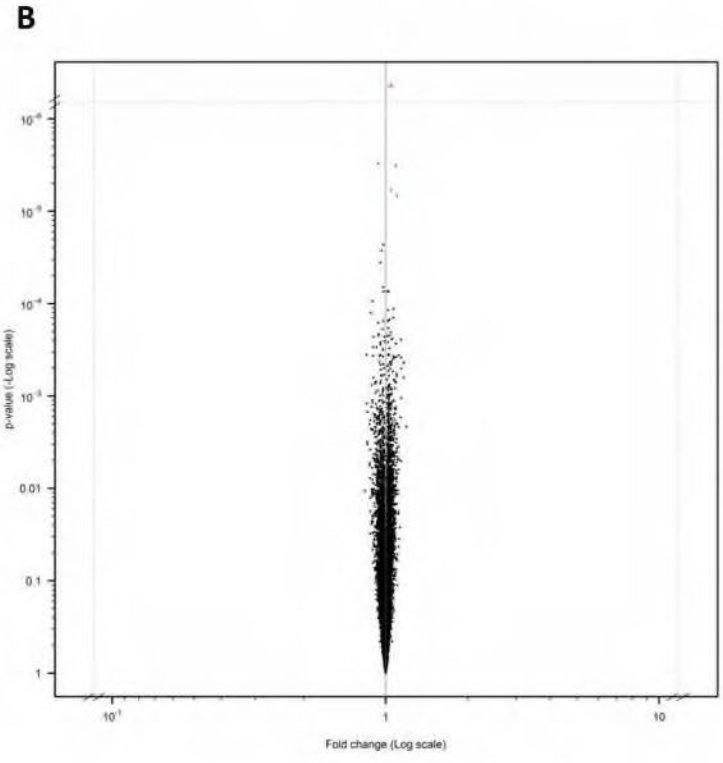

Total
Clonal
Subclonal
A β=2.16, P=8.0×10-9
B β=1.48, P=9.9×10-12
C β=-0.06, P=0.82
D β=0.0039, P=4.9×10-21
E β=0.0071, P=1.8×10-18
F β=0.0009, P=0.023
G β=1.07, P=1.3×10-4
H β=0.72, P=2.3×10-5
I β=-0.06, P=0.74
J β=1.15, P=7.3×10-9
K β=0.80, P=2.7×10-14
L β=0.08, P=0.49
Small deletions
Deletion:SNV ratio
ID5
ID8
Dose (mGy)

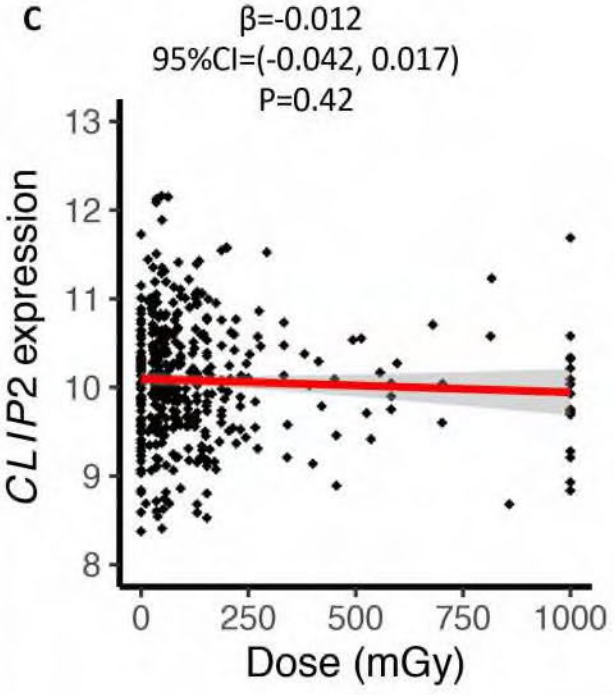

A EOR=2.66, P=1.2×10-14
B EOR=0.93, P=6.6×10-8
C EOR=0.61, P=4.9×10-31
D EOR=18.8, P=5.5×10-19
E EOR=0.037, P=0.41
EOR/100 mGy (95% CI)
Dose (mGy)

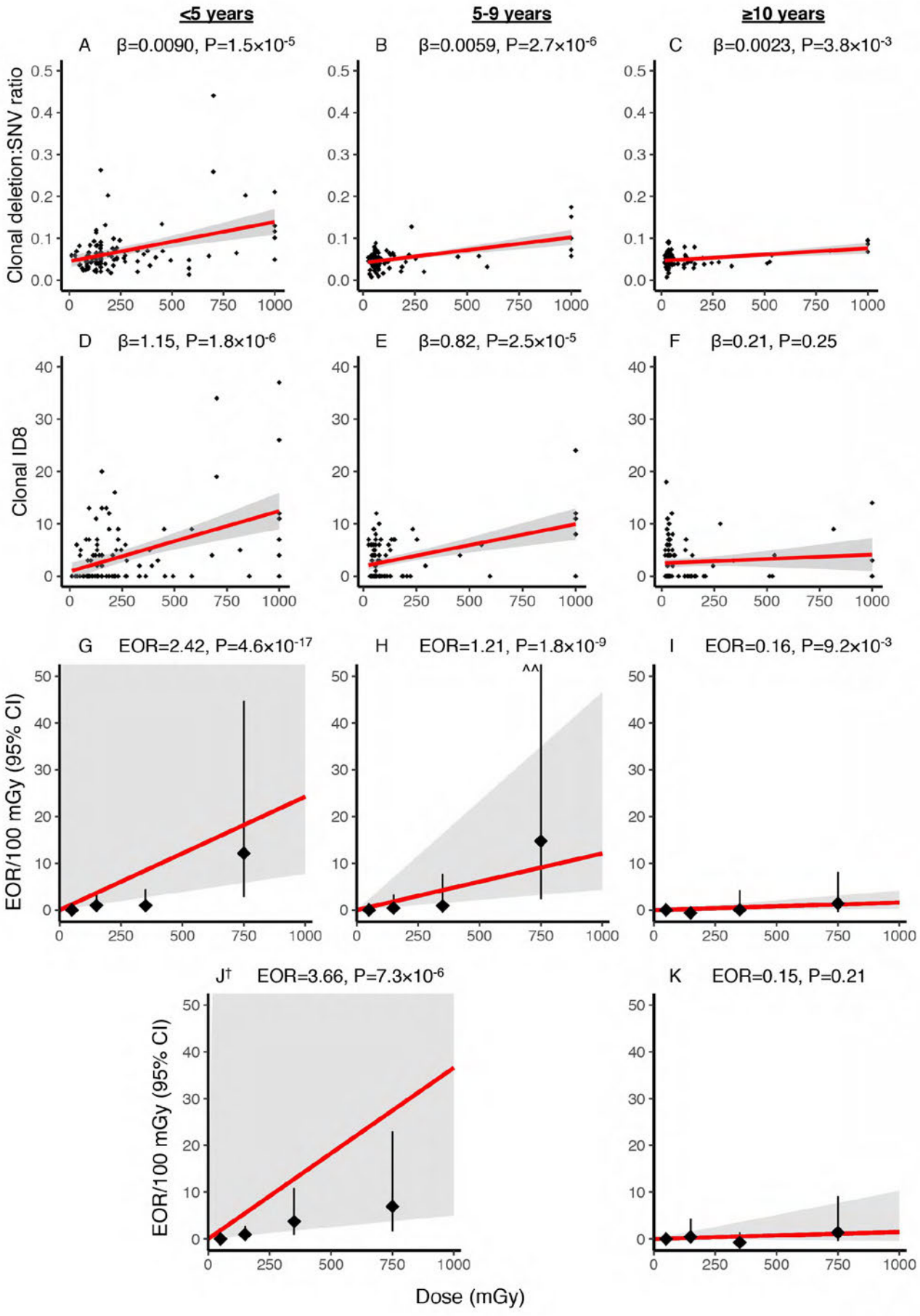

Fusion
$P_{heterogeneity}$=0.020
Mutation
$P_{heterogeneity}$=0.17
1000
500
0
Dose (mGy)
Fusion, *RET* (n=73)
Fusion, Other *RTK* (n=64)
Fusion, *BRAF* (n=20)
Fusion, *PPARG* (n=13)
Fusion, *IGF2/IGF2BP3* (n=6)
Mutation, *BRAF* (n=194)
Mutation, *RAS* (n=45)
Mutation, Other (n=15)


β=-0.081
95%CI=(-0.13, -0.036)
P=4.7×10-4
PRS
3
2
1
0
−1
−2
−3
0
250
500
750
1000
Dose (mGy)


A
PC2: 11% variance
PC1: 26% variance
Cluster
1
2
3
4
5
Driver
Fusion.BRAF
Fusion.IGF2/IGF2BP3
Fusion.OtherRTK
Fusion.PPARG
Fusion.RET
Mut.BRAF
Mut.OTHER
Mut.RAS


B
p-value (-Log scale)
Fold change (Log scale)


C
β=-0.012
95%CI=(-0.042, 0.017)
P=0.42
CLIP2 expression
Dose (mGy)


<5 years
5-9 years
≥10 years
A β=0.0090, P=1.5×10-5
B β=0.0059, P=2.7×10-6
C β=0.0023, P=3.8×10-3
Clonal deletion:SNV ratio
D β=1.15, P=1.8×10-6
E β=0.82, P=2.5×10-5
F β=0.21, P=0.25
Clonal ID8
G EOR=2.42, P=4.6×10-17
H EOR=1.21, P=1.8×10-9
^^
I EOR=0.16, P=9.2×10-3
EOR/100 mGy (95% CI)
J† EOR=3.66, P=7.3×10-6
K EOR=0.15, P=0.21
EOR/100 mGy (95% CI)
Dose (mGy)

CAPTIONS FOR DATA S1 TO S3

Data S1. Analytic data.

Data S2. Somatic SSVs in the 383 WGS primary tumor-normal pairs.

Data S3. Somatic SVs in the 383 WGS primary tumor-normal pairs.

Supplementary Materials for

Radiation-related genomic profile of papillary thyroid cancer after the Chernobyl accident

Lindsay M. Morton*, Danielle M. Karyadi*, Chip Stewart*, Tetiana I. Bogdanova†, Eric T. Dawson†, Mia K. Steinberg†, Jieqiong Dai, Stephen W. Hartley, Sara J. Schonfeld, Joshua N. Sampson, Yosi Maruvka, Vidushi Kapoor, Dale A. Ramsden, Juan Carvajal-Garcia, Charles M. Perou, Joel S. Parker, Marko Krznaric, Meredith Yeager, Joseph F. Boland, Amy Hutchinson, Belynda D. Hicks, Casey L. Dagnall, Julie M. Gastier-Foster, Jay Bowen, Olivia Lee, Mitchell J. Machiela, Elizabeth K. Cahoon, Alina V. Brenner, Kiyohiko Mabuchi, Vladimir Drozdovitch, Sergii Masiuk, Mykola Chepurny, Liudmyla Yu. Zurnadzhy, Maureen Hatch, Amy Berrington de Gonzalez, Gerry A. Thomas‡, Mykola D. Tronko‡, Gad Getz‡, Stephen J. Chanock‡

*These authors contributed equally to this work.
†These authors contributed equally to this work.
‡These authors jointly directed this work.

Correspondence to: chanocks@mail.nih.gov, mortonli@mail.nih.gov

This PDF file includes:

Materials and Methods
Figs. S1 to S32
Tables S1 to S12, S15-S16, S18-S22
Captions for Data S1 to S3

Other Supplementary Material for this manuscript includes the following:

Tables S13, S14, S17 (Microsoft Excel)
Data S1 to S3 (text files)
Data S1 data dictionary (PDF)
MDAR Reproducibility Checklist (PDF)

Materials and Methods

Study Populations

The primary study population for this analysis included individuals who developed pathologically-confirmed papillary thyroid cancer (PTC) during young adulthood in the Ukraine following the April 1986 Chernobyl nuclear power plant accident and whose pre-treatment, fresh frozen tumor sample was collected by the Chernobyl Tissue Bank (CTB) (*11*) (**Table S1**). Eligibility criteria included: *in utero* or <19 years of age on April 26, 1986 (cases) or born >9 months after the accident (comparison population of unexposed individuals); residence in one of the most contaminated territories (oblasts or states) of Ukraine, specifically, Zhytomyr, Kiev (Kyiv in Ukrainian), or Chernigov (Chernihiv in Ukrainian); histopathologically confirmed diagnosis of a first primary papillary thyroid cancer based on review of tumor tissue by an international panel of experts and medical record data documenting no prior cancer history (*11*); availability of ^{131}I dose estimates (see details below); availability of fresh frozen thyroid tissue with sufficient, high quality nucleic acids (see details below); and availability of non-tumor thyroid tissue and/or a blood sample (collected years later). **Fig. S1** provides the distribution of available tumor tissue, non-tumor thyroid tissue, and blood in the final dataset of 440 individuals with PTC (n=359 ^{131}I-exposed, n=81 unexposed). Participants (or guardians for minors) provided informed consent for donation and broad research use of their materials through the CTB, and the study was approved by Institutional Review Boards at the tissue collection center (Institute of Endocrinology in Kiev, Ukraine), the CTB coordination center (Imperial College of London, UK), and the United States National Cancer Institute.

Among the 440 individuals with PTC included in our final analysis, the majority (n=365, 83.0%) underwent a total thyroidectomy and had lesions <2.0 cm (n=247, 56.1%) (**Table S1**). Among those with available non-tumor thyroid tissue that passed quality control assessment (n=416), the sample was taken from the contralateral lobe/side for most individuals (n=359, 86.3%). Non-tumor thyroid tissue from the same (ipsilateral) side (n=56, 13.5%) was taken as far from the tumor as possible. To our knowledge, no study participants had concurrent thyroid disease.

For investigation of the relationship between radiation dose and the PTC driver type (described below), we also included data from 45 non-overlapping individuals with PTC occurring after the Chernobyl accident whose PTC drivers were identified in a previously-published RNA sequencing (mRNA-seq) analysis (**Table S1**) (*9*).

^{131}I Dose Estimation

For ^{131}I-exposed individuals with PTC (individuals who were in utero or <19 years of age on April 26, 1986), radiation doses to the thyroid were reconstructed by an international team of dosimetry experts using well-established methods that have been described in detail previously for studies of Chernobyl-related cancer risks (*14, 15*). Briefly, the dose reconstruction approach varied based on the type of information available for each individual: presence or absence of direct thyroid radioactivity measurements, presence or absence of personal interview, and information on place of residence (oblast/state, raion/county, settlement) in 1986. Among the 359 ^{131}I-exposed individuals included in the primary analytic population, 49 were part of a large-scale thyroid cancer screening cohort (*54*), and their doses were estimated based on individual thyroid radioactivity measurements taken in May-June 1986, personal interview data concerning residential history and intake of milk and green leafy vegetables (the main source of ^{131}I

exposure) after the accident, and results of radio-ecological modeling (**Table S1**). For an additional 4 individuals, dose estimates were calculated based on individual thyroid radioactivity measurements, but not on personal interview. Dose estimates for the largest group of individuals (n=297) were based on measurements made on different individuals who lived in the same residential area. Finally, for the 9 individuals who were *in utero* at the time of the accident, estimated doses were based on the mother's exposure (*55*). Among the 45 ^{131}I-exposed individuals included in analyses of the oncogenic PTC driver from the previously published report, doses were estimated based on direct thyroid radioactivity measurement with personal interview data for 39, and the dose estimation method was unknown for the remaining 6 individuals (**Table S1**) (*9*).

Laboratory Methods

Sample Handling and Nucleic Acid Extraction

Fig. S1 provides a schematic of the study procedures and sample sizes for laboratory work and statistical analyses. Frozen tissue specimens (535 PTC, 522 non-tumor thyroid tissue) were received from CTB and processed by Nationwide Children's Hospital (NCH) Biospecimen Core Resource (BCR) (Columbus, Ohio). A 5 μm section of tissue was cut from the provided block for creation of an H&E slide for pathology review. Specimens were forwarded for total nucleic acid extraction if the tissue necrosis <20% and if the PTC tissue >50% tumor nuclei with matching non-tumor thyroid tissue with <10% tumor nuclei and/or blood available. Specimens for 72 individuals did not pass this inclusion criteria based on 66 PTC failures and 6 non-tumor thyroid failures without blood available, resulting in the removal of 72 PTC, 71 non-tumor thyroid, and 21 blood specimens. A two-column approach was utilized for extraction of DNA and RNA from approximately 10-40 mg of tissue, depending on tissue availability. Tissue was homogenized using the Qiagen Qiagen TissueLyser II. Dual DNA and RNA Extraction was performed utilizing the AllPrep DNA/RNA Mini Kit (Qiagen) for DNA and mirVana miRNA Isolation Kit (Applied Biosystems) for total RNA and small RNA. Purified nucleic acids were quantified and quality checked post-extraction. RNA was tested utilizing the Agilent 2100 Bioanalyzer with the RNA 6000 NanoChip (Agilent). DNA was quantified with the Quant-iT PicoGreen dsDNA Assay Kit (ThermoFisher). DNA molecular weight was evaluated by E-Gel 48 Agarose Gels, 1% (ThermoFisher). Tumor and normal tissue DNA samples were identity matched via SNP analysis MassARRAY system and iPLEX chemistry (Sequenom) across 50 loci.

Whole blood samples (n=326) collected in standard EDTA vacutainers were received from CTB and processed at the Cancer Genomics Research Laboratory (CGR) of the National Cancer Institute. Blood samples were extracted on the QIAsymphony SP® instrument utilizing manufacturer-supplied reagents and protocols (QIAGEN). Double-stranded DNA was quantified with QuantiFluor® dsDNA System (Promega Corporation) for use in downstream assays.

Sample quality and quantity assessment and final inclusion criteria

DNA/RNA yield and the RNA Integrity Number (RIN; Agilent Bioanalyzer) identified that 11 individuals had insufficient yield and/or RNA quality for WGS or RNA-seq analysis and were excluded. Data from the Illumina Infinium OmniExpress SNP array and/or mRNA-seq were used as preliminary assessment of sample quality and to check for sex and/or intra-individual discordance, which identified 12 individuals for exclusion (11 for discordance among matched

samples and one for DNA/RNA tumor contamination). The non-tumor thyroid tissue pathology was reassessed and only tissues with no evidence for tumor nuclei were processed further. Following these exclusions, 440 individuals with 440 PTC (23 excluded), 416 non-tumor thyroid (35 excluded), and 290 blood (15 excluded) samples remained for further laboratory processing.

All available tissue types (PTC, non-tumor thyroid, and blood) that passed the above quality control metrics were attempted on all six platforms (WGS, mRNA-seq, miRNA-seq, SNP array, methylation, and relative telomere length) when possible. PTC WGS required a paired normal tissue sample (non-tumor thyroid or blood) for analysis, thus PTC samples were excluded from the WGS platform if no normal tissue was available. Similarly, NT WGS (non-tumor thyroid tissue) required both a non-tumor thyroid tissue and blood sample. Sufficient DNA/RNA was available to attempt all six platforms for 369/440 PTC samples, 352/416 non-tumor thyroid tissues, and 232/290 blood samples, whereas only a subset of platforms was attempted for the remaining 71/440 PTC samples, 64/416 non-tumor thyroid tissues, and 58/290 blood samples. **Fig. S1** provides further details regarding the number of attempted assays, the number of failed assays per platform, and the final number of samples per platform by sample type.

Whole Genome Sequencing
All WGS library preparation and sequencing was done at the Broad Institute. Libraries were constructed and sequenced on the Illumina HiSeqX with the use of 151 base pair (bp) paired-end reads for whole-genome sequencing. Output from Illumina software was processed by the Picard data-processing pipeline to yield BAM files containing well-calibrated, aligned reads. All sample information tracking was performed by automated LIMS messaging.

WGS Library Construction
Initial genomic DNA input for shearing was reduced from 3 μg to 350ng in 50 μL of solution. In addition, for adapter ligation, Illumina paired end adapters were replaced with palindromic forked adapters with unique 8 base index sequences embedded within the adapter.

Library preparation and sequencing was done in two batches with slightly modified protocols. The first 919 samples were sequenced with the following library preparation protocol: Aliquots of genomic DNA (350ng in 50 μL) underwent fragmentation by means of acoustic shearing using Covaris focused-ultrasonicator, targeting 385 bp fragments. Following fragmentation, additional size selection was performed using a SPRI cleanup. Library preparation was performed using a commercially available kit provided by KAPA Biosystems (product KK8202, name: KAPALIBPREPKT) and with palindromic forked adapters with unique 8 base index sequences embedded within the adapter (purchased from IDT). Following sample preparation, libraries were quantified using quantitative PCR (kit purchased from KAPA biosystems) with probes specific to the ends of the adapters. This assay was automated using the Agilent Bravo liquid handling platform. Based on qPCR quantification, libraries were normalized to 1.7nM. Samples were then pooled into 24-plexes, and the pools were once again qPCRed. Samples were combined with HiSeq X Cluster Amp Reagents EPX1, EPX2 and EPX3 into single wells on a strip tube using the Hamilton Starlet Liquid Handling system. Cluster amplification of the templates was performed according to the manufacturer's protocol (Illumina) using the Illumina cBot. Flowcells were sequenced either on HiSeqX Sequencing-by- Synthesis Kits to produce 151 bp paired-end reads, then analyzed using RTA2. Output from Illumina software was processed

4

by the Picard data-processing pipeline to yield CRAM or BAM files containing demultiplexed, aggregated aligned reads.

The final 224 samples were sequenced with the following minor changes in protocol: Library preparation was performed using a commercially available kit provided by KAPA Biosystems (KAPA Hyper Prep without amplification module, product KK8505), and with palindromic forked adapters with unique 8-base index sequences embedded within the adapter (purchased from Roche). Following sample preparation and qPCR quantification, libraries were normalized to 2.2nM and pooled into 24-plexes. All other aspects of the protocol remained the same as described in the previous paragraph.

Sequencing data (FASTQ files) were aligned to the reference genome (hg19) using BWA-MEM (*56*). Duplicated fragments of DNA were marked to avoid 'double counting' evidence for somatic events using Picard MarkDuplicates (version 1.1310 broadinstitute.github.io/picard) and re-calibrated the base quality scores to more accurately reflect the probability of error using BQSR (broadinstitute.github.io/picard). Since alignments around indels can be different among reads, which affects downstream indel and mutation calling, we performed local realignment on both the tumor and normal for each patient ("co-cleaning" GATK3 IndelRealigner version nightly-2015-07-31-g3c929b0) (*57*). At the end of this step, we obtained hg19 binary alignment files (BAM files) for each of the tumor and normal samples.

Each WGS sample was assessed for coverage (**Table S2**), library complexity, fingerprinting across tumor and normal samples, sequencing error rates, fragment length, chimeric fragment rate, and DNA oxidative damage using a suite of Picard tools (Picard CollectWGSmetrics, CollectSequencingArtifactMetrics for 8-oxoG damage, and CrosscheckFingerprints).

RNA Library Preparation and Sequencing
Quality control was performed on total RNA using the Qubit BR RNA assay (ThermoFisher Scientific) and Agilent RNA 6000 Pico Kit (Agilent Technologies). 100-500 ng of total RNA in 10 µl was used as input. Libraries were prepared using the Kapa RNA HyperPrep Kit with RiboErase per manufacturer's instructions with slight modifications (Kapa Biosystems, part# KK8561). Briefly, following depletion of ribosomal RNA, fragmentation was performed at 85ºC for 4.5 minutes for good quality samples, 85ºC for 4 minutes for average quality, and 65ºC for 1-1.5 min for the lowest quality and/or lowest input samples. Following first and second strand cDNA synthesis, 1.5 µM NEXTflex-96 DNA Barcodes (BioO Scientific) were ligated to the A-tailed cDNA. Eight cycles of library amplification were performed, followed by two rounds of 1x Ampure purification. Final libraries were quantified by Qubit, equal molar pooled at 16 samples per pool and sequenced on the Illumina HiSeq 2500 using the SBS 2x125 bp and Cluster v4 kits. Runs generated an average of 125,000,000 reads/sample, with 44,000 transcripts and 19,000 genes detected. The sequenced paired-end reads were trimmed using trimmomatic/0.36. Trimmed reads were aligned to the GRCh38 human reference genome (illumine iGenomes NCBI GRCh38) using STAR/2.5.4a, and gene reads count was quantified according to illumine iGenomes NCBI GRCh38 annotation file.

For miRNA sequencing, the Illumina Ribo-Zero Gold rRNA Removal Kit (Illumina, part# MRZG12324) was used for ribosomal RNA depletion from 500 ng purified total RNA per

manufacturer's instructions. 500ng of the rRNA depleted sample was then processed as described in the NEBNext Multiplex Small RNA Library Prep Set for Illumina kit (NEB, part #E7300L) with minor modifications. Following first strand synthesis, Illumina indexes were added using 12 cycles of PCR amplification, the products purified with 1.8x Ampure XP beads and recovered in 15 μL low TE buffer. Size selection of the miRNA libraries was performed on Blue Pippin using 3% Agarose, dye free gel with internal standards selecting for 105-190 bp products (Sage Sciences, part# BDQ3010). Quantitation and quality control checks were performed using Qubit dsDNA HS assay and on Agilent 2100 Bioanalyzer system with the Agilent HS DNA assay. Libraries were equal molar pooled at 16 samples per pool and sequenced on the Illumina HiSeq 2500 using the 50 cycle single read SBS and Cluster v4 kits according to the manufacturer's instructions. The sequenced single-end reads were processed according to the ENCODE microRNA-seq pipeline (https://www.encodeproject.org/microrna/microrna-seq/#references). Briefly, reads were trimmed using Cutadapt/1.18, and after adaptor trimming and quality filtering only those with lengths of 15-31 nt were kept. Trimmed reads were aligned to the GRCh38 human reference genome (illumine iGenomes NCBI GRCh38) using STAR/2.5.4a, and microRNA reads count was quantified according to GENCODE V24 genome annotation file which was the microRNA subset from comprehensive GENCODE annotations.

FASTQC/0.11.5 was used for the quality control analysis of post-trimmed RNA-seq and miRNA-seq reads. Samples that received warning or fail messages on the analysis of Mean Quality Scores, per sequence quality scores, per base N content, or adapter content were filtered. STAR alignment scores were used for alignment quality control analysis. Samples over 60% of any type of unmapped reads were filtered. Code for RNA-seq quality control and alignment is available at https://github.com/NCI-CGR/ChernobylThyroidCancer-RNAseq and https://github.com/NCI-CGR/ChernobylThyroidCancer-miRNAseq and archived on Zenodo (*58, 59*).

Illumina Infinium OmniExpress Single Nucleotide Polymorphism (SNP) Arrays
High-throughput, genome-wide SNP genotyping, using Infinium BeadChip technology (Illumina Inc.), was performed at the Cancer Genomics Research Laboratory (CGR) of the National Cancer Institute. Genotyping was performed per the manufacturer's guidelines using the Infinium automated HTS Assay protocol. Briefly, 200 ng genomic DNA, quantitated using Quant-iT PicoGreen dsDNA Reagent (ThermoFisher Scientific) was denatured and neutralized, then isothermally amplified by whole-genome amplification. The amplified product was enzymatically fragmented, then precipitated and re-suspended. Resuspended samples were denatured, then hybridized to locus-specific 50-mer oligonucleotides, which were attached to 1-micron beads on the BeadChip. These 50-mer probes stopped one base before the location of interest. Enzymatic single-base extension of the oligos on the BeadChip, using the captured DNA as a template, incorporated tagged nucleotides on the BeadChip, which were subsequently fluorophore-labeled during staining. The fluorescent label determined the genotype call for the sample. The Illumina iScan scanned the BeadChips at two wavelengths to detect the fluorescent label, creating image files that were converted into genotype calls based on the detected fluorescence.

All samples in this study were scanned on the Infinium HumanOmniExpress-24 (v1.1, v1.2) array using the standard Illumina microarray data analysis workflow

(https://www.illumina.com/documents/products/technotes/technote_array_analysis_workflows.pdf) and data quality check was performed using PLINK (v.1.90b5.4). A two-stage filter by completion rate threshold of >0.8 for samples and >0.8 for loci, followed by >0.95 for samples and >0.95 for loci was performed. Sample contamination was examined by running the tool VerifyIDintensity(https://genome.sph.umich.edu/wiki/VerifyIDintensity) on each sample that passed completion rate filters or had a median raw intensity >6000. Additionally, sex verification, autosomal heterozygosity, and genotype concordance checks across all samples were performed to identify any problematic samples.

Methylation EPIC Array

400 ng of sample DNA, according to Quant-iT PicoGreen dsDNA quantitation (ThermoFisher Scientific), was treated with sodium bisulfite using the EZ-96 DNA Methylation MagPrep Kit (Zymo Research) according to manufacturer-provided protocol. Bisulfite conversion modified non-methylated cytosines into uracil, leaving 5-methylcytosine (5mC) and 5-hydroxymethylcytosine (5hmC) unchanged. For every 95 samples, an internal control, NA07057 (Coriell Cell Repositories), was utilized to confirm the efficiency of bisulfite conversion during subsequent methylation analysis.

High-throughput epigenome-wide methylation analysis, using the Infinium MethylationEPIC BeadChip (Illumina Inc.), which uses both Infinium I and II assay chemistry technologies, was performed according to manufacturer's protocol. Bisulfite-treated samples were denatured and neutralized and whole genome amplified isothermally to increase the amount of DNA template. The amplified product was enzymatically fragmented, precipitated and resuspended in hybridization buffer. Twelve samples were applied to each BeadChip and hybridized overnight, where fragmented DNA samples anneal to locus-specific 50mers (covalently linked to bead types for more than 850,000 methylation sites). Two bead types corresponded to each CpG locus for Infinium I assays (one bead type corresponded to methylated and another bead type to the unmethylated state of the CpG site), while one bead type corresponded to each CpG locus (both methylated and unmethylated) for Infinium II assays. Single-base extension of the oligos on the BeadChip, using the captured DNA as template, incorporated tagged nucleotides on the BeadChip, which were subsequently fluorophore-labeled during staining. The Illumina iScan scanned the BeadChips at two wavelengths to create image and intensity files.

The intensity files from the Illumina methylation assay on the MethylationEPIC BeadChip were processed and analyzed with the R programming language using the R package "minfi". Briefly, raw intensity file (idats) were loaded into R using minfi. Samples were excluded if the percent of probes with detection p value >0.01 was greater than 4%, where the detection p-value=1-p-value as computed from the background model characterizing the chance that the target sequence signal was distinguishable from the negative controls. Concordance was checked for both expected and unexpected replicates using the ~60 polymorphic SNPs on the array. Raw methylation beta values were normalized according to previously published methods (*60*).

Relative Telomere Length Measurement

Relative telomere length measurement was performed on DNA using a qPCR assay adapted from Cawthon's originally published protocol which is briefly summarized below (*61, 62*). Relative telomere length determination by qPCR measured the ratio of telomere (T) signals,

specific to the telomere hexamer repeat sequence TTAGGG, to autosomal single copy gene (S) signals. This ratio was standardized by internal control DNA samples to yield relative standardized T/S ratios proportional to average telomere length. In this technique, reactions for each assay were performed independently, in triplicate, so a standard curve of pooled gDNA samples was utilized to assess the amount of each signal, while compensating for inter-plate variations in PCR efficiency.

In this dataset, the mean coefficient of variation (CV) of triplicates for the telomere assay was 0.59% and for the 36B4 assay (single copy gene, S) was 0.32%. The CV for the internal controls (n=85) standardized T/S ratio across all plates was 5.14%. In this dataset, the intraclass correlation coefficient (ICC) was 0.958 (95% confidence interval: 0.947, 0.967). The mean CV for the standardized T/S ratio of technical replicates was 4.9% based on 61 subjects.

Bioinformatic Analysis

All bioinformatic analyses were conducted without knowledge of radiation dose. The bulk of WGS processing was done within the Terra workflow framework (Terra.bio) (*63*). All workflows described below are available from a public workspace REBC_methods_only. Some of the input parameters for the workflows (particularly the Panels-of-Normals [PoN] - used for mutation, structural variation, and copy number detection) are protected data which requires dbGaP application (accession #phs001134 / PRJNA324143) approval for access. The same pipeline as described below was run on the cohort of WGS tumor-normal pairs as well as the WGS non-tumor thyroid tissue-blood normal pairs. Additionally, the pipeline was run on 42 individuals without known radiation exposure who had available tumor-normal paired WGS data from The Cancer Genome Atlas (TCGA) data set according to current quality control criteria (*10*). Note that the subset of individuals selected for WGS from the full TCGA analysis of PTC were more likely to have an unidentified driver (*10*) due to sampling of WGS for this reason.

Mutation Detection, Merging, and Filtering Pipeline

A consensus calling approach for somatic mutations combined evidence from multiple detection algorithms (**Fig. S6**). Single nucleotide variants (SNVs) were detected by MuTect 1.0 version GATK3 v1.1.6 (*64*) (Terra task wgs_pip_m1_fragcounter_oxoq_1), MuTect2.0 version GATK3 "3.6-97-g881c5e9" (*65*) (Terra task wgs_pip_m2_64core), Strelka 1 version 1.0.11 (*66*) (Terra task strelka), and Strelka 2 version 2.8.3 (*67*) (Terra task strelka2), all with default parameters except as specified in Terra workspace REBC_methods_only. Insertion/deletion variants (indels) were detected by MuTect2.0, Strelka 1, and Strelka 2, as well as PCAWG_snowman version 1.0 (*68*) (Terra task pipette_wgs_SV), and SvABA version 134 (*68*) (Terra task SvABA_xtramem) all with default parameters except as specified in Terra workspace REBC_methods_only.

To account for algorithms that were based on similar approaches and/or development teams (Strelka version 1 and Strelka version 2, PCAWG snowman and SvABA), a consensus "voting" scheme was used to select the final calls. Specifically, the consensus voting scheme (Terra task rebc_consensus_maf) gave MuTect 1.0 and 2.0 one vote each because of their different approaches to mutation calling, whereas Strelka 1 and 2 were combined to provide one vote if either algorithm detected an event, and PCAWG snowman and SvABA were combined to provide one vote if either algorithm detected an event. The post-process consensus filter required at least 2 votes from all the algorithms and was applied following the artifact filters described

below (**Fig. S7**). Mutations passing all filter criteria were included in the next layer of mutation analysis (MutSig2CV, SigProfiler signature analysis, ABSOLUTE purity and ploidy estimation, clonality estimation, and association analyses).

The first computational step in MuTect (1.0 and 2.0) was to estimate sample DNA contamination from other individuals (ContEst version Queue-1.4-437-g6b8a9e1-svn-35362.jar (*69*), Terra task wgs_pip_m1_fragcounter_oxoq_1) which was used internally within MuTect to set somatic evidence thresholds. The ContEst tumor sample contamination estimate was also used by a post-process filter (described below) on the consensus mutation calls so that algorithms other than MuTect were also desensitized to tumor sample contamination. Mutations that passed somatic mutation criteria for each algorithm were converted from their native format (usually VCF format (*70*)) to a common "maf-lite" format (*71*) (Terra task maflite_merge_maf_workflow) so that algorithms detecting a given variant could be merged into a common format before being annotated and converted to the standard MAF format by oncotator (*71*).

Among the decisions imposed by the merging algorithm, multiple algorithms often have differences in allele counts for the same variant. This was resolved by ordering the algorithms (MuTect 1, MuTect 2, PCAWG Snowman, Strelka 1, Strelka 2, SvABA) such that the first algorithm in the ordered list with a call at the specific allele would be the algorithm to provide the merged allele counts. Indels were merged when the indel start occurred within a window of three bases. The merged mutations were then filtered (Terra task contest_oxoG_PoN_blat_Filter_Workflow) for possible sources of artifacts including 8-oxoG damage, PoN, local realignment around candidate mutations, tumor sample contamination, a hard threshold against more than one alternate supporting read in the normal, consensus among algorithms (**Fig. S7**). At each stage in the analysis a large fraction of the mutation candidates were manually reviewed in IGV (*72*), particularly those found to be outliers in terms of overlap with repeat regions (*73*), coverage spikes (>200x), low evidence (number of ALT reads < 5), or evidence of the ALT allele a normal (either by the matched normal or the PoN). Conclusions from manual review were applied to the list of candidate mutation in terms of modifications to the filter rules uniformly applied to all candidate mutations rather than as separate manual review judgements for particular mutations. The modification of rules included filter threshold adjustments for sample contamination, number of ALT alleles in the normal, and the consensus voting (described below).

OxoG filter: The deToxoG filter (*74*) was used to remove candidate SNV that were likely to arise from 8-oxoG DNA damage in library prep. The OxoG filter was included in the Terra task contest_oxoG_PoN_blat_Filter_Workflow. Briefly, the deToxoG filter was based on the balance of alternate allele counts of two possible fragment "orientations" (F1R2 and F2R1 in which read 1 of a pair is mapped forward - F1R2 - or reverse - F2R1). The artifact null model expected that the F1R2 and F2R1 should be equally balanced while mutations arising from 8-oxoG damage would be highly skewed (~96%) in favor of F1R2 for G>T and F2R1 for C>A mutations mapped to the reference. The filter calculated a p-value that a given SNV was balanced, and any mutation with a Benjamini-Hochberg FDR less than 1% was removed, which was designed to leave a pool of candidate mutations with less than 1% arising from 8-oxoG damage.

PoN filters: There were several rounds of PoN filters applied. Several algorithms had their own internal PoN filters (eg. MuTect1, MuTect2, SvABA) which were either in VCF or bed format and were used as a blacklist to remove common germline variants or sites of artifacts. The merged MAF was subsequently filtered based on "Token PoN" evidence. The Token PoN filter method has been used in many previous cancer projects (*10, 74-77*), the only difference being that one of the PoNs was specifically constructed from the CTB WGS cohort. A Token PoN consisted of counts from each sample in the PoN at each site of the genomic classified into 8 bins according to the reference and non-reference coverage with Variant Allele Fractions (VAF) of the sample at that site. The bins for each site were defined as:

1. Count samples with sequencing depth $< 8x$
2. Count samples with sequencing depth $\geq 8x$, and not included in bins 3-8
3. Count samples with depth $\geq 8x$, alternate alleles > 1, and $0.1\% < VAF \leq 0.3\%$
4. Count samples with depth $\geq 8x$, alternate alleles > 2, and $0.3\% < VAF \leq 1.0\%$
5. Count samples with depth $\geq 8x$, alternate alleles > 3, and $1.0\% < VAF \leq 3.0\%$
6. Count samples with depth $\geq 8x$, alternate alleles > 3, and $3.0\% < VAF \leq 20.0\%$
7. Count samples with depth $\geq 8x$, $3 \leq$ alternate alleles ≤ 10, and $VAF > 20.0\%$
8. Count samples with depth $\geq 8x$, alternate alleles >10, and $VAF > 20.0\%$

Counts of samples in these bins were used to approximate a PoN likelihood vector for each site in VAF bins 0-0.1%, 0.1-0.3%, 0.3-1%, 1-3%, 3-20%, and 20%-100%. For each candidate mutation a corresponding data likelihood was constructed based on the beta distribution of VAF for the observed alternate and reference counts of supporting reads. The joint likelihood between the PoN and data was the bin-by-bin sum of the product of the two likelihood vectors. A candidate mutation failed the token PoN filter when log10(PoN joint likelihood) > -2.5, a threshold which was empirically determined from this and previous projects with combinations of validation data and manual review.

There were two independent PoNs used for mutation filtering included in the Terra task contest_oxoG_PoN_blat_Filter_Workflow. One PoN was constructed from 248 normal blood samples with TIN=0 (see "deTiN" below) from this cohort (dbGaP accession # phs001134 / PRJNA324143). The other token PoN was derived from PCAWG normal blood samples (dbGaP accession # phs000178.v1.p1, EGA accession # EGAS00001001692). Each PoN was used as a statistically separate token PoN filter, although in most cases if a mutation failed one of the PoN filters it would also fail the other.

Realignment filter: Alternate reads from each candidate mutation were realigned to the hg19 reference using BLAT (*78*). This filter was part of the Terra task contest_oxoG_PoN_blat_Filter_Workflow. Any mutations with 3 or more reads with an alignment score to another mapped position greater than or equal to the alignment score at the position supporting the alternate allele were rejected.

Contamination filter: The presence of germline mutations from another individual's DNA contaminating the tumor sample can lead to false detection. MuTect 1.0 and MuTect 2.0 explicitly took this into account in their statistical model detection threshold, but Strelka (1 or 2), SvABA and PCAWG_snowman did not, so a post-process contamination filter (Terra task

postFilter_contEst) was applied to the merged set of mutation calls. The contamination filter calculated the VAF beta cumulative distribution for each mutation's count of reference and alternate supporting reads integrating from 0 to the contEst contamination level for that tumor sample. The VAF beta cdf was compared to a threshold of 1e-5 and any mutation exceeding the threshold was rejected as a likely consequence of sample contamination.

NALT≤1 filter and deTiN: The final post-process filter (Terra task filter_NALT01_maf) removed any mutation with more than 1 alternate allele supporting read in the normal sample. This would potentially contradict the effect of the deTiN (*79*) algorithm, which first estimated the level of tumor DNA in the matched normal sample (TiN) and restored mutations that were previously rejected due to evidence of the alternate allele in the normal that were consistent with the TiN estimate. The deTiN algorithm was slightly modified in that the input candidate mutations from the MuTect1 "call_stats" file was filtered prior to deTiN using the PoN filters described above, modified so that it could operate on call_stats files in addition to maf formatted files as input. This step in the pipeline was implemented in Terra as Filter_call_stats. After deTiN processing we found that the bulk of mutations with 2 or more alternate allele supporting reads occurred in samples with TiN=0, so we excluded all such mutations.

TERT mutation detection: To identify tumors with non-coding *TERT* hotspot mutations (C228T at hg19 chr5:1295228 and C250T at hg19 chr5:1295250) we used MuTect 1.0 in "forcecall" mode (Terra task Mutect1_ForceCall) across the *TERT* UTR region from chr5:1295103-1295257, which reported coverage and alternate allele counts across the region.

Microsatellite Insertions and Deletions

Somatic microsatellite insertions and deletions (indels) were ascertained using MSMuTect, as described previously (*21*). Briefly, microsatellite loci (sequences with at least five successive motifs, regardless of the motif size) and alleles were identified separately in tumor and normal samples. Microsatellite loci with inferred alleles that differed between tumor and normal samples were considered potential somatic mutations. PoN filtering to account for either missed germline events or sequencing artifacts excluded loci that were identified in >2 samples from a set of 210 individuals without cancer from the Ukraine collected for another study. Analyses assessed the total number of microsatellite indels as well as insertions and deletions separately.

Structural Variant Detection and Filtering Pipeline

Like the mutation detection pipeline, the SV detection pipeline was based on the consensus of calls among four structural variation detection algorithms (**Fig. S13**). The four algorithms were dRanger/Breakpointer (*80*), SvABA (*68*), PCAWG_snowman (*81*), and Manta (*82*) (Terra task manta). Default parameters were used for all algorithms as specified in the configuration files in Terra workspace REBC_methods_only. Output SV events from each algorithm were converted into a common format (tab delimited list of events patterned after the Breakpointer format) and filtered using a PoN based on PCAWG data (dbGaP accession # phs000178.v1.p1, EGA accession # EGAS00001001692). The conversion was done by Terra tasks svaba_snowmanvcf2dRangerForBP, mantavcf2dRangerForBP, extract_dRanger_intermediates, and pcawg_snowmanvcf2dRangerForBP (with the relevant algorithm in the task names). The merged set of SV events across the four algorithms was constructed by clustering the breakpoints and strands of each event within a window of 350 bp (approximate fragment length) by the Terra

task SV_cluster_forBP. The consensus SV calls generally had slightly different breakpoints and allele counts from the various algorithms, so the selected variant breakpoints and allele counts were set according to the algorithm order dRanger, Manta, SvABA, and PCAWG snowman. After the set of calls from the algorithms were combined into a single call set, a final Breakpointer job (Terra task breakpointer) detected the consensus breakpoint positions, counts of alternate and reference supporting split-reads and read-pairs, and identified any sequence homology or novel sequence at the breakpoints.

The consensus SV filter (Terra task REBC_SV_consensus_filter_v3) required at least two algorithms to detect a mutation for the SV event to pass to the next layer of analysis. Each algorithm was given one vote in the consensus. There was no need for a more sophisticated consensus scheme since the contribution of calls based only on PCAWG snowman and SvABA was negligible (2 events) after filtering (**Fig. S14**), while dRanger and Manta were considered as "independent" algorithms. SV post-process filters demanded at least four alternate allele supporting reads (split-reads or read pairs, with each read pair counted at most once) from the tumor sample and at most one alternate supporting read in the normal sample. The Variant Allele Fraction of a given SV was estimated as

$$VAF=TALT/(TALT+TREF/2)$$

where *TALT* and *TREF* are the counts of supporting pairs (split-read or read pairs, but each fragment counts at most once for fragments with both read pair and split read support for the alternate allele). SV calls with VAF<0.1were rejected by the filtering task. The SV filter also excluded of SVs with breakpoints within centromere or telomere regions.

At a later stage in the analysis, we found that 10% of the candidate SV events had the same precise breakpoints in multiple tumor samples, adjacent tissue samples, and/or unmatched normal samples. These "hotspot" SVs had low counts of supporting reads and tended to occur in in regions of germline structural variation and were interpreted as hotspot somatic artifacts. None of these hotspot SVs occurred in SV driver genes. These hotspot SV events were rejected as artifacts using a custom matlab script REBC_SV_hotspots.4May2020.m outside of the Terra framework. Code is available at https://github.com/getzlab/REBC_tools/releases/tag/v1.1.2 and archived on Zenodo (*83*).

The final step in SV processing was to identify simple/balanced, simple/unbalanced, and complex clusters of SV events based on breakpoint proximity of the SV calls, similar to the recent PCAWG approach (*84*). SVs with both breakpoints within 1kb of another SV in the same sample with opposite strands (+- and -+) were classified as simple/balanced SVs, which include balanced interchromosomal translocations, balanced intrachromosomal translocations, and inversions. SVs with a breakpoint within 50kb of another SV in the same sample regardless of strand were considered clustered/complex SVs consistent with possible chromoplexy. SVs without reciprocal SVs identified were considered simple/unbalanced and represent deletions, tandem duplications, and undetected balanced partner SVs (inversions or translocations). To improve sensitivity to finding SV clusters, SVs that failed post-process filters and were not called by PCAWG snowman or SvABA only were included as potential "links" in the chain. The inclusion of SVs that had failed filters only marginally expanded the list of clustered SVs by less

than 10%. The classification of SVs into simple/balanced, simple/unbalanced, and complex chains was done using a custom matlab script REBC_balanced_inv2_clusters_unfiltered_27Jun2020.m outside of the Terra framework. Code is available at https://github.com/getzlab/REBC_tools/releases/tag/v1.1.2 and archived on Zenodo (*83*).

Chromothripsis and Chromoplexy
Chromothripsis was defined as SV complex clusters with uninterrupted oscillations between two copy number states in at least seven adjacent segments, according to the recent PCAWG approach (*84*). Only one of the 383 PTC tumors was found to have chromothripsis, with the cluster involving chromosomes 11 and 22, which resulted in an *IGF2* overexpression driver.

Chromoplexy events were defined as SV complex clusters with ≥3 DNA breaks involving ≥2 chromosomes that create a loop, similar to the recent PCAWG approach (*84*). Loops were connected if the gap was <500kb or if there was a corresponding SCNA for gaps ≥500kb. Chromoplexy events were manually checked to confirm if the cluster was indeed a loop, except for the chromoplexy events with ≥30 SV calls (n=2 in two different PTC tumors). Chromothripsis and chromoplexy were considered mutually exclusive; the one tumor with chromothripsis was not assessed for chromoplexy.

SCNA Detection and Filtering Pipeline
Copy number detection was performed on the WGS data using the GATK 4.1.4 CNV workflows (**Fig. S16**). The first step was to build a PoN (Terra task 1-CNV_Somatic_Panel), followed by detection of allele copy number alterations (Terra task 2-CNV_Somatic_Pair). Both of these GATK4.1.4 method configurations were based on workflows from the public Terra workspace help-gatk/Somatic-CNVs-GATK4. The PoN consisted of 423 CTB normal samples that showed no sign of Tumor-in-Normal (TiN) contamination. The combination of total copy number based on normalized read coverage and germline heterozygous SNP allele fraction shifts allowed an estimate of the allelic copy number ratio across the genome and to assign allelic copy number ratios to discrete segments. Following the 2-CNV_Somatic_Pair workflow, germline copy number polymorphisms were removed and the allelic copy number information was transformed to AllelicCapSeg (*85*) format using the Terra task Model_Segments_PostProcessing_canonical_gatk414. A preliminary collapsing step combined allelic copy ratio segments that were within the estimated error on the mean for the respective segments, which produced a substantial reduction in noise in the segments while preserving arm-level and focal events. The preliminary collapsing step was implemented in Terra as task MAF_AC_PP_CCF_fit_v3.

A further collapsing step was implemented (available at github.com/hartleys/REBC_SCNA_utils and archived on Zenodo (86)) to group SCNA events of the same type across intervening segments without an SCNA designation (untyped event, see below), which most often occurred when segments had no heterozygous SNPs. For example, a series of DEL-Untyped-DEL segments would count as one DEL compared to DEL-GAIN-DEL segments, which would count as two DELs and one GAIN. Merged events were marked clonal if at least one of the component events was clonal (defined as CCF≥0.75).

For analyses testing the association of radiation exposure with SCNA events, rather than utilize the typical arm-level designation, we separated SNCAs that result from aneuploidy (chromosome level) from those that were likely the result of DNA double-strand breaks (sub-chromosome level). Chromosome level SCNA events were counted when the entire chromosome had only one merged event and that event spanned the entire chromosome. This required the absence of any "non-event" segments. Sub-chromosome level events were SCNA events that did not span the whole chromosome, with either sections of normal copy number or multiple event types.

Despite best efforts to optimize parameters of GATK4.14 CNV detection, one sample suffered from excessive coverage dropout and copy ratio noise using GATK4.1.4 CNV and was dropped from the SCNA radiation exposure association analyses. Only for that sample an alternative CNV pipeline was used that was based on the AllelicCapSeg algorithm (Terra tasks wgs_pip_m1_fragcounter_oxoq_1 and allelic_Capseg_WGS). The output formats of both allelic_Capseg_WGS and Model_Segments_PostProcessing_canonical_gatk414 were equivalent so the downstream copy number analyses (GISTIC2.0 and ABSOLUTE) were the same for all samples or cohorts.

Purity and Ploidy Assessment

ABSOLUTE (*85*) was run on all pairs, however only 20% of the tumors showed sufficient allelic copy number signal to make tumor purity and ploidy estimates based on ABSOLUTE manual review of all tumors. To estimate purity for the remainder of tumors a matlab script (alleleFraction_clonal_hets_Purity_estimate.m, and REBC_consensus_mutations.m available at https://github.com/getzlab/REBC_tools/releases/tag/v1.1.2 and archived on Zenodo (*83*)) was developed to estimate purity based on identifying the somatic clonal allele fraction peak of multiplicity 1 mutations. Briefly, the beta distribution for the variant allele fraction:

$$p(VAF|TALT, TREF)=\beta(VAF, TALT+1, TREF+1)$$

was calculated for each mutation to model the variant allele fraction (VAF) probability distribution for each mutation with TALT alternate allele supporting reads, and TREF reference supporting reads. Beta distributions in bins of 0.002 VAF units for mutations passing "high stringency" filters (eg. Only mutations with no ALT alleles in the normal sample, NALT=0, and excluding regions of copy number alterations) were summed into a combined VAF distribution and the highest peak with a VAF<0.5 was taken as an initial estimate of the clonal VAF. Mutations consistent with this clonal VAF (p-value>0.05) were then selected as the mutations most likely to be clonal and the joint likelihood VAF was constructed across all of these "clonal het" mutations. The VAF distribution defines the clonal VAF confidence interval and the median of the VAF distribution was the estimated clonal VAF value. The tumor purity was then estimated as 2*VAF and the confidence interval of the purity estimate was the 68% (1-sigma) or 95% (2-sigma) width of the 2 x VAF joint likelihood distribution.

Final estimate of purity considered both ABSOLUTE and mutation VAF methods, but in most cases the purity estimate was based on mutation VAFs since relatively few tumors had sufficient copy number variation. A potential limitation of the mutation VAF method was the lack of constraint on tumor ploidy, but this was not a practical limitation because the samples that had

exhibited copy number alternations used the ABSOLUTE algorithm, which did include a ploidy estimate. Only seven tumors had a tumor ploidy estimate inconsistent with 2.0.

For the purposes of most statistical analyses, we excluded samples with tumor purity <20% or with evidence of tumor contamination in the normal tissue (**Fig. S1**). We further excluded two tumors as low purity samples because the fraction of clonal mutations used to predict the purity at the time of final sample eligibility determination was <1% of the total variants (review of the VAF distribution revealed that these outlier variants were inflating the purity estimate).

Variant Clonality (Cancer Cell Fraction) Estimation
SCNA CCFs: The ABSOLUTE algorithm (*85*) included an estimate of the cancer cell fraction (CCF) and alternate allelic copy number for each allelic copy ratio segment, however since the bulk of the tumors did not exhibit sufficient copy number to constrain ABSOLUTE purity and ploidy solutions with corresponding allelic Somatic Copy Number Alterations (aSCNA) and mutation CCFs so a custom matlab script MAF_AC_PP_CCF_fit_v3.m (available at https://github.com/getzlab/REBC_tools/releases/tag/v1.1.2 and archived on Zenodo (*83*)) was implemented as Terra task MAF_AC_PP_CCF_fit_v3. The logic of this task was largely based on the logic described in the ABSOLUTE paper (*85*) with an additional constraint penalizing solution in which the fitted absolute allelic copy number fluctuates slightly above an integer value, leading to a sharp discontinuity in the SCNA CCF. A simplifying assumption in both ABSOLUTE and MAF_AC_PP_CCF_fit_v3 was that each aSCNA segment represents a combination of the WT allele (copy number 1 for each allele in the autosomes), copy number NA on the A allele (minor lower CN allele), and NB on the B (major allele) variant alleles in fraction (CCFA and CCFB) of tumor cells. The basic logic was to fit the allelic copy number (*NA* and *NB* for the minor A and major B alleles) with CCFs (*CCFA* and *CCFB*) to the observed allelic copy ratios:

$$CRA \sim (CCFA*\alpha*NA + (1-CCFA)*\alpha + (1-\alpha))$$
$$CRB \sim (CCFB*\alpha*NB + (1-CCFB)*\alpha + (1-\alpha))$$

for each allelic copy ratio segment, where α is the tumor purity. NA and NB were by definition alternate alleles (not 1 on the autosomes) so segments of normal copy number had CCFs equal to zero, or very close to zero due to the uncertainty in the copy ratio measurement.

Mutation CCF: ABSOLUTE (*85*) included an estimate of the cancer cell fraction (CCF) and multiplicity (m) for each mutation, however as in aSCNA CCF estimation, the bulk of the tumors did not exhibit sufficient copy number, so mutation CCFs and multiplicities were estimated by the custom matlab script MAF_AC_PP_CCF_fit_v3.m (available at https://github.com/getzlab/REBC_tools/releases/tag/v1.1.2 and archived on Zenodo (*83*), Terra task MAF_AC_PP_CCF_fit_v3). The modified aSCNA constraint also helped to constrain mutation CCF and multiplicity for those mutations within problematic SCNA regions. The CCF and multiplicity of a given mutation was fit based on the observed ALT and REF allele counts, the local copy number state (NA, NB, CCFA, CCFB), and tumor purity α:

$$VAF = (CCF*\alpha*m) / TotDNA$$

$$TotDNA = \alpha * (NA*CCFA + NB*CCFB + (1-CCFA) + (1-CCFB)) + (1- \alpha)$$

The multiplicity *m* of a mutation depends on the substrate of allelic copy number (NA and NB) at the site of the mutation, where the mutation may occur on either A or B copy number alleles (unless the allele is a deletion) or occurs in tumor cells that have normal copy number. The likelihood fit was done for each possible copy number substrate and the solution with the highest likelihood was selected. The six possible configurations for a mutation to occur on a copy substrate of NA, CCFA and NB, CCFB were:

1) Mutation on allele A (NA, CCFA) with m=1
2) Mutation on allele B (NB, CCFB) with m=1
3) Mutation on allele A (normal CN, 1-CCFA), m=1
4) Mutation on allele B (normal CN, 1-CCFB), m=1
5) Mutation on allele A (NA, CCFA) with m=NA
6) Mutation on allele B (NB, CCFB) with m=NB

The mutation VAF was calculated for each configuration over the full range of mutation CCFs, and the likelihood was estimated by the binomial pdf using the mutation ALT counts, sequencing depth, and VAF. The maximum likelihood over mutation CCFs and configuration set the final mutation CCF and CCF confidence interval. The posterior likelihood included a small prior (1%) favoring higher CCF solutions was used to break ties between different solutions. Note that the overwhelming bulk of mutations in this cohort occurred in regions without measurable copy number alternations such that configuration 3 (the same as 4 since CCFA=CCFB=0) was the only possible configuration.

SV CCF: Estimating the CCF of SV events was similar to the method used for mutations, except that SVs incur additional complications. The first complication was that each breakpoint could have its own copy number substrate such that the variant allele fractions for the two breakpoints could be different, although the cancer cell fractions for both the breaks must be the same. The second complication was that the observed counts of ALT and REF supporting is more prone to bias against the ALT allele than is the case for mutations.

For each breakpoint, the somatic copy number substrate was determined by matching the side of the break containing the ALT supporting reads to the local copy number segment NA, NB, CCFA, and CCFB. Since SV breakpoints can also be copy number breaks it is important to match the local number segment on the side of the break with the supporting reads. Once the copy number state was found for each breakpoint, the SV CCF and multiplicity for each break was found using the same procedure as for mutations, providing two estimates of the SV CCF with confidence intervals. In some cases, a breakpoint occured in a region without a measured copy number segment (eg. noisy SCNA region or a segment not containing any germline hets used to estimate allelic copy ratios). No breakpoint CCFs were estimated without a corresponding copy number state. The SV CCF distribution was estimated as the average of the breakpoint CCF distributions. The SV CCF was the median of the CCF distribution and the confidence intervals (95% CI and 68% CI) were calculated from the CCF distribution. The SV CCFs were calculated by the Terra task SV_CCF_v3, which was based on the matlab script by the same name (available at https://github.com/getzlab/REBC_tools/releases/tag/v1.1.2 and archived on Zenodo (*83*)).

CCF Clonal and Subclonal Thresholds: For the SSV mutations, clonal variants were defined as those with a CCF hat ≥0.9 in order to generate an ultra-clean clonal set (**Fig. S8**). Subclonal SSV variants were those with a CCF hat <0.6. For both the SV and SCNA variants, clonal variants were defined as those with a CCF hat ≥0.75 with subclonal variants having a CCF hat <0.75.

Cohort-Level Analysis

Mutsig2CV: MutSig2CV performs an unbiased assessment of all somatic mutations, identifying candidate driver genes as those with recurrent mutations occurring significantly more often than expected from the null model or in unexpected patterns (**Fig. S20**) (*87*) (Terra task Mutation_MutSig2CV_hg19_consensus_fix_NALT01_maf). MutSig2CV identified eight genes as significantly mutated with an FDR<0.1: *BRAF*, *NRAS*, *HRAS*, *TG*, *KRAS*, *TSHR*, *CR2*, and *DICER1* (**Fig. S20**).

GISTIC2.0: Significantly recurrent copy number regions were detected using GISTIC2.0 (*88*) (Terra task CopyNumber_Gistic2_hg19_GATK414) for both chromosome arms and focal peaks. GISTIC identified 9 significant arm-level results, 2 significant focal amplifications, and 7 significant focal deletions (**Fig. S19**). Three of the seven recurrent deletion peaks were associated with driver fusions (*RET*, *NTRK3*, and *ALK*), which was interpreted as additional evidence for these fusion partners.

Mutational Signature Analysis

Mutational signature classification was performed on total, clonal, and subclonal single base substitutions (SBS) and small indel (ID) variants separately using SigProfiler (*20, 22*), combining samples from our study with the 42 individuals without known radiation exposure who had available tumor-normal paired WGS data from the TCGA analysis (*10*). Briefly, SBS were classified according to the 6 possible base substitutions (C>A, C>G, C>T, T>A, T>C, T>G, considering the pyrimidine of the mutated bp), plus the flanking 5′ and 3′ bases. Indels were first classified as deletions or insertions. Single base indels were then classified by the homopolymer length (length of the mononucleotide repeat tract in which they occurred; 1, 2, 3, 4, 5, or 6+ for single base deletions; 0, 1, 2, 3, 4, 5+ for single base insertions). Indels >1 bp were then classified by the whether they occurred at repeats or with overlapping microhomology at deletion boundaries, and finally by the indel size. We identified these SBS and ID patterns using SigProfilerMatrixGenerator (version 1.1.0), with modification using presig, version 0.0.1 to identify the single base indels using our untrimmed MAF files as inputs (available at https://github.com/edawson/presig/releases/tag/0.1.0 and archived on Zenodo (*89*)).

We then performed nonnegative matrix factorization-based signature extraction using SigProfilerExtractor version 1.0.3 via the SigProfilerHelper wrapper (available at https://github.com/edawson/SigProfilerHelper and archived on Zenodo (*90*)), performing 1000 iterations to optimally attribute the mutational patterns to one of the known 96 SBS or 83 ID signatures (signature deconvolution) from the Catalogue of Somatic Mutations in Cancer (COSMIC v3, https://cancer.sanger.ac.uk/cosmic/signatures) (*20*) or to identify *de novo* signatures. SBS and ID signature analyses were run on the set of samples from the CTB and TCGA combined to facilitate comparison of results among the study populations (**Fig. S10-S12**). **Table S5** shows the fraction of mutations attributable to each known COSMIC or *de novo*

signature and the correlation amongst different signatures in the full study population. Signature decomposition analyses restricted only to those from the CTB overall, those who were exposed to any radiation, or those with an estimated thyroid radiation dose >200 mGy were highly correlated with those from the combined analysis with the TCGA samples and thus are not presented (data not shown). Results were plotted using tidysig, version 0.0.1 (available at https://github.com/edawson/tidysig/releases/tag/0.0.1 and archived on Zenodo (*91*)), an R package developed to maintain a consistent style among the plots and supporting normalized counts across signatures in the plots.

For further evaluation of the deconvolution SBS signatures, we also utilized SignatureAnalyzer, which has a slightly different approach to nonnegative matrix factorization compared with SigProfiler (*92*). As shown in previous studies (*20*), results from the two approaches were highly correlated and yielded similar results; herein we present data from SigProfiler.

SNP Array Data Processing and Subject Ancestry

In order to understand the underlying population genetic structure of study population, we used genotypes drawn from a study of 7,544 individuals from Europe (*93*), which included countries adjacent to Ukraine in Eastern Europe. Additionally, 157 European individuals from the Human Genome Diversity Project (*94*) also were included from France, Italy, Orkney Islands, and Russia. The total number of individuals by country were Czech Republic, n=902; Denmark, n=137; Finland, n=1935; France, n=300; Germany, n=108; Greece, n=36; Hungary, n=259; Italy, n=139; Norway, n=521; Orkney Islands, n=15; Poland, n=1075; Romania, n=228; Russia, n=1593; Slovakia, n=209; Spain, n=55; Sweden, n=130, and the Netherlands, n=59.

Subject genotypes were cleaned using PLINK 1.90 (https://www.cog-genomics.org/plink/1.9/general_usage#cite) with the following thresholds: SNP-level missingness <2%, Hardy-Weinberg equilibrium exact test P>0.001, and minor allele frequency >0.01. Variants were pruned for linkage disequilibrium with PLINK 1.9 --indep and --indep-pairwise, and heterozygosity outliers were screened at |F|>0.2. Subject ancestry was computed with GRAF (*95*). Variants with informative missingness as computed with PLINK 1.9 --test-missing (permutation $p<0.05$) or --test-mishap ($p<1\times10^{-5}$) were removed. PCA was run using smartpca (from EIGENSOFT v6.1.4) (*96*) with outliers flagged at >6 standard deviations (n=8). For analyses of germline genetic variants, the top 10 principal components were generated for inclusion in multivariable models, excluding these 8 outlier individuals, as well as 3 individuals with estimated East Asian ancestry >10%, and 1 individual in the set of twins.

Germline Mutation Detection and Filtering Pipeline

Germline variant calling from the WGS data was performed using HaplotypeCaller (docker version broadinstitute/gatk:4.0.6.0, Terra task haplotypecaller-gvcf-gatk4), FreeBayes (v1.1.0-46-g8d2b3a0), and Strelka (version 2.8.3). For HaplotypeCaller, the GATK combineGVCFs (v3.8.0) utility was used to joint call all samples together. For FreeBayes and Strelka variants were called individually for each sample. All individual sample-level variant files were left aligned and trimmed, and multiallelic variants were split apart using vArmyKnife (v2.2.167, concordanceCaller utility) and vcftools (v0.1.16). GATK CombineVariants (v3.8.0) was used to create a merged, multi-sample variant file.

Primary identification of genotypes was based on HaplotypeCaller, with the secondary callers (Strelka and/or FreeBayes) used to confirm the existence of each variant. We filtered poor quality data based on caller concordance and hetAB fraction (the ratio of the alternative allele read depth versus the total read depth among heterozygotes). Variants were required to be detected by HaplotypeCaller and Strelka and have hetAB>0.2 at a minimum, as well as fulfilling one of the following: 1) called by all three callers, 2) hetAB>0.3, or 3) <3 observed heterozygotes and hetAB>0.25.

From these filtered germline mutations, candidate gene investigation was assessed for potentially protein damaging variants in genes associated with thyroid cancer predisposition specifically, cancer predisposition more generally, and/or DNA damage response (*97*). Variants were annotated from external variant databases using the SnpSift software library, accessed via vArmyKnife, filtering out those variants that had a frequency of ≥1% in any ancestral population in the Exome Aggregation Consortium (ExAC; excluding TCGA) (*98*), 1000 Genomes Project (*99*), Exome Sequencing Project (ESP; Exome Variant Server, NHLBI GO Exome Sequencing Project (ESP), Seattle, WA; http://evs.gs.washington.edu/EVS/), gnomAD exomes (excluding TCGA) or gnomAD genomes. Variants were filtered if >10% of the CTB sample set had one or more alternative alleles. Variants with set frequencies between 1 and 10% were flagged and manually reviewed by visualization in Integrative Genomics Viewer (IGV). Finally, we identified potentially protein-damaging variants in the genes of interest, defined as either SnpEff (*100*) classic high-impact variants without a ClinVar (*101*) designation of B/LB, or SnpEff moderate- or low-impact variants with a ClinVar designation of P/LP.

SNPs were extracted from the WGS data to construct a polygenic risk score (PRS) from 12 SNPs previously reported to be associated with thyroid cancer (**Table S15**) (*102*). The previously reported meta-analysis ORs range from 1.20 to 1.71 (*102*). The risk allele frequencies in gnomAD non-Finnish Europeans ranged from 3% to 75%, with five risk alleles having ≥45% frequency.

RNA-Based Fusion Detection

mRNA-seq was analyzed with four fusion detection programs: ChimeraScan (*103*), EricScript (*104*), STAR-Fusion (*105*), and MapSplice 2 (*106*). EricsScript and Mapsplice 2 were selected based on previous reviews and reports on accuracy and performance (*107, 108*). Potential fusions were ranked and scored by consensus detection and the number of supporting reads. A fusion score of 4.0 would indicate that the fusion was the top-ranked fusion for all four programs. For lower values, multiple scenarios could result in the same score. For a fusion score of 3.0, the fusion could be the top-ranked fusion in three callers but not detected (or ranked low) by the fourth caller (1+1+1+0) or could have been the top-ranked fusion in two callers and the median ranked fusion in the other two callers (1+1+0.5+0.5). Similarly, a score of 2.0 could indicate that a fusion was the top-ranked fusions for two programs and not detected (or ranked low) for the other two programs (1+1+0+0) or that the fusion was the median ranked fusion for all four programs (0.5+0.5+0.5+0.5). Code for RNA fusion calling is available at https://github.com/NCI-CGR/ChernobylThyroidCancer-RNAFusionCalling and archived on Zenodo (*109*).

RNA-Based Mutation Detection

mRNA-seq was analyzed with VarDict to identify SSVs (*110*). Variant processing was carried out with vArmyKnife (v2.2.305). Variants were left aligned and trimmed and annotation was performed using SnpEff v4.3t. Code for RNA variant calling is available at https://github.com/NCI-CGR/ChernobylThyroidCancer-RNAVariantCalling and archived on Zenodo (*111*).

mRNA, miRNA, and Methylation Clustering Analyses

We performed unsupervised consensus clustering using ConsensusClusterPlus. Input data included the variance stabilizing transformation (vst) expression of the 1000 most variably expressed genes for mRNA analysis, the vst expression of the 100 most variably expressed miRNAs for miRNA analysis, and the normalized beta value of 3000 most variably methylated CpG islands for methylation analyses. Code for clustering analyses is available at https://github.com/NCI-CGR/ChernobylThyroidCancer-Clustering and archived on Zenodo (*112*). Code for detection of differentially methylated cpg islands is available at https://github.com/NCI-CGR/ChernobylThyroidCancer-Methylation and archived on Zenodo (*113*).

The appropriate cluster number (k) was determined by identifying the largest cluster with a delta area value >0.3. Because PTC formed a distinctive cluster from non-tumor thyroid tissue in initial mRNA clustering analyses including both sample types (**Fig. S21**), subsequent clustering analyses for mRNA, miRNA, and methylation was restricted to PTC samples only (**Fig. S22-S23**).

Signaling and Thyroid Differentiation Scores

Based on the TCGA analysis (*10*), we constructed three scores to reflect transcriptional patterns related to key signaling and thyroid differentiation pathways (**Fig. S24; Table S12**). Since nearly all PTC oncogenic drivers are members of the MAPK pathway, we constructed a score to distinguish the transcriptional patterns of tumors with the two most common activating point mutations, $BRAF^{V600E}$ and *RAS* ($BRAF^{V600E}$-*RAS* score [BRS]). We constructed the BRS score using mRNA, miRNA, and methylation data. Based on mRNA data, the 100 significantly differentially expressed genes between $BRAF^{V600E}$ and *RAS* tumor-normal paired samples were determined, based on a DESeq2 q-value (adjusted p-value (*114*)) ≤0.01 and fold change ≥2. The variance stabilizing transformed (vst) expression of these 100 genes was used to quantify the degree to which each tumor's mRNA profile resembled that of either $BRAF^{V600E}$ or *RAS*-mutated PTC, as described previously (*10*). A miRNA BRS was constructed, based on 77 miRNAs significantly differentially expressed between $BRAF^{V600E}$ and *RAS* tumor-normal paired samples (DESeq2 q-value≤0.05 and fold change ≥1.5) in our study, and a methylation BRS, based on the normalized beta value of 1000 significantly differential methylated cpg islands between $BRAF^{V600E}$ and *RAS* PTC samples, as determined by the overlap of results from two tools: minfi (*115*) and ChAMP (*116*) (q-value≤0.01 and fold change ≥2.0). To confirm the validity of the mRNA BRS score generated using our internal gene expression data, we also reconstructed the mRNA BRS score using data for 70 of the 71 genes differentially expressed between $BRAF^{V600E}$ or *RAS*-mutated PTC in the TCGA analysis (*10*) (excluding *ANXA2P2*, a pseudogene not included in our GRCh38 gene annotation file). **Table S12** shows the high correlation (Pearson

correlation, r=0.98) between the internal- and TCGA-based mRNA BRS scores, as well as among the mRNA, miRNA, and methylation BRS (r=0.78-0.92).

An ERK-activity score was constructed to estimate the expression profiles for genes that were shown in *BRAF*^{V600E}-mutated melanoma cell lines to be responsive to MEK inhibition (*117*), as per the previous TCGA analysis (*10*). Briefly, we compared the vst expression of 52 genes in tumors, standardized based on the expression of each gene in *BRAF*^{V600E} -like (BRS<0) or *RAS*-like (BRS>0) tumors. Finally, we constructed a thyroid differentiation score (TDS), also according to the previous TCGA analysis (*10*), whereby we calculated the mean fold change in vst expression level across 16 thyroid function genes. Code for generating all scores is available at https://github.com/NCI-CGR/ChernobylThyroidCancer-Scores and archived on Zenodo (*118*).

RNA-Seq Differential Expression and Gene Set Enrichment Analysis
We conducted exploratory analyses evaluating whether radiation dose was related to differential expression of specific genes and gene sets, following the approach used by PCAWG (*119*). Briefly, for analyses of individual genes, normalization factors for gene-level read-pair counts (generated as described above) were calculated using the "UQCT" method, which takes the 75 percentile of the counts for each sample, excluding zero-count genes. The raw counts were increased by 1 (to eliminate log-0 errors), divided by the normalization factor, and then $\log_2$-transformed. These log-normalized counts were used to fit a standard multivariable linear regression, as described below in the *Statistical Analysis*, with additional adjustment for experiment batch (phase) in addition to age at PTC and sex.

Patterns of RNA-Seq expression in previously identified pathways and gene sets were extracted from the Molecular Signatures Database (MSigDB v7.1; https://www.gsea-msigdb.org/gsea/msigdb) (*31*). All gene sets related to hallmark biological processes, thyroid, radiation, and the genes from our germline analyses were included, resulting in 3,213 gene sets. GSVA, an R package that performs "Gene Set Variation Analysis," was used to collapse expression information across gene sets. This tool took log-normalized counts for each gene and set of genes, outputting a single value for each geneset/sample combination (specifically the Kolmogorov-Smirnov-like rank statistic) (*120*). Linear regression analyses were performed on these statistics, as described below.

Methylation Age
Exploratory analyses were conducted to evaluate whether radiation dose was associated with epigenetic age acceleration, estimated from tumor methylation profiles using two well-established approaches (*38, 39*). Briefly, we regressed epigenetic age against chronological age in the non-tumor thyroid tissue and then compared the residuals from this predicted age in the PTC tissue. These residuals were utilized as outcomes in linear regression models described below.

PTC Driver Identification
Candidate mutation and fusion drivers were identified in the 440 PTC tumors by interrogating both the WGS and mRNA-seq with a comprehensive candidate driver gene list. For the simple somatic variants or mutation drivers, candidates included genes significantly mutated in the MutSig2CV analysis of 383 WGS tumors (**Fig. S20**), genes previously reported as

mutation drivers in the TCGA analysis (*10*), and genes reported in the COSMIC Cancer Gene Census (CGC) v90 (https://cancer.sanger.ac.uk/census) with frameshift, missense, nonsense, or splice site mutation types. For the SV or fusion drivers, candidates included previously identified fusion drivers or focally deleted genes (*BRAF* and *PTEN*) in the TCGA analysis (*10*) and genes reported as oncogenes or tumor suppressors in the COSMIC CGC with fusion indicated for either the "role in cancer" or "mutation type." Fusions involving *HRAS*, *KRAS*, and *NRAS* were included because of the substantial contribution of RAS-activating mutations in thyroid cancer.

For mutation drivers, we identified somatic protein altering variants that had a corresponding match in the COSMIC CGC v90 database; additionally, for *CR2*, which did not have a COSMIC CGC v90 entry, we considered the variants identified by MutSig2CV (described above). Mutation identification was carried out first in the WGS using the final somatic variant calls, which have inherent matched normal sample, and PoN filters (see *Mutation Detection, Merging, and Filtering Pipeline* section above). Since mRNA-seq variant calling is not as robust as WGS calling, additional rules were applied to exclude variants meeting any of the following criteria: 1) evidence in a PoN comparison set, created using the 392 high-quality non-tumor thyroid tissue samples that had a corresponding PTC mRNA-seq sample; 2) alternate allele read depth $\leq$10; 3) splicing variants; or 4) variants in genes not identified as drivers in the WGS data. Recurrent *BRAF* and *RAS* variants in the WGS dataset were force called to avoid the problem of recurrent drivers being present in the non-tumor thyroid tissue samples. For both WGS and mRNA-seq, we also manually reviewed doublet and indel mutations near *BRAF* p.V600 because of the strong supporting evidence for this locus in driving PTC. Two indels near *BRAF* p.V600 were identified and determined to be mutation drivers: one resulted in p.600_601VK>E and had a direct COSMIC v90 database match, and other resulted in the insertion of six amino acids and was similar to another COSMIC v90 database entry. Because annotated databases are often SNV-biased and do not always match on doublets appropriately, we interrogated all nine WGS doublet calls individually and determined that three were drivers because the corresponding protein changes had a COSMIC v90 database match. Finally, *TG* variants were excluded as driver mutations because most of the *TG* variants were noncoding (1:17 coding:noncoding in *TG* versus 10:1 in *BRAF*), which is a hallmark of hypermutation due to lineage-specific overexpression (*121*).

For fusion drivers, we queried the WGS SV and mRNA-seq gene fusion calls to identify events that occurred in both the WGS (final SV calls) and mRNA-seq (RNA fusion score $\geq$2). Events occurring in only WGS or mRNA-seq utilized more stringent criteria, requiring SV calls to have 1) tumor alt reads $\geq$10, 2) normal alt reads=0, 3) number of SV callers (dRanger + max(pcawg_snowman, SvABA) + Manta $\geq$ 2, and 4) breakpointer type contains fusion or deletion and is not antisense, transcript fusion or out of frame protein fusion. mRNA-seq-only calls required RNA fusion score $\geq$3. Our approach allowed for identification of high-confidence fusion drivers in the set of tumors with both WGS and mRNA-seq (n=374) as well as those with only WGS (n=9) or only mRNA-seq (n=57). The approach ensured identification of fusion drivers resulting from a complex set of multiple SV events, in which mRNA-seq identified the final gene fusion product but the WGS identified multiple intermediate steps, for example, *NCOA4-RET* versus *NCOA4-SHOC2*, and *SHOC2-RET*. After the fact, we performed an unbiased assessment of the confirmed SVs utilizing the stringent WGS fusion criteria without

restricting the analysis to the fusion candidate gene list and did not identify additional recurrent fusion driver candidates.

For tumors without an identified driver based on the above approach, we utilized PTC mRNA expression (clustering, overexpression outliers) and SCNAs to identify candidate drivers. Unsupervised mRNA clustering of tumors identified 5 clusters (as described above), which were correlated with the already-identified drivers (**Table S11**). Cluster 5 included two tumors, one of which had both a frameshift and a stop-gained *TSC2* variant suggestive of biallelic loss of the tumor suppressor *TSC2*, which forms a complex with *TSC1*. Further review of the other tumor revealed a stop-gained germline *TSC1* variant with an SCNA loss over the *TSC1* coding region, suggesting biallelic loss of *TSC1* as the candidate driver. For the two tumors in cluster 3, further review of high impact (for example, frameshift and stop-gained) somatic and germline variants revealed biallelic loss of *APC* as the candidate driver, with one tumor having a somatic *APC* frameshift variant (no COSMIC v90 database match) and an SCNA loss over the *APC* coding region, and other having a germline stop-gained pathogenic variant (based on ClinVar) and an SCNA over *APC*.

THADA-fusions are known as drivers in thyroid cancer (*10*) and have been found to result in overexpression of *IGF2BP3* (*122*). Three tumors with *THADA* fusions and corresponding *IGF2BP3* overexpression (vst expression >6 standard deviations from the mean) were identified with the rules above. We designated *IGF2B3* as the candidate driver for the one additional tumor with similar overexpression. Overexpression of *IGF2BP3* leads to an increase in IGF2 protein levels and activation of the PI3K and MAPK pathways (*122*), thus we also checked for *IGF2* overexpression outliers. We identified two tumors (one with mRNA-seq only, one with multiple SVs near *IGF2*) without a candidate driver based on the rules above with *IGF2* overexpression, which we designated as the candidate driver.

All candidate drivers are listed in **Table S7**. For **Fig. 1**, driver genes were displayed for oncogenes if they were recurrent within the dataset and for tumor suppressor genes if they were recurrent and had evidence for biallelic loss. For all driver analyses, final driver designations were made according to the following rules: 1) if individual has only one candidate driver that is recurrent (observed in at least one other sample); or 2) if >1 recurrent candidate driver, all drivers with ≥ 5 recurrences were outputted and further evaluated (n=3 tumors). For the tumor with a *PPARG* fusion and *NRAS* mutation, the *NRAS* mutation was designated as the final driver because it had higher CCF, whereas the CCF of the *PPARG* fusion was low and the tumor did not cluster with the other 13 *PPARG* fusions in the PTC mRNA cluster analysis. For the tumor with a *BRAF* p.V600E and *THSR* with similar CCF, the *BRAF* mutation was designated as the final driver due to its overwhelming recurrence rate. For the tumor with a non-V600E *BRAF* and *KRAS* mutations with similar CCFs, no final driver was designated.

For the 351 individuals that had both a high purity (>20% purity) WGS and mRNA PTC sample, designated mutation driver concordance was 100% (n=215 mutations), and designated fusion driver concordance was 100% (n=130 fusions), after accounting for the final fusion being identified in mRNA-seq and fusion intermediates in WGS, for example, *NCOA4-RET* versus *NCOA4-SHOC2*, and *SHOC2-RET*.

Analyses by the driver pathway combined drivers by biological function for those identified in small numbers of samples, specifically other RTK (receptor tyrosine kinase) fusions (*ALK*, *LTK*, *NTRK1*, and *NTRK3* fusions), *RAS* mutations (*HRAS*, *KRAS* and *NRAS* mutations), and *IGF2* and *IGF2BP3* overexpression drivers. Finally, the small number of other mutation drivers (*APC*, *DICER1*, *NFE2L2*, *TSC1*, and *TSC2*) were combined for model stability.

Identification of DNA Repair Mechanisms for SVs and Small Deletions
DNA double-strand breaks—the most important type of radiation-related DNA damage—can be repaired by various mechanisms, including two key types of end-joining repair: non-homologous end-joining (NHEJ) and alternative end-joining (alt-EJ or theta-mediated end-joining [TMEJ]) (*33-35*). We performed a series of analyses to classify the DNA repair mechanisms that generated the SVs and small indels in our dataset.

SV confirmation was based on a series of steps. Among individuals with a WGS sample (n=383), manual review in IGV was conducted for 145/150 designated fusion drivers (excluding four drivers without an available SV call and one where the breakpoint could not be evaluated due to the repetitive nature of the local sequence). During manual review, each fusion was categorized by the number of DNA breaks (2 [simple] versus >2 or local sequence bridge repair [complex]); SV type (deletion, inversion, interchromosomal translocation, intrachromosomal translocation, or complex); balanced (<1kb gained/lost at breakpoint) versus unbalanced (≥1kb gained/lost at breakpoint); end-joining (<20 bp for both breakpoints) versus non-end-joining/other (≥20 bp at one breakpoint); and microhomology at the breakpoint, which was determined utilizing blast within the UCSC genome browser (http://www.genome.ucsc.edu/). Agreement was acceptable between the automated and manual calls for all metrics except microhomology (22/226 or 9.7% discordant breakpoints) and accordingly, microhomology was not included in the final categorization. Notably, the review of fusion drivers indicated that certain variant groups (simple/unbalanced SVs and complex SVs from individuals with multiple complex clusters) were most likely to be false positives, thus all SVs in these categories were manually checked in IGV. The discordant events and false positives were corrected or removed to generate the final SV dataset (**Table S6**).

Following SV confirmation, SVs were first categorized as simple and balanced and end-joining (simple/balanced/end-joining) versus complex, unbalanced, or non-end-joining (complex/unbalanced/other). Simple/balanced/end-joining SV events with <4 bp of intervening loss/gain at both breakpoints, representing enrichment for NHEJ, were then separated from SV events with 4-19 bp of intervening loss/gain for at least one breakpoint, representing both NHEJ and alt-EJ/TMEJ repair mechanisms.

For small deletions called as indels (**Fig. S29**), direct counting of NHEJ and alt-EJ/TMEJ features within the 83 ID mutational signature classifications was performed to circumvent potential misattribution of the indels to ID6 and ID8, both of which have been ascribed to end-joining repair. In contrast to SVs, end-joining repair is most enriched when assessing deletions ≥5 bp due to noise from other small indel generating mechanisms with deletions <5 bp in length. The patterns consistent with end-joining repair were defined as deletions ≥5 bp that are not within repeats and have any amount of microhomology (≥0 bp of microhomology.) The amount of microhomology was utilized to further group the deletions by events enriched for NHEJ (0-1

bp microhomology at the deletion boundary) and those that are a mix of NHEJ and alt-EJ/TMEJ mechanisms (≥2 bp of microhomology at the deletion boundary). Locally templated insertion events (TINS), which are characteristic only of TMEJ repair, were identified as described previously (*34*). Briefly, small insertions ≥3 bp were interrogated for whether either the direct or reverse complement sequence was present within 50 bp either upstream or downstream of the indel breakpoint.

Identification of Genomic Locus-Based Attributes for Small Insertions and Deletions
Following the approach described previously (*8*), we annotated small insertions and deletions according to a series of genomic locus-based attributes:
Continuous metrics:

- Distance from the centromere ($\log_{10}$)
- Distance from the nearest telomere ($\log_{10}$)
- Fraction of G/C bases (flanking 100 bp in either direction)
- Trinucleotide complexity (flanking 50 bp in either direction; the sum of the squares of the occurrence rate for each possible trinucleotide combination. Higher values indicate lower complexity).
- Chromatin state (selecting one of the 25 chromatin states [heterochromatin] from ROADMAP and taking consensus across all 127 cell types because no data specific to the thyroid were available)
- Replication timing (average of the wavelet-smoothed replication timing signals in 1 kb bins across the genome, in three samples: NHEK [normal skin], GM12878 [normal blood], and IMR90 [normal lung]
- LADs (Tig3ET normal human embryonic lung fibroblasts)

Dichotomous metrics indicating whether the variant is within 100 bp of the given event:

- Genes (known protein coding gene found in GENCODE)
- CpG Islands (known CpG island)
- Direct Repeats
- G-quadruplexes
- Cruciform inverted repeat
- Triplex mirror repeat
- Short tandem repeat
- z-DNA motif
- ALU repeats
- MIR repeats
- L1 repeats
- L2 repeats
- LTR repeats
- DNA repeats
- Simple repeats

To compare the distribution of the small insertions and deletions observed in our study compared with a random background distribution, we randomly selected 100,000 loci from across the genome and annotated them using identical methods.

Statistical Analysis

Multivariable regression models were employed to assess the relationship between radiation dose and PTC molecular characteristics. Unless otherwise specified (**Table S4**), models were mutually adjusted for sex, age at PTC (continuous), and radiation dose (continuous, with doses >1000 mGy truncated [assigned the value of 1000 mGy] to reduce their influence on the estimated model coefficients) (**Fig. S4**). Two-sided P-values were generated using likelihood ratio tests, comparing model fit with and without the variable of interest.

The regression model type depended on the distribution of the molecular characteristic and is specified for each characteristic in the supplementary tables that present model results (**Table S4, Table S18, Table S20-S22**). For continuous characteristics, such as the number of deletions, we utilized linear regression to estimate the expected value (E[Y]) as:

$$E[Y] = \beta_0 + \beta_1 * Dose + \beta_2 * Age_{PTC} + \beta_3 * Sex$$

where β_1 represented the change in the value of the molecular characteristic per unit dose, which was expressed per 100 mGy. Normality of the residuals was confirmed visually. Analyses were conducted using SAS version 9.4 (Cary, NC) and R (Foundation for Statistical Computing, Vienna, Austria).

For molecular characteristics that were dichotomous, such as presence or absence of chromoplexy, we utilized logistic regression to estimate the odds ratio (OR; the odds of the characteristic being present) as:

$$OR=\exp(\alpha_1 * Age_{PTC} + \alpha_2 * Sex)(1 + \beta_1 * Dose)$$

where β_1 represented the excess OR (EOR) per 100 mGy so that the effect of dose is linear (rather than log-linear), the standard approach in radiation epidemiology (*123*). For molecular characteristics with discrete counts over a limited range where the residuals were not normally distributed in linear regression models, such as the number of SVs, we utilized proportional odds models, collapsing the highest values into a maximum category that included at least 5% of the total study population. For "n" categories of each characteristic with this distribution, we created n-1 replications of the dataset; within each replication (i), we defined a new outcome with a value of 1 if the original outcome was $\geq$i or 0 if <i (missing values retained a missing value). We then included in the logistic regression model the index as a categorical variable in the log-linear term (along with other covariates such as sex and age at PTC), while modeling dose in the linear term, as in the standard dichotomous model described above. This proportional odds model assumed that the EOR/100 mGy is consistent across the categories of the molecular characteristic outcome strata. We confirmed the validity of this assumption visually for radiation-associated characteristics (as defined below and shown in **Table S20**) by fitting a polytomous model. Polytomous models were utilized for molecular characteristics without inherent ordering, such as mRNA clusters or driver gene, whereby we included the index term as a categorical variable crossed with every other term in the model (index*age at PTC and index*sex in the log-linear term, and index*dose in the linear term), thereby fitting a separate EOR/100 mGy for each level of the characteristic relative to the referent category. Logistic,

proportional odds, and polytomous regression analyses were conducted using the GMBO module of Epicure, version 2.0 (Risk Sciences International, Ottawa, Canada) (*124*).

Our primary analyses included 68 PTC molecular characteristics derived from a comprehensive landscape analysis (**Fig. 1, Table S4**). We defined radiation dose-associated molecular characteristics based on $P<7.4\times10^{-4}$, which represents a Bonferroni correction for multiple testing ($\alpha=0.05/68$). For associated variables, we conducted analyses of more specific molecular characteristics as well as stratifying the study population into tertiles by age at PTC, age at exposure, and time since exposure (latency) because these factors influence radiation-related thyroid cancer risk (**Table S1**) (*17*). We tested for heterogeneity (modification) of the radiation dose effect on the molecular characteristic across these factors using continuous variables, comparing the model fit with and without an interaction term (Dose*age at PTC, Dose*age at exposure, or Dose*latency) using likelihood ratio tests. The models evaluating modification of the radiation dose effect by age at exposure and latency also included main effects of these variables, as follows:

Linear regression:

Modification by age at PTC:

$$E[Y] = \beta_0 + \beta_1*Dose + \beta_2*Age_{PTC} + \beta_3*Sex + \beta_4*Dose*Age_{PTC}$$

Modification by age at exposure or latency (Age/Lat):

$$E[Y] = \beta_0 + \beta_1*Dose + \beta_2*Age_{PTC} + \beta_3*Sex + \beta_4*(Age/Lat) + \beta_5*Dose*(Age/Lat)$$

Logistic and proportional odds regression:

Modification by age at PTC:

$$OR=\exp(\alpha_1*Age_{PTC} + \alpha_2*Sex)(1 + [\beta_1*Dose \times \exp(\beta_2*Age_{PTC})]$$

Modification by age at exposure or latency (Age/Lat):

$$OR=\exp(\alpha_1*Age_{PTC} + \alpha_2*Sex + \alpha_3*Age/Lat)(1 + [\beta_1*Dose \times \exp(\beta_2*Age/Lat)])$$

We conducted sensitivity analyses to assess whether the results were consistent when we restricted the population to individuals with lower dose exposure (1-<500 mGy, resulting in n=326 with mean estimated dose=110 mGy), a critical question in radiation epidemiology (*18, 19*). Finally, we evaluated whether there was a statistically significant departure from a linear dose model by fitting linear quadratic (Dose squared) and linear exponential [exp(Dose)] models, comparing the fit of these models to that of a linear model using likelihood ratio tests, as follows:

Linear regression:

Linear quadratic:

$$E[Y] = \beta_0 + \beta_1*Dose + \beta_2*Age_{PTC} + \beta_3*Sex + \beta_4*Dose^2$$

Linear-exponential:

$$E[Y] = \beta_0 + \beta_1*Dose + \beta_2*Age_{PTC} + \beta_3*Sex + \beta_4*\exp(Dose)$$

Logistic and proportional odds regression:

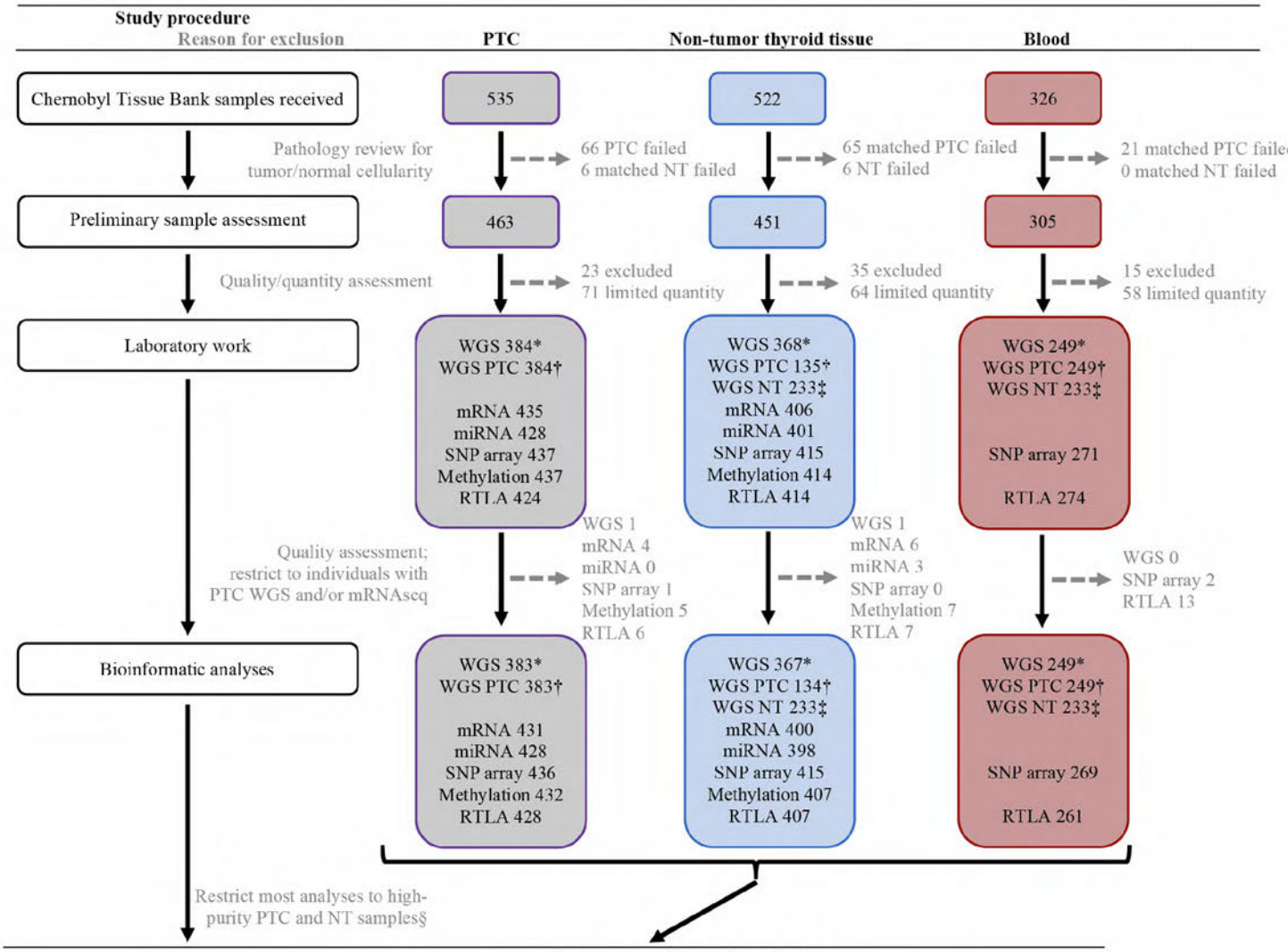
Linear quadratic:

$$OR=\exp(\alpha_1*Age_{PTC} + \alpha_2*Sex)(1 + \beta_1*Dose + \beta_2*Dose^2)$$

Linear-exponential:

$$OR=\exp(\alpha_1*Age_{PTC} + \alpha_2*Sex)(1 + [\beta_1*Dose \times \exp(\beta_2*Dose)])$$

For the analyses of genomic locus-based attributes for small insertions and deletions, we conducted two analyses. First, we stratified the study population by ^{131}I-exposure category (unexposed and 1-99, 100-199, 200-499, and ≥500 mGy) and performed dichotomous logistic regression, modeling the observed versus background locus as the response variable and all genomic characteristics as independent variables. Predicted values for each of the 100,000 randomly selected loci across the genome were calculated using the results of each logistic regression, representing the estimated variant density at each locus based on the linear predictors (**Fig. S31**). Second, to test for the effect of radiation dose, we conducted multivariable linear regression models with dose as the response variable and age at surgery and all genomic characteristics as independent variables.



	Data source for each analysis						
Statistical analyses	WGS	mRNA-seq	miRNA-seq	SNP array	Methylation	RTL	n
PTC driver±	X	X					440
Mutations & mutational patterns	X						356
Structural variants	X						356
SCNAs	X						355
PTC mRNA expression patterns		X					409
PTC miRNA expression patterns			X				405
PTC methylation patterns					X		410
Relative telomere length PTC						X	406
Relative telomere length NT						X	399
Relative telomere length NB						X	261
Germline variation	X						383
Population substructure±				X			440
Non-tumor thyroid tissue	X						218

Fig. S1. Schematic of study procedures and sample sizes for laboratory work and statistical analyses.
Gray font indicates samples for exclusion. Reasons for exclusion and thresholds for exclusion metrics are provided in the methods.
Abbreviations: normal blood (NB), non-tumor thyroid tissue (NT), papillary thyroid carcinoma (PTC), relative telomere length (RTL).
* WGS: total count of WGS for that tissue type.
† WGS PTC: count of that tissue type utilized for analyses of PTC-matched normal tissue pairs.
‡ WGS NT: count of that tissue type utilized for analyses of NT-matched blood pairs.
§ Most statistical analyses were restricted to high purity samples, defined as those with tumor purity >20% and no evidence of tumor contamination in the normal tissue.
± Analyses that include all individuals with available data (not restricted to high purity samples).

1

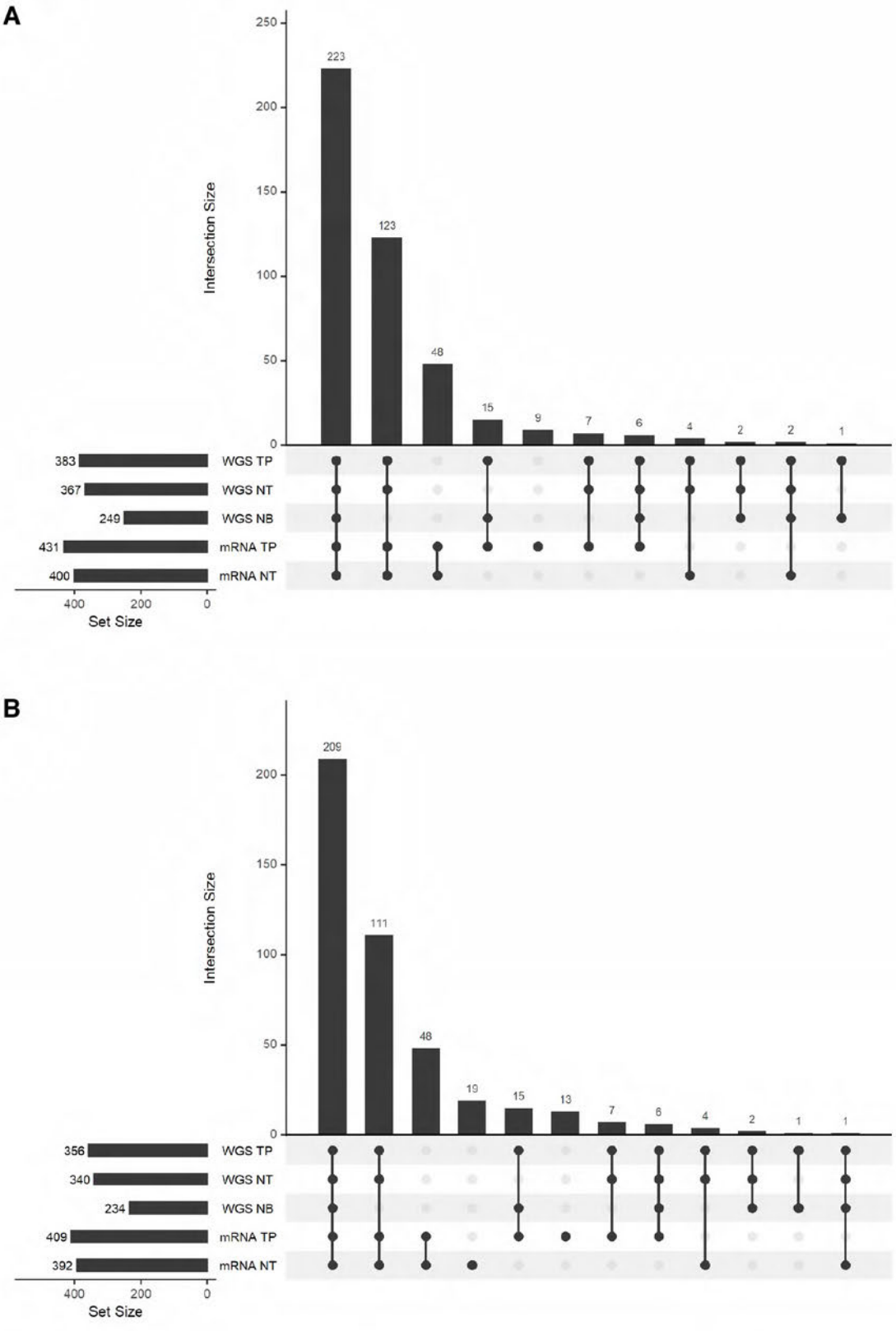
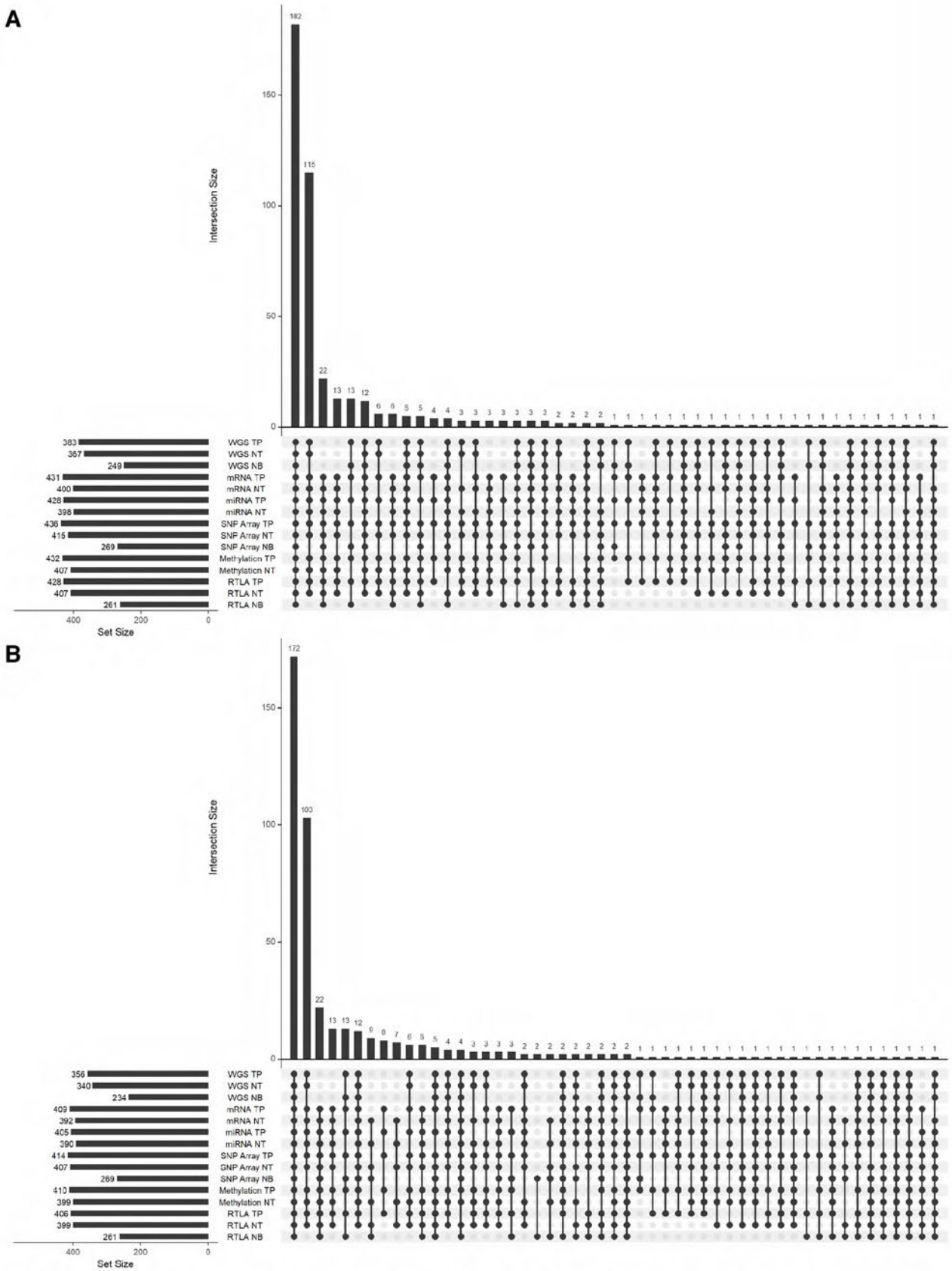


Fig. S2. Distribution of samples passing quality control metrics for WGS and/or mRNAseq.
(**A**) All samples. (**B**) Restricted to high purity samples (tumor purity >20% and no evidence of tumor contamination in the normal tissuc).

2


A
Intersection Size
182
115
22
13 13 12
6 6 5 5 4 4 3 3 3 3 3 3 3 2 2 2 2 1 1 1

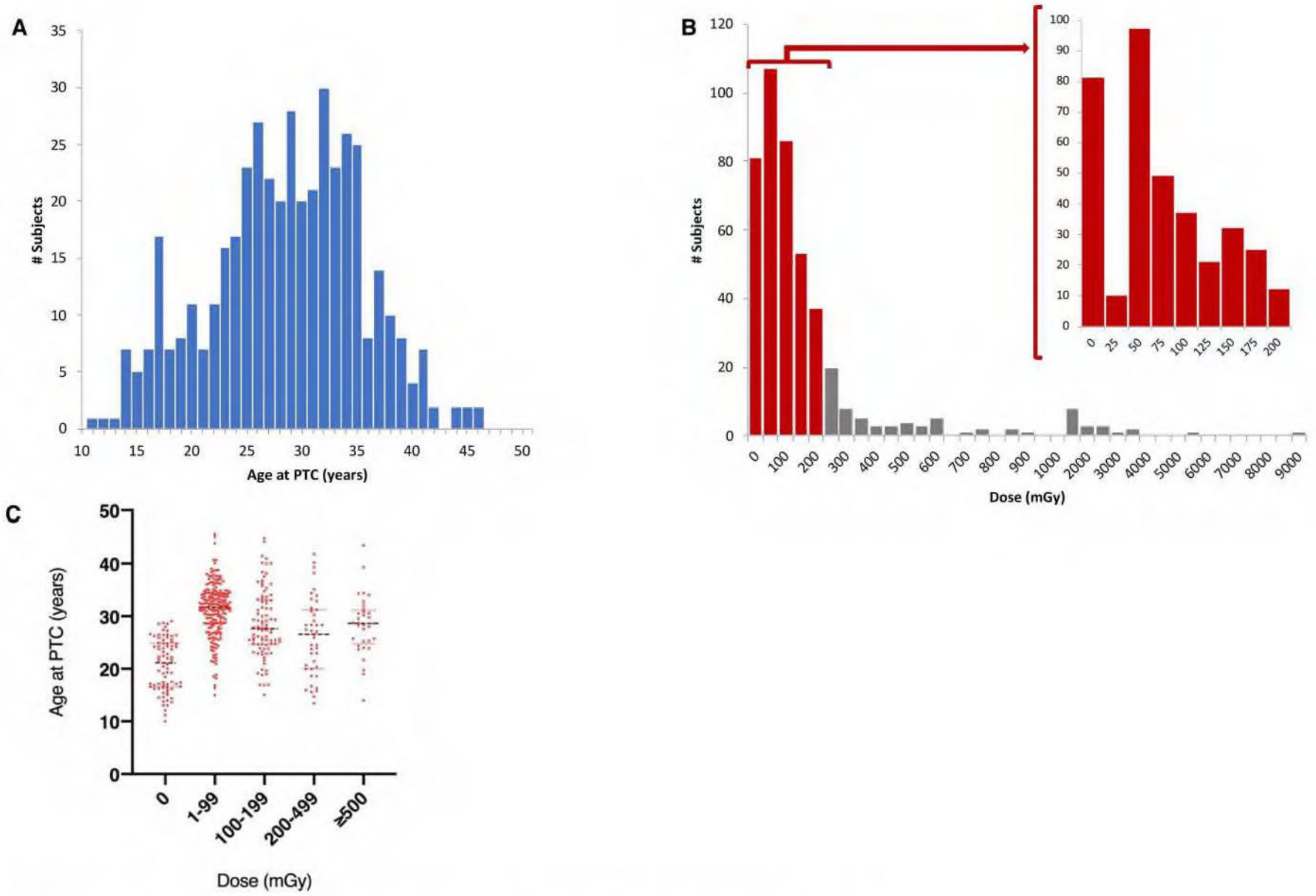


Fig. S4. Detailed distributions of age at PTC diagnosis and radiation dose from ^{131}I exposure.
(**A**) Age at PTC diagnosis. (**B**) Radiation dose from ^{131}I exposure, with an inset panel for doses <200 mGy because this dose range accounts for the majority of our study population. (**C**) Joint distribution of age at PTC and radiation dose to demonstrate slight differences in the age distribution among dose groups.

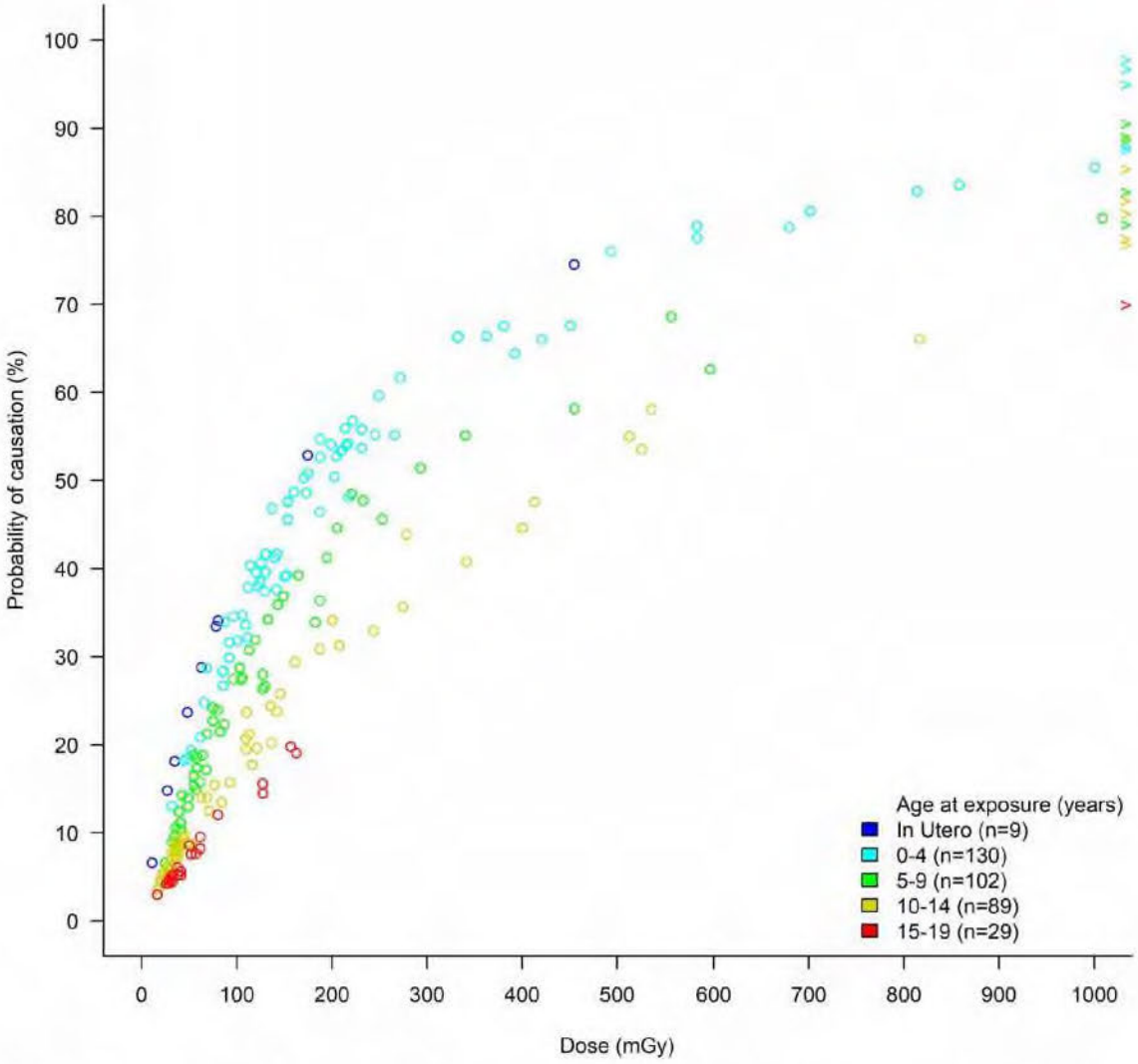


Fig. S5. Relationship between radiation dose and the probability of causation, by age at ^{131}I exposure, for the 440 individuals in our study population.

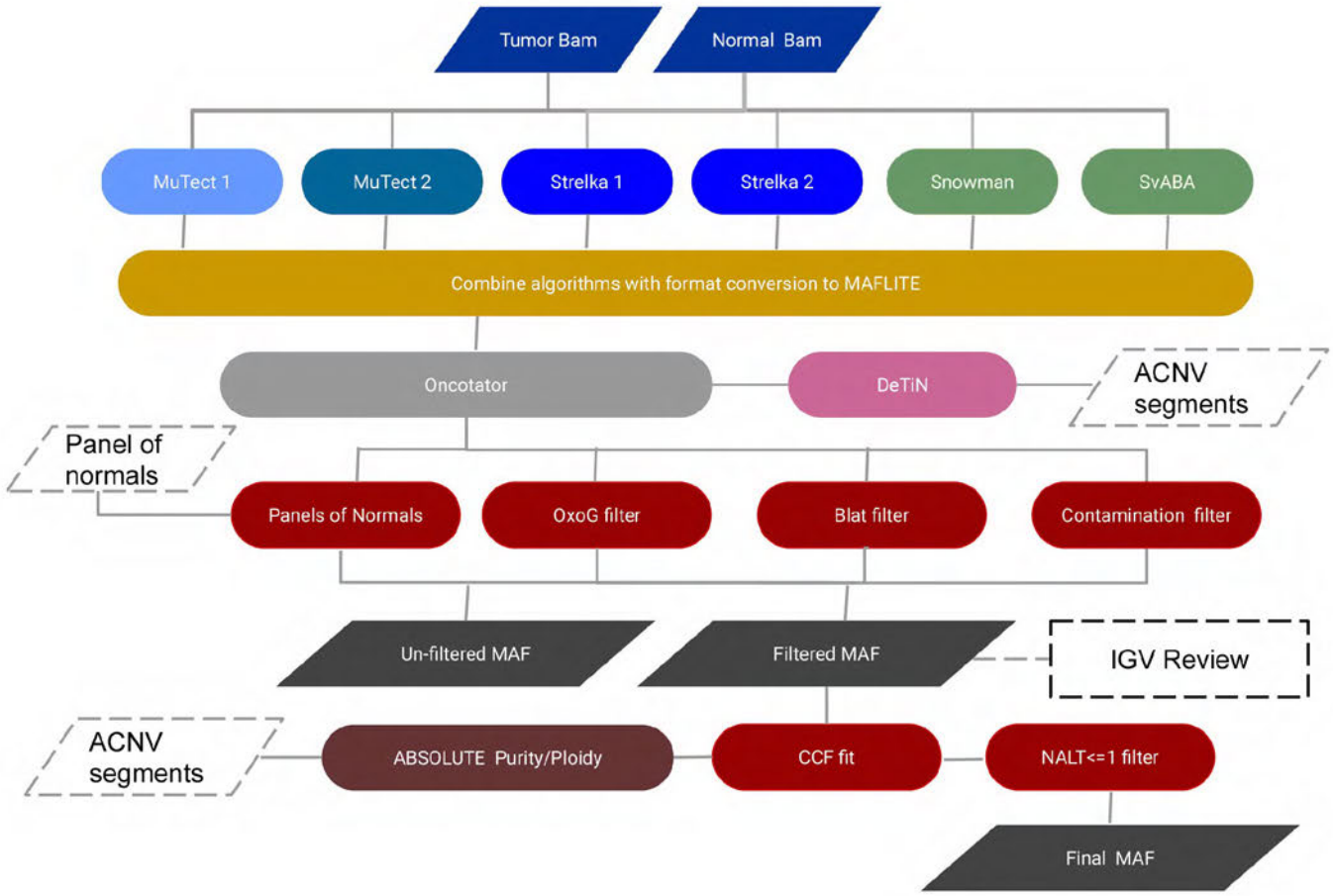


Fig. S6. Mutation analysis pipeline.

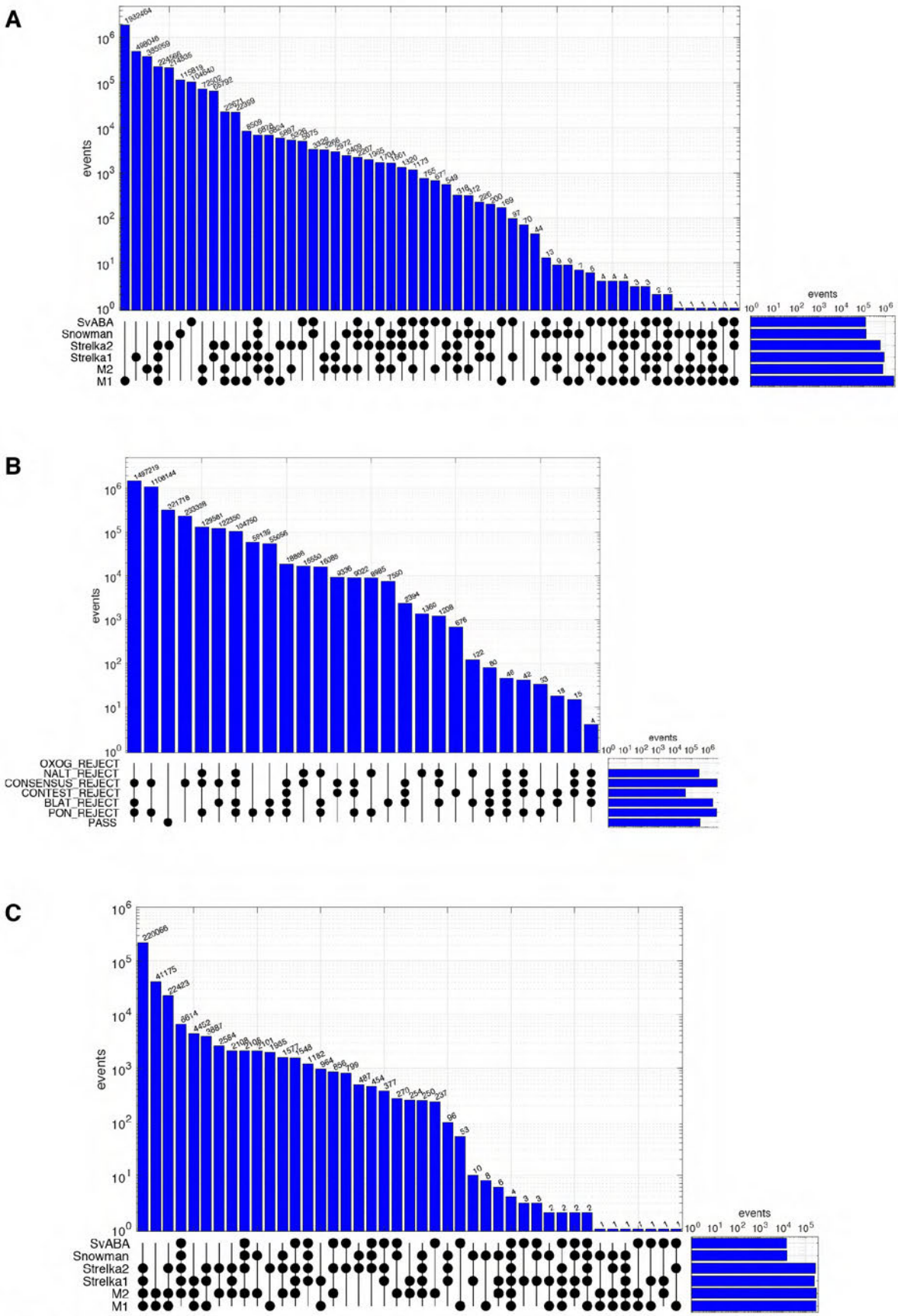


Fig. S7. Distribution of mutation filters for PTC samples.
(**A**) Pre-filtered calls. (**B**) Filtered calls. (**C**) Final mutational call algorithm.

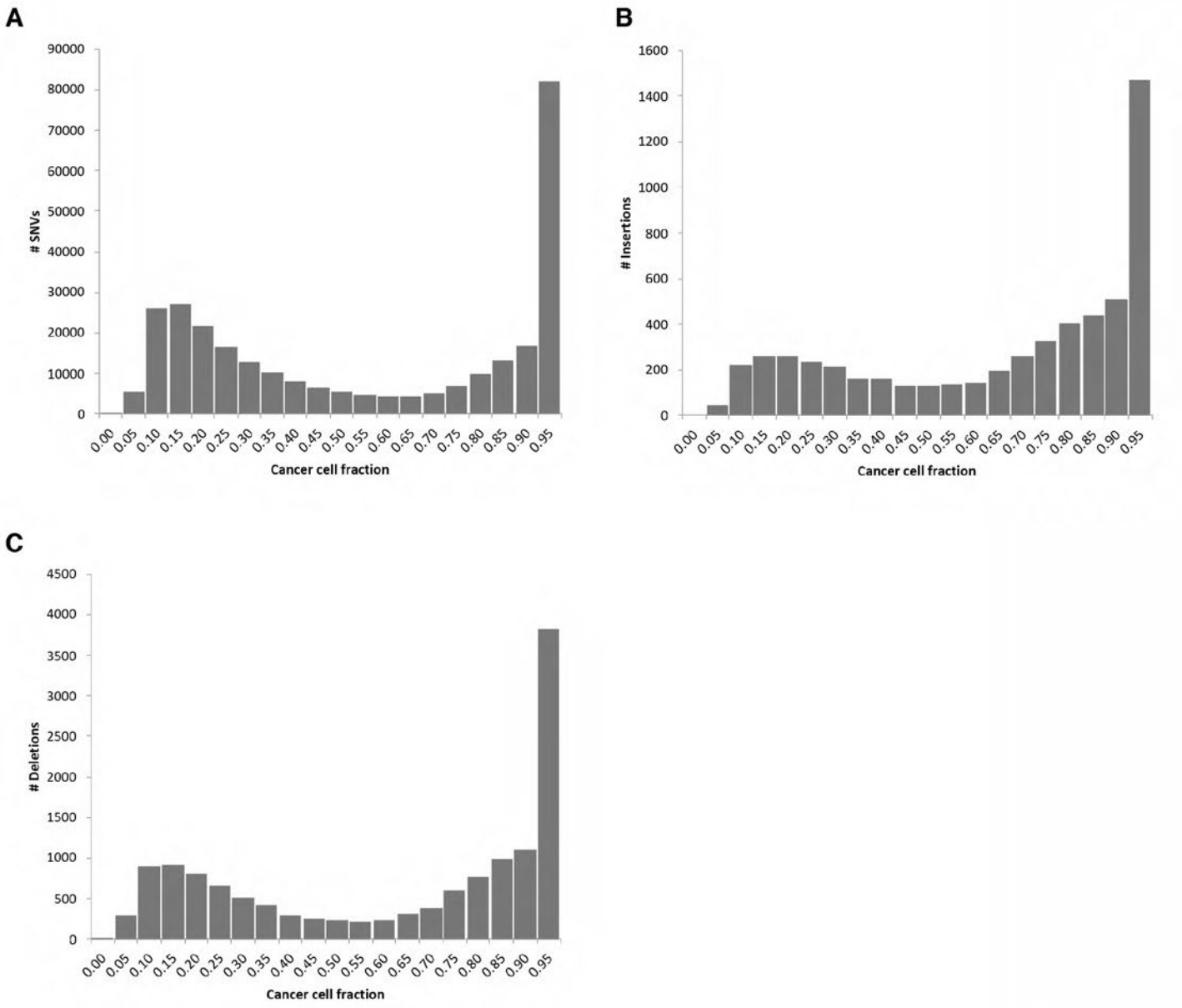


Fig. S8. Distribution of cancer cell fraction.
(A) SNVs (n=286,534). (B) Insertions (n=5699). (C) Deletions (n=13,706). Counts are restricted to n=356 individuals with high purity samples. As described in the Materials and Methods, cancer cell fraction reflects the variant allele fraction, accounting for the purity of the tumor sample. Clonal mutations were defined as those with cancer cell fraction ≥0.9, whereas subclonal mutations were defined as those with cancer cell fraction <0.6. Mutations with cancer cell fraction 0.6-0.9 had undetermined clonality. Counts by mutation type and clonality are provided in Table S3.

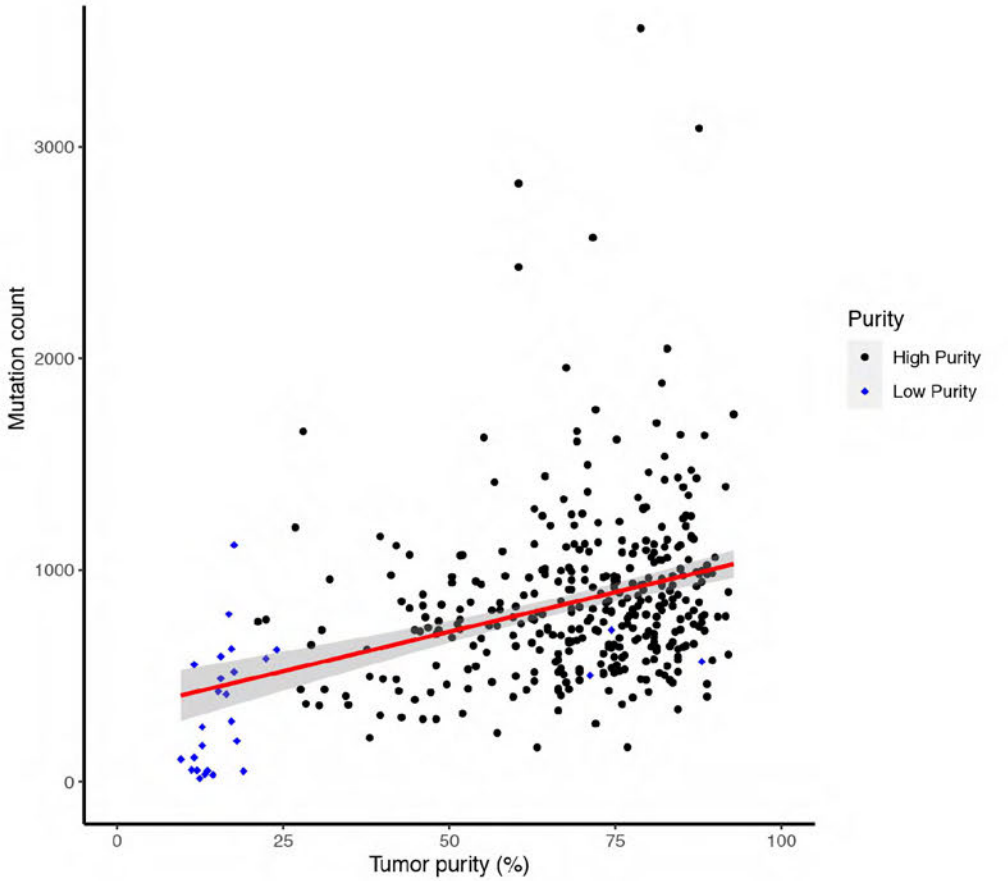


Fig. S9. Distribution of the total number of single nucleotide variants by tumor purity for 383 tumors with whole genome sequencing data.

High purity samples were defined as those with tumor purity >20% and no evidence of tumor contamination in the normal tissue (n=356). Individuals with low purity samples (n=22 with tumor purity <20%; n=2 low purity tumors where outlier variants were inflating the purity estimate; n=3 with evidence of tumor contamination in the normal tissue) were excluded from selected analyses (Fig. S1).

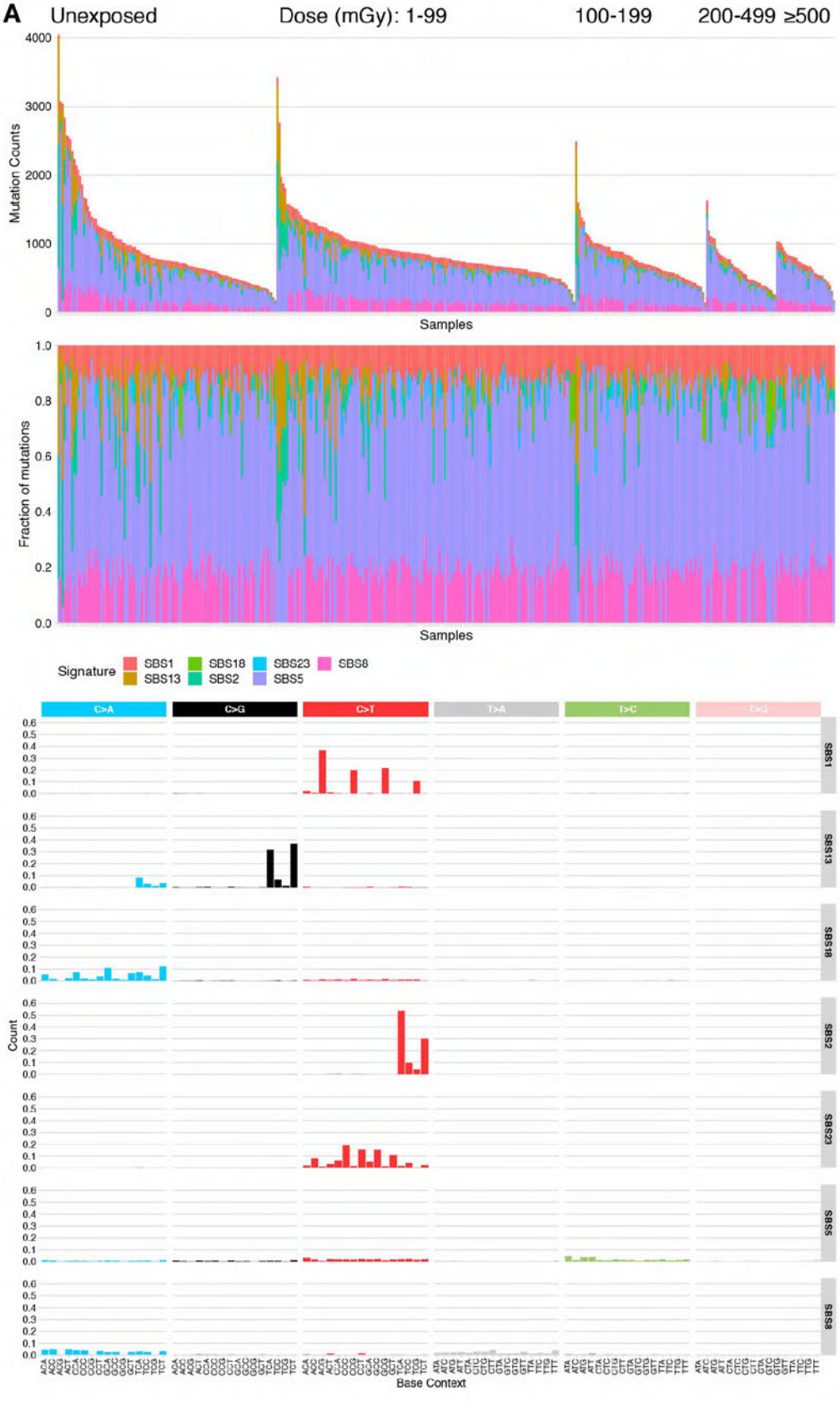

A
Unexposed
Dose (mGy): 1-99
100-199
200-499
≥500
Mutation Counts
Samples
Fraction of mutations
Samples
Signature
SBS1
SBS13
SBS18
SBS2
SBS23
SBS5
SBS8
C>A
C>G
C>T
T>A
T>C
T>G
Count
Base Context



Fig. S10. Distribution of SBS signatures by radiation dose from ^{131}I exposure and mutation count.
(**A**) Decomposed into known COSMIC signatures. (**B**) Identified de novo.

11

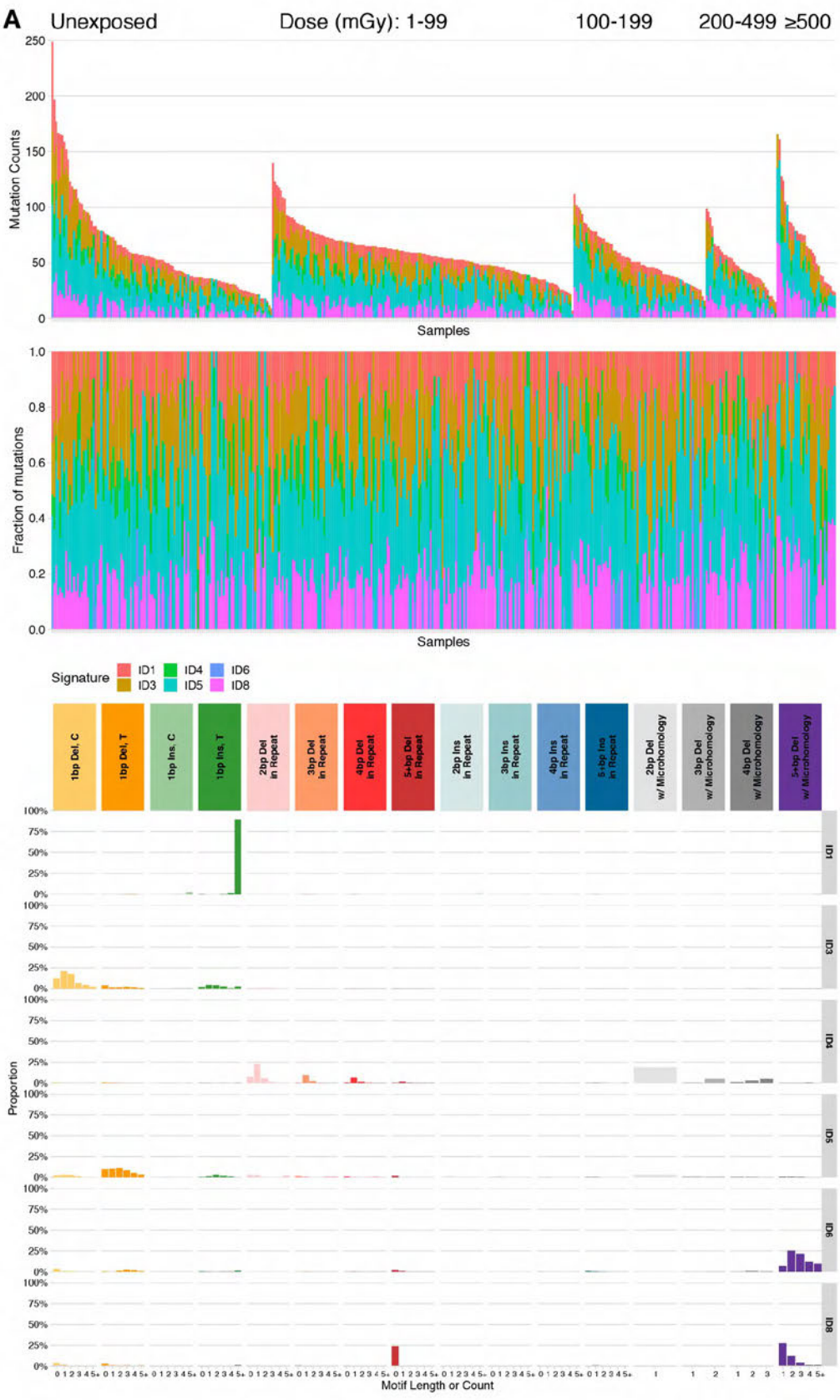

A
Unexposed
Dose (mGy): 1-99
100-199
200-499
≥500
Mutation Counts
Samples
Fraction of mutations
Samples
Signature
ID1
ID3
ID4
ID5
ID6
ID8
1bp Del, C
1bp Del, T
1bp Ins, C
1bp Ins, T
2bp Del in Repeat
3bp Del in Repeat
4bp Del in Repeat
5+bp Del in Repeat
2bp Ins in Repeat
3bp Ins in Repeat
4bp Ins in Repeat
5+bp Ins in Repeat
2bp Del w/ Microhomology
3bp Del w/ Microhomology
4bp Del w/ Microhomology
5+bp Del w/ Microhomology
Proportion
Motif Length or Count



Fig. S11. Distribution of ID signatures by radiation dose from ^{131}I exposure and mutation count.
(**A**) Decomposed into known COSMIC signatures. (**B**) Identified de novo.

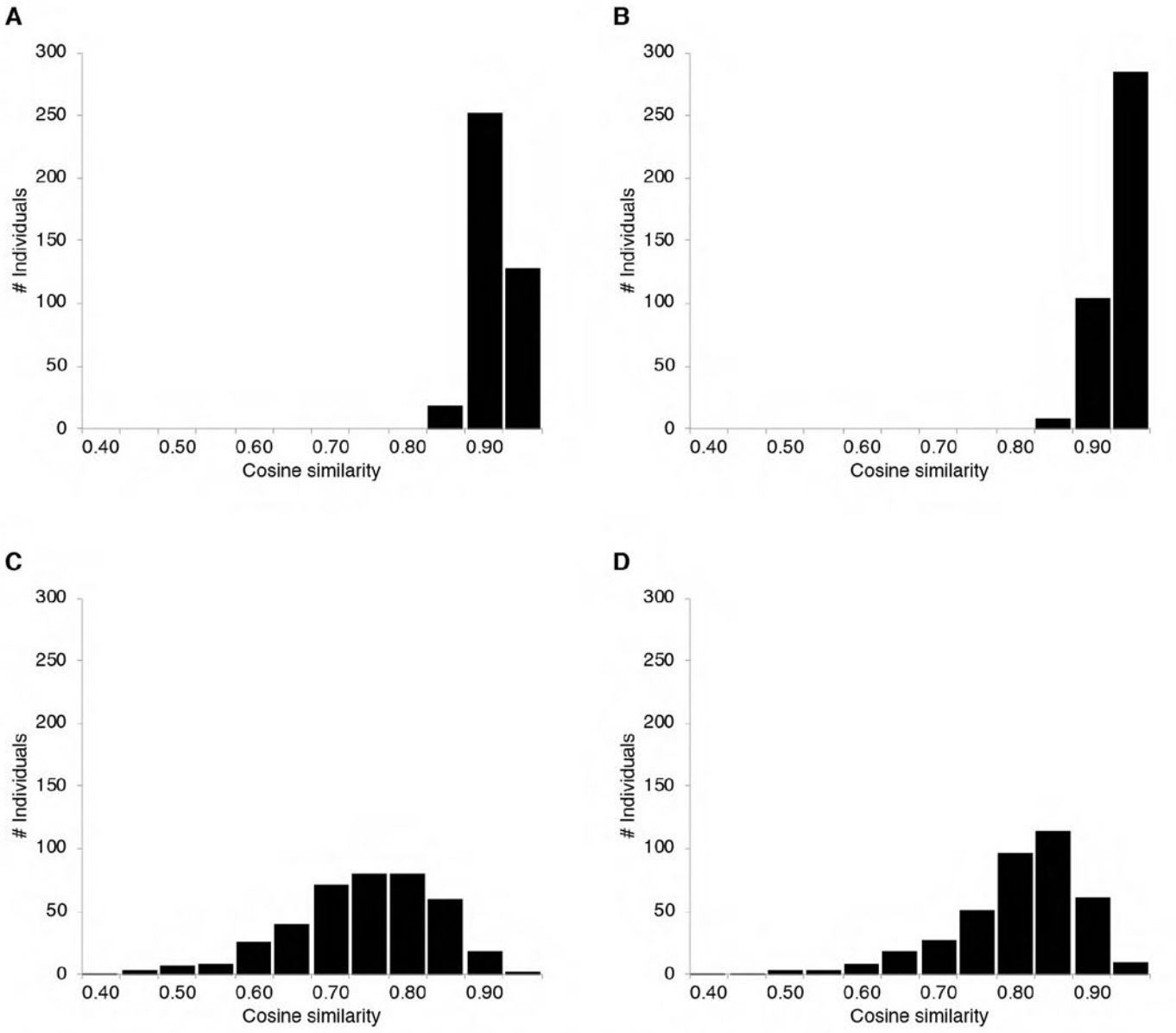
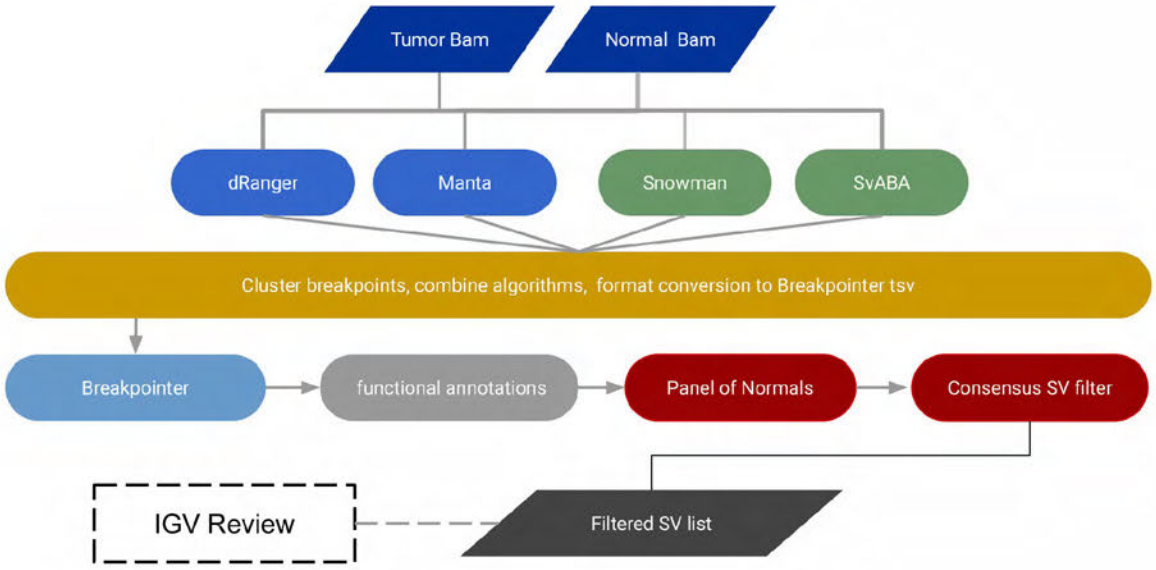


Fig. S12. Distribution of cosine similarities between actual mutation counts and those extracted using SigProfiler.

(**A**) SBS decomposition, Mean=0.94. (**B**) SBS de novo, Mean=0.96. (**C**) ID decomposition, Mean=0.77. (**D**) ID de novo, Mean=0.83.



43

Fig. S13. Structural variant calling pipeline.

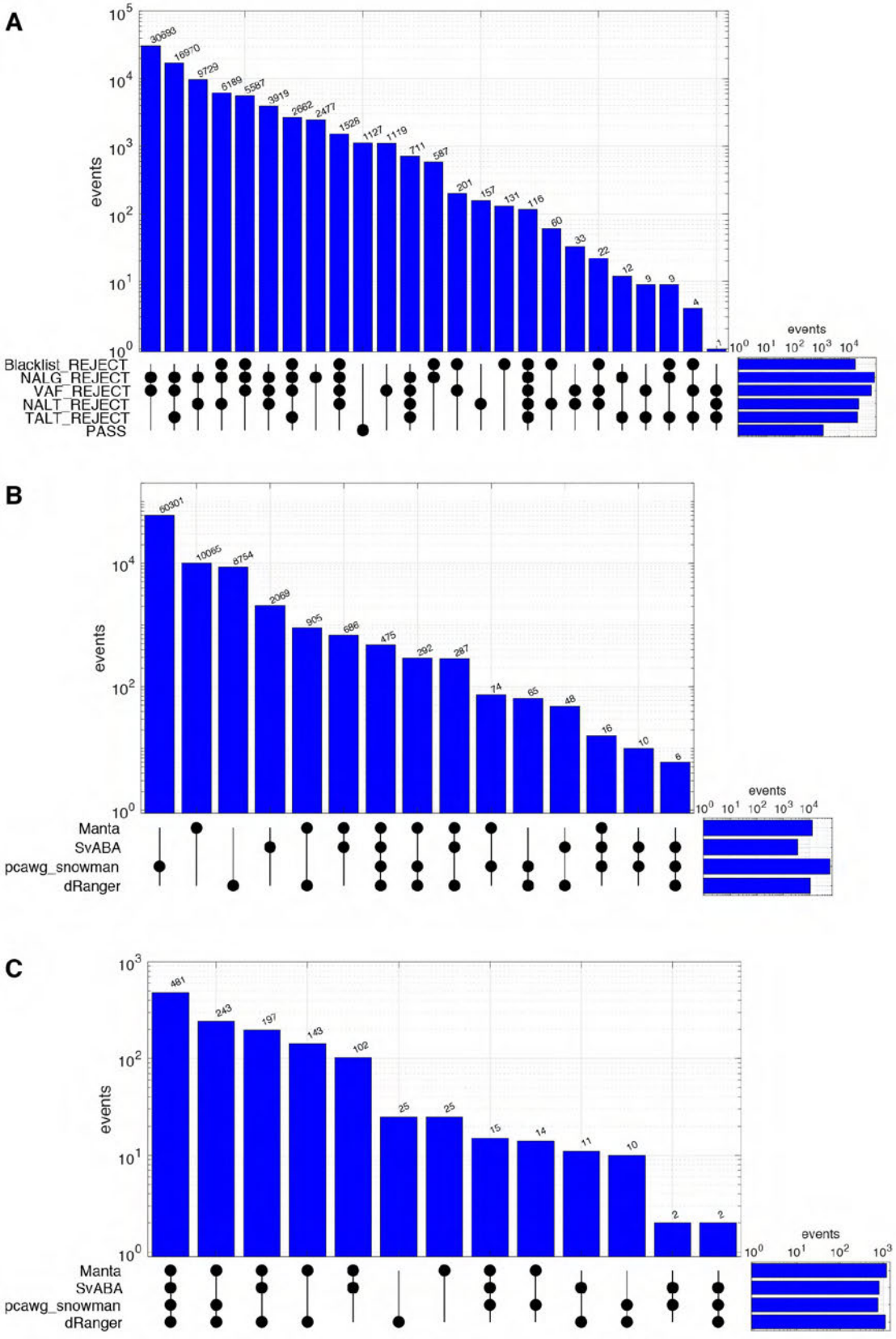


Fig. S14. Distribution of structural variant filters and calling algorithms.
(**A**) Filters. (**B**) Raw calls. (**C**) Final calling algorithm.

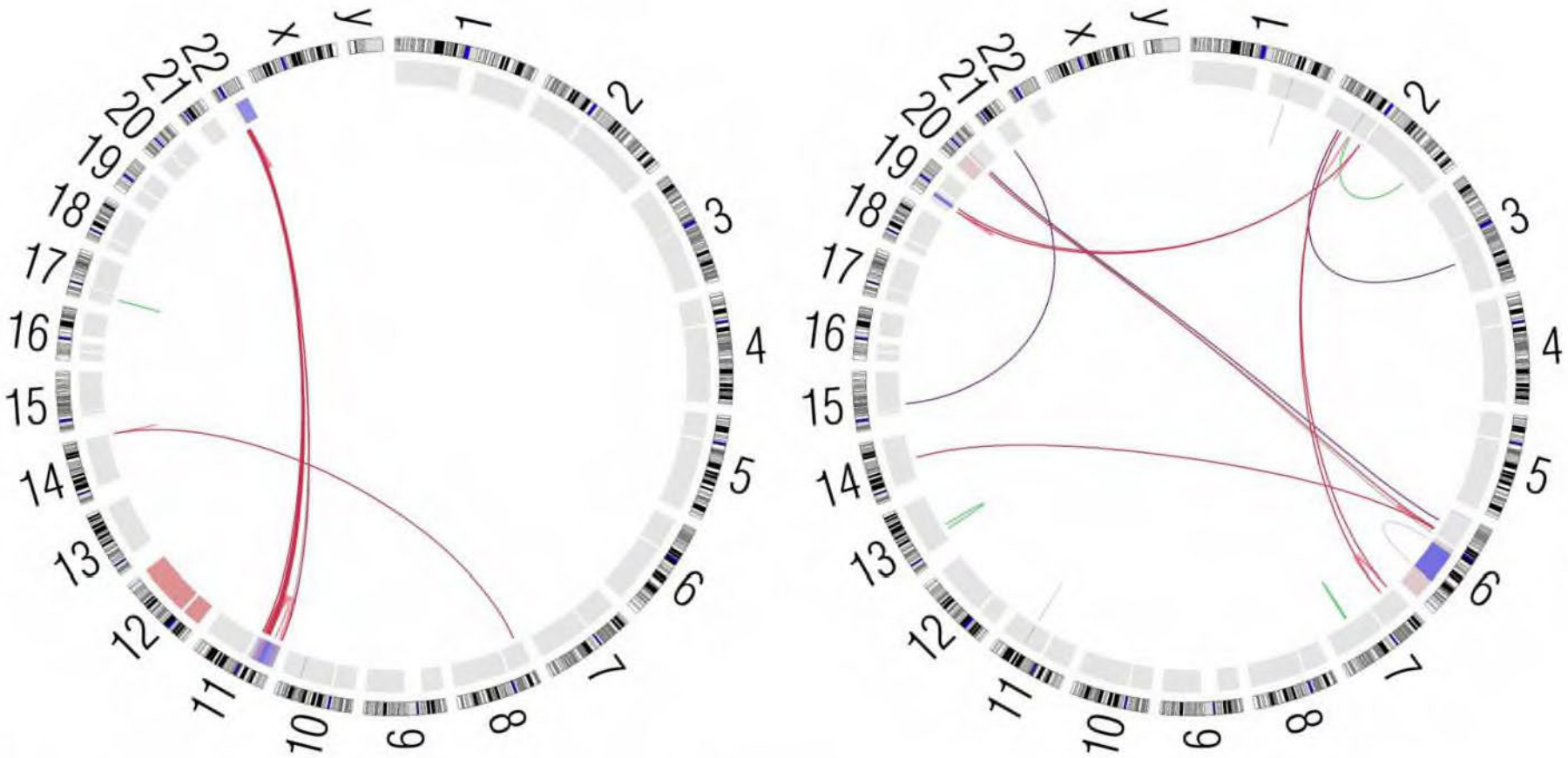


Fig. S15. Circos plots depicting tumors with >10 structural variants each.
The tumor depicted on the left also had evidence for chromothripsis and had ≥20 somatic copy number alterations. The outer ring shows cytoband structure within each chromosome. The inner ring shows the copy ratio (blue deletion, red amplification) across each chromosome. Red lines indicate SVs with breakpoints are clustered within 50 kb of another SV to form chains of events. Purple lines indicate balanced translocations. Green indicate SVs forming inversions in which both inversion breakpoints were detected. Gray lines are isolated SVs with breakpoints more than 50 kb from other SVs.

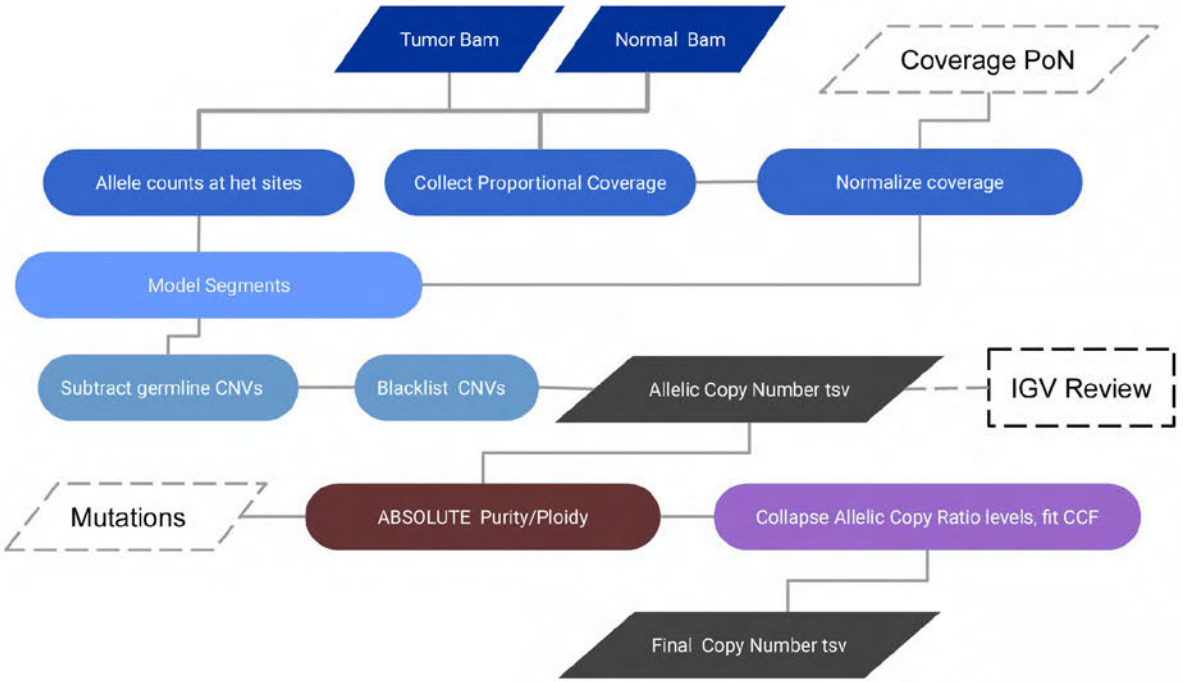


Fig. S16. Somatic copy number alteration calling pipeline.

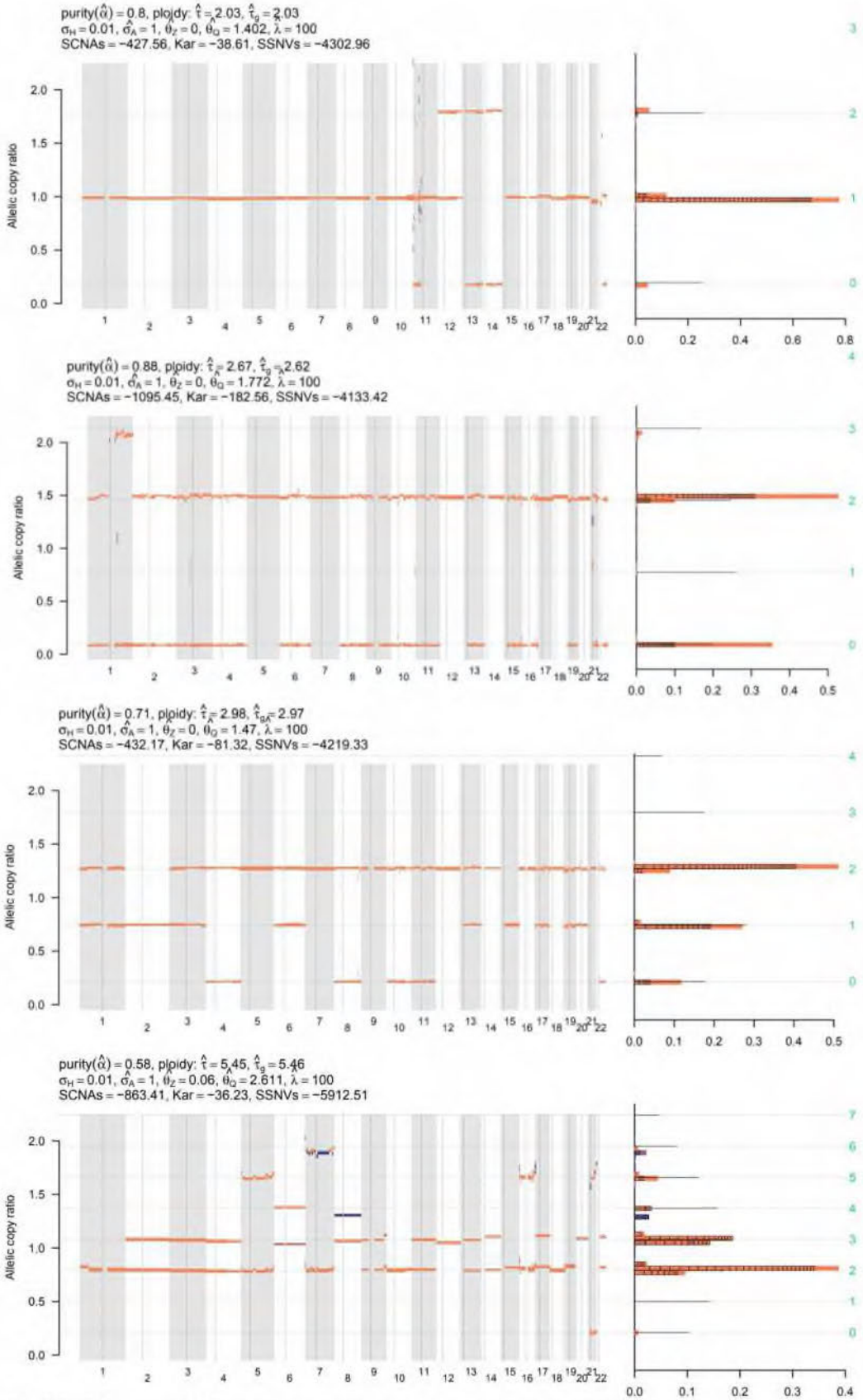


Fig. S17. Tumors with ≥20 somatic copy number alterations.
The tumor depicted in the top panel also had evidence for chromothripsis and had >10 structural variants.

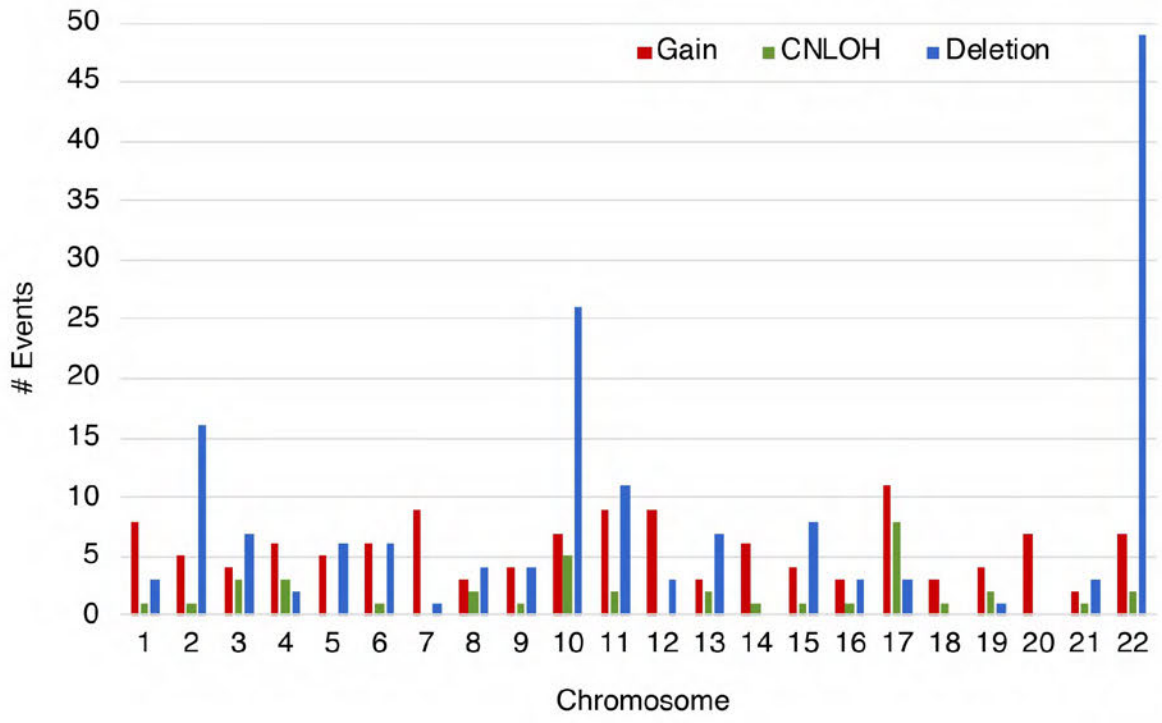


Fig. S18. Distribution of SCNAs, by chromosome number and SCNA type.

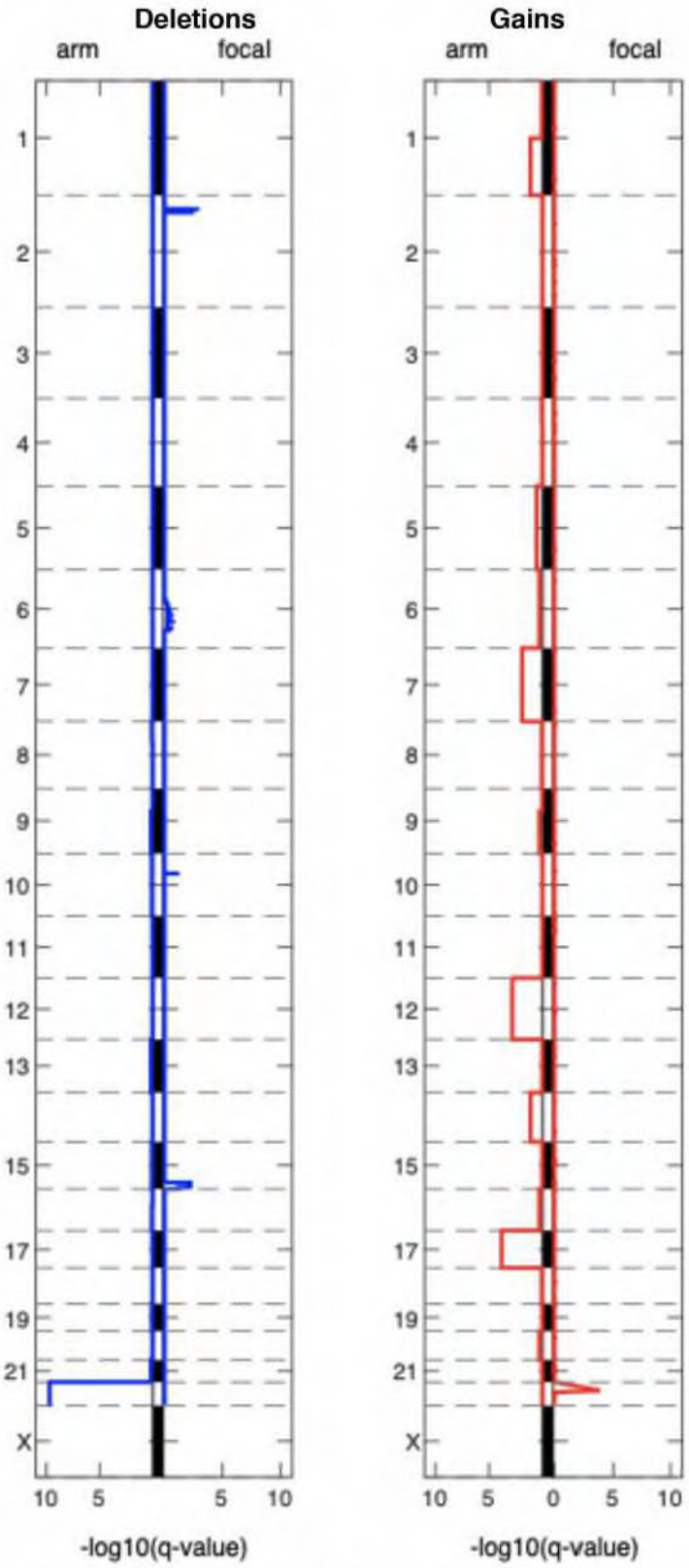


Fig. S19. Results from GISTIC2.0 for the 383 tumors with WGS data.
The horizontal scale shows the Benjamini-Hochberg corrected FDR (q-value) estimates for arm-level (SCNAs that cover more than half of an arm) and focal SCNAs. The FDR for 22q deletion is shown truncated to 1.0×10^{-10}. FDR<0.1 can be considered as significantly recurrent relative to the null model.

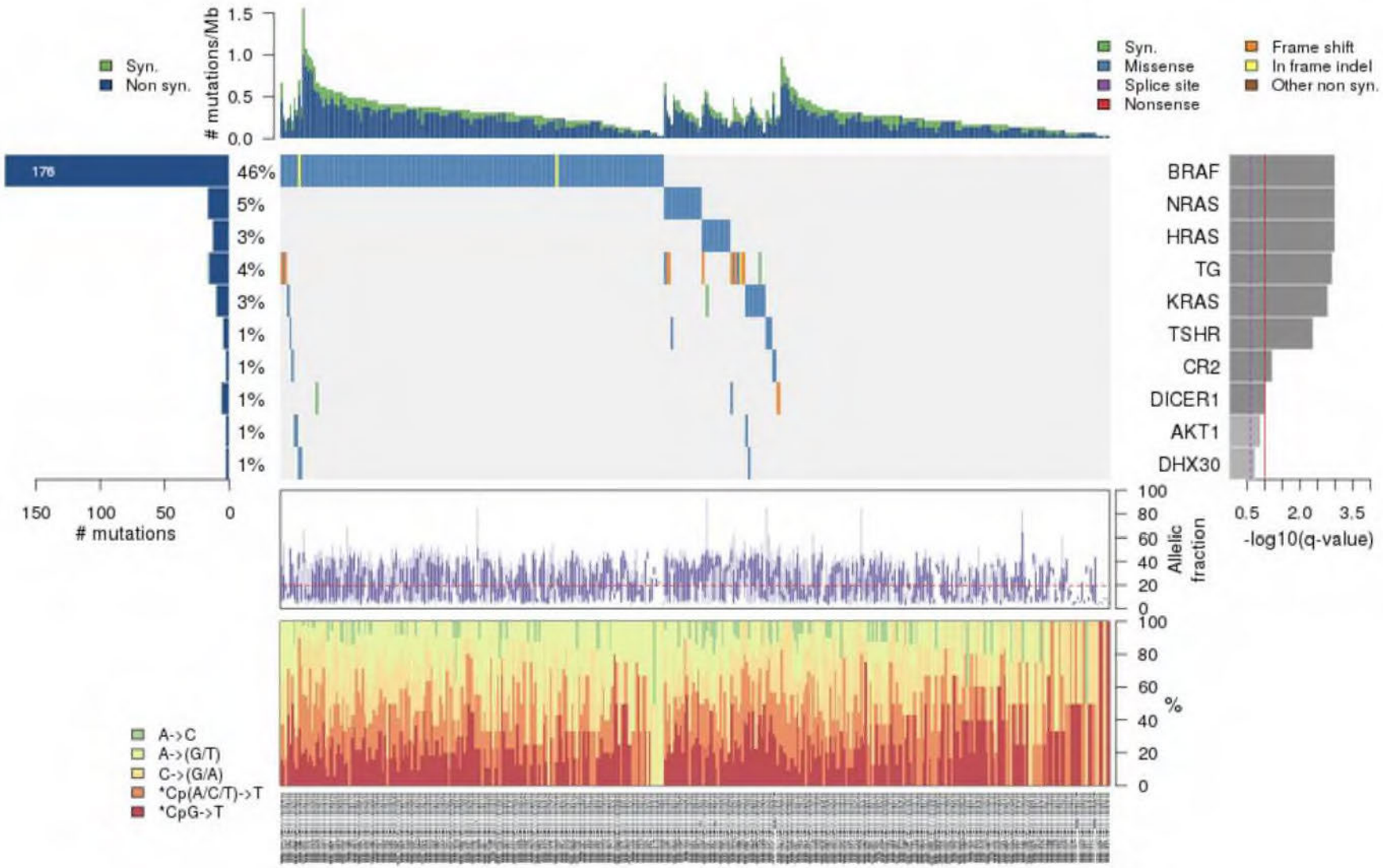


Fig. S20. Results from MutSig2CV for the 383 tumors with WGS data.
The MutSig2CV FDR is shown on the right side, with *BRAF, NRAS, HRAS, KRAS, TSHR, CR2, DICER1*, and *TG* found as significantly recurrent with an FDR<0.1. *TG* was not considered as a driver gene due to a preponderance of non-coding mutations in an overexpressed lineage-specific gene.

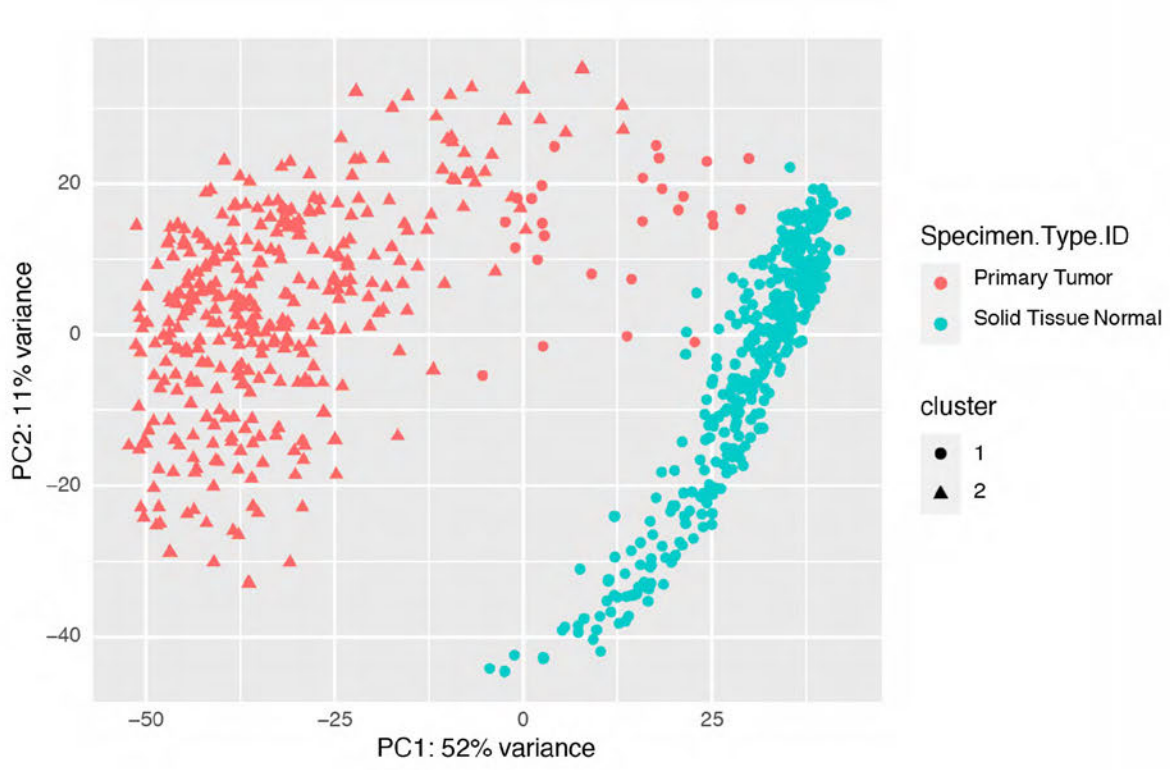


Fig. S21. Unsupervised mRNA clustering analyses of paired PTC and non-tumor thyroid tissue revealed two clusters strongly correlated with tissue type.

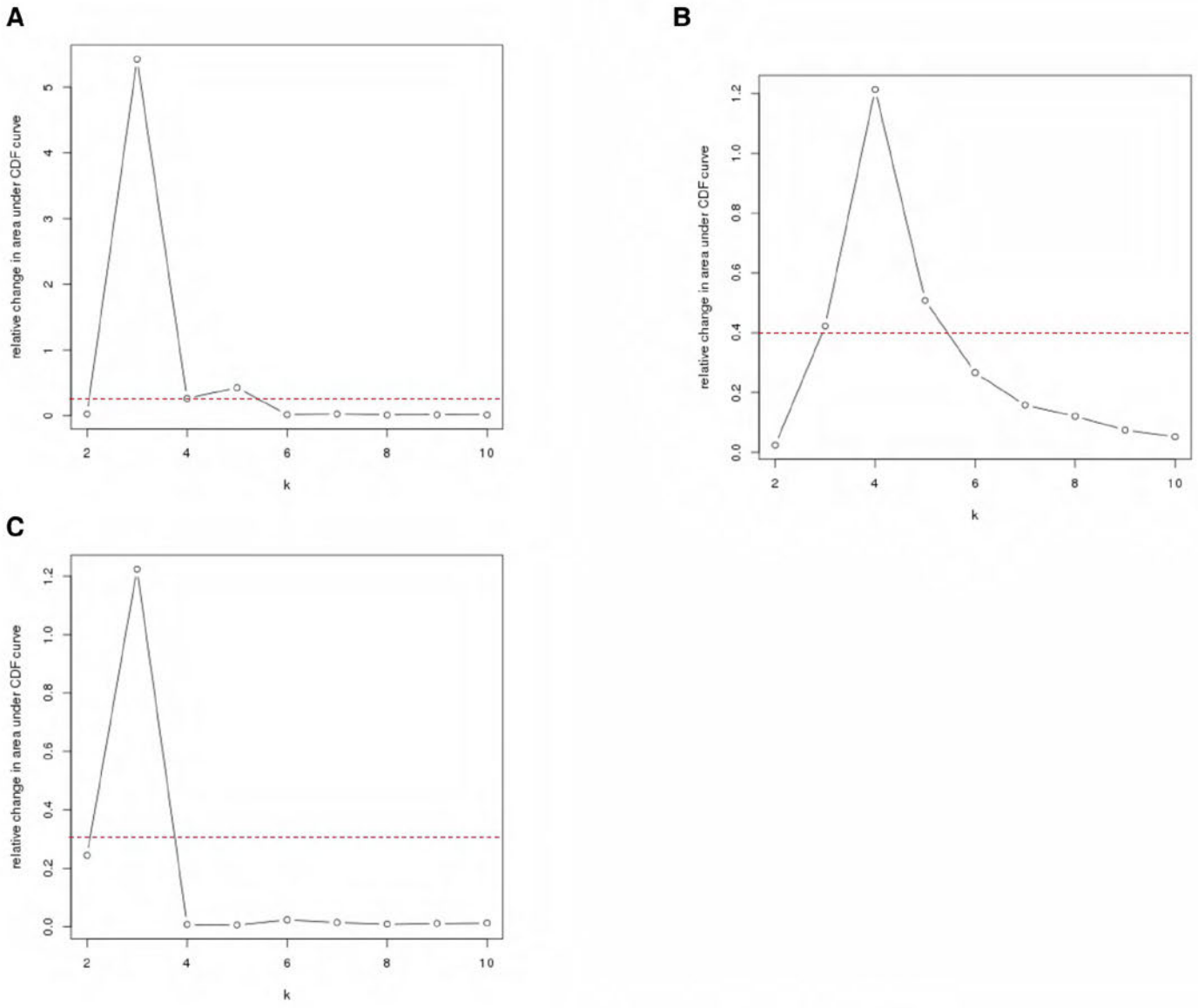
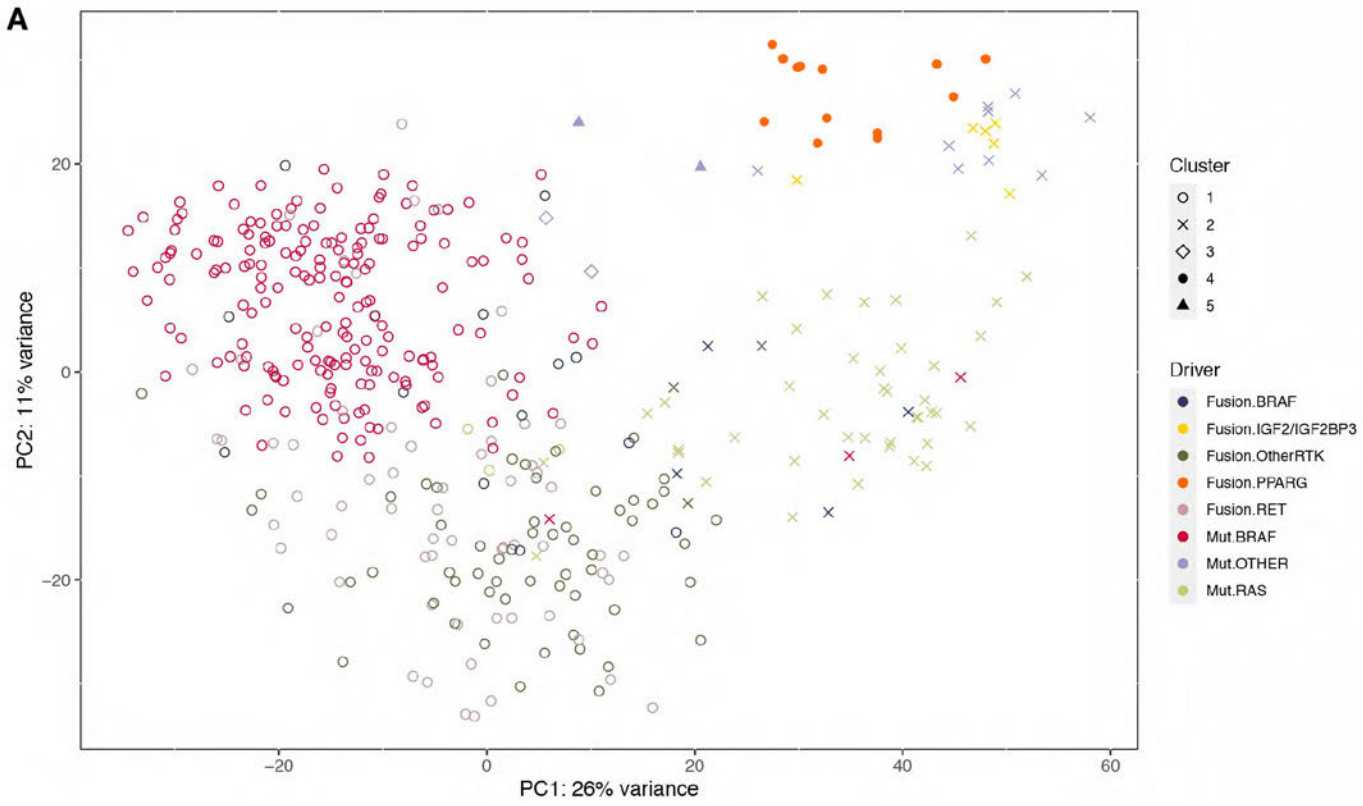
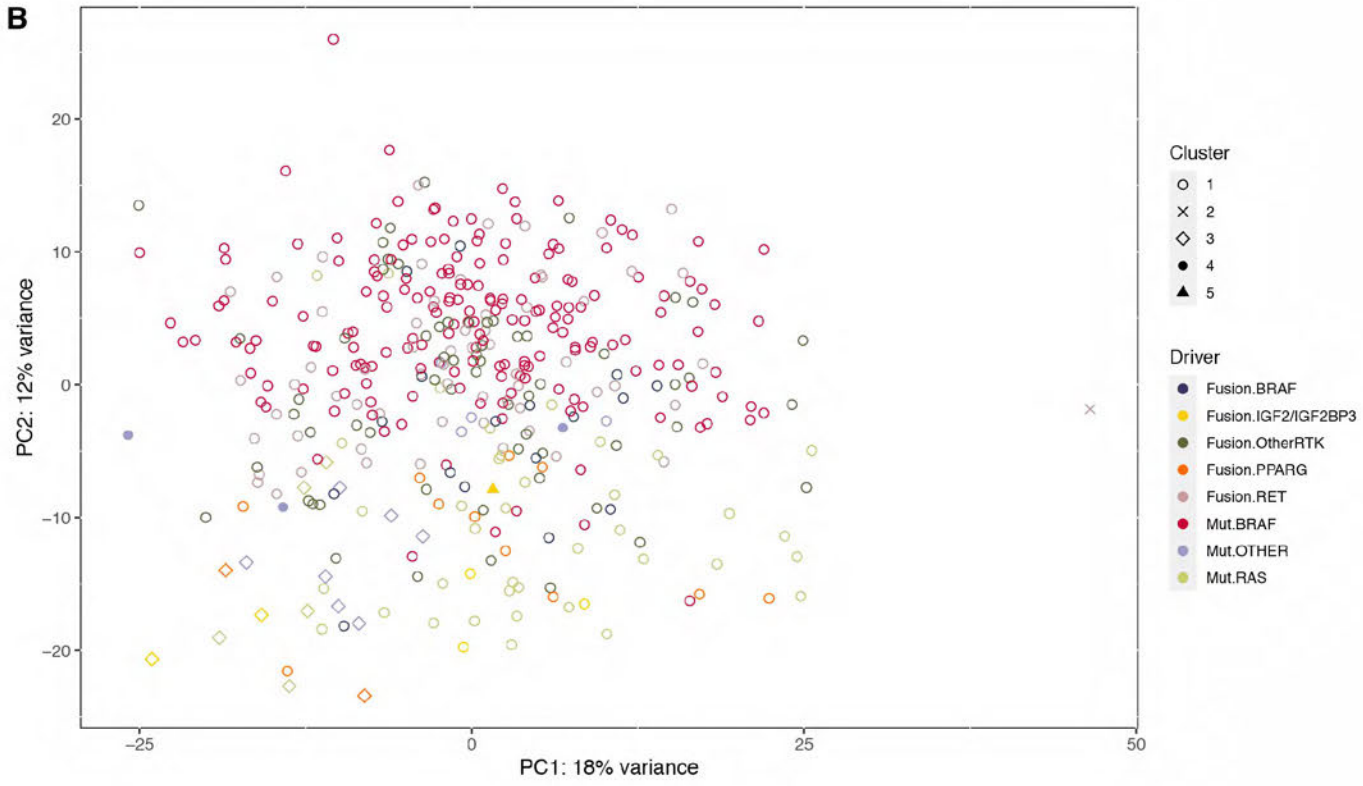


Fig. S22. Unsupervised clustering analysis of PTC only using ConsensusClusterPlus.
(A) mRNA, k=5. (B) miRNA, k=5. (C) Methylation, k=3. The appropriate cluster number (k) was determined by identifying the largest cluster with a delta area value >0.3, denoted with the dashed red line.


A
PC2: 11% variance
PC1: 26% variance
Cluster
1
2
3
4
5
Driver
Fusion.BRAF
Fusion.IGF2/IGF2BP3
Fusion.OtherRTK
Fusion.PPARG
Fusion.RET
Mut.BRAF
Mut.OTHER
Mut.RAS


B
PC2: 12% variance
PC1: 18% variance
Cluster
1
2
3
4
5
Driver
Fusion.BRAF
Fusion.IGF2/IGF2BP3
Fusion.OtherRTK
Fusion.PPARG
Fusion.RET
Mut.BRAF
Mut.OTHER
Mut.RAS

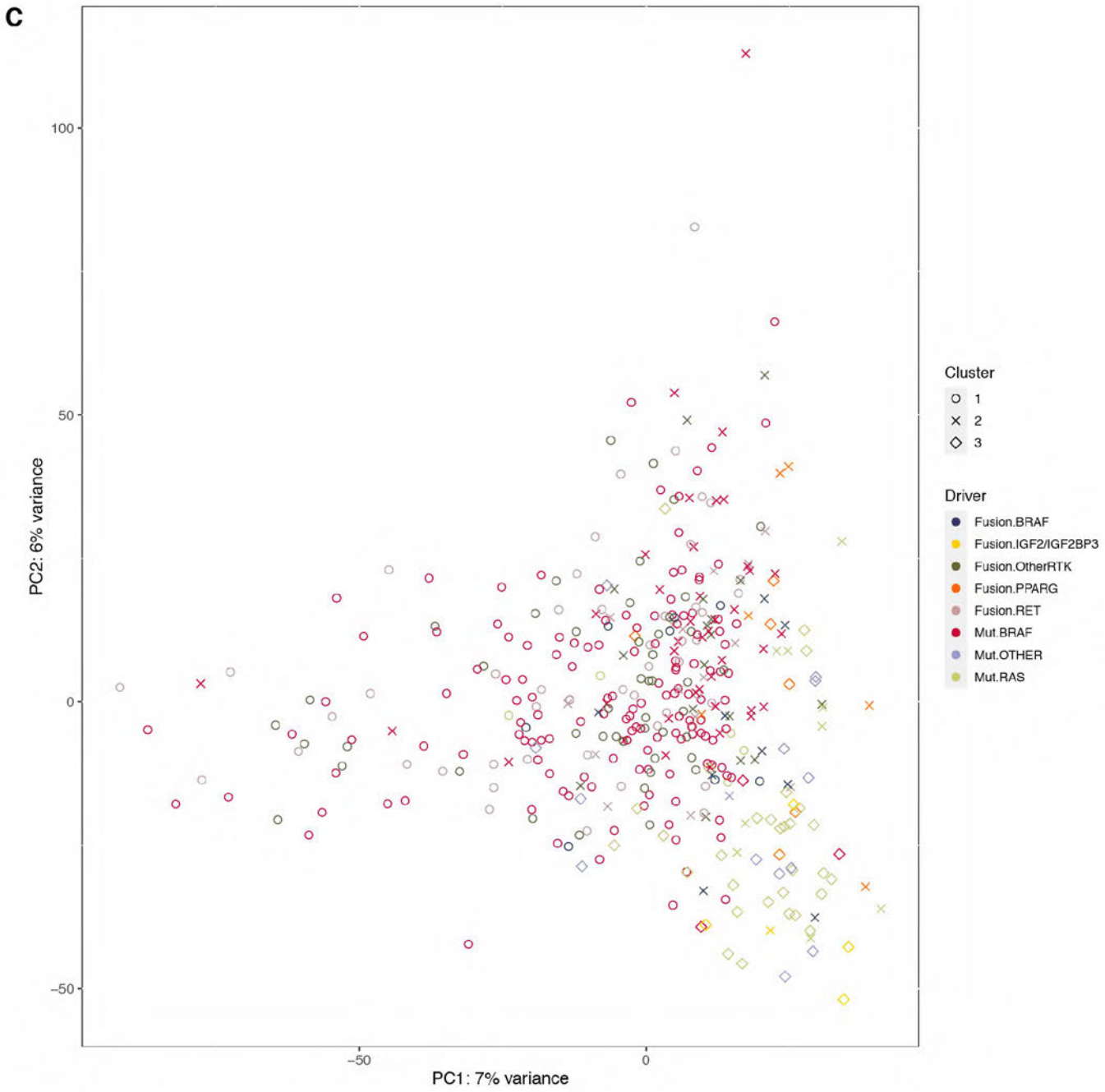


Fig. S23. Relationship of clusters to PTC driver.
(**A**) mRNA. (**B**) miRNA. (**C**) Methylation. Table S11 provides the distribution of clusters by driver.

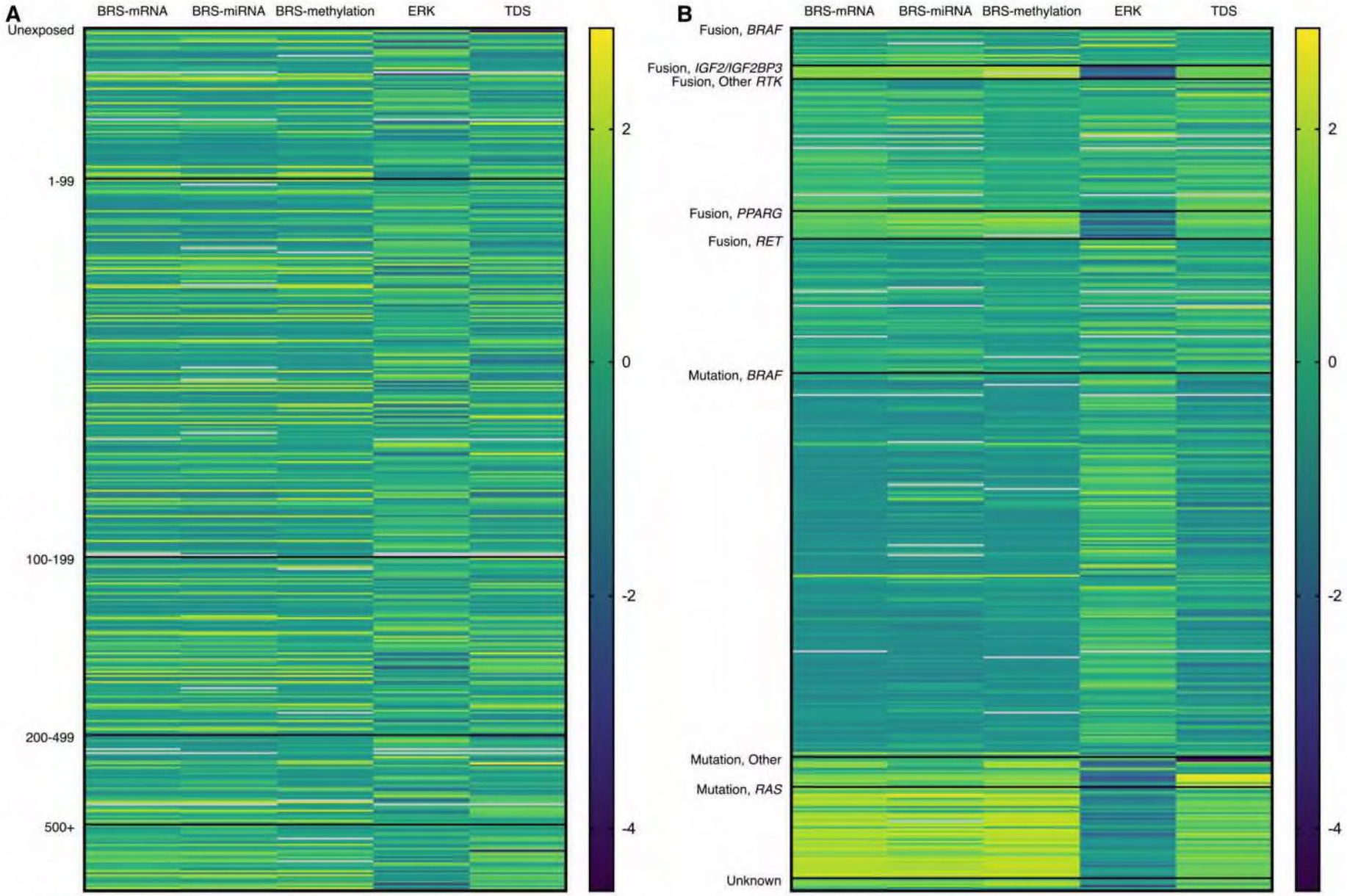


Fig. S24. Distribution of the *BRAF*^{V600E}-*RAS* (BRS) score from mRNA, miRNA, and methylation; ERK-activity score; and thyroid differentiation score.

(**A**) By radiation dose. (**B**) By PTC driver. Scores were standardized (mean=0, standard deviation=1) to facilitate comparison across the different measures.

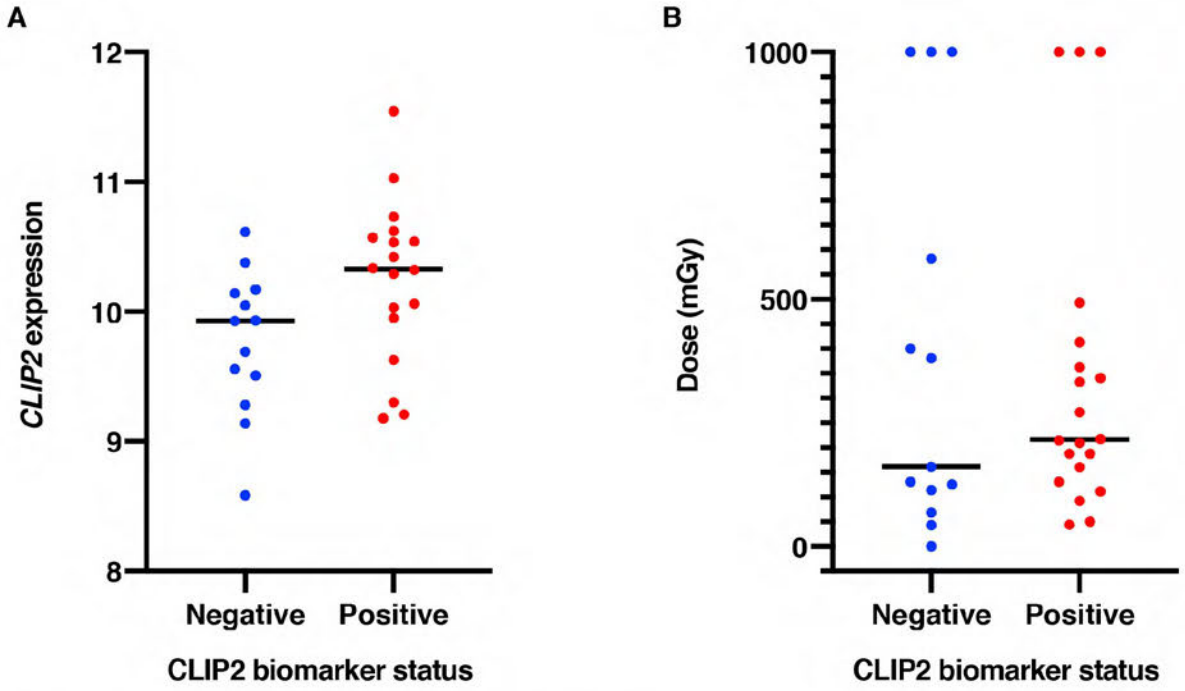
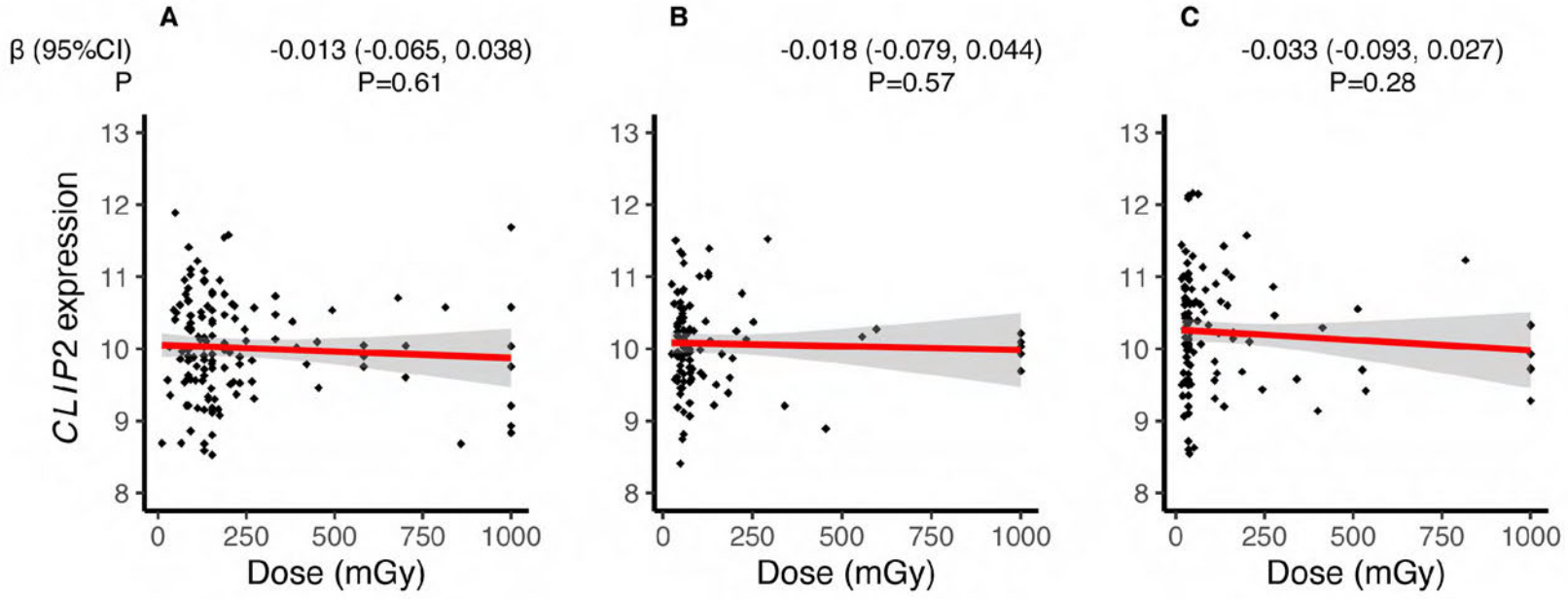


Fig. S25. Distribution of CLIP2 biomarker status.
In 33 overlapping samples between our study and a previously-published analysis (*25*), the CLIP2 biomarker status identified in that study correlated with *CLIP2* mRNA expression as measured by RNA-seq in our study (**A**) but did not correlate with radiation dose (**B**).



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Fig. S26. Relationship between radiation dose from ^{131}I exposure and expression of *CLIP2* by age at exposure.
(**A**) <5 years at exposure, (**B**) 5-9 years at exposure, and (**C**) ≥10 years at exposure. Results for the total study population are provided in Fig. 5C.

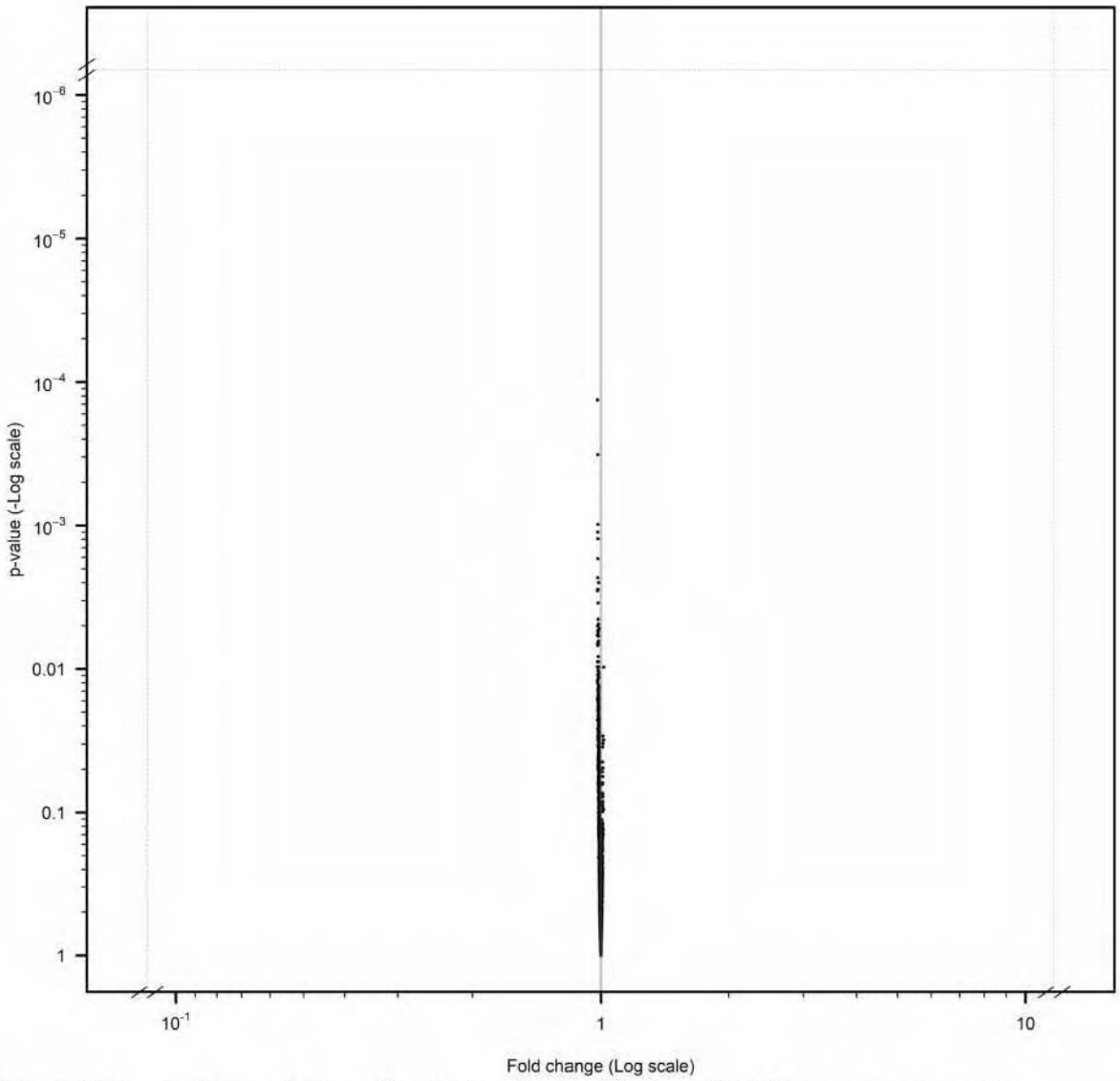
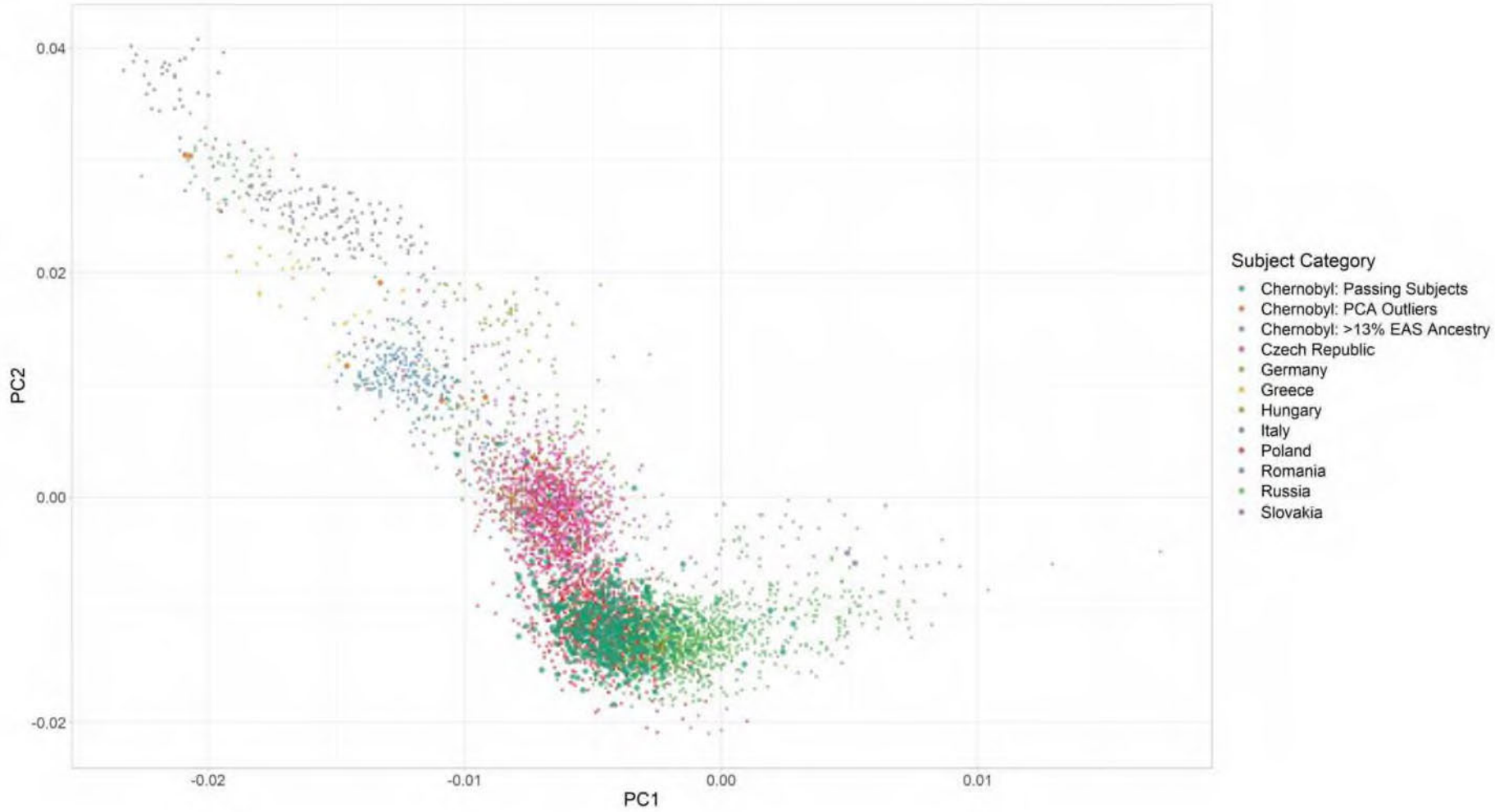


Fig. S27. Lack of association of radiation dose with any of 3,213 gene sets from the Molecular Signatures Database.

A


0.04
0.02
0.00
-0.02
PC2
-0.02
-0.01
0.00
0.01
PC1
Subject Category
Chernobyl: Passing Subjects
Chernobyl: PCA Outliers
Chernobyl: >13% EAS Ancestry
Czech Republic
Germany
Greece
Hungary
Italy
Poland
Romania
Russia
Slovakia

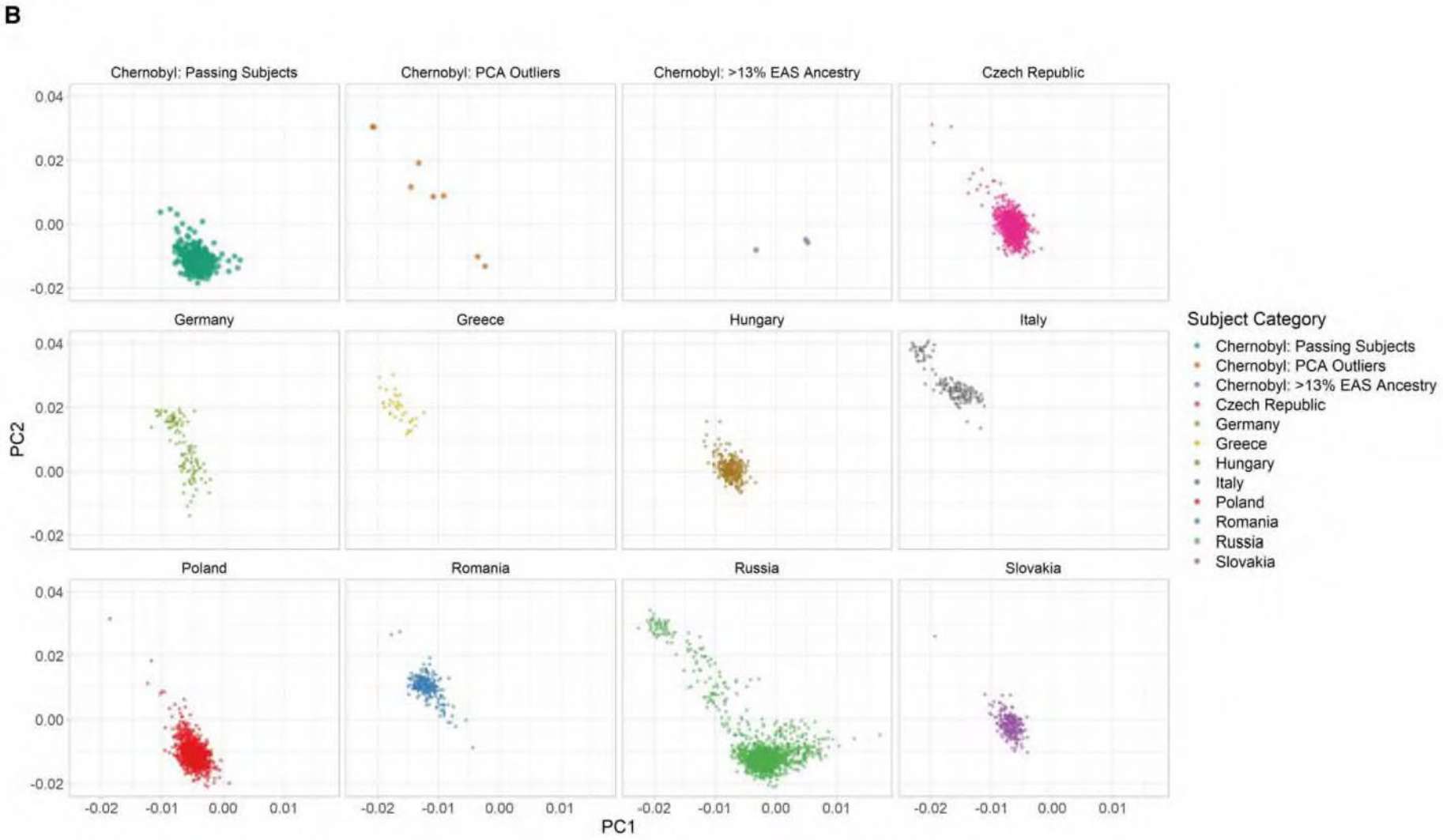


Fig. S28. Population substructure based on SNP array data.
(**A**) All ancestries combined in a single panel. (**B**) Each ancestry category in separate panels. Abbreviation: EAS=East Asian.

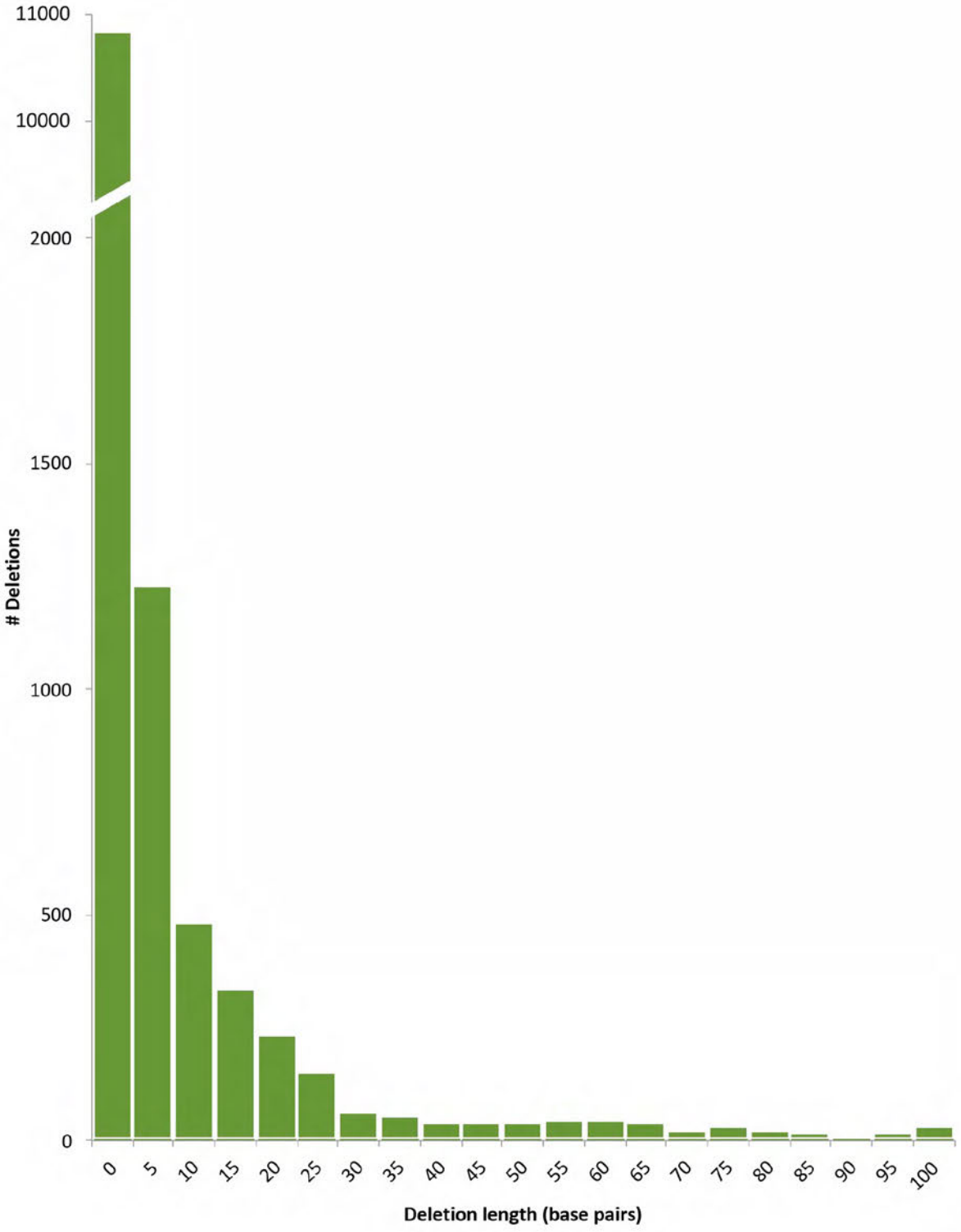


Fig. S29. Distribution of small deletions by length in n=356 individuals with high purity samples.

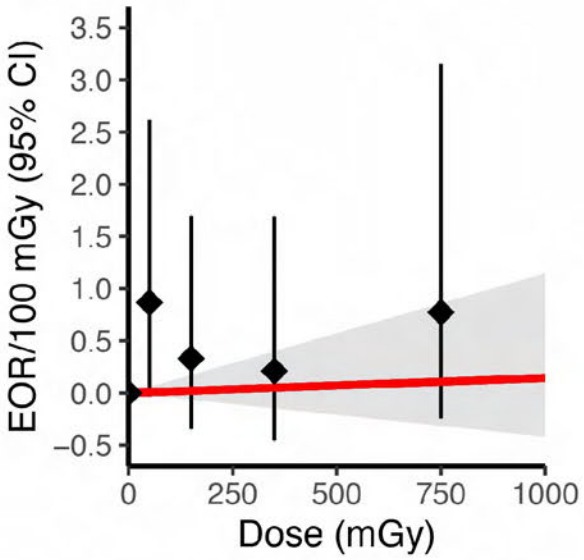


Fig. S30. Association between count of locally templated insertions (TINS) and radiation dose from ^{131}I exposure.

TINS are characteristic of alternative end-joining repair of DNA double-strand breaks (EOR/Gy=0.037, 95%CI= -0.039-0.18; P=0.69).

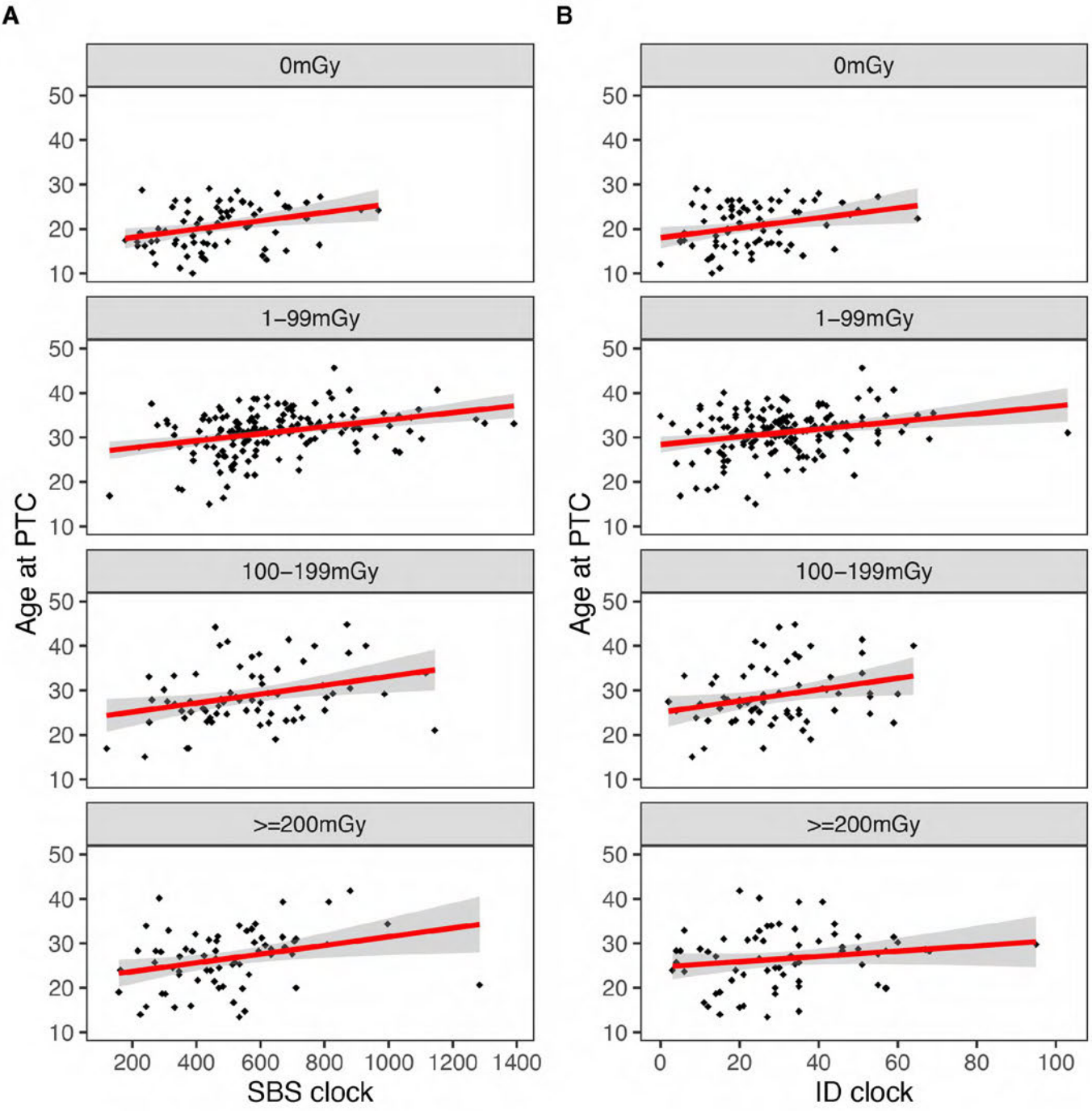


Fig. S31. Association for age at papillary thyroid cancer (years) with number of clock-like SBS and ID signatures, by radiation dose from ^{131}I exposure.

(A) SBS clock-like signatures (SBS1, SBS5), $P_{heterogeneity}$=0.63. (B) ID clock-like signatures (ID1, ID5), $P_{heterogeneity}$=0.93. $P_{heterogeneity}$ was derived from a generalized linear regression model, comparing model fit with and without an interaction term between radiation dose (continuous, truncated at 1 Gy) and age at PTC (continuous).

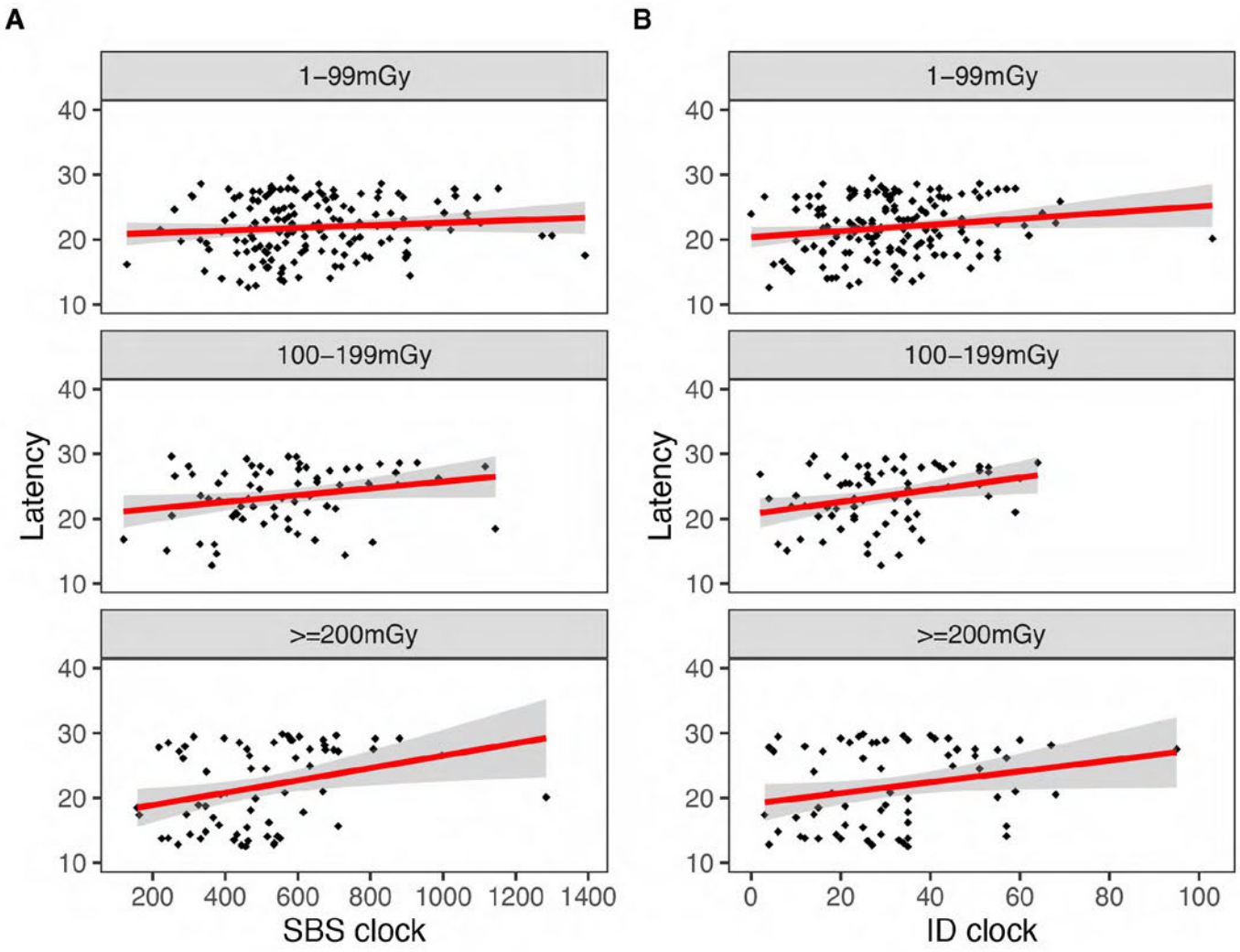


Fig. S32. Association for latency (years) with number of clock-like SBS and ID signatures, by radiation dose from ^{131}I exposure.

(A) SBS clock-like signatures (SBS1, SBS5), $P_{heterogeneity}$=0.28. (B) ID clock-like signatures (ID1, ID5), $P_{heterogeneity}$=0.21. $P_{heterogeneity}$ was derived from a generalized linear regression model, comparing model fit with and without an interaction term between radiation dose (continuous, truncated at 1 Gy) and age at PTC (continuous). Analyses were restricted to ^{131}I-exposed individuals.

Table S1. Demographic characteristics of the study populations.

Characteristic	^{131}I Exposed, Chernobyl Tissue Bank (n=359)	^{131}I Unexposed, Chernobyl Tissue Bank (n=81)	^{131}I Exposed, Efanov et al. (9) (n=45)
Sex			
Female	269 (74.9%)	66 (81.5%)	27 (60.0%)
Male	90 (25.1%)	15 (18.5%)	18 (40.0%)
Age at PTC (years)			
<15	4 (1.1%)	11 (13.6%)	1 (2.2%)
15-19	25 (7.0%)	25 (30.9%)	11 (24.4%)
20-24	48 (13.4%)	26 (32.1%)	12 (26.7%)
25-29	98 (27.3%)	19 (23.5%)	13 (28.9%)
30-34	125 (34.8%)	0 (0.0%)	8 (17.8%)
35-39	43 (12.0%)	0 (0.0%)	0 (0.0%)
40-44	14 (3.9%)	0 (0.0%)	0 (0.0%)
≥45	2 (0.6%)	0 (0.0%)	0 (0.0%)
Mean (± SD)	*29.7 (± 6.1)*	*20.7 (± 4.9)*	*24.2 (± 5.4)*
Radiation dose (mGy) †			
0	0 (0.0%)	81 (100.0%)	0 (0.0%)
1-99	193 (53.8%)	0 (0.0%)	8 (17.8%)
100-199	90 (25.1%)	0 (0.0%)	6 (13.3%)
200-499	43 (12.0%)	0 (0.0%)	6 (13.3%)
≥500	33 (9.2%)	0 (0.0%)	25 (55.6%)
Mean (± SD)	*247 (± 665)*	na	*1045 (± 1126)*
Age at exposure (years)			
<5	139 (38.7%)	na	17 (37.8%)
5-9	102 (28.4%)	na	14 (31.1%)
≥10	118 (32.9%)	na	14 (31.1%)
Mean (± SD)	*7.3 (± 5.1)*	na	*7.2 (± 4.5)*
Time since exposure (years)			
<20	119 (33.1%)	na	38 (84.4%)
20-24	109 (30.4%)	na	7 (15.6%)
≥25	131 (36.5%)	na	0 (0.0%)
Mean (± SD)	*22.4 (± 4.9)*	na	*17.0 (± 2.5)*
Probability of causality (%)			
0	0 (0.0%)	81 (100.0%)	0 (0.0%)
1-24	178 (49.6%)	0 (0.0%)	8 (17.8%)
25-49	108 (30.1%)	0 (0.0%)	8 (17.8%)
50-74	46 (12.8%)	0 (0.0%)	6 (13.3%)
≥75	27 (7.5%)	0 (0.0%)	23 (51.1%)
Dose reconstruction data source			
Direct measurement, with interview	49 (13.6%)	na	39 (86.7%)
Direct measurement only	4 (1.1%)	na	0 (0.0%)
Area measurements	297 (82.7%)	na	0 (0.0%)
In utero	9 (2.5%)	na	0 (0.0%)
Unknown	0 (0.0%)	na	6 (13.3%)
Residence at the time of the accident			
Chernigov (Chernihiv in Ukrainian)	53 (14.8%)	8 (9.9%)	25 (55.6%)
Kiev (Kyiv in Ukrainian)	222 (61.8%)	64 (79.0%)	10 (22.2%)
Kirovograd	1 (0.3%)	0 (0.0%)	0 (0.0%)
Zhytomyr	83 (23.1%)	9 (11.1%)	10 (22.2%)
Thyroid surgery volume			
Hemithyroidectomy	46 (12.8%)	12 (14.8%)	0 (0.0%)
Total thyroidectomy	298 (83.0%)	67 (82.7%)	0 (0.0%)
Unknown	15 (4.2%)	2 (2.5%)	45 (100.0%)
Lesion size (cm)			
<1.0	47 (13.1%)	8 (9.9%)	4 (8.9%)
1.0-1.9	157 (43.7%)	35 (43.2%)	32 (71.1%)
2.0-2.9	66 (18.4%)	14 (17.3%)	2 (4.4%)
3.0-3.9	34 (9.5%)	11 (13.6%)	1 (2.2%)
≥4.0	42 (11.7%)	5 (6.2%)	0 (0.0%)
Unknown	13 (3.6%)	8 (9.9%)	6 (13.3%)
Mean (± SD)	*2.1 (± 1.3)*	*2.0 (± 1.1)*	*1.4 (± 0.5)*

Abbreviation: not applicable (na).

Table S2. Whole genome sequencing coverage, by study population and sample type.

	Primary tumor			Primary tumor control (blood or non-tumor thyroid)			Non-tumor thyroid			Non-tumor thyroid control (blood)		
Study population	n	Mean (± SD)	Range (min-max)	n	Mean (± SD)	Range (min-max)	n	Mean (± SD)	Range (min-max)	n	Mean (± SD)	Range (min-max)
Chernobyl Tissue Bank	383	88.8 (± 12.3)	(50.2 - 144.5)	383	33.2 (± 4.5)	(23.3 - 51.5)	233	33.3 (± 4.8)	(24.1 - 67.1)	233	33.2 (± 4.3)	(25.5 - 51.5)
^{131}I Exposed	305	91.2 (± 12.4)	(50.2 - 144.5)	305	33.2 (± 4.6)	(23.3 - 51.5)	178	33.6 (± 4.7)	(25.4 - 67.1)	178	33.2 (± 4.4)	(25.5 - 51.5)
^{131}I Unexposed	78	79.6 (± 6.0)	(71.1 - 98.1)	78	32.9 (± 4.2)	(24.5 - 43.9)	55	32.3 (± 5.1)	(24.1 - 45.5)	55	33.4 (± 3.9)	(26.2 - 43.9)

Table S3. Distribution of simple somatic variants by type and clonality in 383 tumors with whole genome sequencing data.

	Total number of mutations				Mutations per tumor					
		By clonality*					By clonality*			
	Total	Clonal	Subclonal	Undetermined	Total		Clonal		Subclonal	
Simple somatic variant	n (column %)	n (row %)	n (row %)	n (row %)	Mean (± SD)	Range	Mean (± SD)	Range	Mean (± SD)	Range
Total	318956 (100.0%)	114898 (36.0%)	153803 (48.2%)	50255 (15.8%)	832.8 (± 417.5)	(15 - 3560)	300.0 (± 196.2)	(14 - 2256)	401.6 (± 351.1)	(0 - 3238)
By type										
SNV	297512 (93.3%)	106881 (35.9%)	145665 (49.0%)	44966 (15.1%)	776.8 (± 401.0)	(14 - 3427)	279.1 (± 188.5)	(13 - 2238)	380.3 (± 336.9)	(0 - 3123)
Doublet	1351 (0.4%)	456 (33.8%)	680 (50.3%)	215 (15.9%)	3.5 (± 2.6)	(0 - 14)	1.2 (± 1.4)	(0 - 8)	1.8 (± 1.9)	(0 - 13)
Triplet	20 (0.006%)	8 (40.0%)	5 (25.0%)	7 (35.0%)	0.1 (± 0.2)	(0 - 2)	0.0 (± 0.1)	(0 - 1)	0.0 (± 0.1)	(0 - 2)
Small insertions	5842 (1.8%)	2143 (36.7%)	1951 (33.4%)	1748 (29.9%)	37.2 (± 18.7)	(0 - 140)	14.1 (± 10.1)	(0 - 77)	5.1 (± 5.1)	(0 - 38)
Small deletions	14231 (4.5%)	5410 (38.0%)	5502 (38.7%)	3319 (23.3%)	15.3 (± 8.7)	(0 - 89)	5.6 (± 3.9)	(0 - 31)	14.4 (± 11.8)	(0 - 73)

* As described in the Materials and Methods, cancer cell fraction reflects the variant allele fraction, accounting for the purity of the tumor sample. Clonal mutations were defined as those with cancer cell fraction ≥0.9, whereas subclonal mutations were defined as those with cancer cell fraction <0.6. Distributions of cancer cell fraction by mutation type are provided in Fig. S8.

Table S4. Relationship for selected molecular characteristics with radiation dose from ^{131}I exposure, age at papillary thyroid cancer, and sex.

Molecular characteristics †	Regression model*	Dose	Age at PTC	Sex
Simple somatic variants				
Total	Linear regression	5.4E-02	6.9E-07 ‡	5.9E-01
SNV	Linear regression	2.3E-02	3.2E-06 ‡	5.8E-01
Doublet	Linear regression	1.4E-01	2.7E-05 ‡	1.0E+00
Triplet	Logistic regression	6.8E-01	7.0E-01	6.9E-01
Small indels	Linear regression	2.6E-06 ‡	3.1E-15 ‡	9.2E-01
Small insertions	Linear regression	4.0E-01	1.5E-06 ‡	9.2E-01
Small deletions	Linear regression	8.0E-09 ‡	7.4E-16 ‡	1.0E+00
Indel:SNV ratio	Linear regression	9.5E-19 ‡	4.8E-02	1.3E-01
Insertion:SNV ratio	Linear regression	2.4E-03	5.9E-01	3.8E-01
Deletion:SNV ratio	Linear regression	4.9E-21 ‡	6.7E-03	1.6E-01
Microsatellite indels				
Total	Linear regression	9.8E-02	6.1E-02	1.2E-01
Insertion	Linear regression	8.2E-01	1.5E-01	2.9E-01
Deletion	Linear regression	2.1E-02	1.5E-01	2.3E-01
Total:SNV ratio	Linear regression	9.7E-03	3.5E-04 ‡	5.5E-01
Insertion:SNV ratio	Linear regression	1.5E-03	3.7E-04 ‡	5.9E-01
Deletion:SNV ratio	Linear regression	8.1E-01	1.7E-01	7.6E-01
SBS signatures				
Clock (SBS1,SBS5)	Linear regression	3.9E-02	9.1E-17 ‡	9.2E-01
SBS1	Linear regression	5.3E-01	1.9E-07 ‡	5.6E-01
SBS5	Linear regression	2.9E-02	6.8E-17 ‡	8.4E-01
APOBEC (SBS2,SBS13)	Proportional odds	8.9E-04	1.7E-01	8.0E-01
SBS2	Proportional odds	1.9E-03	3.8E-01	7.4E-01
SBS13	Proportional odds§	5.3E-02	3.4E-01	8.5E-01
SBS8	Linear regression	4.1E-01	4.3E-11 ‡	1.4E-01
SBS18	Proportional odds	4.8E-01	2.0E-08 ‡	5.6E-01
SBS23	Proportional odds	3.9E-01	3.5E-02	6.5E-01
SBS *de novo* A	Linear regression	9.6E-03	3.0E-19 ‡	8.9E-01
SBS *de novo* B	Linear regression	2.8E-01	2.2E-04 ‡	4.7E-01
SBS *de novo* C	Proportional odds§	2.2E-02	4.8E-01	9.6E-01
SBS *de novo* D	Proportional odds	2.0E-01	2.4E-05 ‡	9.9E-01
Indel signatures				
Clock (ID1,ID5)	Linear regression	1.6E-03	5.8E-09 ‡	1.0E+00
ID1	Linear regression	1.0E+00	6.9E-02	8.4E-01
ID5	Linear regression	1.3E-04 ‡	1.9E-09 ‡	9.2E-01
End-joining DNA repair (ID6,ID8)	Linear regression	1.5E-10 ‡	6.9E-05 ‡	8.9E-01
ID6	Proportional odds	9.4E-01	4.8E-01	3.0E-01
ID8	Linear regression	7.3E-09 ‡	6.6E-04 ‡	8.2E-01
ID3	Linear regression	7.8E-01	1.9E-07 ‡	1.0E+00
ID4	Proportional odds	5.9E-01	3.1E-02	6.2E-01
Indel *de novo* A	Linear regression	4.5E-07 ‡	9.4E-13 ‡	8.4E-01
Indel *de novo* B	Linear regression	7.9E-01	2.0E-02	7.1E-01
Fusion vs. mutation PTC driver	Logistic regression	6.6E-08 ‡	5.4E-09 ‡	2.0E-01
Structural variants				
Total	Proportional odds	1.4E-08 ‡	4.9E-04 ‡	7.2E-01
Simple/balanced	Proportional odds	1.2E-14 ‡	4.2E-06 ‡	1.9E-02
Complex	Proportional odds	5.2E-01	7.5E-01	7.3E-02
Simple/unbalanced	Proportional odds	5.6E-03	4.2E-01	1.5E-01
Chromoplexy	Logistic regression	7.0E-01	2.3E-01	2.9E-01
Somatic copy number alterations				
Total	Proportional odds	2.0E-03	4.7E-02	3.3E-02
Chromosomal (aneuploidy)	Logistic regression	2.0E-01	9.6E-01	7.1E-01

Sub-chromosome, total	Proportional odds	3.5E-05 ‡	4.8E-02	1.2E-02
Deletions	Proportional odds	7.0E-04 ‡	2.2E-02	6.6E-03
Gains	Logistic regression	3.2E-01	4.7E-01	4.3E-01
CNLOH	Logistic regression	5.2E-01	2.4E-01	3.1E-01
22q deletion	Logistic regression	3.7E-01	7.6E-01	7.4E-01
Unsupervised clustering analyses				
mRNA (k=5)‖	Polytomous regression	8.5E-01	9.6E-01	1.8E-01
miRNA (k=5)‖	Polytomous regression	3.8E-01	6.7E-01	8.8E-01
Methylation (k=3)‖	Polytomous regression	1.0E-01	8.1E-01	‖
BRAF-RAS score (BRS)				
mRNA BRS	Linear regression	2.1E-03	1.6E-01	4.4E-01
miRNA BRS	Linear regression	5.5E-03	8.4E-01	4.1E-01
Methylation BRS	Linear regression	8.2E-02	1.0E+00	4.3E-01
ERK-activity score	Linear regression	1.1E-02	5.9E-01	4.7E-01
Thyroid differentiation score	Linear regression	7.8E-03	6.8E-01	2.2E-01
Germline variants ¶				
Nature 2014 CSGs	Logistic regression	6.0E-01	9.4E-01	4.9E-01
Clinical radiation sensitivity syndromes	Logistic regression	7.6E-01	7.8E-01	6.5E-01
Any DNA damage response gene	Logistic regression	2.5E-01	2.9E-01	7.0E-01
Single strand break repair	Logistic regression	4.8E-01	3.5E-01	5.2E-01
Double strand break repair	Logistic regression	1.1E-01	6.1E-01	8.0E-01
Fanconi anemia	Logistic regression	7.1E-01	4.8E-01	9.8E-01
Homologous recombination	Logistic regression	6.1E-01	5.1E-01	5.4E-01
Polygenic risk score	Linear regression	4.7E-04 ‡	9.0E-02	7.3E-02

Abbreviation: cancer susceptibility gene (CSG).

* P-values were generated using likelihood ratio tests, comparing model fit with and without the variable of interest (dose, age at PTC, sex), based on multivariable generalized linear, proportional odds, or logistic regression models, depending on the distribution of the molecular characteristic. All models were mutually adjusted for radiation dose (linear, truncated at 1 Gy), age at PTC, and sex, unless otherwise noted below.

† Methods for defining each characteristic are described in the Materials and Methods.

‡ Associations of selected molecular characteristics with radiation dose with $P<7.4\times10^{-4}$ were considered statistically significant based on a Bonferroni correction for the 68 characteristics listed above.

§ Dose was modeled as a ordinal variable based on the means of the categories shown in Table S1 because models with the linear dose variable did not converge.

‖ Models were restricted to strata with >10 cases (mRNA: N=3, miRNA: N=2; see Table S11). Models of methylation clusters did not converge with sex in the model and thus included only radiation dose and age at PTC.

¶ Details regarding the germline variants are provided in the Materials and Methods and Tables S16-S17. Selected variables include those with >25 carriers of potentially protein damaging rare variants. All models of germline variants were additionally adjusted for population substructure (top 10 principal components).

Table S5. Fraction of mutations attributed to specific ID or SBS signatures and correlation amongst different signatures among N=356 tumors with high purity and available whole genome sequencing data (n=66 when restricted to dose ≥200 mGy).

Pearson correlation (black font), P (gray font); light red shading indicates |r|>0.4

Signature	Mutation count	Mutation fraction	Known ID signatures from COSMIC v3*								de novo ID signatures		de novo ID signatures (dose ≥200 mGy)		Known SBS signatures from COSMIC v3*										de novo SBS signatures				de novo SBS signatures (dose ≥200 mGy)
			ID3	ID4	Clock	ID1	ID5	End joining	ID6	ID8	A	B	A	B	SBS8	SBS18	SBS23	Clock	SBS1	SBS5	APOBEC	SBS2	SBS13	A	B	C	D	A
Known ID signatures from COSMIC v3*																													
ID3	4138	21.2%																											
ID4	1135	5.8%	0.17																										
			1.53E-03																										
Clock	10535	54.0%	0.01	-0.08																									
			0.823	*0.136*																									
ID1	2773	14.2%	0.12	0.00	0.56																								
			0.023	*0.982*	*6.83E-31*																								
ID5	7762	39.8%	-0.05	-0.10	0.89	0.13																							
			0.336	*0.072*	*8.47E-126*	*0.013*																							
EJ	3718	19.0%	0.14	0.08	0.39	0.08	0.42																						
			0.008	*0.149*	*2.60E-14*	*0.112*	*1.11E-18*																						
ID6	639	3.3%	0.04	0.03	0.05	0.14	-0.01	0.11																					
			0.509	*0.525*	*0.326*	*0.009*	*0.820*	*0.031*																					
ID8	3079	15.8%	0.12	0.06	0.35	0.02	0.40	0.90	-0.33																				
			0.025	*0.274*	*1.62E-11*	*0.708*	*1.75E-15*	*2.72E-139*	*2.20E-10*																				
de novo ID signatures																													
A	12536	64.2%	0.41	0.23	0.49	-0.19	0.69	0.70	-0.01	0.67																			
			3.90E-16	*1.21E-05*	*9.48E-23*	*3.79E-04*	*7.04E-51*	*2.17E-54*	*0.858*	*2.90E-48*																			
B	6990	35.8%	0.18	0.08	0.56	0.97	0.14	0.11	0.17	0.03	-0.16																		
			4.97E-04	*0.118*	*3.43E-30*	*2.39E-213*	*0.007*	*0.045*	*0.002*	*0.609*	*0.003*																		
de novo ID signatures (restricted to cases with dose ≥200 mGy)																													
A	2426	62.2%	0.26	0.01	0.67	-0.10	0.76	0.88	-0.08	0.88	0.94	-0.11																	
			0.035	*0.906*	*6.28E-70*	*0.416*	*1.32E-13*	*1.15E-22*	*0.503*	*1.45E-23*	*4.90E-32*	*0.364*																	
B	1476	37.8%	0.27	0.10	0.10	0.73	-0.11	-0.31	0.21	-0.37	-0.29	0.75	-0.52																
			0.027	*0.402*	*0.439*	*2.61E-12*	*0.398*	*0.011*	*0.087*	*0.002*	*0.020*	*2.81E-13*	*8.03E-06*																
Known SBS signatures from COSMIC v3*																													
SBS8	43397	15.1%	0.38	0.01	0.42	0.26	0.36	0.22	0.06	0.18	0.37	0.28	0.33	0.26															
			1.86E-13	*0.795*	*0.000*	*4.80E-07*	*1.19E-12*	*3.97E-05*	*0.270*	*0.001*	*6.54E-13*	*6.68E-08*	*0.007*	*0.032*															
SBS18	2632	0.9%	-0.02	0.03	-0.02	0.05	-0.06	-0.01	0.04	-0.03	-0.07	0.07	-0.14	0.04	-0.33														
			0.745	*0.533*	*0.655*	*0.354*	*0.300*	*0.855*	*0.467*	*0.623*	*0.200*	*0.215*	*0.271*	*0.758*	*2.04E-10*														
SBS23	4532	1.6%	0.13	0.04	0.18	0.18	0.12	0.10	-0.02	0.11	0.10	0.20	0.04	0.17	0.29	0.03													
			0.016	*0.483*	*0.001*	*0.001*	*0.021*	*0.035*	*0.668*	*0.044*	*0.071*	*9.88E-05*	*0.728*	*0.172*	*1.80E-08*	*0.564*													
Clock	201505	69.9%	0.44	0.18	0.56	0.26	0.53	0.37	0.07	0.32	0.58	0.31	0.44	0.25	0.43	-0.06	0.02												
			3.79E-18	*0.001*	*2.14E-30*	*5.91E-07*	*9.96E-27*	*4.35E-13*	*0.198*	*4.20E-16*	*2.99E-33*	*2.67E-09*	*2.60E-04*	*0.039*	*1.31E-17*	*0.242*	*0.700*												
SBS1	28137	9.8%	0.40	0.13	0.56	0.42	0.44	0.26	0.05	0.23	0.40	0.46	0.29	0.42	0.52	0.06	0.24	0.71											
			8.72E-15	*0.011*	*1.07E-30*	*1.82E-16*	*1.18E-18*	*4.34E-07*	*0.309*	*1.47E-05*	*6.50E-15*	*2.97E-20*	*0.019*	*0.0003*	*2.54E-26*	*0.297*	*2.92E-06*	*2.57E-55*											
SBS5	173368	60.2%	0.42	0.18	0.53	0.22	0.51	0.37	0.07	0.32	0.58	0.27	0.44	0.22	0.39	-0.08	-0.02	0.99	0.62										
			9.24E-17	*0.001*	*9.53E-27*	*2.55E-05*	*4.58E-25*	*6.59E-13*	*0.207*	*5.41E-16*	*5.54E-33*	*3.21E-07*	*0.0002*	*0.077*	*1.23E-14*	*0.142*	*0.745*	*0.00E+00*	*2.52E-39*										
APOBEC	36115	12.5%	0.08	0.13	-0.06	-0.07	-0.04	0.01	0.02	-0.004	0.06	-0.06	0.05	-0.04	-0.29	-0.08	-0.13	0.12	0.04	0.13									
			0.116	*0.013*	*0.243*	*0.199*	*0.481*	*0.905*	*0.668*	*0.941*	*0.242*	*0.291*	*0.677*	*0.762*	*3.32E-08*	*0.130*	*0.015*	*0.020*	*0.188*	*0.011*									
SBS2	17780	6.2%	0.08	0.14	-0.05	-0.06	-0.02	0.02	0.02	0.01	0.07	-0.04	0.09	-0.04	-0.28	-0.08	-0.13	0.14	0.05	0.14	0.98								
			0.141	*0.008*	*0.380*	*0.280*	*0.640*	*0.715*	*0.730*	*0.854*	*0.167*	*0.398*	*0.495*	*0.750*	*1.35E-07*	*0.129*	*0.013*	*0.010*	*0.342*	*0.007*	*9.18E-254*								
SBS13	18335	6.4%	0.07	0.12	-0.07	-0.08	-0.05	-0.01	0.02	-0.02	0.05	-0.06	0.00	-0.02	-0.29	-0.08	-0.12	0.11	0.02	0.11	0.99	0.93							
			0.164	*0.022*	*0.166*	*0.154*	*0.373*	*0.929*	*0.642*	*0.766*	*0.344*	*0.252*	*0.974*	*0.843*	*2.67E-08*	*0.143*	*0.021*	*0.043*	*0.656*	*0.030*	*1.52E-274*	*8.38E-160*							
de novo SBS signatures																													
A	140368	48.7%	0.38	0.14	0.45	0.15	0.46	0.33	0.07	0.29	0.54	0.19	0.41	0.15	0.48	-0.17	0.06	0.90	0.43	0.92	0.10	0.10	0.10						
			5.11E-14	*0.009*	*2.58E-19*	*0.095*	*3.87E-20*	*1.32E-10*	*0.212*	*3.66E-08*	*2.54E-28*	*4.31E-01*	*0.001*	*0.217*	*3.49E-22*	*0.001*	*0.222*	*6.67E-128*	*1.46E-17*	*1.34E-150*	*0.065*	*0.069*	*0.070*						
B	97010	33.7%	0.35	0.06	0.49	0.41	0.37	0.22	0.04	0.19	0.31	0.44	0.26	0.45	0.63	0.18	0.32	0.47	0.83	0.38	-0.38	-0.36	-0.38	0.20					
			8.67E-12	*0.226*	*3.63E-33*	*1.30E-15*	*5.15E-13*	*2.92E-05*	*0.431*	*3.00E-04*	*3.07E-09*	*1.79E-18*	*0.035*	*0.0002*	*3.13E-40*	*0.001*	*6.50E-10*	*8.51E-21*	*9.27E-92*	*6.37E-14*	*1.28E-13*	*1.30E-12*	*1.06E-13*	*1.49E-04*					
C	25527	8.9%	0.07	0.12	-0.07	-0.08	-0.04	0.002	0.03	-0.01	0.06	-0.07	0.09	-0.13	-0.29	-0.08	-0.11	0.11	0.02	0.12	0.98	0.93	1.00	0.11	-0.39				
			0.174	*0.020*	*0.194*	*0.132*	*0.488*	*0.969*	*0.627*	*0.861*	*0.269*	*0.210*	*0.494*	*0.305*	*2.63E-08*	*0.126*	*0.030*	*0.031*	*0.764*	*0.019*	*1.21E-251*	*4.05E-123*	*0.00E+00*	*0.057*	*1.61E-14*				
D	25276	8.8%	0.13	0.16	0.04	-0.01	0.05	0.08	0.02	0.06	0.15	0.01	0.22	0.07	-0.17	-0.08	-0.09	0.23	0.15	0.23	0.89	0.95	0.81	0.16	-0.26	0.79			
			0.015	*0.003*	*0.491*	*0.842*	*0.350*	*0.143*	*0.644*	*0.735*	*0.005*	*0.899*	*0.079*	*0.595*	*0.001*	*0.151*	*0.106*	*8.89E-68*	*0.006*	*7.79E-06*	*1.72E-177*	*1.08E-183*	*7.54E-83*	*0.002*	*7.60E-07*	*1.58E-78*			
de novo SBS signatures (restricted to cases with dose ≥200 mGy)																													
A	37095	84.0%	0.54	0.11	0.53	0.35	0.47	0.29	0.04	0.27	0.50	0.36	0.36	0.29	0.76	-0.07	0.16	0.74	0.73	0.72	-0.42	-0.42	-0.37	0.69	0.76	-0.35	-0.09		
			2.55E-06	*0.382*	*5.44E-06*	*0.004*	*6.07E-05*	*0.017*	*0.728*	*0.029*	*1.69E-05*	*0.003*	*0.003*	*0.017*	*1.78E-13*	*0.590*	*0.195*	*9.06E-13*	*3.88E-12*	*1.46E-11*	*4.35E-04*	*0.001*	*0.002*	*1.06E-10*	*1.14E-13*	*0.004*	*0.473*		
B	7055	16.0%	-0.11	-0.16	0.14	0.07	0.13	0.15	0.03	0.13	0.07	0.04	0.08	-0.02	-0.11	-0.15	-0.22	0.28	0.04	0.30	0.98	0.98	0.84	0.27	-0.15	0.70	0.85	-0.40	
			0.393	*0.202*	*0.279*	*0.589*	*0.308*	*0.239*	*0.823*	*0.287*	*0.372*	*0.726*	*0.531*	*0.875*	*0.350*	*0.224*	*0.076*	*0.025*	*0.768*	*0.014*	*1.35E-46*	*5.32E-50*	*8.08E-19*	*0.028*	*0.222*	*4.14E-11*	*1.32E-19*	*0.061*	

* Catalogue of Somatic Mutations in Cancer (COSMIC) v3, https://cancer.sanger.ac.uk/cosmic/signatures

Table S6. Distribution of structural variants and somatic copy number alterations by type and clonality.

Event	Total n (column %)	By clonality: Clonal n (row %)	By clonality: Subclonal n (row %)
Structural variant events (Total)			
Total	479 (100.0%)	259 (54.1%)	220 (45.9%)
Simple/balanced	132 (27.6%)	106 (80.3%)	26 (19.7%)
Complex	94 (19.6%)	66 (70.2%)	28 (29.8%)
Simple/unbalanced	253 (52.8%)	87 (34.4%)	166 (65.6%)
Structural variant events (excluding 2 PTC cases with >10 SVs)			
Total	450 (100.0%)	240 (53.3%)	210 (46.7%)
Simple/balanced	125 (27.8%)	100 (80.0%)	25 (20.0%)
Complex	83 (18.4%)	60 (72.3%)	23 (27.7%)
Simple/unbalanced	242 (53.8%)	80 (33.1%)	162 (66.9%)
Confirmed structural variant events (Total)			
Total	309 (100.0%)	227 (73.5%)	82 (26.5%)
Simple/balanced	139 (45.0%)	110 (79.1%)	29 (20.9%)
<20 bp intervening loss/gain	91 (29.4%)	88 (96.7%)	3 (3.3%)
<4 bp intervening loss/gain	45 (14.6%)	43 (95.6%)	2 (4.4%)
4-<20 bp intervening loss/gain	46 (14.9%)	45 (97.8%)	1 (2.2%)
Inversion	52 (30.2%)	50 (96.2%)	2 (3.8%)
Translocation	39 (22.7%)	38 (97.4%)	1 (2.6%)
Complex	90 (29.1%)	61 (67.8%)	29 (32.2%)
Simple/unbalanced	80 (25.9%)	56 (70.0%)	24 (30.0%)
Confirmed structural variant events, excluding SV/fusion drivers			
Total	172 (100.0%)	99 (57.6%)	73 (42.4%)
Simple/balanced	58 (33.7%)	34 (58.6%)	24 (41.4%)
<20 bp intervening loss/gain	26 (15.1%)	23 (88.5%)	3 (11.5%)
<4 bp intervening loss/gain	15 (8.7%)	13 (86.7%)	2 (13.3%)
4-<20 bp intervening loss/gain	11 (6.4%)	10 (90.9%)	1 (9.1%)
Inversion	19 (11.0%)	17 (89.5%)	2 (10.5%)
Translocation	7 (4.1%)	6 (85.7%)	1 (14.3%)
Complex	45 (26.2%)	18 (40.0%)	27 (60.0%)
Simple/unbalanced	69 (40.1%)	47 (68.1%)	22 (31.9%)
Confirmed structural variant events, restricted to SV/fusion drivers			
Total	137 (100.0%)	128 (93.4%)	9 (6.6%)
Simple/balanced	81 (59.1%)	76 (93.8%)	5 (6.2%)
<20 bp intervening loss/gain	65 (47.4%)	65 (100.0%)	0 (0.0%)
<4 bp intervening loss/gain	30 (21.9%)	30 (100.0%)	0 (0.0%)
4-<20 bp intervening loss/gain	35 (25.5%)	35 (100.0%)	0 (0.0%)
Inversion	33 (19.2%)	33 (100.0%)	0 (0.0%)
Translocation	32 (18.6%)	32 (100.0%)	0 (0.0%)
Complex	45 (32.8%)	43 (95.6%)	2 (4.4%)
Simple/unbalanced	11 (8.0%)	9 (81.8%)	2 (18.2%)
Somatic copy number alterations (Total)			
Total	326 (100.0%)	248 (76.1%)	78 (23.9%)
Chromosome level (aneuploidy)			
Total	132 (40.5%)	113 (85.6%)	19 (14.4%)
Deletions	48 (14.7%)	33 (68.8%)	15 (31.3%)
Gains	65 (19.9%)	61 (93.8%)	4 (6.2%)

CNLOH	19 (5.8%)	19 (100.0%)	0 (0.0%)
Sub-chromosome level (DNA double strand breaks)			
Total	194 (59.5%)	135 (69.6%)	59 (30.4%)
Deletions	115 (35.3%)	96 (83.5%)	19 (16.5%)
Gains	60 (18.4%)	28 (46.7%)	32 (53.3%)
CNLOH	19 (5.8%)	11 (57.9%)	8 (42.1%)
Somatic copy number alterations (excluding 4 PTC cases with ≥20 SCNAs each)			
Total	239 (100.0%)	165 (69.0%)	74 (31.0%)
Chromosome level (aneuploidy)			
Total	69 (28.9%)	50 (72.5%)	19 (27.5%)
Deletions	48 (20.1%)	33 (68.8%)	15 (31.3%)
Gains	20 (8.4%)	16 (80.0%)	4 (20.0%)
CNLOH	1 (0.4%)	1 (100.0%)	0 (0.0%)
Sub-chromosome level (DNA double strand breaks)			
Total	170 (71.1%)	115 (67.6%)	55 (32.4%)
Deletions	106 (44.4%)	87 (82.1%)	19 (17.9%)
Gains	51 (21.3%)	23 (45.1%)	28 (54.9%)
CNLOH	13 (5.4%)	5 (38.5%)	8 (61.5%)

Table S7. Designated and candidate drivers for N=440 PTCs included in the study.

Driver gene	Designated driver*	Additional candidate driver	n
Mutations			
BRAF	*BRAF* ^{V600E}		175
BRAF	*BRAF* ^{V600E}	*AKT1*	2
BRAF	*BRAF* ^{V600E}	*PIK3R1*	2
BRAF	*BRAF* ^{V600E}	*ARID2*	1
BRAF	*BRAF* ^{V600E}	*BCOR*	1
BRAF	*BRAF* ^{V600E}	*CR2*	1
BRAF	*BRAF* ^{V600E}	*FAT3*	1
BRAF	*BRAF* ^{V600E}	*GPC3*	1
BRAF	*BRAF* ^{V600E}	*MTOR*	1
BRAF	*BRAF* ^{V600E}	*PIK3CA*	1
BRAF	*BRAF* ^{V600E}	*RET*	1
BRAF	*BRAF* ^{V600E}	*RGS7*	1
BRAF	*BRAF* ^{V600E}	*SETD2*	1
BRAF	*BRAF* ^{V600E}	*TSHR*	1
BRAF	*BRAF* $^{Non\text{-}V600E}$		3
BRAF	*BRAF* $^{Non\text{-}V600E}$	*PTEN-PXT1* fusion	1
NRAS	*NRAS*		15
NRAS	*NRAS*	*SETD2*	1
NRAS	*NRAS*	*SF3B1*	1
NRAS	*NRAS*	*TP53*	1
NRAS	*NRAS*	*NEBL-TCF7L2* fusion	1
NRAS	*NRAS*	*PAX8-PPARG* fusion	1
HRAS	*HRAS*		14
HRAS	*HRAS*	*TP53*	1
KRAS	*KRAS*		8
KRAS	*KRAS*	*AKT1*	1
TSHR	*TSHR*		6
DICER1	*DICER1*		3
APC	*APC*		2
NFE2L2	*NFE2L2*		1
NFE2L2	*NFE2L2*	*GPHN-RAF1* fusion	1
TSC1	*TSC1*		1
TSC2	*TSC2*		1
Fusions			
RET	*CCDC6-RET*		39
RET	*CCDC6-RET*	*PIK3R1*	1
RET	*NCOA4-RET*		14
RET	*NCOA4-RET*	*SETD2*	1
RET	*RET* -Other		18
NTRK3	*ETV6-NTRK3*		31
NTRK3	*ETV6-NTRK3*	*CR2*	1
NTRK3	*NTRK3* -Other		3
NTRK3	*NTRK3* -Other	*BCOR*	1
BRAF	*AGK-BRAF*		6
BRAF	*BRAF-SND1*		4
BRAF	*BRAF* -Other		9
NTRK1	*NTRK1-TPR*		5
NTRK1	*NTRK1-TPM3*		4
NTRK1	*NTRK1* -Other		4
PPARG	*CREB3L2-PPARG*		6
PPARG	*PAX8-PPARG*		5
PPARG	*PAX8-PPARG*	*CR2*	1
PPARG	*PPARG* -Other		1
ALK	*ALK-STRN*		6
ALK	*ALK-STRN*	*H3F3B*	1
ALK	*ALK-STRN*	*PTPRT*	1
ALK	*ALK* -Other		4
LTK	*LTK* -Other		3
Structural variants			
BRAF	*BRAF*		1
IGF2	*IGF2*		2
IGF2BP3	*IGF2BP3*		4
Not designated			
~	~	*BRAF*, Other; *KRAS*	1
~	~		7
~	~	*CTTNBP2-MET* fusion	1
~	~	*CCDC30-ROS1* fusion	1
~	~	*NUTM1-WHSC1L1* fusion	1

~ Indicates not applicable.

* Rules for specifying designated and candidate drivers are provided in the Materials and Methods.

Table S8. Distribution of designated mutation drivers, by mutation type and gene.

	Oncogenic mutation driver type				Tumor suppressor mutation driver types			
Gene	SNV	Doublet	Insertion	Deletion	SNV+SCNA	SNV+Deletion	Deletion+SCNA	Total
Oncogenes								
BRAF ^{V600E}	190	0	0	0				190
BRAF $^{Non\text{-}V600E}$	2	0	1	1				4
NRAS	20	0	0	0				20
HRAS	14	1	0	0				15
KRAS	3	6	0	0				9
TSHR	6	0	0	0				6
NFE2L2	2	0	0	0				2
Tumor suppressor genes								
DICER1					0	3	0	3
APC					1	0	1	2
TSC1					0	0	1	1
TSC2					0	1	0	1
Total	237	7	1	1	1	4	2	253

Table S9. Distribution of designated fusion or structural variant drivers, by oncogene and fusion partner.

Oncogene	Fusion*	n
Fusions		
RET	*CCDC6-RET* (*RET-PTC1*)	40
RET	*NCOA4-RET* (*RET-PTC3*)	15
RET	*RET*-Other*	18
NTRK3	*ETV6-NTRK3*	32
NTRK3	*NTRK3* -Other*	4
BRAF	*AGK-BRAF*	6
BRAF	*BRAF-SND1*	4
BRAF	*BRAF* -Other*	9
PPARG	*PAX8-PPARG*	6
PPARG	*CREB3L2-PPARG*	6
PPARG	*PPARG*-Other*	1
NTRK1	*NTRK1-TPR*	5
NTRK1	*NTRK1-TPM3*	4
NTRK1	*NTRK1* -Other*	4
ALK	*ALK-STRN*	8
ALK	*ALK*-Other*	4
LTK	*LTK*-Other*	3
Structural variants		
BRAF	*BRAF* , Large deletion	1
IGF2BP3	*IGF2BP3*	4
IGF2	*IGF2*	2

* All recurrent fusions are listed separately; a full list of fusion partners, including those for fusions that occurred only once in our dataset, is provided in Data S1.

Table S10. Distribution of 22q deletions by driver type and pathway.

	22q deletion		
	No	Yes	
	n (%)	n (%)	$P_{heterogeneity}$*
Driver type			
Fusion	125 (83.3%)	13 (8.7%)	0.07
Mutation	178 (79.1%)	34 (15.1%)	
Driver pathway			
Fusion, *RET*	50 (82.0%)	2 (3.3%)	2.8E-10
Fusion, Other *RTK*	49 (87.5%)	7 (12.5%)	
Fusion, *BRAF*	15 (75.0%)	3 (15.0%)	
Fusion, *PPARG*	8 (88.9%)	0 (0.0%)	
Fusion, *IGF2/IGF2BP3*	3 (75.0%)	1 (25.0%)	
Mutation, *BRAF*	152 (86.9%)	12 (6.9%)	
Mutation, *RAS*	16 (41.0%)	22 (56.4%)	
Mutation, Other	10 (90.9%)	0 (0.0%)	

*$P_{heterogeneity}$ computed using a likelihood ratio test, comparing logistic regression model fit with and without the variable of interest.

Table S11. Distribution of mRNA, miRNA, and methylation clusters from unsupervised clustering analyses, by radiation dose and PTC driver.

		By radiation dose (mGy)					Total with designated driver	By PTC driver							
Cluster number	Total n (%)	0 n (%)	1-99 n (%)	100-199 n (%)	200-499 n (%)	≥500 n (%)	n (%)	Fusion, *RET* n (%)	Fusion, Other *RTK* n (%)	Fusion, *BRAF* n (%)	Fusion, *PPARG* n (%)	Fusion, *IGF2/IGF2BP3* n (%)	Mutation, *BRAF* n (%)	Mutation, *RAS* n (%)	Mutation, Other n (%)
mRNA															
1	323 (79.0%)	55 (77.5%)	145 (80.6%)	67 (77.9%)	32 (80.0%)	24 (75.0%)	320 (79.4%)	62 (100.0%)	58 (95.1%)	14 (77.8%)	0 (0.0%)	0 (0.0%)	182 (98.4%)	3 (6.8%)	1 (7.1%)
2	69 (16.9%)	14 (19.7%)	28 (15.6%)	16 (18.6%)	5 (12.5%)	6 (18.8%)	66 (16.4%)	0 (0.0%)	3 (4.9%)	4 (22.2%)	0 (0.0%)	6 (100.0%)	3 (1.6%)	41 (93.2%)	9 (64.3%)
3	2 (0.5%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.1%)	2 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (14.3%)
4	13 (3.2%)	1 (1.4%)	7 (3.9%)	3 (3.5%)	1 (2.5%)	1 (3.1%)	13 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	13 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
5	2 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.0%)	0 (0.0%)	2 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (14.3%)
Total	409 (100.0%)	71 (100.0%)	180 (100.0%)	86 (100.0%)	40 (100.0%)	32 (100.0%)	403 (100.0%)	62 (100.0%)	61 (100.0%)	18 (100.0%)	13 (100.0%)	6 (100.0%)	185 (100.0%)	44 (100.0%)	14 (100.0%)
miRNA															
1	383 (94.6%)	65 (91.5%)	170 (96.6%)	81 (95.3%)	37 (90.2%)	30 (93.8%)	378 (94.7%)	62 (98.4%)	61 (100.0%)	17 (100.0%)	11 (84.6%)	3 (50.0%)	182 (100.0%)	38 (88.4%)	4 (28.6%)
2	1 (0.2%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3	17 (4.2%)	3 (4.2%)	5 (2.8%)	4 (4.7%)	4 (9.8%)	1 (3.1%)	16 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (15.4%)	2 (33.3%)	0 (0.0%)	5 (11.6%)	7 (50.0%)
4	3 (0.7%)	3 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (21.4%)
5	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.1%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	405 (100.0%)	71 (100.0%)	176 (100.0%)	85 (100.0%)	41 (100.0%)	32 (100.0%)	399 (100.0%)	63 (100.0%)	61 (100.0%)	17 (100.0%)	13 (100.0%)	6 (100.0%)	182 (100.0%)	43 (100.0%)	14 (100.0%)
Methylation															
1	252 (61.5%)	48 (66.7%)	115 (63.2%)	51 (60.7%)	24 (57.1%)	14 (46.7%)	250 (61.9%)	49 (76.6%)	47 (73.4%)	9 (50.0%)	0 (0.0%)	0 (0.0%)	140 (76.5%)	5 (11.4%)	0 (0.0%)
2	101 (24.6%)	13 (18.1%)	45 (24.7%)	17 (20.2%)	14 (33.3%)	12 (40.0%)	98 (24.3%)	15 (23.4%)	17 (26.6%)	9 (50.0%)	6 (50.0%)	1 (20.0%)	40 (21.9%)	9 (20.5%)	1 (7.1%)
3	57 (13.9%)	11 (15.3%)	22 (12.1%)	16 (19.0%)	4 (9.5%)	4 (13.3%)	56 (13.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (50.0%)	4 (80.0%)	3 (1.6%)	30 (68.2%)	13 (92.9%)
Total	410 (100.0%)	72 (100.0%)	182 (100.0%)	84 (100.0%)	42 (100.0%)	30 (100.0%)	404 (100.0%)	64 (100.0%)	64 (100.0%)	18 (100.0%)	12 (100.0%)	5 (100.0%)	183 (100.0%)	44 (100.0%)	14 (100.0%)

Table S12. Pearson correlation coefficients among the scores constructed to reflect transcriptional patterns related to key signaling and thyroid differentiation pathways.

	Pearson correlation (black font), P (gray font), sample size (N, black font)				
	mRNA BRS, TCGA genes	mRNA BRS	miRNA BRS	Methylation BRS	ERK-activity score
mRNA BRS	0.98 2.9E-277 n=409				
miRNA BRS	0.83 4.0E-103 n=402	0.86 9.6E-117 n=402			
Methylation BRS	0.94 2.7E-191 n=402	0.92 3.5E-166 n=402	0.78 2.5E-82 n=398		
ERK-activity score	-0.66 8.1E-52 n=409	-0.61 1.7E-43 n=409	-0.54 2.9E-31 n=402	-0.62 3.0E-44 n=402	
Thyroid differentiation score	0.69 5.7E-60 n=409	0.73 5.0E-68 n=409	0.61 1.8E-42 n=402	0.64 1.3E-47 n=402	-0.56 2.3E-35 n=409

Table S13. Results from differential expression modeling of individual genes.

Provided as a separate Excel file available on the *Science* website.

Table S14. Results from differential expression modeling for gene sets from the Molecular Signatures Database.

Provided as a separate Excel file available on the *Science* website.

Table S15. Relationship of germline SNPs with radiation dose from ^{131}I exposure, including the 12 SNPs that comprised the PRS.

			gnomAD genomes (n=12,857 individuals)					Meta-analysis results for PRS construction				Risk allele frequency								
			Alleles		Alternative allele frequency							Total	Radiation dose (mGy)					Effect size per 100 mGy		
SNP	Chr	Position†	Ref	Alt	NFE	EAS	AFR	Risk allele	Frequency	OR	(95% CI)	(n=383)	0 (n=78)	1-99 (n=165)	100-199 (n=73)	200-499 (n=36)	≥500 (n=31)	EOR	(95% CI)	P*
rs12129938	1	233412561	A	G	0.22	0.13	0.18	A	0.80	1.32	(1.20 , 1.43)	0.82	0.84	0.82	0.83	0.83	0.81	0.0004	(-0.06 , 0.14)	0.99
rs11693806	2	218292158	C	G	0.75	0.36	0.53	C	0.32	1.43	(1.33 , 1.54)	0.26	0.27	0.25	0.29	0.28	0.18	-0.05	(-0.08 , 0.02)	0.11
rs6793295	3	169518455	T	C	0.27	0.68	0.39	T	0.76	1.23	(1.15 , 1.33)	0.72	0.70	0.74	0.66	0.75	0.74	0.02	(-0.05 , 0.16)	0.70
rs10069690	5	1279790	C	T	0.27	0.15	0.59	T	0.28	1.20	(1.12 , 1.29)	0.29	0.31	0.28	0.32	0.29	0.21	-0.06	(-0.09 , 0.00)	0.054
rs73227498	5	111485904	A	T	0.14	0.02	0.08	A	0.87	1.37	(1.23 , 1.49)	0.91	0.92	0.92	0.90	0.93	0.90	-0.04	(-0.08 , 0.12)	0.46
rs2466076	8	32432796	G	T	0.53	0.85	0.54	G	0.48	1.32	(1.23 , 1.41)	0.56	0.56	0.56	0.55	0.67	0.48	-0.04	(-0.08 , 0.03)	0.20
rs1588635*	9	100537802	A	C	0.65	0.89	0.81	A	0.40	1.70	(1.59 , 1.82)	0.50	0.52	0.52	0.55	0.42	0.34	-0.11	(-0.18 , -0.02)	0.012
rs7902587	10	105694301	C	T	0.10	0.00	0.17	T	0.11	1.41	(1.27 , 1.56)	0.10	0.11	0.10	0.12	0.13	0.06	-0.05	(-0.09 , 0.08)	0.31
rs368187	14	36532576	G	C	0.45	0.55	0.76	G	0.58	1.39	(1.30 , 1.47)	0.58	0.59	0.59	0.56	0.61	0.53	-0.02	(-0.06 , 0.06)	0.57
rs116909374*	14	36738361	C	T	0.03	0.00	0.01	T	0.04	1.71	(1.47 , 2.00)	0.03	0.02	0.03	0.03	0.01	0.02	-0.10	(-0.16 , 0.19)	0.28
rs56062135	15	67455630	C	T	0.23	0.02	0.09	T	0.25	1.24	(1.16 , 1.34)	0.28	0.28	0.28	0.32	0.25	0.24	-0.04	(-0.07 , 0.04)	0.28
rs2289261	15	67457485	G	C	0.64	0.35	0.60	C	0.68	1.23	(1.15 , 1.32)	0.63	0.65	0.62	0.68	0.56	0.53	-0.06	(-0.08 , -0.01)	0.030

Abbreviations: African ancestry (AFR); alternate allele (alt); chromosome (chr); East Asian ancestry (EAS); non-Finnish European ancestry (NFE); referent allele (ref).

* Position from UCSC human genome assembly hg19.

† P-values were generated using likelihood ratio tests, comparing model fit with and without each SNP (modeled assuming an additive genetic effect), based on multivariable proportional odds models mutually adjusted for radiation dose (linear, truncated at 1 Gy), age at PTC, sex, and 10 principal components. Exceptions to this approach included use of logistic regression for rs116909374 because no individuals in our study were homozygous for the effect allele, and use of an ordinal dose variable (based on the means of the categories above) for rs1588635 because the linear EOR/Gy model would not converge.

Table S16. Distribution of rare potentially protein-damaging variants in selected gene sets or pathways in our study population, overall and by radiation dose, and in external reference population data from gnomAD.

	Number of alleles			Number of individuals					
	gnomAD NFE exomes (n=51,377 individuals)*	gnomAD NFE genomes (n=7718 individuals)*	Chernobyl Tissue Bank, Total (n=383 individuals)	Chernobyl Tissue Bank, Total (n=383)	Radiation dose (mGy) 0 (n=78)	1-99 (n=165)	100-199 (n=73)	200-499 (n=36)	≥500 (n=31)
Gene set or pathway†	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Thyroid susceptibility	156 (0.2%)	37 (0.2%)	4 (0.5%)	4 (1.0%)	2 (2.6%)	2 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cancer susceptibility	7509 (7.3%)	1248 (8.1%)	57 (7.4%)	50 (13.1%)	9 (11.5%)	22 (13.3%)	10 (13.7%)	3 (8.3%)	6 (19.4%)
Autosomal dominant cancer susceptibility	1520 (1.5%)	303 (2.0%)	15 (2.0%)	15 (3.9%)	4 (5.1%)	7 (4.2%)	2 (2.7%)	1 (2.8%)	1 (3.2%)
Clinical radiation sensitivity	4063 (4.0%)	689 (4.5%)	27 (3.5%)	26 (6.8%)	8 (10.3%)	8 (4.8%)	5 (6.8%)	3 (8.3%)	2 (6.5%)
DNA damage response, total	29952 (29.1%)	3822 (24.8%)	228 (29.8%)	172 (44.9%)	42 (53.8%)	65 (39.4%)	33 (45.2%)	21 (58.3%)	11 (35.5%)
Single strand break repair	13824 (13.5%)	1066 (6.9%)	43 (5.6%)	39 (10.2%)	8 (10.3%)	16 (9.7%)	5 (6.8%)	6 (16.7%)	4 (12.9%)
Base excision repair	11167 (10.9%)	567 (3.7%)	22 (2.9%)	19 (5.0%)	4 (5.1%)	8 (4.8%)	2 (2.7%)	3 (8.3%)	2 (6.5%)
Nucleotide excision repair	2183 (2.1%)	401 (2.6%)	16 (2.1%)	14 (3.7%)	3 (3.8%)	6 (3.6%)	2 (2.7%)	1 (2.8%)	2 (6.5%)
Mismatch repair	1056 (1.0%)	208 (1.3%)	6 (0.8%)	6 (1.6%)	2 (2.6%)	2 (1.2%)	2 (2.7%)	0 (0.0%)	0 (0.0%)
Direct repair	432 (0.4%)	58 (0.4%)	6 (0.8%)	6 (1.6%)	0 (0.0%)	2 (1.2%)	1 (1.4%)	2 (5.6%)	1 (3.2%)
Double strand break repair	9548 (9.3%)	1581 (10.2%)	101 (13.2%)	91 (23.8%)	22 (28.2%)	35 (21.2%)	22 (30.1%)	7 (19.4%)	5 (16.1%)
Fanconi anemia pathway	3545 (3.4%)	666 (4.3%)	44 (5.7%)	44 (11.5%)	12 (15.4%)	13 (7.9%)	12 (16.4%)	4 (11.1%)	3 (9.7%)
Homologous recombination	6245 (6.1%)	992 (6.4%)	54 (7.0%)	51 (13.3%)	14 (17.9%)	23 (13.9%)	6 (8.2%)	4 (11.1%)	4 (12.9%)
Non-homologous end joining	1541 (1.5%)	235 (1.5%)	15 (2.0%)	14 (3.7%)	5 (6.4%)	3 (1.8%)	5 (6.8%)	1 (2.8%)	0 (0.0%)
Translesion synthesis	1855 (1.8%)	309 (2.0%)	21 (2.7%)	21 (5.5%)	4 (5.1%)	8 (4.8%)	5 (6.8%)	1 (2.8%)	3 (9.7%)
Checkpoint factor	2390 (2.3%)	406 (2.6%)	27 (3.5%)	25 (6.5%)	6 (7.7%)	6 (3.6%)	7 (9.6%)	3 (8.3%)	3 (9.7%)
Chromatin remodeling	458 (0.4%)	75 (0.5%)	4 (0.5%)	4 (1.0%)	3 (3.8%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chromosome segregation	611 (0.6%)	120 (0.8%)	10 (1.3%)	9 (2.3%)	1 (1.3%)	5 (3.0%)	1 (1.4%)	2 (5.6%)	0 (0.0%)
Nucleotide pools	122 (0.1%)	26 (0.2%)	2 (0.3%)	2 (0.5%)	0 (0.0%)	1 (0.6%)	0 (0.0%)	0 (0.0%)	1 (3.2%)
p53 pathway	115 (0.1%)	15 (0.1%)	1 (0.1%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)
Telomere maintenance	1343 (1.3%)	204 (1.3%)	14 (1.8%)	13 (3.4%)	2 (2.6%)	6 (3.6%)	1 (1.4%)	4 (11.1%)	0 (0.0%)
Topoisomerase and topoisomerase damage reversal	114 (0.1%)	20 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ubiquitin response	525 (0.5%)	65 (0.4%)	6 (0.8%)	6 (1.6%)	2 (2.6%)	3 (1.8%)	0 (0.0%)	0 (0.0%)	1 (3.2%)

* Carrier frequencies from the gnomAD whole exome and whole genome sequencing are provided for reference only. Although the gnomAD data were restricted to individuals of non-Finnish European (NFE) descent, the methods are not directly comparable to the Chernobyl Tissue Bank samples due to likely differences in both the sequencing methods (for example capture kit, sequencing chemistries) and bioinformatics analysis (for example variants in gnomAD were only called using HaplotypeCaller and utilized different quality control filters). Additionally, note that gnomAD data are provided at the allelic rather than individual level.

† Details on the gene sets and pathways are provided in the Materials and Methods and Table S17.

Table S17. Distribution of rare potentially protein-damaging variants in selected genes in our study population, overall and by radiation dose, and in external reference population data from gnomAD.

Provided as a separate Excel file available on the *Science* website.

Table S18. Relationship between detailed molecular characteristics and radiation dose from ^{131}I exposure, separately for characteristics modeled using linear regression and logistic or proportional odds regression.

Molecular characteristics	Regression model*	Effect size (per 100 mGy)		P*
		β	(95% CI)	
Small deletions				
Total	Linear regression	2.16	(1.44 , 2.87)	8.0E-09
Subclonal	Linear regression	-0.06	(-0.57 , 0.45)	8.2E-01
Clonal	Linear regression	1.48	(1.06 , 1.89)	9.9E-12
Length: 1-4 base pairs	Linear regression	0.0094	(0.0062 , 0.013)	1.9E-08
Length: ≥5 base pairs (see proportional odds models below)				
Deletion:SNV ratio				
Total	Linear regression	0.0039	(0.0032 , 0.0047)	4.9E-21
Subclonal	Linear regression	0.0009	(0.0001 , 0.0017)	2.3E-02
Clonal	Linear regression	0.0071	(0.0056 , 0.0086)	1.8E-18
ID5				
Total	Linear regression	1.07	(0.53 , 1.61)	1.3E-04
Subclonal	Linear regression	-0.06	(-0.43 , 0.31)	7.4E-01
Clonal	Linear regression	0.72	(0.39 , 1.06)	2.3E-05
ID8				
Total	Linear regression	1.15	(0.77 , 1.54)	7.3E-09
Subclonal	Linear regression	0.08	(-0.14 , 0.29)	4.9E-01
Clonal	Linear regression	0.80	(0.60 , 1.00)	2.7E-14
		EOR	(95% CI)	
PTC driver type				
Fusion vs. mutation PTC driver	Logistic regression	0.93	(0.37 , 2.11)	6.6E-08
Sub-chromosome somatic copy number deletions				
Total	Proportional odds	0.23	(0.07 , 0.51)	7.0E-04
Subclonal	Logistic regression	0.29	(-0.05 , 2.39)	1.7E-01
Clonal	Proportional odds	0.19	(0.03 , 0.48)	9.7E-03
Confirmed SVs†				
Total simple/balanced	Proportional odds	2.09	(0.89 , 5.07)	2.5E-13
Subclonal simple/balanced	Logistic regression	0.01	(-0.08 , 0.31)	9.1E-01
Clonal simple/balanced	Proportional odds	4.65	(1.81 , 12.98)	1.4E-16
Clonal simple/balanced/EJ	Logistic regression	18.81	(5.07 , 94.61)	5.5E-19
<4 bp intervening loss/gain	Logistic regression‡	7.84	(>0 , 150)	2.0E-08
≥4 bp intervening loss/gain	Logistic regression	3.61	(0.86 , 24.44)	6.1E-08
Inversion	Logistic regression	21.42	(3.98 , 400)	3.6E-14
Translocation	Logistic regression	0.74	(0.17 , 3.24)	4.4E-04
Clonal non-simple/balanced/EJ	Proportional odds	0.04	(-0.04 , 0.18)	4.1E-01
Clonal deletions, Length: ≥5 bp	Proportional odds	0.56	(0.38 , 0.79)	5.1E-29
Patterns consistent with EJ				
Total	Proportional odds	0.61	(0.42 , 0.86)	4.9E-31
0-1 bp microhomology at the deletion boundary	Proportional odds	0.54	(0.33 , 0.84)	1.3E-18
≥2 bp microhomology at the deletion boundary	Proportional odds	0.48	(0.27 , 0.80)	3.6E-13

Clonality of ID-EJ (ID6, ID8 combined) was not considered because no ID6 mutations were identified when the analyses were restricted to clonal mutations.

* P-values and effect estimates were derived from multivariable generalized linear, proportional odds, or logistic regression models, depending on the distribution of the molecular characteristic. All models were mutually adjusted for radiation dose (linear, truncated at 1 Gy), age at PTC, and sex.

† Analyses were restricted to confirmed SVs, as described in the Materials and Methods and Table S6.

‡ Lower bound would not converge.

Table S19. Analyses of genomic locus-based attributes for small insertions and deletions.

Attribute	Unexposed		1-99 mGy		100-199 mGy		200-499 mGy		≥500 mGy		
	β	P	β	P	β	P	β	P	β	P	P_{trend}
Insertions											
Replication timing	-0.005	3.79E-03	-0.006	1.78E-07	-0.006	1.22E-03	-0.003	0.30	-0.009	7.75E-04	0.40
GC content	-3.053	2.92E-12	-3.499	8.61E-40	-3.161	7.30E-14	-2.486	9.56E-06	-3.107	3.39E-07	0.33
Trinucleotide complexity	22.997	8.72E-06	22.661	5.14E-09	24.696	2.40E-06	23.320	7.96E-05	25.079	1.89E-05	0.15
ALU repeats	0.193	0.044	0.126	0.032	0.179	0.055	0.256	0.036	0.055	0.69	0.52
MIR repeats	0.004	0.98	-0.177	0.040	-0.187	0.19	0.122	0.46	-0.283	0.19	0.88
L1 repeats	0.145	0.058	0.015	0.75	0.022	0.77	-0.004	0.97	0.172	0.10	0.63
L2 repeats	-0.165	0.27	-0.038	0.65	-0.201	0.17	-0.219	0.27	0.149	0.42	0.39
LTR repeats	-10.032	0.95	-10.125	0.92	-10.107	0.95	-9.517	0.96	-9.312	0.96	na
DNA repeats	0.037	0.78	-0.024	0.77	-0.149	0.28	-0.318	0.11	0.275	0.10	0.16
Simple repeats	-0.139	0.37	-0.105	0.27	-0.114	0.46	-0.233	0.26	0.280	0.18	0.34
Genes	0.122	0.073	0.083	0.042	0.005	0.94	-0.007	0.93	-0.033	0.72	0.23
CpG islands	0.649	0.10	0.827	2.28E-04	1.073	6.48E-04	0.821	0.062	0.085	0.91	0.34
Direct repeats	0.153	0.28	-0.025	0.77	-0.254	0.085	0.116	0.54	-0.423	0.048	0.12
G-quadruplexes	-0.234	0.39	-0.220	0.18	-0.154	0.54	-0.094	0.77	-0.032	0.93	0.61
Cruciform inverted repeats	0.014	0.84	-0.002	0.97	0.055	0.40	0.131	0.14	-0.059	0.53	0.53
MIR repeats	-0.083	0.46	-0.010	0.88	0.159	0.12	-0.083	0.58	0.075	0.62	0.67
Short tandem repeats	0.414	1.82E-06	0.442	1.98E-17	0.433	2.29E-07	0.440	9.59E-05	0.625	6.83E-08	0.45
z-DNA motif	-0.280	0.20	0.067	0.55	0.059	0.75	-0.261	0.35	0.007	0.98	0.72
LADs	0.028	0.70	-0.038	0.37	-0.064	0.36	0.100	0.28	-0.165	0.10	0.53
Distance from the centromere	0.346	2.77E-05	0.333	1.43E-11	0.320	5.88E-05	0.445	6.03E-05	0.358	1.74E-03	0.77
Distance from the nearest telomere	0.138	2.78E-05	0.089	1.12E-07	0.112	1.24E-04	0.123	2.46E-03	0.162	1.45E-03	0.45
Chromatin state (heterochromatin)	4.460	5.01E-04	-9.592	0.98	-9.664	0.99	-9.172	0.99	-8.688	0.99	0.52
Deletions											
Replication timing	-0.007	6.19E-08	-0.005	2.58E-11	-0.007	5.81E-09	-0.003	0.06	-0.001	0.37	0.010
GC content	-2.634	4.42E-19	-2.220	5.05E-39	-1.862	6.94E-13	-2.277	1.28E-09	-1.341	5.33E-05	0.015
Trinucleotide complexity	21.906	1.92E-07	24.192	4.77E-17	18.986	1.85E-06	20.155	4.50E-05	14.530	4.86E-03	0.050
ALU repeats	-0.040	0.58	-0.142	6.42E-04	-0.214	9.45E-04	0.021	0.81	-0.074	0.35	0.24
MIR repeats	-0.117	0.22	-0.054	0.31	-0.116	0.17	-0.105	0.40	-0.115	0.29	0.82
L1 repeats	-0.066	0.24	-0.066	0.041	-0.056	0.26	-0.058	0.42	-0.096	0.14	0.46
L2 repeats	0.077	0.40	-0.057	0.30	-0.088	0.31	0.072	0.54	0.002	0.99	0.94
LTR repeats	-9.828	0.93	0.468	0.45	0.246	0.81	-9.262	0.93	-9.562	0.93	0.64
DNA repeats	-0.138	0.16	-0.108	0.053	-0.076	0.37	-0.018	0.88	-0.076	0.48	0.92
Simple repeats	0.194	0.070	0.237	1.24E-04	-0.049	0.61	0.081	0.56	0.130	0.30	0.57
Genes	0.019	0.69	-0.024	0.39	-0.025	0.55	0.076	0.22	-0.072	0.18	0.22
CpG islands	1.458	5.74E-17	1.146	1.46E-25	1.270	2.69E-16	1.124	9.31E-07	0.581	0.017	0.014
Direct repeats	0.028	0.79	-0.047	0.43	0.145	0.10	-0.138	0.31	0.014	0.91	0.71
G-quadruplexes	0.134	0.37	0.125	0.14	0.084	0.51	0.379	0.026	-0.083	0.64	0.29
Cruciform inverted repeats	0.101	0.029	0.081	2.67E-03	0.081	0.052	0.209	4.58E-04	0.172	1.21E-03	0.065
MIR repeats	-0.098	0.22	-0.016	0.73	-0.005	0.94	0.181	0.062	-0.012	0.89	0.88
Short tandem repeats	0.029	0.67	0.111	3.65E-03	0.244	1.71E-05	0.084	0.32	-0.044	0.58	0.33
z-DNA motif	0.062	0.65	-0.272	2.15E-03	-0.227	0.082	0.253	0.11	-0.085	0.62	0.74
LADs	-0.080	0.10	0.006	0.84	-0.072	0.10	-0.066	0.30	-0.012	0.84	0.70
Distance from the centromere	0.423	2.45E-13	0.374	4.16E-30	0.407	1.95E-15	0.390	1.96E-07	0.464	6.19E-12	0.34
Distance from the nearest telomere	0.086	8.69E-06	0.082	2.93E-14	0.075	4.71E-06	0.051	0.017	0.083	9.33E-05	0.96
Chromatin state (heterochromatin)	-9.069	0.98	-7.283	0.93	-6.422	0.94	-8.795	0.98	-8.995	0.98	na

Abbreviation: not applicable (na). No indel was observed in our study for that genomic feature, thus the models testing for trend in radiation dose excluded those parameters.

Table S20. Sensitivity analyses restricted to exposed (total) and those with <500 mGy exposure, and tests for departure from a linear radiation dose-response relationship.

Molecular characteristics	Regression model*	Linear dose model: Effect size (per 100 mGy)* β	(95% CI)	Linear dose model: P*	Tests for departure from linearity*: Linear quadratic P*	Tests for departure from linearity*: Linear exponential P*
Polygenic risk score						
Total	Linear regression	-0.08	(-0.13 , -0.04)	4.7E-04	0.99	0.54
Exposed		-0.08	(-0.12 , -0.03)	2.1E-03		
Exposed, <500 mGy		0.00	(-0.15 , 0.15)	9.9E-01		
Clonal small deletions						
Total	Linear regression	1.48	(1.06 , 1.89)	9.9E-12	6.63E-05	1.77E-03
Exposed		1.61	(1.14 , 2.08)	1.0E-10		
Exposed, <500 mGy		-0.65	(-1.88 , 0.58)	3.0E-01		
Clonal deletion:SNV ratio						
Total	Linear regression	0.0071	(0.0056 , 0.0086)	1.8E-18	0.86	0.25
Exposed		0.0071	(0.0053 , 0.0088)	5.0E-14		
Exposed, <500 mGy		0.0046	(0.0009 , 0.0084)	1.5E-02		
Clonal ID5						
Total	Linear regression	0.72	(0.39 , 1.06)	2.3E-05	0.03	0.21
Exposed		0.80	(0.42 , 1.18)	3.7E-05		
Exposed, <500 mGy		-0.21	(-1.23 , 0.81)	6.8E-01		
Clonal ID8						
Total	Linear regression	0.80	(0.60 , 1.00)	2.7E-14	0.08	0.18
Exposed		0.82	(0.59 , 1.05)	1.5E-11		
Exposed, <500 mGy		0.22	(-0.32 , 0.77)	4.2E-01		
		EOR	(95% CI)			
Fusion vs. mutation PTC driver						
Total	Logistic regression	0.93	(0.37 , 2.11)	6.6E-08	0.54	0.56
Exposed		0.58	(0.16 , 1.89)	8.0E-05		
Exposed, <500 mGy		0.59	(0.04 , 2.66)	2.6E-02		
Clonal sub-chromosome somatic copy number deletions						
Total	Proportional odds	0.19	(0.03 , 0.48)	9.7E-03	0.01	†
Exposed		0.59	(0.15 , 2.35)	1.7E-04		
Exposed, <500 mGy		0.01	(-0.21 ,1.10)	9.8E-01		
Clonal simple/balanced/EJ SVs						
Total	Logistic regression	18.81	(5.07 , 94.61)	5.5E-19	0.60	0.60
Exposed		4.37	(0.76 , 476)	4.7E-08		
Exposed, <500 mGy		12.38	(0.90 , 1894)	4.6E-05		
Clonal deletions, Length: ≥5 bp, EJ						
Total	Proportional odds	0.61	(0.42 , 0.86)	4.9E-31	8.4E-09	†
Exposed		0.73	(0.46 , 1.18)	9.0E-28		
Exposed, <500 mGy		0.13	(-0.03 , 0.40)	1.4E-01		

* P-values were generated using likelihood ratio tests, comparing model fit with and without the variable of interest (dose, dose squared, or exp(dose)), based on multivariable generalized linear, proportional odds, or logistic regression models, depending on the distribution of the molecular characteristic. All models were mutually adjusted for radiation dose (linear, truncated at 1 Gy), age at PTC, and sex, unless otherwise noted below.

† Model did not converge.

Table S21. Tests for departure from a multiplicative relationship between radiation dose from ^{131}I exposure and age at PTC, age at exposure, and latency, among exposed individuals.

Molecular characteristics †	Regression model*	Dose × Age at PTC P*	Dose × Age at exposure P*	Dose × Latency P*
Polygenic risk score	Linear regression	7.8E-01	2.2E-01	5.2E-01
Clonal small deletions	Linear regression	5.4E-01	2.9E-02 ‡	2.4E-02 ‡§
Clonal deletion:SNV ratio	Linear regression	2.3E-01	1.8E-04 ‡	1.2E-01
Clonal ID5	Linear regression	6.8E-01	1.1E-01	4.5E-01
Clonal ID8	Linear regression	3.6E-01	1.4E-03 ‡	2.8E-03 ‡§
Fusion vs. mutation PTC driver	Logistic regression	2.4E-02 ‡‖	2.4E-02 ‡	9.2E-01
Clonal sub-chromosome somatic copy number deletions	Proportional odds	6.1E-02	1.6E-01	2.6E-02 ‡
Clonal ≥5 bp EJ deletions	Proportional odds	4.9E-01	1.1E-04 ‡	1.6E-02 ‡§

* P derived from likelihood ratio tests comparing model fit with and without the interaction term of interest. Multivariable models included age at PTC (continuous), dose (continuous, truncated at 1 Gy), and sex. Models testing the multiplicative relationship of dose × age at exposure (continuous) or dose × latency (continuous) also included those main effects.

† Clonal simple/balanced/EJ SVs were excluded from these analyses because models did not converge.

‡ Indicates P<0.05.

§ Because all models adjusted for age at PTC, the latency effects for these variables appeared to actually reflect effects of age at exposure (because age at PTC=age at exposure + latency). Additional modeling evaluating interactions for dose with both age at exposure and latency (excluding age at PTC) demonstrated stronger interaction for age at exposure.

‖ Additional modeling of the driver type considering both age at PTC and age at exposure suggested a stronger interaction for age at exposure.

Table S22. Relationship between detailed molecular characteristics and radiation dose from ^{131}I exposure, by age at exposure, separately for characteristics modeled using linear regression and logistic or proportional odds regression.

Molecular characteristics Age at exposure	Regression model*	Effect size (per 100 mGy)		P*
Clonal small deletions	Linear regression			
<5 years		2.19	(1.34 , 3.04)	1.3E-06
5-9 years		1.36	(0.66 , 2.07)	2.3E-04
≥10 years		0.86	(0.04 , 1.68)	3.9E-02
Clonal deletion:SNV ratio	Linear regression			
<5 years		0.0090	(0.005 , 0.013)	1.5E-05
5-9 years		0.0059	(0.0035 , 0.0082)	2.7E-06
≥10 years		0.0023	(0.00076 , 0.0039)	3.8E-03
Clonal ID5	Linear regression			
<5 years		1.23	(0.58 , 1.88)	2.9E-04
5-9 years		0.46	(-0.22 , 1.13)	1.8E-01
≥10 years		0.40	(-0.31 , 1.10)	2.7E-01
Clonal ID8	Linear regression			
<5 years		1.15	(0.70 , 1.61)	1.8E-06
5-9 years		0.82	(0.45 , 1.18)	2.5E-05
≥10 years		0.21	(-0.15 , 0.57)	2.5E-01
		EOR	(95% CI)	
Fusion vs. mutation PTC driver†	Logistic regression			
<10 years		3.66	(0.50 , 308)	7.3E-06
≥10 years		0.15	(-0.04 , 1.03)	2.1E-01
Clonal ≥5 bp EJ deletions	Proportional odds			
<5 years		2.42	(0.78 , 492)	4.6E-17
5-9 years		1.21	(0.43 , 4.66)	1.8E-09
≥10 years		0.16	(0.03 , 0.41)	9.2E-03

* P-values and effect estimates were derived from multivariable generalized linear, proportional odds, or logistic regression models, depending on the distribution of the molecular characteristic. All models were stratified (run separately) by the age at exposure groupings specified in the table, with each model mutually adjusting for radiation dose (linear, truncated at 1 Gy), age at PTC, and sex.

† Models evaluating the effect of dose on driver type restricted to <5 years of age at exposure did not converge, so we combined individuals exposed at <5 and 5-9 years. EOR/100 mGy for 5-9 years alone=1.78, 95%CI=0.12-226.

CAPTIONS FOR DATA S1 TO S3

Data S1. Analytic data.

Data S2. Somatic SSVs in the 383 WGS primary tumor-normal pairs.

Data S3. Somatic SVs in the 383 WGS primary tumor-normal pairs.

[EXTERNAL] B@B

From: Eric S Lander (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Date: Sat, 24 Apr 2021 07:37:33 -0400

On Tue, Sep 10, 2019 at 10:47 AM Eric S Lander (b) (6) wrote:

Fellow Broadies,

In light of the stories about relationship with MIT and Harvard, several Broadies have asked whether the Broad had any association with Epstein and, more generally, about the Broad's practices on philanthropic and other support.

The Broad had no association with him or his foundations, nor did I. Neither the Broad nor I requested or received any financial support for any purpose from him or his foundation. He also did not facilitate any funding to either the Broad or me.

To the best of our knowledge, he never visited the Broad. I did briefly meet him, at two events in Spring 2012, involving multiple Harvard donors, faculty, and others. I never met him thereafter. I'm glad we chose to have no dealings with him.

Nonetheless, these events raise thoughtful questions concerning appropriate sources for institutional support. For example, questions have also recently been raised, at various institutions, about support from Saudi Arabia (in light of the killing of Jamal Khashoggi) and the Sackler family (in light of the connection to the sale of opioids).

Justine Levin-Allerhand, our chief development and external relations officer, has been reviewing our practices on accepting support, to see if any changes may be appropriate.

I would welcome input from Broadies about how to think about these important questions.

Sincerely,
Eric

RE: [EXTERNAL] Re: Bill, Dick <> Tara

From: "Schwetz, Tara A. EOP/OSTP" (b) (6)

To: Richard Van Atta (b) (6) ,(b) (6)

Date: Fri, 30 Apr 2021 13:46:04 -0400

Jason, thanks so much for the introduction! Moving you to bcc to spare your inbox a bit...

Dick and Bill, I would really appreciate the opportunity to speak with both you about your general thoughts on the processes and approaches that have been successful for "ARPAs", lessons learned and best practices, and any advice (e.g., pitfalls, red flags) that could be offered as I navigate the establishment of this new entity.

Unfortunately, I will be out of the office next week, but happy to try to connect the week of May 10. Are there any times that week that might work well for you?

Thanks and I look forward to meeting!

Best,

Tara A. Schwetz, PhD
Assistant Director for Biomedical Science Initiatives
Office of Science and Technology Policy
Executive Office of the President
(b) (6)

From: Richard Van Atta (b) (6)

Sent: Friday, April 30, 2021 12:54 PM

To: Matheny, Jason G. EOP/OSTP (b) (6)

Cc: Schwetz, Tara A. EOP/OSTP (b) (6) ; (b) (6)

Subject: [EXTERNAL] Re: Bill, Dick <> Tara

Jason — I'd be delighted to talk with her. I'm down in Charleston, SC most of the time but only a phone call away (b) (6) . I will be coming up to DC at end of May for a few weeks.
Cheers,
Dick

Sent from my iPhone

On Apr 30, 2021, at 12:44 PM, Matheny, Jason G. EOP/OSTP(b) (6) wrote:

Bill and Dick,

Tara (cc:ed) is working on plans to establish ARPA-Health. Given your deep knowledge of ARPA models, I suggested that she talk with you both.

With admiration,
Jason

[EXTERNAL] Inclusive entrepreneurship at DOE

From: Doug Rand (b) (6)

To: "Koizumi, Kei EOP/OSTP" (b) (6)

Date: Fri, 30 Apr 2021 12:38:55 -0400

Hi Kei,

I hope you're doing well these days and enjoying the springtime!

Check out this new Third Way paper I co-authored, which I hope you find useful:

Breaking Down Barriers: How the Department of Energy Can Immediately Advance Racial and Gender Equity for Entrepreneurs

Nick Montoni and I present a menu of actions that the Department of Energy can take immediately—without additional congressional action—to support clean energy startups and make important progress on three of the Biden Administration's highest priorities: economic recovery, tackling the climate emergency, and racial equity.

- DOE has a moral and economic imperative to achieve a more diverse pipeline of clean energy entrepreneurs and investors—and it already has the tools to do so.
- Tucked into the recently-enacted bipartisan Energy Act of 2020 are many new authorities to break down barriers facing clean energy startups, and we review how DOE can take full advantage of them.
- We also present new data showing how DOE's main startup funding program, Small Business Innovation Research (SBIR), delivers only a small fraction of awards to companies majority-owned by women (8.2%) or minority founders (7.0%).
- We found that the National Science Foundation has achieved a much more equitable distribution of SBIR awards, compared with its peer agencies—and compared with its own track record just 10 years ago. Clearly, more progress is possible.
- DOE also has the ability to diversify who funds clean energy startups. A recent pilot program provided seed funding for 10 organizations proving out different models for sustainable long-term investment in clean energy technologies. One third of these organizations had a woman in the top job—far more than the 5.6% among venture capital firms overall.

Please don't hesitate to send me any questions or feedback.

Thanks and take care,
Doug

Doug Rand
Senior Fellow
Federation of American Scientists
(b) (6)
Bio / LinkedIn / Twitter

RE: [EXTERNAL] Inclusive entrepreneurship at DOE

From: "Koizumi, Kei EOP/OSTP" (b) (6)

To: Doug Rand (b) (6)

Date: Mon, 03 May 2021 12:08:03 -0400

Doug, I'll send an invite. I wanted to talk to you in part ABOUT Nick so I will send an invite just to you.

Kei

Kei Koizumi
(he/him)
Acting Director and Chief of Staff
Office of Science and Technology Policy
(b) (6)

From: Doug Rand (b) (6)

Sent: Monday, May 3, 2021 11:59 AM

To: Koizumi, Kei EOP/OSTP (b) (6)

Cc: Nick Montoni (b) (6)

Subject: RE: [EXTERNAL] Inclusive entrepreneurship at DOE

Hi Kei,

Thanks for your positive feedback! I'm looping Nick (CCed), and my calendar is available here. Let us know what time you're open tomorrow afternoon!

Looking forward,
Doug

On Mon, May 03, 2021 at 10:07 AM, Kei EOP/OSTP Koizumi (b) (6) wrote:

> Thank you, Doug. I love this paper, and would like to talk to you about it, and about you and Nick. Let me know if you have time to talk in the next few days. I have some windows today, and time tomorrow afternoon.

Kei

Kei Koizumi
(he/him)
Acting Director and Chief of Staff
Office of Science and Technology Policy
Executive Office of the President
(b) (6)
Cell (b) (6)

From: Doug Rand (b) (6)
Sent: Friday, April 30, 2021 12:39 PM
To: Koizumi, Kei EOP/OSTP (b) (6)
Subject: [EXTERNAL] Inclusive entrepreneurship at DOE

Hi Kei,

I hope you're doing well these days and enjoying the springtime!

Check out this new Third Way paper I co-authored, which I hope you find useful:

Breaking Down Barriers: How the Department of Energy Can Immediately Advance Racial and Gender Equity for Entrepreneurs

Nick Montoni and I present a menu of actions that the Department of Energy can take immediately—without additional congressional action—to support clean energy startups and make important progress on three of the Biden Administration's highest priorities: economic recovery, tackling the climate emergency, and racial equity.

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- We also present new data showing how DOE's main startup funding program, Small Business Innovation Research (SBIR), delivers only a small fraction of awards to companies majority-owned by women (8.2%) or minority founders (7.0%).
- We found that the National Science Foundation has achieved a much more equitable distribution of SBIR awards, compared with its peer agencies—and compared with its own track record just 10 years ago. Clearly, more progress is possible.
- DOE also has the ability to diversify who funds clean energy startups. A recent pilot program provided seed funding for 10 organizations proving out different models for sustainable long-term investment in clean energy technologies. One third of these

organizations had a woman in the top job—far more than the 5.6% among venture capital firms overall.

Please don't hesitate to send me any questions or feedback.

Thanks and take care,
Doug

Doug Rand
Senior Fellow
Federation of American Scientists
(b) (6)
Bio / LinkedIn / Twitter

[EXTERNAL] Helping Nepal with AstraZeneca vaccine

From D.B.Jay Mahat (b) (6)
:
To: "Lander, Eric S. EOP/OSTP" <(b) (6)>, Phillip A Sharp (b) (6)
Cc: Laxman Arya (b) (6)
Date: Tue, 04 May 2021 14:14:23 -0400

Dear Eric,
Now knowing the email address for OSTP, I sent the following email to your Broad email address a moment ago:

> Dear Eric,
>
> I am writing today to ask for your help for Nepal, which is where I am from. Jorge and I are working on several questions on single-cell transcriptomics and we will update you on that some other day.
> Some senior citizens of Nepal have received the first dose of AstraZeneca vaccine more than two months ago. However, due to the export ban of vaccines from India, the Government of Nepal has not been able to secure the second dose. Much of the nation remains unvaccinated.
> The number of cases are exponentially rising in Nepal (~250/M despite severe under testing, whereas India is at ~270/M), and hospitals beds and oxygen are running out.>https://www.nytimes.com/2021/05/01/world/nepal-india-covid.html<
> The scientific community of Nepal appealed to the U.S. Ambassador to Nepal Mr. Randy Berry for his help in allocation of AstraZeneca vaccines to Nepal.
> I would be extremely grateful if you could help in any way to add Nepal to the list of AZ vaccine recipient nations.
> I have cced Mr. Laxman Aryal - The Secretary of Health & Population Ministry of Nepal.
> Thank you.
> Best,
> Jay Mahat
> Sharp Lab
> KI - MIT

Best,

Jay Mahat
Research Scientist
Sharp Lab
KI - MIT

[EXTERNAL] Congressional letter re: DOJ amnesty program

From:	Maria Zuber (b) (6)
To:	"Lander, Eric S. EOP/OSTP" (b) (6) >, Frances H. Arnold (b) (6)
Cc:	"Koizumi, Kei EOP/OSTP" (b) (6)
Date:	Fri, 07 May 2021 09:48:25 -0400
Attachments:	47ED1394537C0ECDFCAB0D3DB8828899.05.04.21-rubio-sjc-cotton-portman-young-ceg-sasse-collins-to-doj-re-amnesty-for-china.pdf (237.51 kB)

Worth reading.

Maria

United States Senate
WASHINGTON, DC 20510-0908

May 5, 2021

The Honorable Merrick Garland
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530

Dear Attorney General Garland:

A January 2021 *Wall Street Journal* article indicated that the Department of Justice (DOJ) was "weighing an amnesty program under which U.S. academics could disclose past foreign funding without fear of punishment for their disclosures."[1] That article further indicated that "High-level officials … have discussed the program in recent months, and circulated a draft proposal for it."[2]

It has come to our attention that DOJ is planning to implement this amnesty program within the next few weeks, just months after Congress took action to deter foreign influence in academia. In section 1299C of the *National Defense Authorization Act (NDAA) for Fiscal Year 2021*, P.L. 116-283 (Jan. 1, 2021), Congress required the Secretary of Defense and other government agencies to work with higher education institutions to limit foreign influence and exploitation of U.S. technology within the Department of Defense research, science and technology, and innovation enterprise. In addition, section 1281 of the *NDAA for Fiscal Year 2020*, P.L. 116-92 (Dec. 20, 2019) built on a provision from the prior year's NDAA, requiring the Secretary of Defense and other government agencies to provide training and resources to limit foreign influence, protect national security information, and protect against threats to institutions of higher education, including counterintelligence information developed for academic researchers based on identified threats.

Yet despite these congressional initiatives – as enacted in recent laws – DOJ has not consulted with Congress on this amnesty program. It is also our understanding that DOJ did not properly consult with the relevant Inspector General community. Inspectors General from large grant-making agencies, such as the National Science Foundation and the National Institutes of Health, are on the frontlines of combatting grant fraud by corrupt researchers seeking to take advantage of the openness and funding that the U.S. research enterprise provides.

We applaud federal prosecutors for bringing more than a dozen criminal cases against researchers and professors who allegedly stole intellectual property or failed to disclose

[1] Melissa Korn and Aruna Viswanatha, *Justice Department Weighs Amnesty for Academics to Disclose Foreign Funding,* WALL ST. J. (Jan. 22, 2021), https://www.wsj.com/articles/justice-department-weighs-amnesty-for-academics-to-disclose-foreign-funding-11611345451.
[2] *Id.*

partnerships with foreign governments, including with the People's Republic of China (PRC). We are concerned about the effect that this amnesty program will have on those ongoing criminal cases and the signal that it sends to future researchers contemplating breaking U.S. law to steal research or hide affiliations with foreign governments or militaries. According to DOJ's January 20, 2021 press release, Dr. Gang Chen – the individual cited in the article[3] – was indicted and charged with holding "various appointments with the PRC . . . often in exchange for financial compensation", and "was serving in several advisory roles for the PRC and PRC entities [when he] applied for and obtained a U.S. Department of Energy (DOE) grant in order to fund a portion of his research at MIT."[4]

To better understand this significant and potentially deleterious impending policy change, please provide a briefing detailing the scope, nature, and timeline of DOJ's amnesty program no later than May 12, 2021.

America's successful research enterprise is built on reciprocity, integrity, and transparency. These values foster a free exchange of ideas and ensure that researchers and institutions receive the benefit of hard work. As a result, America attracts the best and brightest. It needs to stay that way. But the United States must also take reasonable steps to protect taxpayer-funded research from theft, diversion, and ultimately weaponization against our own long-term national interests. This is a complex problem, but an amnesty program rewarding individuals who broke federal law to steal U.S. taxpayer-funded research is simply not the answer.

Sincerely,

Marco Rubio
U.S. Senator

John Cornyn
U.S. Senator

Tom Cotton
U.S. Senator

Susan Collins
U.S. Senator

[3] *Id.*
[4] *MIT Professor Indicted on Charges Relating to Grant Fraud*, DOJ USAO (D. Mass.) (Jan. 20, 2021), https://www.justice.gov/usao-ma/pr/mit-professor-indicted-charges-relating-grant-fraud.



Ben Sasse
U.S. Senator



Rob Portman
U.S. Senator



Todd Young
U.S. Senator



Charles Grassley
U.S. Senator

From: Google Calendar on behalf of "Hal Abelson" (b) (6)
Sent: Mon, 10 May 2021 19:44:15 -0500
To: Young, Jessica L. EOP/OSTP
Subject: [EXTERNAL] Accepted: MIT RAISE initiative discussion @ Wed May 19, 2021 3pm - 3:30pm (EDT) (Young, Jessica L. EOP/OSTP)
Attachments: invite.ics

Hal Abelson has accepted this invitation.

MIT RAISE initiative discussion

When Wed May 19, 2021 3pm – 3:30pm Eastern Time - New York

Where >https://pitc.zoomgov.com/(b) (6) (map)

Calendar Young, Jessica L. EOP/OSTP

Who
- Young, Jessica L. EOP/OSTP - organizer
- Hal Abelson - creator
- Cynthia Breazeal
- Jeff Freilich
- (b) (6)
- (b) (6)
- Eric Klopfer
- Lynch, Justin R. EOP/OSTP
- Parker, Lynne E. EOP/OSTP
- (b) (6) - optional

[>https://www.zoomgov.com/(b) (6)

Hi there,

Jessica Young is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile:

US: (b) (6) or (b) (6)

Meeting URL:

>https://pitc.zoomgov.com/(b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: (b) (6) or (b) (6) or (b) (6) or (b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

International numbers

Invitation from Google Calendar

You are receiving this courtesy email at the account (b) (6) because you are an attendee of this event.

To stop receiving future updates for this event, decline this event. Alternatively you can sign up for a Google account at >https://calendar.google.com/calendar/< and control your notification settings for your entire calendar.

Forwarding this invitation could allow any recipient to send a response to the organizer and be added to the guest list, or invite others regardless of their own invitation status, or to modify your RSVP. Learn More.

From: Google Calendar on behalf of "Eric Klopfer" (b) (6)
Sent: Mon, 10 May 2021 18:09:43 -0500
To: Young, Jessica L. EOP/OSTP
Subject: [EXTERNAL] Accepted: MIT RAISE initiative discussion @ Wed May 19, 2021 3pm - 3:30pm (EDT) (Young, Jessica L. EOP/OSTP)
Attachments: invite.ics

Eric Klopfer has accepted this invitation.

MIT RAISE initiative discussion

When Wed May 19, 2021 3pm – 3:30pm Eastern Time - New York

Where >https://pitc.zoomgov.com(b) (6) (map)

Calendar Young, Jessica L. EOP/OSTP

Who
- Young, Jessica L. EOP/OSTP - organizer
- Eric Klopfer - creator
- (b) (6)
- (b) (6)
- Cynthia Breazeal
- Jeff Freilich
- Lynch, Justin R. EOP/OSTP
- Parker, Lynne E. EOP/OSTP
- (b) (6) - optional

[>https://www.zoomgov.com/(b) (6)

Hi there,

Jessica Young is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile:

US: (b) (6) or (b) (6)

Meeting URL:

>https://pitc.zoomgov.com(b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: (b) (6) or (b) (6) or (b) (6) or (b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

International numbers

Invitation from Google Calendar

You are receiving this courtesy email at the account (b) (6) because you are an attendee of this event.

To stop receiving future updates for this event, decline this event. Alternatively you can sign up for a Google account at >https://calendar.google.com/calendar/< and control your notification settings for your entire calendar.

Forwarding this invitation could allow any recipient to send a response to the organizer and be added to the guest list, or invite others regardless of their own invitation status, or to modify your RSVP. Learn More.

[EXTERNAL] Accepted: MIT RAISE initiative discussion

From: (b) (6)

To: "Young, Jessica L. EOP/OSTP" (b) (6)

Date: Mon, 10 May 2021 18:59:35 -0400

Attachments: ATT00001.ics (0 bytes); reply.ics (0 bytes)

Re: [EXTERNAL] MIT The Engine Meeting: Jason Matheny, Orin Hoffman, Michael Kearney, David Goldston Zoom Meeting

From: Helen C Haislmaier (b) (6)

To: "Matheny, Jason G. EOP/OSTP" (b) (6)

Date: Tue, 18 May 2021 16:30:28 -0400

No worries Jason. They quite understand! Thank you for offering a weekend meeting – that's above & beyond, but if you had some time on Sunday morning before noon, they would love to take you up on your offer!

Kindest regards,

Helen

Helen Haislmaier
Program Coordinator
MIT Washington Office/Federal Relations
Cell: (b) (6)

From: "Matheny, Jason G. EOP/OSTP" (b) (6)

Date: Tuesday, May 18, 2021 at 3:36 PM

To: Helen C Haislmaier (b) (6)

Subject: Declined: [EXTERNAL] MIT The Engine Meeting: Jason Matheny, Orin Hoffman, Michael Kearney, David Goldston Zoom Meeting

With apologies (again), this is being bumped by a last-minute PC here. Let me know if sometime over the weekend would be possible – so far none of my weekend meetings have been bumped!
With thanks,
Jason

[EXTERNAL] RE: Big Invitation from the UK!

From Andrew Morris (b) (6) >
:
To: "Lo, Kevin C. EOP/OSTP" <(b) (6)
Cc: Cecilia Lindgren (b) (6) , (b) (6) HDR UK events (b) (6)
Date: Tue, 25 May 2021 09:44:22 -0400

Dear Kevin,

I hope this email finds you well.

Many thanks for your message about the UK National Core Studies Symposium event – Thursday 24, June 2021.

As we are progressing with the development of the event agenda, could I please confirm if your team has managed to secure a time slot within Eric's calendar which would allow him to join us for this event?

Should you have further information, I would be most grateful.

With all best wishes.

Andrew

Professor Andrew Morris CBE MD FRCP FRSE FMedSci
Director

Health Data Research UK, Gibbs Building, 215 Euston Road, London, NW1 2BE
(b) (6)

>www.hdruk.ac.uk< |@HDR_UK

HDRUK
Health Data Research UK

From: Lo, Kevin C. EOP/OSTP (b) (6)
Sent: 18 May 2021 21:30
To: Andrew Morris (b) (6) ;(b) (6)
Cc: Cecilia Lindgren (b) (6)
Subject: RE: Big Invitation from the UK!

Professor Morris:

I hope this note finds you well. My name is Kevin Lo, and I'm a special assistant at OSTP.

I wanted to pass along Eric's sincere thanks for the note and invitation.

We are currently working out Eric's schedule for June (given the slight uncertainty on timeline for his confirmation), and I was wondering if we might be able to circle back regarding the invitation.

Apologies for the delay.

With best wishes,
Kevin

Kevin Lo *(he/him)*
Special Assistant
Office of Science and Technology Policy
Executive Office of the President
(b) (6)
Cell (b) (6)

From: Andrew Morris (b) (6)
Sent: Thursday, May 13, 2021 5:03 PM

To: (b) (6) Lander, Eric S. EOP/OSTP (b) (6)
(b) (6)
Cc: Cecilia Lindgren (b) (6)
Subject: [EXTERNAL] Big Invitation from the UK!

Dear Eric

I hope all is well despite these very challenging times.

I am sorry to trouble you but I was chatting to Cecilia (copied above) and she suggested I drop you a note on these email addresses to see if you would be able to give your friends in the UK a guest appearance at a national symposium that Patrick Vallance, myself and many other people you know are hosting on 24th June.

I attach the invitation

In brief, we have suggested a 20 minute slot that would be chaired by Dame Ottoline Leyser, CEO of UKRI. It would be 0735-0755 ET

It would be terrific if you were able to join us

Many thanks for considering this

All best wishes

Andrew

Professor Andrew Morris CBE MD FRCP FRSE FMedSci
Director

Health Data Research UK, Gibbs Building, 215 Euston Road, London, NW1 2BE
(b) (6)

>>www.hdruk.ac.uk<<; |@HDR_UK

[EXTERNAL] Fwd: Electric vehicle contact

From: Jesse Souweine (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6) >

Date: Sun, 30 May 2021 18:29:01 -0400

Attachments: Resume_(b)(6) PII _transpoMay21.pdf (293.21 kB)

Should have sent this to your White House email - sorry!

---------- Forwarded message ---------

From: **Jesse Souweine** <(b) (6)

Date: Sun, May 30, 2021 at 6:20 PM

Subject: Electric vehicle contact

To: Eric S Lander (b) (6)

Cc: Sira Dooley Fairchild (b) (6) >

Eric:

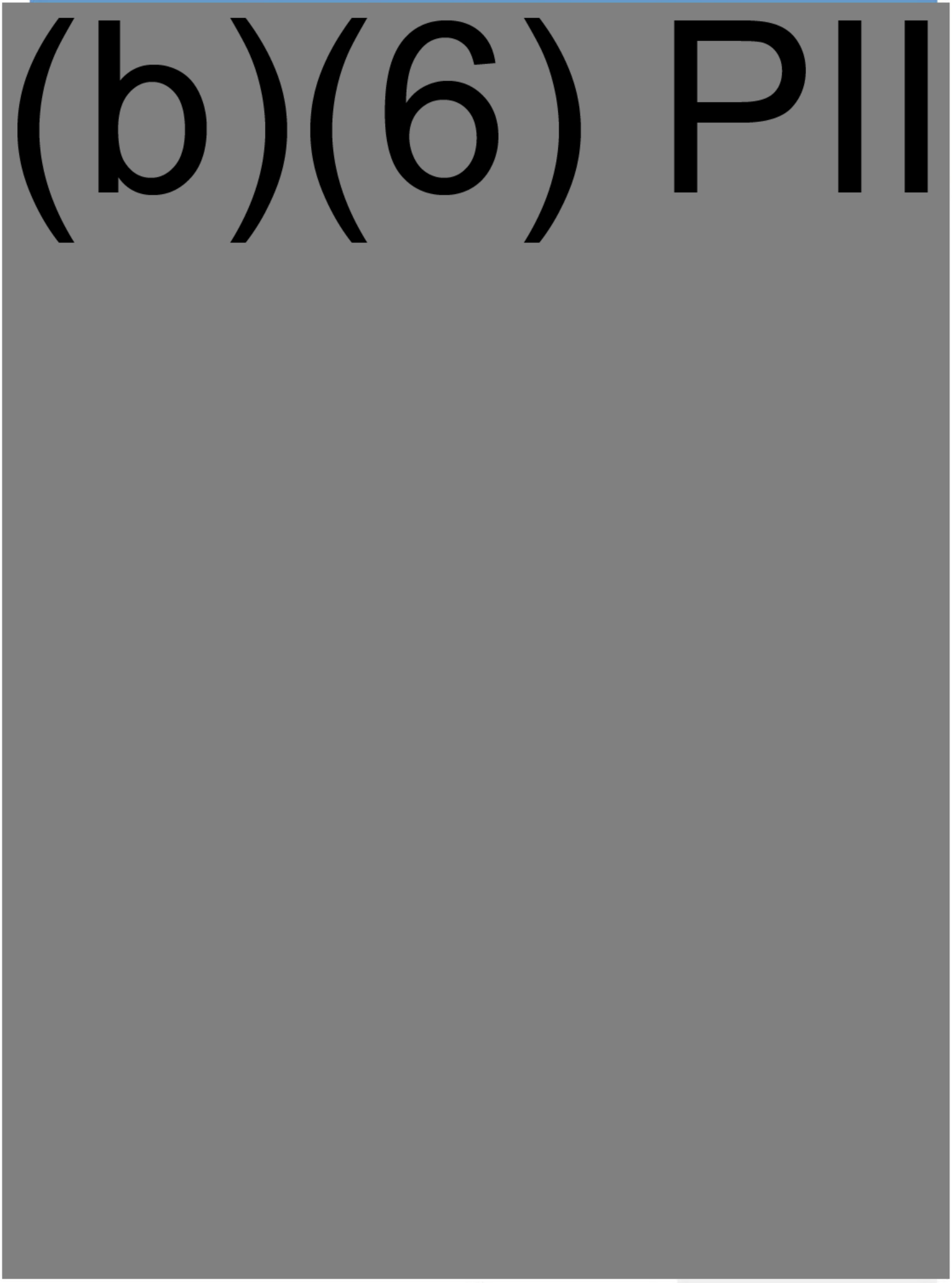
You may remember that I mentioned a friend who is an electric vehicle advocate (b)(6) PII (resume attached) and she's currently looking for her next opportunity, (b)(6) PII Anyway, she's been in discussions with folks at the White House and the Dept of Transportation but I thought it might be useful to make a connection with you as well.

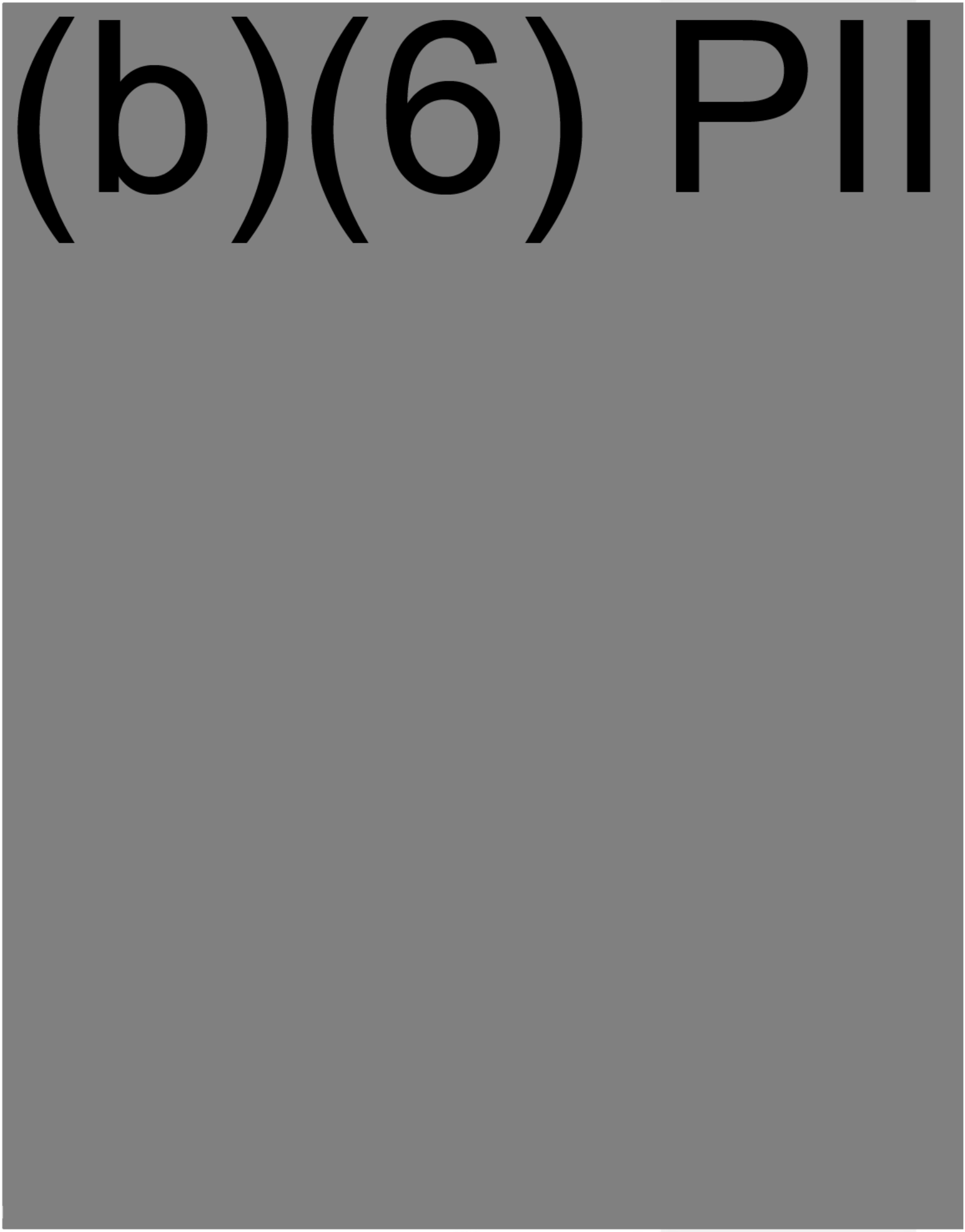
(b)(6) PII

Anyway, if you have time to have a quick chat with her, let me know. She's very talented and knows this space well.

Thanks!

Jesse


(b)(6) PII


(b)(6) PII

[EXTERNAL] Re: Blogpost

From: Jesse Souweine (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Cc: Justine Levin-Allerhand (b) (6)

Date: Mon, 31 May 2021 12:22:49 -0400

This is so great - so meaningful for you to make this selection (in the context of so many other important selections that came before you) and I'm sure it will be meaningful for the OSTP community and beyond. I am reminded again of how important it is to attend to these moments (and am always astounded at your prolific writing!).

The timing of your note is coincidental for me, as I was just reading about the Mishnah last night in Sarah Hurwitz's new book - finding meaning through Judaism (she was Michelle Obama's main speechwriter). I love to see the text used in this context.

Anyway, thanks for sharing - I greatly enjoyed reading this piece!

Best,
Jesse

On Mon, May 31, 2021 at 6:16 AM Lander, Eric S. EOP/OSTP (b) (6) wrote:

> Dear Justine and Jesse:
>
> First, thank you both so much for all your help and support in getting through Senate confirmation! It meant so much to me.
>
> The current plan is for the Vice-President to administer my oath of office on Wednesday. When the VP's office asked what book I wanted

to use for the ceremony, the question triggered an evening of family discussion followed by a research expedition on my part.

I wrote a short essay on my choice of book, which I thought would be meaningful to both of you.

It would be great to see you each when I am back in Cambridge on weekends.

With warmest wishes,

Eric

[EXTERNAL] Out of Office Re: Blogpost

From: Jesse Souweine (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Date: Mon, 31 May 2021 06:16:19 -0400

Hi. I will be out of the office for the Broad extended Memorial Day weekend and will respond as soon as I am able. If you need immediate assistance, please text me at (b) (6)

Thanks,

Jesse

--

Jesse Souweine
COO and EVP
Broad Institute of MIT and Harvard
415 Main Street, Cambridge, MA 02142
(b) (6)
(b) (6) (w)
(b) (6) (c)
she/her/hers



Re: [EXTERNAL] Fwd: Electric vehicle contact

From: Jesse Souweine (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Date: Mon, 31 May 2021 12:16:05 -0400

Awesome - thanks so much. I'll connect the two of you now.

On Mon, May 31, 2021 at 11:24 AM Lander, Eric S. EOP/OSTP (b) (6) wrote:

> Hi Jesse: I'd be very interested in talking (b)(6) PII, perhaps next weekend. Could you connect us? Much thanks, Eric

---

From: Jesse Souweine (b) (6) >

Date: Sunday, May 30, 2021 at 6:30 PM

To: "Lander, Eric S. EOP/OSTP" <(b) (6)

Subject: [EXTERNAL] Fwd: Electric vehicle contact

Should have sent this to your White House email - sorry!

---------- Forwarded message ---------

From: **Jesse Souweine** (b) (6)

Date: Sun, May 30, 2021 at 6:20 PM

Subject: Electric vehicle contact

To: Eric S Lander (b) (6)

Cc: Sira Dooley Fairchild (b) (6)

Eric:

You may remember that I mentioned a friend who is an electric vehicle advocate - (b)(6) PII (resume attached) and she's currently looking for her next opportunity, (b)(6) PII Anyway, she's been in discussions with folks at the White House and the Dept of Transportation but I thought it might be useful to make a connection with you as well.

(b)(6) PII

Anyway, if you have time to have a quick chat with her, let me know. She's very talented and knows this space well.

Thanks!

Jesse

RE: [EXTERNAL] reducing infectious diseases' impact

From "Hebbeler, Andrew M. EOP/OSTP" (b) (6)
:
To: Mike Fisher (b) (6)
Cc: "Segre, Julie A. EOP/OSTP" (b) (6), "Wolinetz, Carrie D. EOP/OSTP" (b) (6), "Schmoyer, Michael W. EOP/OSTP" (b) (6), "Waterman, Paige E. EOP/OSTP" (b) (6), "Guerra, Stephanie L. EOP/OSTP" (b) (6), "McKelvey, Greg G. Jr. EOP/OSTP" (b) (6), "Sheehan, Jerry R. EOP/OSTP" (b) (6)
Date: Wed, 02 Jun 2021 17:19:22 -0400

Hi Mike: Great chatting with you too, and thanks for sending these resources! Would be great to hear how your discussions with Doug and India go.

+others FYSA, in case these FAS/D1P docs aren't already on their radar.

Thanks again!
Andrew

From: Mike Fisher <(b) (6)
Sent: Wednesday, June 2, 2021 8:59 AM
To: Hebbeler, Andrew M. EOP/OSTP <(b) (6)>
Subject: [EXTERNAL] reducing infectious diseases' impact

Hi Andrew,

Thank you again for talking with me the other week. Following up on our conversation, if any additional OSTP priorities have crystallized beyond pandemic preparedness / taking measures to reduce the impact of infectious diseases, it would be great to schedule another call.

And regarding pandemic preparedness / infectious diseases, just sharing six FAS Day One papers in our portfolio that may be of interest to you and your team (happy to prepare a brief on any of these or work with the authors to further develop ideas in a direction you are pursuing):

Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats

Shift from reacting to disease outbreaks – which is economically devastating – to detecting, addressing, and mitigating the major upstream factors that contribute to the emergence of diseases prior to an outbreak.

Improving Federal Management of Wildlife Movement and Emerging Infectious Disease

Reduce the risk of emerging infectious diseases entering the United States, offer greater protection to citizens from zoonotic diseases, and protect American biodiversity from losses due to wildlife diseases.

A National Bioeconomy Manufacturing and Innovation Initiative

Ramp up cross-cutting, cutting-edge research and development across the areas of healthcare, food & agriculture, energy, environment, and industrial applications to develop fundamental and publicly available tools, and bolster American biomanufacturing.

Open Access to Federally-funded Research Data

Accelerate scientific progress by (i) requiring scientists who receive federal funding to share their research data and (ii) directing federal research agencies to coordinate to build an International Research Data Commons that allows research data to be easily discovered and shared.

Creating a COVID-19 Commission on Public Health Misinformation

Examine our nation's response to the 2020 pandemic using a mechanism that is modeled on the 9/11 Commission, with one Commission focusing on public health communication and messaging that would assess the information about the pandemic: what was made publicly available, how the information affected our societal response, and what should be done to limit the impact of false and dangerously misleading information moving forward.

A National Strategy to Counter COVID-19 Misinformation

Establish an office at the Department of Health and Human Services dedicated to countering COVID-19 misinformation.

Also possibly of interest, on Friday I'll be meeting with Doug Friedman of BioMADE and India Hook-Barnard of the Engineering Biology Research Consortium to discuss the potential of sourcing policy ideas from the synbio community.

Thanks again, Andrew, and looking forward to talking again soon!

Best,

Mike

--
Michael A. Fisher, Ph.D.
Senior Fellow
Federation of American Scientists

1112 16th Street NW, Suite 400
Washington, DC 20036

Email (b) (6)

LinkedIn: bit.ly/MAFisher
Twitter: @mykfish
Join up to contribute your expertise to the science and technology knowledge-base for policymakers: Congressional Science Policy Initiative

[EXTERNAL] Pirkei Avot!

From: Joseph Jacobson (b) (6)

To: "Lander, Eric S. EOP/OSTP" (b) (6)

Date: Thu, 03 Jun 2021 13:42:39 -0400

Hi Eric - Yasher Koach! Beautiful quote from Pike Avot.

Wishing you wonderful success.

Very Best, Joe

P.S. Spent the day in Boston yesterday with former cabinet member Jack Lew. I'll need to ask him what he swore in on...

RE: [EXTERNAL] ai.gov and MIT

From: "Young, Jessica L. EOP/OSTP" (b) (6)

To: Jeff Freilich (b) (6), "Lynch, Justin R. EOP/OSTP" (b) (6)

Cc: (b) (6) " (b) (6)

Date: Fri, 04 Jun 2021 15:51:34 -0400

Hi Jeff,

Thanks for reaching out. Justin is currently out of the office until Wednesday. I know he's tracking related follow-up items and will likely want to be engaged in such a conversation.
We'll wait until he's back to confirm availability, but look forward to circling back soon.

Have a great weekend,
Jessica

From: Jeff Freilich (b) (6)

Sent: Friday, June 4, 2021 12:24 PM

To: Young, Jessica L. EOP/OSTP (b) (6) Lynch, Justin R. EOP/OSTP (b) (6)

Cc: (b) (6)

Subject: [WARNING: UNSCANNABLE EXTRACTION FAILED]Re: [EXTERNAL] ai.gov and MIT

Hi Jessica and Justin,

Cynthia Breazeal asked if we might schedule a follow-up conversation about MIT RAISE with you (and with Lynne, if she's available) since we ran out of time during our last call?

Please suggest some options and I'll coordinate from the MIT side?

Thank you!

Jeff

Jeff Freilich
Massachusetts Institute of Technology
(b) (6)
Cell: (b) (6)

>https://www.linkedin.com/in/mishuma/<
>https://mit.zoom.us/my/mishuma<
he/him/his

On May 10, 2021, at 18:05, Jeff Freilich (b) (6) wrote:

Hi Jessica,

The PIs are able to meet with you next Wednesday, May 19th from 3-4pm.

Please send a new invite with the Zoom link to everyone?

Cynthia Breazeal (b) (6)
Hal Abelson (b) (6)
Eric Klopfer (b) (6)
Haewon Park
Jeff Freilich

Thank you!

Jeff Freilich
Massachusetts Institute of Technology
(b) (6)
Cell: (b) (6)
>https://www.linkedin.com/in/mishuma/<
>https://mit.zoom.us/my/mishuma<
he/him/his

On May 10, 2021, at 15:39, Young, Jessica L. EOP/OSTP (b) (6) wrote:

Hi Jeff,
Apologies for the inconvenience - we've had an internal scheduling conflict pop up this Thursday. Would it be possible to reschedule our meeting?

Our calendars are open next Tuesday and Wednesday anytime after 12pm ET. Would any time in those windows work for Cynthia, Hal, Eric, and Hae Won? If not, we can find the next mutually available time that would be convenient on your side.

Apologies again, and thanks for your help coordinating,
Jessica

From: Young, Jessica L. EOP/OSTP
Sent: Friday, May 7, 2021 10:19 AM
To: 'Jeff Freilich' (b) (6)
Cc: Lynch, Justin R. EOP/OSTP <(b) (6) ; (b) (6)
Subject: Re: [EXTERNAL] ai.gov and MIT

Hi Jeff,

Thanks for confirming! We've saved 5/13 at 4pm Eastern for the call.
Our preference would be to use Zoom Gov to avoid any issues on our end.
I've just shared a calendar invite with Cynthia and you, that can be shared with Hal, Eric and Hae Won.
(If you'd like to send me their email address, I'm also happy to directly add them to the invitation.)

Looking forward to the discussion,
Jessica

From: Jeff Freilich (b) (6)
Sent: Thursday, May 6, 2021 11:35 PM
To: Young, Jessica L. EOP/OSTP (b) (6)
Cc: Lynch, Justin R. EOP/OSTP (b) (6) (b) (6)
Subject: [WARNING: UNSCANNABLE EXTRACTION FAILED]Re: [EXTERNAL] ai.gov and MIT

Jessica,

Please reserve Thursday, May 13th at 4pm EDT for an introductory call with the principal investigators of the MIT RAISE initiative: Cynthia Breazeal, Hal Abelson, Eric Klopfer and Hae Won Park (still confirming with Hae Won).

I assume a Zoom call will
work? >>https://mit.zoom.us/(b) (6) <

Looking forward!

Jeff

On May 6, 2021, at 18:50, Jeff Freilich (b) (6) wrote:

Thanks, Jessica. I've alerted the four PIs on this project, including Cynthia, and I'm trying to get something nailed down ASAP.

Jeff Freilich
Massachusetts Institute of Technology
(b) (6)
Cell: (b) (6)
>>https://www.linkedin.com/in/mishuma/<<;
>>https://mit.zoom.us/my/mishuma<<;
he/him/his

On May 6, 2021, at 17:30, Young, Jessica L. EOP/OSTP (b) (6) > wrote:

Hi Cynthia,
We're looking forward to speaking soon and learning more about the RAISE initiative! (I'm shifting you and Lynne to bcc you spare your inboxes.)

Jeff,
Thank you for helping us find an ideal time to meet. Would any of the following times work next week?

- Monday: 3-4pm
- Tuesday: 1-2pm, 4-5pm
- Wednesday 10-11am, 2-3pm
- Thursday or Friday: 3-5pm

Best,
Jessica

From: Cynthia Breazeal (b) (6)
Sent: Thursday, May 6, 2021 5:11 PM
To: Parker, Lynne E. EOP/OSTP (b) (6)
Cc: Cynthia Breazeal (b) (6) Jeff Freilich (b) (6) Lynch, Justin R. EOP/OSTP (b) (6) >; Young, Jessica L. EOP/OSTP (b) (6) >
Subject: Re: [EXTERNAL] ai.gov and MIT

Awesome! Jeff will help with schedule on ours

Jeff, let's be sure to include Hal, Eric and Hae won

Looking forward to it!

cynthia

On May 6, 2021, at 5:01 PM, Parker, Lynne E. EOP/OSTP (b) (6) wrote:

Hi Cynthia!

Great to hear from you. I hope you're doing well.

Yes, we would love to talk with you about the RAISE initiative. I'm copying a couple of colleagues in my office – Justin Lynch, who heads up our AI education efforts, and Jessica Young, who heads up our responsible AI efforts. They can also help with the scheduling at our end. Looking forward to talking with you soon!

Lynne

From: Cynthia Breazeal (b) (6)
Sent: Thursday, May 6, 2021 11:36 AM
To: Parker, Lynne E. EOP/OSTP (b) (6)
Cc: Cynthia Breazeal (b) (6); Jeff Freilich (b) (6)
Subject: [EXTERNAL] ai.gov and MIT

Hi Lynne!

I hope you are safe and well.

We say this announcement with interest. I have a new MIT-wide initiative on Responsible AI for Social Empowerment and Education (RAISE) that has a huge broad educational and outreach effort on AI, ethical design, and its societal implications.
For K12, voc-tech/community college, and adult workforce

Would love to set up a time to discuss how we can help your effort. We have a lot of curricular materials for K12 and several impact programs to reach K12 underserved and under-resourced communities nationwide.

best

cynthia

On May 5, 2021, at 8:22 PM, Hal Abelson (b) (6) wrote:

The White House has just launched ai.gov, which is meant to bring AI to the general public. One of the focus areas is computing classroom resources
>>>>https://www.nsf.gov/news/classroom/computing.jsp<<<<;;;
including a resource site by NSF.

Let's get aieducation.mit.edu listed here.

== Hal

Hal Abelson
(b) (6)
Prof. of Comp. Sci. and Eng.
MIT Dept. of Elec. Eng. and Comp. Sci.

--
Jessica Young
Policy Advisor for AI
Office of Science and Technology Policy
Executive Office of the President
Cell (b) (6)

--
Jessica Young
Policy Advisor for AI
Office of Science and Technology Policy
Executive Office of the President
Cell (b) (6)

[EXTERNAL] Re: Meet with Eric Lander this Weekend?

From: Rajeev Ram (b) (6)

To: "Lo, Kevin C. EOP/OSTP" (b) (6)

Date: Wed, 16 Jun 2021 20:23:34 -0400

My schedule is relatively flexible overt the weekend. Please let me know what works for Eric.

On Wed, Jun 16, 2021, 5:52 PM Lo, Kevin C. EOP/OSTP (b) (6) wrote:

> Dear Professor Ram:
>
> I hope you're doing well. My name is Kevin Lo, and I'm a special assistant at OSTP.
>
> I wanted to reach out and see if you might have time to meet with Eric this weekend in Boston.
>
> Thanks so much in advance,
>
> Kevin
>
> Kevin Lo *(he/him)*
>
> Special Assistant
>
> Office of Science and Technology Policy
>
> Executive Office of the President
> (b) (6)
>
> Cell: (b) (6)

Re: [EXTERNAL] Re: Meet with Eric Lander this Weekend?

From: Rajeev Ram (b) (6)

To: "Lo, Kevin C. EOP/OSTP" (b) (6) >

Date: Sat, 19 Jun 2021 16:00:19 -0400

Is there a separate entrance for (b) (6)

On Sat, Jun 19, 2021, 7:42 AM Lo, Kevin C. EOP/OSTP (b) (6) wrote:

> Good morning, Professor Ram!
>
> I wanted to see if you needed any more information for this afternoon or if you're all set to meet Eric at his home at 4pm today!
>
> Thanks so much,
>
> Kevin
>
> Sent from my iPhone
>
> > On Jun 18, 2021, at 11:46 AM, Lo, Kevin C. EOP/OSTP (b) (6) wrote:
> >
> > Perfect. Might meeting at Eric's home work for you? He's at (b) (6)
> >
> > Thanks so much,
> >
> > Kevin
> >
> > Kevin Lo *(he/him)*
> >
> > Special Assistant
> >
> > Office of Science and Technology Policy

Executive Office of the President
(b) (6)

Cell: (b) (6)

From: Rajeev Ram (b) (6)
Sent: Friday, June 18, 2021 10:04 AM
To: Lo, Kevin C. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] Re: Meet with Eric Lander this Weekend?

Sure 4pm Saturday is fine.

On Fri, Jun 18, 2021, 9:47 AM Lo, Kevin C. EOP/OSTP (b) (6) wrote:

> Dear Rajeev:
>
> I wanted to quickly follow up here! Might tomorrow at 4pm work for you to meet in-person with Eric?
>
> Thanks so much,
>
> Kevin
>
> Kevin Lo *(he/him)*
>
> Special Assistant
>
> Office of Science and Technology Policy
>
> Executive Office of the President
> (b) (6)
>
> Cell: (b) (6)

From: Lo, Kevin C. EOP/OSTP
Sent: Thursday, June 17, 2021 11:39 AM
To: 'Rajeev Ram' (b) (6)
Subject: RE: [EXTERNAL] Re: Meet with Eric Lander this Weekend?

Thanks so much for the quick response!

We're still locking down a few details for this weekend, but might we be able to tentatively plan on Saturday at 4pm? And if that gets moved, Sunday at 3pm?

Thanks so much,
Kevin

Kevin Lo *(he/him)*

Special Assistant

Office of Science and Technology Policy

Executive Office of the President
(b) (6)

Cell: (b) (6)

From: Rajeev Ram (b) (6)
Sent: Wednesday, June 16, 2021 8:24 PM
To: Lo, Kevin C. EOP/OSTP (b) (6)
Subject: [EXTERNAL] Re: Meet with Eric Lander this Weekend?

My schedule is relatively flexible overt the weekend. Please let me know what works for Eric.

On Wed, Jun 16, 2021, 5:52 PM Lo, Kevin C. EOP/OSTP (b) (6) wrote:

> Dear Professor Ram:
>
> I hope you're doing well. My name is Kevin Lo, and I'm a special assistant at OSTP.
>
> I wanted to reach out and see if you might have time to meet with Eric this weekend in Boston.
>
> Thanks so much in advance,
>
> Kevin
>
> Kevin Lo *(he/him)*
>
> Special Assistant
>
> Office of Science and Technology Policy
>
> Executive Office of the President
> (b) (6)
>
> Cell: (b) (6)

[EXTERNAL] Re: Rules

From Jared Cohen (b) (6) >
:
To: "Lander, Eric S. EOP/OSTP" (b) (6)
Cc: Diana Skurka (b) (6) , "Lo, Kevin C. EOP/OSTP"
(b) (6) Lori Lander (b) (6) >
Date: Sun, 20 Jun 2021 10:07:13 -0400

Thanks, Eric. We are very excited to have you and we look forward to adhering perfectly to all of these rules. Adding Diana so she also has the details. Thank you again for putting the effort in to find a path forward.

On Sat, Jun 19, 2021 at 7:00 PM Lander, Eric S. EOP/OSTP (b) (6) wrote:

> Hi Jared:
>
> Good to talk. WH Legal says that I can attend in my personal capacity. The relevant rules for identifying me are below. Please take care concerning identifying me, especially as noted in the bold below.
>
> Best,
>
> Eric
>
> - You are not authorized to speak in an official capacity on behalf of the US government.
> - You should make a disclaimer that the views expressed are your personal views and are not necessarily the views/positions of the White House, the Administration or the US government.
> - You may not use your official title or position in a way that could suggest that you are speaking in your official capacity.
> - Please ensure that the organizer of this event is aware that you are participating solely in your personal capacity, and does not advertise the event in a way that suggests otherwise. ***Importantly, please inform the organizer not to identify you by your official title or position in any promotional materials, or on any website or invitation, except that your official title or position can be used as part of a bio which also contains at least three additional***

biographical details about yourself, and which does not give any greater prominence to your official title/position over your other biographical details. If the organizer asks that you provide a bio for use in connection with this event, please send it to me so that I can review and approve it.

- If you plan to provide a paper or publish any materials (including PowerPoint slides) as part of this engagement, please ensure that they do not contain non-public information, alert you to any concerns over the display of your official position or title, and provide an appropriate disclaimer if needed.
- You may not make any use of your official US government photograph, or any United States or Executive Office of the President logos.
- You may not use any official time or resources to prepare for or participate in this event. You must take personal leave or otherwise establish that you are not working pursuant to your supervisor's/office's policies if the event occurs when you would otherwise be on duty.
- You may not use or release non-public US government information.

--

Jared Cohen | Tel: (b) (6) | Twitter: @jaredcohen | Linked-In

My Books:

Life After Power *(Simon & Schuster - Forthcoming)*

Accidental Presidents *(Simon & Schuster)*

The New Digital Age - Co-authored w/Eric Schmidt *(Knopf)*

Children of Jihad *(Gotham Books/Penguin)*

One Hundred Days of Silence: America and the Rwanda Genocide *(Rowman & Littlefield)*

[EXTERNAL] Re: Rules

From: Adam Topper (b) (6)

To: Diana Skurka (b) (6)

Cc: "Lander, Eric S. EOP/OSTP" (b) (6), "Lo, Kevin C. EOP/OSTP" (b) (6), Lori Lander (b) (6), Jared Cohen (b) (6), Yellowstone Weekend Info (b) (6)

Date: Wed, 23 Jun 2021 13:54:16 -0400

Hi Eric,

We've received your biography and headshot - thank you for coordinating.

Our program packets are being sent to the printers tomorrow and I want to confirm if you would like us to include your current title, or not list any title under your name in the packets. As a reminder, these packets are not promotional and are exclusively for attendees to use while they are at the Yellowstone Weekend.

If you would like us to include your current title, can you confirm that the below title is permissible? I can confirm that your biography contains at least three additional biographical details about yourself, and does not give any greater prominence to your official title/position over your other biographical details as suggested by White House Counsel.

We plan to list your title as: **Director, White House Office of Science and Technology Policy**.

Many thanks,
Adam Topper
Office of Eric Schmidt
Schmidt Futures

On Mon, Jun 21, 2021 at 11:29 AM Adam Topper (b) (6) > wrote:

> Thanks for sharing all of these details with us, Eric, we are very excited to have the family attend again this year.

Our programs are scheduled to go to the printer this week and we want to ensure that your information is included. Will you be able to share your personal bio and headshot by Wednesday, June 23?

Many thanks,
Adam Topper
Office of Eric Schmidt
Schmidt Futures

On Mon, Jun 21, 2021 at 8:25 AM Diana Skurka (b) (6) wrote:

Thrilled that you are able to join Eric. These details have been noted on our end.

On Sun, Jun 20, 2021 at 10:07 AM Jared Cohen (b) (6) wrote:

Thanks, Eric. We are very excited to have you and we look forward to adhering perfectly to all of these rules. Adding Diana so she also has the details. Thank you again for putting the effort in to find a path forward.

On Sat, Jun 19, 2021 at 7:00 PM Lander, Eric S. EOP/OSTP (b) (6) wrote:

Hi Jared:

Good to talk. WH Legal says that I can attend in my personal capacity. The relevant rules for identifying me are below. Please take care concerning identifying me, especially as noted in the bold below.

Best,

Eric

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Jared Cohen | Tel: (b) (6) | Twitter: @jaredcohen | Linked-In

My Books:

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The New Digital Age - Co-authored w/Eric Schmidt *(Knopf)*

Children of Jihad *(Gotham Books/Penguin)*

One Hundred Days of Silence: America and the Rwanda Genocide *(Rowman & Littlefield)*

--

Diana Skurka

Senior Manager & Head of Community

(b) (6)

>http://schmidtfutures.com/<

RE: [EXTERNAL] Optimizing H-1B fees for domestic STEM training programs

From "Alstott, Jeffrey D. EOP/NSC'(b) (6)
:
To: Doug Rand (b) (6), "Nice, Amy M. EOP/OSTP" (b) (6)
"Matheny, Jason G. EOP/OSTP'(b) (6)>, "Lynch, Justin R. EOP/OSTP" (b) (6)
Cc: Lindsay Milliken (b) (6)
Date: Fri, 25 Jun 2021 13:42:01 -0400

Many thanks, Doug!
Jeff

From: Doug Rand (b) (6)
Sent: Friday, June 25, 2021 10:32 AM
To: Nice, Amy M. EOP/OSTP (b) (6) Matheny, Jason G. EOP/OSTP (b) (6) Alstott, Jeffrey D. EOP/NSC (b) (6); Lynch, Justin R. EOP/OSTP (b) (6)>
Cc: Lindsay Milliken (b) (6)
Subject: [EXTERNAL] Optimizing H-1B fees for domestic STEM training programs

Hi Jason, Amy, Jeff, and Justin,

Lindsay Milliken and I have a new paper out this week from the FAS Day One Project, which might be of interest to you—it's a way to raise a lot more money for domestic STEM education and training without increasing appropriations:

***Building an Evergreen $1 Billion Fund for Science and Technology Career Advancement**: How to Expand H-1B Fees for Innovative Workforce Training and Inclusive Graduate STEM Education*
(summary here, and full paper attached)

We provide a brief history of the H-1B fee-based funding stream for STEM training and education, which was created by Congress in the late 1990s but has not been meaningfully updated in the succeeding decades.

We argue that Congress should increase the fees paid by H-1B employers to reflect (a) the increase in inflation over the past two decades, as well as (b) the ability of major corporations, which are

often the most prolific sponsors of H-1B workers, to pay more than small businesses. An updated three-tier fee schedule could raise over $1 billion each year for domestic STEM talent development.

We also provide recommendations for how the executive branch can use the existing H-1B fund to launch innovative programs that advance U.S. economic competitiveness and diversify the STEM talent pipeline—two mutually reinforcing goals:

- Reestablishing the TechHire Initiative to rapidly train U.S. workers for in-demand technology jobs

- Establishing a new Advanced Research Projects Agency—Labor (ARPA-L) to conduct high-impact R&D programs that create breakthroughs to meet America's workforce challenges

- Significantly increasing the number of graduate research fellowships dedicated to students in STEM fields who completed their undergraduate education at emerging research universities

- Significantly increasing the number of faculty training grants in STEM fields where a dearth of professors has created a bottleneck for graduate education (e.g. artificial intelligence)

Please don't hesitate to send us any immediate questions or feedback, and we would be happy to discuss any of these ideas in more detail.

Thanks and take care,
Doug

Doug Rand
Senior Fellow
Federation of American Scientists
(b) (6)
Bio / LinkedIn / Twitter

RE: Thank you!

From: "Koizumi, Kei EOP/OSTP" (b) (6)

To: Helen C Haislmaier (b) (6)

Date: Sun, 27 Jun 2021 21:15:28 -0400

Helen, Thank YOU for the opportunity.

It was a pleasure to meet the students, and I hope I see some of them soon, in the future.

Kei

Kei Koizumi
(he/him)
Chief of Staff
Office of Science and Technology Policy
(b) (6)

From: Helen C Haislmaier (b) (6) >

Sent: Monday, June 21, 2021 1:24 PM

To: Koizumi, Kei EOP/OSTP (b) (6)

Subject: [EXTERNAL] Thank you!

Dear Kei,

Thank you SO much for taking the time to chat with our summer interns last Wednesday (and please accept my apologies for taking so long to send this – I thought I'd sent it last week but just found it under several open emails on my desktop!)

The kids feedback has been very positive and they definitely enjoyed learning about OSTP and hearing all your insights.

You were a real star to do this for us and we all really appreciate it! Now Eric is officially 'on-board', I'm sure you going to be even busier – but what a great place to be in.

Have a great summer and once again, thanks for taking time out of your busy schedule talk to the students. Hope I/we can return the favor some time!

Best wishes,

Helen

Helen Haislmaier
Program Coordinator
MIT Washington Office/Federal Relations
Cell: (b) (6)

From: "Koizumi, Kei EOP/OSTP" (b) (6)
Date: Monday, June 14, 2021 at 2:10 PM
To: Helen C Haislmaier <(b) (6)
Subject: RE: invitation to talk with MIT and UVA students this summer

Helen,

Thank you. I already have the Zoom and I will see you Wednesday.

Attached is a bio you can share.

Feel free to share this email address.

Kei

Kei Koizumi
(he/him)
Chief of Staff
Office of Science and Technology Policy
(b) (6)

From: Helen C Haislmaier (b) (6)
Sent: Monday, June 14, 2021 12:37 PM
To: Koizumi, Kei EOP/OSTP (b) (6)
Subject: [EXTERNAL] Re: invitation to talk with MIT and UVA students this summer

Hi Kei,

We're looking forward to hosting you on Wednesday at 5pm. I'm not sure if Kate sent you the zoom invitation but just in case, here it is:

Join Zoom Meeting
>>https://mit.zoom.us/(b) (6)

2 quick questions:

1. Do you have a brief bio you'd like me to use to introduce you or is your LinkedIn info. ok?
2. We have a couple of students – 1 from MIT and one from UVa – who like to send out a Thank You note to each speaker so I wanted to check if you'd be ok with me giving them your email address – or would you rather they send them to me and I forward them to you?

Thanks again for agreeing to speak to the summer interns – we're all looking forward to hearing from you!

Best regards,

Helen

Helen Haislmaier
Program Coordinator
MIT Washington Office/Federal Relations
Cell: (b) (6)

From: "Koizumi, Kei EOP/OSTP" (b) (6)
Date: Wednesday, May 26, 2021 at 3:56 PM
To: Kate Stoll (b) (6)
Cc: David Goldston (b) (6) >, Helen C Haislmaier (b) (6)
Subject: RE: invitation to talk with MIT and UVA students this summer

Thank you all, I'm confirmed to participate on June 16th 5 PM. Looking forward to it!

Kei

Kei Koizumi
(he/him)
Acting Director and Chief of Staff
Office of Science and Technology Policy
(b) (6)

From: Kate Stoll (b) (6)

Sent: Tuesday, April 20, 2021 4:38 PM

To: Koizumi, Kei EOP/OSTP <(b) (6)

Cc: David Goldston(b) (6) Helen C Haislmaier (b) (6)

Subject: [EXTERNAL] invitation to talk with MIT and UVA students this summer

Dear Kei,

I hope you are getting a chance to enjoy the beautiful spring weather, though I know you are exceedingly busy. I'm writing to ask if you would consider talking to a group of MIT and UVA student interns this summer?

The MIT Washington Summer Internship Program is for undergraduates of any major and allows students the opportunity to apply their specialized knowledge and problem-solving skills to public policy issues. Selected students spend a minimum of two summer months in Washington, DC participating in work at the intersection between science, technology, and public policy, through hands-on, research-oriented work at agencies, advocacy groups, corporations, and legislative and executive offices.

Unfortunately, the program will have to be conducted online due to the pandemic, but we still aim to give our students the best possible experience. With this in mind, **we would like to invite you to virtually address the students on a topic of your choice, any Wednesday between June 2nd and July 28th. Our invited speaker meetings usually take place from 5:00 – 6:00pm**, allowing plenty of time for questions, but given how busy your schedule is, we have the flexibility to offer the meeting **any time after 3:00pm EST, as your calendar allows.**

For the last 20 years, we have combined our extra-curricular speaker program with summer students from the University of Virginia, so there would be approximately 20 students in attendance (with the majority from MIT). We realize how busy your schedule is, and would greatly appreciate it if you were able to spare some time to talk to the students this summer. If you are amenable to a virtual meeting with the students, my colleague, Helen Haislmaier (cc'ed), would be happy to schedule it.

Thank you for considering this request.

All the best,
Kate and Helen

Kate Stoll, Ph.D.
Senior Policy Advisor
MIT Washington Office
Tel: (b) (6)

(b) (6)

Helen Haislmaier
Program Coordinator
MIT Washington Office/Federal Relations
Cell: (b) (6)
(b) (6)

Re: [EXTERNAL] reducing infectious diseases' impact

From Mike Fisher (b) (6)
:
To: "Guerra, Stephanie L. EOP/OSTP" (b) (6)
Cc: "McKelvey, Greg G. Jr. EOP/OSTP" (b) (6) >, "Schmoyer, Michael W. EOP/OSTP" (b) (6)
Date: Mon, 28 Jun 2021 21:10:41 -0400

Got it; thanks Steph!

On Mon, Jun 28, 2021 at 8:31 PM Guerra, Stephanie L. EOP/OSTP (b) (6) > wrote:

Thanks Mike- piggybacking off of Michael's priorities I'd also like to better understand:

- What triggers a signal from noise in this type of system and how that leads to a targeted prevention approach
- How the infrastructure and/or capacity building could also be leveraged for detecting accidental/deliberate threats

Best,

Steph

From: Mike Fisher (b) (6)
Sent: Monday, June 28, 2021 6:40 PM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Cc: Guerra, Stephanie L. EOP/OSTP <(b) (6) ; McKelvey, Greg G. Jr. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Thanks for this, Michael - we'll see what Alex's availability is like on the 9th.

Greg, Steph - if you have additional questions or points of interest you'd like us to share with Alex ahead of time, please don't hesitate to pass along.

Have a good one,

Mike

On Mon, Jun 28, 2021 at 5:18 PM Schmoyer, Michael W. EOP/OSTP
(b) (6) wrote:

> Hi Mike-
>
> I'm actually trying to be on leave that week, but how do things look on the 9th? I'm also cc'ing Greg and Steph as they would likely be interested.
>
> For me, I'm most attracted to 1) an overall summary brief on the paper (and the rationale for his perspective) and 2) a deeper dive on elements pertaining to predictive analytics/forecasting/modeling as it relates to early indications/warnings of emerging biological threats.
>
> Thanks for helping this come together,
>
> Michael
>
> **From:** Mike Fisher (b) (6)
> **Sent:** Monday, June 28, 2021 1:33 PM

To: Schmoyer, Michael W. EOP/OSTP (b) (6)

Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Hi Michael (bcc to save inbox: Andrew),

We reconnected with Alex Dehgan, the author of Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats, and he's looking forward to delivering a briefing on the paper.

Can you suggest three time blocks that work well for you on July 6th, or other days that same week / week after?

Also, would you like us to prepare an agenda for the briefing, or is a more freeform Q&A-style session better for you?

Lastly, are there any questions about the paper that you have for Alex that you'd like us to get to him ahead of the briefing, or specific points he raises in the paper that you'd especially like him to speak to?

Thank you,

Mike

On Sun, Jun 27, 2021 at 10:16 AM Mike Fisher (b) (6) wrote:

> Good to know; thanks Michael!

- Mike

On Sun, Jun 27, 2021 at 6:59 AM Schmoyer, Michael W. EOP/OSTP
(b) (6) wrote:

> That sounds great, thanks Mike. Related, I'm chairing an interagency working group that is along these lines … there may be a second request for a follow-on brief to a larger group.
>
> Best,
>
> Michael

From: Mike Fisher (b) (6)
Sent: Friday, June 25, 2021 5:51 PM
To: Hebbeler, Andrew M. EOP/OSTP (b) (6)
Cc: Schmoyer, Michael W. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

> Hi Andrew, and nice to be connected, Michael -
>
> We will rally the authors and touch back early next week re briefing on the preventing the next pandemic paper. Happy to do it!
>
> Have a nice weekend,
>
> Mike

On Fri, Jun 25, 2021 at 4:48 PM Hebbeler, Andrew M. EOP/OSTP
(b) (6) wrote:

Hi Mike: Connecting you with Michael. We'd love if you could help arrange a briefing by the preventing the next pandemic authors. Thank you!

Sent from my iPhone

On Jun 25, 2021, at 9:30 AM, Schmoyer, Michael W. EOP/OSTP
<(b) (6) > wrote:

Hi Andrew-

I would be interested in connecting with the author(s) for Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats

Relates to epi forecasting/modeling work I'm doing

Thanks for asking,

mws

From: Hebbeler, Andrew M. EOP/OSTP (b) (6)
Sent: Friday, June 25, 2021 8:28 AM
To: DL OSTP HLS <(b) (6) DL OSTP Biorisk
(b) (6)
Subject: FW: [EXTERNAL] reducing infectious diseases' impact

FYI – does anyone want to hear from any of the day one paper authors? Happy to connect you with Mike if so…..

From: Mike Fisher (b) (6)
Sent: Friday, June 25, 2021 8:22 AM
To: Hebbeler, Andrew M. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Morning Andrew, hope your week has gone well! Just wanted to re-up re any crystallization of OSTP priority issues in the life sciences / modern biotechnology / synbio space, or if you or any of your colleagues would find it useful to work with the authors of any of the infectious diseases-related Day One papers to further develop ideas in a direction you are pursuing.

Best,

Mike

On Tue, Jun 15, 2021 at 3:33 PM Mike Fisher (b) (6) wrote:

> Hi Andrew, just wanted to update you on our conversations with Doug and India. There is mutual interest in pursuing a collaboration that makes sense for both our orgs. Our next step is to put together some ideas about research and analysis projects / convenings we could potentially collaborate on in advance of our next conversation with EBRC.
>
> Have your OSTP priorities around life sciences / modern biotechnology / synbio been shaping up (outside of reducing the impacts of infectious diseases)? Some ideas we have been mulling over include...
>
> - updating the U.S. framework for the regulation of genetically engineered products

- a framework for a National Synthetic Biology Initiative (inspired by the National Artificial Intelligence Initiative, overseeing and implementing the U.S. AI strategy - AI.gov)

- maximizing the contributions of foreign nationals to U.S. engineering biology while maintaining scientific integrity
- promoting ethical use of engineering biology practices

- leveraging the use of standards and standardization in the synthetic biology industry and biomanufacturing

...and it would be great to get your feedback on whether any of these, or perhaps others not on the list, are priority issues.

Also curious if any follow-on regarding those six Day One resources re pandemic preparedness / infectious diseases is in order. Let us know!

Hope you're holding up okay!

Best,

Mike

On Wed, Jun 2, 2021 at 5:19 PM Hebbeler, Andrew M. EOP/OSTP (b) (6) wrote:

> Hi Mike: Great chatting with you too, and thanks for sending these resources! Would be great to hear how your discussions with Doug and India go.
>
> +others FYSA, in case these FAS/D1P docs aren't already on their radar.

Thanks again!

Andrew

From: Mike Fisher (b) (6)
Sent: Wednesday, June 2, 2021 8:59 AM
To: Hebbeler, Andrew M. EOP/OSTP (b) (6)
Subject: [EXTERNAL] reducing infectious diseases' impact

Hi Andrew,

Thank you again for talking with me the other week. Following up on our conversation, if any additional OSTP priorities have crystallized beyond pandemic preparedness / taking measures to reduce the impact of infectious diseases, it would be great to schedule another call.

And regarding pandemic preparedness / infectious diseases, just sharing six FAS Day One papers in our portfolio that may be of interest to you and your team (happy to prepare a brief on any of these or work with the authors to further develop ideas in a direction you are pursuing):

Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats

Shift from reacting to disease outbreaks – which is economically devastating – to detecting, addressing, and mitigating the major upstream factors that contribute to the emergence of diseases prior to an outbreak.

Improving Federal Management of Wildlife Movement and Emerging Infectious Disease

Reduce the risk of emerging infectious diseases entering the United States, offer greater protection to citizens from zoonotic diseases, and protect American biodiversity from losses due to wildlife diseases.

A National Bioeconomy Manufacturing and Innovation Initiative

Ramp up cross-cutting, cutting-edge research and development across the areas of healthcare, food & agriculture, energy, environment, and industrial applications to develop fundamental and publicly available tools, and bolster American biomanufacturing.

Open Access to Federally-funded Research Data

Accelerate scientific progress by (i) requiring scientists who receive federal funding to share their research data and (ii) directing federal research agencies to coordinate to build an International Research Data Commons that allows research data to be easily discovered and shared.

Creating a COVID-19 Commission on Public Health Misinformation

Examine our nation's response to the 2020 pandemic using a mechanism that is modeled on the 9/11 Commission, with one Commission focusing on public health communication and messaging that would assess the information about the pandemic: what was made publicly available, how the information affected our societal response, and what should be done to limit the impact of false and dangerously misleading information moving forward.

A National Strategy to Counter COVID-19 Misinformation

Establish an office at the Department of Health and Human Services dedicated to countering COVID-19 misinformation.

Also possibly of interest, on Friday I'll be meeting with Doug Friedman of BioMADE and India Hook-Barnard of the Engineering Biology Research Consortium to discuss the potential of sourcing policy ideas from the synbio community.

Thanks again, Andrew, and looking forward to talking again soon!

Best,

Mike

--

Michael A. Fisher, Ph.D.

Senior Fellow

Federation of American Scientists

1112 16th Street NW, Suite 400

Washington, DC 20036

Email: (b) (6)

LinkedIn: bit.ly/MAFisher

Twitter: @mykfish

Join up to contribute your expertise to the science and technology knowledge-base for policymakers: Congressional Science Policy Initiative

--

Michael A. Fisher, Ph.D.

Senior Fellow

Federation of American Scientists

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Michael A. Fisher, Ph.D.

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LinkedIn: bit.ly/MAFisher

Twitter: @mykfish

Join up to contribute your expertise to the science and technology knowledge-base for policymakers: Congressional Science Policy Initiative

RE: [EXTERNAL] reducing infectious diseases' impact

From "Schmoyer, Michael W. EOP/OSTP" (b) (6)
:
To: Mike Fisher (b) (6)
Cc: "McKelvey, Greg G. Jr. EOP/OSTP" (b) (6), "Guerra, Stephanie L. EOP/OSTP" (b) (6)
Date: Mon, 28 Jun 2021 17:18:48 -0400

Hi Mike-

I'm actually trying to be on leave that week, but how do things look on the 9th? I'm also cc'ing Greg and Steph as they would likely be interested.

For me, I'm most attracted to 1) an overall summary brief on the paper (and the rationale for his perspective) and 2) a deeper dive on elements pertaining to predictive analytics/forecasting/modeling as it relates to early indications/warnings of emerging biological threats.

Thanks for helping this come together,
Michael

From: Mike Fisher <(b) (6)>
Sent: Monday, June 28, 2021 1:33 PM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Hi Michael (bcc to save inbox: Andrew),

We reconnected with Alex Dehgan, the author of Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats, and he's looking forward to delivering a briefing on the paper.

Can you suggest three time blocks that work well for you on July 6th, or other days that same week / week after?

Also, would you like us to prepare an agenda for the briefing, or is a more freeform Q&A-style session better for you?

Lastly, are there any questions about the paper that you have for Alex that you'd like us to get to him ahead of the briefing, or specific points he raises in the paper that you'd especially like him to speak to?

Thank you,

Mike

On Sun, Jun 27, 2021 at 10:16 AM Mike Fisher (b) (6) > wrote:

> Good to know; thanks Michael!
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> > **Sent:** Friday, June 25, 2021 5:51 PM
> > **To:** Hebbeler, Andrew M. EOP/OSTP (b) (6)
> > **Cc:** Schmoyer, Michael W. EOP/OSTP (b) (6)
> > **Subject:** Re: [EXTERNAL] reducing infectious diseases' impact
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> > We will rally the authors and touch back early next week re briefing on the preventing the next pandemic paper. Happy to do it!
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Sent from my iPhone

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I would be interested in connecting with the author(s) for Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats
Relates to epi forecasting/modeling work I'm doing

Thanks for asking,
mws

From: Hebbeler, Andrew M. EOP/OSTP (b) (6)
Sent: Friday, June 25, 2021 8:28 AM
To: DL OSTP HLS (b) (6); DL OSTP Biorisk (b) (6)
Subject: FW: [EXTERNAL] reducing infectious diseases' impact

FYI – does anyone want to hear from any of the day one paper authors? Happy to connect you with Mike if so.....

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To: Hebbeler, Andrew M. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Morning Andrew, hope your week has gone well! Just wanted to re-up re any crystallization of OSTP priority issues in the life sciences / modern biotechnology / synbio space, or if you or any of your colleagues would find it useful to work with the authors of any of the infectious diseases-related Day One papers to further develop ideas in a direction you are pursuing.

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On Tue, Jun 15, 2021 at 3:33 PM Mike Fisher (b) (6) wrote:

Hi Andrew, just wanted to update you on our conversations with Doug and India. There is mutual interest in pursuing a collaboration that makes sense for both our orgs. Our next step is to put together some ideas about research and analysis projects / convenings we could potentially collaborate on in advance of our next conversation with EBRC.

Have your OSTP priorities around life sciences / modern biotechnology / synbio been shaping up (outside of reducing the impacts of infectious diseases)? Some ideas we have been mulling over include...
- updating the U.S. framework for the regulation of genetically engineered products
- a framework for a National Synthetic Biology Initiative (inspired by the National Artificial Intelligence Initiative, overseeing and implementing the U.S. AI strategy - AI.gov)
- maximizing the contributions of foreign nationals to U.S. engineering biology while maintaining scientific integrity
- promoting ethical use of engineering biology practices
- leveraging the use of standards and standardization in the synthetic biology industry and biomanufacturing

...and it would be great to get your feedback on whether any of these, or perhaps others not on the list, are priority issues.

Also curious if any follow-on regarding those six Day One resources re pandemic preparedness / infectious diseases is in order. Let us know!

Hope you're holding up okay!

Best,

Mike

On Wed, Jun 2, 2021 at 5:19 PM Hebbeler, Andrew M. EOP/OSTP
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>
> +others FYSA, in case these FAS/D1P docs aren't already on their radar.
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> Thanks again!
> Andrew
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> **Sent:** Wednesday, June 2, 2021 8:59 AM
> **To:** Hebbeler, Andrew M. EOP/OSTP (b) (6)
> **Subject:** [EXTERNAL] reducing infectious diseases' impact

Hi Andrew,

Thank you again for talking with me the other week. Following up on our conversation, if any additional OSTP priorities have crystallized beyond pandemic preparedness / taking measures to reduce the impact of infectious diseases, it would be great to schedule another call.

And regarding pandemic preparedness / infectious diseases, just sharing six FAS Day One papers in our portfolio that may be of interest to you and your team (happy to prepare a brief on any of these or work with the authors to further develop ideas in a direction you are pursuing):

Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats
Shift from reacting to disease outbreaks – which is economically devastating – to detecting, addressing, and mitigating the major upstream factors that contribute to the emergence of diseases prior to an outbreak.

Improving Federal Management of Wildlife Movement and Emerging Infectious Disease
Reduce the risk of emerging infectious diseases entering the United States, offer greater protection to citizens from zoonotic diseases, and protect American biodiversity from losses due to wildlife diseases.

A National Bioeconomy Manufacturing and Innovation Initiative
Ramp up cross-cutting, cutting-edge research and development across the areas of healthcare, food & agriculture, energy, environment, and industrial applications to develop fundamental and publicly available tools, and bolster American biomanufacturing.

Open Access to Federally-funded Research Data
Accelerate scientific progress by (i) requiring scientists who receive federal funding to share their research data and (ii) directing federal research agencies to coordinate to build an International Research Data Commons that allows research data to be easily discovered and shared.

Creating a COVID-19 Commission on Public Health Misinformation
Examine our nation's response to the 2020 pandemic using a mechanism that is modeled on the 9/11 Commission, with one Commission focusing on public health communication and messaging that would assess the information about the pandemic: what was made publicly available, how the information affected our societal response, and what should be done to limit the impact of false and dangerously misleading information moving forward.

A National Strategy to Counter COVID-19 Misinformation
Establish an office at the Department of Health and Human Services dedicated to countering COVID-19 misinformation.

Also possibly of interest, on Friday I'll be meeting with Doug Friedman of BioMADE and India Hook-Barnard of the Engineering Biology Research Consortium to discuss the potential of sourcing policy ideas from the synbio community.

Thanks again, Andrew, and looking forward to talking again soon!

Best,

Mike

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RE: [EXTERNAL] reducing infectious diseases' impact

From "Schmoyer, Michael W. EOP/OSTP" (b) (6)
:
To: Mike Fisher (b) (6), "Guerra, Stephanie L. EOP/OSTP"
(b) (6)
Cc: "McKelvey, Greg G. Jr. EOP/OSTP" (b) (6) >
Date: Tue, 29 Jun 2021 09:34:39 -0400

Good morning-
How about:

-between 1030 and 130 on the 13th

-between 1100 and 300 on the 14th

Best,
Michael

From: Mike Fisher (b) (6)
Sent: Tuesday, June 29, 2021 9:29 AM
To: Guerra, Stephanie L. EOP/OSTP (b) (6)
Cc: McKelvey, Greg G. Jr. EOP/OSTP (b) (6); Schmoyer, Michael W. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Hi all,

Alex is not available on 7/9; are there any days / time blocks that would work for you the week of July 12?

Best,

Mike

On Mon, Jun 28, 2021 at 9:10 PM Mike Fisher (b) (6) > wrote:

Got it; thanks Steph!

On Mon, Jun 28, 2021 at 8:31 PM Guerra, Stephanie L. EOP/OSTP (b) (6) wrote:

Thanks Mike- piggybacking off of Michael's priorities I'd also like to better understand:

- What triggers a signal from noise in this type of system and how that leads to a targeted prevention approach
- How the infrastructure and/or capacity building could also be leveraged for detecting accidental/deliberate threats

Best,
Steph

From: Mike Fisher (b) (6)
Sent: Monday, June 28, 2021 6:40 PM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Cc: Guerra, Stephanie L. EOP/OSTP (b) (6) >; McKelvey, Greg G. Jr. EOP/OSTP <(b) (6) >
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Thanks for this, Michael - we'll see what Alex's availability is like on the 9th.

Greg, Steph - if you have additional questions or points of interest you'd like us to share with Alex ahead of time, please don't hesitate to pass along.

Have a good one,

Mike

On Mon, Jun 28, 2021 at 5:18 PM Schmoyer, Michael W. EOP/OSTP (b) (6) wrote:

Hi Mike-

I'm actually trying to be on leave that week, but how do things look on the 9th? I'm also cc'ing Greg and Steph as they would likely be interested.

For me, I'm most attracted to 1) an overall summary brief on the paper (and the rationale for his perspective) and 2) a deeper dive on elements pertaining to predictive analytics/forecasting/modeling as it relates to early indications/warnings of emerging biological threats.

Thanks for helping this come together,
Michael

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[EXTERNAL] PLEASE READ: Yellowstone Weekend Itinerary & Pre-Departure Logistical FAQ

From:	Adam Topper (b) (6)
To:	Lori Lander (b) (6) "Lander, Eric S. EOP/OSTP" (b) (6)
Cc:	"Lo, Kevin C. EOP/OSTP" (b) (6) Yellowstone Weekend Info (b) (6)
Date:	Sun, 11 Jul 2021 10:00:00 -0400
Attachments:	Yellowstone Weekend_ PRE DEPARTURE LOGISTICAL FAQ .pdf (166.52 kB); Yellowstone Weekend_ AGENDA .pdf (159.24 kB)

Dear Lander Family,

On behalf of your hosts, Eric Schmidt and Jared Cohen, we are so looking forward to welcoming you next week to the 10th Annual Yellowstone Weekend!

This email contains critical details related to your travel, accommodations and participation, which we ask you to review in full before your scheduled departure.

Attached, you will find the following information:

- Schedule of Events & Venue Location Map
- Pre-Departure Logistical FAQ

TRAVEL

Your party's travel details are as follows:

- **Inbound Flight to BZN:** Schmidt Futures Charter from Dulles International Airport, departing at 10:00am ET, please arrive no later than 8:45 am ET.
- **Outbound Flight from BZN:** Schmidt Futures Charter from BZN departing at 10:00am MT and arriving to Dulles International Airport at 3:30pm ET

ACCOMMODATIONS

Your traveling party's accommodation will be as follows: [Address]

- **[Eric and Lori Lander]:** 12B Echo Lane: Bedroom 5: King Bed, Bath (Lower Level)
- **[Jessica Lander]:** 12B Echo Lane: Bedroom 4: Queen Bed, Bath (Lower Level)

Listed here are the other Yellowstone Weekend guests that you will be housed with:
Senator Matteo Renzi, Agnese Landini, and Mathias Cormann

ACTIVITIES
Please note that if you would still like to sign up for an activity you may do so at the Yellowstone Club on Thursday evening at the Welcome Dinner.

- If you are interested in participating in one of our morning activity offerings on Friday or Saturday, please read page 8 and follow the sign-up instructions in order to confirm your participation.
- If you have been notified that the Spa is your scheduled afternoon activity on Friday or Saturday, please email spa@yellowstoneclub.com or call (b) (6) to confirm your specific appointment time and type of treatment.

In addition, please allow us to highlight a few critical policies and logistical details that require action from your end:

COVID-19

- Guests ages 12 or older are required to provide proof of full vaccination against COVID-19 by emailing digital copies or photos of your party's vaccine cards to info@yellowstoneweekend.com by **today.**
- For our international and unvaccinated attendees (including children), we will require proof of a negative PCR test taken 72 hours prior to the event. This applies to vaccinated and unvaccinated members of your traveling party. **Please submit this to info@yellowstoneweekend.com prior to arrival or show your paperwork to a member of our concierge team upon arrival in Bozeman.**
- All attendees will receive a rapid COVID test prior to the start of Yellowstone Weekend. By July 14, each member of your traveling party is required to pre-register by creating an account prior to being tested. **Please use THIS LINK to register in advance of your departure.** Your testing location will depend on your confirmed flight details, please refer to pages 1-2 of our Pre-Departure Logistical FAQ for these details.

YELLOWSTONE
WEEKEND

Yellowstone Weekend 2021 Schedule of Events

THURSDAY, JULY 15

- 12:00pm – 4:00pm: Guest Arrivals
- 6:00pm – 7:30pm: Night Under the Stars Welcome Reception
- 7:30pm – 9:00pm: Dinner
- 9:00pm – 11:00pm: Dessert Reception

FRIDAY, JULY 16

- 8:00am – 9:00am: Breakfast
- 9:00am – 12:30pm: Sessions
- 12:30pm – 2:00pm: Lunch & The Lightning Round Session
- 2:30pm – 4:30pm: Activities
- 6:30pm – 9:30pm: Family Rodeo Evening: Dinner, Activities & Concert
- 10:00pm on: After Hours Party
- **8:00am – 5:00 pm: Optional COVID testing will be available for any guest who would like to opt into being tested daily while attending Yellowstone Weekend or requires testing prior to their outbound travel.**

SATURDAY, JULY 17

- 8:00am – 9:00am: Breakfast
- 9:00am – 12:30pm: Sessions
- 12:30pm – 2:00pm: Lunch
- 2:30pm – 4:30pm: Activities
- 5:30pm – 6:30pm: Teach Me Something Session
- 6:30pm – 7:30pm: Sunset Reception
- 7:30pm – 10:00pm: Closing Dinner
- 10:15pm on: After Hours Party
- **8:00am – 5:00 pm: Optional COVID testing will be available for any guest who would like to opt into being tested daily while attending Yellowstone Weekend or requires testing prior to their outbound travel.**

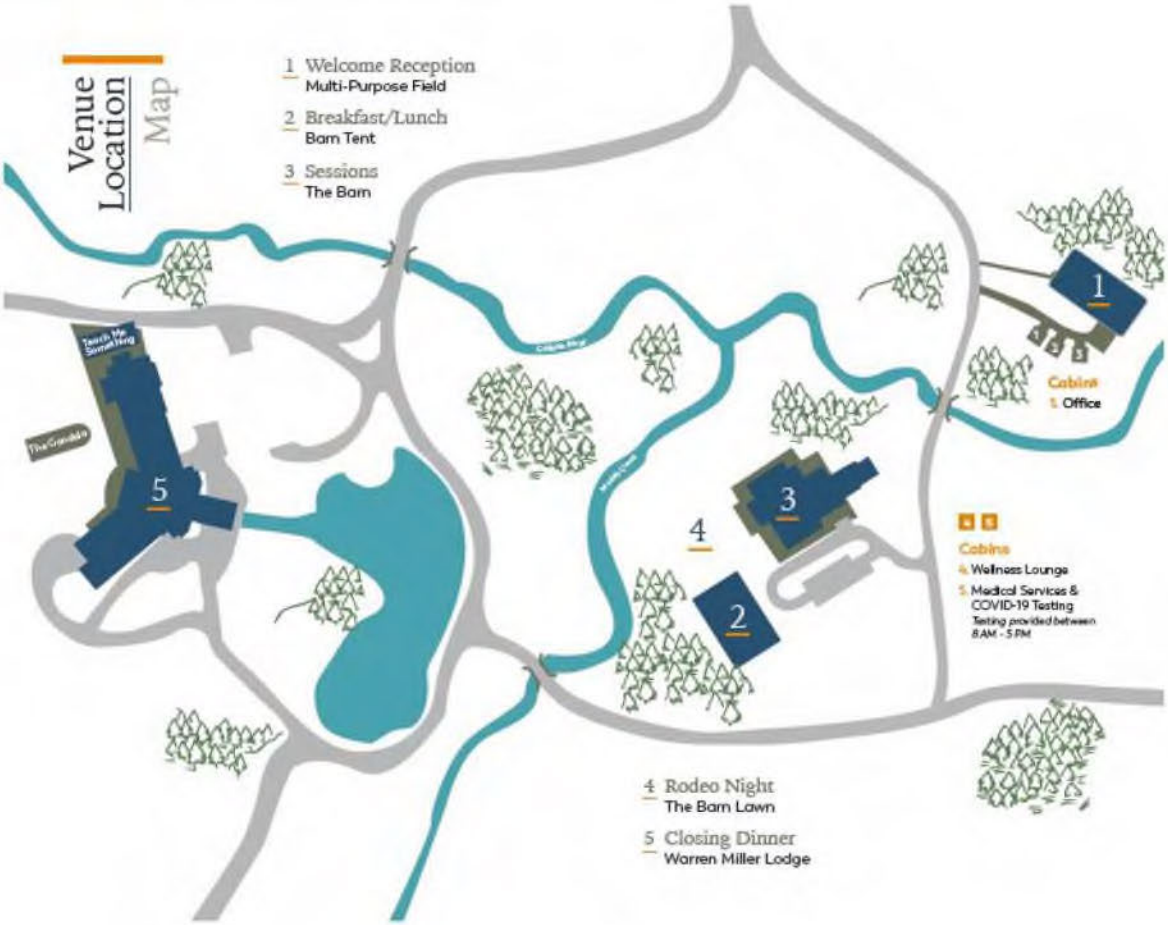
SUNDAY, JULY 18

- 7:30am – 9:30am: Breakfast
- 7:30am – 10:00am: Guest Departures

YELLOWSTONE
WEEKEND

Please note that you will receive our session descriptions, the guest list, additional details on our special evening events, venue locations and much more as you board the charter from our departure locations. If you and your traveling party are flying commercially or via a private charter that has not been arranged by the Yellowstone Weekend team, your program book will be found in your pre-assigned accomodations upon arrival at the Yellowstone Club.

Yellowstone Club Venue Location Map



YELLOWSTONE
WEEKEND

Yellowstone Weekend 2021 Pre-Departure Logistical FAQ

COVID POLICY

We will implement the following COVID-19 safety precautions listed below during Yellowstone Weekend, in accordance with Yellowstone Club rules and CDC guidance applicable to large gatherings like ours. Please contact the Yellowstone Weekend team at info@yellowstoneweekend.com for any questions you or your traveling party have about any of our outlined safety precautions.

Prior to Yellowstone Weekend:

- **In accordance with the Yellowstone Weekend policy, guests ages 12 or older are required to provide proof of full vaccination against COVID-19 by emailing digital copies or photos of your party's vaccine cards to info@yellowstoneweekend.com by July 9.** We will provide this information to the Yellowstone Club in advance of your arrival to facilitate a smooth arrival. If you or any member of your traveling party are unable to provide us with advance proof of vaccination, please reach out to the Yellowstone Weekend team at info@yellowstoneweekend.com.
- **For our international and unvaccinated attendees (including children above the age of 2), we will require proof of a negative PCR test taken 72 hours prior to the event. This applies to vaccinated and unvaccinated members of your traveling party. Please send this info@yellowstoneweekend.com prior to arrival or show your paperwork to a member of our concierge team upon arrival in Bozeman.**

During Yellowstone Weekend:

- **All attendees (including children above the age of 2) will receive a rapid COVID test prior to the start of Yellowstone Weekend. Our testing partner for the event is AmbuInz. By July 14, each member of your traveling party is required to pre-register by creating an account prior to being tested. Please use the following link to register in advance of your departure https://app.rrtesting.com/#/registration/facilities/586.** For those bringing children, there is an option to add those family members to your account. Once you have been tested, you will receive your test results via text & email within 15 minutes of administration.
    - For our guests who are departing from one of our pre-arranged charter city locations, you and all members of your traveling party will receive a rapid COVID test at the FBO prior to boarding the aircraft. Your required arrival time for your departure FBO in order to efficiently and effectively facilitate pre-boarding testing has been included in your traveling party's attached itinerary.

  - For our guests who are traveling commercially, upon arrival into Bozeman your pre-arranged ground transportation will be directed to the Bozeman FBO to facilitate rapid COVID testing.
  - For our travelers arriving via private charter that has been arranged on your end, upon arrival into Bozeman you will be rapid COVID tested at the Bozeman FBO.
  - For our travelers driving to the Yellowstone Club, you will be directed to Cabin 5 on the Yellowstone Club's property to facilitate rapid COVID testing upon arrival on July 15.
  - In the unique circumstance that you or a member of your traveling party will be arriving prior to July 15, the event start, you will be directed to Cabin 5 on the Yellowstone Club's property to facilitate rapid COVID testing on July 15.
- You and all members of your traveling party will be required to wear a mask on our private charters in accordance with the FAA. You will be required to wear a mask at all times while at the FBO, during the boarding and deplaning process and for the duration of the flight.
- While on site at the Yellowstone Club, fully vaccinated attendees will not be required to wear masks or socially distance. Unvaccinated attendees (including children) will be required to wear masks and socially distance in accordance with CDC public health guidance for large gatherings.
- Staff, vendors, and others on-site at Yellowstone Weekend will follow generally similar safety precautions as guests.
- An on-site medical consultant will be present throughout the event to serve as a resource should you require coordination in obtaining medical assistance.

SOCIAL MEDIA & STRICT CONFIDENTIALITY

Our core principle is to ensure that Yellowstone Weekend maintains its 10 year tradition of being both a comfortable and strictly confidential environment for all guests to relax and speak freely. Since Yellowstone Weekend's inception, the event has successfully gone without a media or social media related leak. We ask that you refrain from mentioning the weekend, its participants or the content discussed on social media, or in public remarks or to non-Yellowstone Weekend attendees. Please help us maintain this operating standard by adhering to our confidentiality and social media policy. All discussions during the weekend will also be under the Chatham House Rules.

VENUE

The Yellowstone Club is nestled in the rocky mountains, just west of the famed Gallatin River near the northwest corner of Yellowstone National Park and the picturesque mountain town of Big Sky, Montana. 15,200 rolling acres are surrounded by 10,000 foot peaks, world-class skiing and blue-ribbon trout streams. Yet as beautiful and untouched as its surroundings, the

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Yellowstone Club is approximately one hour from Bozeman, Montana, giving members and their guests access from major metropolitan areas throughout the country by either commercial airline or private jet service.

ATTIRE

The attire for the weekend is relaxed and casual. The average temperature at the Yellowstone Club during the month of July is around 75ºF with a high of 85ºF and a low of 50ºF. The mornings are crisp and clear, with warm and breezy afternoons and cool nights. As the evenings are a bit cooler, we recommend you pack a sweater or jacket.

For our Thursday and Friday evening events, we recommend that you wear flat, non-heeled shoes as the event will take place outdoors on an earthy surface. Our Saturday evening event is the sole evening with an increased sense of formality.

For our optional morning activities, please pack athletic clothes, comfortable shoes and socks. For our afternoon activities, please refer to our activity specific recommended packing list.

TRAVEL

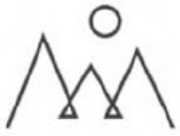
Please find your confirmed flight details for you and your traveling on the attached itinerary. Reservations on our charters or via a commercial route must be confirmed in advance of departure with the Yellowstone Weekend team in order for us to be prepared for your arrival.

If you and your traveling party are confirmed on one of our charters departing from EWR, IAD, SFO or LAX or on July 15, greeters will meet you upon arrival at the FBO to provide you personalized luggage tags with your name and accommodation details.

If you and your traveling party are confirmed on one of our charters on July 18, a valet will arrive at your Yellowstone residence 3 hours prior to your scheduled charter departure time to pick up your luggage and deliver it to the appropriate charter. A second car will pick up you and your party 2 hours prior to the scheduled charter departure time.

If you are traveling via your own personal charter, please provide your aircraft tail number, arrival date and time, and departure date and time so that we are able to set up ground transportation for you and your traveling party.

If you are traveling commercially on any leg of your journey, please make sure you have finalized your flight details with Jill Catling: JCatling@tzell.com and copy



info@yellowstoneweekend.com so that we can set up ground transportation for you and your traveling party.

Our confirmed charter timing and the FBO locations for arrivals on July 15 and departures on July 18 are noted below.

LOS ANGELES

Los Angeles LAX (FBO: Signature Flight Support, 6201 West Imperial Hwy, Los Angeles, CA 90045, Ph: (b) (6))

Thursday, July 15

Passenger Arrival Time (for pre-flight flight testing & check in): Please refer to your personalized itinerary for your required arrival time
Departs: LAX Los Angeles, 10:15 AM Local Time
Arrives: BZN Bozeman, 2:00 PM Local Time
Appx Flight Time: 2 hours, 30 minutes
Time Change: +1.0 hour

Sunday, July 18

Departs: BZN Bozeman, 11:00 AM Local Time
Arrives: LAX Los Angeles, 12:30 PM Local Time
Appx Flight Time: 2 hours, 30 minutes
Time Change: -1.0 hour

NEW YORK CITY

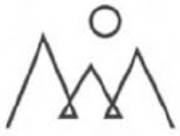
Newark EWR (FBO: Signature Flight Support, 15 Brewster Road, Newark, NJ 07114, Ph: (b) (6))

Thursday, July 15

Passenger Arrival Time (for pre-flight flight testing & check in): Please refer to your personalized itinerary for your required arrival time
Departs: EWR Newark, 12:30 PM Local Time
Arrives: BZN Bozeman, 2:30 PM Local Time
Appx Flight Time: 3 hours, 54 minutes
Time Change: – 2.0 hours

Sunday, July 18

Departs: BZN Bozeman, 12:30 PM Local Time
Arrives: EWR Newark, 6:00 PM Local Time



Appx Flight Time: 3 hours, 30 minutes
Time Change: +2.0 hours

SAN FRANCISCO

San Francisco SFO (FBO: Signature Flight Support, 1052 North Access Road, San Francisco, CA 94128, Ph. +1-650-877-6800)
Thursday, July 15
Passenger Arrival Time: 9:00 AM Local Time
Departs: SFO San Francisco, 10:30 AM Local Time
Arrives: BZN Bozeman, 1:30 PM Local Time
Appx Flight Time: 1 hour, 55 minutes
Time Change: +1.0 hour

Sunday, July 18
Departs: BZN Bozeman, 11:45 AM Local Time
Arrives: SFO San Francisco, 12:45 PM Local Time
Appx Flight Time: 2 hours
Time Change: -1.0 hour

WASHINGTON DC

Dulles IAD (FBO: Signature Flight Support, 23950 Wind Sock Drive, Sterling, VA 20166, Ph: (b) (6))

Thursday, July 15
Passenger Arrival Time (for pre-flight flight testing & check in): Please refer to your personalized itinerary for your required arrival time
Departs: IAD Dulles, 10:00 AM Local Time
Arrives: BZN Bozeman, 12:00 PM Local Time
Appx Flight Time: 3 hours, 42 minutes
Time Change: -2.0 hours

Sunday, July 18
Departs: BZN Bozeman, 10:00 AM Local Time
Arrives: IAD Dulles, 3:30 PM Local time
Appx Flight Time: 3 hours,18 minutes
Time Change: +2.0 hours

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GROUND TRANSPORTATION

We will provide ground transportation for you and your traveling party around the Yellowstone Club. Once you arrive in Bozeman, the Yellowstone Weekend team will meet you at the airport and coordinate all your ground transportation to the Yellowstone Club and throughout the weekend. This applies to all arrivals, no matter the method. For your departure, the same method of transportation applies.

Throughout the weekend, cars will be pre-stationed at all homes every morning and at all events throughout the weekend for easy access. If you have any ground transportation needs throughout the event, please contact the Yellowstone Weekend Transportation team at 855-233-3907.

All cars will be equipped with phone chargers and water. If you are traveling with a young child, we will have forward-facing car seats readily available at the Bozeman hangar. Due to liability reasons, we ask that you self-install the car seat into your assigned vehicle.

ACCOMMODATIONS

All guests will be staying in luxurious, mountain-style homes often with dramatic views of the surrounding area. In keeping with the collaborative spirit of the weekend, most guests will share private homes with other participants (each guest will have his/her own bedroom and bathroom). Some guests will have their own homes due to the size of their families and/or the size of the particular home. Your housing assignment, as well as details on other guests you will be sharing a home with, can be found in your traveling party's attached itinerary.

All homes are equipped with washers, dryers, and detergent. There will be basic groceries and amenities / toiletries provided in each home, along with drinks (coffee, tea, juice, soda, beer and wine). The kitchen is fully stocked with cookware and utensils.

All homes are outfitted with Wi-Fi. Passwords will be located inside the home.

FOOD

Breakfast, lunch and dinner will be provided for our guests at the various event venues, as well as for children and nannies at the Kids Club throughout the event. As the Yellowstone Club does not operate like a hotel, please note that room service is not an available amenity on the property. Our food options are healthy, mountain-inspired American fare. There will be vegetarian, vegan, and gluten-free options, as well as pre-arranged accommodations for all previously flagged dietary restrictions.

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Meals will be provided for our guests' security details/staff who are attending at pre-assigned venues and locations. Further information on times and locations have been sent directly to those for whom this applies.

MEDICAL CONCIERGE & EMERGENCY ASSISTANCE

A private medical consultant will be present throughout the event to serve as a resource should you require coordination in obtaining any medical assistance. The medical concierge will be equipped with basic first aid supplies, inclusive of supplies to help alleviate altitude sickness. If you feel unwell during your time with us, please find one of our team members who can show you to Cabin 5 which is located within a brief walking distance of our day time venue.

The Yellowstone Club has a full-time paramedic on duty and a medical unit adjacent to the on-site fire station. In the case of a medical emergency, please contact the Yellowstone Club emergency team at 406-993-2002. The nearest hospital is Big Sky Medical Center located at 334 Town Center Avenue, Big Sky.

WELLNESS LOUNGE

We have dedicated a private and comfortable room during the daytime sessions next to the Barn to accommodate nursing mothers. Please find one of our team members who can show you Cabin 4 which is a private space located within a brief walking distance from our daytime session venue. The lounge will be equipped with a small refrigerator, a pump with multiple accessories, electrical outlets and a selection of teas and snacks.

CONNECTIVITY & PRIVATE SPACE

There will be Wi-Fi in all event venue locations. While on-site at any of our event venue locations, please connect to the network named Yellowstone Weekend; there will be no password to get connected.

There is cell phone coverage at the Yellowstone Club, but please note that it can be spotty based on your location on the property. AT&T has the most reliable coverage, and all major US networks should work, if roaming is enabled. International guests should be able to roam on AT&T.

If you are in need of a private space to take a phone call during the event, please find one of our team members who can show you Cabin 1 which is located within a brief walking distance from our daytime session venue.

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GYM

There are 3 fitness centers on-site (which are operational 24 hours a day). Rainbow Gym includes an outdoor lap pool and hot tub, the Village Core gym includes 4 hot tubs and the Camphouse gym includes a hot tub, an outdoor pool, and tennis courts. Fitness centers are for use by ages 16+ and pools are accessible for all ages.

MORNING ACTIVITIES

If you are interested in participating in one of our morning activity offerings, please read through the below details and follow the sign-up instructions in order to confirm your participation.

HIIT (High Intensity Interval Training)
Friday, July 16 and Saturday, July 17 from 7:00am - 8:00am
Meet at YC Core. This class is held outside, weather permitting.
Each session of this very popular cardiovascular exercise class is different as the instructor bases the class on the specific participants' wants, needs, and skill levels.
Please email fitness@yellowstoneclub.com to reserve your spot. Charges for this class are billed individually and should kindly be arranged at the time reservations are made.
Please bring: Athletic clothes, Comfortable shoes

Personal Training
Personal trainers will be available by reservation (based on availability), both at Yellowstone Club fitness facilities and guest residences. Please email fitness@yellowstoneclub.com if you are interested in using these services. Charges for personal training are billed individually and should kindly be arranged at the time reservations are made and appointments are limited.
Please bring: Comfortable shoes, Athletic clothes

Yoga
Friday, July 16 and Saturday, July 17 from 7:00am - 8:00am
Meet poolside at Camphouse. In inclement weather, meet at Yoga Movement Studio.
Pre-registration is required. Please email fitness@yellowstoneclub.com to reserve your spot.
This class is a wonderful blend of "Hatha" and "Vinyasa" yoga. Progressing through various poses will connect movement to breath with conscious intention and awareness. Each dynamic class will leave the participant feeling stronger, and empowered both mentally and physically! All levels are welcome to join.
Please bring: Athletic clothes, Comfortable workout socks or footwear

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AFTERNOON ACTIVITIES

If you have signed up for an afternoon activity, you will be able to find your confirmed activity for Friday and Saturday on your traveling party's attached itinerary. Please note that you will be asked to sign a waiver prior to participating in your assigned activity.

If you have not signed up for an activity, please advise our team of your preferences prior to arrival or on Thursday evening at our Night Under the Stars Welcome event. As capacity for all of our activities is quite limited at this stage, we will do our best to confirm something for you as we are able.

Archery

The 3D archery course is located on Eglise Mountain, just a short drive from the Warren Miller Lodge. This experience begins at the practice range, where archers are taught the basics of using a bow and take some shots on the bullseye targets to get comfortable. From the practice range, the group heads out onto the 3D course. The course takes archers through a range of 3D animal targets on a slightly maintained mountain trail. The trail has rocks, uneven dirt, rugged terrain, and at times tall grass; sturdy tennis shoes or hiking boots are recommended.
Please bring: Baseball hat, Sturdy closed toe shoes, Long pants [highly recommended], Rain jacket, Sunglasses

Five Star Shooting

This form of clay target shooting uses five stations and multiple clay target launchers to provide a complete experience. Come out and shoot with our certified shooting instructors. There is a variety of target options ranging from those who have never held a shotgun to the experienced sportsman.
Please bring: Baseball hat, Sunglasses [sunglasses or safety glasses are required], Sturdy closed shoes, Rain jacket, Extra layers of clothing

Fly Fishing

Montana is one of the last strongholds of truly wild trout, and Yellowstone Club delivers the solitary beauty and passion it takes to pursue them like nowhere else. With an estimated 900 fish per mile in the streams, one can catch over 20 fish a day. A Montana fishing license is included.
Please bring: Baseball hat [required], Polarized sunglasses [required], Extra clothing layers, Rain jacket

Hanging Out

For our attendees who are not inclined to join our afternoon outdoor pursuits activities, we have arranged a location to relax, take in the fresh mountain air and enjoy one another's company and conversation.

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Hiking and Zip Lining
Yellowstone Club guides will lead a hike through a wooded trail on the mountain from the top of the gondola up to the top of Eglise Rock -- and if you'd like, enjoy an exhilarating zip line ride high above the trees, too. The trail is rated moderate and is a 2–3 hour experience with breathtaking views.
Please bring: Sunglasses, Long sleeved shirts, Rain jacket, Sturdy closed toe shoes, Hiking socks, Backpack

Horseback Riding
Expand your opportunity to explore the beautiful Montana wilderness by spending the afternoon on horseback. Participants do not need to be experienced equestrians. Beginners are welcome!
Please bring: Sunglasses, Long pants or jeans (required), Extra clothing layers, Rain jacket, Athletic shoes / hiking boots / boots with a heel [required]

Moon Hikes
On Friday, July 16, explore the light of the New Moon when the stars are the brightest as you discover Yellowstone's beautiful trails. You can also join us on Saturday, July 17, as you walk 2 miles and explore Big Sky's finest hiking trails under the illumination of the full moon. Light snacks and water will be provided.
Please bring: Sunglasses, Long sleeved shirts, Rain jacket, Sturdy closed toe shoes, Hiking socks

Mountain Biking
Learn how to ride a mountain bike and enjoy miles of trails right here at Yellowstone Club. All abilities and ages are welcome, and you can join us to enjoy a leisurely tour, or charge the downhill. Discover a great variety of trails, ranging from flowy downhill to technical single-track.
Please bring: Sunglasses or goggles, Sturdy closed shoes, Activewear clothing, Tall socks, Rain jacket, Extra layers of clothing

Spa
The skilled therapists at Yellowstone Club Spa take a holistic approach to your well-being and will pamper you with a relaxing, customized treatment. If you have been notified that the Spa is your scheduled afternoon activity on either Friday or Saturday, please email spa@yellowstoneclub.com or call 406-995-7909 x 1718 to confirm your specific appointment time and type of treatment. The Spa Concierge will have your name with your reservations and ready to assist.

Wine Tasting
Join our renowned, guest sommelier for an intensive tasting session. Attendees will leave not only with a great taste in their mouth, but a better understanding of the world of wine and the ability to make an educated guess as to what the wine is they are drinking. And perhaps, a greater appreciation for the subtleties that make wine so special.

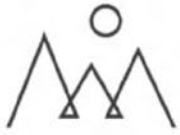
CHILDREN
We look forward to welcoming all spouses and significant others. Unfortunately due to limited space, we do not have room for children to attend sessions. However, we would like to include all family members and children in Friday's Rodeo Night and hope your family will plan on joining us there.

Youth services programs will be provided for the families of conference attendees. Children of all ages are welcome. All activities are tailored to their age and interests and are facilitated by professional caregivers at the Yellowstone Club. Activities include, but are not limited to: indoor/ outdoor playtime, arts and crafts, nature walks, story time, puppet shows, learning games, basketball, T-ball, kickball, tag, soccer, badminton, volleyball, archery, orienteering, golf, hiking, and mountain biking.

We are also happy to be able to offer in-home babysitting services on a part-time or full-time basis through the Yellowstone Club's child care program. We strongly encourage that babysitting requests be made in advance by emailing babysitting@yellowstoneclub.com. After you have arrived at the Club, if you desire to make a last-minute request for babysitting services, we will do our best to accommodate you. Please call our Yellowstone Weekend Concierge Team at 855-233-3906 for assistance.

Our confirmed schedule of events for children ages 1-12 at the Kids Club, known as 20 Below, can be found below. Please note that in advance of dropping your child off, the Yellowstone Club requires you as the parent of the child complete this waiver: https://waiver.smartwaiver.com/w/5df128db4e9b7/web/. This will ensure an efficient drop off process for you and the team at 20 Below. Please note that their nanny policy does not apply to Yellowstone Weekend attendees, and your accompanying nannies are welcome to stay with your child while they are at 20 Below.

Thursday, July 15
All Ages
6:00 PM Drop-off at 20 Below
6:00 – 10:00 PM Dinner & Activities
10:00 PM Pick-up at 20 Below



Friday, July 16

Ages 1-5

9:00 AM Drop-off at 20 Below
9:00 – 10:00 AM Welcome Project
10:00 – 12:00 PM Outdoor Activities (nature walk & art project)
12:00 – 1:00 PM Lunch at 20 Below
1:00 – 2:30 PM Break
2:30 – 5:00 PM Outdoor Activities & Crafts (scavenger hunt)
5:00 PM Pick-up at 20 Below

Ages 6-12

9:00 AM Drop-off at 20 Below
9:00 – 10:30 AM Games and Activities
10:30 – 12:30 PM Outdoor Activities (gondola scavenger hunt)
12:30 – 1:30 PM Lunch at 20 Below
1:30 – 4:30 PM Line Dance Instruction
4:30 PM Pick-up at 20 Below

Saturday, July 17

Ages 1-5

9:00 AM Drop-off at 20 Below
9:00 – 10:00 AM Welcome Project
10:00 – 12:00 PM Outdoor Activities (art project)
12:00 – 1:00 PM Lunch in 20 Below
1:00 – 2:30 PM Break
2:30 - 4:30 PM Outdoor Activities
5:00 PM Pick-up at 20 Below
6:00 PM Drop-off at 20 Below
6:00 – 9:00 PM Evening Event (movie night)
9:00 PM Pick-up at 20 Below

Ages 6-12

9:00 – 9:30 AM Meet at 20 Below
9:30 – 12:00 PM Outdoor Activities (survival skills)
12:00 – 1:00 PM Lunch
1:00 – 5:00 PM Outdoor Activities & Games
5:00 PM Pick up at 20 Below
6:00 PM Drop-off at 20 Below
6:00 – 9:00 PM Evening Event (movie night)
9:00 PM Pick-up at 20 Below

[EXTERNAL] Confirm your Scratch account

From: (b) (6)

To: OSTP Press Office (b) (6)

Date: Tue, 13 Jul 2021 13:52:17 -0400

Does this email look weird? - Click Here



Confirm your Scratch account

You just signed up for a new Scratch account with the username: (b) (6)

To finish creating your account, click on the link below:

Confirm my account

Having trouble? Copy this link into your browser instead:

>https://scratch.mit.edu (b) (6)

Scratch On!

—The Scratch Team

Using Scratch, children can create interactive stories, games, and animations.

Scratch is available for free, thanks to generous support from our donors. We are grateful to our Founding Partners: Massachusetts Institute of Technology, the National Science Foundation, and the Siegel Family Endowment.

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[EXTERNAL] 18 MIT faculty letter on ARPA-H

From: Kate Stoll (b) (6)

To: "Koizumi, Kei EOP/OSTP" (b) (6) "Schwetz, Tara A. EOP/OSTP" (b) (6) >

Cc: David Goldston (b) (6), Grace Y Song (b) (6)

Date: Fri, 16 Jul 2021 10:06:36 -0400

Attachments: ARPAH_letter MIT.pdf (157.48 kB)

Dear Kei and Tara,

I hope you are both well! Kei, it was nice to see you on zoom yesterday, if just for a few minutes. Tara, it's been years, but glad to be connecting again!

We wanted to let you know that 18 biomedical, bioengineering, and healthcare experts at the Massachusetts Institute of Technology drafted a letter with their views on ARPA-Health in response to the request for information posed by the *21st Century Cures 2.0* team in the House. Please find attached their letter.

We hope it proves to be useful as you stand up the new agency. We are happy to meet to discuss if that's of interest to you.

All the best,
Kate

Kate Stoll, Ph.D.
Senior Policy Advisor
MIT Washington Office
Tel: (b) (6)



Massachusetts Institute of Technology

July 16, 2021

Thoughts on ARPA-H

As biomedical, bioengineering, and healthcare researchers at the Massachusetts Institute of Technology, we write to offer our views on the proposal to establish an Advanced Research Projects Agency for Health (ARPA-H). We support the creation of ARPA-H, and we believe that, if properly focused and organized, it would have great potential to advance science and technology, and improve the prevention and treatment of disease. We believe ARPA-H could offer a significant addition to the portfolio of research approaches to biomedical science and engineering, which must of course continue to include robust programs at the National Institutes of Health (NIH) and other federal agencies.

The Gap to be Filled by ARPA-H

NIH's traditional programs have many strengths, but they are not well adapted to tackle problems that require a concentrated effort involving collaborations among many fields of science and technology (and experts outside of biomedicine). Therefore, biomedicine has much it might gain through the addition of the ARPA model – which emphasizes a focus on the solution of specific problems, a team-based approach, linkages between engineering and science, risk-taking, milestones designed to enable projects to fail quickly or advance, and partnerships between academia and industry.

Problems such as figuring out how to predict the onset of certain cancers (such as pancreatic and ovarian cancers, which today are usually discovered when it is too late to treat them effectively) could benefit from fundamental advances that are more likely to occur through an ARPA approach, in part, because of the need to draw on computation, engineering, and other fields in addition to studies of basic disease biology.

An ARPA-H approach could also facilitate the invention of new instruments and materials for medical care; such efforts require close collaboration among physical and life scientists and engineers.

ARPA-H should focus on issues that do not fit the current two mechanisms for medicine and health research: fundamental science (essential research supported by federal agencies such as NIH, before translation to commercial products); and translational (product-focused research to gain access to the commercial sector). ARPA-H should take a portfolio approach to solving health challenges, with an emphasis on fundamental research breakthroughs to solve problems, but including the range of work needed to ensure that research advances are finding their way into medical practice. It should be careful, though, to avoid funding work that can be readily done by the thriving U.S. biotech and pharmaceutical sectors.

Work Across Disciplines Will be a Key to ARPA-H Advances

As noted above, multidisciplinary work at the intersection of the physical and life sciences, and engineering, sometimes called "convergence," holds greater promise for accelerated advancements in health than traditional life sciences alone.

The work of DARPA's Biological Technologies Office (BTO) – created in 2014 – can provide a sense of what an ARPA-H might achieve. The DARPA office, for example, helped fund research on the technology that would lead to mRNA vaccines which have proved so central to the fight against COVID-19. (The DARPA effort built on prior NIH-funded research, and the DARPA funding helped move the mRNA technology into use.) BTO also funded technology research that has accelerated the development of organs on a chip, and neural-controlled prosthetics. But DARPA is defense-focused and cannot alone fill the current gap in biomedical research.

NIH has not fully embraced such interdisciplinary approaches. According to MIT's 2016 report *Convergence: The Future of Health*, in fiscal 2015, less than 3 percent of NIH award funding was allocated to principal investigators in engineering, physical sciences, or math/statistics and computation. Scientists in these disciplines are frequently not familiar with NIH and feel their expertise is not given sufficient weight by NIH's peer-review system.

Biomedical and Health Problems Well Suited for ARPA-H

Building on our general points above, here are some initial thoughts on the kinds of problems (spanning from pre-clinical to post-market) that ARPA-H could take on:

- Advancing precision medicine by integrating state-of-the-art computation sciences such as machine learning, physics-based modeling, and data systems to link real-world clinical and demographic data to genetic and molecular biomarkers. Such work could improve the ability to predict which drugs will be most effective in which subpopulations.
- Analyzing the intersection of medical data, molecular tests, and imaging technologies to predict the onset of disease earlier. Intercepting disease processes before a patient becomes debilitated would advance the treatment of cancers that are currently hard to identify in their early stages such as pancreatic and ovarian cancers.
- Developing surveillance platforms to integrate data that are now held by different private and public organizations on how well drugs and other treatments are working under real-world conditions, improving the use of such treatments by better tailoring them to patients.
- Creating innovations in biomanufacturing technologies to help decrease the costs of biologic drugs.
- Developing broad approaches to propel new breakthroughs in synthetic biology. One promising area is ultra-sensitive biological circuits which have potential applications as environmental sensors or diagnostics that could reveal disease states (like heart attacks) in real time.
- Developing better disease surveillance tools including sensors and data systems to help counter outbreaks of infectious diseases.

Essential ARPA-H Characteristics

Regardless of whether ARPA-H is part of NIH or is established as an independent entity, it must operate differently from the rest of NIH to be successful. Its leadership must have the latitude to set up and operate an entity with its own goals, approaches and procedures. If ARPA-H is established within NIH, it should report to the NIH Director, not to another institute or center. ARPA-H will need new legal authority to bring in program managers, who – like DARPA's – should be hired for limited three- to five-year periods and should come from a range of technical backgrounds with an emphasis on expertise in computing and information sciences, machine learning and AI, physics-based modeling, physics and engineering, in addition to the life sciences. ARPA-H contracts should be larger than typical NIH grants and should go to multi-disciplinary and multi-sectoral teams (rather than funding individual groups).

The ideal ARPA-H director would have personal experience with the ARPA model, with work in a range of scientific fields, and with coordinated efforts across academia, industry, and governmental agencies. The director should be someone willing to forge an independent path. Crucially, the director should have a deep understanding of what can be gained from utilizing knowledge from areas beyond biomedical science to advance health, including understanding the importance of computation and engineering. The culture of a new entity tends to lock-in very quickly and the expertise and abilities of the first director, including working experience with the ARPA model, will play a key role in creating the agency's lasting culture.

Addressing Concerns

One source of DARPA's success that is not easily transferrable to other ARPA agencies is that DARPA often has a direct link to a Defense Department-supported customer base for its ideas, through its procurement activities. While the linkages between the government and the health sector are substantial, they are not as direct as the Pentagon's – NIH is not a procurement agency. ARPA-H should examine models both from DARPA and from ARPA-E in working to move promising new ideas into widespread use. For example, the Tech-to-Market teams that both ARPA-E and now DARPA use could be a constructive approach to help move ARPA-H's advances toward implementation.

At the same time, ARPA-H's approach should include working on important health problems that are not of immediate interest to the private sector. Creating new vaccines, overcoming antibiotic resistance, and addressing the health concerns of relatively small and underserved subpopulations in the U.S. or in poor countries are kinds of work that should engage ARPA-H even though they may not have the immediate private sector appeal of the next "blockbuster" drug. Even in such cases, ARPA-H would need to create linkages to the private sector to create pathways to the marketplace.

ARPA-H should pay attention to many aspects of diversity. Its staff and its awardees should reflect the rich diversity of our population. Among other reasons, this will help ensure that ARPA-H intentionally pays sufficient attention to the health needs of minorities and other marginalized populations.

Also, ARPA-H should work to involve researchers at a wide range of academic institutions. This could also strengthen the link between ARPA-H work and the public health community.

NIH should recognize that ARPA funding models are often not ideal for training graduate students given the speed of progress expected and the uncertainty of consistent funding. To ensure that graduate students who are funded through ARPA-H awards have sufficient, enduring support, NIH may want to consider providing additional funding for their work.

In addition, ARPA-H may want to examine ARPA-E's approach of hiring a group of fellows who are recent PhDs to assist program managers.

We hope that the ARPA-H initiative will be part of a broader effort to enhance U.S. research and education capacity in a way that benefits all Americans and improves health around the world.

We would be happy to elaborate on our views on ARPA-H. We do want to emphasize that we are drawing on our experience, and are not attempting to speak on behalf of others at MIT, or for MIT as an institution.

Signed,

Angela Belcher, *Head of the Department of Biological Engineering, James Mason Crafts Professor of Biological Engineering and Materials Science and Engineering*

Emery Brown, *Director of the Harvard–MIT Program of Health Sciences and Technology; Edward Hood Taplin Professor of Medical Engineering and of Computational Neuroscience; Associate Director, Institute for Medical Engineering and Science; Professor of Health Sciences and Technology; Warren M. Zapol Professor of Anaesthesia, Harvard Medical School, Massachusetts General Hospital*

Richard Braatz, *Edwin R. Gilliland Professor of Chemical Engineering*

Arup Chakraborty, *Institute Professor, Founding Director of (IMES) Institute for Medical Engineering and Science, Professor in Chemical Engineering, Physics, and Chemistry*

Elazer R. Edelman, *Edward J. Poitras Professor of Medical Engineering and Science, Director MIT Institute for Medical Engineering and Science, Senior Attending Physician Brigham and Women's Hospital and Professor of Medicine, Harvard Medical School*

Paula Hammond, *Institute Professor, Head of the Department of Chemical Engineering*

Gigi Hirsch, *Executive Director, MIT's Center for Biomedical Innovation & New Drug Development Paradigms (NEWDIGS)*

Susan Hockfield, *President Emerita of MIT, Professor of Neuroscience*

Richard Hynes, *Daniel K. Ludwig Professor for Cancer Research*

Tyler Jacks, *David H. Koch Professor of Biology, Daniel K. Ludwig Scholar, Co-director, Ludwig Center for Molecular Oncology*

Bob Langer, *David H. Koch Institute Professor; Recipient of both the National Medal of Science and the National Medal of Technology and Innovation*

Jacquin Niles, *Professor of Biological Engineering, Director of the Center for Environmental Health Sciences (CEHS)*

Kenneth Oye, *Professor of Political Science, Professor of Data Systems and Society, Director of the Program on Emerging Technologies (PoET)*

Rajeev Ram, *Professor of Electrical Engineering*

Phil Sharp, *Institute Professor and Professor of Biology; Nobel Laureate*

Anthony Sinskey, *Professor of Microbiology, Co-Director of the Malaysia-MIT Biotechnology Partnership Program, Faculty Director of the MIT Center for Biomedical Innovation*

Stacy Springs, *Senior Director of Programs; Executive Director, Biomamufacturing Initiatives, MIT's Center for Biomedical Innovation*

Matthew Vander Heiden, *Director, Koch Institute for Integrative Cancer Research; Lester Wolfe Professor of Molecular Biology, Professor of Biology*

RE: [EXTERNAL] reducing infectious diseases' impact

To: Mike Fisher (b) (6)

Cc: "Guerra, Stephanie L. EOP/OSTP" (b) (6) "McKelvey, Greg G. Jr. EOP/OSTP" (b) (6), Joshua Schoop (b) (6)

Date Tue, 20 Jul 2021 13:20:55 -0400

:

Hi Mike-
Not a problem.

From: Mike Fisher (b) (6)
Sent: Tuesday, July 20, 2021 11:52 AM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Cc: Guerra, Stephanie L. EOP/OSTP (b) (6); McKelvey, Greg G. Jr. EOP/OSTP (b) (6)>; Joshua Schoop (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Hi all, apologies for the delay in getting a briefing on Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats on the books. Might you have availability for the briefing next week? If you send some time blocks that could work for you, we can schedule. Thank you again for your patience!

Best,

Mike

On Tue, Jul 6, 2021 at 12:23 PM Mike Fisher (b) (6)> wrote:

> Hi Michael, apologies for the delay in response on our end. Folks have been in and out around the holiday weekend and we've been trying to lock down a time with Alex; we will circle back as soon as we have clarity on his schedule. Thank you for your patience!
>
> Best,
>
> Mike

On Tue, Jun 29, 2021 at 9:34 AM Schmoyer, Michael W. EOP/OSTP (b) (6) > wrote:

Good morning-
How about:

-between 1030 and 130 on the 13th

-between 1100 and 300 on the 14th

Best,
Michael

From: Mike Fisher (b) (6)
Sent: Tuesday, June 29, 2021 9:29 AM
To: Guerra, Stephanie L. EOP/OSTP (b) (6) >
Cc: McKelvey, Greg G. Jr. EOP/OSTP (b) (6) ; Schmoyer, Michael W. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Hi all,

Alex is not available on 7/9; are there any days / time blocks that would work for you the week of July 12?

Best,

Mike

On Mon, Jun 28, 2021 at 9:10 PM Mike Fisher (b) (6) wrote:

Got it; thanks Steph!

On Mon, Jun 28, 2021 at 8:31 PM Guerra, Stephanie L. EOP/OSTP (b) (6) wrote:

Thanks Mike- piggybacking off of Michael's priorities I'd also like to better understand:

- What triggers a signal from noise in this type of system and how that leads to a targeted prevention approach

- How the infrastructure and/or capacity building could also be leveraged for detecting accidental/deliberate threats

Best,
Steph

From: Mike Fisher <(b) (6)
Sent: Monday, June 28, 2021 6:40 PM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Cc: Guerra, Stephanie L. EOP/OSTP (b) (6) ; McKelvey, Greg G. Jr. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Thanks for this, Michael - we'll see what Alex's availability is like on the 9th.

Greg, Steph - if you have additional questions or points of interest you'd like us to share with Alex ahead of time, please don't hesitate to pass along.

Have a good one,

Mike

On Mon, Jun 28, 2021 at 5:18 PM Schmoyer, Michael W. EOP/OSTP (b) (6) > wrote:

Hi Mike-

I'm actually trying to be on leave that week, but how do things look on the 9th? I'm also cc'ing Greg and Steph as they would likely be interested.

For me, I'm most attracted to 1) an overall summary brief on the paper (and the rationale for his perspective) and 2) a deeper dive on elements pertaining to predictive analytics/forecasting/modeling as it relates to early indications/warnings of emerging biological threats.

Thanks for helping this come together,

Michael

From: Mike Fisher (b) (6)
Sent: Monday, June 28, 2021 1:33 PM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Hi Michael (bcc to save inbox: Andrew),

We reconnected with Alex Dehgan, the author of Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats, and he's looking forward to delivering a briefing on the paper.

Can you suggest three time blocks that work well for you on July 6th, or other days that same week / week after?

Also, would you like us to prepare an agenda for the briefing, or is a more freeform Q&A-style session better for you?

Lastly, are there any questions about the paper that you have for Alex that you'd like us to get to him ahead of the briefing, or specific points he raises in the paper that you'd especially like him to speak to?

Thank you,

Mike

On Sun, Jun 27, 2021 at 10:16 AM Mike Fisher (b) (6) wrote:

> Good to know; thanks Michael!
> - Mike
>
> On Sun, Jun 27, 2021 at 6:59 AM Schmoyer, Michael W. EOP/OSTP (b) (6) wrote:

That sounds great, thanks Mike. Related, I'm chairing an interagency working group that is along these lines … there may be a second request for a follow-on brief to a larger group.
Best,
Michael

From: Mike Fisher <(b) (6)
Sent: Friday, June 25, 2021 5:51 PM
To: Hebbeler, Andrew M. EOP/OSTP (b) (6) >
Cc: Schmoyer, Michael W. EOP/OSTP (b) (6)
Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Hi Andrew, and nice to be connected, Michael -

We will rally the authors and touch back early next week re briefing on the preventing the next pandemic paper. Happy to do it!

Have a nice weekend,

Mike

On Fri, Jun 25, 2021 at 4:48 PM Hebbeler, Andrew M. EOP/OSTP (b) (6) wrote:

> Hi Mike: Connecting you with Michael. We'd love if you could help arrange a briefing by the preventing the next pandemic authors. Thank you!
>
> Sent from my iPhone
>
> > On Jun 25, 2021, at 9:30 AM, Schmoyer, Michael W. EOP/OSTP (b) (6) > wrote:
> >
> > Hi Andrew-
> >
> > I would be interested in connecting with the author(s) for Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats

Relates to epi forecasting/modeling work I'm doing

Thanks for asking,

mws

From: Hebbeler, Andrew M. EOP/OSTP

(b) (6)

Sent: Friday, June 25, 2021 8:28 AM

To: DL OSTP HLS (b) (6) >; DL OSTP Biorisk

(b) (6)

Subject: FW: [EXTERNAL] reducing infectious diseases' impact

FYI – does anyone want to hear from any of the day one paper authors? Happy to connect you with Mike if so…..

From: Mike Fisher (b) (6)

Sent: Friday, June 25, 2021 8:22 AM

To: Hebbeler, Andrew M. EOP/OSTP (b) (6)

Subject: Re: [EXTERNAL] reducing infectious diseases' impact

Morning Andrew, hope your week has gone well! Just wanted to re-up re any crystallization of OSTP priority issues in the life sciences / modern biotechnology / synbio space, or if you or any of your colleagues would find it useful to work with the authors of any of the infectious diseases-related Day One papers to further develop ideas in a direction you are pursuing.

Best,

Mike

On Tue, Jun 15, 2021 at 3:33 PM Mike Fisher (b) (6) wrote:

> Hi Andrew, just wanted to update you on our conversations with Doug and India. There is mutual interest in pursuing a collaboration that makes sense for both our orgs. Our next step is to put together some ideas about research and analysis projects / convenings we could potentially collaborate on in advance of our next conversation with EBRC.

Have your OSTP priorities around life sciences / modern biotechnology / synbio been shaping up (outside of reducing the impacts of infectious diseases)? Some ideas we have been mulling over include...
- updating the U.S. framework for the regulation of genetically engineered products
- a framework for a National Synthetic Biology Initiative (inspired by the National Artificial Intelligence Initiative, overseeing and implementing the U.S. AI strategy - AI.gov)
- maximizing the contributions of foreign nationals to U.S. engineering biology while maintaining scientific integrity
- promoting ethical use of engineering biology practices
- leveraging the use of standards and standardization in the synthetic biology industry and biomanufacturing

...and it would be great to get your feedback on whether any of these, or perhaps others not on the list, are priority issues.

Also curious if any follow-on regarding those six Day One resources re pandemic preparedness / infectious diseases is in order. Let us know!

Hope you're holding up okay!

Best,

Mike

On Wed, Jun 2, 2021 at 5:19 PM Hebbeler, Andrew M. EOP/OSTP (b) (6) wrote:

> Hi Mike: Great chatting with you too, and thanks for sending these resources! Would be great to hear how your discussions with Doug and India go.
>
> +others FYSA, in case these FAS/D1P docs aren't already on their radar.

Thanks again!
Andrew

From: Mike Fisher (b) (6) >
Sent: Wednesday, June 2, 2021 8:59 AM
To: Hebbeler, Andrew M. EOP/OSTP
(b) (6) >
Subject: [EXTERNAL] reducing infectious diseases' impact

Hi Andrew,

Thank you again for talking with me the other week. Following up on our conversation, if any additional OSTP priorities have crystallized beyond pandemic preparedness / taking measures to reduce the impact of infectious diseases, it would be great to schedule another call.

And regarding pandemic preparedness / infectious diseases, just sharing six FAS Day One papers in our portfolio that may be of interest to you and your team (happy to prepare a brief on any of these or work with the authors to further develop ideas in a direction you are pursuing):

Preventing the Next Pandemics: An Upstream Approach to Novel National Security Threats
Shift from reacting to disease outbreaks – which is economically devastating – to detecting, addressing, and mitigating the major upstream factors that contribute to the emergence of diseases prior to an outbreak.

Improving Federal Management of Wildlife Movement and Emerging Infectious Disease
Reduce the risk of emerging infectious diseases entering the United States, offer greater protection to citizens from zoonotic diseases, and protect American biodiversity from losses due to wildlife diseases.

A National Bioeconomy Manufacturing and Innovation Initiative

Ramp up cross-cutting, cutting-edge research and development across the areas of healthcare, food & agriculture, energy, environment, and industrial applications to develop fundamental and publicly available tools, and bolster American biomanufacturing.

Open Access to Federally-funded Research Data
Accelerate scientific progress by (i) requiring scientists who receive federal funding to share their research data and (ii) directing federal research agencies to coordinate to build an International Research Data Commons that allows research data to be easily discovered and shared.

Creating a COVID-19 Commission on Public Health Misinformation
Examine our nation's response to the 2020 pandemic using a mechanism that is modeled on the 9/11 Commission, with one Commission focusing on public health communication and messaging that would assess the information about the pandemic: what was made publicly available, how the information affected our societal response, and what should be done to limit the impact of false and dangerously misleading information moving forward.

A National Strategy to Counter COVID-19 Misinformation
Establish an office at the Department of Health and Human Services dedicated to countering COVID-19 misinformation.

Also possibly of interest, on Friday I'll be meeting with Doug Friedman of BioMADE and India Hook-Barnard of the Engineering Biology Research Consortium to discuss the potential of sourcing policy ideas from the synbio community.

Thanks again, Andrew, and looking forward to talking again soon!

Best,

Mike

--

Michael A. Fisher, Ph.D.
Senior Fellow
Federation of American Scientists
1112 16th Street NW, Suite 400
Washington, DC 20036

Email: (b) (6)
LinkedIn: bit.ly/MAFisher
Twitter: @mykfish
Join up to contribute your expertise to the science and technology knowledge-base for policymakers: Congressional Science Policy Initiative

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[EXTERNAL] Re: call-in info for OSTP team for this Sunday pandemic preparedness call

From: Amy Chung-Yu Chou (b) (6)

To: Jack Hidary (b) (6)

Cc: "Lander, Eric S. EOP/OSTP" (b) (6)

Date: Wed, 21 Jul 2021 18:37:00 -0400

Dear Eric,

Hope that you are well. It's an honor to be in touch again!

Kindly find information on this week's COVID Medical Network sync below.

Date & Time: Sunday, July 25th, 2pm to 3:30pm PDT (5pm to 6:30pm EDT)

Agenda & Speakers:

[Kindly see the linked papers as pre-reads.]

[1] Future Wave/Pandemic Preparedness

Open discussion moderated by Jack Hidary

[2] Updates on Variants and Low Dose Moderna Study from the La Jolla Institute of Immunology

Dr. Alessandro Sette

Professor, Center for Autoimmunity and Inflammation, Center for Infectious Disease and Vaccine Research, La Jolla Institute for Immunology

Pre-reads:

- *Tarke, A. et al. Impact of SARS-CoV-2 variants on the total CD4+ and CD8+ T cell reactivity in infected or vaccinated individuals. Cell Reports Medicine (2021).*
- *Grifoni, A. et al. SARS-CoV-2 human T cell epitopes: Adaptive immune response against COVID-19. Cell Host Microbe (2021).*
- *Mateus, J. et al. Low dose mRNA-1273 COVID-19 vaccine generates durable T cell memory and antibodies enhanced by pre-existing crossreactive T cell memory. bioRxiv (2021).*

[3] Common Disease Clinical Trials

Dr. Anthony Philippakis

Chief Data Officer of the Broad Institute of MIT and Harvard, Co-Director of the Eric and Wendy Schmidt Center at the Broad Institute, Venture Partner at Google Ventures, Cardiologist at Brigham and Women's Hospital

[4] Nanobodies from Camelid Mice and Llamas Neutralize SARS-CoV-2 Variants

Dr. Jianliang Xu

Research Fellow, Lymphocyte Nuclear Biology, NIAMS, National Institutes of Health

Pre-read: Xu, J. et al. Nanobodies from camelid mice and llamas neutralize SARS-CoV-2 variants. Nature 595, 278–282 (2021)

Connection Details:

Video conference link: meet.google.com/t(b) (6)

Dial-in number: +(b) (6) / PIN: (b) (6)

Please let me know if there are any questions I can answer for the OSTP Team. We are at your service!

With my very best wishes,
Amy, on behalf of the team

On Wed, Jul 21, 2021 at 12:07 PM Jack Hidary(b) (6) wrote:

> Hi - here is the info for this Sunday's COVID call at 5pm Eastern, July 25th.
>
> Topic 1 from 5pm -5:30pm is future pandemic preparedness. Amy can field any questions from the OSTP team prior to the call.
>
> J
>
> Meeting ID
> meet.google.com/trm-mzgq-sjs
> Phone Numbers
> (b) (6)
> PIN: (b) (6)

--

Amy Chung-Yu Chou | Program Manager, Research & Innovations, Imaging & Diagnostics | Google Health | (b) (6)

[EXTERNAL] Re: Jeff<>Charlie

From Charina Chou <(b) (6)
:
Cc: "Matheny, Jason G. EOP/OSTP" (b) (6) Tahan, Charles G. EOP/OSTP" (b) (6) Kate Weber (b) (6)
Date: Mon, 26 Jul 2021 13:57:49 -0400

Jeff to bcc
hi Charlie (and Jason) - let us know some good times for you in the next week & we'll find one that works. talk soon, charina

On Mon, Jul 26, 2021 at 10:21 AM Jeff Dean (b) (6) > wrote:

Hi Jason and Charlie,

Thanks for reaching out. I'm actually out of the office for the next little while, so I'd like to suggest you meet or have a phone call with my colleagues Charina Chou and Kate Weber, so they can better understand the event and then suggest an appropriate Google representative. I've cc'ed them here and will let you coordinate with them.

Thanks,
Jeff

On Sun, Jul 25, 2021, 5:30 PM Matheny, Jason G. EOP/OSTP
(b) (6) wrote:

Jeff,

I hope you're well!

My colleague Charlie Tahan, cc:ed, leads quantum information science policy at the White House. He's planning a White House quantum industry event and would like your advice on who to invite from Google, given some of the goals. Do you have time for a quick phone call with him?

Best wishes,

Jason

Jason Matheny

Deputy Assistant to the President for Technology and National Security

Deputy Director for National Security, Office of Science and Technology Policy

Coordinator for Technology and National Security, National Security Council

The White House

(o) (b) (6)

(m) (b) (6)

From: Google Calendar on behalf of "Anurag Acharya"(b) (6)
Sent: Tue, 27 Jul 2021 15:21:22 -0500
To: LaBovick, Hannah EOP/OSTP
Subject: [EXTERNAL] Accepted: Public Access, Anurag/Alondra/Jerry/Ryan/Jorge/ESL @ Thu Aug 19, 2021 12pm - 12:30pm (PDT) (LaBovick, Hannah EOP/OSTP)
Attachments: invite.ics

Anurag Acharya has accepted this invitation.

Public Access, Anurag/Alondra/Jerry/Ryan/Jorge/ESL

When Thu Aug 19, 2021 12pm – 12:30pm Pacific Time - Los Angeles

Where >https://pitc.zoomgov.(b) (6)
< (map)

Calendar LaBovick, Hannah EOP/OSTP

Who
- LaBovick, Hannah EOP/OSTP - organizer
- Anurag Acharya - creator
- Sheehan, Jerry R. EOP/OSTP
- Nelson, Alondra R. EOP/OSTP
- Lander, Eric S. EOP/OSTP
- Ochoa, Jorge A. EOP/OSTP
- Donohue, Ryan C. EOP/OSTP

[>https://www.zoomgov.com/(b) (6)

Hi there,

Hannah LaBovick is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile:

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Meeting URL:

>https://pitc.zoomgov.com/(b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

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Meeting ID:

(b) (6)

Passcode:

(b) (6)

International numbers

Join from an H.323/SIP room system

H.323:

(b) (6) (US West)

(b) (6) (US East)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

SIP:

(b) (6)

Passcode:

(b) (6)

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You are receiving this courtesy email at the account (b) (6) because you are an attendee of this event.

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Forwarding this invitation could allow any recipient to send a response to the organizer and be added to the guest list, or invite others regardless of their own invitation status, or to modify your RSVP. Learn More.

From: Google Calendar on behalf of "Anurag Acharya" (b) (6)
Sent: Tue, 27 Jul 2021 16:18:02 -0500
To: LaBovick, Hannah EOP/OSTP
Subject: [EXTERNAL] Accepted: Anurag Acharya / OSTP @ Thu Aug 19, 2021 12pm - 12:30pm (PDT) (LaBovick, Hannah EOP/OSTP)
Attachments: invite.ics

Anurag Acharya has accepted this invitation.

Anurag Acharya / OSTP

When Thu Aug 19, 2021 12pm – 12:30pm Pacific Time - Los Angeles

Where >https://pitc.zoomgov.com/(b) (6) (map)

Calendar LaBovick, Hannah EOP/OSTP

Who
- LaBovick, Hannah EOP/OSTP - organizer
- Anurag Acharya - creator
- Sheehan, Jerry R. EOP/OSTP
- Nelson, Alondra R. EOP/OSTP
- Lander, Eric S. EOP/OSTP
- Ochoa, Jorge A. EOP/OSTP
- Donohue, Ryan C. EOP/OSTP

To discuss public access; OSTP attendees: Eric Lander, Alondra Nelson, Jerry Sheehan, Ryan Donohue

[>https://www.zoomgov.com/(b) (6)

Hi there,

Hannah LaBovick is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile:

US: (b) (6) or (b) (6)

Meeting URL:

>https://pitc.zoomgov.com/j(b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: (b) (6) or (b) (6) or (b) (6) or (b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

International numbers

Join from an H.323/SIP room system

H.323:

(b) (6) (US West)

(b) (6) (US East)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

SIP:

(b) (6)

Passcode:

(b) (6)

Invitation from Google Calendar

You are receiving this courtesy email at the account (b) (6) because you are an attendee of this event.

To stop receiving future updates for this event, decline this event. Alternatively you can sign up for a Google account at >https://calendar.google.com/calendar/< and control your notification settings for your entire calendar.

Forwarding this invitation could allow any recipient to send a response to the organizer and be added to the guest list, or invite others regardless of their own invitation status, or to modify your RSVP. Learn More.

RE: email scamming

To: Tyler E Jacks (b) (6)

Date: Tue, 27 Jul 2021 17:34:15 -0400

Great, thank you! Eric will give you a call at 6!

Hannah

From: Tyler E Jacks (b) (6)

Sent: Tuesday, July 27, 2021 4:53 PM

To: LaBovick, Hannah EOP/OSTP (b) (6) >

Subject: [EXTERNAL] Re: email scamming

Hi Hannah,

I could do 10 minutes at 6 tonight. I will have friends over at dinner, so won't be able to talk for too long.

My number is (b) (6)

Thanks,

Tyler

Sent from my iPhone

> On Jul 27, 2021, at 12:56 PM, LaBovick, Hannah EOP/OSTP (b) (6) wrote:
>
> Hi Tyler!
>
> Hope all is well.

Might you have 10-15 minutes to chat with Eric this evening either at 6pm or at 7pm?

Thanks in advance!
Hannah

From: Lo, Kevin C. EOP/OSTP
Sent: Tuesday, July 27, 2021 12:48 PM
To: 'Tyler E Jacks' (b) (6)
Cc: LaBovick, Hannah EOP/OSTP (b) (6)
Subject: RE: email scamming

Hi Tyler!

Eric would indeed like to chat! Hannah can help find a time.

Thanks so much,
Kevin

Kevin Lo *(he/him)*
Special Advisor for Director's Initiatives
Office of Science and Technology Policy
Executive Office of the President
(b) (6)
Cell: (b) (6)

From: Tyler E Jacks (b) (6)
Sent: Tuesday, July 27, 2021 12:42 PM
To: Lander, Eric S. EOP/OSTP (b) (6)
Subject: [EXTERNAL] email scamming

Hey Eric-

I am guessing this was scamming effort. Please let me know if you would really like to talk sometime.

I'd actually like to fill you in on progress at Break Through Cancer—and maybe update President and Mrs. Biden some time.

I hope you are well and prospering.

Best,

Tyler

Begin forwarded message:

From: Eric S Lander (b) (6)
Subject: 5 min?
Date: July 25, 2021 at 9:16:24 AM EDT
To: Tyler Jacks (b) (6)

Hi Tyler:

Would you have 5 min for a quick call this morning?

Best,

Eric

[EXTERNAL] Urgent: Updating Pillar Award letter in support of Anna Greka

From: "Gerstein, Rebekah" (b) (6)

To: "Lander, Eric S. EOP/OSTP" <(b) (6)>

Cc: (b) (6)

Date: Wed, 04 Aug 2021 12:01:29 -0400

Attachments: Greka_PillarAward_ResearchInnovation_ESL.pdf (91.47 kB)

Dear Dr. Lander,

I am following up on an email Dr. Bonventre wrote you last week about updating the letter you submitted in support of Anna Greka for the Pillar Award in 2020. Would you be willing to update the letter? The nomination package is due this Friday, August 6, 2021. Your 2020 letter is attached.

Best,

Rebekah

Rebekah S Gerstein

Executive Secretary to

Joseph V Bonventre, MD, PhD

Renal Division

Brigham and Women's Hospital

Harvard Medical School

Harvard Institutes of Medicine Rm 570A

4 Blackfan Circle

Boston, MA 02115

Office: (b) (6)

(b) (6)

brighamandwomens.org



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BROAD INSTITUTE

415 Main Street
Cambridge, MA 02142
T(b) (6)
www.broadinstitute.org

July 15, 2020

To the Selection Committee:

I am writing with my greatest enthusiasm to support the nomination of **Dr. Anna Greka for the Pillar Research Innovation Award for her pathbreaking discoveries on the molecular and cellular biology of kidney function and the development of therapeutic leads for kidney disease.**

I believe that Dr. Greka is the most innovative and impactful scientist working on kidney function and disease. The elegance and importance of her work is already helping to transform work in a field that has seen little progress over the past 40 years.

I also note that, in addition to her beautiful work on kidney disease, she has also been doing rapid and innovative work with implications for COVID19.

I. TRP channels in kidney health and disease

Dr. Greka began her career as a graduate student at Harvard Medical School, where she sought to uncover the function of a newly discovered class of ion channels, the Transient Receptor Potential (TRP) channels. In pioneering electrophysiology recordings of growth cones in hippocampal neurons, coupled with detailed cell biological, biochemical and imaging studies, she identified a role for TRPC channels in the developing brain (Greka et al., 2003, *Nature Neuroscience;* Bezzerides et al., 2004, *Nature Cell Biology*).

Unexpectedly, her attention was drawn to the kidney — when the first (and to date only) known TRPC channelopathy was identified in a family with an autosomal dominant progressive kidney disease: familial focal and segmental glomerulosclerosis (FSGS). Driven by scientific curiosity, and recognizing the power of human genetics for therapeutic discovery, Dr. Greka established her independent group aiming to understand the role of TRPC channels in FSGS. First, she found that two channels, TRPC5 and TRPC6, play an antagonistic role in actin remodeling and cell motility in kidney podocytes – postmitotic cells critical for kidney filter function (Tian et al., 2010, *Science Signaling*). Next, her team demonstrated a central role for TRPC5 in podocyte injury *in vitro* using calcium imaging and measurements of actin dynamics in podocytes, as well as studies in TRPC5 knockout mice (Schaldecker et al., 2013, *Journal of Clinical Investigation*).

In award-winning follow-up work, Dr. Greka and her team developed the first specific TRPC5 ion channel blocker and showed that it prevents podocyte injury and loss, and protects rats from kidney disease progression (Zhou et al., 2018, *Science*). Most excitingly, the therapeutic benefit was applicable to highly prevalent forms of kidney disease, marking

a groundbreaking discovery for the field. As a direct result of this work, TRPC5 inhibitors are currently being tested in the clinic.

Given that there had been no new therapies in kidney disease over the past 40 years, her research was recognized by the American Society for Clinical Investigation with its Seldin-Smith Award for Pioneering Research and by the Presidential Early Career Award for Scientists and Engineers.

Dr. Greka's exquisite mechanistic and cell biological work thus laid the foundation for the development of the first mechanism-based therapeutic strategy for progressive kidney diseases.

II. Fundamental studies on the role of cargo receptors in toxic proteinopathy, and a novel therapeutic strategy

Struck by the lack of mechanistic insights into kidney biology in health and disease, Dr. Greka and her team took on another autosomal dominant disease called Mucin1 (MUC1) kidney disease (MKD). She found that the mutant form of the transmembrane glycoprotein mucin 1 (MUC1) — known as frameshift MUC1 (MUC1-fs) — accumulates intracellularly, leading to kidney epithelial cell injury and loss. MKD was thus newly defined as a toxic proteinopathy.

Most interestingly, Dr. Greka found that MUC1-fs accumulates in vesicles enriched for the cargo receptor TMED9. Her studies revealed that mutant MUC1-fs was trapped in TMED9-enriched vesicles between the cis-Golgi and the ER, leading to the activation of the ATF6 branch of the unfolded protein response (UPR) and ultimately, to cell death. The team then discovered a small molecule, BRD4780, that binds TMED9 and releases MUC1-fs, allowing the mutant protein to traffic through the secretory pathway into lysosomes, where it is degraded. This reverses the activation of the UPR and rescues kidney epithelial cells from injury and death.

Excitingly, Dr. Greka showed that the same molecule, BRD4780, can *also* ameliorate the cellular phenotype of two other toxic proteinopathies involving aberrant transport through the ER: a disease similar to MKD called uromodulin-associated kidney disease, and retinitis pigmentosa, a cause of progressive blindness.

Dr. Greka's detailed mechanistic work thus points to a therapeutic strategy with the potential to treat more than a dozen currently incurable toxic proteinopathies. In addition, her work provides new, fundamental cell biological insights into the role of cargo receptors in the early secretory pathway.

III. Additional contributions

- Dr. Greka's lab has led the way in understanding fundamental podocyte cell biology, in particular the regulation of the actin cytoskeleton. Her team demonstrated that several proteins — Nck1, the Rac1 GEF Vav2 and synaptopodin — regulate actin Rho GTPase signaling, thereby controlling podocyte actin dynamics (Buvall et al., 2013, *Nature Communications;* Buvall et al., 2016, *JASN*).

- The central role of podocytes in kidney health and disease was further explored in a study of inducible podocyte ablation by deletion of the essential chromatin structure regulator CCCTC-binding factor (CTCF). This study showed that podocyte ablation is sufficient to drive the progression of kidney disease (Christov et al., 2018, *JCI Insight*).

- Dr. Greka also led an exploration of a chemical library in search of compounds that protect podocytes from cell death (Sieber et al., 2017, *Cell Chemical Biology*). Remarkably, the team identified a BRAF inhibitor, originally designed to treat melanoma, as a novel podocyte-protective strategy, uncovering MAPK signaling in podocytes as a therapeutically relevant pathway.

- Using single-cell transcriptomics, Dr. Greka's lab has profiled more than 400,000 human cells from iPSC-derived kidney organoids — the largest single-cell profiling of kidney cells to date — revealing new cell types and states relevant to kidney biology in health and disease (Subramanian et al., 2019, *Nature Communications*). Importantly, in this study, Dr. Greka's team discovered that transplantation of human organoids under the kidney capsule of immunocompromised mice is a new mechanism to diminish off-target cells, a long-sought goal for the kidney organoid field.

- Committed to uncovering the cellular composition of the kidney in health and disease, Dr. Greka currently serves as the chair and Core Principal Investigator of the Kidney Network, a part of the Human Cell Atlas Project, an international collaborative scientific effort to generate a comprehensive atlas of all human cells and tissues at single cell resolution.

- As a follow-up to detailed mechanistic studies (Yu et al., 2013, *NEJM*), Dr. Greka is spearheading the translation of discoveries from the lab to the clinic by leading a 25-center clinical trial of Abatacept (CTLA4-Ig), a repurposed targeted therapy for FSGS (centered on the inhibition of CD80 in podocytes).

- For the past 5 years, Dr. Greka has been leading Kidney-NExT, an annual symposium she founded, aiming to bring state-of-the-art genetics, genomics and cell biology to the development of next-generation therapeutics for kidney diseases.

- Finally, Dr. Greka has been responding to the current pandemic — doing very innovative work under difficult circumstances to demonstrate that an FDA approved drug, Fostamatinib, may be useful for the treatment of COVID19 acute lung injury.

IV. Awards and honors

Dr. Greka is the recipient of multiple awards for innovative research both in basic cell biology and with clinical impact, including the Henry Asbury Christian Award (2004, HMS) for outstanding research during her training as a physician-scientist; the Claflin Distinguished Scholar Award (2010) and Alexander Lief Excellence in Science Award (2014) from Massachusetts General Hospital; the Young Physician-Scientist Award (2014) and the Seldin-Smith Award for Pioneering Research (2018) from the American Society for Clinical Investigation; the Presidential Early Career Award for Scientists and Engineers (PECASE) (2017); and most recently, the 2020 Donald W. Seldin Young Investigator (Lifetime Achievement) Award from the American Society of Nephrology (ASN).

V. Conclusion

In summary, Dr. Greka's achievements are stunning — arguably the most exciting mechanistic work today in kidney biology and disease.

For her many accomplishments already and her future promise, Dr. Greka would be a superb recipient of the Pillar Research Innovation Award.

Sincerely,



Eric S. Lander

President and Founding Director, Broad Institute of MIT and Harvard
Professor of Biology, MIT
Professor of Systems Biology, Harvard Medical School

[EXTERNAL] Register for Google Cloud Next, October 12–14

From: Google Cloud (b) (6)

To: "Koizumi, Kei EOP/OSTP" (b) (6)

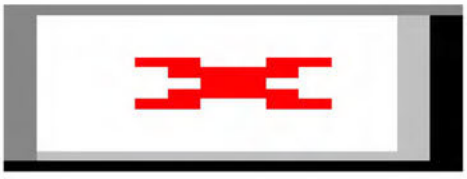
Date: Wed, 04 Aug 2021 13:13:55 -0400

Join us at Next '21.

Google Cloud Next is back. Starting October 12, let's tackle today's greatest business challenges together.

October 12–14

Register now



Hi Kei,

We're back. Join us for **Google Cloud Next, October 12–14, 2021**, for a fresh approach to digital transformation.

This year, our flagship event is a customizable digital experience, allowing you to map out a personalized journey that's just right for you. Participate in engaging sessions, take part in live Q&As with experts, and collect new insights. You can curate your online experience with a mix of live and on-demand content to suit your interests.

At Next '21, you can:

- **Build your own experience.** We know your calendar is packed, so we've made it easy for you to create a program that perfectly fits your interests and your schedule.
- **Connect with experts.** Have questions about your cloud transformation? Join conversations with trusted Google experts and developer advocates to help get the answers.
- **See the latest tech in action.** Immerse yourself in our latest products and solutions, dive even deeper during live Q&As and interactive demos, and be inspired by the latest Google Cloud and Google Workspace technology.
- **Sharpen your skills.** Expand your expertise and learn new things in our transformative workshops and training sessions alongside your peers in the Google Cloud community.

This year, Google Cloud Next is free, so be sure to grab your spot today and stay tuned for more exciting updates as the event nears.

Together, let's start solving for what's next.

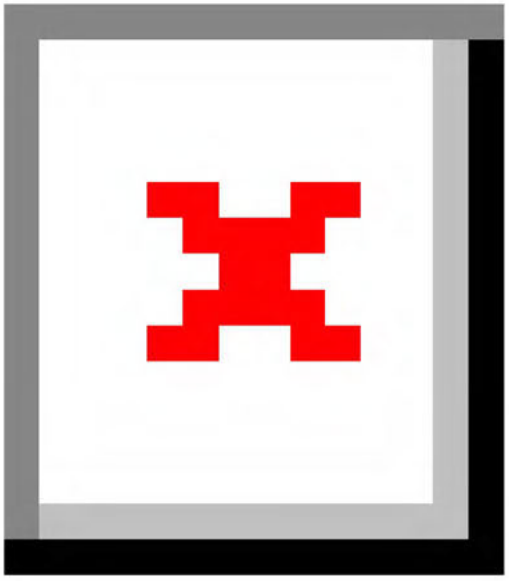
Register now Decline this event

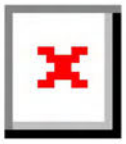
See you in the cloud,

The Google Cloud Team

- Have questions? Reach out to us at (b) (6)

- For news and updates leading up to Next '21, follow @GoogleCloud and the #GoogleCloudNe Twitter.





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<>







[EXTERNAL] Follow up on pandemic preparedness discussion

From: Joshua Schoop(b) (6)

To: "Schmoyer, Michael W. EOP/OSTP" (b) (6)

Cc: Mike Fisher (b) (6)

Date: Thu, 05 Aug 2021 16:36:11 -0400

Attachments: Innovation Toolkit_Grand Challenges.docx (151.58 kB); Innovation Toolkit_Calls to Actions and Partnerships.docx (463.85 kB); Innovation Toolkit_Evidence Based Policy.docx (1.21 MB); Innovation Toolkit_Innovative Procurement Mechanisms.docx (424.21 kB)

Hi Michael,

Thanks for taking the time to speak last week. We enjoyed the discussion and opportunity to share ideas on preventing the next pandemics, as well as learn more about your objectives and portfolio at OSTP.

Mike and I have been digging in to the EO and National Security directive and are excited to pull together some thoughts and recommendations to support the identified priorities. Let us know if you have any additional context on areas of focus we might consider as we look to source and document possible directions.

Within that vain, I'd mentioned the innovation toolkit that I helped develop during the final year of the Obama Administration. Unfortunately the "innovation.gov" website never saw the light of day but I pulled a few of the tools out that might be helpful for your work (attached).

Happy to say more if useful and think through where pieces might apply to your focus areas. Note the content is written modularly as it was designed to sit on a website.

Looking forward to continuing the discussion soon and let us know if you have any additional thoughts.

Josh

--

Joshua Schoop, PhD
Deputy Director
(b) (6)
Cell: (b) (6)

Evidence-Based Policy

Note on structure/outline: Evidence-based policy is treated here as a broad umbrella comprising 3 distinct areas. A visual:

Evidence Based Policy		
Tiered Grantmaking	Learning Agenda	Pay for Success

Further note: Content addresses overarching elevator pitch, rationale, and category of uses for evidenced-based policy as a whole, before addressing D1-D9 (see below) for the learning agenda, followed by Pay for Success. Tiered grantmaking content can be found separately.

Content structure outline:

1. **An "elevator pitch," which provides highlights of the content, such as why the approach is important, how it works, and examples of where it has worked**
2. **A short, digestible summary of underlying premises and rationales, supported by research (i.e., not a report)**
3. **Profiles of major categories of candidate users, including specific examples of when, and under what circumstances, the approach may be employed, supported by research into the target audience and their needs**
4. **One or more "success stories" or other learning narratives that highlight the impact of and justification for using this approach.**
5. **Documentation of challenges to deployment, and potential limitations of the approach, including barriers or obstacles encountered within agencies employing the approach**
6. **A "How-To" document, detailing key steps for deploying the approach, including promising practices in adaptation and deployment**
7. **An online inventory of resources**
8. **Examples of policy (e.g. legislation, Executive Order, etc.) that have enabled or encouraged the approach**
9. **Future directions (next practices as opposed to best practices)**

Pull Quotes:

"What does it mean [...] to create 'evidence-based initiatives?' It means that the administration strives to be as certain as possible that Federal dollars are spent on social intervention programs that have been proven by rigorous evidence to work." [Haskins, R and Margolis, G., *Show Me the Evidence: Obama's Fight for Rigor and Results in Social Policy,* Brookings Institution Press, 2014.]

"Where evidence is strong, we should act on it. Where evidence is suggestive, we should consider it. Where evidence is weak, we should build the knowledge to support better decisions in the future." ["Use of Evidence and Evaluation in the 2014 Budget," Office of Management and Budget Memorandum M-12-14, May 2012.]

"Moneyball for Government Principles: Building evidence about the practices, policies and programs that will achieve the most effective and efficient results so that policymakers can make better decisions;

[APG]

investing limited taxpayer dollars in practices, policies and programs that use data, evidence and evaluation to demonstrate they work; and directing funds away from practices, policies, and programs that consistently fail to achieve measurable outcomes." ["Moneyball Principles," Moneyball for Government.]

Evidence Based Policy

Broad EBP - Deliverable 1: Elevator pitch summary

Evidence-based policy helps to achieve greater impact per taxpayer dollar by focusing resources on what works. Evidence-based approaches are a framework that emphasizes assessing the efficacy of program by evaluating what's working, where it's succeeding, for whom, and under what circumstances. Through the use of data, performance metrics, and assessments, agencies can target their resources to invest in programs and initiatives shown to be the most effective while divesting from programs shown to have minimal or negative effects. Using existing evidence and also expanding the knowledge base can produce greater impact and advance important agency goals.

Why

Taking an evidence-based approach to policy elevates the most efficient and cost- effective methods. Evidence-based strategies are a promising alternative to more informal or fragmented ways of assessing performance of Federal programs. Evidence-based policy strategies propose to routinely and rigorously use data and program evaluations to inform funding decisions. The approach contributes to growing the knowledge base of programs which have been validated, functioning as an important mechanism to continuously learn and improve. This collective knowledge can be leveraged by decision-makers and investors at all levels–municipal, state, philanthropic or private—to better inform decisions, improve performance, and increase return on the public's investment.

How

Strategies to implement evidence-based policies across the Federal government can be divided into three broad approaches. These approaches share in common an emphasis on producing additional evidence and understanding about the interventions funded:

1. Implementing a Learning Agenda
   A learning agenda emphasizes that Federal employees and grantees understand how to apply evidence and data-based decision making and that they have the resources, capacity, and data needed to implement this approach. [See call-out box below]
2. Creating or adapting existing grant programs to be evidence-based
   This strategy can use various means (legislative, regulatory, or agency initiative) to include evidence requirements in Federal grant making and funding. Tiered-evidence grant making programs and directive evidence appropriations for replicating evidence-backed programs (such as the Teen Pregnancy Program) are an example of this.
3. Using public-private partnerships to achieve outcomes through evidence-based programs
   This strategy focuses on ways in which the public sector can establish partnerships through programmatic means to increase investment in and support of evidence-based interventions. One example of this is Pay for Success programs (otherwise known as Social Impact Bonds).

Important Terms

[APG]

What is "Evidence"?
OMB defines "evidence" as "the available body of facts or information indicating whether a belief or proposition is true or valid. Evidence can be quantitative or qualitative and may come from a variety of sources, including performance measurement, evaluations, statistical series, retrospective reviews, and other data analytics and research." ["Analytical Perspectives: Budget of the United States Government, Fiscal Year 2017," c. 7, p. 71-72, Office of Management and Budget, 2016.]

Using a continuum framework, programs can begin implementing one of these information collection techniques with minimal effort. With increasing experience and capacity, a program can grow the amount and quality of information and the rigor of its information sourcing, moving it further along the continuum. The cumulative effect is an increasingly robust evidence-base of its program's effectiveness.

It's important to note that program information collected through evidence-based practices is intended to be useful, not compulsory. When considering what evidence-building initiatives to employ and how, agency leadership and staff should consider what information will best contribute to a program's goals and help improve performance. This will help determine which type of information collection process to use.

Evidence comes in many forms, and different types of evidence are appropriate for different purposes. Agencies should strive to develop a portfolio of evidence that includes some or all of the following approaches:

High quality performance measurement:
During performance measurement, programs identify outcome and related output measures that directly align with their theory of change. They then create systemic and reliable methods to collect data on these measures and report them on a regular ongoing basis.

Implementation or process evaluations:
These are types of evaluations that investigate how a program is being enacted and whether it is being carried out as intended. They typically include quantitative and qualitative methods that will capture measurable units (i.e. number of participants, hours of programming, number of staff, survey results) as well as descriptive elements (i.e. written descriptions of program space, participant interview narratives). These studies can answer questions about how a program was implemented, what challenges it experiences, and how it might be adapted in the future.

Formative evaluations:
This type of evaluation ensures that a program or program activity is feasible, appropriate, and acceptable before it is fully implemented. It is usually conducted when a new program or activity is being developed or when an existing one is being adapted or modified.

Outcome evaluation:
An assessment that tracks whether identified desired outcomes were achieved by the program. This type of evaluation might use pre- and post-measurements to mark changes that occurred during a program's implementation.

Impact Evaluation:
An evaluation designed to determine if the outcomes observed among program

[APG]

participants are due to having received program services or the intervention. An impact evaluation is the only way to determine causality. This type of evaluation requires a comparative element that contrasts outcomes achieved by the program against outcomes observed from a control or comparison group comprised of individuals who did not participate in the program. There are several methodologies that can be used to achieve this:

Quasi-Experimental Design:
A design that includes a comparison group formed using a method other than random assignment, or a design that controls for threats to validity[1] using other counterfactual situations, such as groups which serve as their own control group based on trends created by multiple pre/post measures. Quasi-experimental design, therefore, controls for fewer threats to validity than an experimental design.

Randomized Control Trials (RCTs)
A research design in which the effects of a program, intervention, or treatment are examined by comparing individuals who receive it with a comparable group who do not. In this type of evaluation, individuals are randomly assigned to the two groups to try to ensure that, prior to taking part in the program, each group is statistically similar in both observable (i.e., race, gender, or years of education) and unobservable ways (i.e., levels of motivation, belief systems, or disposition towards program participation).

A special note on low-cost RCTs:
The use of low-cost RCTs has been strongly supported by OMB and the Arnold Foundation. Low-cost RCTs are an avenue of achieving rigorous evaluations while significantly reducing costs. This is done by using existing data, which reduces the need for expensive data collection efforts, and by embedding evaluations into existing programs, which reduces the need to spend more money on the intervention program. [Feldman, A. and Haskins R., "Low Cost Randomized Control Trials", Evidence-Based Policymaking Collaborative, November 16th, 2016.]

Read more:

- "How low cost RCTs can drive effective spending"
- "Funding what works: The importance of low cost randomized controlled trials"
- "Low-cost Randomized Controlled Trials"

Additional glossary resources:

- Useful chart of evaluation definitions from the Center for Disease Control
- Department of Education's What Works Clearinghouse Glossary of Terms
- Social Innovation Fund's Evaluation Planning Guidance with Glossary of Terms
- International Initiative for Impact Investing (i3) resource list including public and subscriber resources for impact investing (glossaries, videos, toolkits, etc.)

How do you build a strong evidence-base for a program?

[1] Validity generally refers to how accurately a conclusion, measurement, or concept corresponds to what is being tested.

[APG]

There are a variety of ways to build evidence of what works, including data collection, performance measurement, and program evaluation. Looking across Federal evaluation initiatives, OMB identified five guiding principles that should inform evaluation policy:

- Rigor: Use the most rigorous methods that are appropriate to the evaluation questions and feasible within budget or other constraints. This applies to all forms of evaluation, not just impact evaluations. (Rigor comes up frequently when describing evaluations that are considered in a program's evidence-base.)

- Relevance: The evaluation priorities will take into account legislative requirements, Congressional Interests, and reflect the interests and needs of other stakeholders, including the Administration leadership, the agency, the implementing program, and other partners and stakeholders.

- Transparency: Evaluation plans, ongoing evaluation work, and evaluation findings should be easily accessible, and should be released regardless of the findings.

- Independence: While stakeholders should actively participate in identifying evaluation priorities and questions, and assessing the implications of findings, the actual evaluation functions should be insulated from undue influence, and from both the appearance and actuality of bias

- Ethics: Evaluations should be conducted in an ethical manner and safeguard the dignity, rights, safety, and privacy of participants.

["Analytical Perspectives: Budget of the United States Government, Fiscal Year 2017," c. 7, p. 71-74, Office of Management and Budget, 2016.]

How do you define "rigorous" evaluation?
Evaluations should use the most rigorous design that is appropriate and feasible based on available resources and accounting for other constraints. Each type of evaluation method has its own protocol for ensuring high-quality implementation, data capture, and data analysis. A rigorous evaluation design will employ the best method to answer the questions posed and will implement the methodology in a high-quality manner. The Department of Labor notes:

> "Rigor is required for all types of evaluations, including impact and outcome evaluations, implementation and process evaluations, descriptive studies, and formative evaluations. Rigor requires ensuring that inferences about cause and effect are well founded (internal validity); requires clarity about the populations, settings, or circumstances to which results can be generalized (external validity); and requires the use of measures that accurately capture the intended information (measurement reliability and validity).
> ["Department of Labor Evaluation Policy," US Department of Labor, November 2013.]

Broad EBP - Deliverable 2: Summary of underlying rationales / empirical research

Benefits of Evidence-Based Policy:

[APG]

The benefits of implementing evidence-based policy are multifold. First, the private sector has shown that a culture emphasizing continuous learning and program improvement leads to better overall performance [Garvin, D., Edmondson, A., and Gino, F., "Is Yours a Learning Organization?," Harvard Business Review, March 2008.] Second, implementing evidence-based grant investments have been shown to achieve significant cost-savings.

How does evidence-based programming generate better outcomes and save money?

The Nurse Family Partnership (NFP) program is an evidence-based program that has been evaluated by multiple randomized control studies and shown to produce positive outcomes for both children and mothers. Based in part of the strength of its evaluations, it has been replicated in 47 states including statewide in Pennsylvania and Colorado. One of several evidence-based home visitation programs supported by Health Resources and Services Administration's Maternal and Child Health program, NFP has been evaluated by DHHS and designated as meeting its criteria for an evidence-based program model, with findings of multiple positive outcomes for both the youth and mothers ["Nurse Family Partnership (NFP)," US Department of Health and Human Services, May 2016.] One study found that every dollar invested in the program returned $5.70, or a net benefit of $34,148 per family served ["Invest in a Strong Start for Children: A Toolkit for Donors on Early Childhood," The Center for High Impact Philanthropy, The University of Pennsylvania, no date.]

Because studies have demonstrated the impact and cost-effectiveness of NFP and other evidence-based home visitation programs, various Federal funding streams now support them including: MIECHV Program, Medicaid, and the Maternal and Child Health Services Block Grant (Title V), Temporary Assistance for Needy Families (TANF), Child Care Development Block Grant, Healthy Start, Early Head Start, Title IV-B and other child welfare and foster care prevention funds, juvenile justice, child abuse prevention funds through the Administration for Children & Families (ACF). This has allowed the program to expand and serve an even greater number of mothers and youth, increasing the number of families served by 10,000 since 2011 ["Nurse Family Partnership," The Edna McConnell Clark Foundation, 2016.]

Broad EBP - Deliverable 3: Profiles of major categories of candidate users - examples of when to deploy

All Federal programs can use and benefit from components of an evidence-based approach. The extent to which they implement evidence-based practices can be understood on a continuum. On one end of the continuum are programs at the early stages of using evidence – starting to collect data and use it to understand their performance and make improvements. On the other end of the continuum are programs who are able to implement highly sophisticated program evaluations and use resulting data to effect wide ranging policy or scale and improve national programs. It is not appropriate or prudent for all programs to aspire to move to the far end of the continuum. However, all programs will benefit from enhancing their ability to collect and use data and employ appropriate types of program assessment to understand what is and is not working, and strive towards continuous improvement.

Learning Agenda

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Learning Agenda - Deliverable 2: Summary of underlying rationales / empirical research

The Learning Agenda Approach

Agencies are encouraged "to adopt 'learning agenda' approaches in which agencies collaboratively identify the critical questions that, when answered, will help their programs work more effectively and develop a plan to answer those questions using the most appropriate tools.
The key components of this learning agenda approach are that agencies:

- Identify the most important questions that need to be answered in order to improve program implementation and performance. These questions should reflect the interests and needs of a large group of stakeholders, including program office staff and leadership, agency and Administrative leadership, program partners at state and local levels, and researchers, as well as legislative requirements and Congressional interests.
- Strategically prioritize which of those questions to answer within available resources, including which studies or analyses will help the agency make the most informed decisions.
- Identify the most appropriate tools and methods (e.g. evaluations, research, analytics, and/or performance measures) to answer each question.
- Implement studies, evaluations, and analysis using the most rigorous methods appropriate to the context.
- Develop plans to disseminate findings in ways that are accessible and useful to program officials, policy-makers, practitioners, and other key stakeholders—including integrating results into performance.

[Directly sourced from: "Analytical Perspectives: Budget of the United States Government, Fiscal Year 2017," c. 7, Office of Management and Budget, 2016.]

Historical evolution:

> *"Everyone wants to know whether programs work and, if they are not working, how they can be improved. In politics it has always been popular for policymakers to tell their constituents and taxpayers that they can show that they are spending taxpayer dollars wisely. What is new is the public definition of "good evidence," brought to Federal policymaking by the Bush administration's OMB and Institute for Education Sciences and expanded greatly by the Obama OMB team, which has raised the bar on the quality of evidence."*
> [Haskins, R., and Margolis, G., "Show Me the Evidence: Obama's Fight for Rigor and Results in Social Policy," Kindle Locations 3062-3065, Brookings Institution Press, 2014.]

The evolution of a "learning agenda approach" and using evidence-based policy goes back several administrations. During the Clinton Administration, a law called the Government Performance and Results Act, which aimed "to provide for the establishment of strategic planning and performance measurement in the Federal Government, "was passed ["Government Performance and Results Act, 1993," OMB 1993]. The George W. Bush Administration built upon this framework and implemented the Program Assessment Rating Tool (PART). This program review identified a program's strengths and weaknesses, looking at all factors that affect and reflect program performance including: program purpose and design; performance measurement, evaluations, and strategic planning; program management; and program results ["Archive: Assessing Program Performance," Office of Management and Budget, 2008.]

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At the same time, a number of private foundations, including the Edna McConnell Clark Foundation and W.T Grant Foundation, made significant operational shifts to invest in evidence-building by funding evaluations of their investments, investing in evaluation capacity-building, or requiring evidence baselines to receive funding. [Fitzsimmons, K., "Getting the Most out of Evaluation," The Edna McConnell Clark Foundation, March 16, 2016; Du Mont, K., "Leveraging Knowledge: Taking Stock of the William T. Grant Foundation's Use of Research Evidence Grants Portfolio," W.T. Grant Foundation, November 23rd, 2015.] Building on this, a number of philanthropic and non-profit leaders lobbied both Presidential candidates in 2008 to use similar tactics – expanding Federal investment in evidence-backed scaling efforts that would expand the reach of effective social programming [Haskins, R, and Margolis, G. "Show Me the Evidence: Obama's Fight for Rigor and Results in Social Policy," p. 137, Brookings Institution Press, 2014.]

In 2010, OMB established guidance to systematize and encourage evaluation across government agencies. Standards were needed to define what strong evidence looked like, and Federal agencies and program managers needed to develop capacity for building evidence-based programming. The first priority was establishing an understanding of evidence as a continuum – that is, to encourage agencies to build a body of evidence by conducting additional increasingly rigorous evaluation studies and studies in multiple contexts. By focusing first on improving agency staff's understanding of evaluation methods and how to interpret results, programs would be better positioned to assess their existing programs and formulate a means for validating current and future interventions. [Spera, C., phone interview with Policy Design Lab, November 30th, 2016].

Chris Spera, former Director of Research and Evaluation at the Corporation for National and Community Service explained: "The learning agenda was about embedding evaluation into the work of the agency - to ensure they are using inquiry to improve. What do we need to know to do our work better? How do we get that information? How do we change practice based off information once we have it?" [Spera, C., phone interview with Policy Design Lab, November 30th, 2016].

Other agencies and programs took the charge to promote evidence and evaluation beyond their agency. Evidence clearinghouses and public websites like the Department of Education's What Works Clearinghouse, HHHS/ACF's Home Visiting Evidence of Effectiveness, the Clearinghouse for Labor Evaluation and Research at Department of Labor, and the youth.gov Investing in What Works are all examples of externally facing websites that seek to provide multiple audiences access to evaluations and evidence-based programs.

Deliverable 3: Profiles of major categories of candidate users - examples of when to deploy

OMB's learning agenda approach articulated a Federal-wide strategy for improving program performance and impact. It has been implemented in a variety of ways based on an agency or program's resources, capacity, leadership's commitment to evidence, and ability to act based on their individual legislative or regulatory authority. All programs can find an appropriate place to start as they strategize how to implement pieces of the learning agenda. [Zandniapour, L., "Introducing the Impact Evaluability Assessment Tool," Corporation for National and Community Service, 2014.]

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Beginning Stages of Implementing a Learning Agenda:
An agency at the beginning stages of implementing evidence-based policy might start by asking: "*What is it I want to know about our programs? About the field? Or the topic area we focus on*?" The answer may be performance or impact related; "*Are the programs meeting their performance goals?*" or "*Are the programs having the effect that is intended*?" Agency staff answers to these questions should be combined with questions routinely received or reported on from Congress, appropriators, and OMB. Ideally, programs can also identify the frequency with which assessments should occur. Does this information need reporting on a one-time, quarterly, annual, or five-year basis? Based on the answers to these questions, a learning strategy can be developed which identifies the data or information needed to provide answers and means for collecting this data. An agency or program can then map resources and staffing capacity needed to implement the strategies. This approach was used by evaluation and program staff in Department of Labor and the Corporation for National and Community Service; their experiences are highlighted as case studies.

Building on Existing Efforts:
Agencies and programs who have already begun implementing learning agenda activities can explore how to increase use of data and evaluation across all programs or assess if implementing new evidence-based programming is feasible.

If establishing new programs is not a feasible option, agencies can continue to build the reach and use of the data being collected. This might entail increasing cooperation between program and evaluation or research staff as well as providing training and technical assistance to ensure programs are using data and evaluation in decision making. Agencies can also contribute to existing clearinghouses or establish their own, thereby making data and evaluation reports open to the public so that policymakers, practitioners at the state, city, and privately-funded local level can benefit from them. The Department of Education's Institute for Education Science developed the "What Works Clearinghouse." By making evaluation reports available on a host of education-related interventions, local philanthropies, school districts and even principals can search and identify vetted, research-backed programs they may wish to implement.

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Important Steps for All Programs:
Regardless of where an agency or program falls on the evidence-based policy continuum, three elements will be important for successful implementation:

1. Building staff capacity
2. Developing a coalition of support
3. Budgeting for activities

Building Staff Capacity:
Effectively using data and evaluation may require expertise that an agency or program does not currently have. It is important to ensure there are staff on hand who are deeply steeped in evaluation and data collection methodologies and can also translate these concepts to other program staff. There may also be technical skills required in terms of creating or maintaining data systems and generating useful reports. It may be that this expertise exists or can be brought on through in-house hiring. Agencies may also be able to procure additional expertise through contracts. In addition to staffing, ongoing consultations with general counsel may be needed to interpret policies around information collection, reporting, and using funds for these activities. (See discussions of DOL, CNCS, and the DOE What Works Clearinghouse for examples of staffing approaches).

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Developing a Coalition of Support:
Insights from several practitioners suggest that building and maintaining support from all levels of the agency is an important task when implementing evidence-based policy. Changes in policy may lead to shifts in programmatic approaches and even decisions to curtail support or resources for certain types of programs. Such changes can be uncomfortable and threatening. Having visible leadership buy-in and investing in making an effective case to program officers and staff on the ground are critical to managing these potential tensions.

Additional roles and offices that can help further evidence-based efforts include:

- Senior Leadership. Leadership -- including CEO, CCO, and CFO, --can provide cover, financial support, and internal pressure needed to push through adaption roadblocks.
- General Counsel. The office can ensure new efforts are within legislative and budgetary authority.
- External Affairs. The office can ensure efforts are properly and effectively communicated to key constituencies.
- Governmental Affairs. The office can ensure that efforts are responsive to congressional interest and are well-communicated to appropriators.
- Chief Program Leadership and Program Leads. As the staff closest to the "ground" and the staff who frequently interact with programs or grantees implementing the interventions to be evaluated, having their buy-in and willingness to translate policy into action is important.

[Healy, A., phone interview with Policy Design Lab, December 16th, 2016; Spera, C., phone interview with Policy Design Lab, November 30th, 2016.]

Budgeting for activities:
Agencies must assess if there is a budgetary authority for evaluation spending or if there is flexibility within an agency or program's budget to set aside funds for evaluation activities. In some cases, there will be a line item for evaluation activities; in others, there may be an allowable set aside and staff will need to assess whether it has historically been fully used. If not, explore using the set-aside to fund new activities, being mindful that it may entail shifting funds from existing allocations.

Case Study: Department of Labor
["A 2016 Policy Playbook, Invest in What Works: How to Solve Our Nations' Greatest Challenges," Results for America, March 2015; Irwin, M., personal correspondence with Policy Design Lab, January 6th, 2017.]

Starting in FY 2010, Congress has appropriated approximately $8 million per year for program evaluation at the Department of Labor under the direction of the Chief Evaluation Officer. Additionally, Congress allows the Secretary of Labor to set aside dollars from specified DOL accounts for use by the Chief Evaluation Officer for program evaluation. For example, the Consolidated Appropriations Act of 2016 stipulates that the Secretary of Labor may reserve not more than 0.75 percent from specific budget accounts for transfer to and use by the Office of the Chief Evaluation Officer for departmental program evaluation. The Chief Evaluation Officer must submit a plan to Congress describing the evaluations to be carried out at least 15 days in advance of any transfer. Appropriations acts have included similar provisions for the past several years. In FY16, approximately $25 million was transferred under this authority to the CEO for evaluations.

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The Chief Evaluation Office directly funds evaluations and also combines its own funds with agency funds to jointly sponsor some evaluations (e.g., within the Employment and Training Administration, Occupational Safety and Health Administration, Wage and Hour Division, Office of Federal Contract Compliance, Veterans Employment and Training Program, Office of Disability Employment Programs, Office of Workers Compensation, and Women's Bureau). In addition to appropriated department evaluation dollars, funding for some large competitive grants allow a percentage of grant funding to be devoted to evaluation. For example, DOL uses H-1B dollars to fund a number of discretionary grant programs that provide training and related activities to workers to assist them in gaining the skills and competencies needed to obtain or upgrade employment in high-growth industries or economic sectors. Job training programs funded by the H-1B Visa program for foreign workers can be used for evaluation and technical assistance as well as for the training program activities in occupations typically requesting visas.

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In FY 16, DOL's CEO will directly oversee an estimated $30 million in evaluation funding. ["Overview of Federal Evidence-Building Efforts," Office of Management and Budget, July 15th, 2016.]

Learning Agenda - Deliverable 4: One or more "success stories" or learning narratives to underscore impact

Case study profiles:

1. Department of Labor
2. Department of Education: What Works Clearinghouse

Case 1: Department of Labor

Summary:

The Department of Labor has been one of the leading agencies to adopt a robust learning agenda approach. This approach has been multifaceted and resulted in a cultural shift towards staff and programs thinking strategically about both program's evaluation and evidence but also how staff can use data and evaluation to meet their own learning and improvement needs.

Introducing a Chief Evaluation Officer: DOL's Experience

Over the last six years, the Department of Labor (DOL) has made significant progress in institutionalizing a culture of evidence and learning. The Chief Evaluation Office (CEO), established in 2010, plays a critical role in developing and maintaining this culture within DOL. As a part of its primary responsibility to manage DOL's evaluation program, the CEO focuses on a strong commitment to conducting rigorous, relevant, and independent evaluations. CEO is also committed to identifying and funding research and evaluation priorities established through a collaborative learning agenda process with DOL's various agencies.

These agencies cover a broad range of topics, from employment and training programs to worker protection and enforcement activities. CEO plays an important role in initiating research that cuts across these agency and program silos. CEO also serves as an "honest broker" on evidence issues within DOL, and its work is not limited to implementing evaluations. CEO actively participates in the performance management and strategic planning processes of the Department, and disseminates the results of their evaluations in formats that enable use by programs and policy makers.

Some of the key capacities that DOL developed to support this work include:

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- Hiring staff with expertise to strengthen the CEO's capacity to manage rigorous evaluations of various methodologies. For example, using behavioral insights, CEO worked with Occupational Safety and Health Administration to implement a large random assignment study that identified an effective way to support establishments that have injury and illness rates above the national average.
- Launching the Clearinghouse for Labor Research and Evaluation (CLEAR), which makes research on labor topics more accessible to practitioners, policymakers, researchers, and the public more broadly, thus increasing the transparency and relevance of the Department's evaluation efforts.
- Implementing a learning agenda process for the Department, in which CEO collaborates with each agency to identify key evaluation and research priorities.
- Securing the budget authority to set aside a portion of specified program funds (.75% in 2016) to support these evaluations.
- Creating a data analytics unit to support and complement agencies on their analytic needs and work; build data, statistical, and analytical expertise and capacity for the Department; and promote and innovate DOL administrative and public use data.
- Establishing an evaluation policy to institutionalize and guide the Department's evaluation efforts.

Factors for Strengthening a Learning Culture at the Department of Labor

Reflecting on key components that drove the Department of Labor's learning agenda approach, former Deputy Secretary, Seth Harris, identified 7 key factors—leadership commitment, set-aside funding, establishing a learning agenda, creating a Chief Evaluation Officer and office, building relationships, and connecting performance with evaluations, policy development, and creating a clearinghouse of evaluation information:

Commitment from leadership. The commitment of the Secretary and Deputy Secretary to build a culture of evidence and learning has been critical. That includes their support for the role of the Chief Evaluation Officer (CEO) as an "honest broker" about evidence issues; the requirement from leadership that operating agencies create learning agendas; and top leadership's inclusion of the CEO in key policy and management discussions (e.g., agency performance reviews) so that the CEO is knowledgeable about leadership's priorities.

0.5% set aside for program evaluation. The DOL Secretary can set aside up to 0.5% of appropriated funds from funds from specific budget accounts for evaluation. Once set aside, these funds get transferred to the Chief Evaluation Officer's budget. Many of the agencies also have separate evaluation funds, so this (up to) half percent supplements those funds.

Learning agendas. Learning agendas are an important planning tool at DOL. Each operating agency within the Department (there are 15) is required to create a five-year learning agenda, which gets updated every year. The learning agendas highlight priority questions and/or priority studies that the agencies would like to have done. They may also convey themes for their upcoming evaluation efforts or analysis that might be needed. They draw on a range of learning tools, including rigorous impact evaluation (i.e., randomized controlled trials or well-designed quasi-experiments), basic analysis or research, and performance analysis (looking at factors that are associated with outcomes). Learning agendas are a catalyst for setting priorities for studies and for conceptualizing studies that need to be done. Evaluations that Congress has required of agencies are also included. Importantly, the learning

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agendas communicate and engage operating agencies to help focus the resources and services of the Chief Evaluation Office.

Chief Evaluation Officer (and office). The role of the CEO is to coordinate, encourage and build the capacity and understanding around evaluation throughout the department. As noted above, the CEO's budget includes appropriated dollars for use by the CEO for evaluation, which she can then allocate to advance agencies' learning agendas. The CEO role is not designed to direct or centrally control all evaluation at DOL, but rather to encourage good evaluation. By 2016 there were approximately 50 studies underway and 30 more being planned. In 2016, the CEO was converted to a career positon to provide stability and institutionalize it within the Department.

Building strong relationships with operating agencies around relevance of evaluation. The Chief Evaluation Office has worked to create strong and productive relationships with the operating agencies-particularly in terms of showing that evaluation can be useful to those agencies-in at least two ways. First, they have framed their office's work around a spirit of collaboration and learning, rather than emphasizing requirements. Second, the focus of the CEO, just like the learning agendas, is primarily on learning and performance improvement, not an "up or down" verdict on particular programs. That has helped build trust with the agencies around evaluation and to see the CEO's office as useful to them.

Connecting performance and evaluation efforts. Performance and evaluation efforts can sometimes be siloed within Departments. DOL has been able to build bridges between these analytical approaches (and between staff in each area). In particular, the CEO also sits in all quarterly performance reviews with agencies run by the Deputy Secretary. In most meetings, there is often some discussion of evaluations underway. The CEO also provides input and assistance about existing or proposed performance measures, including identifying ways to add outcome measures or build more knowledge about whether an agency's (or program's) performance measures are correlated with impacts. That, in turn, can lead to updates to the agency's learning agenda.

Departmental evaluation policy statement. The statement posted on DOL's website in 2014 presents the principles that guide DOL's planning, conduct, and use of program evaluations. It emphasizes a commitment to conducting rigorous, relevant evaluations and to using evidence from evaluations to inform policy and practice. The statement also addresses the topics of rigor, relevance, transparency, independence, and ethics in the conduct of evaluations.

Clearinghouse of evidence-based approaches. DOL's Clearinghouse for Labor Evaluation and Research (CLEAR) is designed to make research on labor topics more accessible to practitioners, policymakers, researchers, and the public more broadly so that it can inform their decisions about labor policies and programs.

Source: [Harris, S., "Innovation Exchange 2015," p. 15, Department of Education, July 10th, 2015.]

Source: ["Analytical Perspectives: Budget of the United States Government, Fiscal Year 2017," c. 7, Office of Management and Budget, 2016.]

For more information, contact Dr. Molly Irwin, Chief Evaluation Officer, chiefevaluationoffice@dol.gov

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To Learn More:
Visit the Department of Labor's Evaluation website
Read the Department of Labor's Evaluation policy
The Role of a Chief Evaluation Officer: An interview with Demetra Nightingale, Chief Evaluation Officer, U.S. Department of Labor

Case 2: Department of Education/Institute for Education Science What Works Clearinghouse

When describing a "learning agenda," OMB includes dissemination: "Develop plans to disseminate findings in ways that are accessible and useful to program officials, policy-makers, practitioners, and other key stakeholders—including integrating results into performance." Source: ["Analytical Perspectives: Budget of the United States Government, Fiscal Year 2017," c. 7, Office of Management and Budget, 2016.]

In the 2017 Analytic Perspectives, this process is further elaborated on in the context of clearinghouses. Clearinghouses or online depositories of information help ensure that the learnings from agencies evaluation work can be used by practitioners and policymakers beyond their own programs. The Department of Education's Institute of Education Sciences has been producing evaluation information since its inception in the Education Sciences Reform Act of 2002. Responsible for running the "What Works Clearinghouse," their experience implementing evaluation reviews and creating a public-facing clearinghouse can be informative for other agencies or programs who wish to do so.

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Summary:
In 2002, the No Child Left Behind Act actively encouraged the adoption and funding of "scientifically based research" educational programs. However, practitioners had difficulty identifying which programs had evidence of effectiveness and what to make of the wide range of evaluation quality. With a limited time period for implementation and lacking the training to evaluate research quality, practitioners didn't know how to source evidence-based programs as NCLB instructed. Agency staff and appropriators identified this challenge and worked to address it. As a part of the Education Sciences Reform Act, the Department of Education's Institute of Education Science created the What Works Clearinghouse (WWC). An Initiative of the National Center for Education Evaluation and Regional Assistance, the mission of the WWC is to "be a central and trusted source of scientific evidence for what works in education. [Seftor, N., "Raising the Bar," Evaluation Review, 2016.]

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WWC is now one of the longest running Federal clearinghouses and has served as a model for other searchable evidence databases like those for Teen Pregnancy Prevention and Opportunity Youth programs.

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[Image Source: What Works Clearinghouse]

How They Did It:

1. Staffing and capacity building:

Use contractors to enhance capacity and capabilities to produce and run a robust clearinghouse. The contractor scope for the backbone components of the WWC included helping to set standards and review protocols, conducting reviews, synthesizing and reporting results. IES is now implementing its third 5-year contract to manage and run the WWC and has expanded to include additional contractors handling other related scopes of work.

2. Develop and implement a review process:

The WWC developed a systematic review process. This guide helped define the purpose, process, and results the WWC review strives to achieve. As several types of programs are included in the WWC, the review process allowed each to develop its own tailored protocol.

It is important to note that the bulk of the systematic evidence review process is focused on the quality, methodology, and rigor of the evaluation process - not necessarily the outcomes of the evaluations. Also, external contractors are responsible for the reviews and report writing so a detailed process was important to ensure consistency and continuity across rotating contracted staff. Studies are gathered through a comprehensive search of published and unpublished publicly available research literature

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using electronic databases, outreach efforts, and public submissions. Studies are also screened for eligibility against the criteria specified in the review protocol, and each eligible study is reviewed against WWC standards (see image below). The details of the review and its findings are summarized in a report, which may synthesize findings from multiple studies. Reports cover students from pre-kindergarten through postsecondary schooling and span a range of education topics, including academic achievement, behavior, and progress through school, as well as programs targeting specific populations, such as students with learning disabilities and English language learners.

Determinants of a WWC Rating

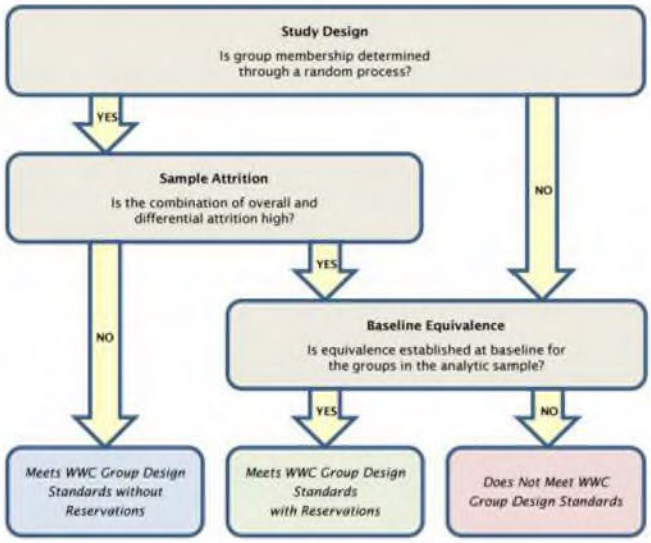


Image Source: ["Procedures and Standards Handbook Version 3.0", What Works Clearinghouse, March 2014.]

For further reading on the WWC review protocol, see "Raising the Bar." [Seftor, N., "Raising the Bar," Evaluation Review, 2016.]

The WWC currently produces four types of reports based on reviews of studies:

1. **Intervention reports** summarize the findings of the highest quality research that examines the effectiveness of a program, practice, or policy in education.
2. **Practice guides** contain practical recommendations that educators can use to address specific challenges in their classrooms and schools.
3. **Quick reviews** are brief, timely assessments of education research garnering notable mention in the press.
4. **Single study reviews** are evaluations of individual research studies of IES-funded studies and studies submitted in support of applications for grants (e.g., i3 and School Improvement Grants). The results of these reviews are made public but official reports aren't created for these.

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3. Review, Revise, Repeat

The protocols for evaluation reviews, including the definition of ratings, were collected into a handbook in 2008. It has since been revised three times to reflect changes in standard, revised procedures, and provide clarifications, taking into account lessons learned after running more than 10,000 studies through this protocol. As of December 2014, the WWC has conducted systematic reviews for 568 intervention reports [Seftor, N., personal correspondence with Policy Design Lab, January 13th, 2017.] To create these reports, the WWC processed 8,125 studies through its literature search [Seftor, N., "Raising the Bar," Evaluation Review, 2016.]

Insights from Implementation:

Neil Seftor, Deputy Director at the WWC and Senior Researcher with Mathematica, identified several challenges in implementing the program [Seftor, N., phone interview with Policy Design Lab, December 6th, 2016.]

Limited Supply for the Clearinghouse Market

One issue that the WWC encountered was the relative lack of available rigorous research program effectiveness in the education field. In the first few years of the WWC reviews, 23% of studies met the WWC criteria [Seftor, N., "Raising the Bar," Evaluation Review, 2016.] This number has steadily gone up as studies submitted are increasingly meeting the review criteria. According to the RCTs conducted by IES, 12% of evaluations showed projects produced positive impacts [Seftor, N., "Raising the Bar," Evaluation Review, 2016.] While this is in line with other sectors who rely on rigorous evaluation, for a clearinghouse hoping to promote and encourage adoption of effective programs, this number of effective interventions is disappointingly low.

Limited Awareness for Clearinghouse Products

The WWC is evolving and aims to provide resources for policy makers, practitioners, and funding organizations—from philanthropic to individual school districts. The WWC is still struggling to accomplish this objective. User information and the extent to which external groups use the WWC has been hard to identify. In the beginning, staff across the Department of Education were not that familiar with the WWC or its definitions and protocols [Seftor, N., phone interview with Policy Design Lab, December 6th, 2016] though with the implementation of tiered-evidence grantmaking this has changed and now the role of the WWC has expanded throughout agency programs. While traffic to the WWC website has increased, and usability has improved greatly with a recent redesign, it is not yet clear if users, such as external evaluators or private philanthropy, are fully leveraging the potential value of the knowledge base curated by the WWC.

For more information, contact the What Works Clearinghouse Help Desk: (866) 503-6114

Read more:

What Works Clearinghouse Website
What Works Clearinghouse Glossary of Terms
Results for America "What Works Marketplace" summary policy report
Results for America commissioned report on "What Works Marketplaces"
Report on IES randomized control study findings

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Learning Agenda - Deliverable 5: Challenges to deployment / approach limitations for implementing a Learning Agenda

Implementing a learning agenda across or within agencies can be challenging. Conversations and research regarding the implementation of learning agenda strategies revealed similar important lessons that can be useful to agencies seeking to implement these strategies themselves. Based on the experiences at the Corporation for National and Community Service, USAID, Department of Labor, and Department of Education's WWC, consider the following five ingredients for success:

- **Establish consistent evidence vocabulary, then teach it and use it**
- **Ensure sustained expert leadership to drive the charge**
- **Think strategically about creating culture change**
- **Embed evidence and evaluation within programs**
- **Generate cross-government or senior leadership support**

1) Establish consistent evidence vocabulary, then teach it and use it

The issue of evaluation vocabulary and translation is an ongoing challenge when implementing a strategic push towards evidence-based practice. It is important for agencies to define "evidence" and "evaluation." Based on the program focus or sector, there may be a different expectation for what is authoritatively understood as a high quality, valid evaluation. Or there may be a range of definitions: one reflecting a less rigorous understanding used by practitioners and one the more rigorous definition an agency is striving towards.

"Effectiveness" or "what works" is another definition that will need to be clarified. For example, "best practices" is often thrown about to mean effective ways of tackling a specific problem or challenge but rarely are the practices entitled "best" vetted by rigorous scientific evaluation. Similarly, the definition of "what works" may need to specify "for whom" an intervention works and "under what circumstances." These semantics will need to be carefully teased apart. As one practitioner cautioned, "if you come in saying 'I'm for evidence, and we want to only invest in evidence-based programs defined this way...you've essentially just told your agency colleagues that what they have been doing, sometimes for decades, is not good enough and not effective. Be thoughtful about your language so you don't end up burning bridges." [Healy, A., phone interview with Policy Design Lab, December 16th, 2016.]

2) Ensure that there is sustained expert leadership to drive the charge

In order to help explain and implement an evidence-based learning agenda across a department or agency, it is important to have expertise on hand who can help lead the charge and to position that expertise in a part of the organization that has a cross-cutting, agency-wide mandate. In some agencies, the first step was to establish a Chief Evaluation Officer. In others, it was to task an existing Director of Research and Evaluation to take on this role. The proper title and placement of such a person will vary depending on the agency but one thing seems unanimously voiced - the person must have the full support of leadership and be empowered to work alongside deputies and program directors to ensure a true adoption of evidence or data-based decision making occurs.

3) Think strategically about creating culture change

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Implementing culture change requires pressure (and cover) to ensure it happens. It can be a painful process to disrupt the status quo. The effort behind advancing the evidence-based policy agenda is akin to turning around a massive ship, according to Neil Seftor, project director for the What Works Clearinghouse; it will take time, energy, incentives, and a lot of manpower to achieve a complete change. [Seftor, N., phone interview with Policy Design Lab, December 6th, 2016.]

Think in the short and long term, advises Chris Spera, formerly at the Corporation for National and Community Service (CNCS). [Spera, C., phone interview with Policy Design Lab, November 30th, 2016.] The evaluation team at CNCS thus planned out projects or initiatives that could achieve early wins - along a six month, 1 year and 2 year calendar. "Most of our evaluations are on a 3 to 5 year study period. You can't ask colleagues to wait that long to see your value. Our early wins helped keep momentum going." [Spera, C., phone interview with Policy Design Lab, November 30th, 2016.]

"You have to understand where different staff are coming from and use different types of engagement techniques," advises Anne Healy, who leads Development Innovation Ventures at USAID. [Healy, A., phone interview with Policy Design Lab, December 16th, 2016.] "Some people will respond to the scientific appeal of evidence-based decision making. Others might be responsive if they see their leaders being responsive. Others may focus may focus more on relationships and be open to discussion only after multiple conversations where you listen to what they do and what their concerns and needs are and then show how evidence and evaluation can help address these. You have to use multiple forms of influence for this to really be embraced as a cultural shift," she adds. [Healy, A., phone interview with Policy Design Lab, December 16th, 2016.]

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4) Embed evidence and evaluation within programs

Traditionally, evaluation and research shops have worked fairly siloed from programmatic shops. This can be a strength when ensuring independence of the program evaluation offices and staff, but it can be a deterrent for diffusing an evidence-based learning agenda approach across an agency. Both CNCS and DOL highlight a successful effort to build relationships between the evaluation or research office and the program offices, and both noted the importance of outreach and relationship building between the two staff to achieve this.

At CNCS, the Director of Research and Evaluation tasked his staff to work with program staff to collaboratively plan their own assessment agendas. The teams were already working collaboratively on grant decisions because of newly added agency evidence policies. Getting evaluators into team meetings to ask *"What do you want to know? What would be helpful in meeting your own performance goals?"* helped illustrate how the work was valuable to the program officers in the weekly monitoring of their portfolios. It helped demonstrate that this was not an "add on" to an already large "to do list," but a way of helping re-prioritize and organize the support they provided to their grantees [Spera, C., phone interview with Policy Design Lab, November 30th, 2016.]

5) Generate cross-government or senior leadership support

Practitioners observed that cross-agency or even cross-department learning was a challenge, but the evidence-based policy agenda benefits from centralized support and coordination. For instance, if there is a call for a single coordinated set of definitions of what "strong" evidence means or what constitutes "high" versus "low" evidence ratings, empowering a facilitator with decision-making authority can coordinate and generate consensus.

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Agencies may have a hard time reaching cross-agency consensus, as each may prefer authority to make their own decisions on definitions and policy language, and each have their own programmatic goals and objectives. However, "There needs to be a high-level, neutral entity working to identify who should be at the table, convening the table, and driving discussions," advises Neil Seftor: "Otherwise this work just won't get done...it won't be prioritized." [Seftor, N., phone interview with Policy Design Lab, December 6th, 2016.]

Learning Agenda - Deliverable 6: How-To: Steps for deploying, practices for adapting

Agencies or programs should assess where they are in terms of creating and implementing a learning agenda. Their approach for next steps will depend on if they fall towards the beginning, middle or end of the evidence-based practice continuum.

At the outset:
If you are just beginning to implement evidence-based policy, consider the tactics undertaken by DOL and CNCS:

- Start by asking what questions do you have about your program or topic area that would be helpful to answer.
    - Conduct conversations and/or create a survey that can be used by program and leadership staff to ascertain key questions about a program's performance. Add any program questions you may have received from OMB examiners or congressional staff.
- Review the questions and determine the best method for answering these questions. This should include:
    - What is the appropriate and more rigorous evaluation design or method to answer this question?
    - What data do you need to answer the question?
    - What is your timetable for answering the questions?
    - Who is best situated to provide the data you need (i.e. grantees, beneficiaries, evaluators, program staff, etc.)
- Create strategies for data collection and reporting.
    - Develop new or refine existing performance reporting to collect identified data points
    - Develop and implement a program evaluation
    - Manipulate existing data sets to produce useful reports that can be used for decision making
- Distribute and review results, and ensure they are used.
    - Provide reports or briefings that are easily used by the targeted audience (e.g. technical reports may be appropriate for an evaluation office, summary reports with infographics or other visuals may be appropriate for program staff or grantees)
    - Provide technical assistance to ensure audiences can interpret and act on the data provided
    - Model effective and transparent use of data and evaluation – communicate how programs or policies are proactively changing in response to reports

Experienced Practitioners:
For programs that are already employing evidence-based programs, consider how you can enhance the rigor of evaluations and expand use of evaluation results. For example, if a program has been implemented for a few years with positive performance data, consider engaging an external evaluator to

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conduct and impact evaluation. Promote lessons learned from all evaluations to both internal and external audiences, modeling an emphasis on learning and improvement.

Shared Considerations across the evidence-based policy continuum
These considerations will apply to all programs, regardless of whether they are just starting or building on existing efforts.

1) Staffing and Capacity

Assess the agency's evaluation needs and most appropriate methodologies for meeting these needs. Then assess the existing evaluation capacity and expertise. It may be that there is a mismatch of needs and capacity. If this is the case, explore various means of recruiting the expertise or talent needed. This can be through traditional new hires, details from other departments or agencies, or using technical assistance contracts. The staffing path will depend on a given agency's staffing and contracting budget.

2) Assess access to funding

Review budget authority and regulations to determine if it is possible to use existing funding to support evaluations. Several agencies have either budget or statutory authority to set aside a percentage of funding for the purpose of evaluation. [Ayers, J., personal communication with Policy Design Lab, January 13th, 2017.] If there is a history of this set-aside not being used, explore why and if there is a way to take advantage of it going forward. This is likely to be a delicate conversation as program staff may be defensive of any dollars being diverted from programming.

Examples of Departmental set asides include:

1. Department of Labor's universal set-aside for the CEO office (.75% of almost all programs);
2. Department of Education's set-aside of .5% of all ESEA (K-12) programs; and
3. Administration for Children and Families' set-aside of .5% of Child Care and Development Block Grant funds.) [Ayers, J., personal communication with Policy Design Lab, January 13th, 2017

3) Plan out short and long term milestones

Work with program staff to identify meaningful intermediate outcomes or learnings and embed these into strategic plans with "early wins" identified. This could include short term milestones with interim program outcomes and long term milestones that look at overall effectiveness or outcomes that require longer time periods to capture and measure.

4) Plan and implement strategies for building support

As you begin implementation, brainstorm several approaches for building internal support and adoption of evidence-based practice. Successful programs used both leadership directives (top-down) and relationship building and educational efforts (bottom-up) to gain traction. Have "hearts and minds" approaches ready that can demonstrate the value of evidence-based policies to your agency's beneficiaries, program staff, leadership, and oversight entities.

Learning Agenda - Deliverable 9: Future directions ("next practices as opposed to best practices")

One of the key concerns regarding the promotion of evidence-based policy is the current lack of a robust evaluation library. A key contributing factor to this has historically been cost and access to data needed for rigorous evaluations. The Commission on Evidence-Based Policymaking (CEP) was established by the

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bipartisan Evidence-Based Policymaking Commission Act of 2016. This commission is focused on expanding access to data needed to conduct rigorous evaluations. The members are exploring several key issues related to the use of survey and administrative data, with recommendations expected to be issued in Fall 2017:

- Existing barriers to accessing and using data government already collects
- Strategies for better integrating existing data with appropriate infrastructure and security, to support policy research and evaluation
- Practices for monitoring and assessing outcomes of government programs
- Whether a data clearinghouse could enhance program evaluation and research opportunities

Read more about the Commission on Evidence-Based Policymaking.

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Learning Agenda - Deliverable 8: Examples of policy that have enabled or encouraged approach (legislation, exec order)

Legislation:
H.R. 1831 - Evidence-Based Policymaking Commission Act of 2016

Policy Guidance:
"Increased Emphasis on Program Evaluations." OMB M-10-01. Oct 7 2009.
"Next Steps in the Evidence and Innovation Agenda." OMB M-13-17. Jul 26 2013.
"Analytical Perspectives: Budget of the United States Government, Fiscal Year 2017." c. 7. Office of Management and Budget. 2016.

See also:
Policy Brief on State and Federal Evidence-Based Legislation (Pew/MacArthur Results First Initiative, 2015)

Learning Agenda - Deliverable 7: Online inventory of resources

Communities of Practice:
The Science of Science Policy Interagency Working Group (IWG) was established in 2006 by the National Science and Technology Council. In 2008, the IWG published a roadmap that outlined recommendations to advance evidence-based science and innovation policy. The IWG continues as an informal community of interest, led by the National Science Foundation, and is focused on ways to improve administrative data on research awards across Government and the non-Federal evaluation community.
For more information on the Science of Science Policy IWG, contact Maryann Feldman, NSF, mfeldman@nsf.org

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Resources

- Results for America,
- Arnold Foundation's Evidence-Based Policy Innovation Initiative
- Archive for Coalition for Evidence-Based Policy (now based at Arnold Foundation)
- Evidence-Based Policymaking Collaborative

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Books

- Nussle, J., and Orszag, P., "Moneyball For Government," Disruption Books, 2015.
- Haskins, R. and Margolis, G., "Show Me the Evidence," Brookings Institution Press, 2014.

Multimedia content:
Gov Innovator Podcast: Conversations on evidence-based policy from public sector innovators and experts, hosted by Andy Feldman, a Visiting Fellow at the Brookings Institution and former Special Advisor for Evidence-Based Policy at OMB:

- Important tools for evidence-based decision making: Margery Turner, Urban Institute
- How one Federal agency, the Corporation for National and Community Service (CNCS), strengthened the role of evidence in a key grant program, AmeriCorps: Diana Epstein and Carla Ganiel, CNCS
- Insights for evidence-based grant making from the Teen Pregnancy Prevention Program: Evelyn Kappeler, U.S. Department of Health and Human Services
- The Federal evidence agenda and lessons for state and local leaders: Ron Haskins, Brookings Institution
- Becoming an evidence focused grant-making organization: Kelly Fitzsimmons, Edna McConnell Clark Foundation
- Building an evidence base for agency programs: Chris Spera, Corporation for National and Community Service
- Harnessing Silicon Valley funding approaches to drive breakthrough solutions in the public sector: Jeffrey Brown, U.S. Agency for International Development (USAID)
- Strengthening evidence-based grant making at the U.S. Department of Education: Jim Shelton, Deputy Secretary of Education

Watch:

- "How to create a culture of evidence in your community/organization"
- "Identifying and Contributing to "What Works,"
- "Evaluation and Evidence-Based Decision-Making"
- "Innovative Funding Models to Advance "What Works"

Additional specific resources:
Related topics, including evidenced-based policy, program evaluation, and research design:

- Five Steps to Building an Evidence-Based Culture in Government
- Child Trends Brief on Performance Management
- U.S. Department of Education: Guide for recognizing and conducting opportunistic experiments:
- Key Items to Get Right When Conducting a Randomized Controlled Trials of Social Programs
- Using Evidence-Based Approaches to Improve Program Performance
- **Rigorous Program Evaluations on a Budget: How Low-Cost Randomized Controlled Trials Are Possible in Many Areas of Social Policy**
- Social Innovation Fund Evaluability Assessment Tool

Additional articles and references
Keegan, M., "Invest in What Works: A Conversation with John Bridgeland and Bruce Reed," IBM Center for the Business of Government, April 22nd, 2016.

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Bornstein, D., "The Dawn of the Evidence-Based Budget," New York Times, May 30th, 2012.

"Evidence-Based Policymaking: A Guide for Effective Government." Pew-MacArthur Results First Initiative, November 13, 2014.

Pay for Success: Public and Private Partnerships to Drive Evidence-Based Investment

Pull quote:
"Pay for Success is an innovative way of partnering with philanthropic and private sector investors to create incentives for service providers to deliver better outcomes at lower cost—producing the highest return on taxpayer investments. The concept is simple: pay providers after they have demonstrated success, not based on the promise of success, as is done now."
["Paying for Success: Federal Budget Fiscal Year 2012," Office of Management and Budget, 2012.]

PFS - Deliverable 1: Elevator pitch summary

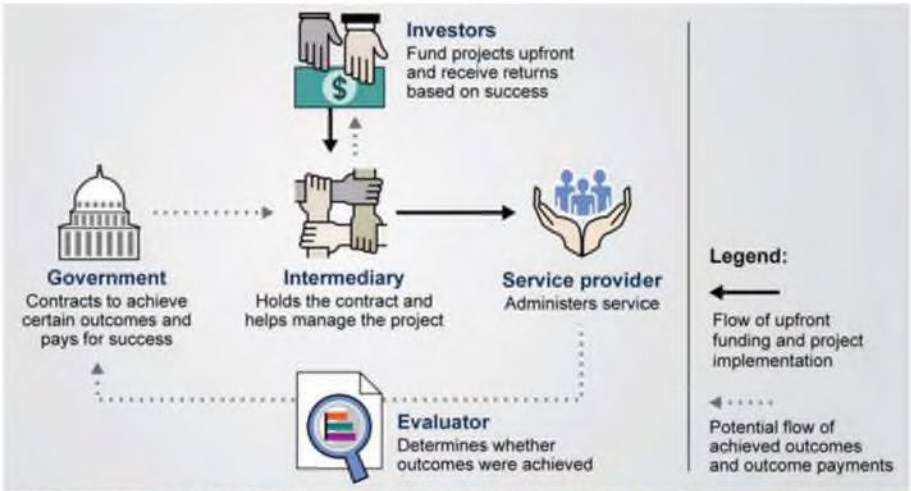
Pay For Success is a means of promoting evidence-based programs at the local, state, and Federal level to achieve outcomes and pay for them in a more cost-effective way. It may be understood as a new type of financing model, a new form of outcomes-focused contract, or a new approach to public-private partnership.

"Pay for Success refers to a performance-based contract between government agencies and service providers, with the government paying only if the provider generates results," notes Results for America, a nonpartisan advocate of the approach. ["Invest in What Works: Pay for Success Factsheet," Results for America, August 18th, 2015.] "Under a Pay for Success (PFS) deal, also known as Pay-for-Performance or Social Impact Bonds, a government agency enters into a contract with an intermediary organization to achieve specific outcomes that will produce government savings. The contract specifies how results will be measured and the level of outcomes that must be achieved for government to make payments. The intermediary selects one or more service providers to deliver a proven or promising intervention expected to produce the desired outcomes. Funding for service delivery comes from outside investors, often secured by the intermediary. If the desired outcomes are achieved, then government pays the intermediary, which in turn pays investors." ["Invest in What Works: Pay for Success Factsheet," Results for America, August 18th, 2015.]

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While simple in concept, the contracting and financing involved is complicated. GAO developed the following infographic to help illustrate partners and funding flow in the pay for success model. To date, at least six different agencies are implementing some form of Pay for Success project.

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["Pay for success: Collaboration among Federal Agencies Would be Helpful as Governments Explore New Financing Mechanisms," US Government Accountability Office, September 9th, 2015.]

PFS - Deliverable 2: Summary of underlying rationales / empirical research

In the context of restricted Federal spending and intractable social needs, Federal officials along with philanthropists and impact investors have been exploring Pay for Success models as a potential solution. Pay for Success programs are outcomes- and evidence-based investments. They allow an agency to invest specifically in an issue area where they hope to move the needle by achieving positive outcomes and then scaling interventions that have demonstrated impact. [Fogel, A., phone interview with Policy Design Lab, December 12th, 2016.]

Pay for Success contracts transfer risk, as the government payor only pays proportionally for the level of outcomes achieved. If the service provider is not able to achieve these outcomes, the outside investors are on the hook for program costs incurred, notes Anna Fogel, director at Social Finance and previous program manager for SIF's Pay for Success. [Fogel, A., phone interview with Policy Design Lab, December 12th, 2016.]

Finally, the structured nature of Pay for Success arrangements create an avenue for investing in multi-year collaborations. Pay for Success contracts are inherently several years long to allow time for recruitment of participants, implementation of the service intervention, and evaluation to measure and validate the outcomes. Interventions are rarely shorter than one year. For this reason, agencies interested in participating in long-term collaborations may find Pay for Success attractive, as the financing mechanism creates a pathway for investing beyond a given budget year, administration term, or election cycle without interrupting commitments to partners.

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PFS - Deliverable 3: Profiles of major cats of candidate users - examples of when to deploy

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Pay for Success literature and advocates frequently make the same cautionary statement: Pay for Success is not appropriate for all contexts. [] Not all challenges will fit with the measurement and evaluation requirements for this model of outcomes-based contracting. Additionally, the partnerships required take time to develop and must all be met to ensure success - at the government level, the financier level, the service-provider level, and the evaluation level. [crosslink V5 – collective impact]

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Common programmatic elements from agencies implementing some form of Pay for Success include:

- Budgetary authority or flexibility to attempt these
- Access to expertise via Technical Assistance contracts or internal staffing
- Agency focus on an issue that lends itself well to Pay for Success
    - It's defined and measurable - both in terms of outcomes and specific costs.
    - There are interventions with evidence of effectiveness existing that achieve the desired outcomes.

As of January 2017, fifteen PFS programs have launched. Only a handful of transactions have come to fruition, with mixed results in terms of achieving the outcomes specified by contract. From an operational standpoint, these deals worked as intended; they established a contract to finance and support the implementation of an evidence-based intervention, evaluated the outcomes of this intervention, and used outcomes to learn more about its effectiveness and further scaling.

There has been significant Federal support for the piloting of Pay for Success projects, which has been matched by support and interest from private philanthropies and city and state governments as well. Federal programs have granted funds that have been used to provide technical assistance to PFS participants – existing and future. Federal funds have also been used to pay for feasibility studies, evaluations, and to support transactional costs. More recently, several Federal programs have also contracted for outcomes as well including Pay for Success initiatives at Department of Labor, a collaborative project between Veterans Affairs and the CNCS, and a partnership between HUD and DOJ:

Federal Pay for Success Funding Activities

Social Innovation Fund (SIF): Program of the Corporation for National and Community Service that has used tiered-evidence approach to award more than $240 million in funding for program expansion and evaluation in communities across the country since 2010; 2014 and 2015 appropriations included up to $21.7 million to support development of PFS projects.

Education: Investing in Innovation Fund (i3) supports expansion of in programs with demonstrated impact in improving secondary and post-secondary achievement; both the House of Representatives and Senate approved the inclusion of PFS initiatives as an allowable use of state and local funds in various titles of their respective versions of the Every Student Succeeds Act of 2015.

Housing and Urban Development: In 2015 HUD issued a Request for Proposal, using funding from the Department of Justice, for PFS projects that use supportive housing to improve outcomes for formerly incarcerated individuals upon reentry.

Workforce Development: The Workforce Innovation Fund provides grant funds to projects with evidence-based approaches, including two early PFS projects; the 2014 Workforce Innovation and Opportunity Act (WIOA) authorizes states and local workforce investment boards to invest up to 10 percent of funds in PFS projects.

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[Directly sourced from "Pay for Success Learning Hub," Nonprofit Finance Fund, 2016.]

PFS - Deliverable 4: One or more "success stories" or learning narratives to underscore impact

PFS Transaction Case Focus: Utah High Quality Preschool Program

The Utah High Quality Preschool Program was launched and had its first successful payout in 2013. This PFS initiative was built on a pilot study that showed 33 percent of low-income students in Utah would likely need special education services during their primary school years (UWSL, 2013). The project hypothesized that if at-risk students participated in preschool programs, the number of students requiring special education would decrease, creating a cost savings to the government by decreasing costs associated with providing special education services.

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["Pay for Success: We're seeing BIG Progress!," United Way of Salt Lake, 2016.]

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The key partners for this Pay for Success deal include:

- Intermediary: United Way of Salt Lake serves as the intermediary for this project, responsible for the overall implementation of the project and for managing repayments to the lenders. Utah has established a separate Performance Account Manager, under the auspices of the Park City Community Foundation, responsible for holding the repayment funds in a performance account and then distributing repayments as appropriate.
- Service Providers: The Granite School District, Park City School District, Guadalupe School, YMCA of Northern Utah, Children's Express, and Lit'l Scholars are providing the program services to low-income three- and four year-olds.
- Project Coordinator: Voices for Utah Children, a nonprofit child advocacy group, is providing research and analytic support.
- Funders/investors: Goldman Sachs and the J.B. and M.K. Pritzker Family Foundation are the primary investors for the initiative, providing loans of $4.6 million and $2.4 million respectively.
- Evaluator: Utah State University's Early Intervention Research Institute is the third-party evaluator.

How is Success Defined?

Success is defined in terms of a child's use or non-use of special education or remedial services each year between kindergarten and grade 6 (K-6); each year that a student does not use a special education or remedial service will generate a PFS payment.

Did It Work?

A review from an independent evaluator showed that, of the 110 students who were identified as at-risk, only one used special education services in kindergarten. Investors received a payment equal to 95 percent of the State savings for avoided special education services. The 110 students will continue to be monitored through 6th grade, generating further success payments based on the number who avoid use of special education in each year.

Read more:

Stanford Social Innovation Review article on the project's success

PFS -Deliverable 5: Challenges to deployment / approach limitations

Challenges to Pay for Success deployment include:

- Complexity of implementation
- Capacity and expertise constraints
- Limited pipeline of candidates
- Problem of addressing the "Wrong Pockets"

1) Complexity of implementation

One of the critiques of Pay for Success is that it is a complicated approach to implement. It is asking government funding streams to flex in a way they haven't before. To actually participate as a funder, Federal programs would have to change existing procurement procedures to contract for outcomes, enter into contracts with multiple parties, be able to obligate funds for expenditure 2 to 5 years later, and support specific service-providing programs that are evidence-backed and subject to rigorous vetting as opposed to programs selected via formula or traditional competitive means. To be successful,

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staff from counsel's offices, procurement, budget, finance, policy, evaluation and program offices all must work together. This, in itself, is a new way of doing business for many agencies and programs.

But, as Anna Fogel at Social Finance observed, in addition to these challenges, significant time is often needed to negotiate the components of the Pay for Success deal. [Fogel, A., phone interview with Policy Design Lab, December 12th, 2016.] Solid cost-benefit analysis generally supports the named outcomes and values and all parties (payors, funders, and program implementers) must agree to these. Once agreed to, intermediaries must work closely with the government entity to ensure it can enter into the contract – addressing any policy or procedural barriers and making sure that key representatives can and will sign off on the outcomes and negotiated prices. [Fogel, A., phone interview with Policy Design Lab, December 12th, 2016.]

2) Capacity and expertise constraints
Given the complicated nature of PFS transactions, and its divergence from the typical Federal way of doing things, it should not be surprising that another challenge posed by PFS is ensuring the necessary expertise within government agencies. Valuation and deal transactions are skill sets more likely found on Wall Street, not within an agency's traditional civil service pool. Additionally, evaluation expertise and the ability to synthesize and integrate data and evaluation findings is not typical for program or contracting staff to have. To staff PFS programs, agencies have been hiring from the small pool of PFS insiders – people who have had experience working for intermediaries, city or state governments participating in PFS, or academic and private sector shops who are supporting PFS through research and evaluation. The specific nature of these new hires expertise make them valuable but also increases the importance of retaining them and ensuring a sustainability plan is in place to keep PFS programs running should they leave service.

3) Limited pipeline of candidates
The pipeline of evidence-based programs that document positive, measurable outcomes is limited. This has been identified as an issue facing evidence-based policy measures across the board but it is particularly important in the PFS field. In order to convince investors that their bet is a good one, service-programs need to not only be able to demonstrate that they likely will achieve the outcomes promised but also be able to put a dollar figure on these outcomes. There are very few social dilemmas facing our nation to date that lend themselves readily to this type of cost-benefit analysis – that have interventions that have been both well-tested and whose preventative outcomes have cost-savings easily attributed.

4) **Problem of addressing the "Wrong Pockets"**
Since initial Pay for Success discussions began among Federal agencies in 2011, one frequent challenge has been a disconnect between investment and outcomes from an agency perspective. An agency may identify evidence-based interventions they want to invest in, but they may not reap financial savings should the outcomes be achieved. For example, supportive house programs that address chronic homelessness have been shown to improve health outcomes and decrease medical costs, particularly emergency room costs for the treated population, particularly when offered to the most vulnerable homeless populations. While supportive housing programs are typically implemented by the Department of Housing and Urban Development, and municipal public housing authority, or Veterans Services, the cost savings are experienced by Medicaid, Medicare, or other health service-providers and funders. Because of the way agency programs are appropriated, crossing budgetary lines to structure a PFS deal can be a deal breaker. Ways to address this scenario is now being tested through a joint DOJ

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and HUD PFS pilot program. [Roman, J., "Solving the Wrong Pockets Problem," Urban Institute, September 2015.]

PFS - Deliverable 6: How-To: Steps for deploying, practices for adapting

Several Pay for Success toolkits have been developed in coordination with government Pay for Success programs and independently by private actors. A survey of these toolkits suggests programs interested in pursuing PFS projects should evaluate the following components of their potential program:

1) A clearly defined social problem that is going to be addressed
2) Existing evidence-based solution for the identified problem
3) Capacity assessment of both providers and the intermediary project manager
4) Strength of public will from public partners
5) Evaluability of the program
6) Level of private or philanthropic funder interest
7) Appropriateness of fit for the problem, solution, partners, and population to be served in a given jurisdiction

McKinsey and Company and the Nonprofit Finance Fund offer additional questionnaires to further assess readiness for many of these components. These include:

Intervention The evidence-based program model undertaken in order to achieve a desired social outcome. For example, Permanent Supportive Housing is an intervention that addresses homelessness.	Can the impact delivered by this intervention be clearly measured? Does the intervention have a long track record of results? Does the intervention focus on prevention?
Service Provider Service providers deliver the intervention to an identified constituent population, scale up the intervention over a multiyear period, and drive outcomes.	Does the service provider have significant experience with program beneficiaries? Can the organization effectively collect and analyze data? Do they have the capacity to scale operations?
Intermediary The intermediary identifies evidence-based program solutions, raises the money to bring them to scale, conducts ongoing project management, and works with service providers to ensure effective implementation.	Has the organization demonstrated an ability to manage to outcomes? Does the organization have a demonstrated track record in raising capital for new ventures?
Government State, local, or federal governments agree to repay investors - via the intermediary - for positive social outcomes if performance targets are met.	Is there a demonstrated commitment to paying for results? Are there mechanisms in place to ensure repayment to the investors over the multiyear life of a transaction?
Investor Impact investors who want to generate social and financial returns that provide funding to deliver preventive programs. They will be repaid only if the intervention achieves the pre-determined performance targets.	Do the investors prioritize social returns as well as financial returns? Are investors interested in public-private partnerships? Do the investors have a high tolerance for risk?
Independent Assessor An independent assessor reviews the constituent treatment group relative to a counterfactual and reports on whether the target outcomes have been achieved.	Does the organization have demonstrated knowledge and experience with multiple assessment methods? Does the organization have demonstrated experience with evaluating performance-based government contracts?
Evaluation Advisor The evaluation adviser is involved in determining the evaluation approach, defining performance outcomes, monitoring progress, and suggesting course corrections if needed.	Does the organization have a demonstrated track record in coaching partner organizations to more effectively achieve impact? Can the organization translate data into actionable insights?

Source: ["Pay for Success Learning Hub," Nonprofit Finance Fund, 2016.]

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Additional PFS Primers and Toolkits include:

- Urban Institute Pay for Success Project Assessment Tool
- Urban Institute Pay for Success Initiative – Pay for Success 101
- CNCS SIF Pay for Success Resources (includes a Pay for Success primer and reports)
- Pay for Success Learning Hub Practitioner Toolkit
- Green and Healthy Homes Pay for Success Resource Page

See also the Social Finance Pay for Success readiness assessment. The assessment tool is organized by six of the major components of a strong PFS project:

- **Problem definition:** How clearly defined and understood is the problem?
- **Program strength**: How strong is the proposed solution to address the problem?
- **Provider capacity:** How strong (capacity and effectiveness) is the service provider that could deliver the program?
- **Public system partners and political landscape:** How strong is the political and bureaucratic support from the public partner (i.e. government) for the proposed project and financing structure?
- **Project alignment:** How well do the all the key components of the proposed project fit together in a specific jurisdiction?
- **Project evaluability**: To what extent does the proposed project have a clear, rigorous, and feasible evaluation plan?

PFS - Deliverable 8: Examples of policy that have enabled or encouraged approach

Legislation:

PFS authority granted to DOL and CNCS to run PFS programs in 2012 and 2014 respectively. Authority was granted in the WIOA and ESSA to pilot Pay for Success programs at DOL and DOE respectively.

2014 Workforce Innovation and Opportunity Act (WIOA)

Social Impact Partnerships to Pay for Results Act (H.R. 1336/H.R. 5170) passed the House in 2016; the Senate version (S. 1089) failed. There are plans to reintroduce the legislation in 2017.

Relevant summaries of recent legislation and policy guidance:

America Forward: State of Play on Pay for Success Policy – an update on Pay for Success legislation and activity

Authorizing Pay for Success Projects A Legislative Review and Model Pay for Success Legislation

PFS - Deliverable 9: Future directions

The Pay for Success field is still relatively young, with only a few structured deals currently in place but a robust pipeline of potential deals in development. The pipeline development work has been funded by Federal programs under the auspices of feasibility studies, technical assistance, deal support, and evaluation. Nonetheless, there has been notable public and private interest in the use of Pay for

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Commented [CH15]: Can you do me the hugest of favors? Click each of these links. Break each out separately with the title of the law (like WIOA below). Maybe use redundant sentence annotation: "This legislaton granted PFS authority to the Department of Labor. / This legislation authorized Pay fo Success Pilot programs at the Department ot Educaton" (spell out departments – most people see DOE and think Energy)

Success as a means of financing outcomes-based contracts that are rooted in evidence. In November 2015, the White House launched a Pay for Success Interagency Learning Network to deepen and widen knowledge about how PFS can test innovative ideas, scale what's working, and drive better outcomes. The Network builds on Federal work to date and responds to growing interest among states and communities. The FY2016 and FY2017 budget both called for increased spending for Pay for Success initiatives. Pay for Success has wide-ranging, bipartisan support as well as private supporters, raning from the American Enterprise Institute to large foundations like the Kresge Foundation to large investors like Goldman Sachs and Bank of America.

PFS -Deliverable 7: Online inventory of resources

For more information on the Pay for Success Interagency Learning Network, contact:
John Tambornino, Senior Advisor, Evidence Team – OMB, jtambornino@omb.eop.gov

Further Reading

Pay for Success Learning Hub is a comprehensive source of information on Pay for Success. It's run by the Nonprofit Finance Fund, which is supported with some Federal funding through CNCS's SIF grants.

- PFS White Paper

Federal resources:
Improving Outcomes Through Pay for Success FY 2016)
Improving Outcomes Through Pay for Success (FY 2017)
OMB Fact Sheet: Pay for Success

Improving Outcomes through Pay for Success – FY 2016 Fact Sheet – a summary of Pay for Success initiatives included in the 2016 Budget
Results for America: Invest in What Works - Pay for Success brief – a summary of Federal investments and budget requests for PFS programs.

Additional Pay for Success Resources:
Rockefeller Foundation's Social Impact Bond website
CNCS SIF Pay for Success Program Resources
CNCS SIF Pay for Success Briefs
CNCS SIF Pay for Success Primer
1st Generation Pay for Success Report

Articles:
Stanford Social Innovation Review article on PFS pros and cons
A 2015 GAO report

Commented [CH16]: format as articles

Annex of interviews
Anna Fogel, Director, Social Finance, Inc.
Anne Healy, Chief, Development Innovation Ventures (DIV) and Discover & Test Division at USAID
Parita Patel, Sr. Strategy and Innovation Officer, SIF, CNCS

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Neil Seftor, Senior Economist, Mathematica Policy Research
Chris Spera, Division VP, Abt Associates

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Vertical 5. Aligned Public and Private Sector Actions/

External Multi-Stakeholder Collaboration

Deliverables:

1. **An "elevator pitch," which provides highlights of the content, such as why the approach is important, how it works, and examples of where it has worked**
2. **A short, digestible summary of underlying premises and rationales, supported by research (i.e., not a report)**
3. **Profiles of major categories of candidate users, including specific examples of when, and under what circumstances, the approach may be employed, supported by research into the target audience and their needs**
4. **One or more "success stories" or other learning narratives that highlight the impact of and justification for using this approach.**
5. **Documentation of challenges to deployment, and potential limitations of the approach, including barriers or obstacles encountered within agencies employing the approach**
6. **A "How-To" document, detailing key steps for deploying the approach, including promising practices in adaptation and deployment**
7. **An online inventory of resources**
8. **Examples of policy (e.g. legislation, Executive Order, etc.) that have enabled or encouraged the approach**
9. **Future directions (next practices as opposed to best practices)**

Pull quotes

"Those who have been elected have a powerful, but little-used tool at their disposal: The power to convene. This is not a currency to be spent frivolously. You have to be judicious." Roger Moe, former president of the Minnesota state senate [Carlson, C. and Wolf, G., "The Power to Convene", The Council of State Governments, November/December 2005].

"I have a hypothesis that most, if not all, major challenges that we face for our country or for our planet are ones that require multi-sector action, both government, non-profit sector, and the private sector." Talia Milgrom-Elcott, Executive Director and Co-Founder, 100Kin10 [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.]

"For effective change in a complex system, you need to find ways to constructively involve everyone who is impacted. This is because in a complex environment if you are impacted, you exert influence." Seth Kahan [Kahan, S., The Power to Convene and Set Context, Fast Company, October 2008].

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Deliverable 1: Elevator pitch summary

> "The power to convene and the power of setting the right context are value generators. Together they are often far more powerful than the influence one person can exert. The robustness of multiple points-of-view is generally greater than what an individual can wield. And the field of impact grows much larger through the resulting expansion of the social network. For dealing with the most complex problems, we must involve stakeholders from every critical point in the system. Solutions, the good ones, are multi-dimensional. Therefore, we must bring together the most valuable players, helping them to work collaboratively – i.e., lend their enthusiastic engagement – using a framework that embraces their differing needs and unique perspectives. This is what the power to convene and the power of setting the context is all about." Seth Kahan [Kahan, S., The Power to Convene and Set Context, Fast Company, October 2008]

Intro

Aligning public and private sector commitments is a specific iteration of collaboration between the Federal government and outside entities. While not rising to the level of formal partnership, commitment-generating devices like convenings and calls to action can spur an "all hands on deck" approach to catalyzing societal advancements. In particular, the Administration has a unique vantage point and the potent ability to act as an "impatient convener" [Chopra, A., *Innovative State,* Grove/Atlantic, Inc, 2016, p. 88]. A convening can be defined as leaders engaging with all sectors – public, private, non-profit, citizens, and others- to develop effective, lasting solutions to public problems that go beyond what any sector could achieve on its own. ["Public Solutions," Policy Consensus Initiative] By convening interested parties and innovative thinkers, it's possible to launch high-impact multi-sector stakeholder collaborations involving companies, foundations, nonprofits, investors, researchers, regional initiatives, and skilled volunteers. Collective impact principles are often employed by conveners to bring various stakeholders from multiple perspectives together at these gatherings, to broker partnerships, solicit pledges, and support a central call to action for which they have all been called together.

Why

Aligning public and private sector commitments is an innovative tool for spurring collective, transformational change. The Federal government is uniquely positioned to summon multiple stakeholders, and put out clarion calls to action on issues at inflection points for change, adoption, or scale in the country, elevate an issue's national profile from talk to action. Through high-level engagement, public officials can align executive action with specific commitments offered up by the private sector. As former US CTO Aneesh Chopra sees it, it's an approach that leads "through coordination and collaboration, rather than fiat." [Chopra, A., *Innovative State,* Grove/Atlantic, Inc, 2016, p. 134]. Moreover, the Federal government has already used convening tools like calls to action and pledges to catalyze societal advancements and target specific issues like insourcing American jobs and solving the global refugee crisis.

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How

In this approach, the White House uses its platform to call for action and elevate the visibility of external efforts that are aligned with the Administration's goals and interests – but there is no formal partnership mechanism. Instead, external organizations respond to the president's call-to-action, organically building their own coalitions to make financial and in-kind commitments that are aligned with achieving the president's goal. This has been successfully demonstrated by initiatives like BRAIN and 100Kin10. Convenings can be used to bring together stakeholders, and encourage them to cooperate in deliberate acts of transformation. Convenings allow for agenda-setting and open conversation about the desired goal and objectives, among all participants. They create a space for open and transparent discussion and can build trust by creating a common understanding of goals and objectives all participants agree to work towards. External issue-focused organizations often also play an essential role in providing support for the implementation of commitments, complementing the role that the White House and agencies are able to play as convener.

Five Conditions of Collective Impact [Collective Impact Forum, "Collective Impact Principles of Practice", FSG and the Aspen Institute].

- ***Common Agenda***: All participants have a shared vision for change that includes a common understanding of the problem and a joint approach to solving the problem through agreed-upon actions.
- ***Shared Measurement***: Agreement on the ways success will be measured and reported, with a short list of common indicators identified and used across all participating organizations for learning and improvement.
- ***Mutually Reinforcing Activities***: Engagement of a diverse set of stakeholders, typically across sectors, coordinating a set of differentiated activities through a mutually reinforcing plan of action.



- ***Continuous Communication***: Frequent and structured open communication across the many players to build trust, assure mutual objectives, and create common motivation.

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- ***Backbone Support***: Ongoing support by independent, funded staff dedicated to the initiative, including guiding the initiative's vision and strategy, supporting aligned activities, establishing shared measurement practices, building public will, advancing policy, and mobilizing funding. Backbone staff can all sit within a single organization, or they can have different roles housed in multiple organizations.

Deliverable 2: Summary of underlying rationales / empirical research

The credibility to elicit commitment and convene for meaningful collaboration is powerful, and "by virtue of their office, elected leaders have the power to convene people from a variety of sectors to work on public problems." ["Role of the Convener," Policy Consensus Initiative]The White House can use its platform to call for action and elevate the visibility of external efforts that are aligned with the Administration's goals and interests. In such cases, there is no formal partnership but external organizations respond to the president's call-to-action, organically building their own coalitions to make financial and in-kind commitments that are aligned with national priorities.

Benefits of Using Convening Power:

- Multidisciplinary approaches can be deeply valuable for tackling our thorniest problems
- Unexpected coalitions can generate innovative solutions
- High-visibility commitment can spur public engagement and jumpstart new solutions
- Informal convening complements concurrent efforts in the legislative process
- Galvanize additional resources towards shared challenges

Multidisciplinary approaches can be deeply valuable for tackling our thorniest problems.
In many areas, further advancement is limited by the current tools at our disposal. In the instance of the BRAIN initiative [crosslink to case study], further development of scientific tools required that physical sciences and engineering fields collaborated deeply with neuroscience; the initiative created the framework necessary to bridge disciplines and bring experts together. A multidisciplinary approach can offer potential advances for complex social problems, as well. Working through a collective action framework – oriented by strategic guidance from public leadership or backbone organizations – can allow collaborative efforts to reach scale and scope, while also allowing individual participants to focus on their particular domain expertise and contributions.

Unexpected coalitions can generate innovative solutions
The body of research demonstrates that solutions that emerge from collaborative governance processes are "better informed, stronger in concept and content, and more likely to be implemented," according to Terry Amsler, Director of the Collaborative Governance Initiative. ["Integrating Collaborative Activities: Public Deliberation with Stakeholder Processes", National Policy Consensus Center] Pledges are unique in that they mobilize stakeholders to align and act; influence them to mobilize and further be

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influencers in their networks; innovate new products and services through these stakeholders and partnerships for adoption and scale; and, develop foresight for future directions.

Read more: How Diversity Makes us Smarter

High-visibility commitment spurs public engagement and jumpstart new solutions

Professor Rosabeth Moss Kanter explains that a convening model "stimulates more action by more groups in more places. It gets people who already have their fingers on the levers of change moving quickly" [Calmes, J., "Obama Counts on Power of Convening People for Change," New York Times, January 2014]. Stakeholders also respond from a deep sense of civic responsibility; being directly asked to be part of an effort to advance the public good is a powerful appeal. "The sense was that this whole thing was bigger than itself," explains Talia Milgrom-Elcott, co-founder of 100Kin10. [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.] When the goal is much bigger than any one person or organization could possibly achieve, collaborators are drawn by the promise of accomplishing something "big" together. [Chun, M., phone interview with Policy Design Lab, August 11, 2016]

Complements concurrent efforts in the legislative process

External collaboration does not replace the normal processes of government and the primacy of legislative efforts, but it can enable policymakers to focus on areas where legislation is truly essential. "One benefit of collaborative governance," notes a state senator, "is that it can keep issues out of the legal and legislative arena. When people can develop a solution that does not involve more red tape and regulation, everybody benefits". [Carlson, C. and Wolf, G., "The Power to Convene", Council of State Governments, November/December 2005] Federal officials can observe a body of practice for this approach at the state and local level. Examples from the state level include the following, as drawn together by the Policy Consensus Initiative:

Legislators at a Crossroads: Making Choices to Work Differently
At the state and local levels, legislators have seen the virtue of cross-sector collaboration in a way that can be instructive for Federal agencies.

From Oregon: How Business, Government and Philanthropy Intersect to Solve Public Problems

From Florida: Florida Senator Leads Three-County Collaborative

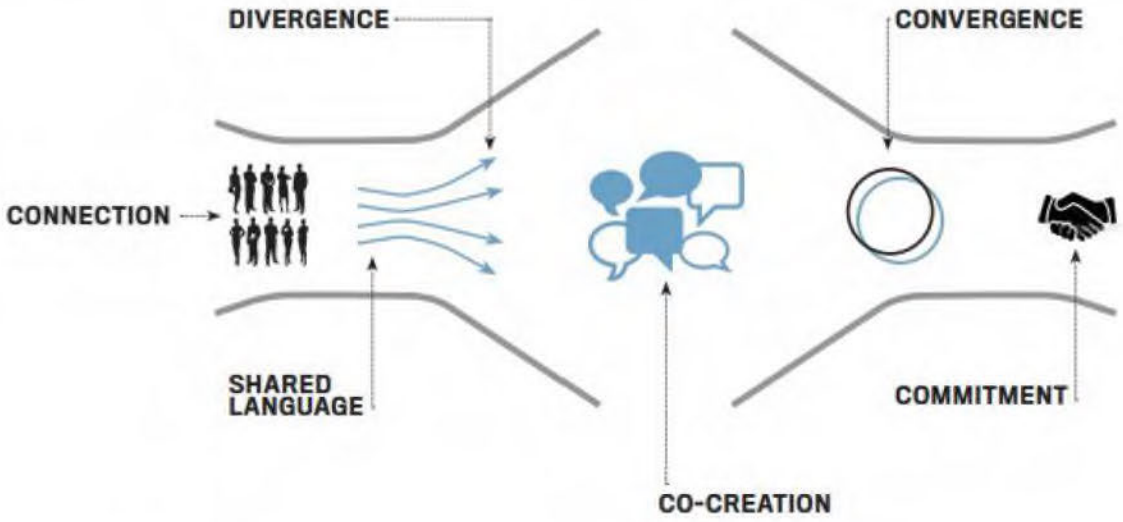
From Utah: Finding Winning Solutions - The Art and Science of Good Governance

Galvanize additional resources towards shared challenges

Another benefit of convening power, and a good measure of success for collaboration between the public and the private sectors, is whether such an effort brought additional resources to bear towards solving a shared challenge – whether by changing private sector practices, in-kind through volunteerism, resource allocation, or collectively towards a shared outcome.

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Deliverable 3: Profiles of candidate users - examples of when to deploy



[Image source: p. 51, http://www.monitorinstitute.com/downloads/what-we-think/gather/GATHER_The_Art_and_Science_of_Effective_Convening.pdf]

When to deploy

Selecting issues for which the executive authority to generate commitments is appropriate is similar to the problem segmenting work that takes place at the outset of Grand Challenge planning. Calls to action, like Grand Challenges, must have a "Goldilocks" level of specificity and focus, balancing ambition with feasibility. [Kalil, T., phone interview with Policy Design Lab, August 1, 2016] Use calls to action to draw attention to high priority challenges which appear to be at a tipping point, and where greater collaboration among stakeholders and greater visibility to potential funders would substantially advance progress. They can also be utilized to meet mounting pressure or be used following a major world event to galvanize domestic resources. Different "organizing principles" for selecting commitments include:

- **Place-based:** "In X cities or communities, IT employers and training providers will work together to help train Y workers."
- **By type of organization:** 120 Engineering Deans agreed to scale programs such as the Grand Challenge Scholars Program to reach 20,000 undergraduate students. [crosslink GCSP case study - GCs]
- **By the goal**: A broad coalition of organizations has come together to prepare and recruit 100,000 high-quality math and science teachers over the next 10 years. [crosslink 100kin10 case study]

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- **By maturity/level of evidence of the approach** e.g. "This is a new idea worth trying," vs. "This intervention has been rigorously evaluated and is ready to scale." [Garg, K. Personal communication with Policy Design Lab, December 20, 2016].

In recent years, the calls to action have spurred movement on a wide range of policy concerns, including:

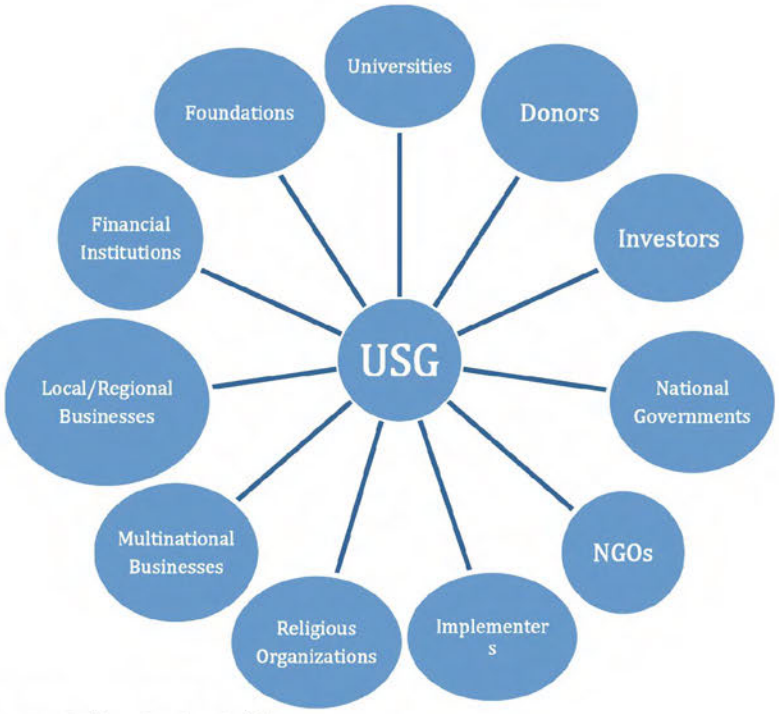
- The global refugee crisis, from initial call to action to collective response
- Expansion of STEM education in K-12 schools
- AIDS policy and response
- Soil erosion
- Expanding college opportunity
- Combatting long-term unemployment
- Insourcing American Jobs

How to deploy

External collaborations that align public and private commitments can take shape in several ways. In some instances, Federal leadership may choose to set an audacious goal without full certainty that an external partner will actually step up and respond to the call; this can be feasible when there's a budget strategy to help bring the goal to fruition, for example, by helping to create the implementing organization. Whether spurred by Federal guidance or arising as a wholly organic, external coalition, external backbone organizations can play critical roles in on-going implementation. Commitments aim to accomplish all of the purposes of convenings described: mobilizing stakeholders to align and act; influencing them to mobilize and further be influencers in their networks; innovating new products and services through these stakeholders and partnerships for adoption and scale; and, developing foresight for future directions.

External collaboration is frequently led by senior White House leadership, but agency leaders can also do vital work to engage with external sectoral leaders. For instance, as a precursor to a July 2014 White House Summit event, in June 2014, the Department of Labor convened six regional summits with key high-growth industry sectors to promote the apprenticeship model and to ensure future Federal investments meet business needs for skilled workers ["Ready to Work: Job-Driven Training and American Opportunity", The White House, July 2014] Other Departments have also used convenings to leverage commitments from the private sector, as well as each other, in order to increase their impact towards a specific challenge [crosslink to individual cases studies in V4 (PPPs) for each of the following cited:]. For example, the Global Alliance for Clean Cookstoves, Feed the Future, FNIH, and PEPFAR show that while one agency may take lead, other agencies can also participate and leverage their own funds and private sector relationships.

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[Image source: Policy Design Lab]

Attributes of a well-designed commitment

- A good commitment achieves three criteria: It is new, specific, and measurable. ("New" does not mean "brand new," but instead may represent an expansion of an existing effort.) ["Commitments to Action", Clinton Global Initiative]
- An effective template for a commitment takes the following form:
  - "Over the next X years, organization A commits to take action B with the goal of achieving outcome C."
- Commitments are powerful when framed as having cumulative impact and value:
  - "These commitments have a total financial and in-kind value of $X and will help Y students excel in STEM education."
- Commitments should take advantage of the "core competencies" of the organizations that are making them. It is worth asking, which organization is in a unique position to accomplish X objective.
- The individuals and organizations involved should pass a White House vet. [Garg, K. Personal communication with Policy Design Lab, December 20, 2016].

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Typology of Convenings

The power to convene can be leveraged to pursue different commitments. Clarifying the purpose of the approach at the outset of planning can help structure more productive engagements with external stakeholders. The following typology is sourced from *Gather: The Art & Science of Effective Convening*, a research guidebook from the Monitor Institute:

Purpose: Align and Act

Mobilize stakeholders in different parts of a system to act in concert. Help build a shared understanding of the system and the problem, develop consensus around a common vision, align strategies around it, and support one another in the execution.

Purpose: Influence

Shape the public conversation and the attitudes of key stakeholders by bringing together important actors and thought leaders to discuss, improve, and customize new concepts for their context.

Purpose: Innovate

Explore new approaches and enable creative disruption by reframing, reimagining, or recombining different elements and perspectives. Use these inputs to prototype transformational new processes or services and develop ideas for their adoption and scale.

Purpose: Develop Foresight

Anticipate potential challenges and identify new opportunities for intervention, by collecting indicators of how the world is evolving today and diverse perspectives about the directions that it could take in the future."

Directly sourced from: Rimland, N. and Muoio, A., "*Gather: The Art & Science of Effective Convening*, Monitor Institute, Deloitte, June 2013].

Deliverable 4: One or more "success stories" or learning narratives to underscore impact

Case studies

1. BRAIN initiative
2. 100Kin10
3. USignite

Case Study 1: BRAIN Initiative

[case derived from Kalil, T., phone interview with Policy Design Lab, August 1, 2016 and Chun, M. and Martin, C., phone interview with Policy Design Lab, August 11, 2016]

Summary:

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The BRAIN Initiative -- Brain Research through Advancing Innovative Neurotechnologies -- was unveiled in April 2013 as a multi-agency Grand Challenge [crosslink GC]. The main goal was "To accelerate development of new technologies that advance understanding of the brain, [thereby] enabling researchers to produce dynamic pictures of the brain that show how individual brain cells and complex neural circuits interact at the speed of thought" ["A Strategy for American Innovation", National Economic Council and Office of Science and Technology Policy, October 2015].The BRAIN Initiative brings the scientific community together with Federal and private funding partners to advance progress. The BRAIN Initiative exemplifies a complex, multi-pronged issue best addressed by a "whole-of-government" approach with widespread agency coordination in conjunction with significant private investment: Since its launch in April 2013, five Federal agencies have invested in the effort, with the Intelligence Advanced Research Projects Activity (IARPA) joining the Defense Advanced Research Projects Agency (DARPA), the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Food and Drug Administration (FDA). [Kalil, T., phone interview with Policy Design Lab, August 1, 2016]

The call to action

The launch of the BRAIN Initiative began with a single question – "What do you believe are the moonshots of the 21st century?" -- that former Office of Science and Technology Policy (OSTP) deputy director Tom Kalil asked of the The Kavli Foundation. [Kalil, T., phone interview with Policy Design Lab, August 1, 2016] Neuroscience research is one of the foundation's priorities. Having witnessed a two to three year lag time before comprehensive reports would reach their desks, White House leadership wanted to directly engage with the scientific community; "We needed to hear those voices as clearly as possible," said Tom Kalil. [Kalil, T., phone interview with Policy Design Lab, August 1, 2016] Dr. Miyoung Chun, Vice President of science programs at Kavli, was an enthusiastic collaborator, agreeing that "Science is very dynamic; the frontier of science is not two years ago; it's today." [Chun, M., phone interview with Policy Design Lab, August 11, 2016]

How the collaboration developed:

After the initial conversation between Kalil and Kavli, the foundation kept an eye out for possible answers to the moonshot question. At a September 2011 meeting between the Kavli Foundation, Allen Institute, and Gatsby Foundation, the seed of an idea emerged that Dr. Chun shared with OSTP. [Martin, C., Personal communication with Policy Design Lab, December 20, 2016]. From there, a workshop was held to invite ideas from top scientists and scope out an initiative that would focus on brain research. Kavli convened top experts from a broad spectrum of physical sciences to identify the key obstacles preventing scientific advancement in areas of brain research. At the convening, a shared understanding emerged about key obstacles stalling progress. Neuroscientists observed how far they were from a theory about how a brain encodes and processes information, focusing on the idea of "missing middle" in what could be observed of the entire neural circuit in real-time. From reflecting on how the field had advanced in the past, it was clear that new tools and new methods had been essential for answering frontier challenges. [Kalil, T., phone interview with Policy Design Lab, August 1, 2016]

Kavli reported back to the White House a strong, genuine interest in the research community for further exploration. "From a foundation's perspective, we thought, 'This is just so unbelievable that the White

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House is eager to hear actual voices of individual scientists," recalled Dr. Chun. [Chun, M., phone interview with Policy Design Lab, August 11, 2016]

It took over 18 months to align all the pieces necessary to realize the collaboration, culminating in Congressional approval for increased funding in December 2015 [Nather, D., "It's Official: The NIH Budget is Getting an Extra $2 Billion", STAT, December 2015] During the lengthy process – fraught with uncertainty – Kavli acted as the "constant convener and the glue" for the scientific community. [Chun, M., phone interview with Policy Design Lab, August 11, 2016] Within government, OSTP coordinated prospective Federal funding agencies. Funding agencies worked together closely in the development and launch of the initiative, with NIH playing a key leadership role. [Kalil, T., phone interview with Policy Design Lab, August 1, 2016] At the outset, expectations were clearly managed; the White House emphasized realism instead of over-promising, with clear communication that through the collaborative process, the articulation of the end goal could shift. Concerted effort went into conveying to outside partners how Federal processes worked to outside partners. Clear lines were drawn for potential conflicts of interest, for example, between Federal funding agencies and scientists who would potentially benefit from funding decisions. [Chun, M., phone interview with Policy Design Lab, August 11, 2016]

The scientific community – about 150 scientists – had its patience tested through the long process, particularly given the uncertain outcome. But they remain engaged in multiple gatherings during that time period because of a shared, collective belief in could be achieved: "The initiative was possible because everyone believed, each one of them, that they were servicing their time and effort for something much greater than what they were doing individually," Dr. Chun added. [Chun, M., phone interview with Policy Design Lab, August 11, 2016]

Impact:

"BRAIN will generate revolutionary new tools to measure the brain activities in thousands to millions of neurons in order to produce a general theory of the brain," Dr. Chun asserts. "We want to understand how we reason, how we memorize, how we learn, how we move, how our emotions work. These abilities define us. And yet we hardly understand any of it" [Pontin, J., "Interview with BRAIN Project Pioneer: Miyoung Chun", MIT Technology Review, April 2013]. Three years into the initiative, there has been "an unbelievable rate of tangible scientific achievement," Dr. Chun says. Hundreds of papers have already been published as a result, and new methods and tools have already been developed. In July 2016, researchers announced they had discovered nearly 100 previously unknown areas of the brain, and published a "spectacular" new map of the brain hailed as "an unprecedented glimpse into the machinery of the human mind" [Zimmer, C., "Updated Brain Map Identifies Nearly 100 New Regions", New York Times, July 2016].

"The President's 2016 Budget includes over $300 million to support the BRAIN Initiative, with investments from the National Institutes of Health, the National Science Foundation, the Defense Advanced Research Projects Agency, the Intelligence Advanced Research Projects Activity, and the Food and Drug Administration. The initiative also catalyzed additional funding across the network. The private sector is also making commitments of hundreds of millions of dollars to support the BRAIN Initiative" ["A

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Strategy for American Innovation", National Economic Council and Office of Science and Technology Policy, October 2015]. "Major foundations and private research institutions, including the Howard Hughes Medical Institute, Allen Institute for Brain Science, and the Kavli Foundation, as well as patient advocacy organizations and universities have committed over $240 million to the BRAIN Initiative. In addition, members of the National Photonics Initiative and other companies such as GE, GlaxoSmithKline and Inscopix have joined this effort through commitments of more than $30 million in research and development investments" ["Obama Administration Proposes Over $300 Million in Funding for The BRAIN Initiative", White House Office of Science and Technology Policy, February 2015.]

Key learning insights:

- Choose the "right problem" at the "right time" [crosslink problem definition content]
- Strong leadership, combined with deep, genuine high-level engagement by members
- Inter-agency cooperation can be essential for fully activated engagement
- Convening is a shared power; sharing the credit augments that power

Right problem, right time

At the outset, problem definition is foundational for success. By selecting a problem that will resonate with a range of stakeholders, it inspires a wide range of engagement from individuals and organizations.

Strong leadership, combined with deep, genuine high-level engagement by members

Deep, sustained engagement from the White House was essential in realizing the collaboration, Kavli explains; "Tom Kalil really brought the right leaders at the right time," Dr. Chun says. "Scientists could never have accomplished this on their own." [Chun, M., phone interview with Policy Design Lab, August 11, 2016] Kavli firmly emphasizes its own role as a neutral, independent mediator between government and the scientific community, noting that many collaborators were proactive in pushing the initiative forward: "Scientists stepped up. Funders stepped up. White House leadership stepped up. [...] We like to think that we stepped up, in our own way -- but the fact is that everyone stepped up." [Chun, M., phone interview with Policy Design Lab, August 11, 2016] The NIH allocated $46 million in 2014 and $81.4 million in 2015, almost doubling its funding ["About Us- Brain Research Through Advancing Innovative Neurotechnologies (BRAIN)", National Institutes of Health, November 2015]. As previously stated, private-sector organizations including foundations, universities, and research institutions have already committed over $240 million.

Inter-agency cooperation can be essential for fully activated engagement

The BRAIN initiative began with the participation of three agencies (NIH, NSF, DARPA) and has since worked with several others, including IARPA and FDA. "What's interesting is that because they have different missions, they were able to tackle different parts of the problem," observes Tom Kalil. [Kalil, T., phone interview with Policy Design Lab, August 1, 2016] NIH brought its expertise to bear on fundamental research and elements related to human health, whereas DARPA focused on its strength – high-risk, high-return research – to immediately respond to aspects of the BRAIN Initiative that might help veterans. The NSF, on the other hand, focuses its BRAIN initiative efforts on its own core

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competencies: integrative and interdisciplinary research; new theories, computation models, and analytical tools that will guide research questions and synthesize experimental data; and the development of innovative technologies and data infrastructure required to handle the large scale datasets resulting from this research ["Obama Administration Proposes Over $300 Million in Funding for The BRAIN Initiative", White House Office of Science and Technology Policy, February 2015.] By concentrating on agency-specific strengths, and facilitating communication amongst agencies, the BRAIN initiative efficiently promotes full participation and expansion.

Sharing credit augments the power of convening

"Spreading the credit around when something succeeds is very powerful," observes Dr. Chun. [Chun, M., phone interview with Policy Design Lab, August 11, 2016] The White House consciously attributed progress to partners in the collective group effort, making sure to involve scientists in announcement events. The Kavli Foundation notes that the continued credit-sharing after initial successes were "tremendously reassuring," and continued to build trust within the collaborative partnership. . [Chun, M., phone interview with Policy Design Lab, August 11, 2016]

Read more:

The 2014 call to action
Interview with BRAIN project pioneer, Dr. Miyoung Chun
February 2016 fact sheet on BRAIN Initiative activities
May 2016 report to the Committees on the activities of the Interagency Working Group on Neuroscience (IWGN)

BRAIN Initiative milestone map: Key moments in brain research

Case Study 2: 100Kin10

[[Link or embed 90 second video: http://vimeo.com/37821939]]

Summary:

100Kin10 unites the nation's top academic institutions, nonprofits, foundations, companies, and government agencies to collectively tackle the goal of training and retaining 100,000 excellent STEM teachers to educate the next generation of innovators and problem solvers [100Kin10 website] As a backbone organization, 100Kin10 represents a network approach to problem-solving. It facilitates opportunities for its partners to collectively address shared challenges larger than any one organization could tackle individually.

The call to action:

In the 2011 State of the Union address, President Obama set an audacious goal: Put 100,000 new science, technology, engineering, and mathematics (STEM) teachers in American classrooms by 2021, in order "to equip a new generation of problem-solvers with the STEM skills they need to revitalize our

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economy, lead our nation, and solve the globe's most pressing challenges ["President Obama Celebrates Great Teachers and Our Nation's Educational Progress", The White House, May 2016].

"The Administration was uniquely positioned to put out this call and keep the drumbeat going," says Talia Milgrom-Elcott, executive director and co-founder of 100Kin10, noting that the President continued to call attention to the issue, whether in stump speeches or his second inaugural address. [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.] The continued drumbeat, she says, put a high degree of emphasis and "oomph" behind the call – which increased the response by stakeholders. [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.]

How the collaboration developed:
100Kin10 emerged directly as a response to the urgent presidential call to action. The White House helped set the Federal levers into motion – using their visibility to prioritize existing Federal funding streams towards STEM [crosslink i3 case study], and deploying its convening power to bring stakeholders together and create accountability. But, she notes, they couldn't deliver the teachers: "There was no way they could set into motion what would be necessary to get to 100,000 excellent STEM teachers -- it truly required a private sector networked response. And so that's what we set out to do and to build." [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.]

Early efforts concentrated on securing private sector commitments, but the organization quickly realized that partners required further support to actualize their programs. 100Kin10 responded by adjusting its focus. The organization now emphasizes a network approach to problem solving so that each partner organization can improve its work while meeting its personal commitment to the goal of 100,000 teachers. This requires trust, explains Milgrom-Elcott. [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.] At the outset, 100Kin10 emphasized the development of a strong trust base with partnering organizations. "Trust is the bedrock of learning. We developed trust [with our partners] before we invested in marketing or even funding," explains Milgrom-Elcott. [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.]

Partners have the opportunity to learn from and adapt the models of other partners as well as the support to innovate new approaches. 100Kin10 offers access to funding and implementation support that spans the spectrum, from small collaboration grants to support knowledge sharing to experimental pilots to catalyze innovation: "Depending on where you are, and what questions you're working on, we support you in those different stages," Milgrom-Elcott adds. [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.]

Impact: [Milgrom-Elcott, T., Personal communication with Policy Design Lab, December 14, 2016]. 100Kin10 and its partners have promoted the importance of STEM as a cross-sector priority. Five years in, 100Kin10 partners have already trained more than 40,000 teachers. The network announced in spring 2016 that it was on track to deliver the full 100,000 STEM teachers on time [President Obama Celebrates Great Teachers and Our Nation's Educational Progress", The White House, May 2016].

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Having begun as 28 organizations responding to the State of the Union call, 100Kin10 now works with over 280 partners, including the nation's top academic institutions, nonprofits, foundations, companies, and government agencies. [Milgrom-Elcott, T., Personal communication with Policy Design Lab, December 14, 2016]. The Funders' Collaborative is comprised of thirty-four funders, including national private foundations, community foundations, corporate sponsors and others, who have made pledges since 2011 totaling more than $90 million to support the goal of 100Kin10 [100Kin10]. Organized as a collection of pledges from funders, members of the collaborative each pledge a minimum of $500,000, to be dispersed over no more than 3 years, to one or more 100Kin10 partner organizations. In 2015, funders distributed over $14 million to 37 100Kin10 partners. ["2015 Was a Great Year, and We're Excited to Show You Why", 100Kin10, 2016] Partners also have the opportunity to submit applications for funding via a 100Kin10 Challenge Grant.

Key learning insights:

- **Structure the collective framework thoughtfully in pursuit of a common goal**
- **Understand partners' context to unleash collaboration**
- **Shift from symptoms to root causes**
- **Focus on quality over quantity when scaling a network**
- **Share learning through the network to accelerate progress**
- **Secure commitments in the presence of public or high authority figures**

Structure the collective framework thoughtfully in pursuit of a common goal

Talia Milgrom-Elcott recounted how at the very outset, 100Kin10 used a series of user-centered design exercises, like backwards mapping, to clarify their strategy. "We ran through a series of questions, asking what would need to have happened for us to have achieved our goal by 2021?" [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.] By mapping backwards the planning became oriented around what commitments to action each organization could make. As a result, 100Kin10 established, at the heart of its mission, a bias towards action. As Milgrom-Elcott explains, partners are pushed to articulate specific actions they plan to undertake; "We are not your grandfather's coalition; you have to have a commitment to action to be a part of the network." [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.]

Milgrom-Elcott adds, "Unlike other coalitions, we don't require our partners to adhere to a set of principles. In fact, the opposite: We intentionally court organizations that disagree with each other or sit on opposite sides of the negotiating table but can agree and even work together on this goal." [Milgrom-Elcott, T., Personal communication with Policy Design Lab, December 14, 2016].

Understand partners' context to unleash collaboration

For 100Kin10, a central focus was understanding the challenges faced by partner organizations and how they interact. By understanding partners' particular context and investing the time to know them and their work well – including asking all partners to share their data, strengths, and struggles -- 100Kin10 was able to act as a matchmaker between partners. This spurred the formation of relevant cross-sector partnerships to enable organizations facing similar challenges to work together, or to learn from one another. Learning the strengths of each participant helped to ensure each partner's comparative

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advantage was capitalized on.

Shift from symptoms to root causes

Working to understand partner organizations on a micro level led to a comprehensive understanding of the landscape, which 100Kin10 captured in a map of the major challenges and their root causes. Milgrom-Elcott explains the thought process for partners as, "'Where are you currently working? Where is your work a Band-Aid because you're in a triage emergency situation, but underlying there's something going on that if you could just get at, you wouldn't have so much bleeding?" [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.] She describes the collective learning process as "Moving people up the diagnosis chain, from dealing with a flesh wound, to understanding the cause of the bleeding, to understanding why so many people are coming in with bleeding." [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.] The network is currently working with its partners to address the core issues that have made this moonshot goal so hard. [crosslink Moonshot V8 blurb]

Focus on quality over quantity when scaling a network

100Kin10 initially focused on growing the number of partners involved in the collective effort, but later came to realize that simply "bringing more organizations on board didn't help those organizations to succeed. [...] Having commitments on paper that couldn't be effectuated was only marginally or normally better than no commitment at all. So we have since focused on innovating different vehicles to support organizations to succeed." [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.]

100Kin10 created a vehicle for growing the network organically. Existing partners could nominate new organizations, which then applied with commitments to action and evidence of prior successes. In addition to tapping the networks of all partners, this approach to growth created an inherent check on 100Kin10's value proposition: If existing partners didn't find it useful, they wouldn't expend their social capital inviting their colleagues to join. [Milgrom-Elcott, T., Personal communication with Policy Design Lab, December 14, 2016].

Secure commitments in the presence of public or high authority figures

Articulating concrete commitments helps to ensure follow-on action. Milgrom-Elcott recounts convening a meeting between partners and Arne Duncan, then Secretary of Education: "We used it as a carrot, knowing there would be no stick for accountability. We had no way to ensure what would happen, but [we thought] if we had people publicly commit in front of the Secretary, that would be a very powerful force and function." [Milgrom-Elcott, T., phone interview with Policy Design Lab, August 16, 2016.] It was an effective strategy. For all partners, 100Kin10 now publishes partner commitments publicly, and each partner shares its progress annually with the network. Successes are widely celebrated at events and in writings, to encourage high achievement.

Share learning through the network to accelerate progress

With annual partner surveys and "Steal This" sessions, the network advances the collective state of learning by encouraging knowledge-sharing. [Milgrom-Elcott, T., Personal communication with Policy

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Design Lab, December 14, 2016].This, in turn, accelerates the rate of collective progress. Through the 100Kin10 Fellowship, teams from partner organizations develop and test new tools, systems, and/or programs that help prepare and support instructors and their students, together achieving ambitious goals for STEM instruction that supports students' active learning in grades P-3.

Read more:
How to Count to 100,000 STEM Teachers in 10 Years
100Kin10's Experiments in Networked Impact

Case Study 3: US Ignite

Summary:
Launched in 2012, US Ignite is a 501c3 nonprofit organization fostering the development of next-generation networks. It creates demonstration projects that illustrate the transformative public benefit of new technologies like software-defined networking and cloud computing, with the ultimate goal is to transform through technology how we receive healthcare, educate our children, become more energy efficient, and manufacture goods. US Ignite creates the necessary tools for pilot applications, and brings together interested partners -- developers, entrepreneurs, innovators, academic researchers, municipal leaders and others -- looking for concrete examples. [Kochan, J., personal communication with Policy Design Lab, December 21, 2016]

The call to action:
From 2010 to 2012, as part of the debate over economic stimulus, there was a "loud public conversation" about the role of Federal, state, and municipal governments in funding critical infrastructure like advanced broadband networks, recounts Joe Kochan, chief operating officer at US Ignite. "Whose job was it? Was it happening fast enough?" [Kochan, J., phone interview with Policy Design Lab, August 16, 2016] White House leadership convened meetings on the issue. Stakeholders didn't necessarily agree on economics or the theory of who was obligated to build it, but consensus emerged that it was urgent more be done – quickly -- to advance the state of broadband infrastructure. There was also agreement that almost all stakeholders, from corporations to public taxpayers, needed a better understanding of why investment in next-gen networks was critical. "US Ignite exists only because of a need for public private partnership" to effectively demonstrate the uses and benefits of next-gen networks, explains Kochan. [Kochan, J., phone interview with Policy Design Lab, August 16, 2016]

How the collaboration developed: [Kochan, J., phone interview with Policy Design Lab, August 16, 2016]
In the first several years of operation, the organization was primarily funded through corporate and philanthropic partners, using MOUs and formalized commitments. Primary Federal partners have included the National Science Foundation and the White House Office of Science and Technology Policy, with the National Institute of Standard and Technology under the Department of Commerce also collaborating. Private sector partners include Verizon, Comcast, AT&T, IBM, CISCO, Juniper, Avaya, Google and a few other telecom and tech companies. While US Ignite began with around fifteen

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commercial partners, today, interested parties can submit inquiries via the website to join the partnership network. As the partnership network has evolved and Federal collaboration has grown, the mission has largely remained the same: Provide the public with tangible answers to the question "Why do we need a gigabit?" [Kochan, J., phone interview with Policy Design Lab, August 16, 2016]



["What We Do", US Ignite]

In general, US Ignite follows a six-step process: [Kochan, J., personal communication with Policy Design Lab, December 21, 2016]

1) Educate people on what is possible with next-gen networks through demonstrations of potential applications.
2) Source resources and innovators to make pilot applications possible, matching funding to need
3) Create prizes, incentives, and recognition for innovative ideas for next-generation applications
4) Secure agreement with network operators for testbeds where new applications can be demonstrated to the public
5) Scale up demonstration projects and connect them to more communities
6) Tell the story and explain the importance of advanced networks as the foundation of these new applications

Many people do not understand that the Internet is a 40 year-old technology, and it's not a monolithic entity, explains Kochan. [Kochan, J., phone interview with Policy Design Lab, August 16, 2016] Instead, it is a collection of 40,000 private networks operated independently, all on a specific set of agreements; "There's no one from the top-down to say, hey, the Internet is 40 years old, we've got to

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upgrade. It doesn't work that way." Kochan, J., phone interview with Policy Design Lab, August 16, 2016] Because of its decentralized nature, deliberate investment must be incentivized.

"When it comes down to it, if you talk to people outside of the technology arena and you challenge them, 'What would you do with the better, faster broadband?' They often can't answer [...] because people don't know what these networks are capable of, and therefore don't know how to answer that question," says Joe Kochan. [Kochan, J., phone interview with Policy Design Lab, August 16, 2016] Most lay people are unfamiliar with concepts of latency and network jitter or with newer technologies like software-defined networks. US Ignite builds demonstration projects to address this knowledge gap. "We show people what is possible, and then we explain, 'If you want this, you've got to invest in a network that can handle the following characteristics.'"[Kochan, J., phone interview with Policy Design Lab, August 16, 2016] The result helps to catalyze the adoption of new technologies – which in turn lowers their cost, and encourages further adoption.

The organization is continuing to engage the academic research community, while also working with municipalities and corporations to encourage and foster deployment of ecosystems of next-generation networking. In June of 2016, US Ignite announced the creation of a national network of Smart Gigabit Communities. Each of the 15 communities involved made a significant commitment toward leveraging next-generation smart city and Internet technologies to keep pace with the world's rapidly changing technology and economy [Kochan, J., "US Ignite Announces 15 Smart Gigabit Communities", US Ignite, June 2016].] ["Administration Announces New "Smart Cities" Initiative to Help Communities Tackle Local Challenges and Improve City Services", The White House, September 2015]. Kochan ultimately challenges cities to think broadly for the long-term: 'OK, Chattanooga, you built a fiber network directly to your end users. Aside from the fact that your internet access is now cheaper, faster, and ubiquitous, [...] you also have the following 100 benefits that you didn't know about with this new technology. What are you going to use them for? What are you going to do with it? What do you think you can do?'" [Kochan, J., phone interview with Policy Design Lab, August 16, 2016]

Impact: With 35 sponsor and partners, in its first years US Ignite has developed and deployed a multitude of applications with diverse social impact. The National Science Foundation (NSF) reports that projects as a whole have "demonstrated the potential societal impact of broad use of ultra-fast, software-defined networks. For example, one NSF Early-concept Grants for Exploratory Research (EAGER) project has resulted in operational improvements in emergency response communications. Another project has generated a commercial product addressing health and wellbeing" ["US Ignite - Program Solicitation", National Science Foundation, January 2015]. As of November 2016, there are 139 applications for this NSF US Ignite project: Eight have been commercialized, 39 have a completed idea, and 65 are currently in development. [Kochan, J., personal communication with Policy Design Lab, December 21, 2016]

In the next five years, the ecosystem created by US Ignite plans to deliver:

- 60 next-generation applications;
- 200 community test beds where applications can be researched, developed, tested and deployed;

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- A forum for collaboration between multi-sector partners. ["What is US Ignite?" USIgnite.]

Key learning insights:

- **Balance stakeholder views, and engage sectors on their own terms**
- **Convey the timeline for working with Federal partners**
- **Formalize commitments**

Balance stakeholder views, and engage sectors on their own terms

Perhaps the most critical key for collaboration, says Kochan, is starting with a basis of agreement between public and private stakeholders. [Kochan, J., phone interview with Policy Design Lab, August 16, 2016] This can set an organizational context for setting a strategy with broad appeal. Ultimately, the balance of public and private partners and funding sources was important for establishing a broad, multi-sectoral perspective for the organization.

Formalize Commitments

It was also important to engage partners with context-appropriate framing; for example, when approaching private sector partners, commitments were designed around clearly defined value propositions (as opposed to a framing for public sector stakeholders). This helped to secure private sector buy-in early on. Commitments were then formalized with clear, specific, and measurable, goals and deliverables helped to sustain longer-term buy-in into the partnership.

Convey the timeline for working with Federal partners

The experience demonstrates how the agility of private funding sources can complement Federal efforts. The NSF issued Dear Colleague letters (DCLs) in 2012 and 2013, but projects only began receiving funds through DCLs in 2015. "The timeframe could have – and almost did – span an entire administration," notes Joe Kochan. [Kochan, J., phone interview with Policy Design Lab, August 16, 2016] Funding from private partners drove the effort for the first 3 years of the organization's existence, with more than 80% of funding initially coming from private sources. OSTP was the primary governmental liaison/inspiration in early stages, while NIST joined in later as a partner.

Read more:

Networking Research and Application Prototypes Leading to Smart & Connected Communities - NSF 2016 solicitation

[[See additional upload documentation from US Ignite]]

Deliverable 5: Challenges to deployment / approach limitations

Combining urgent calls to action with the power of convening can lead to extraordinary collaboration between public and private partners. Several common obstacles are worth noting:

Common pitfalls to watch for when designing convenings and generating commitments

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- Failure to coordinate first with other key Federal stakeholders.
- Only one event on the initiative is held, which limits the opportunities for momentum and an expansion of the coalition of organizations that are involved.
- An organization makes a commitment, but doesn't follow up.
- Commitment fatigue (e.g. Mayors and certain companies and foundations continually asked to make commitments)
- Appearance of favoritism, which can be avoided by making the opportunity available to a broad range of stakeholders, or appearance of quid pro quo.
- Managing expectations. (For example, never promise that they will get to meet the President.)

Necessary ingredients for success

- Choose the right issue for level and levers of influence
- Understand context before engagement
- Commit firmly – and communicate openly
- Funding
- Create accountability and feedback mechanisms

Choose the right issue

Convenings can't just be a photo opp; they have to be a genuine "collaboration opp." [Source: p. 68, Innovative State]. Calls to action need to focus on substantive challenges, and leadership should beware a dilution effect from over-frequent or inappropriate use of the approach. Choosing the right issue is important for generating commitments and follow-through from CEOs, industry leaders, and organizational heads. Be wary of choosing an issue that relies overly on legislative or judicial changes for sufficient advancement, should the convening be seen as unsuccessful and decrease future participation from external stakeholders.

Understand context before engagement

Understand where potential partners are coming from; tailor calls to action to allow each individual respondent to respond with their full potential while also respecting the uniqueness of each actor's goals and agendas. Understand that resource constraints can pose tension and act as a barrier for building the requisite trust to allow partner relationships to grow and mature. Typical partners in collaboration have different goals and agendas: Non-profits compete with one another for a finite number of resources; Foundations do not always value and award funding to support collaborative approaches; private sector contributors evaluate participation based on the bottom line and what collaboration can bring to shareholders and customers; and academic researchers may feel pressured to focus on research questions that are publishable. In these contexts, it can be difficult to ask collaborative partners to devote time to working together.

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Clarifying what each contributing partner gains from the collaboration is key to bringing people to the table and gaining buy-in. Clearly articulate incentives for different partners; by involving them in the creation of the common agenda, participants recognize its value.

Commit firmly – and communicate openly

Deep engagement by Federal leadership and clear forms of communication that effectively manage expectations are essential, especially for larger collaborations which may unfold over months and years. Joe Kochan reflects that at the beginning, US Ignite struggled with a "slightly unrealistic" point of view regarding the timeline for working with Federal partners. [Kochan, J., phone interview with Policy Design Lab, August 16, 2016] The organization realized that each piece of collaboration involving external organizations – partnership announcements with agencies, White House events, developing fact sheets – could be time consuming, but are of "chicken and egg" nature to the engagement: "Companies really value being a part of [high visibility collaborations], so it's important," Kochan says, but getting Federal partners on board requires a certain threshold of company commitments. "You cannot have one without the other," he explains. [Kochan, J., phone interview with Policy Design Lab, August 16, 2016] Trying to advance public and private efforts in parallel must be aligned with a realistic understanding of the mechanics and timeline for Federal processes. It is also important for strong relationship building to occur early on, as partnerships can be tested. For instance, budget cycle timelines do not always align easily, and approval processes may pose additional hurdles. Genuine embrace of a co-creative approach to partnering and a firm commitment to the goals and objectives outlined at the outset of the effort are important foundations when challenges arise.

Funding

Where Federal funding can achieve strong bipartisan support – as evidenced in the experience of the BRAIN initiative – the result is that private funding sources are often inspired to contribute even more. [Chun, M., phone interview with Policy Design Lab, August 11, 2016] The value proposition needs to be worthwhile for commercial partners but often, Federal funding can be seen as a trade-off – if a new initiative requests funding, it may be at the expense of other programs and funding. Funders need to recognize the necessity of directly investing in cross-sector collaboration, and encourage partners to allocate the time and resources to working together. US Ignite has successfully helped leverage resources from other sectors, benefitting greatly from this cross-sector collaboration.

Create accountability mechanisms

Demonstrating the value of collaboration to multi-sector partners can be a significant challenge to sustainability. But over time, the challenge evolves toward maintaining and ensuring accountability of individual partners. Increase the odds of organization follow-through with accountability mechanisms, including:

- Quantify the impact of the collaboration and sharing credit equally with everyone involved;
- Getting partners to communicate commitment openly in public so a record is created;
- Maintain touch points and relationships – as trust grows within the partnerships, people want to remain committed to people they know and support;

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- Define metrics for success at exit, at the beginning. Much like a private investment, defining early on what the group anticipates success for the partnership to look like, and how each will exit at that point, is important to set expectations for roles, communications, level of effort, etc.
- Appoint co-chairs, or coordinators, for the group –who share the management role, scheduling, delegation of tasks and accountability of members, and can ensure long-term sustainability
- Create a web-page for the initiative so that you can provide updates on the progress various stakeholders have made.
- If holding multiple events on the same initiative, devote some time to focusing on progress from past commitments.

At minimum, accountability involves consistent follow-ups to ensure that organizations have followed through on their commitments. Often, an outside organization is in the ideal position to execute this.

Read more:

- Valuable lessons learned for cross-sector partnership from Presidio Institute.
- GDI – Multi-Stakeholder Initiatives report, March 2016

Deliverable 6: How-To: Steps for deploying, practices for adapting

- Ways to inform organizations about the opportunity for them to make commitments
- 5 C's for convening and follow-on implementation
- Guidance on strategically structuring commitments
- Collective impact framework [textbox]
- Textbox on how to solicit public engagement

Ways to inform organizations about the opportunity for them to make commitments

- Issue a "call to action" -- ideally from the senior leadership in a speech or op-ed. It is also possible to publish a blog post that has examples for how different types of organizations that can get involved, and that has an online form or e-mail address. [[Crosslink web form]]
- Organize a workshop devoted to brainstorming ideas for specific commitments, ideally with one or more senior Administration officials present to convey serious intent.
- Leverage associations or professional societies that can inform and mobilize their members – particularly if they have entrepreneurial and highly motivated staff.
- Create a deadline and sense of urgency by scheduling an event.
- Amplify a sense of momentum by identifying a few organizations that are willing to act.
- Show people and organizations past examples of commitments that are relevant.
- Hold one-on-one conversations.
  [Garg, K. Personal communication with Policy Design Lab, December 20, 2016].

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The 5 C's for Convening and Collaborating:
The process for effective impact networks is directly relevant for Federal leaders to keep in mind when considering how to structure effective convenings and their follow-on implementation:

- Clarify purpose.
- Convene the right people.
- Cultivate trust.
- Coordinate actions.
- Collaborate generously.

[Ehrilchman, D., Sawyer, D. and Wei-Skillern, J.,"Five Steps to Building an Effective Impact Network", Stanford Social Innovation Review, November 2015]

Strategic Structuring Guidance

- ***Select the problem by clearly defining concrete pieces of high-priority challenges.*** Use backcasting, or backwards mapping, to identify and segment dimensions of the policy challenge.

- ***Be open to co-creating the solution context.*** Achieve a clear purpose centered on outcome-driven goals, but empower partners to adapt and co-create the collective mission and specific responses. Senior leadership has found it effective to structure by saying, "'Here's the broad goal. What kinds of ideas or commitments do you have to meet it?' One convening participant reported that White House leadership brought suggestions to the convening, "they made it very clear that these weren't exclusive ideas" [Calmes, J., "Obama Counts on Power of Convening People for Change," New York Times, January 2014].

  "To keep the conversation most effective, practical, and focused on generating powerful breakthroughs, you must bring in other points-of-view, not to dominate the conversation, but to challenge it." [Kahan, S., The Power to Convene and Set Context, Fast Company, October 2008]

- ***Structure convenings around action.*** Convey an explicit expectation that participants will produce "deliverables," or commitments for their specific follow-on actions and investments. [Calmes, J., "Obama Counts on Power of Convening People for Change," New York Times, January 2014].

- ***Build trust.*** The Trust Equation is a simple, but powerful framework for understanding the behavioral elements that build trust and enable collaboration. [Source]
  [Embed graphic from source above: *"Trustworthiness = (Credibility + Reliability + Intimacy)/Self-Orientation"]*

- **Keep the focus on realizing the shared outcome.** BRAIN, for instance, has been a success because science was put first at every turn, reports Dr. Miyoung Chun of the Kavli Foundation.

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- **Include the public.** Create a platform where citizens can also contribute new ideas. Input can be solicited through digital engagement tools like webforms. [Click here to download guidance on how to structure webforms.] [crosslink with crowdsourcing toolkit]

Elements of Collective Impact

Five key ingredients underline a collective impact approach:

- ***Common Agenda**: successful partnerships start by coming together to collectively define the problem and create a shared vision to solve it. All participants are brought together to craft a shared vision for how things will look different as a result of the collaboration, one that includes a common understanding of the problem and a joint approach to solving it through agreed upon actions.*
- ***Backbone organization:** a dedicated team within or outside of government orchestrating the work of the group, working behind the scenes to make sure that the collaboration is moving in the right direction. Creating and managing collective impact requires a separate organization and staff with a very specific set of skills to serve as the backbone for the entire initiative. Coordination takes time, and none of the implementing partners has any to spare. The expectation that collaboration can occur without a supporting infrastructure is one of the most frequent reasons why partnerships fail.*
- ***Shared metrics:** shared metrics establish an agreed upon series of measurement that enables all participants to track progress in the same way. This improves the collective understanding of whether the partnership is achieving its goals and allows for continuous improvement.*
- ***Continuous communication:** building trust and relationships across all partners and participants is critical to the sustained success of collaboration. Instituting a strategic approach to communication across partners has demonstrated to be key for addressing complex challenges through collaboration.*
- ***Mutually reinforcing activities:** this means coordinating collective efforts to maximize the end result. This feeds on the trust and relationships across the partners and is supported by continuous communication. Collective impact initiatives depend on a diverse group of stakeholders working together, not by requiring that all participants do the same thing, but by encouraging each participant to undertake the specific set of activities at which it excels in a way that supports and is coordinated with the actions of others.*

[Directly sourced from: "Kania, J. and Kramer, M., "Collective Impact," Stanford Social Innovation Review, 2011]

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How to solicit feedback and incorporate public engagement into the stakeholder process

General suggested structure for public engagement:

- Articulate problem statement
- Appeal directly: "We want to hear from you"
- Ask for specifics: "Tell us about the specific, measurable new steps your organization is taking to help"

An example webform follows below:

Organization Information

Organization

Primary Contact Name *

Title

Phone

Email *

City

State - None -

Media POC *

Announcement Summary

In the space above, please provide a summary of any new announcements(s) or actions your organization will make that are contributing to [addressing the challenge highlighted by the Call to Action] These commitments may reflect a potential scope of work for the coming year. Please quantify each commitment to the extent you are able to do so; in terms of time line, resources required, people potentially impacted. Please limit your response to no more than six lines of text per commitment. This information may inform a fact sheet, report, or similar document released publicly related to this initiative.

Announcement Details

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Please provide as much additional detail as you would like for each of the announcements/actions you described above. You are invited to expand upon the information above, provide background, and note any other information you believe is relevant to the commitment. Note: The subsequent section provides space to describe pre-existing efforts.

Ongoing Efforts to Address [Challenge]



If you are interested in describing existing efforts that your new commitment is building on, please do so above. Please limit a summary description to no more than four lines.

Other



Please feel to share, in succinct format, any other information that you believe would contribute to the success of this work going forward. This can include, for example, key facts and research findings, compelling examples, or ideas for increasing public awareness of this topic.

Source: "White House Call to Action on Closing the Digital Divide", The White House

Deliverable 9: Future directions

Twenty-first century government must be participatory and inclusive, open to sourcing good ideas from anywhere. Leveraging convening power to align public and private sector commitments is an approach that tracks with an evolution towards collaborative governance. "As leadership shifts away from hierarchical decisions-at-the-top-slowly-cascading-downward, to social networks and self-organizing,

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knowing how to use convening power becomes critical, writes Harvard professor Rosabeth Moss Kanter Kanter, R., "How to Use Convening Power", Harvard Business Review, September 2011].

Beyond assessing which other issue areas would benefit from the spotlight of a call to action, senior leadership should reflect strategically on the further potential for change as they structure future convenings. For instance:

- How could we further capitalize on the potential for change from multi-stakeholder collaborations?
- How could we encourage the development of more collaborative, synergistic relationships among the stakeholders that respond to our call to action?
- How can we better utilize technology through backbone organizations to build more collaborative partnerships, assess on shared goals and metrics, and better understand indicators for success or failure?
- What more can be done to encourage respondents to achieve scale and scope around more carefully tailored goals and metrics?
- How to crowd in private investment into multi-stakeholder initiatives launched by the Federal government?
- How to develop multi-stakeholder initiatives that are sustainable independently once incubated or encouraged by government?

Read more: Understanding New Power, Harvard Business Review, December 2014.

Deliverable 8: Examples of policy that have enabled or encouraged approach (legislation, exec order)

Because aligned strategic commitments explicitly do not rise to the level of formalized partnerships, they are not bound by the same legal considerations for more formal public-private partnerships. However, calls to action and aligned commitments are consistent with recent efforts to expand public and civil society participation and to create more open, participatory, and collaborative government:

"2016 Agency Open Government Plans." OMB M-16-16. July 14 2016

"President's Memorandum on Transparency and Open Government - Interagency Collaboration." OSTP, OMB, GSA M-09-12. Feb 24 2009

The Open Government Partnership: Third Open Government National Action Plan for the United States of America, October 27, 2015.
Third plan of efforts to promote transparency and accountability after consultation with partners

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The Open Government Partnership: Second Open Government National Action Plan for the United States of America, December 5, 2013.
Second plan of efforts to promote transparency and accountability

The Open Government Partnership: National Action Plan for the United States of America, September 20, 2011.
Efforts to promote transparency and accountability

Deliverable 7: Online inventory of resources

Contact

Agencies interested in gaining more insight about crafting strategically aligned commitments and creating multi-sector collaborations are welcome to contact the following individuals:

- Talia Milgrom-Elcott at tme@100kin10.org
- Joe Kochan at joe.kochan@us-ignite.org

Resources on Convening Power and Commitments

Gather: The Art & Science of Effective Convening
Free digital guidebook for designing convenings, based on extensive research (both a survey of existing literature and interviews of practitioners). "While convening design is not a plug-and-play process, we discovered a set of critical steps and processes that can increase any convening's chance of success."
Watch a 2 minute video summary on the key concepts surrounding effective convening.

Borgman, S., "The Power of Convening for Social Impact", Stanford Social Innovation Review, March 2016.
The powerful communication strategy of bringing people together

"Understanding the Spectrum of Collaborative Governance Practices", Kitchen Table Democracy (formerly Policy Consensus Initiative).
3 page excerpt covering principles of collaborative governance, misconceptions about consensus processes, and the stages of a collaborative process

"The Role of Convener", Kitchen Table Democracy (formerly Policy Consensus Initiative)
3 page excerpt details best practices for a convening facilitator

Neal, C. and Neal, P., The Art of Convening, 2011.
Guidance for how to address emotional and psychological dimensions of participants' experience

Calmes, J., "Obama Counts on Power of Convening People for Change," New York Times, January 2014.

Convening for collective Impact

Resources from the Collective Impact movement can help contextualize the convening approach, as well as provide actionable guidance for its implementation.

[APG]

"Collective Impact Toolkit", Clear Impact, 2016.

Watch:
Hanleybrown, F., Jesudason, S. and Kanyagia, A., "Is Collective Impact the Right approach for you?", FSG.
72 minute webinar explains the collective impact framework and how to deploy it

Abbate, A., Kania, J. and Stevenson, A., "Collaborating to create a common agenda", FSG.
90 min webinar which covers:

- "How to get to a common understanding of the problem being addressed—What is in? What is out?
- How to conduct research and identify potential indicators for progress
- How to establish ownership and buy-in from key stakeholders and implementers"

Kania, J., McCarver, C. and White, E., "Setting the Scene for Collective Impact", FSG.
88 min webinar which covers:

- How to identify champions and form a cross-sector group
- How to map the landscape and use data to define the problem and make the case for change
- How to include the voices of community members

Resources for public engagement
U.S. Public Participation Playbook

Lukensmeyer, C., Goldman, Joe. and Stern, D., "Assessing Public Participation in an Open Government Era: A Review of Federal Agency Plans",IBM Center for the Business of Government, 2011.
Research into what a more open and participatory government looks like.

Leighninger, M.,"Using Online Tools to Engage – and be Engaged by – the Public", IBM Center for the Business of Government, 2011.
Describes ten different tactics public managers may find useful for engaging the public online, highlighting more than 40 different technologies in use today to support those kinds of engagements.

"Integrating Collaborative Activities: Public Deliberation with Stakeholder Processes", National Policy Consensus Center.
This 38 page report examines how leaders can create even better solutions through collaborative governance processes, examining U.S. case studies where public deliberation and stakeholder processes have enhanced outcomes.

Holman, P. et al., The Change Handbook: The Definitive Resource on Today's Best Methods for Engaging Whole Systems, Berrett-Koehler Publishers, 2006
Covers over 60 tools for facilitating group interactions; includes appreciative inquiry, community summits, dynamic planning, open space, and scenario planning.

[APG]

Resources for other collaborative stakeholders

For implementing staff:

Bingham, L. and O'Leary, R., "A Manager's Guide to Resolving Conflicts in Collaborative Networks", Kitchen Table Democracy, 2007.

A 50 page report that addresses a critical set of skills— negotiation—needed by all managers involved in collaborative networks.

"Guide To Taking Notes And Preparing Meeting Summaries"Center for Collaborative Policy, California State University Sacramento.
A 11 page guide that details best practices for documenting collaborative dialogue. It covers "how to listen, how to distill comments, and how to reframe comments with vocabulary that honors a concern yet takes off any potentially aggressive or offensive edge."

For universities:

"Finding Better Ways to Solve Public Problems: The Emerging Role of Universities as Neutral Forums for Collaborative Policymaking" Policy Consensus Initiative, June 2005.
A 20-page report on the emerging role of universities as forums for collaborative approaches to public policymaking.

For funders:

Scearce, D., "Catalyzing Networks for Social Change: A Funder's Guide", Monitor Institute and Grantmakers for Effective Organizations, 2011.
Describes how convenings are integral to catalyzing networks and creating new opportunities.

For philanthropy:

Ferris, J. and Williams, N., "Philanthropy and Government Working Together: The Role of Offices of Strategic Partnerships in Public Problem Solving" Center on Philanthropy and Public Policy, University of Southern California, 2012.
How and why offices for public-private partnerships are created and how they function.

For private sector partners:

Kramer, M. and Porter, M., "Creating Shared Value", FSG and Harvard Business Review, 2011.
Article and motion graphic on how success for business and society is interdependent.

White, D., "Business Collaboration with Government: Does Reward Outweigh Risk?", Stanford Social Innovation Review, November 2016.
White argues that the challenges the world faces need both private and public sector participation.

Further reading:

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Leighninger, M., The Next Form of Democracy: How Expert Rule is Giving Way to Shared Governance – and Why Politics Will Never Be the Same, Vanderbilt University Press, 2006.

Sawyer, D. and Ehrlichman, D., "The Tactics of Trust", Stanford Social Innovation Review, 2016

Satish Nambisan, "Transforming Government Through Collaborative Innovation," IBM Center for The Business of Government, 2008.

Annex of interviews and reviewers:
Aneesh Chopra, former US CTO
Miyoung Chun, Kavli Foundation – August 11
Tom Kalil, OSTP – August 1
Joe Kochan, USIgnite – August 16
Talia Milgrom-Elcott, 100kin10 – August 16
Kumar Garg, OSTP
Aadil Ginwala, OSTP
Nick Maynard, US Ignite

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Vertical 3. Identify and pursue Grand Challenges

Outline:

1. **An "elevator pitch," which provides highlights of the content, such as why the approach is important, how it works, and examples of where it has worked.**
2. **A short, digestible summary of underlying premises and rationales, supported by research (i.e., not a report).**
3. **Profiles of major categories of candidate users, including specific examples of when, and under what circumstances, the approach may be employed, supported by research into the target audience and their needs.**
4. **One or more "success stories" or other learning narratives that highlight the impact of and justification for using this approach.**
5. **Documentation of challenges to deployment, and potential limitations of the approach, including barriers or obstacles encountered within agencies employing the approach.**
6. **A "How-To" document, detailing key steps for deploying the approach, including promising practices in adaptation and deployment.**
7. **An online inventory of resources.**
8. **Examples of policy (e.g. legislation, Executive Order, etc.) that have enabled or encouraged the approach.**
9. **Future directions (next practices as opposed to best practices).**

Pull quotes: [[For web designer]]

"A Grand Challenge can create and disrupt powerful culture and power paradigms inside of an industry or organization, embracing new players and stimulating long-time experts to lead differently." Dave Ferguson, Director for the Center for Development Innovation, the U.S. Global Development Lab at USAID [Ferguson D., personal communication with Policy Design Lab, November 10th, 2016]

"The secret sauce to a Grand Challenge is in the goal definition. Everything else is about creative program design." Cristin Dorgelo, Chief of Staff at the White House Office of Science and Technology Policy (OSTP) and formerly Vice President of Prize Operations at the XPRIZE Foundation [Dorgelo C., phone interview with Policy Design Lab, August 3rd, 2016]

"By defining our goal more clearly, by making it seem more manageable and less remote, we can help all peoples to see it, to draw hope from it, and to move irresistibly towards it." President John F. Kennedy

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Deliverable 1: Elevator pitch summary

[[Website embed: 18 second clip of Obama introducing Grand Challenge concept]]

A "Grand Challenge" is an articulation of an ambitious yet achievable goal that captures the public's imagination. The power and the value of the Grand Challenge framework lie in its ability to galvanize action. By using Grand Challenges to issue a call for new and audacious thinking, agencies can catalyze significant advances for national priorities. A pioneering vision, large-scale collaborative effort, and an ambitious but concrete target are the defining hallmarks of Grand Challenges that spur transformative breakthroughs:

- **Grand vision:** Explicitly setting grand, ambitious targets – like making solar energy as cheap as coal, understanding the human brain, or destroying cancerous tumors while leaving healthy cells untouched – galvanizes public excitement and draws in new communities of solvers. The term itself suggests a sense of daring and boldness is required [Hicks, D., "Grand Challenges in US Science Policy Attempt Policy Innovation," International Journal of Foresight and Innovation Policy, 2016, pp. 5]. Grand Challenges must be captivating and intrinsically motivating, so much so that many people should be willing to devote a good chunk of their career to the pursuit of one of these goals.
- **All hands on deck:** Grand Challenges can accelerate the rate of progress on sticky problems by engaging a coordinated, "all-hands-on-deck" approach with multi-sectoral collaborations. Agencies can augment their impact by involving contributions from other agencies, foundations, research universities, companies, and citizens.
- **Ambitious yet achievable:** The key lies in a willingness to set bold, audacious goals: Historical examples include landing a man on the moon, the Human Genome Project, and Wikipedia. But Grand Challenge targets must be well defined with a "Goldilocks" level of specificity and focus. "Improving the human condition" is not a Grand Challenge, because it does not provide enough guidance for what to do next or how to measure progress. While "landing a man on the moon and returning him safely to the earth" is daring and ambitious, it is also inherently clear whether it has been achieved.
- **Flexible framework:** Grand Challenges are galvanizing frameworks through which a variety of implementation mechanisms can be used to engage new solvers – including challenge funds, prize competitions, crowdsourced innovations, and strategic partnerships.

Why

Consider using this framework when confronting open-ended policy challenges of considerable magnitude and complexity where there is no obvious solution, but it is possible to envision a different path forward. The call for a Grand Challenge is a priority statement; when it is followed by concerted effort to source new thinking and spur new collaborations through a variety of implementation

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modalities, there is potential for significant progress. Grand Challenges are powerful levers for shifting the framework not only in science and research policy, but also for domains such as health, energy, sustainability, education, economic opportunity, national security, and human exploration.

Grand Challenges can address the biggest problems of our time by:

- Helping to create the industries and jobs of the future;
- Expanding the frontiers of human knowledge about ourselves and the world around us; and
- Serving as a "North Star" for collaboration between the public and private sectors. [CROSSLINK PPP]

How

Grand Challenges are best suited for confronting open-ended, sticky problems with no pre-defined solutions, where "what if?" ambitious thinking can generate new approaches. It's an appropriate tool to consider for societal challenges that need to be worked at scale and with an interdisciplinary approach. Grand Challenge deployments are unique to each agency context, but three overarching themes emerge from program designs:

- An intermediate timeframe (not a year, and not 50 years)
- A quantified target
- Some commitment of resources

The quantified target – "We need to develop more effective ways of treating cancer" – functions as a declaration of priorities. But the resources marshaled to support this call to action can vary tremendously as appropriate for an agency's needs, either with the use of challenge funds, prizes, public private partnerships, or use of administrative authority. Agencies take a lead role by explicitly articulating important and ambitious Grand Challenge targets, and then convening funding and private sector commitments to help realize those goals.

A number of agencies are already using Grand Challenges to support their missions. For example, DOE's SunShot Grand Challenge seeks to make solar energy cost competitive with coal by the end of the decade, and NASA's Asteroid Grand Challenge aims to find and address all asteroid threats to human populations. USAID has eight active Grand Challenges for Development that address challenges in infant and maternal mortality, clean energy for agriculture, water for agriculture, early grade literacy, fighting Ebola, combatting Zika and future threats, accelerating access to off-grid energy, and improving government performance and accountability [A Strategy for American Innovation, National Economic Council and Office of Science and Technology Policy, October 2015].

Deliverable 2: Summary of underlying rationales / empirical research

Benefits of Grand Challenges:

The identification and pursuit of Grand Challenges has a number of benefits:

- Catalyzing innovations that foster economic growth and job creation;

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- Marshaling greater resources with multi-sector collaborations, leading to a greater impact with an "all hands on deck" approach;
- Aligning with the modern collaborative research environment, while offering a "new language" and framework for science and research policy;
- Spurring the formation of multidisciplinary teams of solvers, bringing new expertise to bear on important problems, and encouraging multi-sector collaborations;
- Strengthening the "social contract" between science and society; and
- Inspiring the next generation of scientists, engineers, and entrepreneurs to work on hard and important problems.

Grand Challenges can catalyze innovations that foster economic growth and job creation.
The Human Genome Project demonstrates the potential impact of ambitious research undertakings. From 1988 to 2003, the Federal government invested $3.8 billion in the Human Genome Project, which has since generated an economic output of $796 billion; a return of $141 for every $1 invested [Tripp, S. and Grueber, M., "Economic Impact of the Human Genome Project", Battelle Memorial Institute, May 2011].

Grand Challenges can architect multi-sector collaborations with "all hands on deck" to generate transformative outcomes
Numerous companies have undertaken their own audacious Grand Challenge goals in recent years. Google's self-driving car is a direct outgrowth of the DARPA Grand Challenge. IBM's advances in AI have been driven by Grand Challenge frameworks – including Big Blue that beat Gary Kasparov at chess, and Watson which defeated Ken Jennings at JEOPARDY. Companies and philanthropies can also play a role by sponsoring major incentive prize competitions to address Grand Challenges, such as Qualcomm's $10 million Tricorder XPrize. Angel, venture, and impact investors could back start-ups that are pursuing Grand Challenges. Large companies could partner with these startups by serving as early customers and providing capital, mentoring, and milestone-based payments. Universities can create and launch learning opportunities, research initiatives, and capital campaigns to focus on ambitious Grand Challenge goals. Media companies and other storytelling enterprises could help elevate the role that Grand Challenges and innovators play in our culture—and help make engineers and entrepreneurs the rock stars of the 21st century. [Crosslink here: Prizes/Challenges, collective impact element of partnerships, citizen science crowdsourcing]

Grand Challenges have potential as a "new language" for research frameworks.
It's more than a rhetorical device. The Grand Challenge framing syncs with the "group effort" dynamic that increasingly characterizes research, leading some scholars to observe that Grand Challenges support the new emerging paradigm: "In contrast to the tired categories of basic and applied, Grand Challenges offers a research agenda more appropriate to our times, one that combines intellectual and practical motives, generating excitement to address problems so big that they exceed the capacity of specialist communities" [Hicks, D., "Grand Challenges in US Science Policy Attempt Policy Innovation," International Journal of Foresight and Innovation Policy, 2016, pp. 12].

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Grand Challenges inspires the next generation of scientists, engineers, and entrepreneurs to work on hard and important problems.

In the landmark 2008 Grand Challenges for Engineering report, a committee of world-class scientists and engineers issued a clarion call to the engineering field. The vision? For the engineering field – particularly academia – to orient itself around solving the biggest Grand Challenges facing humanity in the 21st century, including long-term energy solutions, carbon sequestration, cyber security, and advancements in personalized medicine. In embracing the Grand Challenge framework on such a fundamental level, the goal is to inspire the next generation to devote their life's work to solving these audacious challenges. A genuine shift in the field has begun to coalesce: In 2015, deans of 122 engineering programs announced their commitment to integrate Grand Challenge programs into their undergraduate curriculums, pledging that in a decade, 20,000 engineers will be trained to tackle these complex challenges.

References and further reading:

Diana Hicks, "Grand Challenges in US Science Policy Attempt Policy Innovation" International Journal of Foresight and Innovation Policy (2016).

Gerald Holton and Gerhard Sonnett, "A Vision of Jeffersonian Science." Issues in Science and Technology. Volume XVI Issue 1, Fall 1999.

Deliverable 3: Profiles of major categories of candidate users - examples of when to deploy

When/How to use:

Conditions and contexts are optimal for a Grand Challenge when officials are looking to raise the profile of a specific issue, garner multiple and diverse ideas for solving or understanding the problem, and promote cross-sector collaboration between the private sector, universities, researchers, and other public entities. "A Grand Challenge can be a powerful tool to disrupt traditional thinking in a sector and industry and introduce, expand, and evolve what is possible in that industry," says Alexis Bonnell, Division Chief of Applied Innovation, the U.S. Global Development Lab at USAID [Bonnell, A., personal communication with Policy Design Lab, November 10th, 2016]. It's most operative in a context where technological progress has shifted our collective understanding, making it conceivable to imagine that - with focused investment and work - we can render possible what was previously unthinkable. Grand Challenges can harness that potential and translate to real progress.

Such lofty narrative language is in fact where Grand Challenges derive their power. Agency practitioners report that the one of the most crucial ingredients for designing a Grand Challenge is articulating a grand vision to convey to the public and stakeholders. The framing helps shift the burden of proof from "Why would we do that?" to "Why *aren't* we doing that?" The potency comes from articulating not just the grand goal but also making the compelling case for why *now* is the moment for action.

Grand Challenges are powerful but flexible frameworks that accommodate multiple types of modalities. The inherent flexibility has encouraged agencies like USAID to tailor the program design of individual challenges in order to support the greatest holistic impact in each context. USAID has used the Grand

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Challenge call to action and then follows-on with a variety of tools for sourcing, funding, and implementation:

> "The Grand Challenge [framework] allows us to deploy multiple types of methodologies that hit on different parts of that problem; not just the supply of an innovation, but how do we catalyze more of an ecosystem approach, how do we bring more investment to the table? How do we adopt or apply that innovation into a more traditional programming approach? We have different approaches beyond prize and challenge funds to do that in this systems approach. The Grand Challenge gives us that galvanizing force to bring the partners together around the broader goal between this one innovation and the presidential priority. It allows us to play that middle ground of continuing to catalyze and connect these two dots."
> **Seema Patel, Division Chief, Innovation Design and Advisory, the U.S. Global Development Lab at USAID, reflecting how Grand Challenges have been a powerful tool for USAID in their work to tackle critical international development challenges [Patel, S., in-person interview with Policy Design Lab, July 7, 2016].**

There are common implementation ingredients – like imaginative framing, public-private collaborations, and competitive funding approaches that encourage novel solutions and remain agnostic about who the best performers will be. There may be regular convenings within the communities to encourage progress towards the goal, to find what next steps might be, or what needs or platform technologies might be best-suited. But not all Grand Challenge program managers use all of those ingredients in pursuing their Grand Challenge goal, notes Cristin Dorgelo, Chief of Staff at the White House Office of Science and Technology Policy (OSTP) and formerly Vice President of Prize Operations at the XPRIZE Foundation -- either because the goal being pursued didn't call for it, they haven't thought of it, or they don't have enough resources for those activities. [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]

Instead, an emerging taxonomy of Grand Challenge activities is best understood as a spectrum. At one end, a minimal deployment of the approach entails internal problem definition and goal framing work, with the agency then issuing a compelling goal challenge to the public and allowing further action to develop organically. (One example is The National Nanotechnology Initiative's Nano Grand Challenge for Future Computing, where the goal for nanotechnology grand challenges first was announced via blog posts. A public request for information and follow-on engagement work at industry-specific convenings spurred active discussion on what it would take to pursue such a goal, leading to the development of a white paper and statements of support from various agencies and organizations.) At the mid-point of the spectrum, Dorgelo points to efforts like the DARPA Grand Challenges -- including its most recent Cyber Grand Challenge -- which have a grand challenge goal but primarily rely on an incentive prize model, with additional elements of push funding and community convening [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]. At the far and most developed end of the spectrum, rigorous goal definition and announcement can be a lengthy process. For the Department of Energy's SunShot and EV Everywhere Grand Challenges, the process of internal problem definition was followed by an additional year of soliciting input from stakeholders around the country regarding additions or revisions to the stated goal definition [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016].

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Q: What distinguishes a Grand Challenge from prize challenges?
A: "Unlike prizes, where there are well-defined types of incentive prizes for particular types of problems, Grand Challenge programs so far have been designed in a very custom way, based on the goal itself, as well available resources," explains Cristin Dorgelo, Chief of Staff at OSTP and formerly head of prize operations at the XPRIZE Foundation [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]. In other words, a Grand Challenge program manager may choose to encompass a prize competition element as one aspect of their Grand Challenge program, but not necessarily.

Successful challenges demonstrate the array of possible approaches, from all-in funding commitments that fund and scale solutions, offerings to match funding from private and philanthropic sectors, commitments to source a prize without funding the resulting solutions, or even simply high-level commitments that create the space for other stakeholders to develop and fund implementation.

[[Website suggestion: Venn diagram graphic depicting overlap between Grand Challenges and other modalities, including prizes]]

SIDEBAR: History of Grand Challenges: [[embed separately on website]]
The understanding of a "Grand Challenge" framework has evolved considerably over the past 25 years from a narrow technical discipline to a broad call that extends beyond the scientific and research community. Kenneth Wilson first introduced the concept to the research lexicon in 1980 as part of the advocacy for high-performance computing. The High Performance Computing Act of 1991 defined Grand Challenges narrowly as "a fundamental problem in science or engineering, with broad economic and scientific impact, whose solution will require the application of high-performance computing resources and multidisciplinary teams of researchers." A dozen years later, the Bill & Melinda Gates Foundation recognized power and potential of the Grand Challenge framework, setting the stage for their Grand Challenges in Global Health. The elevation of the term by Gates was a milestone in the broader application of the concept. The Gates Foundation saw the agenda-setting power of the Grand Challenge framework as a way to articulate specific scientific or technological innovations that could break through critical research barriers to solving important global health challenges.

A second, concurrent milestone was the first instance of a Grand Challenge undertaken by a Federal agency (DARPA) in 2002. DARPA deployed the approach with the DARPA Grand Challenge for long distance trials of driverless vehicles. The National Academy of Engineering's *Grand Challenges in Engineering* followed in 2008.

In the past decade, with encouragement from the Office of Science and Technology Policy, the Grand Challenges framework has broadened further to encompass a wide range of disciplines. For more on how the common understanding of "Grand Challenge" has evolved in the past 25 years, see Dr. Diana Hicks' summary of the term's evolution [Hicks, D., "Grand Challenges: tracking a topos wandering through US science policy"].

References

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Diana Hicks, "Grand Challenges in US Science Policy Attempt Policy Innovation" International Journal of Foresight and Innovation Policy (2016).
The High Performance Computing Act of 1991
Gates Foundation, "Grand Challenges in Global Health" (2003).
2008 National Academy of Engineering Grand Challenges for Engineering

Deliverable 4: One or more "success stories" or learning narratives to underscore impact

Case studies

1. **DOE: SunShot**
2. **NASA: Asteroid Grand Challenge**
3. **USAID: Grand Challenges for Development**
4. **Grand Challenges Scholars Program**

Case Study 1: DOE: SunShot

[Ulrich, E., and DOE staff, personal communications and interviews with Policy Design Lab, December 2, 2016]

[[Embed 3 min intro video for SunShot]]

Launched in 2011, the Department of Energy's (DOE) SunShot Initiative is a Grand Challenge effort to make solar energy cost-competitive with conventional forms of electricity generation by the end of the decade (2020). The audacious goal -- to drive down the cost of solar electricity to $0.06 per kilowatt-hour or ~$1 per watt – arose from one question: What would it take for solar to become a large portion of nation's energy supply mix? Through SunShot, DOE has leapfrogged progress on an answer to this call, partnering with more than 450 awardees, funding cooperative research, development, demonstration, and deployment projects by private companies, universities, state and local governments, nonprofit organizations, and national laboratories. [Ulrich, E., and DOE staff, personal communications and interviews with Policy Design Lab, December 2, 2016]

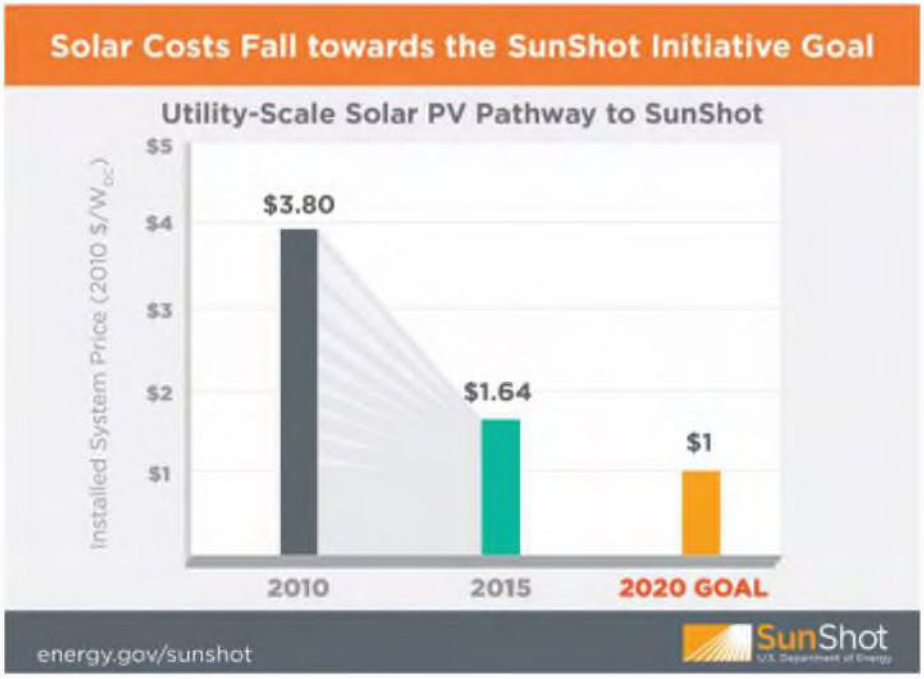
Five years into the Energy Department's decade-long SunShot Initiative, the solar industry is already more than 70% of the way to achieving SunShot's cost target. Longer-term goals are now being set, and one important learning from SunShot is how successful Challenges can sometimes wildly exceed their goals and evolve to push the bar even further.

Key accomplishments:

As a result of DOE's SunShot Initiative, investments and the industry's accelerated pace to meet the SunShot goal, solar-generated electricity is now price competitive with traditional energy sources in 14 states across the United States. [Ulrich, E., and DOE staff, personal communications and interviews with Policy Design Lab, December 2, 2016] Increased deployment of affordable and accessible solar energy continues to grow quickly across the country. Two key points deserve emphasis:

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- *Outstanding ROI:* DOE has spent roughly $2.3 billion on R&D, but net economic benefits total more than $15 billion to date. SunShot has been a catalytic focusing lens, generating significant economic and job growth in the solar industry.
- *Leapfrog Technical Advancement:* The country has more than 10 times more solar installed today than in 2011 when the SunShot Initiative was first launched [Delapez, J., "SunShot Reports: Solar Energy Progress and Challenges", Agri-Pulse, 2016]. Meanwhile, the overall costs of solar have dropped by over 65 percent:



How they did it:

The appeal of using a Grand Challenge framework for DOE was its cost-effective ability to promote scale and impact under a broad umbrella. For SunShot, DOE has held an annual summit; released research papers regarding technical milestones needed to achieve the goal; funded nearly 300 cooperative research, development, demonstration, and deployment projects; and also offered open prize competitions to fuel entrepreneurship and drive innovation in solar technology [Dorgelo, C., personal communication with Policy Design Lab, December 5th, 2016]. SunShot's broad articulation and interagency coordination also enabled a systems-level perspective to emerge during implementation, which highlighted the importance of certain aspects that needed increased attention. Prior to SunShot, there had been an overall cost goal, for example, with emphasis on the cost of cells and modules. But the learning gained through the initiative proved that even if the module were free, the cost goal couldn't be met without addressing other important areas particularly the work in grid integration and soft costs.

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Effective messaging has also been essential to the program's success. The program wasn't originally launched as SunShot; the name came later. Building a brand identity was a central part of establishing the program's narrative.

Key learning insights:

- **Use Grand Challenges to spur holistic impact**
- **Set a big (and timely) goal that can be sufficiently funded**
- **Use a wide variety of funding mechanisms**
- **Hire the right people – and have senior leadership support**
- **Continually iterate and refine processes**

Use Grand Challenges to spur holistic impact

SunShot exemplifies how systems-level perspectives can emerge from Grand Challenge frameworks, and how investing in holistically understanding the problem can lead to more effective problem-solving to advance technology *and* integrate it into the marketplace. SunShot program staff spent a year soliciting feedback from stakeholders into program definition, identifying five areas where innovation was needed: photovoltaics, concentrating solar power, systems integration, soft costs, and technology-to-market. After integrating stakeholder feedback and developing technology white papers, Dorgelo explains, DOE "took their existing solar-technology funding streams and oriented them towards what they had heard would be needed to achieve the overall goal through advances in those five technology areas" [Dorgelo, C., personal communication with Policy Design Lab, December 5th, 2016]. The integrated portfolio approach across multiple technology paths and stages, coupled with collaboration across Federal agencies helped the program to make impacts across the U.S. solar value chain. Iterative assessment of the state of the industry, market and existing programs helped the program to maintain agility.

Set a big (and timely) goal that can be sufficiently funded

Big ideas evolve from issues of our time. A Challenge needs to inspire people to want to propose solutions and be incentivized enough to make it worth their time. Considerable research and industry consultation went into the $1 goal, which fell just outside of what industry felt at the time was feasible. $1 billion was allocated in pursuit of the goal. [Ulrich, E.,personal communication with Policy Design Lab, December 2nd, 2016]

Use a wide variety of funding mechanisms

"In SunShot's case, they used a wide variety of funding mechanisms, including prize competitions as well as funding awards for cooperative research, development, demonstration, and deployment projects," notes Cristin Dorgelo. "They looked holistically about what type of funding would make most sense for certain aspects of pursuing the goal, and deployed standard funding mechanisms such as grants and contracts, but also incentive prizes where appropriate" [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]. Prize competitions, for instance, were a good fit for driving entrepreneurship and meeting software needs that could reduce solar soft costs – by using short timeframes and smaller funding rates, it encouraged software companies to lower hurdle rates. The variety of funding

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approaches also recognized the other kinds of value the program could bring to the table through data and information assets, analyses, training, convenings and by working with stakeholders to identify the right questions to answer together to keep the industry moving forward.

Hire the right people – and have senior leadership support
The Challenge required a highly trained technical team for active management of the grants. A concerted push was made with grantees to assess whether projects would yield results competitive with forward looking estimates for current technologies and approaches, with an overarching emphasis on the ambitious quantitative goal. (This meant that if it would take 10 years for a solution to mature and gain market acceptance, it would have to be competitive with cost reduction curves on current technologies in that same 10 year horizon.) Leadership from the top was also key for ensuring continued, unwavering support for these goals. The Secretary of Energy was integrally involved in the effort.

Continually iterate and refine processes
Internal process improvements piloted within the SunShot program led to updates to how all grants and cooperative agreements were selected and managed within EERE. The time from announcement to award was reduced from about 18 months, to 6 months to keep up with the rapidly changing technology and market environment.

To Learn More:
DOE SunShot factsheet
On the Path to SunShot: A series of 8 reports
SunShot Vison Study: 5-Year Assessment
SunShot Catalyst: "Next Generation of Prize Challenges"
SunShot 2030

Case Study 2: NASA - Asteroid Grand Challenge
Case study derived from interviews with Jenn Gustetic [phone interview with Policy Design Lab, July 25, 2016] and Jason Kessler [phone interview with Policy Design Lab, November 11, 2016].

[[Embed NASA's 2 minute introduction video]]

NASA's Asteroid Grand Challenge (AGC) aims to find and address all asteroid threats to human populations and figure out what to do about them. The Challenge statement is "find all asteroid threats to human populations and know what to do about them." With estimates suggesting less than 10% of objects smaller than 300 meters in diameter and less than 1% of objects smaller than 100 meters in diameter have been discovered, a global effort with innovative solutions is necessary to accelerate the completion of the survey of potentially hazardous asteroids ["Grand Challenge", NASA, June 2013].

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Launched in June 2013, the Challenge is a large-scale effort reliant on multi-disciplinary collaborations and a variety of partnerships with other government agencies, international partners, industry, academia, and citizen scientists to detect, track, characterize, and create mitigation strategies for potentially hazardous asteroids. The AGC demonstrates how the Grand Challenge framework can help to shift the policy environment, while also showing the power of engaging citizen solvers through public appeals for help.

Key accomplishments:

The AGC is an example of how Challenges can seed and sustain continued work in critical mission areas. Marrying serious science and smart engagement with the public (one tag line: "Dinosaurs didn't have a space program"), the Challenge framework and its successes drew significant attention to the program and helped to accelerate NASA's cataloging capabilities for near-earth objects. As a result, the budget for the Near-Earth Object Observations Program more than doubled from $20.4 million in FY2012 to $50 million in FY2016. (Previously, the program had received $4 million per year since the 1990s) [Gustetic, J., phone interview with Policy Design Lab, July 25, 2016].

NASA's Asteroid Grand Challenge Components:

1. Detect: Find the asteroid objects
2. Track: Figure out how to quickly and accurately measure the object's orbit
3. Characterize: Once the orbit is known, learn more about the asteroid's composition
4. Mitigate: Study mitigation solutions, so we'll know what to do if a threat is identified

How they did it:

NASA invested heavily in problem definition at the outset in order to broaden engagement with potential solvers. NASA first used a brainstorming technique ("Big Think") to select a Grand Challenge focus. From there, deconstructing the chosen problem area through a process of problem decomposition was essential: "We wanted to see if there was a way to engage a broader audience and bring a new community to think about this problem in a different way," explains Jason Kessler, formerly NASA's Asteroid Grand Challenge Program Executive [Kessler, J., phone interview with Policy Design Lab, November 11, 2016]. With the help of researchers at George Washington University's systems engineering program, NASA was also able to leverage insights from third-party academic participants. Their observations were useful for decomposing the problem so that "non-expert" groups could meaningfully participate -- for instance, citizen solvers could volunteer labor for pattern recognition, and "distant experts" (experts in other fields) could contribute specialized knowledge [Gustetic, J., phone interview with Policy Design Lab, July 25, 2016].

Key learning insights:

- Problem definition enables meaningfully engagement by citizen solvers, even in technical problems
- Powerful narratives can drive engagement, but decomposed problems also require segmented messaging
- Co-creation and collaborative partnerships are essential
- Follow-on engagement should be integrated into program implementation

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Problem definition enables meaningfully engagement by citizen solvers, even in technical problems

The overriding message of the Asteroid Grand Challenge was that asteroid hunting is an activity everyone can get involved in. "With projects like Asteroid Data Hunter, NASA proved that it could think through 'NASA-hard' programs and find places where the crowd can meaningfully contribute," observes Jenn Gustetic, program executive for NASA's Small Business Innovation Research (SBIR/STTR) division [Gustetic, J., phone interview with Policy Design Lab, July 25, 2016]. Defining the problem into four parts made it possible to ask for engagement from every level, from deep technical experts to leveraging motivated citizens willing to write computer code, build hardware, observe through a telescope, tell stories, and publicize the issue.

At the same time, observes Kessler, program managers should recognize the cultural challenges as well as the time and energy required to engage with technical experts in the problem definition process [Kessler, J., phone interview with Policy Design Lab, November 11, 2016]. It's essential to find technical experts that can describe the problems without explaining *how* they would solve the problems. It requires additional initial work, but collaboration with experts can enable challenge owners to better understand how a problem could be examined by others in a new light.

Powerful narratives can drive engagement – but decomposed problems also require segmented messaging

Developing a solid narrative to enable a meaningful conversation with the public was a critical first step, observes Kessler [Kessler, J., phone interview with Policy Design Lab, November 11, 2016]. The idea of "everyone as an asteroid hunter" was a powerful way to further involve the public in NASA's work. Asking for the public's help was a powerful narrative; by framing the call as, "We can't do this alone, we need you," it drew in motivated citizen scientists and experts alike.

At the same time, segmented messaging that is appropriate and sensitive to each group is required. An existing small community of scientists had been doing "amazing work on a shoestring," recounts Kessler, but some of the initial public messaging seemed to discount the technical challenges they had overcome managed on a daily basis [Kessler, J., phone interview with Policy Design Lab, November 11, 2016]. A segmented, targeted communications plan should be embedded in program implementation, with the goal of ensuring that all relevant constituencies are engaged and motivated. It's especially important to engage expert communities early, to build relationships and ensure that public engagement outcomes can be more easily integrated into existing systems and processes.

Co-creation and collaborative partnerships are essential

NASA's AGC is also an example of agency-driven co-creation, where the agency played a key role in coordinating discussions among global partners. Concerted efforts were made by the agency to think through which aspects of the Grand Challenge could involve not just the general public, but also international actors and other federal agencies. The program enabled NASA to partner with industry and academia in new ways, and gave the Near-Earth Object office the ability to quickly form partnerships with entities they had not worked with before [Gustetic, J., phone interview with Policy Design Lab, July 25th, 2016].

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Integrate follow-on engagement into program implementation

While resource constraints can be a limiting factor, sustaining follow-on engagement can continue to accrue value for agencies. The Grand Challenge motivated great deal of interest and potential for continued engagement from the newly formed community. "There were connections made by people who had never talked together, but could really benefit from collaboration," notes Kessler[Kessler, J., phone interview with Policy Design Lab, November 11, 2016]. He recommends that where possible, program planners invest in infrastructure than can enable communities of solvers to flourish.

To Learn More:

What is the Asteroid Grand Challenge?
What Makes the AGC a Grand Challenge?
3 minute video: "Find them Now"
More recordings and transcripts from the 2014 First Anniversary Event of AGC

Artifacts/Key Historical Documentation:

- Near-Earth Object Survey and Deflection Analysis of Alternatives Report to Congress March 2007
- White paper on the 2013 Planetary Defense Conference
- National Research Council report, Defending Planet Earth: Near-Earth Object Surveys and Hazard Mitigation Strategies, January 2010
- Report of the NASA Advisory Council Ad Hoc Task Force on Planetary Defense, October 6, 2010
- NASA Near Earth Object Survey and Deflection – Analysis of Alternatives Report to Congress, March 2007

Case Study 3: USAID - Grand Challenges for Development

Case study and all figures herein derived from interviews with Seema Patel, Ann Mei Chang, and Tony Bloome, Alexis Bonnell, Karen Clune, Grace Hoerner, Chris Jurgens, Bruce Kay, Marissa Leffler, Ku McMahan, and Ryan Shelby

USAID's Grand Challenges for Development (GCDs) are effective programmatic frameworks that focus global attention and resources on specific, well-defined international development problems and promote the innovative approaches, processes, and solutions to solving them.

Conceived, launched, and implemented in coordination with public and private sector partners, Grand Challenges for Development (see list) emphasize the engagement of non-traditional solvers around critical development problems. The Grand Challenges for Development approach is a complement to USAID's current programming methods, with each GCD is led by experts at the bureau level. These experts work directly with partners to implement the day-to-day activities of the program.

Despite this decentralized approach, there is collective movement that prioritizes systems-level thinking. "It's not enough to simply source innovation," explains Ann Mei Chang, Chief Innovation Officer of the Global Development Lab at USAID: "We must overcome the barriers to adoption and scale, whether that's an organizational limitation like talent, or bringing the right ecosystem of partners including government, investors, and industry together." [Chang, A., In-person interview with Policy Design Lab, July [AMC]

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Furthermore, the Grand Challenges for Development programs show how the power of the framework can be leveraged through a variety of modalities, including partnerships, prizes, challenge grant funding, crowdsourcing, hack-a-thons, ideation, commit fairs, and massive online open courses. [crosslink to Partnerships, Prizes/Challenges] To date, USAID has launched eight Grand Challenges with 18 public and private sector partners to address critical challenges in development, including:

- Saving Lives at Birth a partnership of USAID, Grand Challenges Canada, The Bill and Melinda Gates Foundation, the Government of Norway, UKAid, and the Korean International Cooperation Agency, was designed to increase access to groundbreaking prevention and treatment approaches for pregnant women and newborns in poor, low-resource communities around the 48 hours of delivery.
- All Children Reading brings together USAID, World Vision, and the Australian government to dramatically increase the number of children in low-income countries who leave primary school with basic reading skills.
- Powering Agriculture: An Energy Grand Challenge for Development (2012) is a partnership between USAID, the Swedish International Development Cooperation Agency (SIDA), the German Ministry for Economic Cooperation and Development (BMZ), Duke Energy, and OPIC, that supports clean energy innovations that (1) enhance agricultural yields and productivity; (2) decrease post-harvest losses; (3) improve farmer and agribusiness income; and (4) increase energy efficiency within the operations of farms and agribusinesses to help end extreme poverty and extreme hunger.
- Making All Voices Count supports citizens and governments use of innovation, web, and mobile technologies to improve government performance and accountability.
- Securing Water for Food helps farmers around the world grow more food using less water, enhance water storage, and improve the use of saline water and soil to produce food by ensuring that the entrepreneurs and scientists behind groundbreaking new approaches are getting the support they need to apply and expand their solutions around the world.
- Fighting Ebola sought to address key gaps in the response to the largest Ebola epidemic in history.
- Combating Zika and Future Threats, aims to generate cutting-edge approaches to fight the current Zika outbreak and help strengthen the world's ability to prevent, detect, and respond to future infectious disease outbreaks.
- Scaling Off-Grid Energy, a partnership between Power Africa, USAID, the U.K. Department for International Development, and the Shell Foundation, which aims to accelerate growth in the off-grid energy market with a goal to provide 20 million households in sub-Saharan Africa with access to modern, clean and affordable electricity by 2030.

Key Accomplishments (Impact): []

[All figures herein sourced directly from USAID program managers, personal communication with Policy Design Lab, November 10th, 2016.]

As a result of USAID's investment in Grand Challenges for Development (as of 10/2016), Saving Lives at Birth has funded 94 innovations through 111 awards and reached 1.5 million women and newborns and

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saved nearly 10,000 lives. Securing Water for Food has funded 30 innovations that has saved more than 2 billion liters of water for agriculture and produced 300,000 tons of food for more than 1,000,000 farmers and other customers. Powering Agriculture has supported 24 innovators that have helped keep 2,244 metric tons of carbon dioxide out of the atmosphere and reached more than 200,000 customers with clean energy agricultural solutions.

Grand Challenges allow USAID and its partners to be a driver of innovation in markets that are underserved or perceived to be high risk. They signal demand and also allow for risk-sharing of investments across a number of donors. This has resulted in:

- **Leveraging of Resources**: GCDs leverage the expertise, resources, and assets of partners. Across the GCD portfolio, $312 million has been jointly committed (of which $170 million has been provided by USAID). In addition, some innovators supported by GCDs are then recognized and supported by others. To date, GCD innovators have raised at least $61.4 million in additional capital.

- **Democratizing Innovation:** The GCD approach makes it easier for those who have not worked with USAID previously to engage. Since 2011, USAID has received more than 8,500 applications and awarded more than 270 seed, validation, and transition grants (staged funding) to innovators in more than 60 countries. These results suggest improved outreach in sourcing new solutions from those closest to the problems, new ideas from non-traditional actors, and providing new opportunities for small and local businesses. For example, Powering Agriculture released two Global Calls for Innovations in December 2012 and November 2014. The first call received 473 applications (55% from developing countries) and the second call received 871 applications (62% from developing countries.) Recently, Securing Water for Food's fourth round call for applications yielded 555 applications. Of those applications, 89 percent were from organizations that had not previously applied for funding from USAID, and 76 percent were from developing countries.

In addition, USAID's experience demonstrates the substantial benefit of highly visible market signaling. "Grand Challenges drive value, with outcomes that often are difficult to measure. We tend to measure innovator impact as that helps us determine our immediate progress," notes Seema Patel, "but there's impact through formulating new partnerships and creating a market signal that motivates additional R&D" and other kinds of spillover ROI. [Patel, S., phone interview with Policy Design Lab, July 29, 2016.]

The media attention of the Grand Challenge also helps to drive mission progress forward; it not only reflects positively on the "brand" of the Federal government for the general public, but crucially, it focuses attention around problems worth solving and worth thinking about. For example, Grand Challenges for Development generate significant press coverage for its innovators that helps socialize and promote the adoption of solutions. Some key wins include the significant coverage Fighting Ebola received around its innovations, which has helped reduce timelines to market. Saving Lives at Birth's Odon Device, which provides a simplified way to deliver babies during prolonged labor, has received widespread press attention. Securing Water for Food's Adaptive Symbiotic Technologies was able to

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raise $3.4 million of Series A funding based on coverage in press of its microbial seed treatment innovation [USAID program managers, personal communication with Policy Design Lab, November 10, 2016].

How they did it:

Each Grand Challenge for Development is its own unique prototype, conceived, tailored for the domain and particular challenges associated with a specific development problem, and led Iterative refinements also reflect AID's continuous learning and evaluation. The overriding theme is one of heavy engagement with stakeholders and a reliance on partnership – from sponsors, to partnerships at the activity level, carrying out implementation, and partnering for media communications and scaling. The emphasis on partnership carries into how USAID engaged issues of problem definition, where a first principle is: Find someone else who agrees this is a problem to solve.

Because Grand Challenges take considerable talent and resources for effective execution, USAID has found it most effective to complement agency resources with sourcing external partners in a range of areas, from management of the process, partners for communications and outreach, and partners to help run acceleration and pitch training for innovators.

Key Learning Insights:

- **Define the problem with stakeholder input**
- **Commit resources to multi-year engagement strategies**
- **Leverage the framework's flexibility Put innovation on the fast-track to scale**
- **Continuously learn and refine**
- **Build a community**

Define the problem with stakeholder input

Each Grand Challenge for Development required a significant investment in problem identification to frame the challenge call. This step is essential: It takes the right problem, right partners, and right activities to catalyze global action and create an opportunity for problem-solving. Problem definition work begins broadly, with additional criteria added as the challenge framing is refined. The development phase focuses not just on understanding the problem, but also the market of potential solvers. Partnership is critical, even in this early stage of iterative problem definition. Barrier analysis and state of innovation assessments are key parts to the problem definition process; first identifying what the barriers are to solving, and next taking stock of the existing landscape to understand what sort of call to action is most needed. For instance, is it a technology gap? Or are there already broad solutions out there that need support in order to be viable and scale? Early conversation with partners can enhance understanding of the technical obstacles.

Commit resources to multi-year engagement strategies

To capture the full value of the Grand Challenge for Development framework, invest resources in bringing new solvers to the table. "You don't just put the call out there and expect people will come; you don't motivate new solvers that way," explains Seema Patel [Patel, S., phone interview with Policy

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Design Lab, July 29, 2016. If you want to broaden the community base of problem-solvers, you must have a constant drumbeat through activities and communications. Planning an engagement and communications strategy on a multi-year trajectory, time is needed to build momentum, and catalyze enough activity that a self-sustaining marketplace emerges [Patel, S., phone interview with Policy Design Lab, July 29, 2016].

Leverage the framework's flexibility

Each Grand Challenge for Development has been uniquely structured by technical staff throughout the Agency to most appropriately address the specific problem identified. The variations in the Grand Challenges for Development exemplify how agencies can mix and match modalities for solving within the Grand Challenges framework; in some cases, it was most appropriate to leverage private sector partnerships, while others used an Request for Applications (RFA) to call for grant intake. "There's been a lot of range of experimentation of methodology under the Grand Challenge framework," explains Seema Patel [Patel, S., phone interview with Policy Design Lab, July 29, 2016]. "All of the teams have experimented under the Grand Challenge blueprint to address different parts of the systemic barriers to source innovations to integrate and scale."

In all cases, the value of the framework emerged from the convening power. The call to action – the creation of a sense of urgency and feasibility – draws in the many stakeholders necessary in order to execute meaningful innovation and progress. [Crosslink V5/GDA case study]

Put innovation on the fast-track to scale

"Uncovering an innovation is inconsequential if it is not going to be used or adopted, or if that innovative organization cannot overcome their barriers to success," notes Alexis Bonnell [Bonnell, A., personal communication with Policy Design Lab, November 10, 2016]. Grand Challenges for Development have evolved to include acceleration services (support to innovators other than grant funding) to help innovators and their solutions to reach customers and end-users and overcome organizational barriers. This is achieved through customized technical assistance that helps solvers to establish and meet aggressive targets. "When we fund innovation, it isn't just writing a check. We agree very specifically on the targets and performance growth path of that innovation, and we stage our funding to align with those targets. Innovation must ultimately be accountable for impact. But we don't leave innovators hanging. We provide assistance and support beyond just the money," said Dave Ferguson [Ferguson, D., personal communication with Policy Design Lab, November 10, 2016].

Further, Grand Challenges for Development leverage the power of USAID's networks to support innovators' long-term growth goals by helping them connect with commercial investment and financing, companies and organizations interested in innovation, and public sector and non-governmental organizations seeking solutions. "Innovation must be tied back to the traditional business of the Agency. If we source an incredible innovation but no one uses it, then it doesn't matter. We complement our innovation sourcing work through approaches like Grand Challenges for Development with thoughtful matchmaking to integrate and incorporate the innovations that are discovered into USAID's programs both with players inside the organization and outside. If you stop at discovery, the vision goes

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unrealized," said Alexis Bonnell [Bonnell, A., personal communication with Policy Design Lab, November 10, 2016].

Continuously learn and refine

USAID's experience in deploying Grand Challenges reflects a process of continuous learning and refinement. "Saving Lives at Birth, USAID's first Grand Challenge for Development, helped set the stage and build a framework for Grand Challenges for Development across the Agency. The programs that followed have incorporated new elements such as crowdfunding, incentive prizes, and diverse acceleration service offerings. Further, even within a GCD, each subsequent call for innovations incorporates lessons learned from previous calls. Powering Agriculture and Securing Water for Food, for example, revised requirements for later calls based on learnings from earlier rounds to bring in higher-quality, later-stage innovations. Scaling Off-Grid Energy, a Grand Challenge for Development founded by USAID, Power Africa, the UK Department for International Development and Shell Foundation is the culmination of lessons learned. Seema Patel noted, "This Grand Challenge is not like any of our other Grand Challenges. If you look at our previous Grand Challenges, they have mostly been about sourcing innovations and then scaling them. It's about how to come up with ideas to solve the problem. This Grand Challenge is really about scaling the solar household energy sector in sub-Saharan Africa"[Patel, S., phone interview with Policy Design Lab, July 29, 2016]. Using the Grand Challenge model, USAID is bringing together different partners to concentrate on scaling cluster solutions.

"This focus on adoption and application of the innovations into USAID's larger programming and commercial sustainability is an evolution of what a Grand Challenge can truly be," said Dave Ferguson [Ferguson, D., personal communication with Policy Design Lab, November 10,2016].

Build a community

Grand Challenges for Development has spurred on the development of cross-industry partnerships of major players to ensure that the business intelligence and learning emerging from these programs is being shared and help to consistently inform investment decisions that could be made by innovators, funders, and customers.

This has been accomplished through a variety of mechanisms such as the Saving Lives at Birth DevelopmentXchange which is an annual convening of investors, partners and innovators that convene each year to meet and evaluate Saving Lives at Birth award finalists. The event is interactive and action-oriented and serves as one of the leading maternal and newborn health innovation summits with over 500 attendees each year. Securing Water for Food and Powering Agriculture has also partnered to host the Agricultural Innovation Investment Summit which will bring together leading investors and agriculture innovators.

The Global Innovation Exchange was created to serve as a marketplace of development relevant innovations, funding, partners, and resources. USAID, Gates Foundation, Australia, and South Korea, along with 80 other partners committed to share innovations in a central place so the larger ecosystem of innovation in development could be represented. The Global Innovation Exchange has helped strengthen understanding of what innovations already exist, where they were being used, and which

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organizations and partners support them. As of October 2016, the Exchange has over 4,500 innovations, nearly $100 million in active innovation funding, and more than 15,000 collaborators.

To Learn More:

Grand Challenges for Development:
Saving Lives at Birth
All Children Reading
Making All Voices Count
Powering Agriculture: An Energy Grand Challenge for Development
Securing Water for Food
Fighting Ebola
Combating Zika and Future Threats
Scaling Off-Grid Energy

Grand Challenges for Development Toolkit

Case Study 4: Grand Challenges Scholars Program

The National Academy of Engineering (NAE) Grand Challenge Scholars Program (GCSP) aims to create the next generation of engineers who are specially equipped to address the most challenging problems facing the country and the world. Originally involving a cohort of 20 to 30 undergraduate students at a handful of schools, the goal now is to mainstream the model in engineering programs throughout the country. Currently, over 30 US schools and 4 international schools participate [Atkins, R., personal communication with Policy Design Lab, December 1, 2016].

The Program enables students to organize their coursework, research, service, international studies, and experiential learning around one of the NAE Grand Challenges for Engineering, which cover four thematic areas: sustainability, security, health, and joy of living. (The latter theme, notes NAE communications director Randy Atkins, emphasizes that the Challenges aren't all about solving problems – they're also about innovations that simply make life better) [Atkins, R., phone interview with Policy Design Lab, November 3, 2016]. The program aims to pilot new innovative approaches in education that will eventually shift the mainstream training paradigm for all engineering students. The effort also stresses cross-disciplinary collaboration.

Each university embeds five central components into their program:

1. **A Hands-on Project *or* Research Experience** related to a Grand Challenge;
2. **Interdisciplinary Curriculum:** Complementing engineering fundamentals with courses in other fields, preparing students to work at the intersections of public policy, business, law, ethics, human behavior, risk, and the arts, as well as medicine and the sciences;
3. **Entrepreneurship:** Learning to translate invention to innovation, and preparing students to develop public-interest oriented market ventures that can scale to global solutions;

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4. Global Dimension: Developing the necessary global perspective for tackling worldwide challenges as well as preparing students to lead innovation outside their comfort zones;
5. Service Learning: Using mentored experiential learning (with real clients) to encourage and deepen students' social consciousness and their motivations to apply their technical expertise to societal problems. [Source]

Key Accomplishments:
In 2015, more than 120 US engineering schools announced their commitment to integrate Grand Challenge Scholars Programs into their undergraduate curriculums. They pledged that in a decade, 20,000 engineers will be trained to tackle these complex challenges.

One of the early accomplishments of the program has been to bring more diversity into the engineering field. There are a wide range of participating universities, from school size to disciplinary focus. The demographics of the program are also notably diverse, with more than 50% female enrollment as well as sizeable participation from historically underrepresented minorities. Bringing more diversity into the engineering profession is essential for developing a range of approaches and meeting a large variety of societal needs [Atkins, R., phone interview with Policy Design Lab,November 3, 2016].

The Grand Challenge framework has also begun to filter down to K-12 education, with high schools in Virginia, North Carolina, and other states piloting approaches that are breaking down the silos of class subjects – including STEM, English, art, history, etc. – and connecting them through the frame of the biggest issues of our time.

How they did it:
The program emerged as a response to a 2008 landmark NAE report, Grand Challenges for Engineering, which identified fourteen Grand Challenges for engineering in the 21st century. [[Footnote: The report was written by a select group of some of this generation's leading technological thinkers and doers, and one of the most extensively reviewed reports in the Academy's history, notes Randy Atkins, NAE director of communications. Read more: http://www.engineeringchallenges.org/14365/committee.aspx]] The Academy's goal was to look to the future and "inspire the engineering community to encourage students to pursue engineering fields, to give students opportunities to pursue those fields, and to give the general public and others a reference point for what **audacity** means for engineering and where the interesting problems are," explains Cristin Dorgelo, Chief of Staff at OSTP and former head of prize operations at the XPRIZE Foundation [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016].

Initially spearheaded by Olin College, University of Southern California, and Duke University, the GC Scholars Program has since taken root at dozens of colleges and universities across the country. "The findings took on a life of their own," notes Randy Atkins, NAE director of communications, "because of the sheer power of the message" [Atkins, R., phone interview with Policy Design Lab, November 3, 2016].

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Volunteer efforts by educators across the country have helped to launch the program, but as it continues to scale, the NAE is creating a central coordination office to network participating schools and share best practices. In addition, two Global Grand Challenges Summits (a collaboration between the NAE, the Chinese Academy of Engineering, and the Royal Academy of Engineering), aimed at brainstorming ways that global cooperation can solve these challenges, have already taken place – one in London and one in Beijing – and a third is planned for Washington, DC in 2017. The third summit will be held in conjunction with the FIRST Global Robotics Competition on Grand Challenges.

Read more about the inaugural 2009 summit at Duke University that galvanized the movement.

Key learning insights:

- **Non-Federal partners can use the Grand Challenge framework**
- **Collaboration gives latitude for each implementing partner and promotes diversity**
- **A powerful narrative, not funds, is necessary for shifting the collective conversation**

Influential non-Federal partners can use the Grand Challenge framework
The NAE Grand Challenges Scholars Program highlights the central role that entities outside of the Federal government can play in the identification and pursuit of Grand Challenges. The Grand Challenge call for engineering was first issued by the National Academy of Engineering.

Collaboration gives latitude for each implementing partner and promotes diversity
Similar to Federally implemented Grand Challenges, the GCSP structure also emphasizes flexibility in its framework; each participating institution incorporates the program's five central pillars, but schools are encouraged to tailor curricula to fit their unique school environments.

A powerful narrative, not funds, is necessary for shifting the collective conversation
The original call to action by the NAE was not accompanied by substantial funding, notes Cristin Dorgelo. [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]. Instead, the organization developed a framing document that galvanized the community to rethink its priorities and reorient its approaches. This worked because of NAE's prestige and influential role within the community.

To learn more:
Engineering deans commitment announcement in 2015
Grand Challenges for Engineering – 2008 report
Grand Challenge Scholars and the BRAIN Initiative

[UPLOAD-article attached]

Contact: For more information, contact Randy Atkins, ratkins@nae.edu.

Additional examples of Grand Challenge deployments:

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- BRAIN Initiative [crosslink case study from V5]
- DOE's EV-Everywhere Grand Challenge Blueprint
- A Nanotechnology-Inspired Grand Challenge for Future Computing
- DARPA Cyber Grand Challenge
- National Eye Institute's Audacious Goal Initiative

  Read more about the Audacious Goal Initiative:
  - https://nei.nih.gov/sites/default/files/nei-pdfs/AGI_brochure.pdf
  - https://www.nei.nih.gov/agmeeting/
  - https://www.whitehouse.gov/blog/2013/05/15/audacious-goals-eye-research
  - https://youtu.be/TbSEmzCHfKM [4 min video – what audacious goals do for scientific research]

Deliverable 5: Challenges to deployment / approach limitations (inc. lessons learned from agencies where implemented)

Like any policy tool, Grand Challenges are not appropriate for every context. They work best when the problem is well-defined but the scope of possible solutions is not. Successful execution requires both smart design and smart implementation.

Key ingredients for successful Grand Challenge deployment include:
- Thoughtful program design to appropriately adapt the framework
- Open-minded approach to goal definition and redefinition
- High-level support and receptivity for new problem-solving approaches
- Right team in place to break down silos
- Advanced planning and alignment within budget cycles

Thoughtful program design to adapt the framework appropriately for sectoral contexts
Digging underneath the covers of individual Grand Challenges reveals a wide variation in program structures, including a significant degree of difference in terms of funding levels, formality, and division of roles and responsibilities. "That level of variation has been a real challenge -- no pun intended! -- for Federal agencies and other organizations that say, 'Hey, I think I want to launch a Grand Challenge goal or Grand Challenge program for X. ... What do I do next?' That wide variation has rightfully been a roadblock because it means that the onus is on the program manager to figure out what structure makes the most sense," comments Cristin Dorgelo [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016] She adds, "While that's a challenge, I actually think it's the right thing: When you're thinking about a Grand Challenge -- an ambitious, yet achievable goal -- [...] it makes sense that in each given sector or industry that [...] the means to reach that goal are going to be different, based on the state of the market and based on who the actors are. It requires very savvy and thoughtful program design" [Dorgelo, C., phone interview with Policy Design Lab,August 3, 2016].

Open-minded approach to goal definition and redefinition

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Appropriately defining the scope and boundaries of the challenge goal is foundational for success. It's important not only to invest adequate time and resources in the problem definition process, but to remain receptive to further refining the target based on feedback. It's essential, says Dorgelo, that agency staff retain "the flexibility and willingness to adjust the goal if needed -- if you're learning that what you put forth to the public either is isn't achievable, or it's too hard, or the facts on the ground may mean you need to change it" [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]. She observes that in some Grand Challenge instances, the initial problem definition turned out to need further adjustment – and savvy Grand Challenge managers can respond by tweaking program language in order to orient towards success [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016].

High-level support and receptivity for new problem-solving approaches

A Grand Challenge requires the support of high-level authority, as it requires access to a coalition of diverse stakeholders and the ability to convene them together. Leadership is also key to establishing a culture where a team is brought into the process. Beginning at the top, leadership needs to create a space for people to feel comfortable imagining how they might do their job differently, and how to engage with innovative approaches like challenges to deliver on those objectives. While this holds true for nearly any innovation approach, Grand Challenges in particular require permission to reimagine how we frame, engage with, and solve problems. Identifying clear objectives and how the problem can be best solved using a Grand Challenge helps gain traction within a department.

Breaking down silos requires having the right team

Grand Challenges inherently require multi-sectoral collaboration, which also brings natural organizational challenges. But overcoming barriers to collaboration is essential for Grand Challenges to succeed; this can require challenging conventional arrangements and breaking down silos to bring different stakeholders together. [Crosslink V5 content]

One program director also stressed that "Grand Challenges will not be successful unless you have the right people" assigned to the project internally. Successful implementation requires assembling a team of creative, non-linear thinkers with the ambition to see beyond what will happen next year, and who can instead target longer time horizons.

Advance planning and alignment within budget cycles

A necessary ingredient is a Grand Challenge champion with budget authority. But the reality of the budget and solicitation cycles can be a tough obstacle for Grand Challenge deployment. Program managers and agency leadership may both want to first consider how to structure Grand Challenges for their budgeting within a 1-2 year timeframe. For instance, with solicitation planning cycles beginning 8 months before going public, it's difficult to adjust content two months before launching [Gustetic, J., phone interview with Policy Design Lab, July 25th, 2016].Additionally, budget planning needs to consider long-term plans for integration and follow-on from the outcomes produced by the challenge. There needs to be both a plan and budget for implementation. Although program planning needs to align with budget planning, Grand Challenges must remain unapologetically ambitious.

Deploying in an appropriate context, or, what a Grand Challenge is not:

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Too much deviation from the common understanding of a "Grand Challenge" dilutes the power and efficacy of the approach. While there's great flexibility in how Grand Challenge goals can be pursued, there are bright lines around what it is, and isn't. The quality of the goal matters; it must be audacious, achievable, and innately relatable. It must bring people together and inspire engagement. "There are goals that simply are not Grand Challenge goals. [...] They are not compelling, they are not ambitious, or they're a pipedream and you're highly unlikely to achieve them based on current capabilities and trends in science, technology, and society. Or, they're not understandable to the person on the street who would want to know why an engineer is devoting his life to that goal, or why a scientist is devoting her research to that goal," comments Cristin Dorgelo [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016].

The Grand Challenge framework is also not credible if used as ex-post rationalizations of existing policy, or as a communications framework that merely repackages existing agency initiatives. A misguided application of the Grand Challenge label would be to apply it to in-house strategic planning efforts.

Deliverable 6: How-To: Steps for deploying, practices for adapting

- **What is a moonshot?**
- **Grand Challenge 3 stage process**
- **Recommended checklist**
- **Problem definition textbox**

Grand Challenges are often referred to as "moonshot" goals because of their scale and audacity. Chris Gerdes, former Chief Technology Officer at the Department of Transportation, comments that the term has "become shorthand notation for everything innovative: 'I'm doing a moonshot.'" [Gerdes, C., phone interview with Policy Design Lab, July 1, 2016]. But "a moonshot is not just a moonshot," he argues Gerdes, C., phone interview with Policy Design Lab, July 1, 2016. Transformative breakthroughs are achieved through a series of incremental and additive steps. [Crosslink Moonshot textbox here –from V8]

The broad and inspiring call of a Grand Challenge breaks down into a series of constituent parts and processes for implementation:

Grand Challenge Three-Stage Process

Phase One	Phase Two	Phase 3
Problem Definition	Program Development	Program Implementation

Cristin Dorgelo emphasizes that problem definition is such a key component of instituting a Grand Challenge that agencies need to consider as its own process – with its own timeline, budget, and project management plan [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016] "Just to get to the place where you have the goal you want to pursue is, in itself, its own project," she notes [Dorgelo,

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C., phone interview with Policy Design Lab, August 3, 2016] Then what? "What happens next is essentially a program development effort where, based on that goal, the program managers need to work backwards to figure out 'What resources do we already have or could we develop that would help us pursue the goal? What partners and stakeholders do we need to bring around our planning table?'" [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]

Three key steps:

- Figure out how appropriated funds can be designated for particular purposes
- Develop an engagement strategy and timeline. Assess your communications resources -- event planning, communications roll-out strategy, with the goal of convening the community
- Look at who your partners are or could be, and evaluate authorities, requirements, and responsibilities for partnerships.

Program staff should consider a range of questions about how they can, in a Federal context, engage with other organizations – formally or informally – and which approach is most appropriate for the goal. Questions might include:

- "How much control do I want to maintain?
- "Do I want to just issue this into the world, and let a 501c3 or other entities out there in the public take it forward?"
- "Do I want to formally partner with other organizations to help me run this?"
- "Am I contracting with them, or am I partnering?"

Dorgelo advises: "Figure out what funding and other resources you have. Figure out your plan for getting the word out and attracting people to help you and to work towards your identified goal. Figure out what relevant authorities your agency has at its disposal for partnering or for funding projects flexibly, and what you can and can't do based on those authorities. And figure out what the schedule and timeline is going to be for getting people around the table to execute the Grand Challenge Program. Who is going to be around that planning table, what are you going to ask them to do, and what are you allowed to ask them to do?" [Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]

This stage of program development is very similar to similar planning processes for prize competitions; program managers may find prize competition resources valuable in their planning work. [CROSSLINK Prizes toolkit]

Recommended Checklist for Grand Challenges

Problem Definition

- Identify the ultimate goal; achieve a "Goldilocks" balance between ambition and feasibility.
- Use problem decomposition methodologies or segmenting processes. Invest significant time in breaking the goal down into component parts that can be addressed by different segments of the public so that field experts, distant experts, and citizen solvers can all contribute in different ways. This is particularly true for Grand Challenges focused around technical research questions, where segmenting can help identify the contributions non-experts can still make.

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- Conduct barrier analysis to assess the environment surrounding the problem, sourcing input from stakeholders and incorporating feedback into the goal definition.

Designing a Challenge

- Clearly define measurable targets for success and timing of completion.
    - A Grand Challenge that is too narrowly defined or that presumes some particular technical approach may reduce the opportunity for new and truly effective solutions; to combat this, invest significant planning time in problem definition.
- Set a timeframe: Typically a 5 to 10 years natural timeframe, but at most 20 years.
    - The timeframe often falls outside the customary administrative time frame (four-year term).
    - Multi-year engagement is fundamental; time is necessary to build momentum and catalyze self-sustaining "marketplaces" where stakeholders have truly invested.
- Assess incentive levels if designing prize or grant element:
    - Set a prize level large enough to get people interested and engaged.
    - Balance the level of talent resources (internal and external) needed to service different levels of funding.
- Launch a comprehensive engagement strategy to draw in stakeholders, particularly new voices.

Challenge Implementation

- Pair with a variety of back-end modalities, appropriate for different contexts:
    - An all-in commitment from government (like NASA's space program);
    - Engaging matching funds from private sector'
    - Agency announces commitment framework, creating space for others to support it'
    - Agency makes a commitment and sources a prize with external partnerships, but the agency does not fund resulting solutions.
- Leverage the stakeholder community.
    - Encourage partners and networks to plan follow-on activities around the Challenge, in order to fully capture benefit from the activity generated.
- Set clear benchmarks for progress.
    - The challenge has to be something that's easy to assess progress against, but does not necessarily require a lot of new measurement apparatus.

Deeper insight on the problem definition process

Q: **Is there a particular diagnostic process that you encourage people to go through to help identify the big audacious goal?**

A: There are some proven approaches that I think Grand Challenge program designers should use when it comes to problem definition, and they all focus on the concepts of ever increasing circles of input. It is unlikely that a single individual in a room could conceive of a Grand Challenge goal that could check all those boxes I described as being compelling, of being audacious, of being achievable et cetera.

There are probably some very talented, very bright scientists and engineers who could and have defined that goal by themselves alone in a room. But most program managers who are wrestling with a thorny problem such

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as how to get solar adoption across the United States or how to make electric vehicles as cost-effective as gas powered vehicles, struggle -- like all of us do -- with problem definition. And so, the ways that program managers have approached this that has worked is to engage in a brainstorming process with a diverse set of participants. Often this happens, as I said, in an ever expanding way, where first, they're doing this problem definition within their organization.

NASA for example hosted what they called Big Think sessions where they brought people within the agency, from different aspects of the agency, together to start brainstorming about what those audacious goals might be, where their leadership team then down-selected that list of audacious goals to the most compelling, where some feasibility assessment was done (meaning, how much does this goal match with what Congress is telling us to, what do we have money for already, what is already going to happen without our help). And then they take that more limited set of goals and start expanding their circle to external advisory bodies, to the general public, to get input and reactions. And they are flexible and willing to adjust course, and willing to tweak their concept for their Grand Challenge goal based on feedback received.

Also, you can look to what the Department of Energy did with EV-Everywhere Grand Challenge. They used that internal process that I was describing -- of coming up with the idea, vetting the ideas to figure out how feasible they are, and getting input from key internal stakeholders. And when they went public with their goal, they issued essentially what I think of as their top bullet—we want to make electric vehicle as affordable and cost-effective and convenient to own as gas-powered vehicles. But at the start, they didn't publish any what I think of as the sub-bullets to that overarching goal, because they wanted more input. So even though they had a theory of the case about how you would get an electric vehicle that was as affordable and cost-effective and convenient to own as gas powered vehicle, they didn't publish that immediately. They went out and they talked to tons of stakeholders and said 'What would we need to do this?' And they learned things, and they changed the definition of how they were going to pursue that goal as a result of that input.

If I think back to XPRIZE and to how DARPA also has tried to define the goals that they were going to use for their Grand Challenge prize competitions to pursue their Grand Challenge goals, they did similar things. They talked to a lot of experts. They narrowed down the range of how you might measure success, because like any smart goal, you need it to be measurable, you need it to be time bound, and you need to be realistic. And so they asked, "what are the criteria we're going to use to measure success?" They came up with a few potential framings for how to go after that envisioned future of success.

They usually included in that a few different types of criteria that could be used to measure whether the goal had been reached. So, for example, if you're looking at radically improving the cleanup of oil from water, you could be looking at efficiency of cleanup oil from water. You could be looking at effectiveness of cleanup oil from water, or the total volume of oil collected. You could be looking at the diversity of environments in which that new technology can operate, et cetera. They then took all those potential criteria; they aired them in front of a large number of experts. The experts told them, "Right criteria, wrong criteria. A bar too high. A bar too low." They listened to that and *then* they set the goal.

And so, **if there's one secret sauce, it's that increasing feedback loop until you heard that feedback so frequently that you think you got it right**. And then there's the willingness to put that goal out there publicly and get input on how to define the next level, the next sub bullets down, in terms of how you get there, how you achieve that Grand Challenge goal.

[Dorgelo, C., phone interview with Policy Design Lab, August 3, 2016]

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Deliverable 7: Online inventory of resources

Contact

Agencies interested in learning more about Grand Challenges can contact Lorin Kavanaugh-Ulku at lkavanaughulku@usaid.gov

How-to resources:

- "Moving from a Culture of "Problem Solving" to a Culture of "Problem Definition," Dr. Zoe Szajnfarber, George Washington University researcher [1:15 minutes; 25 minute presentation]
- "Identify and Define the Problem." Problem Definition Toolkit from Tools for Innovative Programming, U.S. Global Development Lab at USAID.

Resources for problem definition

- Spradlin, D., "Are you solving the right problem?" Harvard Business Review, September 2012. A discussion a process for defining the problem.

Further Reading:

[[Upload OSTP Slide deck]]

"Grand Challenges." Office of Science and Technology Policy. Web page that explains the genesis and goals of Grand Challenges

"The Grand Challenges of the 21st Century" Tom Kalil, 2012 speech. Transcription of speech explaining Grand Challenges - their benefits and roles.

"Grand Challenges in US Science Policy Attempt Policy Innovation" *International Journal of Foresight and Innovation Policy* (2016). This paper by Dr. Diana Hicks provides a comprehensive history of the evolution of Grand Challenges outside and within the Federal government.

"From Science Fiction to Science Fact" (OSTP, October 2015). Blog post by OSTP on the imaginative power of science fiction to frame how we dream big.

News Articles:

Lamb, G.M., "Grand challenges spur grand results," Christian Science Monitor, 12 January, 2006. A deeper look into Grand Challenges, especially in specific fields.

Voosen, P., "To Win Funds, Scientists Pursue Sweeping Solutions to Social Ills." The Chronicle of Higher Education, February 2015. Grand Challenges, and their politics and funding, explained.

Domain-specific reading:

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National Science Foundation Advisory Committee for Cyberinfrastructure Task Force on Grand Challenges, 2011 Report: A domain-specific look at how the grand challenge framework is being used to advance discoveries in six specific computer science and engineering domains.

Battelle Memorial Institute,"Economic Impact of the Human Genome Project", May 2011, : This report quantifies the tremendous return on investment generated by the Human Genome Project (a return of $141 for every $1 invested), showing what's achievable with a Grand Challenge framework.

Academic Literature:

Kallerud, E., Amanatidou, E., Upham, P., Nieminen, M., Klitkou, A., Olsen, D.S., Toivanen, M.L., Oksanen, J., Scordato, L. (2013) *Dimensions of Research and Innovation Policies to Address Grand and Global Challenges*. NIFU Working Paper. Working paper on issues brought up by the international development of R&I policies.

Kuhlmann, B.S., Rip, A., *The challenge of addressing Grand Challenges.* University of Twente. January 2014. A think piece on how R&D and innovation definitions and processes themselves need to change to be able to address Grand Challenges.

Leijten, J., Butter, M., Kohl, J., Leis, M., Gehrt, D., January 2012. I*nvesting in Research and Innovation for Grand Challenges*. Joint Institute for Innovation Policy (JIIP). Research into shift and evidence into "grand challenges" style thinking in Europe.

Mowery, D. C. (2012). 'Defense-related R&D as a model for "Grand Challenges" technology policies'. *Research Policy*, 41(10), 1703-1715. How the lesson of defense research can be applied to other challenges.

For more on the modern origins of Grand Challenges:

Wilson, K. G. (1983) *Views on Science Policy of the Nobel Laureates for 1982*, Hearing before the Committee on Science and Technology, U.S. House of Representatives, 98th Congress, 1st Session, February 23, 1983, USGPO, Washington D.C., pp. 10-25.

Wilson, K. G. (1984) 'Science, Industry, and the New Japanese Challenge', *Proceedings of the IEEE*, Vol. 72, No. 1, pp. 6-18. How the US government should support computerization of science and build a network for those working in it.

Wilson, K. G. (1988) 'Grand challenges to computational science', *AIP Conf. Proc.* Vol. 169, pp. 158-169. The supercomputer and its relation to science

Wilson, K. G. (1989) 'Grand Challenges to Computational Science', *Future Generation Computer Systems*, Vol. 5, No. 2, pp. 171-189. Explores opportunities and the "tougher" challenges to the realm of computer science.

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"A Research and Development Strategy for High Performance Computing", Executive Office of the President, Office of Science and Technology Policy, November 20, 1987. Research paper on how high performance computers can be used in relation to federal government research and development.

Deliverable 8: Examples of policy that have enabled or encouraged approach (legislation, exec order)

Legislation

American Innovation and Competitiveness Act 2016
America COMPETES Reauthorization Act of 2010
15 U.S. Code Chapter 81 - High-Performance Computing § 5503

Policy Guidance

"A Strategy for American Innovation", National Economic Council and Office of Science and Technology Policy, October 2015.
Zients, J.D. "Guidance on the Use of Challenges and Prizes to Promote Open Government." OMB M-10-11. March 8 2010
"Memorandum for the Heads of Executive Departments and Agencies." OMB M-10-30. July 21 2010
"Memorandum for the Heads of Executive Departments and Agencies." OMB and OSTP M-12-15. June 6 2012
"Memorandum for the Heads of Executive Departments and Agencies." OMB and OSTP M-13-16. July 26 2013
Holdren, J.and Smith, M., "Exit Memo: Office of Science and Technology Policy" Jan 5, 2017

Deliverable 9: Future directions ("next practices as opposed to best practices")

The next frontier for Grand Challenge deployment is the realm of social policy. Agencies concerned about the bottom half of the income distribution have had less connection, historically, to the entrepreneurial and STEM communities where Grand Challenges have arisen. But the framework could be used to accelerate progress on domestic and societal challenges that relate to poverty alleviation and social mobility, as demonstrated by USAID's track record of success with internationally-focused challenges.

Harnessing the visionary power of the Grand Challenge framework for social policy could lead to big questions like:

> *"Can we shift the unemployment rate by ½ percent? What would that look like?"*
>
> *"Our current workforce development investment programs, on average, increase wages of beneficiaries by $1,800; how do we increase that by a factor of 10?" [Kalil, T., in-person interview with Policy Design Lab, July 21, 2016]*

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More could be done by external stakeholders to further maximize the power of Grand Challenges. What if in 5 years a quarter of Fortune 500 companies had a goal that was ambitious as IBM advancing AI by beating Gary Kasparov at chess or Ken Jennings at Jeopardy? For instance, what if companies focused not just on developing self-driving cars, but using that approach to reduce traffic fatalities by 80%? What if half of leading research universities were involved in at least one Grand Challenge? [Tom Kalil, T., in-person interview with Policy Design Lab, July 21, 2016]

More reflection is needed to assess lessons learned as agencies continue to iterate and refine their Grand Challenge operations. "We must share information insight and resources so that we can make informed decisions around what challenges are needed, what solutions already exist and how they are performing. It doesn't make sense to keep doing Challenges without being transparent and efficient about what it coming out of them, not just the winners, but all of the ideas, funded or not," shares Grace Kim, Global Innovation Exchange Project Manager, U.S. Global Development Lab at USAID [Kim, G., personal communications with Policy Design Lab, November 10, 2016].

In the present, it's also important that current and near-future Grand Challenges continue to push big questions. Once talent is assembled by the call of a challenge, what else can we be doing to fully maximize their contributions? Grand Challenges are opportunities to source catalytic breakthroughs, but they also offer an opening to mobilize the *full* distribution of stakeholders affected by the problem.

Annex of interviews:
Randy Atkins, NAE
Ann Mei Chang, USAID
Dan Correa, OSTP
Cristin Dorgelo, OSTP
Jenn Gustetic, NASA
Tom Kalil, OSTP
Lorin Kavanaugh-Ulku, USAID
Jason Kessler, NASA
Minh Le, DOE
Seema Patel, USAID
Sonal Shah, formerly WHOSI

Grand Challenges for Development program managers: [All: 11/10/16, personal communication]
Tony Bloome, USAID
Alexis Bonnell, USAID
Karen Clune, USAID
Grace Hoerner, USAID
Chris Jurgens, USAID
Bruce Kay, USAID
Marissa Leffler, USAID
Ku McMahan, USAID
Ryan Shelby, USAID

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STPI interviews:
Jesse Goldhammer
Jenn Gustetic
George Hernandez

Points of Contact:
1) Cristin Dorgelo, Chief of Stadff, OSTP, (b) (6)
2) Jenn Gustetic, SBIR/STTR, Program Executive, NASA, jennifer.l.gustetic@nasa.gov
3) Seema Patel, USAID, Division Chief, Innovation and Design Advisory, Global Development Lab, seepatel@usaid.gov

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V18 – Innovative Contracting

Content structure by "Deliverable" area – outline accepted by OSTP and STPI

General D1 (elevator pitch) for entirety of innovative contracting
General D2 (rationale/summary of premise, and benefits) for innovative contracting
General D3 (use cases), containing:
- Discussion of authorities that enable different approaches
- Discussion of push v. pull mechanisms
- Matrix of specified specific approaches (considerations for when to use/what they require

D4: Specific approaches:
- rapid technology prototyping
- staged contracts
- competitive milestone-based payments
- incentive prizes (linked elsewhere)
- challenge-based acquisitions (linked elsewhere)
- non-binding purchase commitments
- advance market commitments

Each will cover
- D1 pitch and D2 rationale
- D3 – when to use
- D4 – a brief case example
- D5 – brief mention of
- D6 – how to guidance
- D7 – resource links specific to that approach
- D8 – briefly clarify under which authority the approach is used

General D4 – one stand-alone case study on HHS Buyer's Club
General D5 – *abbreviated* discussion of challenges for promoting innovative acquisitions generally
General D6 – *abbreviated* general guidance for acquisition training [AND discussion of 2 enabling frameworks]

General D7 – additional links and resources broadly on acquisitions
General D8 – additional legislative resources

General D9 – next or promising practices for innovative contracting (generally)

Content should be read in a modular way; that is, specific D4 approaches are self-contained.

Content is heavily sourced from OSTP's 2014 Innovative Contracting Case Studies document, with the (OSTP) goal of migrating this existing content (with updates and significantly streamlined editing) to be permanently hosted and preserved on GSA's site. Language from Federal sources, such as the 2014 case studies, may be incorporated directly, with attribution/citation. Non-Federal sources are appropriately quoted and cited.
Pull quotes: *[[to consider for website]]*

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"Innovations arise when people are given a problem to solve instead of being told to implement a known solution." ["Innovation is a Contract Sport," Partnership for Public Service, February 6, 2016.]

"Reasonable risk-taking is appropriate as long as risks are controlled and mitigated." FAR 39.102(A)

Deliverable 1: Elevator pitch summary

Intro

Innovative approaches to contracting can help agencies maximize value while minimizing their spending. There are a variety of newer, easier, more effective acquisition models and processes that can be used under existing regulations and authorities. What they share in common is an emphasis on buying what works and paying only for successful outcomes.

Whether used for digital services or physical products, "innovative acquisitions" encompass a variety of procurement approaches that mitigate risk while delivering required outcomes. ["Buyer's Club: Modernizing IT Acquisition by Testing New Methods," Department of Health and Human Services IDEA Lab, 2016.] These approaches improve the likelihood of on-time or early delivery of contracts, increase end user satisfaction, and can reduce the total cost of ownership. Common features of the innovative acquisition methods profiled here include early and frequent collaboration between acquisition and end-user stakeholders and the use of agile, iterative, modular implementation methods.

Current authorities in the Federal Acquisition Regulation (FAR) provide a variety of innovative contracting models that can reduce transaction costs and increase access to innovative contractors while still operating within the confines of existing law and regulation. Other authorities, including Other Transaction Authority and America COMPETES Act, provide additional alternatives. [[Crosslink authorities to authority section below]]

Why

In FY2016, the Federal government spent $462 billion on acquisitions crucial to achieving agency missions. ["Overview of Awards by Fiscal Year," USASpending.gov, 2017.] As budgetary constraints continue to reduce available resources, there is a heightened need to expand the use of innovative procurement practices that ensure Federal agencies pay only for successful results, not just best efforts. [Kalil, T., and Field, L., "Buying What Works: Case Studies in Innovative Contracting," White House, August 21st, 2014.] Innovative strategies are needed to achieve greater efficiency and better value for the American public from our Federal contracts, including more technologies developed by commercial firms and start-ups. [Smith, M. and Kalil, T., "Expanding the Pentagon's Silicon Valley Office," White House blog post, May 20, 2016.]

How

Each of the innovative contracting approaches detailed here share in common an emphasis on stimulating demand in the marketplace for new solutions. As "demand pull" mechanisms, they offer agencies the ability to discover, prove, and scale novel solutions and more impactful outcomes. These approaches include:

- **Rapid technology prototyping** to rapidly and inexpensively try out new technologies
- **Staged contracts** to solicit proposals and quickly assess them

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- **Competitive milestone-based payments** to attract new solutions to well-defined, multi-component problems.
- **Incentive prizes** to source solutions from citizen solvers
- **Challenge-based acquisitions** to break the entry barrier for new actors, especially startups
- **Non-binding purchase agreements** to collaborate with industry and incentivize new solutions, without firmly committing
- **Advance market commitments** to create new markets and commit to long-term pricing for purchases

More broadly, each agency can consider how to create pathways to encourage and allow the workforce to test and adopt new and better ways of doing business as promising ideas present themselves, either in the government or the commercial marketplace. With the dedicated support of an acquisition innovation advocate and an acquisition lab, or similar mechanism, to support this pathway, the government's collective bandwidth to produce better results can be significantly increased. [Rung, A. and Scott, T., "Memorandum to Chief Acquisition Officers, Senior Procurement Executives, Chief Information Officers on Acquisition Innovation Labs & Pilot for Digital Acquisition Innovation Lab," Office of Management and Budget, March 9th, 2016.]

Deliverable 2: Summary of underlying rationales

The Federal acquisition workforce is responsible for awarding and administering more than $450 billion in contracts each year. ["Overview of Awards by Fiscal Year," USASpending.gov, 2017.] The work is complex and requires great skill in promoting competition, spurring innovation, balancing the fulfillment of public policy objectives, maintaining the public's trust, fostering transparency, and obtaining best value for the customer. ["Lean Acquisition," Video, FAI Media Library.] Innovative acquisition approaches can help procurement officers and their agencies source better solutions – often at lower cost, on a quicker delivery timetables, and with a faster time to award. Many of the acquisition tools profiled here can each help the workforce:

- Determine if there are better solutions to a known problem by providing objectives but not specifications
- Pilot and test new concepts less expensively
- Develop discrete areas or modular instances that feed into complex, incremental systems
- Attract innovative start-ups, small businesses, or organizations new to government contracting. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

These approaches to contracting are less encumbered by traditional – and unnecessary – operational and cultural barriers in planning, evaluation, award, and implementation. ["Buyer's Club: Modernizing IT Acquisition by Testing New Methods," Department of Health and Human Services IDEA Lab, 2016.] They promote end user and stakeholder engagement throughout the lifecycle of a project, which helps to ensure that contracting managers and procurement officers are able to make decisions that account for the end users' needs. In addition to shortening the time to acquisition, these methods can lessen frustration between companies and Federal officials while gaining agencies access to better products and new actors who might otherwise not engage with the Federal government. They can also help test and validate new technologies that have potential to save money in the long-run. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

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Innovative acquisitions also help agencies evaluate contractor capabilities based on established requirements, which can help mitigate risk of failure. (For example, evaluating IT service contractors through submission of coding, prototypes, and/or other associated work product as opposed to strictly text-based proposal submissions mitigates risk of failure because the requisite contractors are evaluated based on their capability to perform the government's requirements.) ["Buyer's Club: Modernizing IT Acquisition by Testing New Methods," Department of Health and Human Services IDEA Lab, 2016.] Similarly, non-binding purchase commitments list the concrete specifications for a technology or product being sought, allowing agencies to ensure the result fits their needs.

Deliverable 3: Use cases

Authorities

It bears emphasizing that these contracting approaches are strategies allowed under existing law. New regulations or new statutes have not been introduced, and are not needed to deploy any of these tools. A brief review of the following authorities follows:

1. Federal Acquisition Regulations
2. Other Transactions Authority (OTA)
3. COMPETES Act

1. Federal Acquisition Regulation (FAR)

*"[....A]bsence of direction should be interpreted as **permitting the [Acquisition] Team to innovate** and use sound business judgment."* FAR 1.102-4(E) (emphasis added)

Current authorities in the Federal Acquisition Regulation (FAR) provide a variety of pathways that allow agencies to reshape existing processes to reduce transaction costs while still operating within the confines of existing law and regulation. ["A Strategy for American Innovation," Economic Council and Office of Science and Technology Policy, October 2015.] The FAR actually *welcomes* innovative problem-solving. Subpart 1.102-4(e) specifically encourages contracting officers to evaluate business process innovations when appropriate:

> "If a policy or procedure, or a particular strategy or practice, is in the best interest of the Government and is not specifically addressed in the FAR, nor prohibited bylaw (statute or case law), Executive order or other regulation, Government members of the Team should not assume it is prohibited [...] Contracting officers should take the lead in encouraging business process innovations and ensuring that business decisions are sound." Federal Acquisition Regulation, 48 C.F.R §1.102.

Sub-part (e) is meant to explicitly encourage the use of non-standard contracting approaches, explains Steven Kelman, former administrator for the Office of Federal Procurement Policy, because "[We heard] that many frontline contracting people believed, or even had been taught, that if something wasn't allowed by the regulations, it was prohibited. " [Kelman, S., "FAR Part 1: 'If it's not prohibited, it's allowed,'" FCW, May 6, 2014.]

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"You can use the FAR to structure something that's actually innovative," confirms Dr. Camron Gorguinpour, former director of the Air Force's Office of Transformational Innovation. [Gorguinpour, C., phone interview with Policy Design Lab, December 22nd, 2016.] There are numerous procurement tools that, while not mentioned explicitly in the FAR, are legally allowed under it and in the government's interest to pursue. [Kelman, S., "FAR Part 1: 'If it's not prohibited, it's allowed,'" FCW, May 6, 2014.] These include incentive prizes, staged contracts, competitive milestone based-contracts, and challenge-based acquisitions. [[crosslink each to appropriate content]]

OTA: Other Transactions Authority

"Other Transactions" (OT) are funding mechanisms which target non-traditional sources and allow a high degree of flexibility in how the agreement is awarded. OTs are not standard procurement contracts or standard assistance instruments (grants or cooperative agreements). OT authority allows authorized agencies to execute non-traditional agreements outside of the FAR (10 USC §2371a). The majority of agencies use the agreement for research and development (which may be defined broadly) or for prototyping. It's a channel or conduit, explains Doug Rand, former Assistant Director for Entrepreneurship at OSTP, providing some measure of flexibility to engage commercial companies that are not traditional government contractors. [Rand, D., phone interview with Policy Design Lab, Washington DC, November 14, 2016.] In order to receive cutting edge technology and prototypes in a reasonable amount of time, OTs are typically fixed-price, accomplishment-based, or cost-shared contracts that are not subject to either the FAR or cost accounting standards. Additionally, intellectual property rights are negotiable.

An OT agreement allows agencies and contracting partners considerable flexibility to create arrangements that are tailored to the particular project and needs of the participants. "It can be a great tool when used smartly and creatively for a portfolio of high-impact projects," notes Doug Rand, former Assistant Director for Entrepreneurship at the Office of Science and Technology Policy. [Rand, D., phone interview with Policy Design Lab, November 14, 2016.] "And because it can be a clean sheet of paper that doesn't necessarily draw from the existing base of contracting expertise at a given agency, it's really important to understand how it can be tailored to achieve the agency's mission," he adds. [Rand, D., phone interview with Policy Design Lab, November 14, 2016.]

Typically, OT agreements are used to engage industry and academia for a broad range of research or prototype projects, sometimes with the option to extend to production. ["Other Transaction Authority (OTA)," Air Force Office of Transformational Innovation.] OTs may be fully funded, partially funded (cost-shared), unfunded, and under some statutory authorities, funds may be paid to the agency and its appropriations reimbursed. They may be used to support projects which are not strictly procurement or assistance; in lieu of standard assistance instruments; and, depending on specific statutory authority, for the acquisition of goods and services.

When and Why Should You Use an OT?

Agencies typically use OTA to obtain cutting-edge research and development (R&D) and prototypes quickly. Projects can begin quickly as funding is typically obligated within 45 to 60 days of award. OTs can be one effective method for encouraging participation from non-traditional government contractors, such as startups and other small innovative businesses, who might otherwise be reluctant to contract with the Federal government. OTs can be used to design and implement innovative business models that would not be feasible or practical under FAR-based contracts. This can include instances

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where specific clauses within the FAR would create unnecessary burden on the government or contractor." ["Other Transaction Authority (OTA) Overview," Air Force Office of Transformational Innovation, April, 2016.] In sum, OTs:

- Allow for flexible management of agreements, with lower typical overhead burden
- Permit use of Generally Approved Accounting Procedures (GAAP) rather than Government Cost Accounting Standards (CAS)
- Encourage cost sharing
- Permit negotiation of cost and pricing data and certifications
- Allow for commercially friendly intellectual property provisions ["Other Transactions for Advanced Research," Public Health Emergency, US Department of Health and Human Services, December 7th, 2015.]
- Can be used to promote cooperative relationships among traditional and non-traditional contractors.

Agencies reported to GAO in 2016 that OTs were used mostly for R&D activities, primarily because the authority allowed them the flexibility to develop customized agreements that "addressed concerns over requirements in traditional mechanisms that some companies viewed as potential obstacles to doing business with a federal agency."["Federal Acquisitions: Use of 'Other Transaction' Agreements Limited and Mostly for Research and Development Activities," US Government Accountability Office, January 7th, 2016.] In particular, agency officials cited the protection of intellectual property rights and compliance with government cost accounting standards as two key areas of concern for non-traditional contractors that the OT framework can effectively address. ["Federal Acquisitions: Use of 'Other Transaction' Agreements Limited and Mostly for Research and Development Activities," US Government Accountability Office, January 7th, 2016.]

> [[Footnote: "Most agencies—9 of the 11—used other transaction agreements for RD&D activities for a range of projects from medical research to energy development research. Two of the 9 agencies—DOD and DHS—also used other transaction agreements for prototype activities. Three agencies, including TSA and NASA, used other transaction agreements for activities not related to RD&D or prototype development, including airport security and education and outreach." ["Federal Acquisitions: Use of 'Other Transaction' Agreements Limited and Mostly for Research and Development Activities," US Government Accountability Office, January 7th, 2016.]]

Who Has OT Authority?

Agencies must possess express statutory authority to use OTs. The following table lists authorized agencies and the types of activities they have funded under OT authority in recent years:

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Table 1: Agency Use of Other Transaction Agreements for Fiscal Years 2010 through 2014

Agency	Types of activities		
	RD&D	Prototype	Other
Advanced Research Projects Agency – Energy (ARPA-E)	✓		
Department of Defense (DOD)	✓	✓	
Department of Energy (DOE)	✓		
Department of Health and Human Services (HHS)	✓		
Department of Homeland Security (DHS)	✓	✓	
Department of Transportation (DOT)	✓		
Domestic Nuclear Detection Office (DNDO)[a]			
Federal Aviation Administration (FAA)	✓		✓
National Aeronautics and Space Administration (NASA)[b]	✓		✓
National Institutes of Health (NIH)	✓		
Transportation Security Administration (TSA)			✓

Sources: GAO analysis of agencies' information. | GAO-16-209

[a]DNDO did not enter into any other transaction agreements for fiscal years 2010 through 2014.

[b]According to officials, NASA does not acquire RD&D services using other transaction agreements, but it does conduct collaborative RD&D activities with outside entities.

[[Image source: "Federal Acquisitions: Use of 'Other Transaction' Agreements Limited and Mostly for Research and Development Activities," US Government Accountability Office, January 7th, 2016.]]

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Agency	Other transaction authority as currently enacted[a]	Public Law providing initial authorization
Department of Defense (DOD)		
For research, development, and demonstration activities	10 U.S.C. § 2371	Pub. L. No. 101-189, § 251 (1989)
For prototype activities	10 U.S.C. § 2371 note	Pub L. No. 103-160, § 845 (1993)
Department of Energy (DOE)	42 U.S.C. § 7256	Pub. L. No. 109-58, § 1007 (2005)
Advanced Research Projects Agency-Energy (ARPA-E)	42 U.S.C. § 16538	Pub. L. No. 111-358, § 904 (2011)
Department of Health and Human Services (HHS)	42 U.S.C. § 247d-7e	Pub. L. No. 109-417, § 401 (2006)
National Institutes of Health (NIH)		
For National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program	42 U.S.C. § 285b-3	Pub. L. No. 92-423, § 3 (1972)
For Common Fund		
For certain demonstration projects	Consolidated Appropriations Act, 2015, Pub. L No. 113-235,div. G, title II, § 213,128 Stat. 2487	Pub. L. No. 108-199, div. E, title II, § 221, 118 Stat. 256 (2004)
For Cures Acceleration Network	42 U.S.C. § 284n	Pub. L. No. 109-482, § 105 (2007)
	42 U.S.C. § 287a	Pub L. No. 111-148, § 10409 (2010)
Department of Homeland Security (DHS)	6 U.S.C. § 391	Pub. L. No. 107-296, § 831 (2002)
Domestic Nuclear Detection Office (DNDO)	6 U.S.C.§ 596	Pub. L. No. 109-347, § 501 (2006)
Transportation Security Administration (TSA)	49 U.S.C. § 114(m)	Pub. L. No. 107-71, § 101 (2002)
Department of Transportation (DOT)	49 U.S.C. § 5312	Pub. L. No. 105-178, § 3015 (1998)
Federal Aviation Administration (FAA)	49 U.S.C. § 106(l)	Pub L. No. 104-264, § 226 (1996)
National Aeronautics and Space Administration (NASA)	51 U.S.C. § 20113(e)	Pub. L. No. 85-568, § 203(c) (1958)

Sources: GAO analysis of U.S. code and public laws. | GAO-16-209

[a]As of September 30, 2015.

[[Image source: "Federal Acquisitions: Use of 'Other Transaction' Agreements Limited and Mostly for Research and Development Activities," US Government Accountability Office, January 7th, 2016.]]

For additional information on authorizing language, see **[Uploaded OTA Authorization by Agency document]**

OTs may be useful for authorized agencies that don't want to "reinvent the wheel", frequently identify small businesses with essential capabilities and time restrictions, or are looking to simplify current procurement methods. [Ansari, S., Krieger, B., and Siboni, R., "Buying What Works Memo," Unpublished, August 25, 2016.] For some agencies looking to reach out to startups for innovation in the research and design of prototypes, it may particularly make sense for the agency to use OT authority (or to consider to seeking approval for OT authority). OTs can be administered without FAR competitive procedures, so that if an agency identifies a startup they wish to work with, they can bypass a lengthy selection process. (Note: Agencies using OTs still must ensure their selected partner qualifies for an OT agreement (standards for eligibility vary depending on the agency), and also have to abide by OTA-specific

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management and reporting standards.) [Ansari, S., Krieger, B., and Siboni, R., "Buying What Works Memo," Unpublished, August 25, 2016.]

While OTs accounted for 5 percent or less of authorized agencies' total expenditures in recent years ["Federal Acquisitions: Use of 'Other Transaction' Agreements Limited and Mostly for Research and Development Activities," US Government Accountability Office, January 7th, 2016.], agencies may consider pioneering new ground to fully leverage the flexibility inherent in OT's. While OTs are incredibly powerful potential procurement tool, they are not a silver bullet: "OTA alone is an enabler, it's not the solution; you still need to apply OTA against your acquisition plan and tailor both to optimize outcomes," explains Dr. Camron Gorguinpour. [Gorguinpour, C., phone interview with Policy Design Lab, December 22nd, 2016.]

For more information on OT Authority:

- For extended discussion of which procurement statutes may apply to OT, see p. 19 of a July 2011 Congressional Research Service report on Other Transaction Authority.
- DIUx's Commercial Solutions Opening How-to Guide: (November 2016) Reviews the DIUx's OT authority, explains procedures for completing R&D requirements through Broad Agency Announcements, and explains the process for awarding prototype follow-on contracts.
- Other Transaction Authority Overview: (April 2016) From the Air Force's Office of Transformational Innovation, reviews DOD's OTA authority with an emphasis on how OTAs may be used for prototyping.

COMPETES Act

The 2010 America COMPETES Reauthorization Act established authorities for all Federal agencies to offer incentive prizes and run challenge competitions "to stimulate innovation that has the potential to advance the mission of the respective agency." In December 2016, Congress passed the American Innovation and Competitiveness Act, which updated important parts of this authority. All agencies and programs should be aware of the flexibilities offered by the COMPETES Act prize authority to source solutions from American innovators. Under COMPETES, agencies have authority to establish ambitious prizes to advance national priorities:

- **Scope**: The Act authorizes agencies to conduct any prize competition that will "stimulate innovation that has the potential to advance the mission of the respective agency."
- **Size**: Agencies can offer up to a $50 million prize without further consultation with Congress.
- **Multi-Sector Partnerships**: The Act allows agencies to partner broadly with other government entities and the private sector, as well as solicit and accept philanthropic and private sector funds to support a prize purse or the competition's design and administration.

For more information on the prize authority in the America COMPETES Reauthorization Act, please see the Fact Sheet and Frequently Asked Questions memorandum.

Additional guidance on COMPETES can be found in the incentive prizes toolkit. [[crosslink Prizes]]

Pull vs. Push Mechanisms: Fueling Demand for Better Solutions

"Pull" and "push" mechanisms are two organizing frameworks for understanding the role the Federal government can play in stimulating new solutions and more impactful outcomes.

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Historically, science, technology and innovation policy has emphasized "technology push" by funding R&D to address agency and national priorities. ["A Strategy for American Innovation," Economic Council and Office of Science and Technology Policy, October 2015.] More traditional "push" approaches like grants or contracts for research and development only pay for the creation of specific outputs, even though they may not deliver the desired product or results. Agencies pay upfront for work that may not fully address their requirements or mission goals.

In recent years agencies have started to experiment with approaches that help fuel demand for innovation rather than funding its supply. ["A Strategy for American Innovation," Economic Council and Office of Science and Technology Policy, October 2015.] These "demand pull" mechanisms are deliberate efforts to stimulate activity in areas where private sector activity or investment is inadequate. Incentives such as competition prizes, milestone payments, or advance market commitments ensure that agencies pay for outcomes that meet their pre-specified requirements, rather than inputs.

While some tools, such as incentive prizes [crosslink], are already achieving significant adoption across Federal agencies, more benefit could be derived from using "demand pull" tools to address other national and global priorities. ["A Strategy for American Innovation," Economic Council and Office of Science and Technology Policy, October 2015.]

Demand pull mechanisms can substantially help agencies meet their missions by:

- Paying only for outcomes; respondents receive compensation only if efforts produce results
- Stimulating investment greater than the initial financial commitment, and catalyzing additional resources from the public and private sectors
- Attracting new solvers with unconventional perspectives
- Drawing public attention to a problem or opportunity with its emphasis on novel approaches and nontraditional problem solving ["Secretariat Lessons Learned Series," v. 1, AgResults, January 2016.]

Demand pull is one subset of a broader framework called market shaping, where the primary objective is to maximize the public good impact: "Market shaping is about accelerating the market to a more optimal equilibrium point [...]. It is intended to be a catalytic intervention that achieves lasting results." ["Healthy Markets for Global Health: A Market Shaping Primer," USAID Center for Accelerating Innovation and Impact, Fall 2014.] Market shaping interventions typically use three types of levers:

1. Reduce transaction costs – Lowering structural hurdles to market interactions, such as by simplifying, smoothing, or rationalizing orders without money necessarily changing hands.
2. Increase market information – Generating new data, aligning existing analyses, or improving the visibility of existing data to reduce asymmetries of information.
3. Balance supplier and buyer risks – Transferring financial risks to donors/purchasers to encourage existing and new suppliers to operate more actively in the market. ["Healthy Markets for Global Health: A Market Shaping Primer," USAID Center for Accelerating Innovation and Impact, Fall 2014.]

Read more:
For an in-depth look at how market shaping can be applied to an entire field of work, see USAID's Market Shaping Primer (Fall 2014), which discusses the development field's efforts to respond to

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specific market failures by accelerating the development and adoption of lifesaving products for global health.

Case snapshot: AgResults

Note: AgResults is jointly funded and managed by USAID, the Bill & Melinda Gates Foundation, the U.K's Department for International Development (DFID), the Department of Foreign Affairs and Trade (DFAT) in Australia, and Global Affairs Canada. The World Bank manages the AgResults trust fund.

AgResults is a $118 million multi-donor initiative that designs and implements pull mechanisms in order to incentivize and reward high-impact agricultural technology innovations that serve smallholder farmers in developing countries. The initiative offers monetary prizes to private sector actors to enter new markets and/or increase research and development activities in risky, hard to access, less profitable areas. By offering these prizes, AgResults' donor organizations aim to overcome existing failures and create vibrant markets with sustainable, long-lasting solutions. AgResults is also testing the effectiveness and efficiency of pull mechanisms as a finance mechanism for international development projects with an external impact evaluation.

AgResults is currently implementing six pull mechanism projects throughout the developing world: the Brucellosis Vaccine Development Prize, the Kenya On-Farm Storage Device Pilot, the Nigeria Aflasafe™ Pilot, the Uganda Legume Seeds Pilot, the Vietnam Greenhouse Gas Emissions Reduction Pilot, and the Zambia Bio-fortified Maize Pilot. While four of the pilots are still in the early stages of implementation, two pilots, the Kenya On-Farm Storage Device Pilot and the Nigeria Aflasafe™ Pilot, are showing optimistic results that highlight the potential pull mechanisms can have on creating sustainable markets and to improving the lives of small-scale farmers living in the developing world.

The Kenya On-Farm Storage Device Pilot provides monetary incentives to companies that design, develop, market, and sell new (or redesigned) on-farm storage devices for small-scale farmers. Post-harvest grain losses in the developing world lead to lower incomes and food insecurity among farmers. This problem is particularly acute in Sub-Saharan Africa, where post-harvest losses are estimated at $1.6 billion per year, or about 13.5% of the total value of grain production. Moreover, insufficient on-farm storage often forces farmers to sell their crops right after harvest, causing a surge in supply that lowers the market price for their produce. Companies that commercially sell the greatest amount of storage capacity for farmers in the aggregate receive the largest proportion of the prize. These terms encourage companies to compete, innovate, and create a vibrant on-farm storage market where none existed before.

To date, nine companies have joined the Kenya pilot, and while results cannot be reported until the end of the competition period, early results show that these companies are actively marketing and selling their storage devices; significantly increasing the storage capacity and a post-harvest storage device market that specifically serves the needs of small-scale farmers.

The Nigeria Aflasafe™ Pilot incentivizes the commercial adoption of Aflasafe™ by providing economic incentives to private sector grain aggregators and small-scale farmers themselves. The project reduces barriers of widespread adoption of Aflasafe™ by providing a premium per-unit payment to agggregators for maize verified to contain a high prevalence of Aflasafe™. Aflasafe™ is a biocontrol agent, developed by U.S. Department of Agriculture researchers, that combats aflatoxin contamination, a highly toxic, cancer-causing substance that affects approximately 60% of the maize across Nigeria and Africa. When ingested, and, in some cases, absorbed through the skin, aflatoxins cause a myriad of fatal cancers and sever stunting in children.

The pull mechanism has been operating in Nigeria for three years with exciting results. In addition to a the proportional AgResults prize aggregators report receiving premiums for Aflasafe™ treated maize that are on average 13-17% above the market rate and the number of participating smallholder farmers has grown from

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1000 in the first year to 14,000 in the fourth year. Aflasafe™ has shown to be approximately 98% effective and is now being scaled through commercial and other channels to additional countries in West, East, and Southern Africa. By harnessing U.S. ingenuity and collaboration, and openness to new markets, African farmers can look forward to harvests full of healthy maize.

For an overview of the variety of pull mechanisms used, read more: Lessons Learned Series, January 2016.

For more information on AgResults' approach to using demand pull mechanisms, contact Aviva Kutnick at akutnick@usaid.gov.

["Why Was AgResults Created?," AgResults, October 11, 2016; Kutnick, A., personal communication with Policy Design Lab, January 13th, 2017.]

Demand pull mechanisms overlap significantly with the innovative contracting approaches offered here, with a unifying principle of paying for results and not proposals. "Demand pull mechanisms" considered here fall into two distinct categories:

1. **Pay for performance**
   - Incentive prizes [Link Prizes content]
   - Pay for Success Bonds [Link EBP content]
   - Milestone-based payments [Link further in content]
2. **Purchase commitments**
   - Advance market commitments [Link further in content]
   - Non-binding purchase commitments [Link further in content]
   - Challenge Based Acquisitions [Link further in content]

Deliverable 4: One or more "success stories" or learning narratives to underscore impact

Specific Approaches:

- Rapid Technology Prototyping
- Staged Contracts
- Milestone-based payments
- Incentive Prizes *[link to content elsewhere]*
- Challenge-based acquisitions *[link to content elsewhere]*
- Advance Market Commitments
- Non-binding purchase commitments

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Chart: An Overview of the Different Contracting Models and When to Use

[Charted based on "Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014, with additions.]

Goal	Rapid Technology Prototyping	Staged Contracts	Milestone-Based Competitions	Incentive Prizes	Challenge Based Acquisitions	Non-binding purchase commitments	Advance market commitments
Business Participation							
Attract innovative small businesses	✓	✓	✓	✓	✓	✓	
Attract actors new to government contracting	✓	✓	✓	✓	✓	✓	✓
Mission Requirements							
Develop complex, incremental systems							✓
Develop discrete areas or modules for complex, incremental systems	✓	✓	✓	✓	✓	✓	
Determine if solutions exist to a known problem	✓	✓	✓	✓	✓	✓	✓
Test inexpensively	✓	✓	✓	✓	✓	✓	
Encourage industry investment first				✓	✓	✓	
Obtain concept paper before buying prototype		✓				✓	
Provide for follow-on production contracting			✓				✓
Obtain short proposals (> 10 pages)	✓	✓		✓	✓		
Prototype Requirements							
Test pre-existing prototypes before buying		✓		✓	✓		
Build low-cost prototypes	✓			✓			
Test prototypes in demonstration scenarios	✓	✓	✓	✓	✓	✓	
Solicitation type							
Use a standard solicitation, such as an RFP, for a well-designed, multicomponent problem		✓	✓		✓	✓	
Use and R&D solicitation such as a BAA to provide objectives but not specifications	✓	✓	✓	✓	✓	✓	
Funding							
Use firm fixed type pricing funding	✓	✓	✓	✓	✓		
Utilize milestone based payments		✓	✓	✓	✓		
Legal							
Use special authority outside of the FAR				✓			✓
Use FAR authority	✓	✓	✓				

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Rapid Technology Prototyping: Finding the Right Innovation from Small Businesses

D1: Elevator pitch and summary

A rapid technology prototyping contract is an innovative contracting model that consists of multiple, small, fast, and cheap acquisitions to "try out" innovative technologies. They may be used to rapidly and inexpensively identify whether cutting-edge, unproven, but potentially transformative technologies are viable options for an agency's particular requirements. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Why

Rapid prototyping provides critical information to support agencies' evidence-based technology investment decisions, which can significantly reduce the cost, schedule, and technology risks for any subsequent work. [Carol Lundquist] Should a prototype succeed, offerors can be selected for follow-on work through standard acquisition processes or another innovative contracting model. (Note: Failure is an expected and valuable part of the rapid prototyping process. Because substantial gains in innovation are often accompanied by substantial trial and error on big ideas, a realistic expectation for success rates in terms of establishing follow-on projects is only 10% to 30%.) ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

How

Companies develop prototypes in relevant demonstration scenarios within a defined timeframe (e.g. three to six months). This process eliminates cost risk for agencies and emphasizes that the project is a test to see if the company can deliver a working prototype on schedule and budget. This approach, which uses the BAA acquisition method, can easily be tailored and customized to meet the specific requirements and constraints of different agencies. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D2: Benefits of Rapid Technology Prototyping Contracts

This approach, which uses the Broad Agency Announcement (BAA) acquisition method, can easily be tailored and customized to meet the specific requirements and constraints of different government agencies. Among the innovative contracting models, Rapid Technology Prototyping contracts can uniquely:

- Effectively use limited government resources (time and money) to rapidly assess many technologies and make results-based decisions regarding further investment.
- Encourage small businesses to partner with others (including other small businesses or academia) to transform basic research developments into applied research that could potentially be used to address the agency requirements.
- Facilitate knowledge transfer from the government to small businesses to better enable the small business to support the government's requirements. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D3: Candidate users

Any agency seeking new technical capabilities to expand or upgrade their existing systems should evaluate rapid prototyping contracts, advises Carol Lundquist of the NSA. [Carol Lundquist, NSA – OSTP content].

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D4: Case study: DARPA FastTrack [Ansari, S., Krieger, B., and Siboni, R., "Buying What Works Memo," Unpublished, August 25, 2016.]

From recognition that the high barrier for entry was limiting applicants, Defense Advanced Research Projects Agency (DARPA) piloted the Cyber Fast Track (CFT) program in 2011 to attract small companies or individuals to solve IT problems. By engaging highly agile organizations and individuals who traditionally had not worked with the U.S. government, the goal was to achieve breakthrough capabilities in less time and at a fraction of the typical cost. ["Fast Track Program Invites Non-Traditional Roboticists to Help Bolster National Security," Defense Advanced Research Projects Agency, May 18th, 2015.] Using a GSA engineering services contracting vehicle, DARPA was able to reduce the contracting time from application to task order to one month and reach more potential applicants. [Micire, M., personal communication with Policy Design Lab, January 12, 2017.]

The program manager was responsible for recruiting applicants, receiving and evaluating proposals, and making recommendations to DARPA for those to subcontract. DARPA created task orders for the chosen recommendations, matched with the relevant statement of work, negotiated the subcontract, and delivered the funding. CFT effectively executed on relatively short projects (roughly 6 months) of small dollar amounts (approximately $100,000) with non-traditional subcontractors. [Ansari, S., Krieger, B., and Siboni, R., "Buying What Works Memo," Unpublished, August 25, 2016.]

After the success of CFT, DARPA expanded the model to hardware with the Robotics Fast Track (RFT). "We want this new generation of robotics innovators to see DARPA as a partner that can help them develop breakthrough technologies in the areas that personally interest them and help translate their ideas and know-how into game-changing capabilities. We're eager to pioneer this new approach, which could lead to rapid, marked improvements in national security as a whole," said Mark Micire, DARPA program manager. ["Fast Track Program Invites Non-Traditional Roboticists to Help Bolster National Security," Defense Advanced Research Projects Agency, May 18th, 2015.]

Read more: Fast Track Program Invites Non-Traditional Roboticists to Help Bolster National Security (May 2015)

D5: Challenges to deployment:

- Not all technologies are suitable for quick prototyping
- Results require careful evaluation
- Manage risk and establish expectations
- Manage failure

Not all technologies are suitable for quick prototyping

Not all technology lends itself to rapid prototyping. For example, technologies that require a significant investment in facilities and/or personnel are not suitable for rapid prototyping due to the time it requires to get the "startup" costs in place (for example, the development of new computer chips or large-scale system architecture changes). However, components of larger efforts can be successfully demonstrated via rapid prototyping if the scope of work attempted is carefully bounded and necessary resources are in place at the beginning. [Lundquist, C., personal communication with Office of Science and Technology Policy, February, 2016.]

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Results require careful evaluation

A second limitation to rapid prototyping occurs when a successful prototype is not able to be completed within the required timeframe. It is necessary to objectively evaluate why the effort failed. If the failure was due to reasons that could be potentially avoided in the future, then it may be beneficial to attempt the rapid prototyping effort again. However, if the failure was due to a flaw in the technology, then other technologies should be chosen. [Lundquist, C., personal communication with Office of Science and Technology Policy, February, 2016.]

Manage risk and establish expectations

The key to effectively managing small, rapid prototyping projects is to allow the company to manage all execution risk and avoid any dependencies on the government for information, approvals, or other items. The government's expectations for the company should be defined and clearly articulated up front so the company knows what to expect in terms of meetings and teleconferences, prototype demonstrations, and level and amount of technical guidance and advice that will be provided. Very frequent interactions between the company and government personnel, such as participation of government personnel in the company's daily technical meetings, should be avoided to minimize adding too much government bias to the effort and avoid shifting additional risk onto the government. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Manage failure

Substantial gains in innovation are often accompanied by substantial trial and error on big ideas. Thus, in R&D contracting one may need to accept, and even embrace the potential of failure as the mark of innovative thinking. Innovative thinking can thrive in a space that allows for failure in order to leap ahead. Most prototyping attempts will not result in a follow-on project to move the prototype into production; a realistic expectation for follow-on projects success rate is only 10% to 30%. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Although most projects will end in failure, these failures are key to the success of the program and a recognized component of R&D contracting. Four important precepts for managing failure are:

1. **Fail Early.**

All initial prototype projects should be scheduled for three to six months with a hard deadline to produce a working, demonstrable prototype at the end. If the company cannot deliver a working prototype within this timeframe, then the project stops. Although draconian, this approach allows limited government resources to effectively assess a large number of possibilities rapidly and cheaply to identify the ones which are the most viable. Most ideas will not work out, but the few that succeed make the overall effort worthwhile.

2. **Fail Cheaply**

The initial three to six month prototype projects should be done as Firm Fixed Price contracts which are executed in the company's own facilities. This eliminates cost risk to the government and emphasizes that the project is a test to see if they can deliver a working prototype on schedule and budget. Using the company's own facility eliminates extra costs or delays associated with using a government facility for the development work. A contract value between $50,000 and $100,000 is adequate for a prototype project of this duration. Any additional government investment should only be done after there is definite and objective proof the technology is working as advertised to minimize technical risks incurred

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by the government. However, the company should be allowed to contribute its own Internal Research and Development (IR&D) funding to the project to jointly fund this initial effort, if so desired.

3. **Fail Often**

Too high of a success rate is problematic. If a high percentage of the initial projects are succeeding and producing follow-on projects, it is likely that initial projects are not pursuing truly innovative and potentially breakthrough new technologies. If the success rate for establishing follow-on projects for innovative technologies is between 10% and 30%, the projects that are successful are likely to represent valuable new capabilities. Additionally, non-successful projects can generate important knowledge that helps guide the agency's future technology directions. It's important to try as many initial projects as possible, instead of investing a large deal of resources in just a few initial projects.

4. **Fail Smartly**

While most initial projects are expected to fail, they should not fail due to a lack of agency involvement or due to some other confounding variable. Every project should be given the best chance to succeed. It is important that an agency derive lessons learned from each failure and use them to improve the overall program. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D6: How to Guidance

The goal is to design the acquisition approach and the request for proposal (RFP) to result in a large number of good proposals describing innovative technologies, ideas, and approaches relevant to the agency's requirements. A second but equally important objective is to design the RFP so it expedites the overall acquisition process by designing out or mitigating issues that could cause delay to the acquisition process or the resulting prototype development projects. The Broad Agency Announcement (BAA) mechanism can serve as the basis of the acquisition effort. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Rapid Prototyping at a Glance: Eight Steps

Rapid prototyping can be used to assess both internally-developed and externally-developed technologies. Some of the support processes needed may vary depending on whether the work will be done internally by Federal resources or externally using commercial resources. [Carol Lundquist]

1. Establish support processes and allocate resources needed to manage and enable multiple rapid prototyping efforts. Having an overarching process able to support multiple rapid prototyping efforts allows for a systematic assessment of technologies, consistency in evaluation, and economies of scale.
2. Manage technical risk by constraining cost/resources and schedule risk through the use of short duration efforts with defined deliverables or milestones and firm end dates.
3. Cast a wide net to attract as many technology offerings as possible.
4. Use both mission and technical personnel to make the technology selection decisions. In many agencies, this would mean both the initial customer and end user of the technology should be evaluating the technology's merits.
5. Pursue multiple short rapid prototyping efforts. Three months is generally sufficient to obtain an in-depth assessment of the viability of a technology and provide the information necessary to make informed decisions regarding continued investment. Requiring a demonstration at the end of the allotted time serves as a forcing function to produce concrete results. If a technology cannot be developed and demonstrated within three months, it may indicate that the technology requires additional time to mature before being considered for mission operations or the scope of the technology being considered needs to be adjusted.

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6. Minimize expenditure of time and resources until it can be determined whether or not the technology will work effectively.
7. Have potential end user personnel engage with developer personnel to provide technical guidance, ask questions regarding the inner workings of the technology, and provide advice during execution. The rapid prototyping team should drive the design and implementation to reduce outside dependencies that may impact the success of the effort or impact the accuracy of the technology assessment.
8. Produce objective evidence of success by demonstrating the prototype under controlled conditions. It is important that the personnel conducting the evaluation do not act as a proponent for any technology during this stage so as to not bias the outcome from the technology assessment. Many outside technologies do not work as anticipated when brought into Government systems so it is important to allow technologies to succeed or fail on their own merits. Efforts to intervene to "save" an incompatible technology can often end up being a futile expenditure of time and resources that could have been better spent elsewhere.

[Lundquist, C., personal communication with Office of Science and Technology Policy, February, 2016.]

Key steps for deploying rapid prototyping:

Some of the considerations in using rapid prototyping are:

- Identifying the problem and specifying requirements
- Engaging the future end users early-on
- Constraining the solution space
- Identifying participants
- Developing the RFP
    - Common issues with the RFP
    - Sample proposal outline
- Evaluating proposals and selecting for award
- Executing the award
    - Continue to involve end-users
    - Provide technical guidance and advice
    - Demonstrate and test prototypes
- Providing technical guidance and advice
- Demonstrating and testing prototypes
- Pursuing follow-on work

Identifying the problem and specifying requirements

The problems/requirements included in the RFP need to be thought of as "bait" to attract and challenge companies to focus on solutions for these problems. Problems can be very specific with a defined result required (e.g., develop a new algorithm that can solve A, B and C with a run time under Y minutes on X amount of data on a computer with no more than Z processors). Or the problems can be very high level (e.g., looking for new types of analytics that can run effectively on large scale data). The key to the problems is to provide enough background information so a company can make an intelligent assessment about what would be required and desired in a solution. Additionally, even if a company decides to not submit a proposal, the background information provided about the problems/requirements can start to educate industry on the agency's requirements, which assists companies to submit more relevant proposals in the future. In all cases, regardless of whether a problem is specific or general, submission of proposals should not be limited to only the problems/requirements specified in the RFP. There should always be an option for the company to submit a proposal under their own category in case there is relevant innovation in an area of which the

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agency is unaware. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The expectations for problems/requirements should also be sensitive to the time limits of prototype development. Focus on what can realistically be achieved in the allowed timeframe. If a problem/requirement implies a much larger problem, then the problem or requirement can focus on prototyping proofs of concept to illustrate the viability of key components of the solution instead of focusing on prototyping the complete solution. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

It's useful to provide companies a description of approaches or technologies that the agency is not interested in. The "Not Interested In" list could be common approaches which have been tried so often that there is very little value in trying them again. This list could also include approaches the agency knows will not work effectively based on internal research. The reasons the agency is not interested do not have to be included with the description of the "Not Interested In" approach or technology. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

If specific requirements or constraints exist for a particular problem and its potential solutions, this information should also be included in the problem description. Some common specific constraints are: minimum performance requirements, the use of certain software or platforms, minimum data amounts, and the use of a particular set of test data. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Engaging the future end users early-on

Potential end users should be engaged as early as possible, and the end users should be the main participants in identifying the problems/requirements. End users should be identified from among the subject matter experts and power users in an office because they are most likely to truly understand where the gaps exist in their technologies and what new capabilities are needed to take their work to the next level. When an office contributes some of its own funding to support the acquisition effort, the office is much more likely to support continued engagement by the end users. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Constraining the solution space

While it is important to not constrain the ideas, it is very important to constrain the support technologies used to implement the prototype to give each technology its best chance of being integrated into existing systems if the technology proves successful. Unlike the private sector, the reality of many government systems is they are not going to undergo any large scale replacement and, instead, need to evolve in place to incorporate new technologies and capabilities. This makes it necessary to constrain the solution space so potential new capabilities are designed to facilitate integration with existing systems. For example, if most existing systems at an agency use Linux servers and Windows clients, then this type of architecture should be a requirement for potential new capabilities. If the potential capability does not have the flexibility to use the specified architecture, it likely will not be able to be used regardless of its potential benefit. Thus, it is best to discover this issue early. Some constraints to consider are:

- A preference for using open source software where suitable software is available to minimize licensing costs
- No reliance or dependency on proprietary data formats or data storage mechanisms

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- Web-enabled GUIs and user facing applications
- Software developed using a common language such as C, C++, or Java
- Use of specific standards or protocols ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Solutions based on commercial products are generally less successful than solutions based on open technologies because commercial products may be less cutting-edge and innovative due to the amount of time it takes to bring a commercial product to market. Additionally, commercial products generally are associated with significant licensing fees that can be unrealistic for widespread government usage. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Identifying participants

The goal is to have the RFP reach as many suitable companies as possible including a significant number of companies that may be new to Federal contracting. The use of this model, with its shortened timeframe of producing a prototype in 6 months or less, and at a dollar value under the simplified acquisition threshold, should encourage participation by entrepreneurs and innovative small businesses. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

However, recognize that if the agency decides to go into production of the prototype, some of the companies may lack adequate cash flow management or have difficulties adjusting to the government's sometimes lengthy payment schedule, complex Federal Acquisition Regulation (FAR) and Defense Federal Acquisition Regulation (DFAR) contract clauses, and lengthy government acquisition cycles. Therefore, it may be beneficial to prescreen companies for interest using a market survey or some other advance notice of the upcoming acquisition to ensure they understand the requirements of a Federal acquisition.

Developing the RFP

There are two goals for the RFP:
(1) Design the RFP to eliminate as many delays and obstacles as possible and automatically mitigate what cannot be eliminated; and
(2) Have the proposals responding to the RFP include sufficient information to support comprehensive evaluations and allow the proposal to serve as the Statement of Work (SOW) for any resulting contracts.

If the resulting proposals are complete, comprehensive, and contain all information necessary to support proposal evaluation and contract award, the acquisition process can be expedited because the Contracting Officer will not have to hold discussions with the company to resolve areas which are unclear or are contrary to the government's requirements. If the resulting proposal is sufficiently complete, it can serve as the SOW for any resulting contract which will also expedite the acquisition process. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Common delays and obstacles that can be mitigated with RFP specifications

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The delays and obstacles encountered when awarding a contract for technical work will be specific to each agency, but here are some common issues that can be set forth in the RFP:

1. ***IT Governance*** – If an agency has IT Governance requirements dictating or forbidding the use of specific hardware or software, this information should be included in the RFP as requirements for all resulting projects. For example, many agencies are standardized on the use of the Windows operating system for client applications and on the use of the Linux operating system for back end server applications. If this is the case, then this information should be a requirement in the RFP. If there are two possible technical options for supporting potential solutions and additional approvals are required for one option but not the other option, consider limiting the company's IT choices for their prototype to the option that does not require the additional approvals.

2. ***Security*** – Different agencies have different security requirements for companies performing work. If there are options or approaches that require less approval than other options or approaches, to expedite the process, it may be beneficial to make the option requiring less approval mandatory if it will not unduly constrain the resulting prototype development effort. Security requirements and restrictions can always be revisited for successful prototypes when planning for longer term follow-on work.

3. ***Intellectual Property and Government Rights*** – The RFP needs to clearly state the conditions that will apply to all Intellectual Property developed under any contracts resulting from the project and whether the FAR/DFAR (or other agency specific) clauses regarding intellectual property will apply. Additionally, the RFP should state the minimum level of rights the agency is willing to accept, for example, Government Purpose rights, for all work developed under resulting contracts. Companies should also be informed in the RFP that offering to provide the prototype with rights less than the minimum level the agency is willing to accept may negatively impact their proposal evaluation.

4. ***Payments*** – Although contracts are likely to be firm fixed price, most efforts will involve incremental payments. The RFP should identify the payment schedule and tie each payment into a specific deliverable, for example, invoice #1 corresponds to the delivery of monthly status report #1. The company can then propose the amount for each scheduled payment. Having all companies follow the same payment schedule and identifying the payment amounts up front eliminates a common time-consuming item for Contracting Officer discussions with the company and simplifies the management of multiple projects after award.

5. ***Deliverables*** – The RFP needs to clearly define what deliverables are associated with any resulting contracts. If there are requirements for a deliverable that are beyond what is described in the Data Item Description (DID) for that deliverable, these additional requirements need to be clearly noted in the RFP. The minimum technical deliverables should be: 1) written monthly status reports; 2) a prototype and a prototype demonstration; and 3) delivery of all source code, documentation, licenses, and other materials needed to allow the government to install and run the prototype on the agency's hardware in a government facility for a year to fully assess the prototype.

6. ***Automatic Disqualification*** – The RFP should also specifically state the conditions that would automatically disqualify a proposal from consideration. This will save both the agency and the company a great deal of time and should mostly eliminate the receipt of non-compliant proposals. Some common conditions that could cause an automatic disqualification are: 1) proposing a cost exceeding the amount allowed by the government; 2) proposing a schedule that exceeds the time allotted by the government; 3) not adhering to the government's requirements in the RFP when writing the proposal; and 4) proposing to deliver something other than a prototype (e.g., a requirements document, a study).

7. ***Test Data*** – A significant challenge in developing rapid prototypes is obtaining a sufficient amount of suitable test data to make the prototype's operations relevant to the larger agency requirements. Where possible, the RFP should identify publically available collections of test data consistent with the agency's own data as well as describe collections of government test data that could be provided to companies upon contract award.

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8. ***Proposal Content and Format***– If the RFP provides specific instructions on the content and format of the proposals, it will expedite evaluation of the proposals and make it more likely that companies will include all necessary and relevant information in their proposals. See Sample Proposal Outline for suggested content that could be included in the Technical proposal.

["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Sample Proposal Outline

1. Executive Summary – Intended to provide an overview of the salient features of the entire proposal.

2. State-of-the-Art – A description of the current state-of-the-art concerning the proposed technology/approach, a discussion of comparable products, technologies and/or approaches similar to what the company is proposing, and an explanation of why what the company is proposing is well beyond the current state-of-the-art.

3. Description of the Prototype – A discussion of the idea being addressed by the prototype, identification of the key challenges, description of the proposed solution, a detailed research plan and technical approach to implement the functional prototype within the specified timeframe, and identification of the personnel and other resources available for the work.

4. Facilities, Software Frameworks/Data Sets and GFI – A description of the facilities the company has available to use for this work and identification of any equipment that needs to be purchased to support this effort. Any hardware, software, data, or documentation items the company wants to request from the government to support this effort need to be identified in the proposal so potential delays in providing these items to the company can be factored into the proposal evaluation.

5. Technical Data or Computer Software – Identification of all technical data or computer software that will be furnished to the government and the rights that will be provided to the government for each item.

6. Sub-Contracts or Relevant Collaborations – A description of any proposed sub-contracts or relevant collaborations planned or already in place with industry, government organizations, universities, or other institutions.

7. Other Parties – Identification of other parties to whom the proposal has been or will be sent.

8. Deliverables – A detailed description of all deliverables to be provided to the government as a result of the work and in accordance with the requirements in the Contract Data Requirements List.

9. Past Performance in similar R&D work.

10. Relevant Experience of Company and/or Key Personnel in the area being proposed.

The RFP should also specify page limits for the Technical and Management proposals. For short, rapid prototyping efforts, a 15-page Technical Proposal and a 5-page Management Proposal should be sufficient. This length is sufficient to provide a comprehensive description of the work, and it can still support relatively rapid proposal evaluations.

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["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Evaluating proposals and selecting for award

The proposal evaluation plan should reserve the right to fund all, some, or none of the proposals received under the BAA solicitation in order to retain the greatest flexibility for the government. A key point to make in the proposal evaluation plan is that the awards will be done in an effort to achieve a balanced program providing the best value to the government. Focusing on a balanced program will permit the government to consider factors other than absolute technical scores or lowest cost in making the selections so the government can select a mix of awards which provides the biggest benefit to the government. The wording listed below describes one way that this right can be reserved in the RFP:

"The Government reserves the right to shift funding across problem and topic tracks and/or add additional funding based on the quality of the proposals. Award(s) resulting from this BAA will be made to the responsible offerors whose offers, conforming to the BAA, represent in aggregate the greatest potential for contributing to the Government's current technical research needs as described in the BAA. The Government may select proposals for award that have lower technical or overall ratings if it is determined that the mix of topics represented by the awarded proposals represents the best value to the Government by providing a balanced program." ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The proposal evaluation criteria should be simple and straightforward. Three evaluation criteria that work effectively for small, rapid prototyping projects are:

Overall Technical Merit

- Scientific and technical merit
- Innovativeness and uniqueness
- Viability and practicality of technical approach
- Prototype capabilities

Potential Contribution and Relevance to the Mission

- Relevance and importance
- Applicability and validity
- Usefulness and effectiveness

Cost and Schedule Realism

- Schedule feasibility
- Risk management
- Cost realism

A two phase evaluation process also works well for small, rapid prototyping projects. Phase 1 consists of up to three reviewers independently evaluating and rating each proposal. If many proposals are received or if different proposals require different technical expertise, then different reviewers could be assigned to each proposal so the same three people do not have to evaluate each proposal. In Phase 2, a technical peer review is conducted by a small group of stakeholders to consider the evaluation information provided by the three independent reviewers and determine the specific proposals to be

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recommended for award that represent the best value to the government by producing a balanced program. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Executing the award

The main objective in executing the awarded contracts is to produce demonstrable prototypes of the new technologies that are as relevant as possible to the government's requirements thereby allowing informed, results-based decisions to be made regarding any follow-on work and additional investment to turn the prototypes in actual mission capabilities. If the company is able to deliver the prototype on schedule and budget and if the prototype has the capabilities and features stipulated in the original proposal, then this is a good indication that the company is likely to be successful in subsequent work. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Continue to involve end users

It is critical for end users to be involved with oversight of the technology aspects of each project, but it is equally important that the technical end users do not have to spend their limited and valuable time on the administrative aspects of the project, especially when most of the projects will not continue into follow-on work and will just stop at the end of the contract's period of performance. If many of the issues that could cause delays or obstacles to execution are designed out of the program from the beginning, then one person can easily handle the administrative duties for multiple awardees, leaving the technical end users to solely focus on the technical aspects of the work. Offices that have a need for the capabilities potentially offered by the technology and offices that would have to be involved in implementing the prototype into production environments are good sources for technical end users to participate in technical discussions with the company after contract execution. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Provide technical guidance and advice

There should be regular opportunities during the execution of the project for the Government's technical end users to ask questions of the company about the work being done and for the company to ask the technical end users questions about requirements, system environments, demonstration scenarios, relevant use cases, etc. Teleconferences can easily take the place of face-to-face meetings, especially where time or location considerations apply to the personnel participating in these meetings. The objective is to provide the company with sufficient information about the government's needs so that the company can develop the most relevant prototype possible given the cost and schedule constraints. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Demonstrate and test prototypes

A prototype demonstration at the end of the contract provides an effective assessment of the work that has been done and should clearly illustrate how the technology could potentially be applied to mission requirements. The technical end users should assist the company in defining relevant use cases and crafting the demonstrations scenarios so the prototype illustrates relevant operational situations as much as possible. Seeing the technology function under pseudo-operational situations should allow results-based decisions to be made regarding the viability and relevance of the technology. The demonstration of a functional research prototype also serves to verify that the work was actually done and something was built. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

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Pursuing follow-on work

Prototypes selected for follow-on work should be transferred to the standard acquisition processes supporting the development of mission systems. Technical end users who participated in the execution phase of the project are likely candidates for sponsoring the follow-on work. The prototype itself may serve as justification for a sole source follow-on contract for the company. Companies with prototypes that are not considered for follow-on work should be notified and provided with constructive feedback as to why their prototype was not selected for follow-on work so the company can improve its efforts in the future. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

(D7) Resources:

For more information on how to deploy a rapid prototyping approach, contact Carol Lundquist, (b) (6)

(D8) Authority:

Rapid technology prototyping contracts can operate within existing frameworks under the Federal Acquisition Regulations (e.g., FAR Part 35 and Part 15). Prototypes are also an explicit use case for the use of Other Transactions, for the agencies expressly permitted to use Other Transaction Authority. [[crosslink to OTA content/chart]]

Staged Contracts: Identifying Scalable Innovations for Tailored Government Solutions

D1: Elevator Pitch and Summary

Staged contracts offer agencies a tool to solicit proposals widely across the private sector—from established contractors to entrepreneurs—and rapidly assess them. A staged contract is an innovative contracting model that follows a three-phase evaluation process consisting of a short concept paper, invite-only full proposal, and subsequent 1-2 year pilot evaluation. Staged contracts may be used for the rapid and inexpensive assessment of many existing or prototype private-sector technologies. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Why

Staged contracts reduce administrative burden for both offerors and agencies while ensuring that the proposed solutions are well-fitted to an agency's particular needs. Agencies can more rapidly sample the diverse technology landscape for potential solutions by foregoing the extensive requirements of traditional acquisition processes in favor of short concept papers. The concept papers allow respondents to communicate the essence of their proposal without expending undue time and effort; staged contracts require offerors to submit only an initial summary slide and eight page concept paper instead of the hundreds of pages expected in traditional acquisition processes. This dramatic decrease in the burden of doing business with government may better ensure that successful offerors' core competencies lie not in proposal drafting but in delivering technology solutions. By lowering the barrier from a 300+ page RFP response to an eight-page concept paper, agencies can also increase and diversify the participation of small businesses and other innovators that respond to their solicitation. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

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How

Staged contracts' deep evaluative process ensures that solutions are customized to meet an agency's specific requirements. From solicitation to pilot completion, offerors' solutions are vetted during at least three dedicated evaluation periods: concept paper review, full proposal review, and pilot evaluation. Solutions undergoing pilot evaluations are not guaranteed agency-wide scale-up: unsatisfactory pilots can warrant further development, project termination, or user deployment. The hands-on, real-time implementation of pilots and frequent, informal communications with end users during the period of performance also provides offerors invaluable feedback to tailor solutions more precisely to government requirements. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

In general, staged contracts work as follows:

- *Announce:* Agencies release a broad solicitation for contractors to submit short concept papers communicating the essence of their proposed technologies.
- *Study:* Agencies invite promising offerors to submit detailed full proposals with both technical and cost/price components.
- *Evaluate:* Agencies evaluate selected full proposals in 1-2 year pilots, during which there is ample opportunity for offerors to communicate with end users and refine their technology.
- *Deploy:* Agencies decide to deploy, terminate, or further evaluate pilots. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D2: Benefits of Staged Contracts

Not all innovation is relevant to a particular government agency, and many innovations cannot be effectively used to meet an agency's particular requirements. Staged contracts enable rapid funneling of promising private sector technologies into rigorously evaluated pilots to identify the most promising technologies with strong potential for wide impact. Applicants with promising solutions can then submit a full proposal for subsequent pilot testing. The evaluation of the technology allows decisions regarding additional investment of government resources to be results driven and significantly reduces the cost, time, and technology risks for subsequent scale-up work. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Among the innovative contracting models, staged contracts can uniquely:

- Solicit solutions from a wider range of industry by lowering the burden with short concept papers
- Effectively use limited agency resources to rapidly assess many technologies and make results-based decisions regarding further investment
- Ensure extensive agency end user involvement, buy-in, and subsequent technology adoption
- Facilitate knowledge transfer from the government to small businesses, especially during pilots to better enable the small businesses to support the government's requirements ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D3: Candidate users

Staged contracts are useful for rapidly funneling multiple private sector technologies to both identify and validate options for meeting an agency's particular requirements. This approach, which uses the BAA acquisition method, can be easily tailored and customized to meet the specific needs of different agencies. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

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D4: Case study: Department of Veterans Affairs Innovation Initiative (VAi2) Industry Innovation Competition

The Department of Veterans Affairs Innovation Initiative (VAi2) Industry Innovation Competition illustrates the promise of staged contracts. The VAi2 Competition staged contracts followed a three phase process consisting of a four-page concept paper, 50-page invite-only full proposal, and 1-2 year pilot evaluation. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

VA's experience demonstrates the value of the staged contracting approach for testing out promising ideas and sourcing new solutions: The competition has attracted a 50-50 mix of established and first-time government contractors. In four rounds of competitions, the VA has continued to iterate and refine its requirements for proposals to lower the administrative burden. The inaugural VAi2 Industry Innovation Competition solicited 350-page submissions; in subsequent years, organizers later reduced the concept paper requirement first to 28 pages, then 8 pages, and currently the concept paper requirement is no more than a four-page concept paper. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

As of 2014, the VAi2 competition has awarded no fewer than 135 solutions worth $102.5 million, fielded solutions in eight topic areas, received over 20,000 ideas from 600 industry offerors, and collaborated with over 100 subject matter experts. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The VAi2 competition demonstrates that regardless of the outcome of the scale-up phase, agencies can derive significant value from the technology pilots of staged contracts. For example, the VA provided seed funding to VETransfer, a nonprofit startup, to create an end-to-end business accelerator for Veteran entrepreneurs, offering individualized mentorship at a physical incubator facility as well as online resources. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

From 2011 through 2014, VETransfer had generated 24 startups, raised nearly $1.4 million, created 89 jobs, and is scaling nationwide. Moreover, around 400 Veterans have completed the three-month online programs. Another awardee, Agilex Technologies, developed a system that enables providers to access electronic health record information on mobile devices. Most pilot participants (55-70%) reported a positive impact on their productivity and ability to communicate with patients and other providers. The pilot also demonstrated the feasibility of deploying mobile devices in a clinical setting on VA networks. A final example is MedRed's TBI Toolbox, which enables care providers to continuously develop, share, and administer the latest treatment methods in the rapidly evolving field of polytrauma care. Pilot users project the TBI Toolbox will eliminate collection of over 19,000 paper forms per year if deployed across the VA enterprise. When asked for their feedback, 74% of end users strongly agreed or agreed the system provides process improvement; 68% of users strongly agreed or agreed the system improves continuity of care; and 84% of users are extremely satisfied or very satisfied with system scoring and reporting. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D8: Authority: The VAi2 Broad Agency Announcement (BAA) was issued under Federal Acquisition Regulation (FAR) Parts 35.016 and 6.102(d)(2)(i), which provide for the competitive selection of proposals submitted in response to a BAA.

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(D7) Read more:
The VA's Industry Innovation Competition
Detailed information on requirements can be found in the FAQ.

For more information, contact: Amber Schleuning, Deputy Director, VACI, Amber.Schleuning@va.gov

D5: Challenges to deployment

There are limitations to the applicability of staged contracts. Because staged contracts are designed to rigorously implement and evaluate ideas (either novel or established in the private sector) within a short timeframe, this approach may not be optimal for the engineering of complex, incremental systems or for the rapid development of cutting-edge prototypes on the other hand. [[crosslink rapid prototyping content]] ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The process of rapidly funneling solutions into rigorously evaluated pilots also presents several challenges:

- Define the problem clearly
- Provide adequate guidance in the initial solicitation
- Manage risk and establish expectations
- Plan thoughtfully the transition to follow-on contracts ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Define the problem clearly

Agencies must be thoughtful in articulating the problem statement, its scope, and the types of solutions sought. Subject matter experts may be inclined to focus the problem statement too narrowly, excluding potential innovative solutions. Contract officers must be comfortable embracing the fact that the government does not know what the ideal solution looks like and must craft the problem statement accordingly to harness open-ended innovation. [[crosslink to problem definition content in Grand Challenges]] ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Provide adequate guidance in the initial solicitation

The initial solicitation encourages small business participation with its simplicity, and its open-ended nature emphasizes contractor creativity. However, these same qualities require agencies to ensure that the procurement office assists applicants and provides adequate government engagement. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Manage risk and establish expectations

Agencies must acknowledge and prepare for the uncertainty of contract funding, especially because each contract extends across two to three years. Staged contract pilot sites may also experience difficulties handling unforeseen timing issues, integrating prototype technologies within existing systems, and receiving buy-in from pilot staff. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

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Because the majority of pilot staff may have other, perhaps dominant, work responsibilities, agencies should maximize the number of technical end users, contract organizers, or other interested parties overseeing pilot progress. Unforeseen issues, particularly with larger pilots, may arise from an insufficient number of participants, technological bugs, or not getting participants security clearances in time. To mitigate these challenges, the government's expectations for the company and relevant information on the pilot site should be defined and clearly articulated at the outset. Frequent, informal interactions between the company and government personnel can ensure coordination and adequate progress. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Plan thoughtfully the transition to follow-on contracts

The requirements for full and open competition in the Competition in Contracting Act of 1984 may pose obstacles for agencies seeking to transition pilots into sole source follow-on contracts. Despite these challenges, the VAi2 Competition has demonstrated that the technology pilots themselves can provide agencies significant value. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D6: How to Guidance

The main objective using a staged contracting model is to design the acquisition approach and the RFP to result in a large number of high-quality proposals describing innovative technologies, ideas, and approaches relevant to the agency's requirements. A second, but equally important, objective is to design the RFP so that it expedites the overall acquisition process by "designing out" or mitigating any areas or issues that could cause delays to the acquisition process or the resulting prototype development projects. The BAA mechanism can serve as the basis of the acquisition effort. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Key steps for deploying staged contracts

Steps for using staged contracts are:

- Identifying the problem and specifying requirements
- Engaging the future end users early-on
- Constraining the solution space
- Identifying participants
- Developing the BAA
    - Common issues with the BAA
    - Sample concept paper outline
    - Sample full proposal outline
- Evaluating proposals and selecting for award
- Executing the award
    - Continue to involve end-users
    - Provide technical guidance and advice
    - Demonstrate and test prototypes
- Pursuing follow-on work

Identifying the problem and specifying requirements

The problems/requirements included in the BAA can be thought of as "bait" to attract and challenge companies to focus on solution. The key is to provide adequate background information so a company can make an intelligent assessment about what would be required and desired in a solution. Agencies

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should spend considerable time engaging end users to define problems adequately. It's important to resist the temptation to prescribe solution requirements. Clear problem definition is worthy of resource investment, as it generates long-term value; even if a company does not submit a proposal for a particular issue, the background information provided can start to educate industry on the agency's requirements, which assists companies to submit more relevant proposals in the future. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Choose initial areas of interest adjacent to ongoing high-complexity, high-centrality, and high-visibility agency initiatives. Such initiatives are likely to have well-defined challenges and subject matter experts the BAA could draw from. High visibility initiatives may also attract increased private sector interest for the BAA. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

If specific requirements or constraints exist for a particular problem and its potential solutions, this information should also be included in the problem description. Some common specific constraints are: minimum performance requirements, the use of certain software or platforms, minimum data amounts, the use of a particular set of test data, etc. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Engaging the future end users early-on

Potential agency end users should be engaged as early as possible, and these end users should be major participants in identifying the problems/requirements. End users should be identified from among the subject matter experts and "power users" in an office because they are most likely to truly understand where the gaps exist in their technologies and what new capabilities are needed to take their work to the next level. When an office contributes some of its own funding to support the acquisition effort, the office is much more likely to support continued engagement by the end users. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Engaging with potential end users early could also lead to a clearer articulation of agency areas of interest for innovative technologies in the BAA, which is particularly important should the BAA contain multiple areas of interest. For example, the VAi2's BAA prioritizes dialogue with end users and subject matter experts to craft detailed one-pagers for each topic area, providing background on the problem (e.g. scope and impact) and explicitly listing what features the VA was interested in. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Constraining the solution space

While it is important not to define the problem statement too narrowly, at the same time it is critical to constrain the support technologies used to implement the prototype, in order to give each technology its best chance of being integrated into existing systems if the technology proves successful. The reality of many government systems is they are not going to undergo large-scale replacement and, instead, need to evolve in place to incorporate new technologies and capabilities. This makes it necessary to constrain the solution space so potential new capabilities are designed to facilitate integration with existing systems. For example, if most existing systems at an agency use Linux servers and Windows clients, then this type of architecture should be a requirement for potential new capabilities. If the potential capability does not have the flexibility to use the specified architecture, it likely will not be able to be used regardless of its potential benefit. Thus, it is best to discover this issue early. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

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Some important constraints to consider are:

- A preference for using open source software where suitable software is available to minimize licensing costs
- No reliance or dependency on proprietary data formats or data storage mechanisms
- Web-enabled GUIs and user facing applications
- Software developed using a common language such as C, C++, or Java
- Use of specific standards or protocols

Solutions based on commercial products are generally less successful than solutions based on open technologies; commercial products may be less cutting-edge, due to the amount of time it takes to bring a commercial product to market. Additionally, commercial products generally are associated with significant licensing fees that can be unrealistic for widespread government usage. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Requiring concept papers to identify themselves as Development Proposals vs. Field Test Proposals can be helpful in signaling to agencies the technology's maturity. This information informs appropriate expectations and focus for the technical review committee and pilot managers regarding implementation readiness, evaluation, and scale-up potential. For example, pilot managers may prioritize repeatability and rigorous testing for Field Test Proposals, in contrast to achieving a working prototype for Development Proposals. Distinguishing proposals may also inform the selection of appropriate pilot sites. For example, Development Projects may not be well-suited for centralized, fastpaced pilot sites as failure risks may interrupt integral agency services. To coordinate agency efforts, both proposal types should be kept on consistent timelines, such as a 12-24 month period for pilot implementation and evaluation. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The VAi2 BAA provided the following definitions for Development Proposals and Field Test Proposals:

> *Development Proposals: New and untested ideas and technologies or novel customization and application of existing technologies that have the potential to provide benefits outweighing all costs and results that significantly exceed currently deployed solutions. Technologies and products submitted as Development Proposals shall achieve a working prototype or test system.*
>
> *Field Test Proposals: Products and solutions that have demonstrated significant value in commercial or other production environments but are new to the operating environment within Veterans Affairs. Solutions shall be repeatable and ready for small-scale deployment at the VISN [Veterans Integrated Service Networks] or facility level. Should the results from small-scale deployment prove favorable, the solution shall be scalable to a VA-wide implementation. It is anticipated that an award made in response to this BAA will fund the small-scale field testing.* ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Identifying participants

The goal is to have the BAA reach as many suitable companies as possible including a significant number of companies that may be new to Federal contracting. The use of this model, with its staged approach, should encourage participation by entrepreneurs and innovative small businesses. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Developing the BAA

There are two goals for the BAA:

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(1) Design the BAA to eliminate as many delays and obstacles as possible and automatically mitigate what cannot be eliminated; and
(2) Have the proposals responding to the BAA include sufficient information to support comprehensive evaluations and allow the proposal to serve as the Performance Work Statement (PWS) for any resulting contracts. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The acquisition process can be expedited when the resulting proposals are complete, comprehensive, and contain all information necessary to support proposal evaluation and contract award, because the contracting officer will not have to hold discussions with the company to resolve areas that are unclear or are contrary to the agency's requirements. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The delays and obstacles encountered when awarding a contract for technical work will be specific to each agency, but here are some common issues that can be set forth in the BAA:

Common delays and obstacles that can be mitigated with BAA specifications

1. ***IT Governance*** – If an agency has IT Governance requirements dictating or forbidding the use of specific hardware or software, this information should be included in the BAA as requirements for all resulting projects. For example, many agencies require the use of the Windows operating system for client applications and the Linux operating system for back-end server applications.
If this is the case, then this information should be a requirement in the BAA. If there are two possible technical options for supporting potential solutions and additional approvals are required for one option but not the other option, consider limiting the company's IT choices for their solution to the option that does not require the additional approvals.

2. ***Security*** – Different agencies have different security requirements for companies performing work. If there are options or approaches that require fewer approvals than other options or approaches, it may be beneficial to make the option requiring fewer approvals mandatory -- if it will not unduly constrain the resulting prototype development effort. Security requirements and restrictions can always be revisited for successful prototypes when planning for longer term follow-on work.

3. ***Intellectual Property and Government Rights*** – The BAA needs to clearly state the conditions that will apply to all intellectual property (IP) developed under any contracts resulting from the project and whether the FAR/DFAR (or other agency specific) clauses regarding intellectual property will apply. Additionally, the BAA should state the minimum level of rights the agency is willing to accept, for example, Government Purpose rights, for all work developed under resulting contracts. Companies should also be informed in the BAA that offering to provide the prototype with rights less than the minimum level the agency is willing to accept may negatively impact their proposal evaluation.

4. ***Payments*** – Although contracts are likely to be firm fixed price, most efforts will involve a series of payments. The BAA should articulate that only offerors invited for full proposals will be asked to provide their desired funding profile, informed by planned expenditures based on calendar quarters. Agencies may alternatively tie each payment into a specific deliverable, for example, invoice #1 corresponds to the delivery of milestone #1. The company can then propose the amount for each scheduled payment. Having all companies follow the same payment schedule and identifying the payment amounts up front eliminates a common time-consuming item for contracting officer discussions with the company and simplifies the management of multiple projects after the award.

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5. ***Deliverables*** – The BAA needs to clearly define what deliverables are associated with any resulting contracts. The deliverables expected depend on the proposal type, but in all cases should provide sufficient information for continual and final evaluation regarding scale-up potential. Such information could come in the form of milestones. For example, the VAi2 BAA [crosslink] required:

Development Proposals shall include milestones that demonstrate achievement of significant design steps, validation of new technologies and/or architectures, completion of work that indicates substantial risk reduction, etc. Prototype delivery and/or demonstration milestones shall be included, if appropriate.
Field Test Proposals shall include milestones that demonstrate significant steps in design, integration, testing, installation, verification, data collection, etc. The proposal shall clearly identify any required interaction with VA resources, data, facilities, etc. Prototype delivery and/or demonstration milestones shall be included, if appropriate.
All Proposals shall clearly identify the risks involved with their proposed solutions, and plans for mitigation of said risks.

6. ***Concept Paper Content and Format*** — If the BAA provides specific instructions on the content and format of the concept papers and full proposals, it will expedite evaluation of the submissions and make it more likely that companies will include all necessary and relevant information in their submissions.

7. ***Full Proposal Content and Format*** – When it is time for the second stage of this model, the agency will issue a BAA with specific instructions on the content and format of the full proposal to streamline the evaluation process. For example, the BAA could request to include the following content in the proposal:

["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Sample Concept Paper Outline

The BAA should also specify page limits for the concept paper—the VAi2 Competition requests papers limited to four pages in length, including a cover sheet and single-page summary slide.

As an example, the VAi2 Industry Innovation Competition requested concept papers to include the following content:

1. Proposed Approach (Technical Summary) – A concise description of the technical approach, describing the architecture, implementation plan, and the impacts and benefits of the proposed innovation. A short statement of the structure and timeline should be included. Clearly outline any technical challenges inherent in the approach and possible solutions for overcoming potential problems.

2. Supporting Technical Analysis: Address how the proposed technical approach is innovative or revolutionary and how it rises above the current state of practice.

3. Anticipated Requirements for Agency Resources: In addition to the funding requested, please describe any anticipated requirements of the agency to make the pilot or field test successful. Examples include software hosting, access to patient data, etc.

4. Team Expertise: A brief summary of expertise of the key personnel on the project relevant to the program goals. If the team is multi-organizational, a proposed management structure should also be included. In addition to a cover sheet requesting the Technical Point of Contact's information, the proposal type (Development, Field Test, or both), the cost Rough Order of Magnitude (ROM), and the duration of the proposed work, the VAi2 BAA requested a single-page summary slide containing the following sections: one-line description, one-paragraph summary, key picture/chart, ROM and

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schedule, and promised impact to the agency. Together, these three documents should support the rapid assessment of the technology landscape while providing enough technical detail to inform full proposal invites.

["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Sample Full Proposal Outline

The BAA should specify page limits for the full proposal, split into a technical and cost/price volume. The technical volume should be limited to 50 pages and the cost/price volume should have no limit. This length is sufficient to provide a comprehensive description of the proposals selected from the first round of rapid concept paper evaluations.

1. Executive Summary – Intended to provide an overview of the salient features of the entire proposal.

2. Background & Description – A detailed background, discussion and description of the proposed solution, and categorization as a Development Proposal and/or a Field Test Proposal.

3. Impact – A clear, concise definition of the impact, benefits, and scalability of the solution to the stated area of interest. Additional information such as a description of the current state-of-the-art concerning the proposed technology/approach, a discussion of comparable products, technologies and/or approaches similar to what the company is proposing, and an explanation of why what the company is proposing is of value.

4. Description of the Solution Design and/or Architecture – Development Proposals should clearly identify the new technology being developed, including a description of the current technology status and the future development to be undertaken. Field Test Proposals should clearly indicate the current level of deployment of the solution and describe the areas where agency deployment involves new or untested usage. The solution description should be written in a clear and concise manner and shall serve as the basis for a PWS should the proposal submission result in a contract award. Any hardware, software, data, or documentation items the company wants to request from the government to support this effort need to be identified in the proposal so potential delays in providing these at the pilot sites can be factored into the proposal evaluation.

5. Feasibility & Methodology – A reasonably complete discussion that details the feasibility and the methodology of the proposed approach(es) and identifies the level of effort to be employed. Risks associated with the proposers' solutions as well as mitigation strategies should be identified and discussed.

6. Unique Capabilities – A presentation of the offeror's unique capabilities and/or specialized experience. The offeror should also identify and provide resumes for key personnel and the principal investigator showing relevant experience.

7. Cost/Price – As a separate volume in the full proposal, the offeror's cost/price proposal should be prepared in a clear and concise manner that accurately reflects the offeror's total proposed amount for accomplishing the proposed solution. Cost data should include all costs expected during the

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performance of the contract. All details, broken down by cost element, should be prepared for each major task along with supporting rationale. Cost elements include: direct labor, materials, travel, other direct costs, consultants, subcontractors, indirect costs, profit/fee, and desired funding profile. The agency should indicate a preference for Firm Fixed Price (FFP) type contracts.

8. Sub-Contracts or Relevant Collaborations – A description of any proposed sub-contracts or relevant collaborations planned or already in place with industry, government organizations, universities, or other institutions.

9. Past Performance on similar R&D work

["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Evaluating proposals and selecting for award

The proposal evaluation plan should reserve the right to fund all, some, or none of the concept papers and full proposals received under the BAA solicitation in order to retain the greatest flexibility for the government. The BAA should clearly articulate that an invitation to submit a concept paper or full proposal does ***not*** guarantee a contract award. The BAA should also specify that all proposals are treated as sensitive competitive information with disclosure, use, or duplication only for purposes of evaluation, and that no funding is available for direct reimbursement of proposal development costs. To support the rapid assessment of innovative technologies, the BAA should emphasize the importance of clear, concise papers and proposals, as below:

> *Offerors are advised that the quality of the information presented in the proposal is significantly more important than the quantity. It is desired that the proposals, as briefly as possible, provide details of the technology and the design of the proposed solution, the impact on the stated field of interest, the scalability of the solution, the implementation plan, and the capabilities and expertise/experience of the Offeror as described in the section entitled "Proposal Submission Format."* ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The evaluation criteria for concept papers and full proposals should be simple, straightforward, and consistent. Six evaluation criteria that work effectively for pilot proposals are:

1. The potential impact, benefits, and contributions of the solution to the agency mission areas of interest
2. The quality of the proposed solution design
3. The quality of the proposed implementation plan
4. The scalability of the proposed solution
5. The offeror's capabilities, related expertise/experience, past performance, facilities, techniques, or unique combinations of these that are integral factors for the achievement of proposal objectives
6. The cost-effectiveness of the solution in proportion to its potential impact/benefits ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The evaluation of concept papers and full proposals can be streamlined by requiring that submissions be categorized as Development Proposals or Field Test Proposals, and by requiring that full proposals consist of distinct technical volumes and cost/price volumes. The former requirement orients the

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technical review committee to appropriate evaluation standards, while the latter better aligns the evaluation criteria to full proposal submissions. To ensure that offerors with strong paper proposals can deliver on them, agencies should thoroughly review financial backgrounds before award decisions are announced. Consistent with the BAA solicitation to offerors, the technical review committee should be clear that the evaluation process is not a competition, even within a topic area. The lack of a common statement of work precludes fair comparisons among offerors. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The technical committee should consist of both subject matter experts and potential agency end users with membership size dictated by the topic area's complexity. For example, the VAi2 2011 Industry Innovation Competition arranged committees of five to fourteen experts depending on topic area. Subject matter experts involved in the identification of topic areas should serve on the technical review committees to more accurately assess if offerors' technologies indeed satisfy agency needs as well as help identify appropriate pilot sites.

Executing the Award

The main objective in executing the awarded contracts is to establish and thoroughly assess pilots of the offerors' technologies such that promising pilots can be rapidly scaled across the agency through follow-on contracts. Additionally, if the company is able to deliver the pilot on schedule and budget and if the pilot has the capabilities and features stipulated in the full proposal, this is a good indication that the company can succeed in subsequent work. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Continuing to involve end users

It is critical for end users to be involved with oversight of the technology aspects of each project, but it is equally important that the technical end users do not have to spend their limited and valuable time on the administrative aspects of the project, especially when most of the projects will not continue into follow-on work and will stop at the end of the contract's period of performance. If many of the issues that could cause delays or obstacles to execution are "designed out" of the program from the beginning, then one person can easily handle the administrative duties for multiple proposals, leaving the technical end users to solely focus on the technical aspects of the work. Offices that have a need for the capabilities potentially offered by the technology and offices that would have to be involved in scaling up the pilot are good sources for technical end users to participate in technical discussions with the company during contract execution. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Providing technical guidance and advice

Throughout the solicitation and proposal evaluation process, there should be regular opportunities for the contractors to ask questions of the government agency. Within several weeks of the BAA publication, agencies should host an industry day webinar to provide information for each area of interest and address questions from industry. Informal communication should be encouraged, with all questions and responses posted for all contractors to see to avoid duplication and ensure a fair playing field. Procedural questions could be directed to the agency's technology acquisition center (TAC) and substantive questions to subject matter experts. Questions and responses could be posted on an online forum such as FedBizOpps.gov. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

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After the announcement of award decisions, communications should be limited solely to offerors participating in pilots. There should also be regular opportunities during the execution of the pilots for the agency's technical end users to ask questions of the company about the work being done, their progress, and their pilot's potential for scaling up. Teleconferences can easily take the place of face-to-face meetings, especially where time or location considerations apply to the personnel participating in these meetings. The objective is to provide the company with sufficient information about the agency's needs so that the company can develop the most relevant prototype possible given the cost and schedule constraints.

Evaluating Pilots

The monitoring, evaluation, and intervention of technology pilots should be continual, akin to adaptive management—a structured, iterative process of course-correcting that reduces uncertainty over time via system monitoring. Uncertainties associated with introducing a novel technology to a pilot site include its effectiveness, operability, and resistance to adoption. In this way, adaptive management seeks to fulfill short-term objectives while accumulating the knowledge base to optimize long-term pilot outcomes. This process of evaluation and intervention is predicated on frequent and honest dialogue among end users, offerors, and pilot managers. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Once the pilot has been completed, agencies must decide whether the technology is scalable. Such decisions should be informed by the nature of the technology (software vs. hardware), its complexity, and the offerors' financial background and resources. Agencies should also assess the technology landscape to ensure advances have not rendered the pilot technology obsolete, considering the time and cost associated with fully vetting another technology. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Pursuing Follow-on Work

Pilots selected for follow-on work should be transferred to the standard acquisition processes. Technical agency end users who participated in the execution phase of the project are likely candidates for sponsoring the follow-on work. If possible, agencies may cite the pilot as justification for a sole source follow-on contract for the company. Companies with prototypes that are not considered for follow-on work should be notified and provided with constructive feedback as to why their technology was not selected for follow-on work so the company can improve its efforts in the future. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Agencies should acknowledge and prepare for multiple scenarios in scaling up promising pilot technologies agency-wide. The requirements for full and open competition in the Competition in Contracting Act of 1984 may present obstacles for agencies seeking to transition pilots into sole source follow-on contracts. For example, the VAi2 Industry Innovation Competition has observed intense competition for follow-on contracts mandated by full and open competition. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D8: Authorities

The authority to solicit BAAs for staged contracts is outlined under the provisions of Parts 35.016 and 6.102(d)(2)(i) of the Federal Acquisition Regulation (FAR), which provides for the competitive selection of proposals submitted in response to the BAA. Accordingly, proposals selected for award must be considered the result of full and open competition and fully compliant with Public Law 98-369 (The

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Competition in Contracting Act of 1984). Note that staged contract BAAs are only an expression of interest and thus do not commit the government to make an award or pay proposal preparation costs. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Competitive Milestone-Based Contracts: Maximizing Value from Small Businesses

D1: Elevator pitch and summary

Competitive milestone-based contracts are a useful tool for attracting businesses with innovative approaches to well-defined, multi-component problems. A competitive milestone-based contract is an innovative contracting model that promotes competition among a stable pool of selected offerors across a series of clear, technically feasible milestones, with payment withheld until the associated, agreed-upon milestone is completed. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Why:

Agencies need the ability to attract innovative approaches to well-documented problems, while minimizing cost, risk, and liability. Milestone-based contracts accomplish these goals by financing the completion of authorized work, in the form of milestones, withholding payment until the agreed-upon milestone is completed. In crafting the solicitation, the government establishes a series of milestones, each with well-defined requirements, a deadline, and an assigned monetary value. The unique combination of attributes in these contracts—firm-fixed price, indefinite delivery/indefinite quantity (IDIQ), and performance incentives—maximizes value delivered to government and places full financial responsibility on the contractors. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

By foregoing a bulky, long-term deliverable in favor of a series of achievable milestones, these contracts encourage participation from traditionally underrepresented contractors, such as small businesses and high-growth startups. Competitive milestone-based contracts also provide agencies considerable flexibility in contract financing and solicitation. Among the innovative contracting models, competitive milestone-based contracts can uniquely:

- Strengthen small businesses through more accessible financing and recruitment of private investment
- Maximize value and innovation delivered to government on specific, concrete agency challenges
- Ensure government flexibility in financing and solicitation given limited resources ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

How:

In crafting the solicitation, the government establishes a series of milestones, each with well-defined requirements, a deadline, and an assigned monetary value.

In general, competitive milestone-based contracts work as follows:

1. *Announce:* Agencies release a broad solicitation for contractors to compete through a series of milestones, each with a defined problem statement and monetary value.
2. *Select:* Agencies select a pool of competing contractors following the initial solicitation.

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3. *Launch:* Agencies announce which milestones are under competition and provide more specific language on technical constraints and deadlines.
4. *Maintain:* Agencies award first milestone winners and decide when to place the remaining milestones under competition, depending on fiscal constraints. The government is not compelled to compete any milestones beyond the first, and no contractor is entitled to award money beyond the minimum. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D2: Benefits

Competitive milestone-based contracts offer agencies significant flexibility in funding and solicitation while achieving cost-effective results. Agencies may choose which milestones to put in play and withhold others depending on available funds. As each milestone is independent of another, agencies have no ongoing liabilities following the conclusion of one milestone, and possess the flexibility to modify or freeze the contract. For solicitation, the initial BAA need only contain the statement of objectives, baseline requirements, and property/data rights; the details of individual milestones can be augmented with greater specificity later, once the contractor pool is established. The same applies to future milestones not currently underway. This provides government agencies the flexibility to introduce or modify downstream milestone requirements should needs change. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Competitive milestone-based contracts may also be more cost-effective than traditional contracts. For example, contracts for NASA's Innovative Lunar Demonstrations Data (ILDD) (detailed below) paid only $500,000 -- rather than the typical $3-5 million – it its first milestone for propulsion data from innovative rocket injectors using green propellants. A NASA Inspector General report found that NASA's Commercial Orbital Transportation System (COTS) program, by using milestone-based payment approach, produced results at 1/10th the cost of traditional procurement approaches. ["Falcon 9 Launch Vehicle NAFCOM Cost Estimates," NASA, August 2011.]

D3: Use cases

Milestone-based competitions provide agencies the ability to attract innovative approaches to well-documented problems, while minimizing cost, risk, and liability. This approach, which uses the BAA acquisition method, can easily be tailored and customized to meet the specific requirements and constraints of different government agencies. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

As of December 26, 2014, changes made in 2 CFR 200 effectively limit the use of fixed amount sub-awards (including milestone based payments) on new U.S.-based procurements to a threshold of $150,000.Agencies can request waivers on an agency level. Work with your procurement office to learn more. [Kutnick, A., personal communication with Policy Design Lab, January 10, 2017.]

D4: Case Studies : NASA's Innovative Lunar Demonstrations Data (ILDD) and Commercial Orbital Transportation Services (COTS)

Case 1: Innovative Lunar Demonstrations Data (ILDD)

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The NASA Innovative Lunar Demonstrations Data (ILDD) program illustrates the promise of competitive milestone-based contracts. The NASA ILDD program sought responders to deliver specific data related to lunar exploration that could from commercial development of small, robotic lunar landers.. The NASA ILDD program awarded small, firm-fixed price, indefinite delivery/indefinite quantity (IDIQ) contracts over the course of five years, with a small minimum order, followed by sequentially ordered tasks for which a contractor is not paid if work is stopped. "We're not funding the missions themselves," explained Nantel Suzuki, Advanced Exploration Systems program executive. ["New NASA Moon Plan: Pay Others to Go: Discovery News," Seeker, February 11, 2013.] "These teams had to, as part of the proposal, not only explain their technical capabilities, but also their business potential. They had to demonstrate they had viable end-to-end lunar missions ... and some kind of business strategy." ["New NASA Moon Plan: Pay Others to Go: Discovery News," Seeker, February 11, 2013.]

With an open-ended 18-page BAA, the program attracted underrepresented organizations, including small businesses, non-profits, new startups, and university consortia, before ultimately selecting six teams. All six teams are participating in the Google Lunar X PRIZE, which provides a total of $30 million in prizes to privately funded teams to safely land a robot on the moon's surface, have the robot traverse 500 meters, and send data back to Earth. Moreover, the six teams participating in the NASA ILDD program were not established contractors; though most had identified private investors and crafted a business case, none had ever contracted with the government. The NASA ILDD program also encouraged significant private investment tied to government-established milestones: several competitors had private investments dependent on the successful completion of NASA milestones. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D7: Resources
Read: NASA Awards Contracts For Innovative Lunar Demonstrations Data, October 2010

Watch: "Milestone-Based Acquisition with George Xenofos," OFPP and FAI Library

D8: Authority:

The NASA ILDD program drew further authority from NASA FAR Supplement (NFS) Part 1835.

Case 2: Commercial Orbital Transportation Services (COTS)
Case study source: [McAlister, P., personal communication to the Office of Science and Technology Policy, February 2016.]

Summary: NASA's Commercial Orbital Transportation Services (COTS) program was designed to stimulate the U.S. private industry development of cargo space transportation capabilities. Using a milestone-based approach, NASA enabled the development of two new Space Station cargo transportation systems, including the SpaceX Falcon 9 and Orbital Sciences Antares rockets. The project was executed through funded Space Act Agreements (i.e. Other Transactions), with specific payment milestones established every few months. The agreements allowed industry to retain intellectual property, while the agency was assured of only paying for successful contractor performance. ["Innovation is a Contract Sport," Partnership for Public Service, Feburary 6, 2016.] The end result was the development of entirely new commercial space capabilities, and NASA received an extraordinarily good return on investment: Milestone-based contracting meant that NASA paid 10 cents on the dollar

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compared to traditional procurement approaches. ["Falcon 9 Launch Vehicle NAFCOM Cost Estimates," NASA, August 2011.]

"NASA's use of funded Space Act Agreements [e.g. OTA] rather than FAR-based contracts to develop new crew and cargo transportation capabilities has had several benefits," according to a November 2014 NASA Inspector General report: "First, because the partners share development costs and Space Act Agreements involve fewer regulations and require less oversight by NASA, the Agency spent less to develop these capabilities. For example, in the cargo development program, NASA estimated it saved between $1.4 and $4 billion connection with SpaceX's efforts, with similar savings for the transportation obtained by Orbital. Second, because NASA does not impose specific requirements on the companies as part of the Space Act Agreements, the commercial partners are free to develop spacecraft designs that will support the needs of both NASA and other customers. Finally, NASA officials said they believe the greater flexibility offered by the Space Act Agreements promotes creativity and innovation." ["NASA's Top Management and Performance Challenges, November 2014," p. 5, NASA Office of Inspector General, November 14th, 2014.]

D7 - Resources:
For more information, contact:
Phil McAlister, NASA HQ, Washington DC, 202-358-0712, philip.mcalister@nasa.gov
Marc Timm, NASA HQ, Washington DC, 202-358-0373, marc.g.timm@nasa.gov

Read more:

- COTS Program Overview
- COTS Final Report (May 2014)
- Falcon 9 Launch Vehicle NAFCOM Cost Estimates (August 2011)
- [[Uploaded - Rebecca Keiser paper]]
- "NASA Analysis: Falcon 9 Much Cheaper Than Traditional Approach," Parabolic Arc. (May 2015)

Watch:
NASA News Conference on Completion of COTS Program (November 2013)
COTS Highlights (June 2014)

D8: Authority
National Aeronautics and Space Act of 1958,, Pub. L. No. 85-568, 72 Stat. 426-438 (Jul. 29, 1958)
(NASA's ability to use Other Transaction Authority (OTA) is granted under the Space Act of 1958 and is referred to as a Space Act Agreement. NASA's OTA is outlined in Sec. 203 (c) (5).)

D5: Challenges to deployment

There are limitations to the applicability of competitive milestone-based contracts. These contracts may not be suitable for the development of complex, incremental systems, such as the engineering of an entire space shuttle. As milestones may rely on previous milestones' solutions, scenarios of technological incompatibility across contractors or intellectual property rights thickets may arise. Moreover, if the government agency's mission includes the public dissemination of knowledge, it may become frustrated by the lack of insight into contractors' operations and progress. Finally, well-defined milestone requirements may preclude agencies from expanding their scope, although new milestones

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can be introduced. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Additionally, successful competitive milestone-based contracts should:

- Account for unique implications of flexible contracts
- Manage risk and establish expectations

Account for unique implications of flexible contracts

Flexibility in both funding and solicitation result in unique agency challenges. Government agencies must remain cognizant of contractors' different development schedules in announcing new, active milestones to maximize competition. Another challenge arises in the delicate balancing of the initial solicitation's open-ended requirements to foster innovation and providing sufficient information to contractors. This balancing may be an iterative process where agencies publicly post clarifying responses to questions. Contractors may also misrepresent their relationship with the government agency for financial benefit; agencies may consider including language regulating such behavior. After the contract concludes, contractors, especially small businesses, may seek funding from foreign sponsors; agencies should expect such situations. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Manage risk and establish expectations

The key to effectively managing milestone-based projects is to allow the company to manage all execution risk and avoid any dependencies on the government for information, approvals, or other items. Though not as detailed in the initial BAA, task requests for further milestones should clearly articulate the government's expectations so the company knows what to expect in terms of progress checkpoints, deliverable requirements (e.g., prototype demonstrations), and amount of technical guidance and advice that will be provided. Frequent interactions between the company and government personnel such as participation of government personnel in the company's daily technical meetings should be avoided to minimize adding too much government bias to the effort and avoid shifting additional risk onto the government. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D6: How to Guidance

The main objective is to design the competitive milestone-based contract solicitation to result in a large number of good proposals describing innovative technologies, ideas, and approaches relevant to the agency's requirements. A second, but equally important, objective is to design the RFP so it expedites the overall process by clarifying any areas or issues that could cause delays in understanding specific milestone requirements. The BAA mechanism can serve as the basis of the acquisition effort. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Competitive Milestone-based Contracts at a Glance: 9 Steps to Deployment

1. Understand and develop the underlying service requirements, not engineering and design requirements.
2. Perform adequate market research prior to awards to ensure that the private sector is willing to share the financial and technical risk with the government.

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3. Make multiple awards to enhance performance and to ensure that the government is not reliant on a single provider.
4. Include pre-negotiated milestones (including date and technical content), which serve as a mechanism to judge technical and programmatic progress and forms the basis of assessing agreement termination, if needed.
5. Distribute funds to the partner only upon successful completion of pre-negotiated technical and programmatic milestones.
6. State clearly detailed entrance and success criteria for all milestones, so all parties understand exactly what is needed to successfully accomplish a milestone.
7. Include terms and conditions that allow all Intellectual Property to stay with the partner.
8. Require partners to self-fund a percentage of the development cost, so the partner has skin-in-the-game.
9. Maintain a big future carrot (e.g. future services contract) sufficient in size to warrant industry self-funding technical progress and skin-in-the-game.

[McAlister, P., personal communication to the Office of Science and Technology Policy, February 2016.]

Key steps for deploying milestone-based contracts

- Identifying the problem and specifying requirements
- Engaging the future end users early-on
- Constraining the solution space
- Identifying participants
- Developing the BAA
    - Common issues with the BAA
    - Sample concept paper outline
    - Sample full proposal outline
- Evaluating proposals and selecting for award
- Executing the award
    - Continue to involve end-users
    - Provide technical guidance and advice
    - Demonstrate and test prototypes
- Coordinating award & deliverable hand-off
- Pursuing follow-on work

Identifying the problem and specifying requirements

The problems included in the BAA need to be thought of as "bait" to attract and challenge companies to focus on solutions for these problems. In the initial solicitation to select the pool of contractors, requirements can be high level, allowing applicants to pursue innovative yet technically sound approaches. The key to the problems is to provide enough background information so a company can make an intelligent assessment about what would be required and desired in a solution. Additionally, even if a company decides to not submit a proposal, the background information provided about the problems/requirements can start to educate industry on the agency's requirements, which assists companies to submit relevant proposals in the future. Milestone requirements, however, must be very

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specific with a defined result, especially after selection of the competing pool of contractors. Below is an example of a contract milestone in a NASA's ILDD initial solicitation: ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

> ***"CLIN 1: Critical Component Demonstration***
> *NASA's objective is to acquire data as a result of conducting a critical component demonstration test of an item that was one of the top 10 risks as identified in the participant's SDR data package. The participant will be asked to provide information similar to the following:*
> *a. The component should be classified as flight-like with respect to form, fit and function.*
> *b. The functional performance parameters should be defined with allowable margins. For example, 'the temperature sensor shall provide measurement data in the range of -100 deg C up to +100 C with an error of no more than +/- 1 deg C'.*
> *c. The component should be tested in an Earth standard laboratory environment. This should be a space-qualification test (full-up) under operational environment conditions (temperature, pressure, vibration, etc.).*
> *d. The component should meet the identified functional performance parameters."*

The expectations for problems/requirements should focus on what can realistically be achieved in the allowed timeframe. If specific requirements or constraints exist for a particular problem and its potential solutions, this information should also be included in the problem description. Some common specific constraints are: minimum performance requirements, the use of certain software or platforms, minimum data amounts, the use of a particular set of test data, etc. Another type of information very useful to companies when crafting their response is a description of approaches or technologies that the agency is not interested in. The "Not Interested In" list could be common approaches which have been tried so often that there is very little value in trying it again. It could also be approaches the agency knows will not work effectively based on internal research. The reasons the agency is not interested do not have to be included with the description of the "Not Interested In" approach/technology.
With a clear articulation of the problems to be addressed, contracts can encourage significant private investment tied to government-established milestones. For example, several NASA ILDD contractors had private investments dependent on the successful completion of NASA milestones, amplifying the incentives to deliver maximum value to government, strengthening the contractors, and recruiting de facto private partners. Moreover, the six teams participating in the NASA ILDD program were all participating in the Google Lunar X PRIZE, which offers a total of $30 million in prizes. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Engaging the future end users early-on
Potential end users should be engaged as early as possible, and the end users should be the main participants in identifying the problems/requirements. End users should be identified from among the subject matter experts and power users in an office because they are most likely to truly understand where the gaps exist in their technologies and what new capabilities are needed to take their work to the next level. When an office contributes some of its own funding to support the acquisition effort, the office is much more likely to support continued engagement by the end users. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Relating milestone requirements to how end users will use the deliverables towards the agency's larger mission provides contractors valuable context. For example, the NASA ILDD BAA articulated the purpose of purchasing technical data arising from commercial development of small, robotic lunar landers:

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"The ILDD procurement will allow NASA's Lunar Lander Project Office to increase its knowledge and understanding of the design, testing, and flight lessons to be learned through the use of these landers.
Additionally, this information will enable the Lunar Lander Project Office to quickly and efficiently implement a plan for building and testing relevant components of lander hardware to be utilized in future human and robotic landers. Lunar mission scenarios producing data of interest to NASA may include performing lunar landing using a human mission profile, identification of hazards during landing, precision landing, and extended duration operations." ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Constraining the Solution Space

While it is important to not constrain the ideas, it is very important to constrain the support technologies used to implement the deliverable to give each technology its best chance of being integrated into existing systems if the technology proves successful. Unlike the private sector, the reality of many government systems is they are not going to undergo any large scale replacement and, instead, need to evolve in place to incorporate new technologies and capabilities. This makes it necessary to constrain the solution space so potential new capabilities are designed to facilitate integration with existing systems. For example, if most existing systems at an agency use Linux servers and Windows clients, then this type of architecture should be a requirement for potential new capabilities. If the potential capability does not have the flexibility to use the specified architecture, it likely will not be able to be used regardless of its potential benefit. Thus, it is best to discover this issue early. Some good constraints to consider are:

- A preference for using Open Source software where suitable software is available to minimize licensing costs
- No reliance or dependency on proprietary data formats or data storage mechanisms
- Web-enabled GUIs and user facing applications
- Software developed using a common language such as C, C++, or Java
- Use of specific standards or protocols

Solutions based on commercial products are generally less successful than solutions based on open technologies because commercial products may be less cutting-edge and innovative due to the amount of time it takes to bring a commercial product to market. Additionally, commercial products generally are associated with significant licensing fees that can be unrealistic for widespread government usage. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Identifying participants

The goal is to have the BAA reach as many suitable companies as possible including a significant number of companies that may be new to Federal contracting. The use of this model, with its shortened timeframe of producing a prototype in 6 months or less, and at a dollar value under the simplified acquisition threshold, should encourage participation by entrepreneurs and innovative small businesses. However, recognize that if the agency decides to go into production of the prototype, some of the companies may lack adequate cash flow management or have difficulties adjusting to the government's sometimes lengthy payment schedule, complex Federal Acquisition Regulation (FAR) and Defense Federal Acquisition Regulation (DFAR) contract clauses, and lengthy government acquisition cycles. Therefore, it may be beneficial to prescreen companies for interest using a market survey or some other advance notice of the upcoming acquisition to ensure they understand the requirements of a Federal

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acquisition. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Developing the BAA

There are two goals for the BAA: (1) Design the BAA to eliminate as many delays and obstacles as possible and automatically mitigate what cannot be eliminated; and (2) Have the proposals responding to the BAA include sufficient information to support comprehensive evaluations. Competitive milestone-based contract BAAs need only contain the statement of objectives, baseline milestone requirements, and intellectual property and government rights; the details of individual milestones can be augmented with greater specificity later, once the contractor pool is established. If the resulting proposals are complete, comprehensive, and contain all information necessary to support proposal evaluation and contract award, the acquisition process can be expedited because the Contracting Officer will not have to hold discussions with the company to resolve areas that are unclear or are contrary to the Government's requirements. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The delays and obstacles encountered when awarding a contract for technical work will be specific to each agency but here are some common issues that can be designed out of the BAA:

Common delays and obstacles that can be mitigated with BAA specifications

1. ***IT Governance*** – If an agency has IT Governance requirements dictating or forbidding the use of specific hardware or software, this information should be included in the BAA as requirements for all resulting projects. For example, many agencies standardized on the use of the Windows operating system for client applications and on the use of the Linux operating system for back end server applications. If this is the case, then this information should be a requirement in the BAA. If there are two possible technical options for supporting potential solutions and additional approvals are required for one option but not the other option, consider limiting the company's IT choices for their deliverable to the option that does not require the additional approvals.

2. ***Intellectual Property and Government Rights*** – The BAA needs to clearly state the conditions that will apply to all Intellectual Property developed under any contracts resulting from the project and whether the FAR/DFAR (or other agency specific) clauses regarding intellectual property will apply. Additionally, the BAA should state the minimum level of rights the agency is willing to accept, for example, Government Purpose rights, for all work developed under resulting contracts. Companies should also be informed in the BAA that offering to provide property rights less than the minimum level the agency is willing to accept may negatively impact their proposal evaluation.

3. ***Payments*** – The BAA should clearly establish the total value of the contracts, the maximum award to any one offeror, and the minimum order. For example, the NASA ILDD BAA established $30.1 million as the total value, with a maximum of $10 million award to any one offeror. Additionally, the BAA mandated all offerors submit a written System Definition Review (SDR) data package within 21 days of contract award, which would satisfy the $10,000 minimum order, and before competition for milestones. The SDR provided vital information on the selected offeror's proposed system architecture/design and the flowdown to all functional elements of the system. Beyond this SDR, offerors selected to be in the IDIQ pool were not obligated to compete/bid on every milestone and were not guaranteed to receive any additional task orders or payments as agencies may choose which milestones to put in play and withhold others depending on the financing available.

4. ***Deliverables*** – The BAA needs to clearly define what deliverables are associated with the minimum order and the milestones. If there are requirements for a deliverable that are beyond what is described in the Contract

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Line Item Numbers (CLINs) for that deliverable, these additional requirements need to be clearly noted in the BAA. The BAA should specify that each CLIN will be competed in an IDIQ fashion with the government evaluating proposals based on criteria specified in the associated request for a task plan. The BAA should also specify the deadline and submission requirements for the minimum order.

5. ***Proposal Content and Format–*** If the BAA provides specific instructions on the content and format of the proposals, it will expedite evaluation of the proposals and make it more likely that companies will include all necessary and relevant information in their proposals.

["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

For example, the BAA could request the proposal to include the following content:

Sample BAA Response

The BAA should specify page limits for the Technical and Management proposals. For milestone-based contracts, a 10 page Technical Approach; 10 page Business Model, with business strategy and financial plan; and 5 page value proposal should be sufficient. This length is sufficient to provide a comprehensive description of the work and it can still support relatively rapid proposal evaluations.

1. Executive Summary – Intended to provide an overview of the salient features of the entire proposal.

2. Technical Approach – A description of the offeror's technical approach with sufficient detail for the government agency to evaluate its reasonableness and innovativeness, as well as the offeror's performance on previous, relevant projects. For example, the NASA ILDD BAA requested the technical documents: Concept of Operations, Conceptual Vehicle Design, and Demonstrated Performance with Relevant Technical Endeavors. Respectively, these documents described the general description of the proposed lunar mission, major components of the proposed vehicle, and performance on past endeavors and their relation to the BAA. These requirements were relatively open-ended, purposefully crafted to elicit innovative approaches.

3. Business Model — A description of the offeror's business strategy for successful completion of the proposed technical approach. Important information includes: the company's relevant experience, availability of adequate financial resources and financial commitments, access to technical equipment and facilities, and team members with relevant experience along with organizational structure. The business model should also require a financial plan, describing the funding available by government fiscal year that will enable the successful completion of the proposed technical approach as well as potential threats to the plan.

4. Value Proposal — A description of the intellectual property rights the offerors propose to confer beyond internal government use, and a complementary written justification that the government is receiving products of value commensurate with the financial award of each milestone.

5. Sub-Contracts or Relevant Collaborations – A description of any proposed sub-contracts or relevant collaborations planned or already in place with industry, government organizations, universities, or other institutions. Collaborations with foreign entities must be clearly identified so the government agency can arrange with sponsoring foreign agencies for the proposed participation on a no-exchange-of-funds basis.

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6. Other Parties – Identification of other parties to whom the proposal has been or will be sent, in compliance with U.S. export control laws and regulations.

7. Deliverables – A detailed description of all deliverables to be provided to the government as a result of the work and in accordance with the requirements in the Contract Data Requirements List.

8. Past Performance in similar R&D work.

["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Evaluating Proposals and Selecting for Award

The proposal evaluation plan should reserve the right to fund all, some, or none of the proposals received under the BAA solicitation in order to retain the greatest flexibility for the government. The plan should also specify that all proposals are treated as sensitive competitive information with disclosure only for purposes of evaluation, and that no funding is available for direct reimbursement of proposal development costs. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The proposal evaluation criteria should be simple and straightforward. Three evaluation criteria that work effectively for milestone-based contracts are:

Technical Approach

- Scientific and technical merit
- Innovativeness and reasonableness
- Viability and practicality of technical approach
- Previously demonstrated performance

Business Merit

- Realistic and reasonable business strategy
- Funding profile, with identified threats and mitigation
- Applicability and validity to proposal

Value Merit

- Government property/data rights
- Risk Management
- Cost Realism ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

A two phase evaluation process works well for milestone-based contracts. If many proposals are received or if different proposals require different technical expertise, then different reviewers could be assigned to each proposal so the same three people do not have to evaluate each proposal. In phase 1 for each proposal, an assembled peer review team could assign a rating to each evaluation criteria using confidence level ratings: high, medium, and low confidence:

- **High confidence** proposals are of exceptional merit in the specific evaluation factor, are likely to satisfy requirements identified in the solicitation, and any unfavorable observations are minor.

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- **Medium confidence** proposals are of appreciable merit, provide a reasonable likelihood of satisfying requirements, and unfavorable observations moderately detract from the proposal.
- **Low confidence** proposals fail to demonstrate appreciable merit, are not likely to satisfy requirements, and unfavorable observations are significant. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Confidence ratings assigned to each proposal's evaluation criteria can then be aggregated into an overall rating for the proposal. Each proposal could receive one of three category ratings: category I, II, or III:

- **Category I** proposals are recommended for acceptance; they are well-conceived, offer scientific innovation and sound strategy, supported by responsible contractors and sufficient resources, and confer desired property/data rights.
- **Category II** proposals are recommended for acceptance, but at a lower priority than Category I proposals; they are scientifically innovative, supported by a responsible contractor and adequate resources, confer acceptable property/data rights, but require further development technically.
- **Category III** proposals are not recommended for acceptance; they are not technically sound or do not meet agency needs. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

In phase 2, a technical peer review is conducted by a small group of stakeholders to consider the evaluation information provided by the previous peer review team and to determine which of the specific proposals recommended for acceptance into the competitive milestone-based contract represent the best value to the government. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Executing the award

The main objective of milestone-based contracts is to encourage innovation satisfying government requirements at much lower government cost, risk, and liability. As contractors are incentivized to produce maximum value for agencies under strict timelines, agencies avoid intensive, hands-on work throughout. Moreover, milestone-based contracts' flexibility in financing and requirements allows agencies to adapt milestones while executing the program. Contractors that fail to meet milestone requirements incur minimal, defined agency costs, allowing agencies to only reward success. However, the success of milestone-based contracts still depends on agency coordination of contractors and deliverables transfer, management of remaining risk, and provision of technical guidance. Promising contractors may be selected for follow-on work under standard acquisition processes or other innovative contracting approaches. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Continuing to involve end users

Government agencies participating in milestone-based payment systems will find their greatest challenges in coordinating contractors, especially with the limited insight into their progress. In order to ensure the maximum level of competition among contractors for each task request, agencies must be cognizant of each contractor's development schedule and find a juncture in time attractive to most contractors for announcing new requests. Competition can be further fostered through informal communications and technical guidance. Another unique problem may arise when contractors misrepresent their relationship with the government agency as advertisement for their goods or services. Agencies should clearly outline policies regulating such practices to curb public misunderstanding of milestone-based payment's hands-off nature as a formal endorsement. While

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milestone-based contracts provide agencies financial flexibility through sequestration, agencies should establish and communicate expectations on which milestones have secured funding and which have not. Finally, agencies should coordinate with contractors should new requirements be introduced to downstream milestones. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Providing technical guidance and advice

Because of the open-ended nature of the initial BAA, there should be regular opportunities throughout the execution of milestones for the contractors to ask questions of the government agency. To address these questions and gain insight into the contractors' progress, agencies could establish mini-milestones or progress checkpoints, with no additional funding involved. Informal communication should be encouraged, with all questions and responses posted for all contractors to see to avoid duplication and ensure a fair playing field. Teleconferences can easily take the place of face-to-face meetings, especially when time or location considerations apply to the personnel participating in these meetings. The objective is to provide the company with sufficient information about the government's needs that the company can be comfortable in its understanding of the deliverable's nature and scope.

Coordinating award & deliverable hand-off

Comprehensive vetting of the deliverable should occur prior to selection and award for each milestone. There will be variation in vetting and hand-off depending on each milestone's requirements (e.g., data formatting) and deliverable (e.g., prototype, data, etc.). Prototypes should be subjected to a demonstration to provide an effective assessment of the work that has been done and should clearly illustrate how the technology could potentially be applied to mission requirements. The demonstration should be held under pseudo-operational conditions as determined by the technical end users. Data collected should be evaluated to comply with all specified requirements. Government agencies should not hesitate in asking clarifying questions based on observed results, even if the results comply with requirements or threaten to reasonably postpone the delivery date. If questions are asked post-award, responses to these questions should not affect the rating of the contractor's overall performance for future milestones. These clarifications inform government use of the deliverable and promote future communication. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Pursuing follow-on work

Given the milestone-based contract's rewarding of defined, stand-alone deliverables, follow-on work is not expected. However, if additional, related work is sought, the agency should evaluate the proposed deliverable's risk and complexity. As detailed earlier, if the follow-on work involves complex or incremental systems unsuitable for milestone-based contracts, agencies should consider standard acquisition processes or other innovative contracting approaches, such as incentive prizes. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Under standard acquisition processes, end users of the deliverable within the agency—and in other agencies or private firms (with rights from the contractor)—are likely candidates for sponsoring the follow-on work. Solicitations for follow-on work could involve only the current pool of milestone-based payment contractors, a subset of the pool, the public, or a set of prescreened companies. Given milestone-based contracting's attractiveness to small businesses, agencies should expect and consider situations where supported businesses later seek foreign funding. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

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D8: Authorities
The authority to solicit Broad Agency Announcements (BAA) for competitive milestone-based contracts is allowed by Federal Acquisition Regulation (FAR) Part 35. Milestone-based competition BAAs are furthermore only an expression of interest and thus do not commit the government to make an award or pay proposal preparation costs. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Important note:
As of December 26, 2014, changes made in 2 CFR 200 effectively limit the use of fixed amount sub-awards (including milestone based payments) on new U.S.-based procurements to a threshold of $150,000. Agencies can request waivers on an agency level. Work with your procurement office to learn more. [Kutnick, A., personal communication with Policy Design Lab, January 10, 2017.]

Incentive Prizes *(placeholder only – crosslink)*

An incentive prize is a contracting model that promotes innovation by offering a reward upon completion of a specific objective task. Prizes enable the Federal government to pay only for success, establish an ambitious goal, and reach beyond the "usual suspects" to increase the number of minds tackling a problem without having to predict which team or approach is most likely to succeed. Many well-known incentive prizes have focused on catalyzing technology R&D, though prize administrators are increasingly using incentive prizes to drive behavior change, market adoption of existing solutions and interventions, and progress in areas of social policy such as health, energy use, and education. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

[[Crosslink/embed Incentive prize toolkit content]]

Challenge Based Acquisitions: Break the Entry Barrier for new actors

Challenge-based acquisitions (ChBAs) are a "try before you buy" approach. They provide for the small-scale introduction of innovative and cost-saving technologies into existing acquisition programs through "challenge" proposals. Challenge-based acquisition limits the government's risk by requiring the government to express its needs in terms of concrete challenges. This type of acquisition encourages new players to participate and creates a level playing field for all involved. It provides a path to obtaining superior solutions to vexing, time-critical problems. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Note that ChBAs are distinct from the "challenges" listed on Challenge.gov, which are incentive prizes.[[crosslink]]) Challenges (or incentive prizes) are often used to spur the engagement of new communities of solvers for well-designed problems in a time-limited engagement. In contrast, "challenge-based acquisition takes the challenge concept a step further by making it part of the procurement process, bringing the innovation opportunity of a challenge into the procurement framework of the Federal Acquisition Regulation (FAR). This allows the government to use challenges as the core of its evaluations, pay vendors for participation, and most importantly, test and purchase quantities beyond simply prototypes.
It is a mechanism to:

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- Communicate needed capability,
- Encourage innovation in a minimally prescriptive environment,
- Assess candidate offerings, and
- Purchase proven solutions."
  ["Challenge-Based Acquisition Handbook," 2nd Edition, Mitre, September 30, 2015.]

Why:
Challenge-based acquisition is based on the premise that acquisitions are best performed if the solution sought is framed as a need (the challenge) and potential providers are free to respond with unconstrained solutions that fill that need. ["Challenge-Based Acquisition Handbook," 2nd Edition, Mitre, September 30, 2015.] With a challenge-based acquisition, an agency can incentivize private-sector entities to develop and demonstrate their solutions in real-world conditions as a source selection mechanism for the award of contracts or task orders for additional testing, refinement, or production of their proposed solution. The award of contracts and task orders occurs if, and only if, the private-sector entity successfully meets the real-world requirements of the challenge. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

How:
With a challenge-based acquisition, an agency can incentivize private-sector entities to develop and demonstrate their solutions in real-world conditions as a source selection mechanism for the award of contracts or task orders for additional testing, refinement, or production of their proposed solution. The award of contracts and task orders occurs if, and only if, the private-sector entity successfully meets the real-world requirements of the challenge. As a result, challenge-based acquisition helps ensure that the government buys the right thing, buys it the right way, and does this the first time by minimizing investment of major resources upfront before a solution has proven itself. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

"A well-crafted challenge, accompanied by clear and effective assessment methodologies and appropriate contracting vehicles, leads to sound and effective acquisitions." ["Challenge-Based Acquisition Handbook," 2nd Edition, Mitre, September 30, 2015.] With challenge-based acquisitions, agencies should consider:

- *Determine the user's need and decompose complex requirements.* The government must first determine the user's need, and then interpret this need into a series of requirements which can be translated into meaningful challenge events. This provides industry with the maximum opportunity to develop and propose an innovative solution.
- *Communicate user experience and needs to industry.* The government must explain the scope of the challenge to industry by describing how it will evaluate challenge event participation in the same or similar environment for which the solution will ultimately be used.
- *Design and execute the challenge event.* The government must design the challenge event, including the plan on how the challenge event will be executed contractually, specific requirements for challenge participation, and detailed evaluation criteria for successful performance and award of follow-on contracts or task orders.
- *Analyze the challenge results and provide contract or task order awards.* The government must use quantitative and qualitative measurements to evaluate challenge results during or immediately after the challenge, and/or over a longer term, as defined by the initial challenge description contained in the Request for Proposal (RFP). These results are then used to

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determine follow-on contract or task-order awards. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D2 – Benefits

Challenge-based acquisitions allow for the evaluation of a solution in a similar environment to the user, thus permitting major investment decisions of government resources to be results-driven. This can significantly reduce the cost, schedule, and performance risks for the technology being acquired. Using challenges as a source selection mechanism and part of a larger acquisition framework allows maximum flexibility for industry to innovate. Challenge-based acquisition does not ask industry to respond to a prescriptive specification or presupposed solution. Instead, industry is free to propose any solution they believe will meet the challenge criteria. The government will then use the challenge event to assess proven performance before a major commitment of resources is made (e.g. production level buy). ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D3:

D3: ChBAs are appropriate to consider when an agency has an urgent and time-sensitive need, when existing solutions do not seem viable, or when emerging technologies suggest potential promise for providing novel, more effective solutions. ["Challenge-Based Acquisition Handbook," 2nd Edition, Mitre, September 30, 2015.] The approach is not appropriate for major, multi-year major system acquisitions, although challenge-based acquisition may be a viable route of obtaining subsystem or components for those types of programs. ["Challenge-Based Acquisition Handbook," 2nd Edition, Mitre, September 30, 2015.]

ChBA can considered for both unclassified and classified challenges; agencies may employ challenge-based acquisition to identify solutions to classified requirements by using unclassified challenge analogues. ChBA thus can be a powerful tool for expanding the ability of innovative small businesses to contribute potential solutions, as it provides an avenue for participation for vendors who do not have appropriate security clearances and facilities. In these situations, participating challengers need only know the general performance objectives to be met. They may not know the details of the particular setting in which a solution may be deployed. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

It is important to determine whether a challenge-based acquisition approach is appropriate to address an agency's needs. The acquisition team should evaluate the current state of its program against the characteristics listed below:

- Has rapid schedule demands or is responding to an urgent requirement,
- Responds to incremental capability needs,
- Is a sub-system or component of a larger system or acquisition,
- Is small from an Acquisition Category (ACAT) perspective or is not a program of record,
- Depends on emerging or uncertain technology,
- Seeks attention of non-traditional innovation sources,
- Expects a short product life cycle or rapid refresh rate,
- Has a clear acquisition quantity and price,
- Requires simultaneous industry and Government solution discovery, or

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- Wishes to pay only for results.

D4. Case snapshots

[Directly sourced from internal communications provided by Correa, D., Office of Science and Technology Policy, September 20, 2016.]

Culvert Denial Challenge

In August 2014, the Joint Improvised Explosive Device Defeat Organization (JIEDDO) (now called the Joint Improvised-Threat Defeat Agency (JIDA)), sought technologies to improve the speed of inspection of culverts and surveillance for nefarious activity in their vicinity. This was motivated by lessons learned in Afghanistan and a desire for readily available technology to mitigate the effectiveness of culverts as a location for IED emplacement. JIEDDO used a Challenge-Based Acquisition (ChBA) for this need and devised the Culvert Denial Challenge. JIEDDO, in coordination with Army Research Lab (ARL), Adelphi, MD, established a Multiple Award Indefinite Delivery/Indefinite Quantity (IDIQ) contract. The first IDIQ task order, challenge participation, was awarded to 20 vendors in August 2014. The challengers were current IDIQ holders and represented a mix of both small and large businesses. Subsequent task orders will allow JIEDDO and ARL to iterate on the challenges and/or further test, refine, evaluate, and produce, in limited quantity, solutions capable of meeting the Government's objectives.

In coordination with ARL and the Maneuver Center of Excellence, JIEDDO conducted the Culvert Denial Challenge at Ft. Benning, Georgia in October, 2014. The challenge event had two parts, an inspection challenge and a surveillance challenge, each with 10 challengers. The inspection challenge, comprised of Culvert Clearance and a Culvert Investigation, assessed the challenger's technologies and its ability to remotely detect and identify objects of interest, specifically IEDs and paraphernalia, within and around a culvert. The surveillance challenge assessed the challenger's technologies and ability to remotely monitor a culvert in near real-time and detect and identify nefarious activities with a minimal amount of human interaction.

2012 Counter-IED Robotics Challenge

The JIEDDO Counter-IED Robotics Challenge was held in June, 2012, at Fort Benning, GA. The challenge had four independent events: Endurance, Reconnaissance, Detect, and Disrupt. The Endurance Challenge assessed the speed and endurance of mounted, dismounted, and portable unmanned ground vehicles over an improved road. Reconnaissance assessed sensor acuity, platform mobility and spatial accuracy of small robots required to locate objects in a tactical environment. The Detect Challenge assessed robotic ability to locate simulated pressure-actuated, low and non-metallic IED trigger switches buried at hidden locations along a route. Finally, Disrupt Challenge assessed the effectiveness of robotic vehicles to disrupt the operation of IEDs and their triggers buried at various depths along a roadway representative of one in theater. The two-week event drew participation from 26 vendors. The demonstration/validation part of the challenge provided additional insight that helped both applicants and government discover additional user needs (for instance, the challenge illuminated the need for vertical surveillance/detection).[[Directly sourced from internal communications provided by Correa, D., Office of Science and Technology Policy, September 20, 2016; "Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D5: Challenges to deployment

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Designing and deploying a challenge-based acquisition requires developing the required skillsets. Take a team-based approach to program design, involving both legal and contracting offices at the outset. Leverage Federal resources and infrastructure (such as Challenge.gov) to assist in challenge design and challenge management.

D6: How to steps

["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

- **Understand Acquisition Objectives**
- **Design the Challenge**
- **Plan the Contract**
- **Communicate Capability Needs**
- **Establish an Initial Pool**
- **Conduct the Challenge Event**
- **Reduce the Challenger Pool**
- **Procure Solutions**

Understand Acquisition Objectives

First, understand what is needed in terms of a missing capability or an unsatisfied gap in a current capability. Convey this understanding using concepts and terms from the capability domain, and focus on what is needed, *not* how the need should be resolved. This is not a license to be vague; expressions of a sought capability may be very detailed and specific. The important thing is that expressions avoid specifying a solution. When statements of sought capability detail the specifications of a solution, that can unnecessarily limit what industry proposes as a solution. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Design the Challenge

The challenge parameters should be transparent and understandable, and allow challengers to prove that their solution is the capability sought by the government. Design challenge-specific execution and evaluation processes that include:

- A plan for communicating challenges to industry,
- A plan detailing how the challenge will be executed contractually,
- Specific requirements for challenge participation, and
- Detailed evaluation criteria to ensure the challenge evaluation is fair to all participants. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Two distinct approaches – iterative and graduated -- may be useful frameworks for a challenge design.

Under an iterative approach, a task order is run repeatedly. At the end of each round, both the government and challengers gain valuable insight into the solving the problem. These learnings can help guide future task orders, for example, by further refining requirements. [Internal communications provided by Correa, D., Office of Science and Technology Policy, September 20, 2016.]

Under a graduated or "winnowing" approach, applicants are narrowed through multiple task orders. (Example: Ten partners may be selected in the initial task order; in the following task-order, 3 challengers may be selected. Two winning solutions may be selected, and then further refined with

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input from the Federal buyer.) [Internal communications provided by Correa, D., Office of Science and Technology Policy, September 20, 2016.]

Plan the Contract

The purpose of challenge-based acquisition is to acquire a solution that provides a needed capability. Evidence gained from a challenge is part of a source-selection process or part of an evaluation process leading to a production buy. This requires rigor and thoughtful contract planning so that fairness and transparency are maintained. Industry will be incentivized to participate so long as the potential to win a production contract award is present. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Communicate Capability Needs

A challenge in support of acquisition fails if potential challengers are unaware of it. The government can use a wealth of outlets to advertise its intent to hold a challenge, including social media outreach. Messaging should emphasize the challenge description in such a way that industry learns what capability is sought and is stimulated to devise innovative solutions. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Establish an Initial Pool

Determine how many challengers will be invited to participate in the first challenge event. In setting the initial pool size, balance the goal of maximizing the number of challengers against the cost of challenge execution. Qualification for initial pool admission may be as simple as a white paper that demonstrates challengers have relevant experience, understand the problem, and may know how to solve it. ["Challenge-Based Acquisition Handbook," 2nd Edition, Mitre, September 30, 2015.]

Conduct the Challenge Event

Challenge events should be conducted with scientific rigor. Evidence collected at an event should be of sufficient quality to inform acquisition decisions. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Evaluate Challenge Results

Use rigorous quantitative and qualitative measurements to evaluate challenge results. Evaluate the evidence collected during challenge event against the criteria from the challenge planning process to determine whether the needed capability was demonstrated. Past performance on previous task orders may also factor into evaluation. ["Challenge-Based Acquisition Handbook," 2nd Edition, Mitre, September 30, 2015.]This is not necessarily a discrete decision; the field of challengers may show progress in the direction of capability satisfaction without fully meeting the stated evaluation criteria. If that occurs, the government may choose to offer the challenge again, modify the challenge, or stop the process. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Reduce the Challenger Pool

Contracting strategies for a challenge-based acquisition should include provisions to off-ramp non-performers. If it can be determined that a particular challenger is not likely to benefit from further participation in the challenge and that their prospective solution does not or will not fulfill the capability need, that challenger should be eliminated from further consideration. Such a decision can save money

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for both government and industry. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

Procure Solutions
If the evaluation of evidence from one or more challengers is satisfactory and proper contracting procedures were observed, the government can and should purchase the winning solution. If the challenge results did not inspire confidence that any of the products would meet government needs, there is no obligation to procure a product. If results show promise but not fully meet the criteria set, consider refining and reissuing the challenge based on lessons learned during challenge performance. This can become part of an incremental government strategy that includes challenge-based research projects. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

D7: To learn more about challenge-based acquisitions:

- Contact The MITRE Corporation (www.mitre.org)
- Read "Challenge-Based Acquisition Handbook," 2nd Edition, Mitre, September 30, 2015.]

D8: Authorities
Challenge-based acquisitions use the authority of FAR Parts 15 and 35, which provide for the competitive selection of proposals submitted in response to a competitive solicitation or BAA. Accordingly, selection of proposals for award via a Challenge-Based Acquisition approach must be considered to be the result of full and open competition. ["Innovative Contracting Case Studies," White House Office of Science and Technology Policy (OSTP), 2014.]

The FAR permits challenge-based acquisition as a type of business process innovation:

> *The absence of direction should be interpreted as permitting the team to innovate and use sound business judgment that is otherwise consistent with law and within the limits of their authority. Contracting officers should take the lead in encouraging business process innovations and ensuring that business decisions are sound.*

Note that challenge-based acquisition encourages industry to dedicate its own IR&D funds, defined in FAR 31.001 and 31.205-18(a), to develop solutions that meet challenge performance criteria.

As ChBA is a federal contracting vehicle subject to FAR guidelines, all federal acquisition specialists are authorized to use ChBA.

Non-binding purchase commitments

Non-binding commitments to purchase products can create demand for new, more effective solutions where market requirements remain unmet. Frequently developed in partnership between Federal and private sector partners, commitments can catalyze the voluntary market introduction of cost-effective solutions that advance everyone's best interests. Non-binding purchase commitments work best when there is both a clearly defined performance specification and a strong expression of interest from potential buyers. [Rand, D., "Summary of Pull Mechanisms", Unpublished, May 17, 2016.]

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Why

Non-binding purchase commitments act as a strong signal to spur industry innovation without requiring a formally commit of funds to support additional research and development. They're often launched in conjunction with private or public sector partners in order to increase the strength of the market demand signal. They represent a win-win-win scenario for government, private sector partners, and solution offerors: the former can save money and gain greater performance, while the latter receive a strong market signal for a common set of advanced equipment requirements coupled with purchasing power across major potential purchasers. ["DOE and Private Sector Partners Introduce a New Money-Saving Specification for Commercial Air Conditioners," US Department of Energy Building Technologies Program, April, 2012.]

How

Non-binding purchase agreements are frequently cross-sector partnership between Federal and private sector partners to create a marketplace for solutions that advance everyone's best interests. They can be implemented through signed letters of intent that demonstrate (non-obligated) commitment to purchase, followed by a carefully designed challenge to solicit solutions that address clearly defined market-based requirements. Finally, third party testing and evaluation can validate that submitted solutions meet specifications.

D2: Benefits of non-binding purchase agreements

Non-binding purchase agreements spur the voluntary development of buyer-driven, innovative solutions that are more efficient and meet market-based requirements. Non-binding purchase commitments help provide a clear signal from large purchasing partners. Vendors and manufacturers take notice when large purchasers send signals to the market that they want to invest but cannot find a product that meets requirements. Agencies who act as major potential purchasers may partner with industry to send such a clear market signal.

D3 – Users

Non-binding purchase commitments work best when agencies work together, or work with commercial partners, to generate a strong market pull signal to attract manufacturers or vendors. In addition to demonstrating significant market need for the technology or product sought, the effective deployment of non-binding purchase agreements require agencies to dedicate adequate funding to support the development of specifications and follow-on testing and verification.

Case snapshots: Wireless Sub-meter Challenge and Rooftop Unit Challenge (Department of Energy)

Wireless Sub-meter Challenge:

["Federal and Industry Partners Issue Challenge to Manufacturers," Energy.gov, June 6, 2013.]

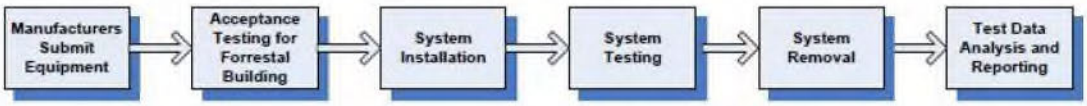
In 2013, the U.S. Department of Energy along with a coalition of over 200 major commercial building partners, issued a challenge to U.S. manufacturers: "If you can build wireless sub-meters that cost less than $100 apiece and enable us to identify opportunities to save money by saving energy, we will buy them." [Rung, A. and Scott, T., "Memorandum to Chief Acquisition Officers, Senior Procurement Executives, Chief Information Officers on Acquisition Innovation Labs & Pilot for Digital Acquisition Innovation Lab," Office of Management and Budget, March 9th, 2016.] At least 18 manufacturers

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responded through a signed letter of intent, agreeing to produce devices that met specifications outlined by DOE and its participating partners in the Commercial Building Energy Alliance.

At the time of the challenge call, sub-meter prices were approximately $1,000, leading to limited market penetration. The challenge from DOE was to bring down the unit cost by 90% while still meeting building operator requirements. DOE and its coalition of commercial partners signed letters of intent demonstrating the need for low-cost sub-meters to research and development community. "This is a perfect example of how government can team up with industry to identify a problem and promote the innovation needed to solve it," said former U.S. Energy Secretary Ernest Moniz. ["Federal and Industry Partners Issue Challenge to Manufacturers," Energy.gov, June 6, 2013.])

The Energy Department worked with National Laboratories, a coalition of building owners, and other Federal agencies to develop a clear **performance-based specification**. Compliance with the specifications was set to be verified through performance testing in an operational, occupied building.



[Image: Steps for in-building test verification. "Low Cost Wireless Electric Energy Meter Specification Version 2.6," Energy.gov, May 16, 2013.]

Rooftop Unit Challenge:

["Install the highest efficiency units that meet the High Performance Rooftop Unit Challenge", US Department of Energy Better Buildings Alliance, 2011.]

In January 2011, the Department of Energy launched a challenge to urge U.S. manufacturers to build and deliver innovative energy-saving rooftop air conditioning units. Working with industry partners and building owners and operators, DOE released a design specification for 10-ton capacity commercial air conditioners known as rooftop units (RTUs), and participating private sector partners jointly announced they would strongly consider purchasing units that met the performance specification. ["DOE and Private Sector Partners Introduce a New Money-Saving Specification for Commercial Air Conditioners," US Department of Energy Building Technologies Program, April, 2012.] Led by DOE's Building Technologies Office, with help from National Laboratories and the interested building owners and operators, coordinated the development of RTU Challenge specification. ["RTY Suite of Projects," US Department of Energy, 2013.] The goal of the specification was to encourage industry to develop a high performance, high-efficiency RTU. ["RTY Suite of Projects," US Department of Energy, 2013.] In addition, DOE provided technical support to manufacturers and analyzed test data. ["RTY Suite of Projects," US Department of Energy, 2013.]

Fourteen months later, in May 2012, DOE verified through laboratory testing that the first manufacturer met the challenge specification. Today, there are a total of five companies offering 195 RTU models that meet the RTU Challenge performance specification, which is 60 percent more efficient than the current building code requirement. ["RTY Suite of Projects," US Department of Energy, 2013.]

Read more:
DOE rooftop challenge winners offer energy, cost savings

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Part-Load Performance Characterization and Energy Savings Potential of the RTU Challenge Unit: Daikin Rebel
High Performance Rooftop Unit Specification
High Performance Rooftop Unit Fact Sheet

For more on the DOE's rooftop chiller challenge and wireless sub-meter challenge, contact Amy Jiron at Amy.Jiron@EE.Doe.Gov

D5 – Challenges

Key ingredients for success:

- Craft a coalition of partners to maximize impact
- Clearly communicate with industry partners
- Invest significant time develop clear but broadly applicable design specifications
- Plan ahead for possible future acquisitions

Craft a coalition of partners to maximize impact

The potential impact of using non-binding purchase agreements is must fully leveraged with agencies collaborate jointly with industry. For collaboration, it's key to develop a basis of agreement between public and private stakeholders that balances all parties' goals. [Kochan, J., phone interview with Policy Design Lab, August 16, 2016] For additional guidance on collaborating with private sector partners to develop non-binding commitments that strategically align with all parties' interests, see [[Crosslink to V5 content – Aligned Strategic Commitments]].

Clearly communicate to industry partners

For agencies already working with industry on various levels, it can be important to distinguish messaging and clearly communicate the difference between funded and voluntary opportunities. DOE works with industry on many levels, including through funding agreements and prize authority -- which are often confused with this type of market-based voluntary challenge, Amy Jiron shares. DOE has found it's important to separate messaging on different types of opportunities, as well as to clearly state the incentive for industry for nonbinding purchase commitments, which offer potential customers rather than complicated Federal funding. [Jiron, A., personal communication with Policy Design Lab, January 10, 2017.]

Invest significant time develop clear but broadly applicable design specifications

With purchasing partners and the manufacturing community, develop clear performance-based specifications. Clear specifications are important for ensuring that resulting outputs align with an agency's intended goals; they also provide confidence to manufacturers by setting clear targets to achieve. For instance, for the wireless submeter challenge, prospective manufacturers had the following clear requirements identified:

- The submeter must collect watt-hour energy for a three-phase circuit.
- Data measurement, transmission and collection must be open protocol.
- The communications must be wireless, although the type of wireless is unspecified. Communications cannot leverage the building's other communication systems.
- The submeter must be self-contained.

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- The submeter must draw power from the power panel the submeter connects to, or from the system being monitored.
- The $100 price point must include the device, sensor, any base station or repeater, and software; it does not have to include design or installation costs.
- The user is assumed to have internet access, but no additional software should be required by the user.
- Two-way communication is not required.
  [Tweed, K. "DOE Launches $100 Electric Submeter Challenge," Greentech Media, May 3, 2013.]

At the same time, specifications should not be so narrow that they are tailored towards a particular party. DOE deliberately facilitated a specification hat was sufficiently broad and achievable by multiple vendors, shares Amy Jiron. [Jiron, A., personal communication with Policy Design Lab, January 10, 2017.] The specification incorporated detailed input from partners and notice was provided to all manufacturers, to ensure DOE was not effectively selecting one product over another just by issuing the challenge. [Jiron, A., personal communication with Policy Design Lab, January 10, 2017.]

Plan ahead for possible future acquisitions

Voluntary challenges issued by Federal agencies need to be well-thought out based on the reality of Federal purchasing and acquisition requirements. As part of the development process, agencies may wish to consider ways to facilitate streamlined on-ramping into agency procurement processes, which could provide additional incentive for manufacturers or vendors to voluntarily participate. A relevant consideration early-on on the design of non-binding purchase commitments is that Federal acquisition requirements can prevent the actual and final purchase of challenge-winning products if there isn't enough competition within the product area.

D6 – Steps to Deployment:

- Develop a coalition of interested partners: manufacturers, other purchasing entities and organizations with targeted interest in more efficient products (for example trade associations).
- Issue a clear market requirements-based performance specification including a phased third party verification plan
- Issue letters signaling intent to purchase
- Develop phased submittal requirements:
  - 1) initial interest
  - 2) cut sheets and other documentation of performance and/or cost
  - 3) product for verification testing.
- Provide third party technical evaluation to determine if submittals meet specification requirements.
- Conduct initial paper reviews to assess whether the product would meet specification requirements.
- Provide third party laboratory verification to demonstrate that the product meets specification requirements.
- Recognize winning units at key industry events.
- Continue support through third party demonstration in building sites: Site Evaluation and Selection, Baseline Measurement, Instrumentation and third party Verification of Performance
- Conduct demonstration and deploy results broadly to key industry groups and utilities.

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[Jiron, A., personal communication with Policy Design Lab, January 10, 2017.]

Private sector partners issue letters of intent:

Sample letter of intent language
It's important to help industry partners understand the legal implications of non-binding purchase commitments. Letters of intent are not firm or binding commitments; they are just simply documentation of an unmet market need. They signal to the manufacturing/vending community there is a significant market opportunity worth pursuing. As a signal of their support for the RTU Challenge, participating CBEA members issued the following statement:

"We will strongly consider purchasing units that meet the specification, are consistent with our cost-effectiveness criteria, and align with our procurement timeframes. We look forward to working with the manufacturers and DOE to factory witness tests of prototype units that meet this specification. We understand that DOE has committed resources and technical assistance to help U.S. manufacturers design and develop products to meet this specification. We look forward to the near-term market introduction of reliable, energy-efficient and competitively priced rooftop units which increase the energy efficiency of the sector."

["High Performance Rooftop Unit Specification," DOE.]

For more on how to develop and implement non-binding purchase agreements, contact Amy Jiron at Amy.Jiron@EE.Doe.Gov.

D8: Authorities
DOE reports that no specific legislation or policy guidance guided the development of their non-binding purchase agreements. Agencies should work with their general counsel to craft appropriate language for engaging with industry.

Advance Market Commitments

Snapshot: Advance Market Commitments (AMCs)
Advance Market Commitments (AMCs) are binding commitments to purchase (or to subsidize purchase) of a certain volume of a product at a fixed price, if the product meets pre-defined performance characteristics. [Rand, D., "Summary of Pull Mechanisms", Unpublished, May 17, 2016.] AMCs incentivize R&D efforts (for example, for finding a vaccine) by providing firm confidence to industry that a market will exist for the product they develop.

This innovative financing mechanism is an example of "demand pull" writ large. The Global Alliance for Vaccine and Immunization's development of a pneumococcal vaccine is the canonical example of advance market commitments in action. In this instance, a global public-private consortium has worked to induce a market for an annual production of 200 million vaccine doses. ["Supplies and Logistics: AMC for Pneumococcal," UNICEF, February 16, 2016.]

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D2: Benefits
Advance market commitments can be effective because they represent a "win-win" for industry and the public sector. Government benefits from spurring the development of new solutions. In addition, the legal mechanisms for putting an advance market commitment in place provide both a guaranteed revenue stream for industry and lock in long-term pricing for the buyer.

D3: When to use:
Pilots of advance market commitments to date have been complex, involving multiple national governments. Nonetheless, agencies may find it useful to assess what's possible with an AMC model. While some level of scale and firm authorization for financing are necessary, agencies may consider using an AMC in cross-agency collaborations.

D4: Case snapshot: Pneumococcal Vaccine AMC (GAVI)

Summary: The development of the vaccine to prevent deaths from pneumococcal diseases was accelerated by a $1.5 billion advance market commitment backed by five governments and a private foundation. [Rand, D., "Summary of Pull Mechanisms", Unpublished, May 17, 2016.]

"The AMC provides a crucial platform for strengthening vaccine delivery because it binds all parties – donors, developing country governments, GAVI and industry – together in a long-term partnership," said Andrew Witty, CEO of GlaxoSmithKline. ["AMC changes mindset of pharmaceutical industry," GAVI, November 24, 2009]

Background:
Conversations regarding the idea of advance market commitments for vaccines began in 2005, with GAVI officially launching the pneumococcal AMC in 2009. By December 2010, vaccines began in-country roll-out. ["Pneumococcal AMC Timeline," GAVI.] The overarching goal of the pilot AMC was to reduce morbidity and mortality from pneumococcal diseases, but additional goals include:

- Accelerating vaccine development for developing country needs
- Scaling up production capacity for effective vaccines
- Accelerating the rate of vaccine uptake by providing predictable vaccine pricing for countries and manufacturers;
- Testing the AMC concept for potential future applications.
  ["About the Pneumococcal AMC," GAVI.]

How it works:
The pneumococcal AMC was developed to provide a predictable finance mechanism to provide pharmaceutical companies the "to invest in the capacity to manufacture pneumococcal vaccines that include the additional serotypes required to combat the most common and fatal strains of pneumococcus in low-income countries." ["GAVI's Business Model: Securing Predictable Financing," GAVI.]

"In this pilot AMC, donors commit funds to guarantee the price of vaccines once they have been developed. These financial commitments provide vaccine manufacturers with the incentive they need to invest in vaccine research and development, and to expand manufacturing capacity. In exchange, companies sign a legally-binding commitment to provide the vaccines at a price affordable to developing countries in the long term." ["How the Pneumococcal AMC Works," GAVI.]

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"In exchange for the certainty provided by the commitment to purchase, participating firms signed legally binding agreements to supply the vaccine at a maximum price of US$ 3.50 a dose. This allows developing country governments to budget and plan for their immunization programs, safe in the knowledge that vaccines will be available in sufficient quantity and at a predictable price." ["GAVI's Business Model: Securing Predictable Financing," GAVI.]

Accomplishments:
Pharmaceutical companies that have agreed to provide the vaccine at $3.50 per dose to low-income countries for the next 10 years will receive additional payments from the $1.5 billion in donor commitments. The AMC increased the size and predictability of the market for pneumococcal vaccines, which increased the willingness of companies to invest in high-volume production of these vaccines for developing country markets. Experts predict that this AMC will save 7 million lives over the next 20 years. [Rand, D., "Summary of Pull Mechanisms", Unpublished, May 17, 2016.] An outcome and impact evaluation study confirmed that the AMC pilot stimulated demand and created additional vaccine supply in developing countries. ["The Advance Market Commitment Pilot for Pneumococcal Vaccines: Outcomes and impact evaluation," GAVI.]

D5: Limitations to deployment
While the GAVI case was the first and largest proof-of-concept, there's no rule that says AMCs must inherently involve billions of dollars and multiple governments. USAID's partnering role in AgResults [crosslink D3 case study] demonstrate how advance market commitments can function in on a less complex scale with a smaller dollar commitment. Agencies considering how to incent large demand shifts in the marketplace should consider the advance market commitment model, and consider cross-agency collaborations for implementation.

Outcome and impact evaluation studies from GAVI have found that the AMC was not as successful in accelerating R&D timelines – either because existing industry actors were far along in the process, or because early-stage candidates encountered significant technical and regulatory barriers. ["The Advance Market Commitment Pilot for Pneumococcal Vaccines: Outcomes and impact evaluation," GAVI.] Agencies that pursue advanced market commitments should incorporate the regulatory context for the solution being sought into their expectations for the timeline for implementation.

D6: How to steps
GAVI provides a wealth of public documentation that outlines the history and execution steps taken to develop the pneumococcal vaccine. While not all guidance is relevant for agencies, those interested in pursuing this model will find helpful guidance about issues to consider and a basic roadmap of design steps to consider, even when pursuing a smaller-scale implementation of the concept.

For the pneumococcal AMC, a simplified process entails:

1. Suppliers must sign a registration agreement relating to the AMC terms and conditions.
2. Calls for Supply Offers are issued, following the publication of a strategic demand forecast.
3. All received offers are assessed, and UNICEF enters into supply agreements with manufacturers whose products are deemed AMC eligible.
4. An independent committee verifies that products developed meet the established target profile.
5. GAVI and governments contribute financing.
6. UNICEF procures vaccine supply, and delivers to country.
   ["How the pneumococcal AMC works," GAVI.]

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Agencies may wish to directly reveal technical documentation, available here:

- Manufacturers registration
- UNICEF call for supply offers
- Supply agreements

The objectives, terms and conditions, and other core elements of the AMC are enumerated here:

- AMC Legal Agreements: detailed list of modifications
- Revised AMC Offer Agreement
- AMC Deed of Amendment and Restatement
- Revised AMC Procedures Memorandum
- Revised Independent Assessment Committee Charter and Bylaws

D7: Resources

Read more:

- Pneumococcal AMC Timeline
- The 2015 Pneumococcal AMC Annual Report gives an overview of the activities linked to the implementation of the pilot Advance Market Commitment in 2015.
- Making Markets for Vaccines: Ideas to Action, Center for Global Development – landmark April 2005 report sparked genesis of AMC approach

Deliverable 4 (Broad): Case study on HHS Buyers Club

HHS Buyers Club

Background

The Department of Health and Human Services launched the HHS Buyers Club in 2014 to educate, test, and operationalize new acquisition methods that are approved under federal regulations to mitigate risk and increase success. ["Innovation as a Problem Solving Tool in Government," Department of Health and Human Services IDEA Lab, 2016.] After a successful pilot, Buyers Club has taken a short pause in 2016; however, its early results in disseminating new acquisition practices within HHS remain deeply informative for other agencies seeking to initiate a transformational shift in their acquisition culture.

Housed within the HHS IDEA Lab [crosslink Labs], Buyers Club was a sponsored project focused on addressing a critical problem in government: modernizing federal acquisition of information technology (IT) and related services. ["Innovation as a Problem Solving Tool in Government," Department of Health and Human Services IDEA Lab, 2016.]] The Buyers Club worked directly with HHS employees to guide them through novel acquisition methods. The initiative's goal was to educate and build a network of innovators across HHS and the Federal government interested in applying creative techniques to achieve more effective and efficient IT acquisitions. ["Innovation as a Problem Solving Tool in Government," Department of Health and Human Services IDEA Lab, 2016.]

IT service and consulting firms have evolved significantly in recent years to support client needs for continuous digital transformation and iteration in a rapidly-evolving market. However, within the confines of traditional Federal procurement practices, change has been slower. Procurement approaches have historically been risk-averse, and governing regulations have evolved more slowly than

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rapidly-changing market conditions. There is ample opportunity to address and modernize existing practices in ways that mitigate risk but also achieving better outcomes. The HHS Buyers Club has proven this can be successfully done. [Naggar, M., personal communication with Policy Design Lab, January 18, 2017.]

How it works

The Buyers Club was essentially an innovative digital acquisition practice internal to HHS. HHS Buyers Club capitalized on the idea that emphasizing new strategies allowed under the FAR or other approved legislation is a powerful means towards modernizing federal acquisition of information technology (IT) and related services. Historically, the proposal processes placed heavy emphasis on contractors' proposals for future work, as opposed to evaluating what bidders had actually done in the past. The goal of the approach was to move the process of selecting contractors from one based on their professional writing skills on grants and contracts to evaluating based on their previous performance and tangible skills in real time.

Projects would initiate with a "customer" consultation to understand their needs, history, and desired outcomes. "It's critical to understand the customer's objectives while explaining our approach in order for everyone to be comfortable and get on the same page," Mark Naggar explains. [Naggar, M., personal communication with Policy Design Lab, January 18, 2017] This process also entailed developing an understanding and documentation of the underlying problems, needs, and objectives in a manner accessible to vendors. From there, Buyers Club would make a preliminary decision regarding which acquisition method and strategy to use. A Statement of Objectives, inclusive of all required materials (i.e. analytics, history, and anything a vendor could use or need) would be drafted, along with preliminary instructions and evaluation criteria. Evaluation criteria are critical and should be adjusted for each requirement in order to determine which vendor is the most capable (and provides the best value) to achieve the specified objectives, notes Naggar. [Naggar, M., personal communication with Policy Design Lab, January 18, 2017] Award and implementation details are just as critical, but the largest investment of time and effort is in the iterative pre-award stage.

Acquisition methods used included, but were not limited to: Multi-stage acquisitions, purchase card utilization to support incentive-based competition, and other advisory methods:

- The Two-Stage (or multi-stage), Down-Select Approach for acquisitions has been replicated throughout HHS and throughout the Federal government dozens of times, notes Naggar. [Naggar, M., personal communication with Policy Design Lab, January 18, 2017.] He explains that like a funnel, the process would winnow the field of offerors in a multi-stage qualification process. This approach lowers the acquisition burden on industry (especially small businesses), government end users/programmatic evaluators, and procurement officials.

- Another approach used was Acquisition 360. Begun at HHS, it's a non-traditional method of surveying the three primary stakeholders in an acquisition in order to improve/iterate for future acquisitions. Typically, industry, programmatic end users, and/or procurement officials do not go through an acquisition debrief to better understand what areas worked or could use improvement. Historically, only industry asks procurement officials about why they won or lost the acquisition. [Naggar, M., personal communication with Policy Design Lab, January 18, 2017.]

Key accomplishments

[APG]



[Image source: "Innovation as a Problem Solving Tool in Government," Department of Health and Human Services IDEA Lab, 2016.]
[]

In less than two years, the Buyer's Club gained in recognition because it offered relevant solutions developed to be easily absorbed for others with limited time.[Naggar, M., phone interview with Policy Design Lab, December 2, 2016.] Buyers Club supported several dozen acquisition projects, with 100% of directly supported projects for IT services awarded to small businesses. ["Innovation as a Problem Solving Tool in Government," Department of Health and Human Services IDEA Lab, 2016.] In one instance, the Buyers Club advised and guided two associated requirements for publication layout and graphic design services utilizing a purchase card, resulting in at least 75% cost savings, at least 65% in time savings, while maximizing competition. Utilizing 99 Designs, the world's largest graphic design crowdsourcing platform enabled significant end-user interaction and collaboration with the graphic designers throughout the acquisition, design, and publication process from start to finish. [Naggar, M., personal communication with Policy Design Lab, January 18, 2017.]

Key learning insights [Naggar, M., personal communication with Policy Design Lab, January 18, 2017.]

- Start small and interact with all stakeholders (internal & external) in a continuous 360-degree manner to understand their problems and/or needs associated with procurement in order to stay engaged.
- Continuous engagement, whether for addressing individual requirements or a historic account, can reveal trends and common problems, raising the likelihood that desired outcomes are achieved.
- Develop a coalition of support as well as ambassadors who've realized savings: Repeat business is based on referral. Early wins bring supporters, which helps to reach a broader audience that can benefit from these new approaches.

Future Practices

After a successful pilot to educate and implement these methods, the Buyers Club has taken a strategic pause. Continuation of the pilot, in whatever form, will require additional resources and active, cross-functional leadership support. While Buyers Club pilot did have support, the act of further scaling any innovative acquisitions vehicles will require robust investment in collaborative effort.

To Learn More:

[APG]

- HHS Buyers Club
- Digital Acquisition Playbook case study on the Buyers Club
- Innovation as a Problem-Solving Tool in Government

Deliverable 5: Challenges to deployment / approach limitations (inc. lessons learned from agencies where implemented)

Key ingredients for success:

- **Provide (or receive) cover to be innovative**
- **Reframe how to identify the problem set and solutions.**
- **Take a team-based approach**
- **Remember that people – not contracts—manage projects**

Provide (or receive) cover to be innovative

While 91% of Federal contracting professionals actively look for ways to do their job better, only 37% feel that creativity and innovation are rewarded, according to FY15 Federal Employee Viewpoint Survey data. ["2015 Federal Employee Viewpoint Survey," Office of Personnel Management, 2015.] Providing institutional cover and empowering contracting officers to take risks will help remove the incentive for procurement staff to select established companies for contracts that are well-known, and encourage procurement officers to engage new actors that provide even better solutions.

Reframe how to identify the problem set and solutions.

At the outset of each new project using innovative acquisition model, create and use Concept of Need/Statement of Objectives that are based on collaboration between old and new adopters. Plan for an iterative, agile process to update it with all collaborators involved. [Naggar, M., phone interviews with Policy Design Lab, December 2, 2016 and December 22, 2016.]

Take a team-based approach

Agencies should build cross-functional teams to allow for the most innovative solutions possible. ["Innovation is a Contract Sport," Partnership for Public Service, February 6, 2016.] Acquisitions entail more than just buying. Early in the process, it's important to bring to the table all relevant expertise, like policy, legal, engineering, design, and security; leveraging the expertise of a cross-functional team will help make sure your agency is solving the problems for your end users. ["Digital Acquisition Playbook," 18F, 2016.]

Remember that people – not contracts—manage projects

It's important to promote a process that features frequent collaboration between the end user and the vendor until the period of performance is complete. Frequently, a contracting officer may work diligently to ensure that all possible contingencies are addressed with clauses within a contract. This approach can overlook the reality that over the life of the contract, conditions may change. Agencies benefit from close communication with vendors, as it helps vendors quickly make decisions that remain aligned to an agency's goals. "Relying too heavily on contract clauses to solve every problem that may arise over the period of performance is an untenable expectation. It's important that you're allotting time for a resource in your agency to be a product owner to ensure the outcome has a greater chance of success," notes 18F's Digital Acquisition Playbook. ["Digital Acquisition Playbook," 18F, 2016.]

[APG]

Five Steps for Transforming Your Agency's Acquisition Culture:

2. **Follow the law instead of tradition**
Agencies at times impose restrictions that are traditional rather than black letter law. One of the first steps to streamlining procurement is to differentiate recommendations from regulations. Indeed, the HHS Buyer's Club recognizes this and seeks to find innovative strategies to find new ways to use existing regulations and laws, rather than assume there is an essential problem within those laws. As the new practices are validated, they can be disseminated internally through informational webinars and then circulated more widely through training courses offered by entities like the Federal Acquisition Institute.

3. **Express needs in the form of problems/outcomes instead of solutions/requirements**
The usual process of procurement is to define the solicitation by the solution requested and the related requirements. By design, the wording of the solicitation is typically narrow such that only a handful of suppliers are eligible, and typically there is a bias against small businesses. If instead solicitations specify the problems to be solved and the outcomes expected, smaller companies will not be immediately disqualified. Additionally, small companies will gain the impression that the government sees them as valuable partners and may be more willing to apply.

4. **Leverage existing training resources and requirements**
The Defense Acquisition University and Federal Acquisition Institute have a number of courses aimed toward enabling the inclusion of small businesses and implementation of agile practices. The procurement lessons learned should be shared, when applicable, through these platforms to maximize impact. Civilian contracting officers are required to take 40 hours of training every 2 years; progress can be made by encouraging staff to take the most innovative courses.

5. **Bring together contracting officers to consolidate steps**
The GSA FASt Lane approach to reducing processing time was to catalog all potential scenarios and consolidate each into 7 standardized steps. This process effectively cut the time to add a new supplier from 110 to 45 days, modify contracts in 24 hours instead of 2 weeks, and finalize awards in 30-45 days. Similar progress is possible by dedicating resources and time to streamlining processes.

6. **Start small, gain quick wins, and scale fast**
Any change takes time and resources. Agile and lean perspectives can be applied to making changes to government procurement. Many small pilots can try out new ideas and quick wins can help convince any skeptics. The pilots that are successful can then be scaled appropriately.

[Directly sourced from Ansari, S., Krieger, B., and Siboni, R., "Buying What Works Memo," Unpublished, August 25, 2016.]

Deliverable 6: How-To: Steps for deploying, practices for adapting

[APG]

Each specific approach contains detailed information for executing a particular contracting tool. For more broadly deploying innovative acquisitions, pair communication strategies that win allies with structural changes to empower innovation acquisitions advocates to create the strongest impact possible:

- **3 ways to garner support**
- **6 recommendations for standing up an effective acquisition innovation lab**
- **6 types of assistance acquisition labs should offer agencies**

Three ways to garner support:

1. **Make it relevant, make it easy**. Focus on developing smaller modules to teach people within the larger contracting umbrella and emphasize information that's actionable for frontline employees.
2. **Find allies**: Seek out allies by having conversations with larger CIO Council, Procurement Council. OMB/OSTP can help stand up new initiatives. Talk to agencies that have not stood up programs to identify their needs and find out what would be helpful to them. Identify agencies, offices, individuals who are in the middle of the bell-curve; that is, they're able and willing to adopt, but would benefit from support in navigating the "how."
3. **Educate the community you are targeting**. Share the value of your approach. For example, Broad Agency Announcements (BAA's) are known to procurement community, but not all approaches are as diffused. Identify successful rapid prototyping communities such as NSA, DIA and share what works. There is lots of existing flexibility within FAR, but many in procurement are not aware.

[Naggar, M., phone interviews with Policy Design Lab, December 2, 2016 and December 22, 2016.]

Six recommendations for standing up an effective acquisition innovation lab:

The Office of Federal Procurement Policy offers six recommendations for creating effective acquisition innovation labs and can support agencies in their efforts:

Agencies should consider the following principles in standing up an acquisition innovation lab or similar mechanism or reviewing the effectiveness of existing programs or approaches:

1. **Promote meaningful collaboration:** Make the lab open to all members of the integrated product team—e.g., program, acquisition, IT, legal, finance—so that appropriate attention may be given to the full range of activities, including requirements development, that impact acquisition outcomes. Where possible, support the lab's activities with a multi-functional team.

2. **Make information technology (IT) a focus area**: An acquisition innovation lab can help to accelerate the development of digital acquisition capabilities within the agency.

3. **Start small when first getting started:** For IT activities, consider engaging on projects or modules that can be delivered within a three to six month period of performance, quickly learn and iterate, document lessons learned and effective practices for knowledge sharing and informing policy, and then scale.

[APG]

4. **Encourage but do not mandate use of the lab by the workforce at large**: Focus on members of the workforce who express an interest and are managed risk takers. Take steps to ensure the workforce is aware of the lab and encourage employees to take advantage of the lab, but, in doing so, make clear that interactions are strictly voluntary (e.g., do not create negative incentives for employees who seek to "wait and see").

5. **Obtain vendor input:** Seek feedback from vendors on pilots and related efforts in order to gauge industry's perspective.

6. **Recognize contributions**: Recognize meaningful contributions by members of the workforce to further promote innovative thinking (e.g., Secretarial recognition awards, documentation of participation in a pilot in employee's personnel file, nomination for the Chief Acquisition Officers Council Acquisition Innovation Award or American Council for technology—Industry Advisory Council Igniting Innovation Award).

[Rung, A. and Scott, T., "Memorandum to Chief Acquisition Officers, Senior Procurement Executives, Chief Information Officers on Acquisition Innovation Labs & Pilot for Digital Acquisition Innovation Lab," Office of Management and Budget, March 9th, 2016.]

Six types of assistance acquisition labs should offer agencies

1. **Informal business advice:** The lab should be a recognized place where agency personnel may go, on a voluntary basis, to brainstorm and flesh out their ideas, whether it is piloting new ideas or taking a fresh look at an existing practice for the purpose of enhancing the value it achieves. This exchange/consultation is, as a general matter, most useful if done before establishing an acquisition strategy or any significant acquisition planning. An agency's acquisition innovation lab is not expected to take the place of agency management, nor to supplant the advice provided by support organizations, such as an agency's Office of General Counsel (OGC). However, lab sponsors may wish to consider conferring with their OGC and determine if it is appropriate to identify an attorney or attorneys who could serve as legal advisor(s) to the agency's lab and, if feasible, provide support for projects that the lab is providing assistance on.

2. **Networking:** Whether approached individually or by a team of acquisition, IT, program, legal and other personnel, the lab should help to facilitate collaboration within the agency with others that may be working to solve similar problems.

3. **Access to talent & expertise:** Whenever possible, use the lab as a talent accelerator, helping the workforce to leverage existing and newly gained expertise. For initiatives involving digital services, for example, this could mean helping the workforce tap into skills learned through the agency's participation in the Digital Service Contracting Professional Training and Development Program (e.g., to develop digital service procurement experts and business advisors), working with GSA's 18F Consulting (e.g., on "discovery sprints" or workshops to support transitioning or modernizing legacy systems through incremental/modular contracting, agile development, and user-driven design) and consultations with the Office of the Federal Chief Information Officer's U.S. Digital Service (e.g., on application of strategies discussed in the Digital Services Playbook).

4. **Shadowing:** Whenever possible, the lab should help to arrange opportunities for in-house personnel to shadow internal or external experts with expertise in applying established and emerging best practices, to supplement training opportunities and accelerate the agency's capability to achieve better results.

5. Information sharing: The lab should encourage information sharing and documentation of processes (through actual documents used and/or descriptions), including through the development of case studies, where feasible, to enable review and replication by others, as appropriate. In addition, information should be shared with other agencies by posting it on the Innovation Hallway of GSA's Acquisition Gateway.

[APG]

6. **Event sponsorship:** Events that promote intra- and interagency brainstorming and information sharing can help to increase awareness of successes and teachable moments and adoption of promising ideas.

[Rung, A. and Scott, T., "Memorandum to Chief Acquisition Officers, Senior Procurement Executives, Chief Information Officers on Acquisition Innovation Labs & Pilot for Digital Acquisition Innovation Lab," Office of Management and Budget, March 9th, 2016.]

Deliverable 9: Future directions ("next practices as opposed to best practices")

The deployment of acquisition innovation labs are a promising step forward for helping agencies to capitalize on the potential benefits of innovative contracting methods, but more collaborative efforts in parallel across the acquisition community will be essential for further supporting the diffusion of innovative contracting techniques across agencies.

A centralized repository of contracting vehicles could provide useful information – both for agencies' contracting offices and for small businesses. "Some innovation hubs are informally acting as contract gurus (e.g. DoD's DIUx, or GSA's 18F), not only advising about good vehicles, but also helping provide the tech savvy to help non-savvy program managers and contract officers through advanced procurement processes." [Ansari, S., Krieger, B., and Siboni, R., "Buying What Works Memo," Unpublished, August 25, 2016.] A centralized repository is the next step to help ensure all agencies are benefiting and sharing in the knowledge gained in recent years.

Deliverable 8: Examples of policy that have enabled or encouraged approach (legislation, exec order)

For guidance specific to each contracting tool, refer to sections for each method's relevant authorities.

Legislation pertaining to authorities:
Other Transaction Authority: 10 USC §2371a
2010 America COMPETES Reauthorization Act
The Stevenson-Wydler Technology Innovation Act of 1980 (Pub.L. 96–480), as amended (codified at Title 15 of the United States Code (U.S.C.), Section 3701 *et seq.*) (94 Stat. 2311)

National Aeronautics and Space Act of 1958, Pub. L. No. 85-568, 72 Stat. 426-438 (Jul. 29, 1958)

FAR Subpart 1.102-4(e) specifically encourages contracting officers to evaluate business process innovations when appropriate:

> "If a policy or procedure, or a particular strategy or practice, is in the best interest of the Government and is not specifically addressed in the FAR, nor prohibited bylaw (statute or case law), Executive order or other regulation, Government members of the Team should not assume it is prohibited [...] Contracting officers should take the lead in encouraging business process innovations and ensuring that business decisions are sound." Federal Acquisition Regulation, 48 C.F.R §1.102.

Selected Policy Memoranda from the Office of Federal Procurement Policy:

[APG]

- "Transforming the Marketplace: Simplifying Federal Procurement to Improve Performance, Drive Innovation, and Increase Savings," OMB, Dec 4 2014.
- "Acquisition Innovation Labs & Pilot for Digital Acquisition Innovation Lab," OMB, Mar 9 2016.
- "Acquisition 360 – Improving the Acquisition Process through Timely Feedback from External and Internal Stakeholders," OMB, Mar 18 2015.
- "Increasing Efficiencies in the Training, Development, and Management of the Acquisition Workforce ," OMB, Sept 3 2013.
- "Memorandum: Contracting Guidance to Support Modular Development," OMB, June 14 2012.
- "Increasing Small Business Participation in Federal Contracting" OMB, Feb 11, 2011.
- "Attracting Talent to the Acquisition Workforce," OMB, Feb 4, 2011.
- ""Myth-Busting": Addressing Misconceptions to Improve Communication with Industry during the Acquisition Process" OMB, Feb 2 2011.
- "Achieving Better Value From Our Acquisitions," OMB, Dec 22 2009.
- "Performance-Based Service Acquisition, Contracting for the Future," OMB, July 2003.

Deliverable 7: Online inventory of resources

Contact

For assistance on setting acquisition labs and more deeply infusing innovative contracting into your agency's work, contact Mathew Blum, Associate Administrator for Federal Procurement Policy, OMB, at mblum@omb.eop.gov.

For insights on applying OTA and other innovative contracting models, contact Lauren Schmidt, at lauren@diux.mil

Federal Resources

- Acquisition.Gov
- **Acquisition Gateway**: GSA's Acquisition Gateway helps Federal buyers from all agencies act as one acquisition community: "The Acquisition Gateway is a workspace that provides accurate, useful, and unbiased advice. It helps Federal acquisition professionals learn what they need to know, connect with others to collaborate and communicate, and act to accomplish their tasks effectively. " [Source]
- TechFAR Playbook highlights flexibilities in the Federal Acquisition Regulation (FAR) that can offers guidance on working with contractors in an iterative, customer-driven software development process
- TechFAR Hub: The TechFAR Hub provides resources to apply industry best practices to the world of digital service acquisition across the Federal government.
- Digital Services Playbook offers private sector best practices to help agencies successfully deliver digital services.
- Defense Acquisition University (DAU)

Other Federal resources from the Federal Acquisition Institute and OFPP include:

[APG]

- Inaugural Conference for Innovative Acquisitions (Federal-wide Buyers Club)
    - "Change Management in an Evolving Acquisition Landscape" Moderated Panel
- Acquisition Seminars

Further reading:

- "Innovative Contracting Case Studies," August 2014, White House Office of Science and Technology Policy.
- "Innovation is a Contract Sport: Ways that agencies can achieve innovative outcomes through acquisitions" February 2016, Booz Allen Hamilton and Partnership for Public Service.
- "Challenge-Based Acquisition: Using challenges to communicate needed capability, encourage innovation in a minimally prescriptive environment, assess candidate offerings, and purchase solutions," September 2015, MITRE Corporation.
- "Simplifying Federal Acquisition: Conversation with Anne Rung, Administrator, Office of Federal Procurement Policy, OMB," IBM Center for the Business of Government, May 2016
- Healthy Markets For Global Health: A Market Shaping Primer USAID, Fall 2014
- "Helping the Federal Government Buy from Start-ups: Cutting out Tolls, Fear, and Mistrust," August 2016, Saad Ansari, Brenna Krieger, and Ruth Siboni. [Unpublished memo]

Outside actors:

- American Council for Technology and Industry Advisory Council's Acquisition Shared Interest group (www.actiac.org),
- Professional Services Council (www.pscouncil.org)
- Acquisition of the Future (www.acquisitionofthefuture.org) – government and industry leaders working together to reform acquisition processes to meet the needs of 21st century government

Interviews:

Doug Rand
Camron Gorguinpour
Mark Naggar
Victor Deal

Text contributed by:

Carol Lundquist
Phil McAlister
Doug Rand
Saad Ansari
Brenna Krieger
Ruth Siboni

OSTP 2014 case study authors

OSTP also would like to thank the many experts who helped develop these case studies, including:
Scott Anderson, MITRE Corporation (formerly)
Michael Arendt, MITRE Corporation
Courtney H. Bailey, NASA

[APG]

Jonah Czerwinski, Department of Veterans Affairs (formerly)
Rick Dunn, DARPA (formerly)
Martin Edwards, MITRE Corporation
Gregory Godbout, General Services Administration
Mary Ann Lapham, Carnegie Mellon University
Patrick Littlefield, Department of Veterans Affairs
Carol Lundquist, National Security Agency
Carol Newcomb, Department of Veterans Affairs
Ryan Novak, MITRE Corporation
Jennifer Pahlka, OSTP (formerly)
Dan Ward, U.S. Air Force
Richard Weatherly, MITRE Corporation
George Xenofos, NASA
Andrew Yang, OSTP (formerly)

[APG]

RE: Pandemic discussion

From "Schmoyer, Michael W. EOP/OSTP" (b) (6)
:
To: "Rudzinski, Christina - 0200 - MITLL" (b) (6)
Cc: "Wack, Edward - 0200 - MITLL" (b) (6), "Norige, Adam - 0221 - MITLL" (b) (6) "Hebner, Greg A. EOP/OSTP" <(b) (6)
Date: Mon, 09 Aug 2021 10:54:00 -0400

Hi Christina-

Always nice to hear from you all! So, there's a good chance that I'll be temporarily pulled away from OSTP for a bit shortly … I'm not sure I'll be available after the 23rd. while I'm away, Dr. Greg Hebner (cc'd) is going to keep an eye on the modeling/forecasting work.

That being said, let's try to get something on the books for all of us and if I can join, I certainly will!

Best,
Michael

From: Rudzinski, Christina - 0200 - MITLL (b) (6)
Sent: Friday, August 6, 2021 11:25 AM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Cc: Wack, Edward - 0200 - MITLL (b) (6); Norige, Adam - 0221 - MITLL (b) (6) >
Subject: [WARNING: UNSCANNABLE EXTRACTION FAILED][EXTERNAL] Pandemic discussion

Hi Michael,

I wanted to follow up and see if you would be willing to re-connect with us late this month or early next month to allow us to present how our thoughts on pandemic "early warning" and data needs have converged, and also to hear any updates from your end on the WH strategy and how it is being rolled out. I know you must continue to be super busy, so we can be flexible to your availability after the 23rd of August. We really appreciate you considering it!

Christina

From: Rudzinski, Christina - 0200 - MITLL
Sent: Tuesday, June 15, 2021 1:28 PM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Cc: Wack, Edward - 0200 - MITLL (b) (6) ; Norige, Adam - 0221 - MITLL (b) (6)
Subject: RE: question for you

Hi Michael!

I hope you are doing well and are planning to take some time off as the summer nears! I wanted to reach out and see if there are any updates on your end regarding the pandemic forecasting priorities. We have continued to work on outlining both outbreak forecasting (pre-zoonotic spillover) data architectures and better decision support tools to optimize preparation and mitigation approaches; I'm aiming for a final briefing of our study in the next month or so and would be happy to share an update with you when we have it. Our hope is to solidify a little more internal funding (and start looking for external support) to explore specific AI tools and advanced models and it would be great to re-connect with you at some point to help us identify the most critical gaps that others aren't tackling (internal funds are competitive so great to tie proposals with clear needs and supporters). We've been talking with the IC, however we are still lacking the right connections at CDC to understand their needs. We've worked successfully with CDC on automatic exposure notification architectures but the team leads on that program aren't directly connected to branches responsible for pandemic forecasting and surveillance. I think you mentioned Dr. Jernigan might be the right POC; do you think he or a colleague might be willing to have a short conversation with us? We also welcome other suggestions.

Best,
Christina

From: Schmoyer, Michael W. EOP/OSTP (b) (6)
Sent: Thursday, April 1, 2021 12:18 PM
To: Rudzinski, Christina - 0200 - MITLL (b) (6)
Cc: Wack, Edward - 0200 - MITLL (b) (6)
Subject: RE: question for you

How about 1:00? Give you some time for lunch after your preceding meeting

From: Rudzinski, Christina - 0200 - MITLL (b) (6)
Sent: Thursday, April 1, 2021 12:15 PM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Cc: Wack, Edward - 0200 - MITLL <(b) (6)
Subject: [EXTERNAL] RE: question for you

Hi again, unfortunately we're tied up in a Directors Office meeting in the AM. Does after noon work? Any time after 12 is fine.
Thanks!
(coffee will be on me then!)

From: Schmoyer, Michael W. EOP/OSTP (b) (6)
Sent: Thursday, April 1, 2021 10:55 AM
To: Rudzinski, Christina - 0200 - MITLL (b) (6) >
Cc: Wack, Edward - 0200 - MITLL (b) (6)
Subject: RE: question for you

Perfect, let's do 0900-1030! I'll donate the virtual coffee ☺

From: Rudzinski, Christina - 0200 - MITLL (b) (6) >
Sent: Thursday, April 1, 2021 10:53 AM
To: Schmoyer, Michael W. EOP/OSTP (b) (6) >
Cc: Wack, Edward - 0200 - MITLL (b) (6)
Subject: [EXTERNAL] RE: question for you

Hi,
16 April is great, we can be flexible any time after noon. Feel free to pick the time and I'll send a calendar invite.
Thanks!
Christina

From: Schmoyer, Michael W. EOP/OSTP (b) (6) >
Sent: Thursday, April 1, 2021 10:16 AM
To: Rudzinski, Christina - 0200 - MITLL (b) (6)

Cc: Wack, Edward - 0200 - MITLL (b) (6) >

Subject: RE: question for you

Hi Christina-

Sounds great to reconnect; I have a few 90 min slots open on 16 APR. does that work for you all?

Perhaps we can chat about an appropriate CDC POC on that day? They're working pretty hard on getting their plan together, as well as who will lead which part.

My best,
Michael

From: Rudzinski, Christina - 0200 - MITLL (b) (6) >

Sent: Wednesday, March 31, 2021 12:56 PM

To: Schmoyer, Michael W. EOP/OSTP (b) (6)

Cc: Wack, Edward - 0200 - MITLL (b) (6)

Subject: [EXTERNAL] RE: question for you

Michael,

This will be a great conversation; hard problems are the fun ones. If it works for you and your timeline with the EO's, let's get a meeting on the calendar for mid-April? We'd love to hear more about how your thinking is shaping up, and to hear your feedback on how we are decomposing the problem to show a process for developing a framework and some suggested advances we feel can begin to chip away at the time/confidence question you ask below. Let me know a few dates that are open on your end and I'll create a placeholder on our calendar. Maybe 90 minutes so we can also pull together a summary on the human performance side and touch on engagement suggestions? On a related note, we would love to learn more about what the leadership at CDC is thinking/doing on this topic; knowing they may be the ultimate home for this capability AND that they bring a lot of expertise and tools to the table so we don't want to duplicate efforts. If you have a point of contact there, we would appreciate the connection but understand if you'd prefer to wait until after we connect again. We are tied in on automated exposure notification efforts and trying to connect to the right CDC offices via that route as well.

Regards,
Christina

From: Schmoyer, Michael W. EOP/OSTP (b) (6) >
Sent: Tuesday, March 30, 2021 11:04 AM
To: Rudzinski, Christina - 0200 - MITLL (b) (6) >
Cc: Wack, Edward - 0200 - MITLL (b) (6)
question for you

Hi Christina-
You are correct, such a complicated question! If you only knew how many times I wrote/rewrote my question below before I sent it to you! ☺

Perhaps when we reconnect in a couple of weeks we can build in some time to discuss this further? I should have some better rationale for the question by then. As you might suppose, I continue to be very involved with both the recent EOs relating to data /and/ related activities surrounding the NSC-directed National Center.

Thanks for the quick response below!
Michael

From: Rudzinski, Christina - 0200 - MITLL (b) (6)
Sent: Monday, March 29, 2021 4:25 PM
To: Schmoyer, Michael W. EOP/OSTP (b) (6)
Cc: Wack, Edward - 0200 - MITLL (b) (6)
Subject: [EXTERNAL] RE: question for you

Hi Michael,

Thanks for reaching out. We are doing great and continuing to refine our thinking on this topic. The question you ask is a complicated one (you knew this!) and probably worth a short conversation but I'll start here with "it depends" and try to lay out the general thinking as there is no single answer. The timeline associated with the ability to predict the emergence and potential surge of a novel disease or disease variant really depends on defining an acceptable confidence level (generally driven by a decision and associated regret if it's the wrong one). As you can imagine, you might predict the potential of an outbreak many weeks in advance however the error bars on the severity/spread will be large. This may be ok, if your response is low regret and you move to, for example, increase surveillance testing or quarantine in priority locations. However, if you are deciding to restrict all travel into and out of the U.S., or start investing in a new vaccine/booster, the confidence of disease severity would need to be greater, thus more data and longer delay (shorter prediction time window) would result. This trade space in timeline/confidence is why we are envisioning a framework for data

collection and integrated decision support system based on key public health/policy decisions. For each major decision and required confidence, you can then model the pandemic progression and determine the earliest point you can achieve the desired certainty given available data. Available data is also an important point; how to determine which data is useful and what gaps exist that we should start to fill or combine to boost our confidence/prediction time. A well-designed data collection effort on COVID variants and other smaller outbreaks would enable analysis to be conducted to determine the value of each data set for a more operational system. I will add more complexity on top of this, that there is also the need to predict the impact of interventions in slowing/preventing disease transmission which has its own timeline dependent on the mobility/interaction of human networks, the effectiveness of the intervention, and compliance.

Again, sorry for the non-answer. There have been assertions that COVID was predicted weeks before the surge, however obviously the information was not sufficient or communicated sufficiently to take high-regret actions. Figuring out what additional data can be leveraged and putting analytics/decision support in place will hopefully improve the confidence level (and possibly timeline) of decisions.

If you are interested, I'd be happy to set up a call and discuss further or refine my thoughts based on your interests. Hopefully I'm not completely missing the mark of your question. I'm also hoping to re-connect in a couple of weeks on the topics we discussed. (pandemic feedback loop, human machine teaming and cognitive/physiological performance, and OSTP-Lab connections)

Best,
Christina

From: Schmoyer, Michael W. EOP/OSTP (b) (6)
Sent: Monday, March 29, 2021 11:40 AM
To: Rudzinski, Christina - 0200 - MITLL (b) (6)
Subject: question for you

Hi Christina-

I hope all is well! So, have been thinking about your Division's work quite a bit lately. If the Pandemic Early Warning System Concept were to come to fruition, what would be the 'timeline metric' that you feel we would arrive at? For example, if we could currently 'predict' a pandemic four weeks out using current analytics and modeling approaches ... what would the PEWS allow us to do? 8 weeks out? 12 weeks? more? I know this is theoretical, of course, and depends on a lot of things, but what would be something to shoot for?

My best,
Michael

Michael W. Schmoyer, PhD
Assistant Director for Health Security Threats

Executive Office of the President
Office of Science and Technology Policy (**OSTP**)
EEOB, Room (b) (6)
1650 Pennsylvania Ave, NW
Washington, DC 20502
(O) (b) (6)
(C) (b) (6)

(JWICS) (b) (6)

[EXTERNAL] Re: Shared Folder and Action Items

From Thomas Benjamin (b) (6)

:

To: Jordan Blashek (b) (6)

Cc: Joanne Isham (b) (6), Gilman Louie (b) (6), "McGuire, Chris R. EOP/OSTP" (b) (6), Kevin McGinnis (b) (6)

Date: Tue, 10 Aug 2021 11:17:17 -0400

Jordan, thanks for this share site; I have uploaded a couple of historical references for background on the InQtel origins. Happy to answer any questions the team may have. Best Regards, Tom Benjamin

On Mon, Aug 9, 2021 at 9:34 AM Jordan Blashek (b) (6) wrote:

Good morning everyone,

We made great progress last week. Thanks to everyone for their insight and hard work on this.

To help organize things going forward, I put together a shared folder here. There are several items inside to highlight:

- Here is a new white paper based on the shift to the 501c3 model
- We need to put together the roadmap for Commerce to show how we can stand this up in the next 2 months. Here is a starter document we can use to collaborate on. Gilman, Joanne and Tom will take the lead on this, since they have the historical knowledge from In-Q-Tel.
- I'm also going to start putting together a Plan of Action and Milestones so we can keep track of our to-dos. Please feel free to add things, and I will organize them.

All the best,

Jordan

RE: [EXTERNAL] Fwd: Any chance to chat?

From: "Matheny, Jason G. EOP/OSTP" (b) (6)

To: "Durnan, Jaymie - 0000 - MITLL" (b) (6)

Date: Sun, 15 Aug 2021 20:32:36 -0400

How about tomorrow or Tue after 6pET?

-------- Forwarded Message --------

Subject: Any chance to chat?

Date: Sat, 14 Aug 2021 18:24:52 +0000

From: Durnan, Jaymie - 0000 - MITLL (b) (6)

To: Jason Matheny (b) (6) >

Jaymie Durnan

Assistant to the Director for Strategic Initiatives

Massachusetts Institute of Technology Lincoln Laboratory

J(b) (6)

(b) (6) *(M)*

(b) (6) *(O)*

(b) (6) *(Asst)*

From: (b) (6)
Sent: Fri, 20 Aug 2021 08:39:14 -0500
To: (b) (6) Andrew Sosanya;Khan, Saif M. EOP/NSC;Eric B;McGuire, Chris R. EOP/OSTP;Daniel Correa;Friedersdorf, Lisa E. EOP/OSTP
Subject: [EXTERNAL] Updated invitation: Day One Project / Heterogeneous Computing @ Wed Sep 1, 2021 12:30pm - 1pm (EDT) ((b) (6))
Attachments: invite.ics

This event has been changed.

Day One Project / Heterogeneous Computing

When **Changed:** Wed Sep 1, 2021 12:30pm – 1pm Eastern Time - New York

Joining info Join Zoom Meeting
(b) (6) , passcode: (b) (6)

Join by phone
(US) (b) (6))

Joining instructions

Calendar (b) (6)

Who
- (b) (6) - organizer
- Andrew Sosanya
- Khan, Saif M. EOP/NSC
- Eric B
- McGuire, Chris R. EOP/OSTP
- Daniel Correa
- (b) (6)

more details »
Going (b) (6) ? **Yes** - **Maybe** - **No** more options »

Invitation from Google Calendar

You are receiving this courtesy email at the account (b) (6) because you are an attendee of this event.

To stop receiving future updates for this event, decline this event. Alternatively you can sign up for a Google account at >https://calendar.google.com/calendar/< and control your notification settings for your entire calendar.

Forwarding this invitation could allow any recipient to send a response to the organizer and be added to the guest list, or invite others regardless of their own invitation status, or to modify your RSVP. Learn More.

From: Google Calendar on behalf of (b) (6)
Sent: Fri, 20 Aug 2021 08:38:33 -0500
To: Andrew Sosanya;Khan, Saif M. EOP/NSC;Eric B;McGuire, Chris R. EOP/OSTP;Daniel Correa
Subject: [EXTERNAL] Invitation: Day One Project / Heterogeneous Computing @ Wed Sep 1, 2021 1:30pm - 2pm (EDT) ((b) (6)
Attachments: invite.ics

You have been invited to the following event.

Day One Project / Heterogeneous Computing

When: Wed Sep 1, 2021 1:30pm – 2pm Eastern Time - New York

Joining info: Join Zoom Meeting
(b) (6) :
JHUSJ2K7)

Join by phone
(US) (b) (6)

Joining instructions

Calendar: (b) (6)

Who:
- (b) (6) - organizer
- Andrew Sosanya
- Khan, Saif M. EOP/NSC
- Eric B
- McGuire, Chris R. EOP/OSTP
- Daniel Correa

more details »
Going (b) (6) ? **Yes** - **Maybe** - **No** more options »

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From: Google Calendar on behalf of "Jennifer Bernal" <(b) (6)
Sent: Thu, 26 Aug 2021 09:03:29 -0500
To: LaBovick, Hannah EOP/OSTP
Subject: [EXTERNAL] Accepted: DeepMind - OSTP @ Tue Sep 21, 2021 4pm - 4:30pm (BST) (LaBovick, Hannah EOP/OSTP)
Attachments: invite.ics

Jennifer Bernal has accepted this invitation.

DeepMind - OSTP

When Tue Sep 21, 2021 4pm – 4:30pm United Kingdom Time

Where >https://pitc.zoomgov.com/(b) (6) (map)

Calendar LaBovick, Hannah EOP/OSTP

Who
- LaBovick, Hannah EOP/OSTP - organizer
- Jennifer Bernal - creator
- (b) (6)
- Demis Hassabis
- Lander, Eric S. EOP/OSTP
- Matheny, Jason G. EOP/OSTP

[>https://www.zoomgov.com/(b) (6)

Hi there,

Hannah LaBovick is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap mobile:

US: (b) (6) or (b) (6)

Meeting URL:

>https://pitc.zoomgov.com/(b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: (b) (6) or (b) (6) or (b) (6) or (b) (6)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

International numbers

Join from an H.323/SIP room system

H.323:

(b) (6) (US West)

(b) (6) (US East)

Meeting ID:

(b) (6)

Passcode:

(b) (6)

SIP:

(b) (6) m

Passcode:

(b) (6)

Invitation from Google Calendar

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