
From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 6/24/2021 11:42:45 AM
To: Simanich, Sasha (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62114870dc66475a8c0ce0047413ed92-simanichs2]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: For 8 AM
Attachments: Lauer NIH Oversight of Grantee-Subgrantee Entrance Conference Agenda...6.21.21.docx

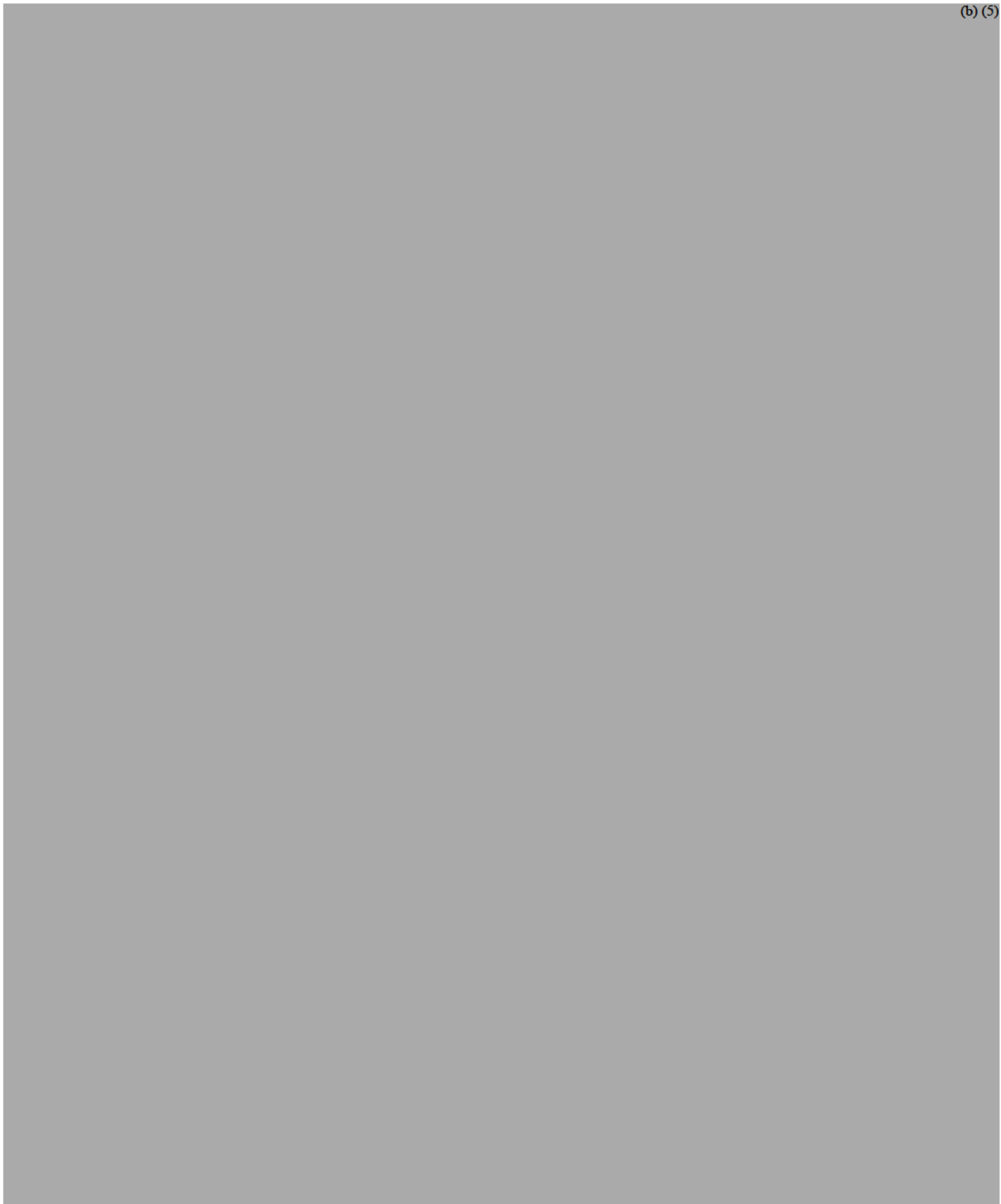
Hi Sasha— here's a draft of answers.

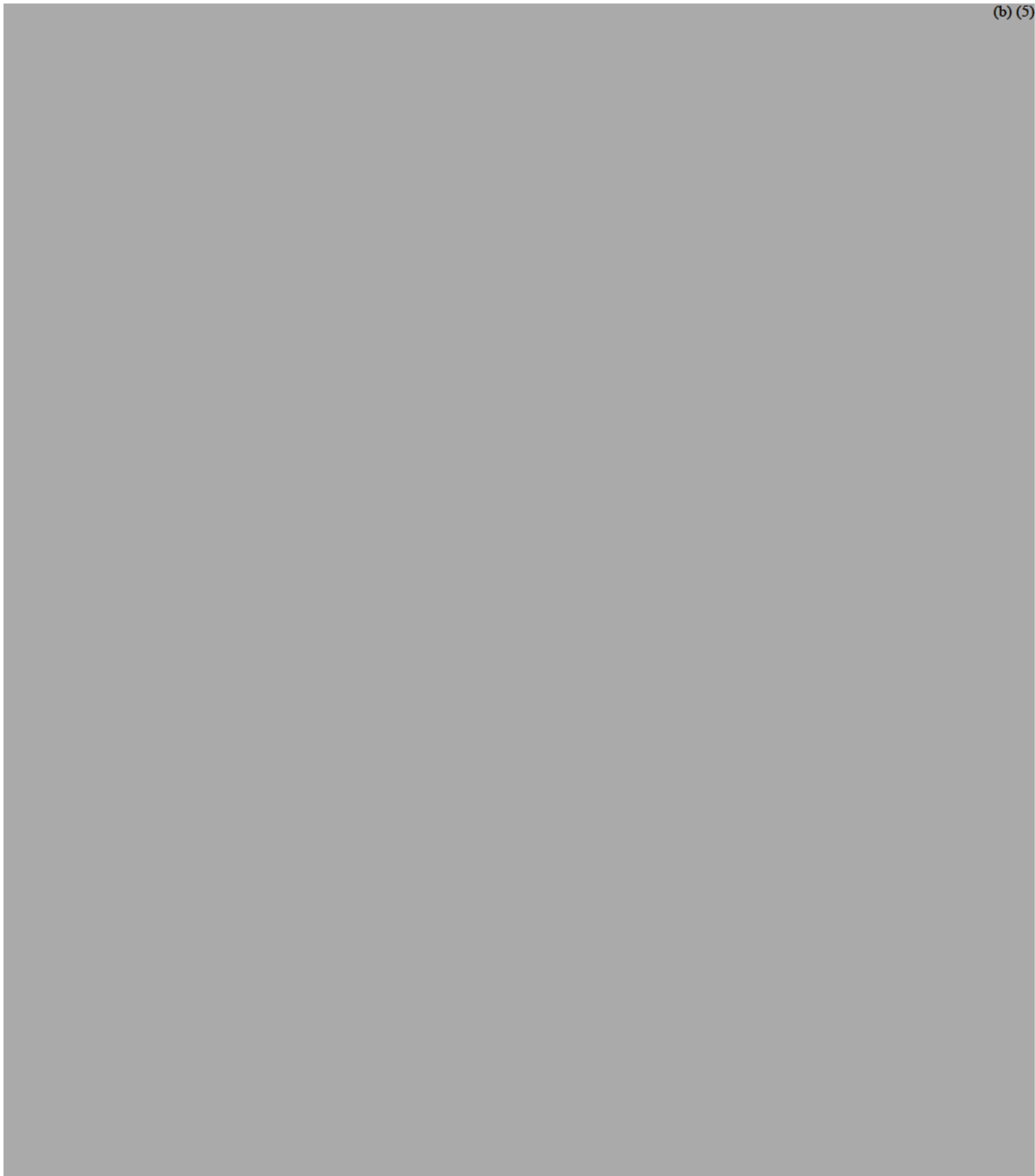
Thanks, Mike

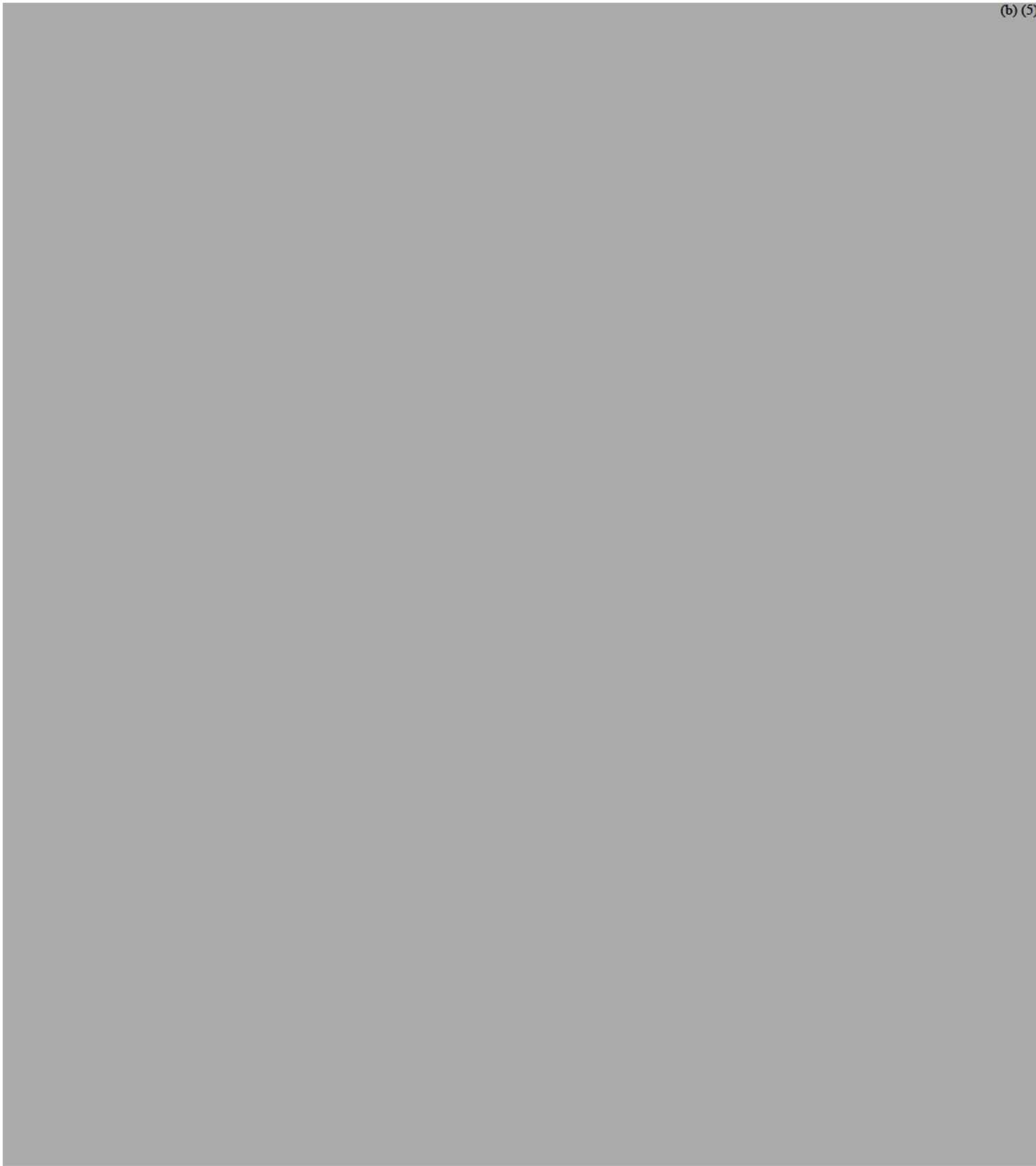
**Audit of National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure
Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees
CIN: A-05-21-00025**

(b) (5)









From: Jacobs, Anna (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E76EEB11DF9A4024B53864FFAC4C4C56-JACOBSAL]
Sent: 6/23/2021 1:12:11 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Stein, Meredith (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3324d143a8c4975b4f1d405d1a54d14-steinme]
CC: Lankford, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Clark, Tamara (OS/OGC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c5382ce18b420780cf8be39025b0d9-Tamara.Clar]
Subject: GAO questions
Attachments: FY21_ALL_STAFF-#611820-v7-104613__NIH_DATA_INFORMATION_REQUEST_#2_(MAY_14__2021).DOCX

As discussed, this is the version of the GAO questions that I read from on today's call.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm.2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)
(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

GAO ENGAGEMENT: 104613—Scientific Integrity

REQUEST #: 2

DATE REQUESTED: May 14, 2021

DUE DATE: June 4, 2021

Description of Request(s):

1. Please describe and provide any documentation that exists illustrating NIH's processes for suspending and terminating a grant and reinstating grant funds. In your descriptions, please include information about:
 - a. The chain of command or clearance process for these decisions;
 - b. How, if at all, the peer review process is involved;
 - c. How, if at all, the process changes based on where a grant is in its award period (e.g., converting from Type 1 to Type 2 or 5 or in the middle of its current award period); and
 - d. Any pre-determined timeframes (e.g., the amount of time a grantee is given to take corrective action following suspension).
2. Please provide a copy of the grant file for the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence," (project number 2R01AI110964-06). Please also provide the following information, if the grant file does not contain it:
 - a. A description of the research and how it fit into NIH/NIAID's goals, priorities, and objectives at the time of approval.
 - b. The name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility. (Please include the Grants Management Officer (GMO); Chief Grants Management Officer (CGMO); Scientific Review Officer (SRO); and Authorized Organization Representative (AOR) for the grant in this list.)
 - c. According to the April 2021 *NIH Grants Policy Statement* (p.IIA-12 and IIA-13), there are two types of grants that could possibly contain foreign subcomponents: 1) A domestic grant with a foreign subcomponent; or 2) A consortium/subaward. What type of grant is the grant in question with respect to its inclusion of the Wuhan Institute of Virology (WIV) as a foreign subcomponent?
3. According to the *NIH Grants Policy Statement* (p. I-43), other NIH, HHS, and federal agency staff (e.g., Office of the Inspector General (OIG) and the Office of Research Integrity (ORI)) coordinate with the GMO, when necessary. Which offices and officials were involved in the suspension and cancellation of the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence" (project number 2R01AI110964-06)? Please describe the date and nature of each office and officials' involvement.

4. According to *SCIENCE*, on April 19, 2020, NIH Deputy Director for Extramural Research Michael Lauer wrote to EcoHealth Alliance and referenced allegations that COVID-19 was released from the WIV, stating: “While we review these allegations during the period of suspension, you are instructed to cease providing any funds to Wuhan Institute of Virology.”¹ Please explain whether NIH conducted an investigation into the allegations involving WIV, and if so, please describe the findings of this investigation and provide any documentation associated with this review.
5. According to the *NIH Grants Policy Statement* (p. IIA-155), a grant recipient may file a grant appeal following an adverse determination. Did EcoHealth Alliance file a grant appeal for the 2019 grant titled “Understanding the Risk of Bat Coronavirus Emergence” (project number 2R01AI110964-06)? If so, please provide all documentation related to EcoHealth Alliance’s grant appeal and its outcome.
6. According to *Politico*, on March 18, 2021, the House Committee on Energy and Commerce wrote a letter to NIH Director Collins to “request information, assistance, and needed leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.”² GAO is interested in reviewing several of the items that were contained in this request, which are listed below: *(Note: If it is easier for NIH to provide the full document request, as opposed to the individual documents requested here, feel free to do so.)*
 - a. “Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.” (Item 11.)
 - b. “In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with “program goals and agency priorities.” Please specify the work that was done by the EcoHealth Alliance that did not align with the agency’s program goals and priorities, and when that work was conducted.” (Item 12.)
 - i. “Was an evaluation of EcoHealth Alliance’s work and whether it aligned with the agency’s goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?” (Item 12a.)
 - c. “In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it “received reports that the Wuhan Institute of Virology...has been conducting research at its facilities in China that pose serious bio-safety concerns.” What are the sources for those reports to NIH and what were the specific allegations reported?” (Item 13.)

¹ See <https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say>.

² See <https://www.politico.com/f/?id=00000178-460d-d27f-ad7e-57cd8e6c0000>.

GAO Data Request for the National Institutes of Health (NIH)
Scientific Integrity Engagement 104613

- d. "After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions." (Item 16.)
 - i. "Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement." (Item 16a.)
 - ii. "What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?" (Item 16b.)
- e. "Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University." (Item 17.)
- f. "Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support." (Item 18.)

From: Jacobs, Anna (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E76EEB11DF9A4024B53864FFAC4C4C56-JACOBSAL]
Sent: 6/24/2021 5:27:02 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: RE: GAO and OIG document productions
Attachments: FOIA Requests Related to EcoHealth and WIV 2020-06-24.xlsx

Got it—that's helpful to know.

Thanks,

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm.2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)
(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Thursday, June 24, 2021 1:24 PM
To: Jacobs, Anna (NIH/OD) [E] (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: FW: GAO and OIG document productions

Hi Anna— I'm not completely following this, but my druthers (if possible) is that OIG sees everything.

Many thanks, Mike

From: "Yueh, Lena (CDC/OCOO/OGC)" (b) (6)
Date: Thursday, June 24, 2021 at 11:48 AM
To: "Jacobs, Anna (NIH/OD) [E]" (b) (6), "Clark, Tamara (OS/OGC)" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6), "Lankford, David (NIH/OD) [E]" (b) (6), "Stein, Meredith (NIH/OD) [E]" (b) (6)
Cc: "Bundesen, Liza (NIH/OD) [E]" (b) (6)
Subject: RE: GAO and OIG document productions

Thank you, Anna.

When we learned that OIG was conducting an audit of the EcoHealth grant, Tamara and I reached out to OIG to make sure that NIH documents that had been requested under FOIA could be released without claiming any (b)(7) exemptions (protecting law enforcement information from disclosure). OIG will not be asserting any (b)(7) exemptions in connection

with its audit. OIG did ask NIH to provide it with any FOIA releases related to the EcoHealth grant, if NIH is amenable. So far, approximately 900 pages of records have been released to FOIA requesters, primarily in connection with ongoing FOIA litigation. Approximately 300 more pages are scheduled to be released next week. A lot of the records are heavily redacted because they contain deliberative information. For those who have not seen it, I'm attaching a chart that lists all of the FOIA requests related to the EcoHealth grant and provides a general description of the documents that have been released. We can also provide a copy of the documents that have been released if anyone wants to see them.

(b) (5)

Please let us know if it would be easier to discuss over the phone and we can set up a call.

Lena Amanti Yueh
Office of the General Counsel
U.S. Department of Health and Human Services
Office: (b) (6)
Cell: (b) (6)

From: Jacobs, Anna (NIH/OD) [E] (b) (6)
Sent: Thursday, June 24, 2021 11:11 AM
To: Clark, Tamara (OS/OGC) (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6); Yueh, Lena (CDC/OCOO/OGC) (b) (6)
Subject: GAO and OIG document productions

Thanks, Tamara and Mike. Tamara, could you also add Lena to the Box folder?

All, I am looping in my other (wonderful) colleague Lena Yueh, from the OGC NCLID, who has been working on the FOIA productions, and who will be working with me, Tamara, and David on the OIG and GAO audits, and specifically, will be reviewing the documents that will be produced to GAO. That would be great if OGC could also have the opportunity to review the documents to be produced to the OIG. We'd be happy to use Box for that as well. Also, for OMA's communications with OGC about the GAO and OIG engagements, that would be great if you could include all four of us (me, Tamara, Lena, and David).

Lena had a discussion with OIG about the audit, as it relates to the FOIA requests, so I'll let her update the group here.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)
(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm.2B-50
Bethesda, MD 20892

(b) (6) (phone)

301-402-1034 (fax)

(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

From: Clark, Tamara (OS/OGC) (b) (6)

Sent: Thursday, June 24, 2021 11:04 AM

To: Lauer, Michael (NIH/OD) [E] (b) (6); Jacobs, Anna (NIH/OD) [E] (b) (6)

Lankford, David (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6)

Cc: Bundesen, Liza (NIH/OD) [E] (b) (6)

Subject: RE: GAO on integrity

Thank you! Invitation sent.

Dr. Bundesen – if you don't receive the invitation to the Box folder, please let me know.

From: Lauer, Michael (NIH/OD) [E] (b) (6)

Sent: Thursday, June 24, 2021 5:07 AM

To: Jacobs, Anna (NIH/OD) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6)

Stein, Meredith (NIH/OD) [E] (b) (6); Clark, Tamara (OS/OGC) (b) (6)

Cc: Bundesen, Liza (NIH/OD) [E] (b) (6)

Subject: GAO on integrity

Good morning – thanks for the meeting yesterday. Here is my draft. I have uploaded documents into the Box folder.

Hi Tamara – could you please add my colleague, Dr. Liza Bundesen, to the Box folder? Her email is

(b) (6)

Many thanks!

Mike

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 6/24/2021 3:37:23 PM
To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]; Clark, Tamara (OS/OGC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c5382ce18b420780cf8be39025b0d9-Tamara.Clar]; Lankford, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Stein, Meredith (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3324d143a8c4975b4f1d405d1a54d14-steinme]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; Yueh, Lena (CDC/OCOO/OGC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81aa35314954970a6a6ba68404cb49f-osh6.CDC]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: GAO and OIG document productions
Attachments: Lauer GAO FY21_ALL_STAFF-#611820-v7-104613_NIH_DATA_INFORMATION_REQUEST_#2_(MAY_14__2021).DOCX

Thanks Anna – Liza is setting up a Box folder for OIG, and we'll include you, Tamara, David, Meredith, and Lena as well.

Mike

From: "Jacobs, Anna (NIH/OD) [E]" (b) (6)
Date: Thursday, June 24, 2021 at 11:10 AM
To: "Clark, Tamara (OS/OGC)" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6), "Lankford, David (NIH/OD) [E]" (b) (6), "Stein, Meredith (NIH/OD) [E]" (b) (6)
Cc: "Bunden, Liza (NIH/OD) [E]" (b) (6), "Yueh, Lena (CDC/OCOO/OGC)" (b) (6)
Subject: GAO and OIG document productions

Thanks, Tamara and Mike. Tamara, could you also add Lena to the Box folder?

All, I am looping in my other (wonderful) colleague Lena Yueh, from the OGC NCLID, who has been working on the FOIA productions, and who will be working with me, Tamara, and David on the OIG and GAO audits, and specifically, will be reviewing the documents that will be produced to GAO. That would be great if OGC could also have the opportunity to review the documents to be produced to the OIG. We'd be happy to use Box for that as well. Also, for OMA's communications with OGC about the GAO and OIG engagements, that would be great if you could include all four of us (me, Tamara, Lena, and David).

Lena had a discussion with OIG about the audit, as it relates to the FOIA requests, so I'll let her update the group here.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)

(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)

(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

From: Clark, Tamara (OS/OGC) (b) (6)
Sent: Thursday, June 24, 2021 11:04 AM
To: Lauer, Michael (NIH/OD) [E] (b) (6); Jacobs, Anna (NIH/OD) [E] (b) (6);
Lankford, David (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6)
Subject: RE: GAO on integrity

Thank you! Invitation sent.

Dr. Bundesen – if you don't receive the invitation to the Box folder, please let me know.

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Thursday, June 24, 2021 5:07 AM
To: Jacobs, Anna (NIH/OD) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6);
Stein, Meredith (NIH/OD) [E] (b) (6); Clark, Tamara (OS/OGC) (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6)
Subject: GAO on integrity

Good morning – thanks for the meeting yesterday. Here is my draft. I have uploaded documents into the Box folder.

Hi Tamara – could you please add my colleague, Dr. Liza Bundesen, to the Box folder? Her email is

(b) (6)

Many thanks!

Mike

GAO ENGAGEMENT: 104613—Scientific Integrity

REQUEST #: 2

DATE REQUESTED: May 14, 2021

DUE DATE: June 4, 2021

Description of Request(s):

1. Please describe and provide any documentation that exists illustrating NIH's processes for suspending and terminating a grant and reinstating grant funds. In your descriptions, please include information about:

- a. The chain of command or clearance process for these decisions;

(b) (5)

- b. How, if at all, the peer review process is involved;

(b) (5)

- c. How, if at all, the process changes based on where a grant is in its award period (e.g., converting from Type 1 to Type 2 or 5 or in the middle of its current award period); and

(b) (5)

- d. Any pre-determined timeframes (e.g., the amount of time a grantee is given to take corrective action following suspension).

(b) (5)

2. Please provide a copy of the grant file for the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence," (project number 2R01AI110964-06). Please also provide the following information, if the grant file does not contain it:

- a. A description of the research and how it fit into NIH/NIAID's goals, priorities, and objectives at the time of approval.

(b) (5)

- b. The name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility. (Please include the Grants Management Officer (GMO); Chief Grants Management Officer (CGMO); Scientific Review Officer (SRO); and Authorized Organization Representative (AOR) for the grant in this list.)

(b) (5)

- c. According to the April 2021 *NIH Grants Policy Statement* (p.IIA-12 and IIA-13), there are two types of grants that could possibly contain foreign subcomponents: 1) A domestic grant with a foreign subcomponent; or 2) A consortium/subaward. What type of grant is the grant in question with respect to its inclusion of the Wuhan Institute of Virology (WIV) as a foreign subcomponent?

(b) (5)

3. According to the *NIH Grants Policy Statement* (p. I-43), other NIH, HHS, and federal agency staff (e.g., Office of the Inspector General (OIG) and the Office of Research Integrity (ORI)) coordinate with the GMO, when necessary. Which offices and officials were involved in the suspension and cancellation of the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence" (project number 2R01AI110964-06)? Please describe the date and nature of each office and officials' involvement.

(b) (5)

4. According to *SCIENCE*, on April 19, 2020, NIH Deputy Director for Extramural Research Michael Lauer wrote to EcoHealth Alliance and referenced allegations that COVID-19 was released from the WIV, stating: "While we review these allegations during the period

of suspension, you are instructed to cease providing any funds to Wuhan Institute of Virology.”¹ Please explain whether NIH conducted an investigation into the allegations involving WIV, and if so, please describe the findings of this investigation and provide any documentation associated with this review.

(b) (5)

5. According to the *NIH Grants Policy Statement* (p. IIA-155), a grant recipient may file a grant appeal following an adverse determination. Did EcoHealth Alliance file a grant appeal for the 2019 grant titled “Understanding the Risk of Bat Coronavirus Emergence” (project number 2R01AI110964-06)? If so, please provide all documentation related to EcoHealth Alliance’s grant appeal and its outcome.

(b) (5)

6. According to *Politico*, on March 18, 2021, the House Committee on Energy and Commerce wrote a letter to NIH Director Collins to “request information, assistance, and needed leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.”² GAO is interested in reviewing several of the items that were contained in this request, which are listed below: (*Note: If it is easier for NIH to provide the full document request, as opposed to the individual documents requested here, feel free to do so.*)

- a. “Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.” (Item 11.)

(b) (5)

- b. “In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with “program goals and agency priorities.” Please specify the work that was done by the EcoHealth Alliance that did not align with the agency’s program goals and priorities, and when that work was conducted.” (Item 12.)

¹ See <https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say>.

² See <https://www.politico.com/f/?id=00000178-460d-d27f-ad7e-57cd8e6c0000>.

(b) (5)

- c. "In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology...has been conducting research at its facilities in China that pose serious bio-safety concerns." What are the sources for those reports to NIH and what were the specific allegations reported?" (Item 13.)

(b) (5)

- d. "After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions." (Item 16.)

- i. "Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement." (Item 16a.)

(b) (5)

- ii. "What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?" (Item 16b.)

(b) (5)

- e. "Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University." (Item 17.)

(b) (5)

- f. "Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through

GAO Data Request for the National Institutes of Health (NIH)
Scientific Integrity Engagement 104613

contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support." (Item 18.)

(b) (5)

From: Jacobs, Anna (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E76EEB11DF9A4024B53864FFAC4C4C56-JACOBSAL]
Sent: 6/24/2021 5:14:21 PM
To: Stein, Meredith (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3324d143a8c4975b4f1d405d1a54d14-steinme]; Clark, Tamara (OS/OGC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c5382ce18b420780cf8be39025b0d9-Tamara.Clar]; Lankford, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Yueh, Lena (CDC/OCOO/OGC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c81aa35314954970a6a6ba68404cb49f-osh6.CDC]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: RE: GAO and OIG document productions
Attachments: Lauer GAO FY21_ALL_STAFF-#611820-v7-104613__NIH_DATA_INFORMATION_REQUEST_#2_(MAY_14__2021).DOCX; FOIA Requests Related to EcoHealth and WIV 2020-06-24.xlsx; RE: GAO and OIG document productions

Thanks, Meredith. I agree that separate Box folders for the OIG and GAO engagements is a good idea.

(b) (5)

Question 6a asks: ““Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.”

*Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892*

(b) (6) (phone)

301-402-1034 (fax)

(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or

otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

From: Stein, Meredith (NIH/OD) [E] (b) (6)
Sent: Thursday, June 24, 2021 12:48 PM
To: Jacobs, Anna (NIH/OD) [E] (b) (6); Clark, Tamara (OS/OGC) (b) (6); Lankford, David (NIH/OD) [E] (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6); Yueh, Lena (CDC/OCOO/OGC) (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: RE: GAO and OIG document productions

Hi Anna, I let Sasha Simanich and Tiffany Brown know to include you, David, Tamara, and Lena on meetings and communications for the OIG audit about EHA.
Yes, of course, we will allocate time to have OGC review the consolidated draft response prior to submitting to the OIG.

I think a separate BOX site would be a good solution to share the files prior to submitting documents to the OIG. We used BOX for a NHBLI audit that worked well for the volumes of documentation.

(b) (5)

What do you think?

Thank you,
Meredith

From: Jacobs, Anna (NIH/OD) [E] (b) (6)
Sent: Thursday, June 24, 2021 11:11 AM
To: Clark, Tamara (OS/OGC) (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6); Yueh, Lena (CDC/OCOO/OGC) (b) (6)
Subject: GAO and OIG document productions

Thanks, Tamara and Mike. Tamara, could you also add Lena to the Box folder?

All, I am looping in my other (wonderful) colleague Lena Yueh, from the OGC NCLID, who has been working on the FOIA productions, and who will be working with me, Tamara, and David on the OIG and GAO audits, and specifically, will be reviewing the documents that will be produced to GAO. That would be great if OGC could also have the opportunity to review the documents to be produced to the OIG. We'd be happy to use Box for that as well. Also, for OMA's communications with OGC about the GAO and OIG engagements, that would be great if you could include all four of us (me, Tamara, Lena, and David).

Lena had a discussion with OIG about the audit, as it relates to the FOIA requests, so I'll let her update the group here.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)
(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)
(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

From: Clark, Tamara (OS/OGC) (b) (6)
Sent: Thursday, June 24, 2021 11:04 AM
To: Lauer, Michael (NIH/OD) [E] (b) (6); Jacobs, Anna (NIH/OD) [E] (b) (6)
Lankford, David (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6)
Subject: RE: GAO on integrity

Thank you! Invitation sent.

Dr. Bundesen – if you don't receive the invitation to the Box folder, please let me know.

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Thursday, June 24, 2021 5:07 AM
To: Jacobs, Anna (NIH/OD) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6);
Stein, Meredith (NIH/OD) [E] (b) (6); Clark, Tamara (OS/OGC) (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6)
Subject: GAO on integrity

Good morning – thanks for the meeting yesterday. Here is my draft. I have uploaded documents into the Box folder.

Hi Tamara – could you please add my colleague, Dr. Liza Bundesen, to the Box folder? Her email is
(b) (6).

Many thanks!

Mike

GAO ENGAGEMENT: 104613—Scientific Integrity

REQUEST #: 2

DATE REQUESTED: May 14, 2021

DUE DATE: June 4, 2021

Description of Request(s):

1. Please describe and provide any documentation that exists illustrating NIH's processes for suspending and terminating a grant and reinstating grant funds. In your descriptions, please include information about:

- a. The chain of command or clearance process for these decisions;

(b) (5)

- b. How, if at all, the peer review process is involved;

(b) (5)

- c. How, if at all, the process changes based on where a grant is in its award period (e.g., converting from Type 1 to Type 2 or 5 or in the middle of its current award period); and

(b) (5)

- d. Any pre-determined timeframes (e.g., the amount of time a grantee is given to take corrective action following suspension).

(b) (5)

2. Please provide a copy of the grant file for the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence," (project number 2R01AI110964-06). Please also provide the following information, if the grant file does not contain it:

- a. A description of the research and how it fit into NIH/NIAID's goals, priorities, and objectives at the time of approval.

(b) (5)

- b. The name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility. (Please include the Grants Management Officer (GMO); Chief Grants Management Officer (CGMO); Scientific Review Officer (SRO); and Authorized Organization Representative (AOR) for the grant in this list.)

(b) (5)

- c. According to the April 2021 *NIH Grants Policy Statement* (p.IIA-12 and IIA-13), there are two types of grants that could possibly contain foreign subcomponents: 1) A domestic grant with a foreign subcomponent; or 2) A consortium/subaward. What type of grant is the grant in question with respect to its inclusion of the Wuhan Institute of Virology (WIV) as a foreign subcomponent?

(b) (5)

3. According to the *NIH Grants Policy Statement* (p. I-43), other NIH, HHS, and federal agency staff (e.g., Office of the Inspector General (OIG) and the Office of Research Integrity (ORI)) coordinate with the GMO, when necessary. Which offices and officials were involved in the suspension and cancellation of the 2019 grant titled "Understanding the Risk of Bat Coronavirus Emergence" (project number 2R01AI110964-06)? Please describe the date and nature of each office and officials' involvement.

(b) (5)

4. According to *SCIENCE*, on April 19, 2020, NIH Deputy Director for Extramural Research Michael Lauer wrote to EcoHealth Alliance and referenced allegations that COVID-19 was released from the WIV, stating: "While we review these allegations during the period

of suspension, you are instructed to cease providing any funds to Wuhan Institute of Virology.”¹ Please explain whether NIH conducted an investigation into the allegations involving WIV, and if so, please describe the findings of this investigation and provide any documentation associated with this review.

(b) (5)

5. According to the *NIH Grants Policy Statement* (p. IIA-155), a grant recipient may file a grant appeal following an adverse determination. Did EcoHealth Alliance file a grant appeal for the 2019 grant titled “Understanding the Risk of Bat Coronavirus Emergence” (project number 2R01AI110964-06)? If so, please provide all documentation related to EcoHealth Alliance’s grant appeal and its outcome.

(b) (5)

6. According to *Politico*, on March 18, 2021, the House Committee on Energy and Commerce wrote a letter to NIH Director Collins to “request information, assistance, and needed leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.”² GAO is interested in reviewing several of the items that were contained in this request, which are listed below: (*Note: If it is easier for NIH to provide the full document request, as opposed to the individual documents requested here, feel free to do so.*)

- a. “Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.” (Item 11.)

(b) (5)

- b. “In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with “program goals and agency priorities.” Please specify the work that was done by the EcoHealth Alliance that did not align with the agency’s program goals and priorities, and when that work was conducted.” (Item 12.)

¹ See <https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say>.

² See <https://www.politico.com/f/?id=00000178-460d-d27f-ad7e-57cd8e6c0000>.

(b) (5)

- c. "In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology...has been conducting research at its facilities in China that pose serious bio-safety concerns." What are the sources for those reports to NIH and what were the specific allegations reported?" (Item 13.)

(b) (5)

- d. "After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions." (Item 16.)

- i. "Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement." (Item 16a.)

(b) (5)

- ii. "What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?" (Item 16b.)

(b) (5)

- e. "Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University." (Item 17.)

(b) (5)

- f. "Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through

GAO Data Request for the National Institutes of Health (NIH)
Scientific Integrity Engagement 104613

contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support." (Item 18.)

(b) (5)

From: Yueh, Lena (CDC/OCOO/OGC) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C81AA35314954970A6A6BA68404CB49F-OSH6.CDC]
Sent: 6/24/2021 3:48:23 PM
To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]; Clark, Tamara (OS/OGC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c5382ce18b420780cf8be39025b0d9-Tamara.Clar]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauer]; Lankford, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Stein, Meredith (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3324d143a8c4975b4f1d405d1a54d14-steinme]
CC: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: RE: GAO and OIG document productions
Attachments: FOIA Requests Related to EcoHealth and WIV 2020-06-24.xlsx

Thank you, Anna.

When we learned that OIG was conducting an audit of the EcoHealth grant, Tamara and I reached out to OIG to make sure that NIH documents that had been requested under FOIA could be released without claiming any (b)(7) exemptions (protecting law enforcement information from disclosure). OIG will not be asserting any (b)(7) exemptions in connection with its audit. OIG did ask NIH to provide it with any FOIA releases related to the EcoHealth grant, if NIH is amenable. So far, approximately 900 pages of records have been released to FOIA requesters, primarily in connection with ongoing FOIA litigation. Approximately 300 more pages are scheduled to be released next week. A lot of the records are heavily redacted because they contain deliberative information. For those who have not seen it, I'm attaching a chart that lists all of the FOIA requests related to the EcoHealth grant and provides a general description of the documents that have been released. We can also provide a copy of the documents that have been released if anyone wants to see them.

(b) (5)

Please let us know if it would be easier to discuss over the phone and we can set up a call.

Lena Amanti Yueh
Office of the General Counsel
U.S. Department of Health and Human Services
Office: (b) (6)
Cell: (b) (6)

From: Jacobs, Anna (NIH/OD) [E] (b) (6)
Sent: Thursday, June 24, 2021 11:11 AM
To: Clark, Tamara (OS/OGC) (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6); Yueh, Lena (CDC/OCOO/OGC) (b) (6)
Subject: GAO and OIG document productions

Thanks, Tamara and Mike. Tamara, could you also add Lena to the Box folder?

All, I am looping in my other (wonderful) colleague Lena Yueh, from the OGC NCLID, who has been working on the FOIA productions, and who will be working with me, Tamara, and David on the OIG and GAO audits, and specifically, will be reviewing the documents that will be produced to GAO. That would be great if OGC could also have the opportunity to review the documents to be produced to the OIG. We'd be happy to use Box for that as well. Also, for OMA's communications with OGC about the GAO and OIG engagements, that would be great if you could include all four of us (me, Tamara, Lena, and David).

Lena had a discussion with OIG about the audit, as it relates to the FOIA requests, so I'll let her update the group here.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)
(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
(b) (6) (phone)
301-402-1034 (fax)
(b) (6)

NOTICE: The contents of this message and any attachments may be privileged and confidential. Please do not disseminate without the approval of the Office of the General Counsel. If you are not an intended recipient, or have received this message in error, please delete it without reading it and please do not print, copy, forward, disseminate, or otherwise use this information. Also, please notify the sender that you have received this communication in error. Your receipt of this message is not intended to waive any applicable privilege.

From: Clark, Tamara (OS/OGC) (b) (6)
Sent: Thursday, June 24, 2021 11:04 AM
To: Lauer, Michael (NIH/OD) [E] (b) (6); Jacobs, Anna (NIH/OD) [E] (b) (6)
Lankford, David (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6)
Cc: Bundesen, Liza (NIH/OD) [E] (b) (6)
Subject: RE: GAO on integrity

Thank you! Invitation sent.

Dr. Bundesen -- if you don't receive the invitation to the Box folder, please let me know.

From: Lauer, Michael (NIH/OD) [E] (b) (6)

Sent: Thursday, June 24, 2021 5:07 AM

To: Jacobs, Anna (NIH/OD) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6)

Stein, Meredith (NIH/OD) [E] (b) (6); Clark, Tamara (OS/OGC) (b) (6)

Cc: Bundesen, Liza (NIH/OD) [E] (b) (6)

Subject: GAO on integrity

Good morning – thanks for the meeting yesterday. Here is my draft. I have uploaded documents into the Box folder.

Hi Tamara – could you please add my colleague, Dr. Liza Bundesen, to the Box folder? Her email is

(b) (6)

Many thanks!

Mike

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 10/14/2020 9:49:01 AM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabak]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Agenda for 1:1 with Larry Tabak on Wednesday, October 14, at 5:45 PM
Attachments: Agenda 1 on 1 with Larry Tabak 10 14 20.docx; Tabak 10 12 20.zip

Hi Larry – I believe we're scheduled to meet at 5:45 PM this afternoon. Here's what I have so far.

Many thanks, Mike

LT agenda 10 12 20

- Clearance for PV?
- U of Arizona and U of Connecticut
- Emory and Cedars-Sinai
- Johns Hopkins and U of Maryland
- Ohio State report
- U of PA report

New England Council
National Institutes of Health Office of Science Policy

Participants

Jim Brett, President, The New England Council

Tim Leshan, Vice Provost for Research Government Affairs & Strategic Partnerships, Northeastern University

Carrie Wolinetz, Associate Director for Science Policy and Acting Chief of Staff, National Institutes of Health

Mike Lauer, Deputy Director for Extramural Research, National Institutes of Health

Program Agenda

3:00 - Intro - Jim Brett

3:03 - Intro – Tim Leshan

3:05 - Remarks – Carrie Wolinetz

3:15 - Remarks – Mike Lauer,

3:25 - Question – Jim Brett

3:30 - Questions – Tim Leshan

3:40 - Questions from audience

3:58 - Jim Brett concluding remarks

Prepared Questions

Policy Matters

In the midst of a global pandemic how is the NIH managing overall?

The agency has received a great deal of new funding to respond to the COVID crisis and you are slated to get more. Can you tell us how NIH is working to fund solutions to this pandemic?

Can you provide your assessment of how impactful those funds have been in addressing this health crisis?

Can you discuss the impact of COVID on faculty researchers? They have lost time on their work because campuses have been shut down, and like others many are caring for loved ones while working from home. Some faculty have said this will set their careers back for years.

How does NIH approach research policy?

What is the NIH decision making process for deciding what research areas to invest in and which grant opportunities should be funded?

Can you discuss the view looking forward on research funding? What areas are NIH focused on for future grants? What are the priorities for NIH, this year and beyond?

How does the NIH work to drive innovation?

Can you tell us the NIH's future plans for support of clinical research?

Regulatory Matters

Can you tell us about the new rules on data sharing? How has NIH addressed data sharing to enhance the outcomes of research funding?

Can you discuss concerns with foreign influence? We all work with international students and are working to navigate this space in a collaborative manner and are concerned with new guidelines and regulations.

Can you discuss your Subcommittee on Training and Career Opportunities for Scientists? How does your office work to support graduate students, postdocs, and early career scientists?

Can you discuss sexual harassment in the research space and efforts NIH is taking to remedy the issue?

NIH Policy for NIH Extramural Staff: Requests Regarding Aggregate Peer Review Rosters

(b) (5)





Certificates of Confidentiality Report, CY2020, 3rd quarter

Contents

Summary

Certificate of Confidentiality (CoC) Statistics

3rd Quarter

Year to Date

CoC Mailbox

Certificate of Confidentiality Online Processing System

Summary

Per NOT-OD-17-109 all NIH funded studies commenced or ongoing on or after December 13, 2016 and within the scope of the Certificate of Confidentiality (CoC) policy are deemed to be issued a Certificate of Confidentiality (CoC). The CoC policy requirements are part of the terms and conditions of the NIH grant awards. On behalf of the Secretary, HHS, as stated in the 21st Century Cures Act, P.L. 114-255, NIH may also issue CoCs to non-NIH funded studies, upon application. These non-NIH funded certificates are processed by a subdivision of OER's Division of Human Subjects Research.

In 2019-2020, OER designed a new online CoC processing system through eRA for issuance of non-NIH funded CoCs. The new system was successfully deployed on March 19, 2020. The old system, supported via a contract by the company, NETE, was utilized by NIH to issue CoCs from April 2015 until it was retired on March 11, 2020. On January 31, 2020, HHS Secretary Azar declared a Public Health Emergency secondary to the global pandemic involving SARS-CoV-2, which is the cause of Novel Coronavirus Disease 2019 (COVID 19). The declaration was retroactive to January 27, 2020. Given much of the research enterprise in the United States was halted or delayed in early-mid 2020, it is highly likely the number of issued CoCs were affected by the Public Health Emergency, particularly in the second quarter.

CoC Statistics

3rd Quarter (July 1 – September 30, 2020):

NIH received a total of 248 CoC requests from July 1 – September 30, 2020. Of the 248 requests:

- A total of 233 requests were approved.
- A total of 2 requests remained in a hold status, one pending communication from the investigator to determine if the request can be approved and the other pending a consultation with OGC to determine if NIH can approve the request.
- A total of 13 requests were rejected.

See Figure 1 for the CoC requests by status and month. See Figure 2 for a table summarizing why the 13 requests were rejected.

Figure 1. Third Quarter CoC Requests by Status and Month
(JUL 1- SEP 30, 2020)

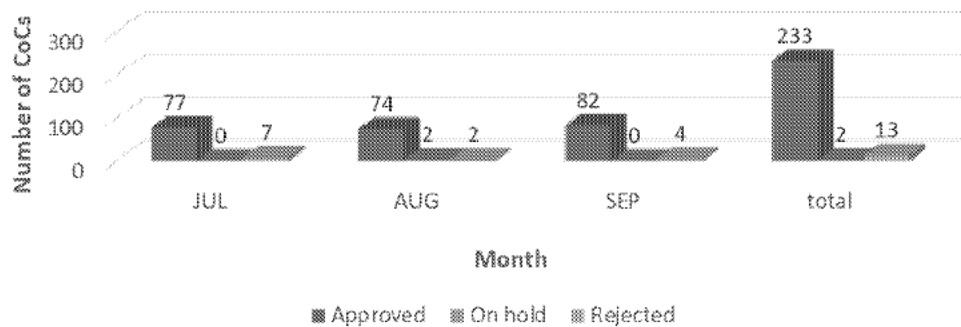


Figure 1. This graph describes the status of the CoC requests NIH received, from July 1 to September 30, 2020 at the end of the 3rd quarter. A total of 233 CoC requests were approved, 2 requests were on hold at the end of the 3rd quarter, and 13 requests were rejected in the 3rd quarter of 2020.

Figure 2. Third Quarter CoC Rejected Requests
(JUL 1 - SEP 30, 2020)

#	Reason Rejected
5	duplicate (accidental resubmission)
5	duplicate (PI and IO are same person – resubmitted)
2	not within NIH mission
1	Duplicate (subsequently resubmitted with corrected information)

Total rejection n = 13

Figure 2. This table describes the reasons that CoC requests were rejected, from July 1 to September 30, 2020. A total of 13 CoCs were rejected in the 3rd quarter of 2020.

NIH staff log into the system regularly to review CoC requests that have not been approved. On average, CoC requests were approved in 1.77 days. NIH staff took 0 to 37 days to approve CoC requests. Four requests took longer than one week to approve. The delay in approving these CoC requests was due to waiting for an email response from the PI for additional information regarding the project description. The NIH Human Subject's Officer reviewed the additional information and determined that these projects fall within the NIH mission, and they were subsequently approved. See Figure 3 for the number of days to approve a CoC request.

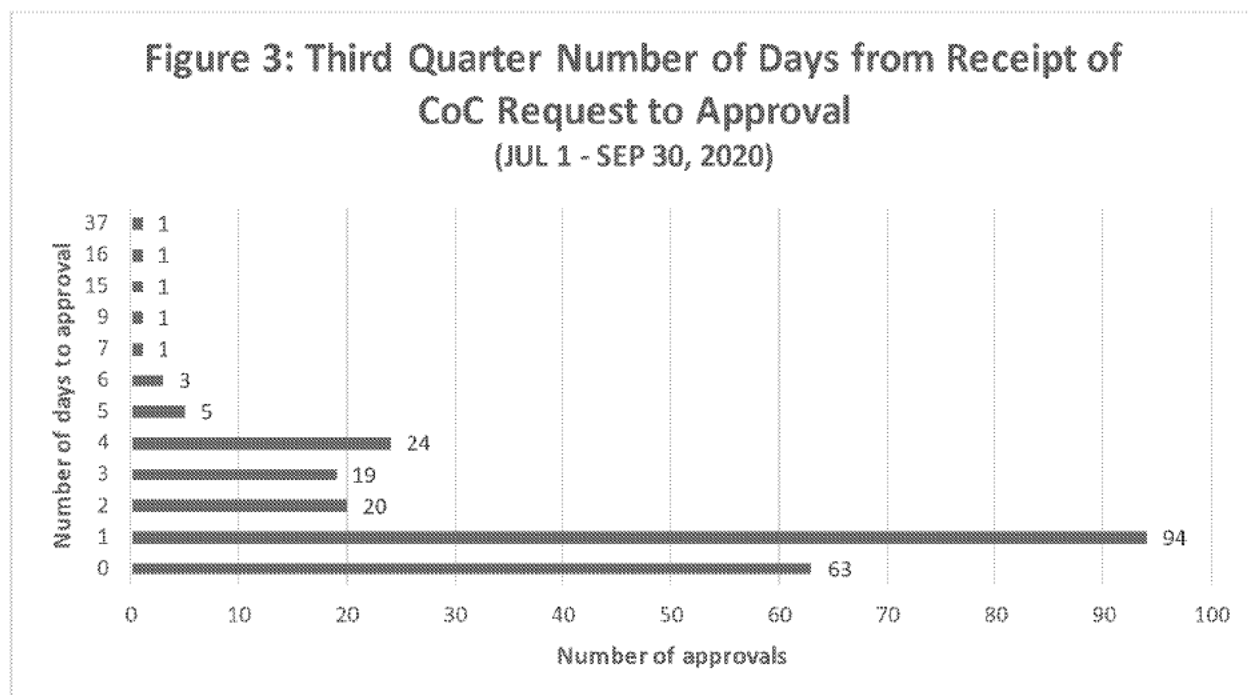


Figure 3. This graph displays the number of days that it took CoC staff to approve a CoC request for those requests received during the 3rd quarter, from the time NIH received the request.

There were seven CoC requests that were listed in a hold status in the 2nd quarter report. See Figure 4 for the final statuses of these requests. Note that the third quarter numbers do not reflect the final action on these seven 2nd quarter CoC requests.

Figure 4. Final Statuses of On-Hold CoCs from the 2nd Quarter Report

final status	#	why request was not approved
approved	1	
rejected	4	3- error- PI and IO are the same, 1- not within NIH mission
deleted	2	2- error- PI and IO are the same

Figure 4. This table displays the final status of the seven CoC requests that were listed as on-hold in the 2nd Quarter report. One of these CoC requests was approved in the 3rd quarter, four were rejected, and two were deleted*. *See the Standardizing CoC Request Processing for additional information.

Year to Date (January 1 – September 30, 2020):

A total of 559 CoC requests were approved from January 1 - September 30, 2020. See Figure 5 for the CoC approvals by month for the 1st, 2nd, and 3rd quarters of 2020. Note: Figure 5 combines the approvals from the old and new system for the month of March.

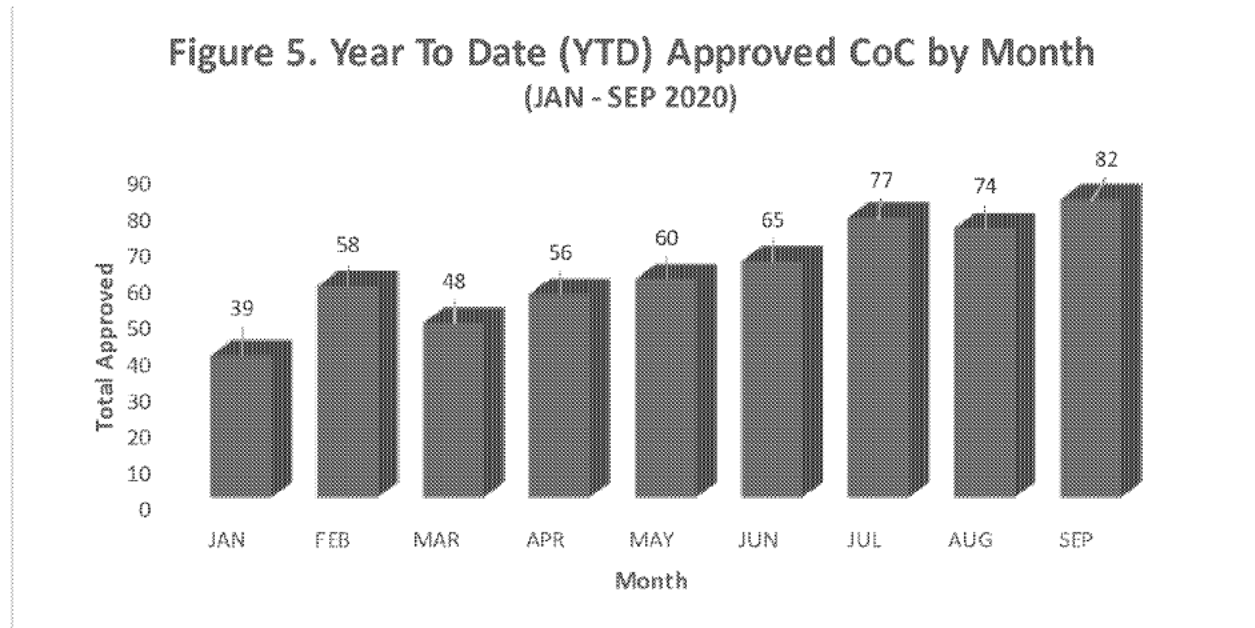


Figure 5. This graph describes the total number of approved CoC requests by month, from January 1 to September 30, 2020. A total of 559 CoCs were approved in this time period.

The CoC system captures the type of funding for each CoC request. Non-federally funded research projects dominated the CoC requests that NIH received. Of the 559 CoCs approved during the 1st, 2nd and 3rd quarters of 2020, 486 were non-federally funded projects, 10 were funded by other HHS agencies, and 63 were funded by other federal departments. See Figure 6 for the CoC approval per month by funding type from January 1 to September 30, 2020. See Figure 7 for the CoC approval per month by funding type in a table format.

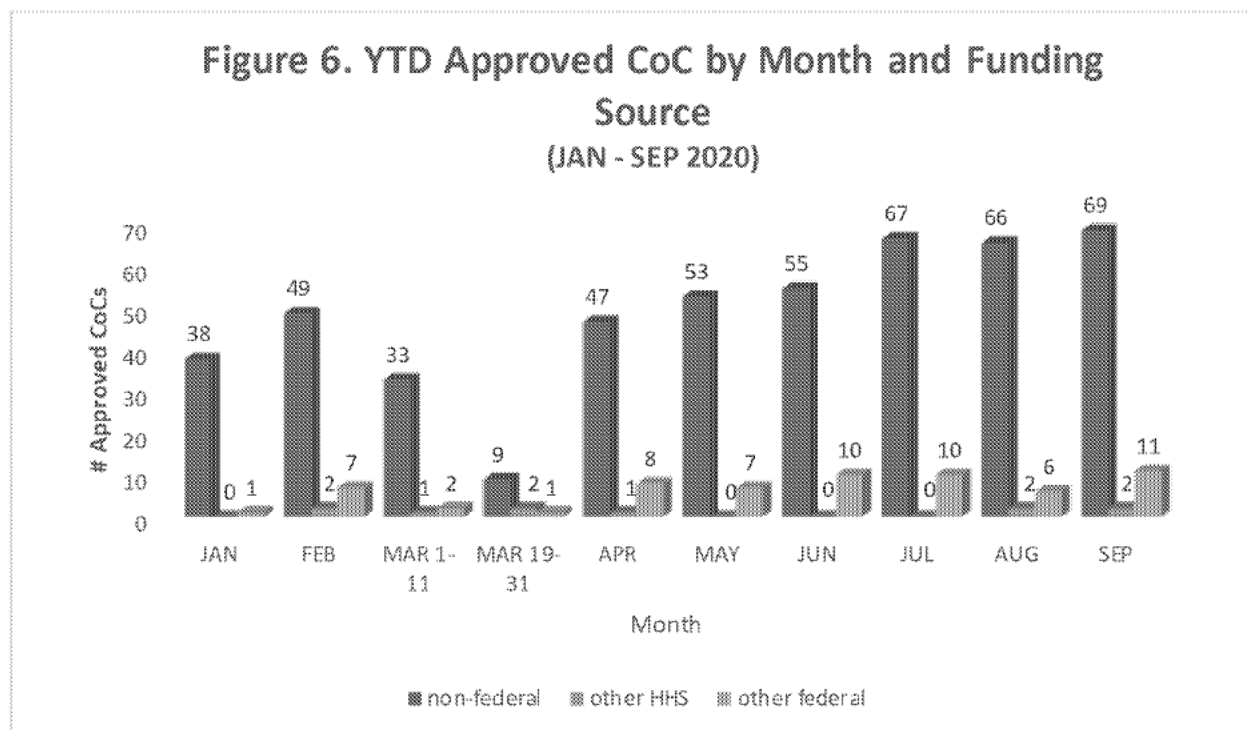


Figure 6. This graph describes the funding source of approved CoC requests by month, from January 1 to September 30, 2020. A total of 559 CoCs were approved in the 1st, 2nd, and 3rd quarters of 2020.

Figure 7. YTD Funding Source of Approved CoCs by Month
(JAN – SEP 2020)

	JAN	FEB	MAR 1-11	MAR 19-31	APR	MAY	JUN	JUL	AUG	SEP	TOTAL
non-federal	38	49	33	9	47	53	55	67	66	69	486
other HHS	0	2	1	2	1	0	0	0	2	2	10
other federal	1	7	2	1	8	7	10	10	6	11	63
total approved	39	58	36	12	56	60	65	77	74	82	559

Figure 7. This table displays the funding source of approved CoC requests by month, from January 1 to September 30, 2020. A total of 559 CoCs were approved in the 1st, 2nd, and 3rd quarters of 2020.

CoC Mailbox

The NIH CoC mailbox received a total of 644 initial queries from January to September 2020. In addition, the NIH CoC mailbox received many follow-up queries from the same individual for a total of 1109 queries during this time period. See Figure 8 for the CoC email queries received during the first three quarters of 2020. NIH CoC staff spend approximately 25 hours per week managing and responding to CoC mailbox queries.

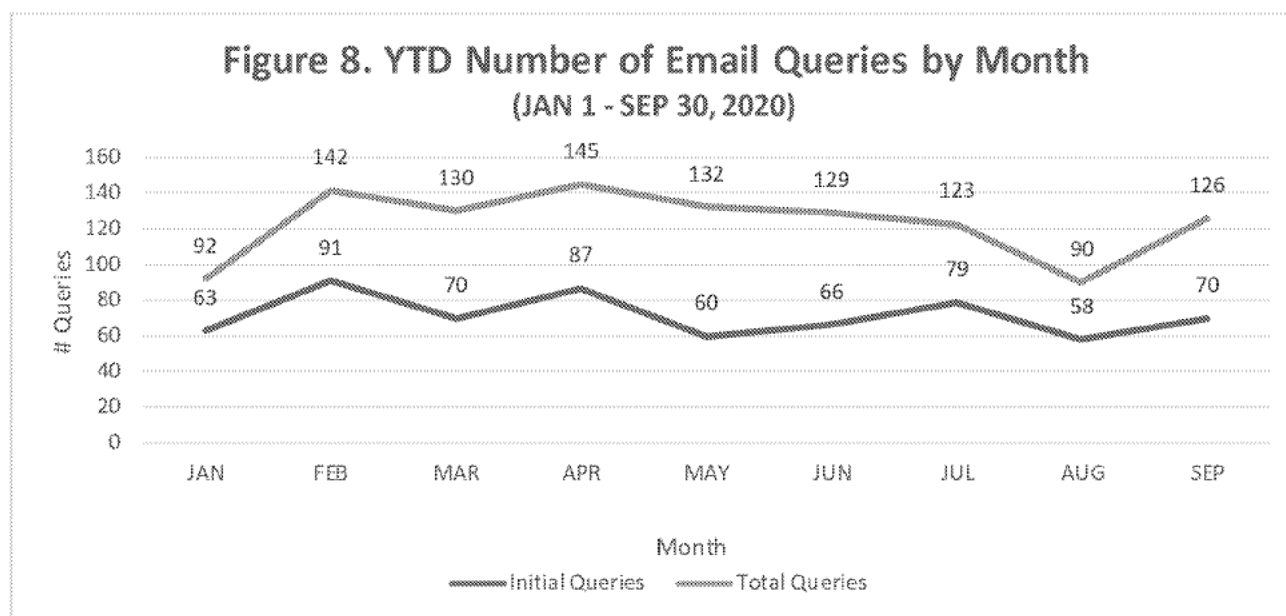


Figure 8. This graph describes the number of queries received to the NIH CoC mailbox by month for the 1st, 2nd, and 3rd quarters of 2020. The initial queries are the original query received from individuals. The total query line shows the actual number of queries received from individuals (initial queries plus follow up queries).

The top four query topics during the 3rd quarter of 2020 were 1) application process, 2) status of CoC, 3) thank you emails, and 4) application/submission issue. See Figure 9 for a list of query topics and frequency that these questions were asked. See Figure 10 for the query topics and frequency asked during the first three quarters of 2020.

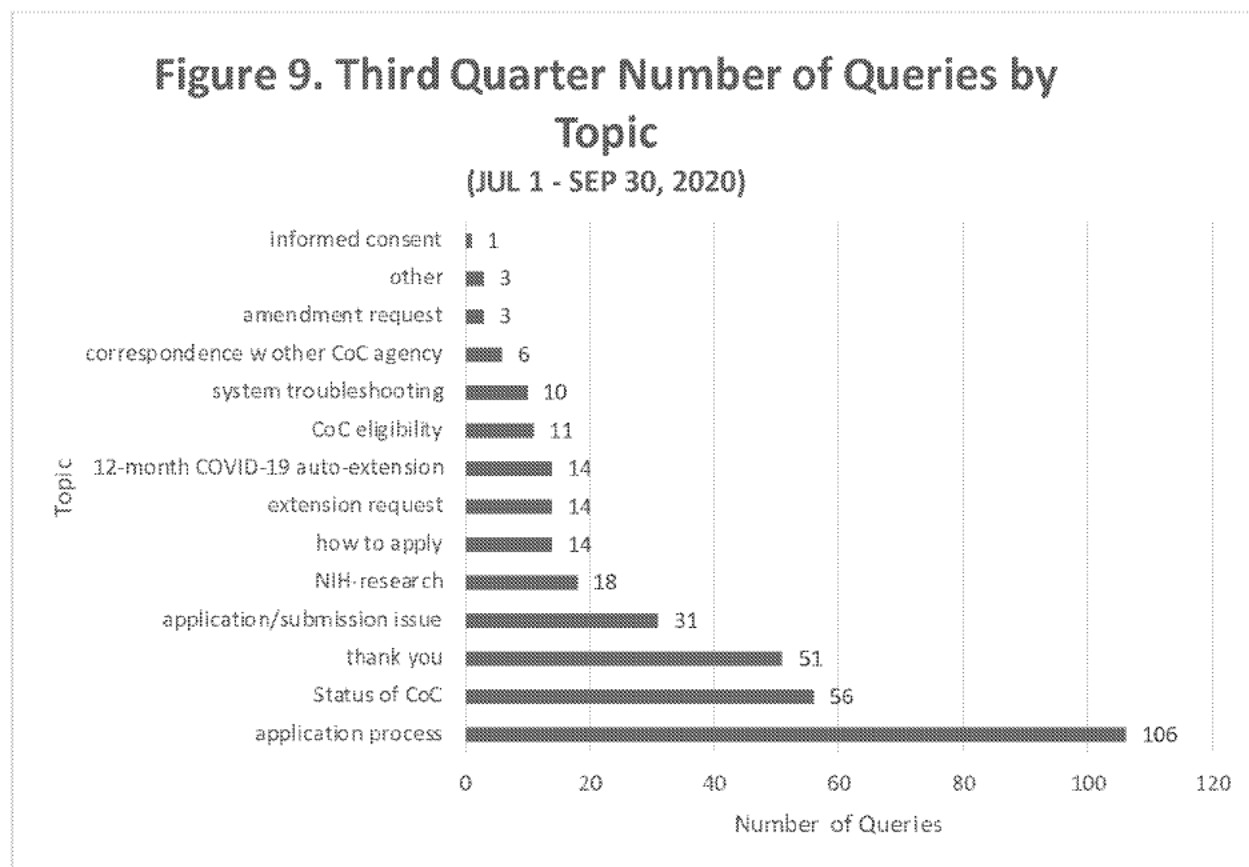


Figure 9. This graph displays the number of queries that NIH CoC staff received in the CoC mailbox during the 3rd quarter of 2020. The queries are grouped by topic, in order of frequency.

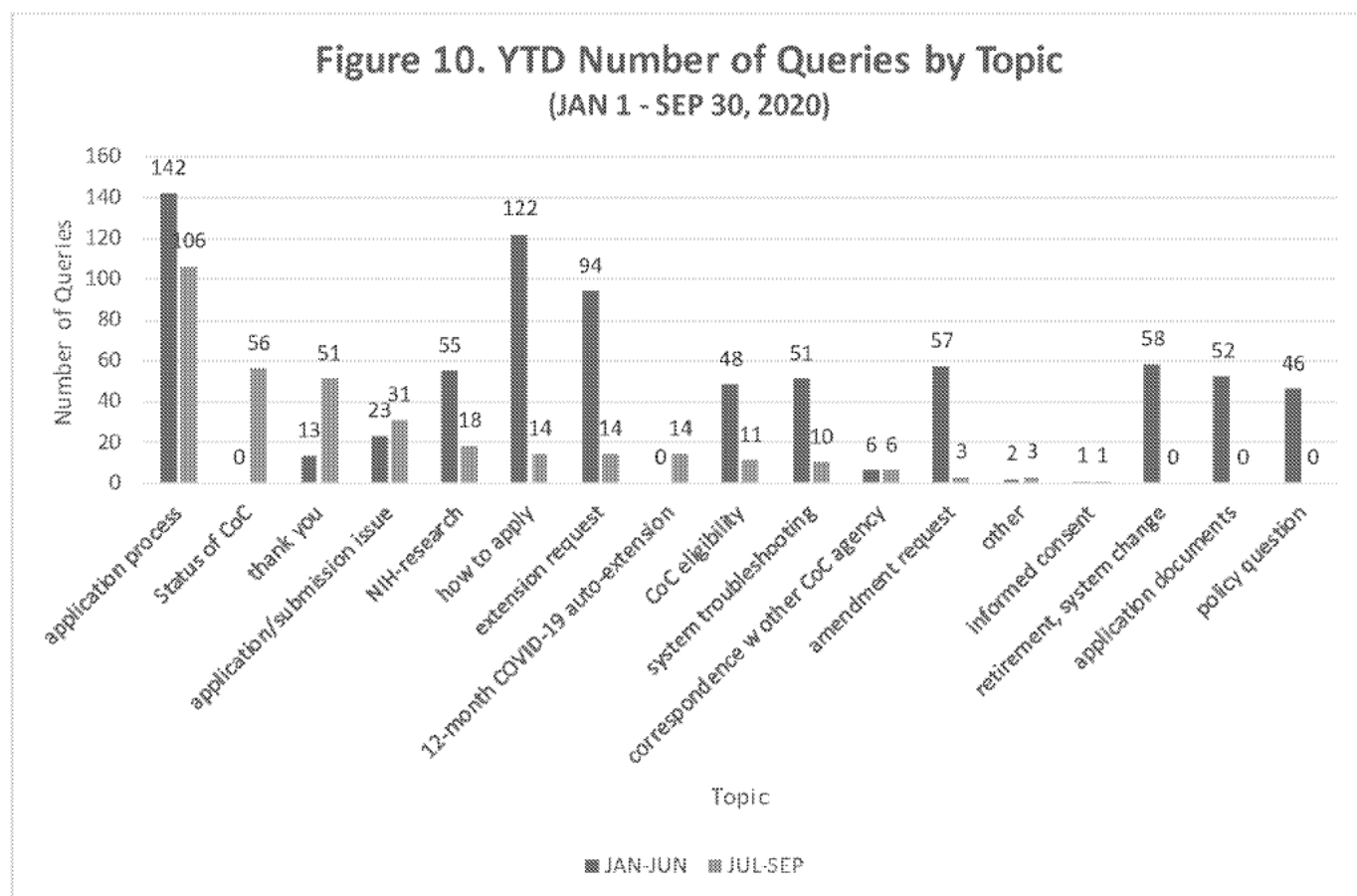


Figure 10. This graph displays the number of queries that NIH CoC staff received in the CoC mailbox 1st, 2nd, and 3rd quarters of 2020.

Certificate of Confidentiality Online Processing System

Deployment of new system:

The new CoC system was successfully deployed in the 2nd quarter on March 19, 2020. Several minor issues were identified by end users and NIH CoC staff. These issues were promptly mitigated or resolved by the eRA team.

Release of Version 2.0

The planned Version 2.0 was also successfully deployed in the 2nd quarter on June 25, 2020. Associated costs for Version 2.0 changes were included in the original budget. The changes included several new features. The project description box was enlarged so the requester and CoC Coordinator can view all text in this field, eliminating the need to scroll through multiple rows of text. For multisite studies, requesters can list each performance site. In addition, an online and pdf CoC System User Guide were released on June 25, to assist persons requesting a non-NIH funded Certificate.

Planned system enhancements

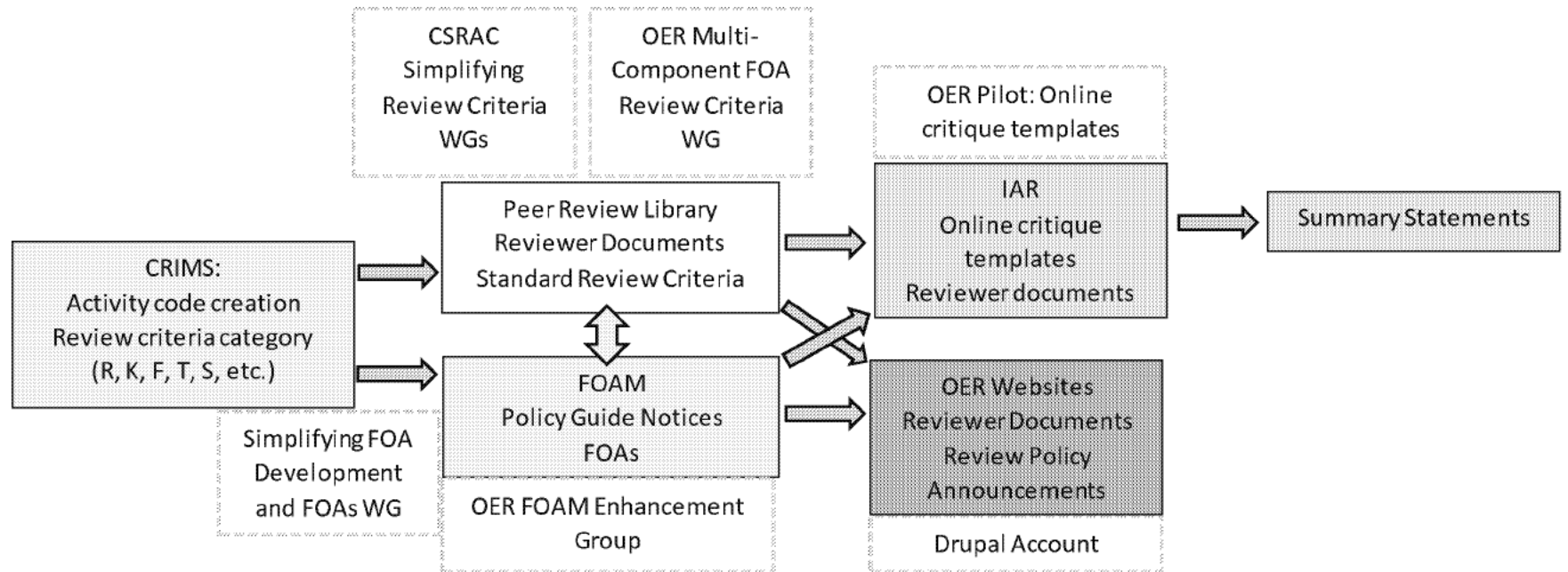
Several new enhancements are planned based on community and staff feedback. The following changes were approved at OER Small Staff for an estimated total cost of \$17,500 and will be deployed in the 4th quarter of 2020 as Version 3.0:

1. Add a link to the user instructions
2. Update the verification email that the system automatically sends to the Institutional Official with the PI name and project title
3. Updated Certificate language, including the removal of the expiration date, and having the Certificate issued on NIH letterhead
4. A warning message to alert the person completing the initial Certificate request when the PI and Institutional Official email address are the same
5. Functionality that allows the NIH CoC Coordinator to enter comments for requests in approved status
6. Allow the NIH CoC coordinator to edit data fields or upload documents to Certificates in approved status without re-approving the Certificate
7. A code change to ensure the “submit” button is immediately inactivated after the first click, preventing the submission of multiple requests to the system and placed in the document briefcase.

Standardizing CoC Request Processing

With the newly deployed CoC System, the CoC staff recognized that a standardized process should be established when using the new system to review and make decisions on the status of CoC requests. The standardized processes include when the “reject” and “delete” buttons will be used, and routine processes associated with CoC requests placed in an on-hold status.

The Living Guide
Office of Extramural Research
October 2020



From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: 10/8/2020 6:54:19 PM
To: Bundesen, Liza (NIH/OD) [E] (b) (6)
CC: Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: FW: Action: By 12pm, Tuesday, 10/13 - Please provide availability to discuss new OIG audit "NIH Technology Controls and Related Efforts to the Grant Program" (A-18-20-06300)
Attachments: OIG Notification Letter (A-18-20-06300).pdf; OIG Entrance Conference Questions (A-18-20-06300).docx; NIH_Best_Practices_for_Controlled-Access_Data_Subject_to_the_NIH_GDS_Policy.pdf

Hi Liza – I think for this one:

(b) (5)

At first blush, the (b) (5)

And yes, when we meet next, let's discuss general process.

Many thanks, Mike

From: "Bundesen, Liza (NIH/OD) [E]" (b) (6)
Date: Thursday, October 8, 2020 at 2:40 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: FW: Action: By 12pm, Tuesday, 10/13 - Please provide availability to discuss new OIG audit "NIH Technology Controls and Related Efforts to the Grant Program" (A-18-20-06300)

Hi Mike,

For these various OIG and GAO audits, Jodi said that she would help to identify which OER staff needed to be involved and would vet responses to you. (b) (5)
We can talk through the process a bit more during our next one on one.

Thanks,
Liza

From: Simanich, Sasha (NIH/OD) [E] (b) (6)
Sent: Thursday, October 8, 2020 2:03 PM
To: Bundesen, Liza (NIH/OD) [E] (b) (6); Ratliff, Shaun (NIH/OD) [E] (b) (6)
Cc: Shannon, Mike (NIH/OD) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6); Chakraborty, Trisha (NIH/OD) [E] (b) (6); Spady, Tyrone (NIH/OD) [E] (b) (6); Mackenzie, James (NIH/OD) [E] (b) (6); Gonzalez, Itzel (NIH/OD) [E] (b) (6); Butler, Benjamin (NIH/OD) [E] (b) (6); Showe, Melanie (NIH/OD) [E] (b) (6)
Subject: Action: By 12pm, Tuesday, 10/13 - Please provide availability to discuss new OIG audit "NIH Technology Controls and Related Efforts to the Grant Program" (A-18-20-06300)

Good Afternoon Dr. Bundesen and Shaun,

The OIG is beginning a new review entitled, “*NIH Technology Controls and Related Efforts to the Grant Program*” (Job code A-18-20-06300) to determine whether NIH has controls in place to ensure grants have appropriate cybersecurity provisions. Please see the attached OIG Notification Letter. OIG has requested an entrance conference to discuss their audit and to get a better understanding of the NIH grants process. This email is to request your availability for two meetings and to share the agenda.

Subject – By 12pm, Tuesday, 10/13 - Please provide your availability for an internal NIH pre-meeting and an entrance conference with the OIG

From – OMA

To – OCIO & OER

Cc – OSP, OCIO, OLPA, OM, OGC

Action 1 – Provide your availability for a 1-hour internal pre-meeting to discuss the attached OIG questions.

- Monday, Oct. 19: 10am-12pm, 2-5pm
- Thursday, Oct. 20: 8am-12pm or 2-3pm

Action 2 – Provide your availability for an entrance conference with the OIG

- Wednesday, Oct. 21: 2-5pm
- Thursday, Oct. 22: 9am-12pm

Action 3 – Provide high level talking points to OIG’s questions prior to the internal pre-meeting (date TBD)

Requestor – OIG

Background – The OIG is beginning this work to determine whether NIH has internal controls in place to ensure grants have appropriate cybersecurity provisions.

POCs – Please send comments and any questions to David Fuller (b)(6) and Sasha Simanich (b)(6)

Additional Instructions –

- Please let me know whether additional offices/individuals should be involved in this audit.
- Use the attached Word file to complete the question set with high level talking points

Attachments –

- OIG Notification Letter
- Entrance conference agenda

Thank you,

Sasha Simanich

Audit Liaison, OIG/GAO Review
NIH/OD/OMA/RMAL
6011 Executive Blvd, Suite 108
Rockville, MD 20852-7669

Email: [REDACTED] (b) (6)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



September 22, 2020

TO: Meredith Stein
Director, Division of Risk Management and Audit Liaison
National Institutes of Health

FROM: Tamara J. Lilly
Assistant Inspector General for Audit Services

Tamara Lilly

Digitally signed by
TAMARA LILLY
Date: 2020.09.22 13:35:00
-04'00'

SUBJECT: Notice of Audit Start: Audit of National Institutes of Health Information
Technology Controls and Related Efforts to the Grant Program (A-18-20-06300)

Assignment: The objective of our audit is to determine if the National Institutes of Health has controls in place to ensure grants have appropriate cybersecurity provisions.

OIG/OAS Division: Cybersecurity and Information Technology Audit Division (CITAD).

Background and General Description of Work:

The National Institutes of Health (NIH) is the primary Federal agency for conducting and supporting biomedical research to enhance health, lengthen life, and reduce illness and disability. Annually, NIH invests nearly \$39.2 billion in medical research projects on a number of common and rare diseases including cancer, Alzheimer's, diabetes, arthritis, heart ailments, and AIDS.

More than 80 percent of the NIH's funding is awarded through approximately 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every State and around the world. According to NIH's Grants Policy Statement, "All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access." Without appropriate cybersecurity provisions and monitoring of grantees, NIH does not have assurance that sensitive data is not at risk, specifically the confidentiality, integrity, and availability of sensitive research data.

Our work will include interviewing key personnel, reviewing applicable Federal regulations, NIST requirements, and industry best practices; grants, policies, procedures, and security documentation, walk-throughs, and selected testing of procedures using automated tools.

Where Work Will Be Performed: National Institutes of Health in Bethesda, Maryland, and select grantees. Due to the COVID-19 pandemic, our work may be completed remotely through the utilization of email, secure teleconferencing, and secure file transfer service(s).

When Work Will Begin: September 2020. We will contact the audit liaison to schedule an entrance conference and submit an initial documentation request list.

Method for Securely Transmitting Audit Information to OAS over the Internet:

When transmitting any audit information to OAS over the Internet, please properly safeguard the information. We request that you use the HHS/OIG Delivery Server, not email or attachments to email. Information transmitted through the HHS/OIG Delivery Server complies with Federal Information Processing Standard (FIPS) 140-2, *Security Requirements for Cryptographic Module*.

We are required to report as a security breach any audit information sent to us that does not meet FIPS 140-2 requirements.

OIG Contacts: Charles Summers, Assistant Director-CITAD, (214) 601-5614
Jarvis Rodgers, Director-CITAD, (202) 836-1183

cc:

Andrea T. Norris
Chief Information Officer

Amy J. Frontz
Deputy Inspector General for Audit Services

OIG Components

GAO

OIG Questions Audit (A-18-20-06300)
NIH Information Technology Controls and Related Efforts to the Grant Program

1. What are the security requirements for grantee(s)?
 - a. The OIG is aware that the NIH web site mentions they are required to meet NIST Standards.
 - b. The OIG is aware that requirements may vary by grant type.
2. Can NIH officials point the OIG to the language in the terms and conditions that contain security requirements for the grantee?
3. What steps does NIH take to ensure grantee(s) meet the security requirements to protect research data, NIH data, etc.?

NIH Security Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy

Updated: 09 MAR 2015

Introduction

This document is intended for officials at academic institutions and scientific organizations whose investigators are granted access under the NIH Genomic Data Sharing (GDS) Policy to controlled-access human genomic and phenotypic data that are maintained in NIH-designated data repositories.¹ It provides an outline of the NIH's expectations for the management and protection of NIH controlled access data transferred to and maintained by institutions whether in their own institutional data storage systems or in cloud computing systems.² Although controlled-access data do not contain direct identifiers, the data are sensitive and must be protected. The principles governing access and use of such data are outlined in the GDS Policy and individual Data Use Certification (DUC) Agreements that investigators submit as part of the process of requesting access to controlled access data. This process is intended to ensure that NIH controlled-access genomic and phenotypic data are kept secure and no one other than users approved by NIH is able to access the data.

The information contained in this document is targeted at two distinct audiences: scientific professionals including institutional signing officials and investigators that will use the data, and information technology professionals, including Chief Information Officers (CIOs), Information Systems Security Officer (ISSOs) and operations staff working for both central IT organizations and embedded within research groups. Accordingly this document is split into two main sections focused on each of these groups.

Information for Scientific and Administrative Staff

General Considerations

Under the GDS Policy, the recipient institution is ultimately responsible for maintaining the confidentiality, integrity and availability of the data to which it is entrusted by the NIH. Failure to provide appropriate controls can subject investigators or institutions to sanctions defined by the GDS Policy as well as significantly erode public confidence in the ability of NIH and its grantees to carry out research using sensitive information. It is therefore essential that all recipients of controlled access data understand their responsibilities for ensuring appropriate information security controls and that the work with their IT organizations to effectively implement those responsibilities.

¹ dbGaP and the Sequence Read Archive are examples of NIH-designated data repositories. NIH has also established Trusted Partnerships with several institutions to serve as NIH-designated data repositories.

² The National Institute of Standards and Technology defines cloud computing as a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. See: <http://csrc.nist.gov/publications/nistpubs/800-145/SP800145.pdf>.

The NIH provides this best practice document so that institutions can obtain an understanding of the types of information security practices that they should be enacting. However, this best practice document is not a substitute for a more formal security plan that is devised for the specific local or cloud configuration chosen by the investigators and institution.

The NIH strongly recommends that investigators consult with institutional IT leaders, including the Chief Information Officer (CIO) and the institutional Information Systems Security Officer (ISSO) or equivalents to develop the formal information security plan prior to receipt of controlled access data from the NIH, and ***institutional signing officials should validate that an appropriate security plan is in place prior to accepting liability for data loss or breach on behalf of the institution.*** This document provides an overview of security principles for data, access, and physical security to ensure confidentiality, privacy, and accessibility of data. This is a minimum set of requirements; additional restrictions may be needed by your institution and should be guided by the knowledge of the user community at your institution as well as your institution's IT requirements and policies.

The single most important element (regardless of type of infrastructure) for maintaining the security of NIH controlled access data is to design security into the chosen environment before the data is transferred rather than attempting to add security controls to an environment after the data has been downloaded. Security controls should be on by default; investigators and users should not have to perform any active action to turn them on. To use an analogy, doors should be locked by default rather than need to be actively locked by someone. A corollary is that all users and support staff associated with the project need to have an information security mindset going into the project, and all must be aware that public support for the collection and dissemination of these types of data are their individual responsibilities, and it is essential that all staff members that will interact with the data or the systems that maintain the data have appropriate information security training. This is particularly true for groups that wish to use cloud computing, and in these cases, NIH recommends additional training to inform staff of the special risks that the use of such infrastructure entails.

Part of having an information security mindset is being aware of the multiple dimensions of ***access control*** and ***accountability*** at all times. This means ensuring that passwords and/or access devices (smart cards, soft or physical tokens, etc.) are physically safe, strong and not shared with anyone and that data is both physically and logically (i.e. electronically) secure. Particular care must be taken with copies of data on portable electronic media and devices (i.e. laptops, tablets, USB thumb drives, tapes, etc.). Generally speaking, users should avoid putting controlled access data on such devices wherever possible. If it is necessary, such devices must be encrypted and should be treated as if they are cash, with appropriate physical and electronic controls, including remote wipe capability wherever possible. In addition, please remember that collaborators at different institutions must file a separate data access request ***even if they are working on the same project.***

Finally, remember that data downloaded from NIH-designated data repositories must be destroyed if they are no longer needed or used, or if the project is to be terminated and closed-out in the dbGaP Authorized Access System. Investigators may retain only encrypted copies of the minimum data necessary at their institution to comply with institutional scientific data retention policy and any data stored on temporary backup media as are required to maintain the integrity of the general institutional data protection (i.e. backup) program.

Additional Information Related to the Use of Cloud Computing

Cloud computing, as defined by the National Institute for Standards and Technology (NIST), is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or cloud service provider interaction. In contrast to traditional computing on local servers and hardware, cloud computing often entails the transfer and storage of controlled-access data on systems managed by a third party. Cloud computing offers a number of advantages for authorized investigators but also requires additional security considerations.

Most of the recommendations described above apply to cloud computing; indeed, the primary difference is that while information security in cloud environments is still the responsibility of the institution, ***the implementation of that security is shared between the institution and the cloud service provider.*** Thus, it is essential that institutions validate that they are partnering with a reputable cloud service provider. Institutions should ensure that they understand the security policies and practices utilized and recommended by their cloud service provider of choice, and may wish to obtain third party reviews or audits from the cloud service provider. Institutions should utilize these best practices, work with their cloud service provider to understand and implement the best practices associated with their specific environment and ensure that the cloud service provider can meet institutional information security requirements. Because the use of cloud computing has the potential for being higher risk than using local infrastructure, the NIH strongly recommends that you consult with your institutional CIO, ISSO and IT staff to ensure that an appropriate security plan is developed and that necessary technical, training and policy controls are in place before data is migrated to cloud environments. Remember – ***you and your institution are accountable for ensuring the security of this data, not the cloud service provider.***

Information for IT Professionals

Local Infrastructure Guidance

General Information Security Guidelines

- When using local infrastructure, make sure these files are never exposed to the Internet with the exception of such connections as are required to download data from source repositories. Infrastructure should be behind local and/or institutional firewalls that block access from outside of the institution. For cloud infrastructure, investigators must restrict external access to instances and storage under the investigator's control (see section on cloud computing for more details).
- Data must never be posted on servers in any fashion that will make them publically accessible, such as an investigator's (or institution's) website, because the files can be "discovered" by Internet search engines, e.g., Google, Bing.

- Institutions must not set up web or other electronic services that host data publicly, or that provide access to other individuals that are not listed on the Data Use Request even if those individuals have access to the same dbGaP data. Providing such access requires that an organization be an NIH Trusted Partner, with different requirements above and beyond those required for access to NIH controlled data.
- Utilize strong authentication technology for access control. Two factor authentication technologies (smart cards, hard or soft token, etc.) are preferred. When using single factor passwords, set policies that mandate the following requirements:
 - Minimum length of 12 characters
 - Does not contain user names, real names or company names
 - Does not contain a complete dictionary word
 - Contains characters from each of the following groups: lowercase letters, uppercase letters, numerals, and special characters
 - Passwords should expire every 120 days or at the rate required by institutional policies, whichever is more frequent.
- Avoid allowing users to place controlled access data on mobile devices (e.g. laptops, smartphones, tablets, mp3 players) or removable media such as USB thumb drives (except where such media are used as backups and follow appropriate physical security controls). If data must be placed on mobile devices, it must be encrypted. NIH recommends the use of NIST validated encryption technologies.
- Keep all software patches up-to-date.

Physical Security Guidelines

- Data that are in hard copy or reside on portable media, e.g., on a USB stick, CD, flash drive or laptop should be treated as though it were cash, with appropriate controls in place. Such media must be encrypted and stored in a secured in a locked facility with access granted to the minimum number of individuals required to efficiently carry out research.
- Restrict physical access to all servers, network hardware, storage arrays, firewalls and backup media only to those that are required for efficient operations.
- Log access to secure facilities, ideally with electronic authentication.

Controls for Servers

- Keep servers from being accessible directly from the Internet, (i.e. must be behind a firewall or not connected to a larger network) and disable unnecessary services. It is better to begin with a server image that disables all non-essential services and restore those that are needed than to start with a full-featured image and disable unnecessary services.

- Enforce principle of Least Privilege to ensure that individuals and/or processes grant only the rights and permissions to perform their assigned tasks and functions, but no more.
- Secure controlled-access genomic and phenotypic data on the systems from other users (restrict directory permissions to only the owner and group) and if exported via file sharing, ensure limited access to remote systems.
- If accessing systems remotely, use encrypted data access (such as Secure Shell (SSH) or Virtual Private Network (VPN)). It is preferred to use a tool such as Remote Desktop (RDP), X-windows or Virtual Network Computing (VNC) that does not permit copying of data and provides “View only” support.
- If data is used on multiple systems (such as a compute cluster), ensure that data access policies are retained throughout the processing of the data on all the other systems. If data is cached on local systems, directory protection must be kept, and data must be removed when processing is complete. Requesting investigators must meet the spirit and intent of these protection requirements to ensure a secure environment 24 hours a day for the period of the agreement.

Source Data and Control of Copies of Data

- Approved users must retain the original version of the encrypted data, track all copies or extracts and ensure that the information is not divulged to anyone except authorized staff members at the institution. NIH therefore recommends ensuring careful control of physical copies of data and providing appropriate logging on machines where such data is resident.
- As collaborating investigators from other institutions must submit an independent DAR and be approved by NIH to access to the data, restrict outbound access from devices that host controlled access data.

Destruction of Data

- Data downloaded from NIH-designated data repositories must be destroyed if they are no longer needed or used, or if the project is to be terminated and closed-out in the dbGaP Authorized Access System. Delete all data for the project from storage, virtual and physical machines, databases, and random access archives (i.e., archival technology that allows for deletion of specified records within the context of media containing multiple records).
- Investigators and Institutions may retain only encrypted copies of the minimum data necessary at their institution to comply with institutional scientific data retention policy and any data stored on temporary backup media as are required to maintain the integrity of the institution’s data protection program. Ideally, the data will exist on backup media that is not used by other projects and can therefore be destroyed or erased without impacting other users/tenants. If retaining the data on separate backup media is not possible, as will be the case with many users, the media may be retained for the standard media retention period but may not be recovered for any purpose

without a new Data Access Request approved by the NIH. Retained data should be deleted at the appropriate time, according to institutional policies.

- Shred hard copies and CD ROMs or other non-reusable physical media.
- Delete electronic files securely. For personal computers, the minimum would involve deleting files and emptying the recycle bin or equivalent with equivalent procedures for servers. Optimally, use a secure method that performs a delete and overwrite of the physical media that was used to store the files.
- Ensure that backups are reused (data deleted) and any archive copies are also destroyed.
- Destroy media according to (NIST) Guidelines for Information Media Sanitization (<https://csrc.nist.gov/publications/detail/itl-bulletin/2015/02/nist-special-publication-800-88-revision-1-guidelines-for-media/final>).

Additional Guidance for Cloud Computing

Institutions that wish to use cloud computing must work with their cloud service provider to devise an appropriate security plan that meets the general dbGaP Information Security Best Practices as well as these additional requirements that derive from the nature of multi-tenant clouds with default access to the internet. Please refer to the specific cloud service provider for methods, processes and procedures for working with controlled-access data subject to the GDS Policy in the cloud.

General Cloud Computing Guidelines

- Whenever possible, use end-to-end encryption for network traffic. For example, use Hypertext Transfer Protocol (HTTPS) sessions between you and your instance. Ensure that your service uses only valid and up-to-date certificates.
- Encrypt data at rest with a user's own keys. SRA-toolkit includes this feature; other software providers offer tools to meet this requirement.
- Use security groups and firewalls to control inbound traffic access to your instance. Ensure that your security profile is configured to allow access only to the minimum set of ports required to provide necessary functionality for your services and limit access to specific networks or hosts. In addition, allow administrative access only to the minimum set of ports and source IP address ranges necessary.
- Be aware of the top 10 vulnerabilities for web applications and build your applications accordingly. To learn more, visit Open Web Application Security Project (OWASP) - Top 10 Web Application Security Risks. When new Internet vulnerabilities are discovered, promptly update any web applications included in your Virtual Machine (VM) images. Examples of resources that include this information are [SecurityFocus](#) and the NIST National Vulnerability Database.

- Review the Access Control Lists (ACLs), permissions, and security perimeter to ensure consistent definition.

Audit and Accountability

- Ensure that data is accessible only to those approved for access, and controls for changing that access are retained by the investigator who submitted the DAR and the appropriate IT staff. A mechanism for monitoring and notification needs to be in place to monitor changes in permission changes.
- Ensure that account access is logged along with access controls and file access and this information is reviewed by the investigator on regular basis to ensure continued secure access.

Image Specific Security

- Ensure images do not contain any known vulnerabilities, malware, or viruses. A number of tools are available for scanning the software, such as Chkrootkit, rkhunter, OpenVAS and Nessus.
- Ensure that Linux-based Images lock/disable root login and allow only sudo access. Additionally, root password must not be null or blank.
- Ensure that images allow end-users with OS-level administration capabilities to allow for compliance requirements, vulnerability updates, and log file access. For Linux-based Images, this is normally through SSH, and for Windows-based virtual machine images, this is normally through RDP.

Best Practices for Specific Cloud Service Providers:

Examples of cloud service provider best practices are provided in the links below, links to the best practices of additional cloud service providers will be periodically appended to this document when they become available. Please be aware that these are provided for convenience only, and do not imply endorsement by the NIH or the United States Government for any of these services, nor does the government guarantee that these links lead to the most current version of these best practices. NIH recommends that investigators consult with their cloud service provider to ensure that they are using the most up to date best practice documents.

Amazon Web Services:

- <http://docs.aws.amazon.com/AWSEC2/latest/UserGuide/AMIs.html>
- <http://docs.aws.amazon.com/AWSEC2/latest/UserGuide/ec2-best-practices.html>
- <http://aws.amazon.com/documentation/ec2/>

Google Cloud Platforms:

- <https://cloud.google.com/developers/articles/best-practices-for-configuring-permissionson-gcp>

Others Sources of Information for Cloud Best Practices:

Examples of cloud best practices from organizations that leverage the cloud are provided in the link below. Links to additional documentation will be periodically appended to this document when they become available. Please be aware that these are provided for convenience only, and do not imply endorsement by the NIH or the United States Government for any of these services, nor does the government guarantee that these links lead to the most current version of these best practices. NIH recommends that investigators consult with these organizations to ensure that they are using the most up to date best practice documents.

DNAexus: https://dnanexus.com/papers/Compliance_White_Paper.pdf

Additional Resources for Testing and Best Practices

Center for Internet Security (CIS)

CIS (<http://www.cisecurity.org/>) is the only distributor of consensus best practice standards for security configuration. The Benchmarks are widely accepted by U.S. government agencies for Federal Security Information Act (FISMA) compliance, and by auditors for compliance with the International Organization for Standardization (ISO) standard as well as the Gramm-Leach-Bliley (GLB) Act, SarbanesOxley (SOX) Act, federal Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA) and other regulatory requirements for information security. End user organizations that build their configuration policies based on the consensus benchmarks cannot acquire them elsewhere. See Appendix A for checklists based on CIS best practices, customized for use with controlled-access data. Content of this document has been adapted from NIH Center for Information Technology (CIT), NIST and CIS.

National Institute of Standards and Technology (NIST)

NIST, an agency of the US Department of Commerce provides information security standards and best practices for the federal government. The NIST Special Publications (SP) and Federal Information Processing Standards (FIPS) provide useful and concrete guidance to users of information technology systems (<http://csrc.nist.gov/publications/>).

United States Government Configuration Baseline (USGCB)

USGCB (<http://usgcb.nist.gov>) provides security configuration baselines for information technology products widely used across the federal government including desktop computers.

NIH Staff Checklist for Clinical Trial Standard Operating Procedures (SOP) Elements

Draft Version 11 October 1, 2020

(b) (5)



NIH Staff Checklist for Clinical Trial Standard Operating Procedures (SOP) Elements

Draft Version 11 October 1, 2020

(b) (5)



NIH Staff Checklist for Clinical Trial Standard Operating Procedures (SOP) Elements

Draft Version 11 October 1, 2020

(b) (5)



NIH Staff Checklist for Clinical Trial Standard Operating Procedures (SOP) Elements

Draft Version 11 October 1, 2020

(b) (5)



NIH Staff Checklist for Clinical Trial Standard Operating Procedures (SOP) Elements

Draft Version 11 October 1, 2020

(b) (5)



NIH Staff Checklist for Clinical Trial Standard Operating Procedures (SOP) Elements

Draft Version 11 October 1, 2020

(b) (5)



NIH Staff Checklist for Clinical Trial Standard Operating Procedures (SOP) Elements

Draft Version 11 October 1, 2020

(b) (5)



NIH Staff Checklist for Clinical Trial Standard Operating Procedures (SOP) Elements

Draft Version 11 October 1, 2020

(b) (5)

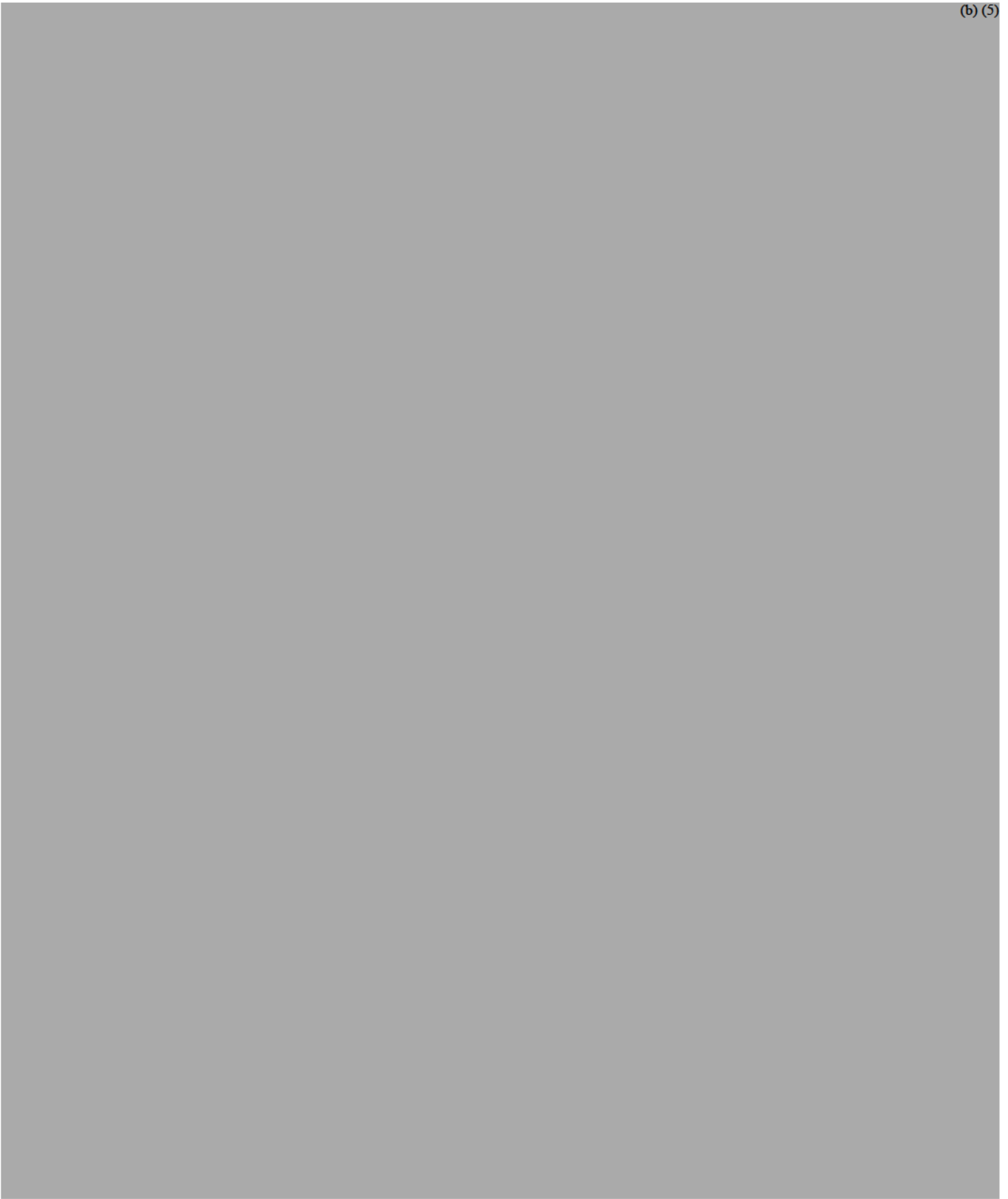


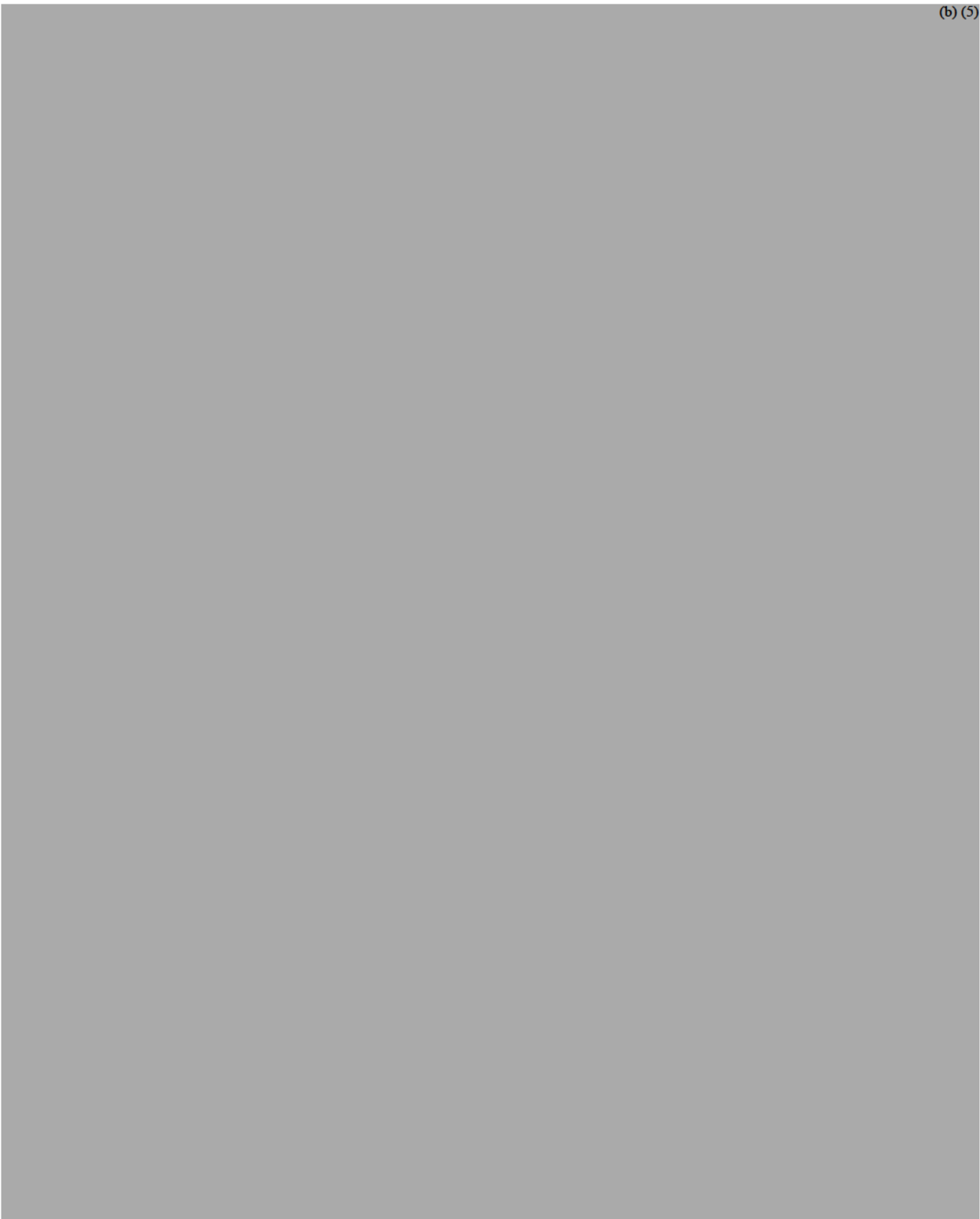
DRAFT – A Framework to Harmonize Clinical Trials Standard Operating Procedure (SOP) Elements Across NIH Institutes and Centers (ICs)

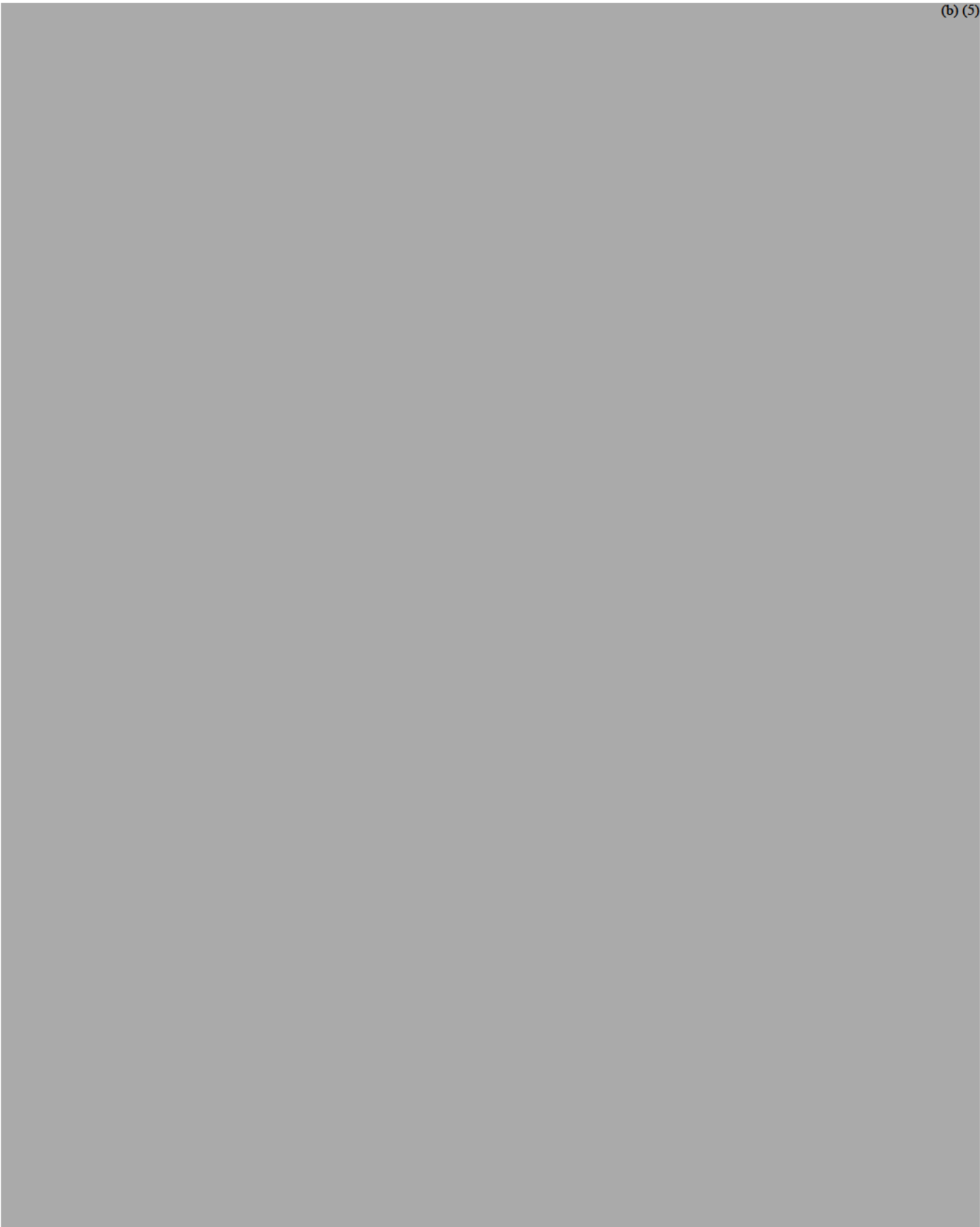
NIH Clinical Trials Operations Workgroup (CTOW) Clinical
Trial SOP Subcommittee

October (TBD), 2020

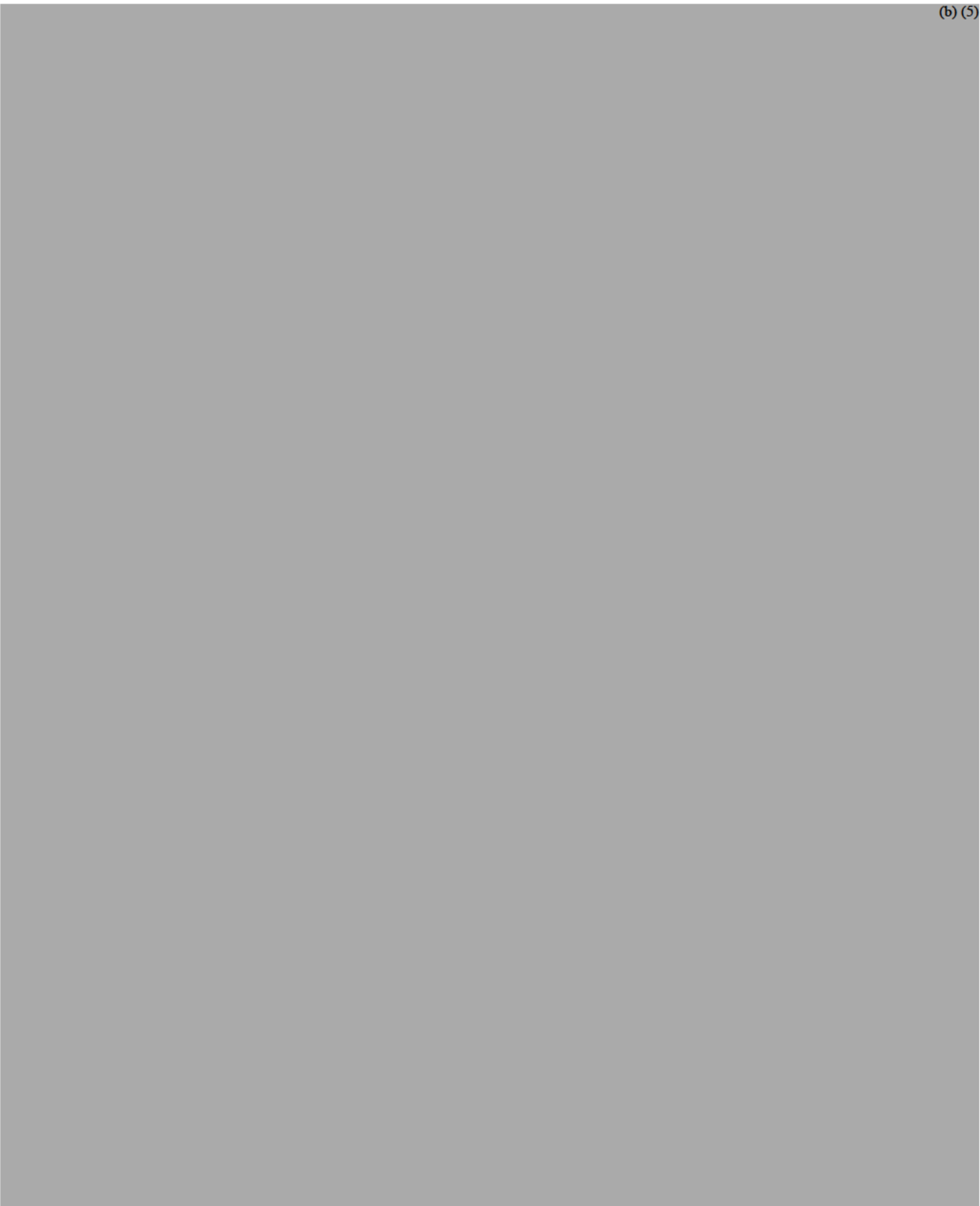


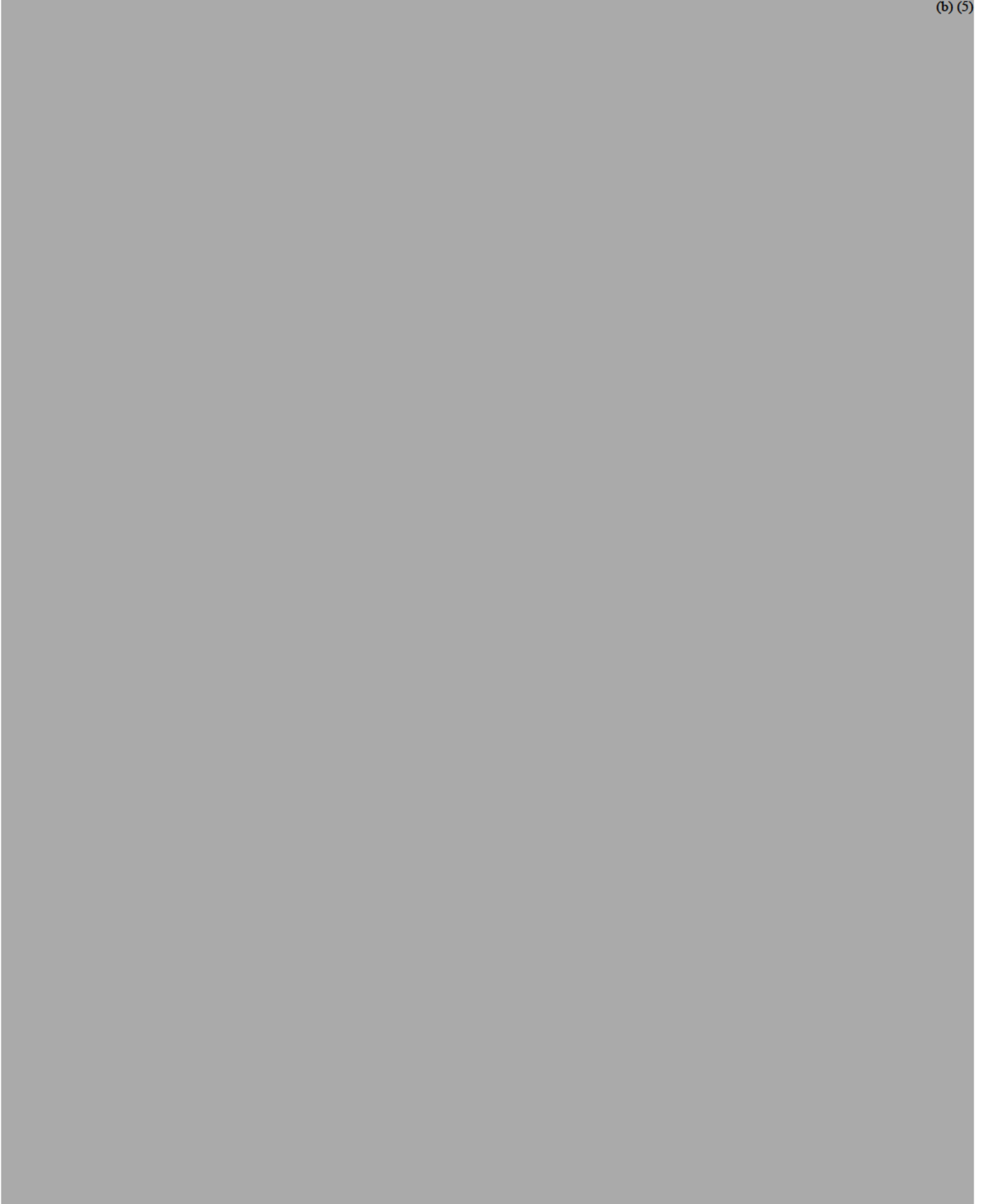














DR

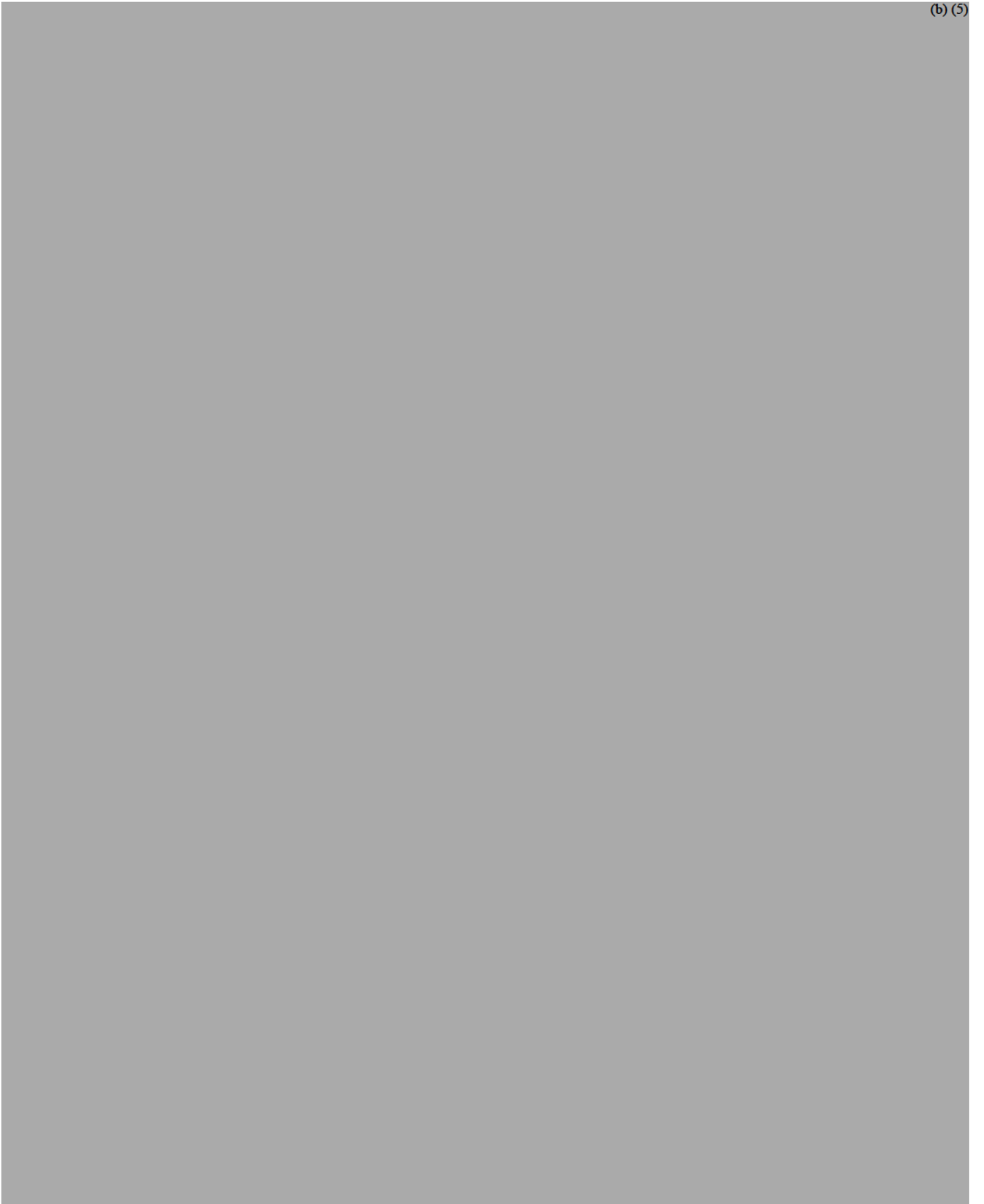


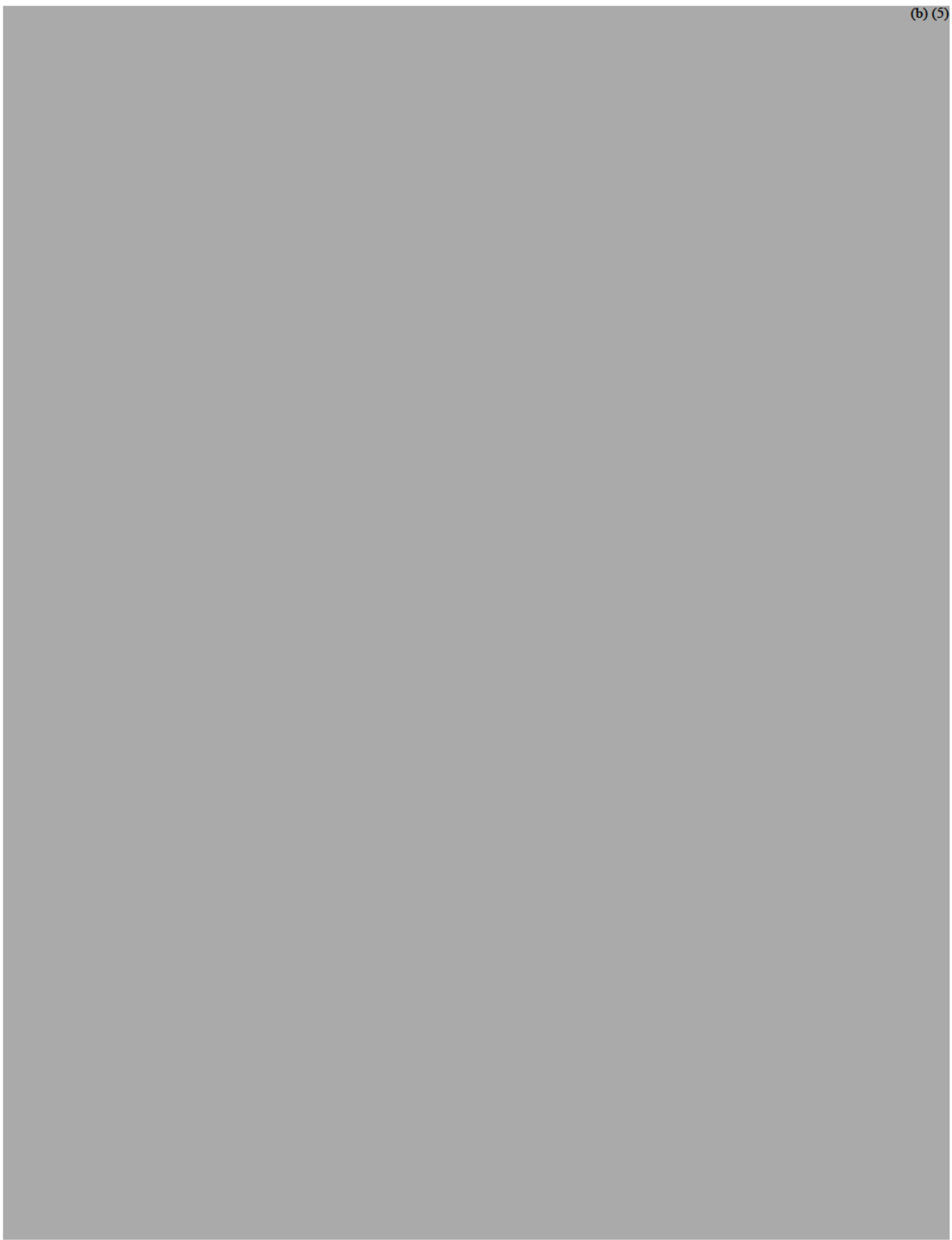
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

(b) (5)





|

|

|

|



|

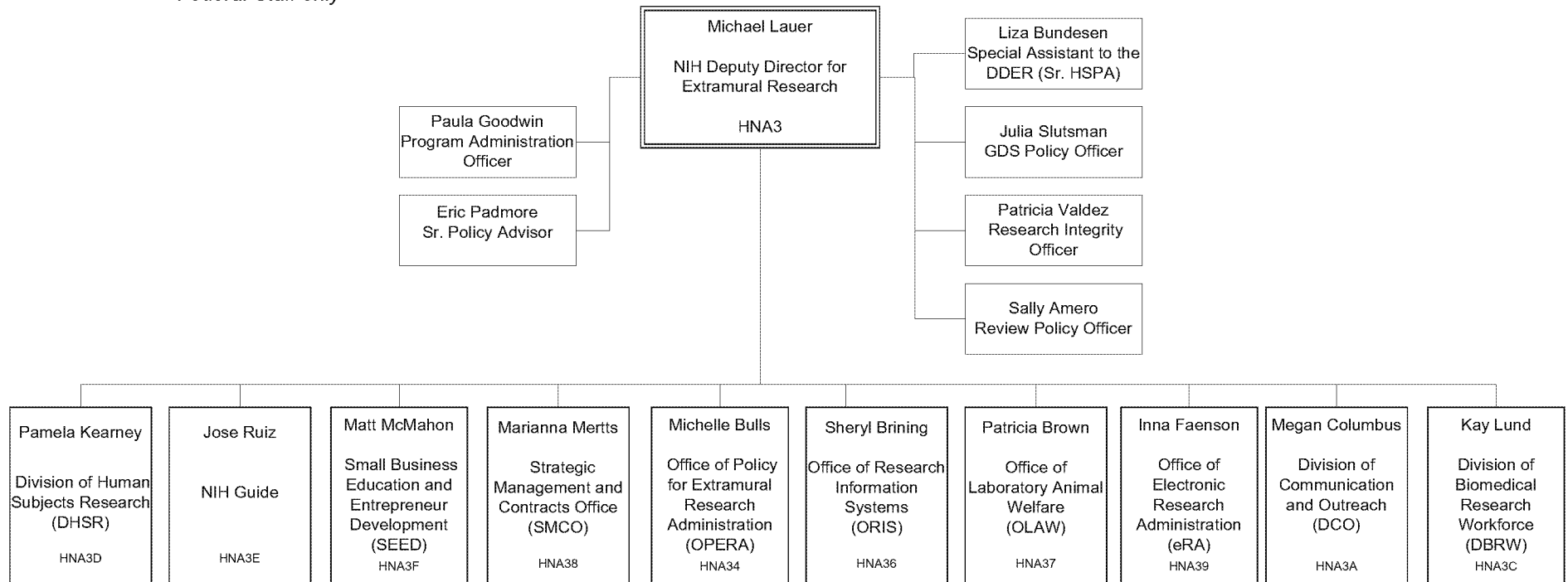
|

|

Office of Extramural Research (OER)

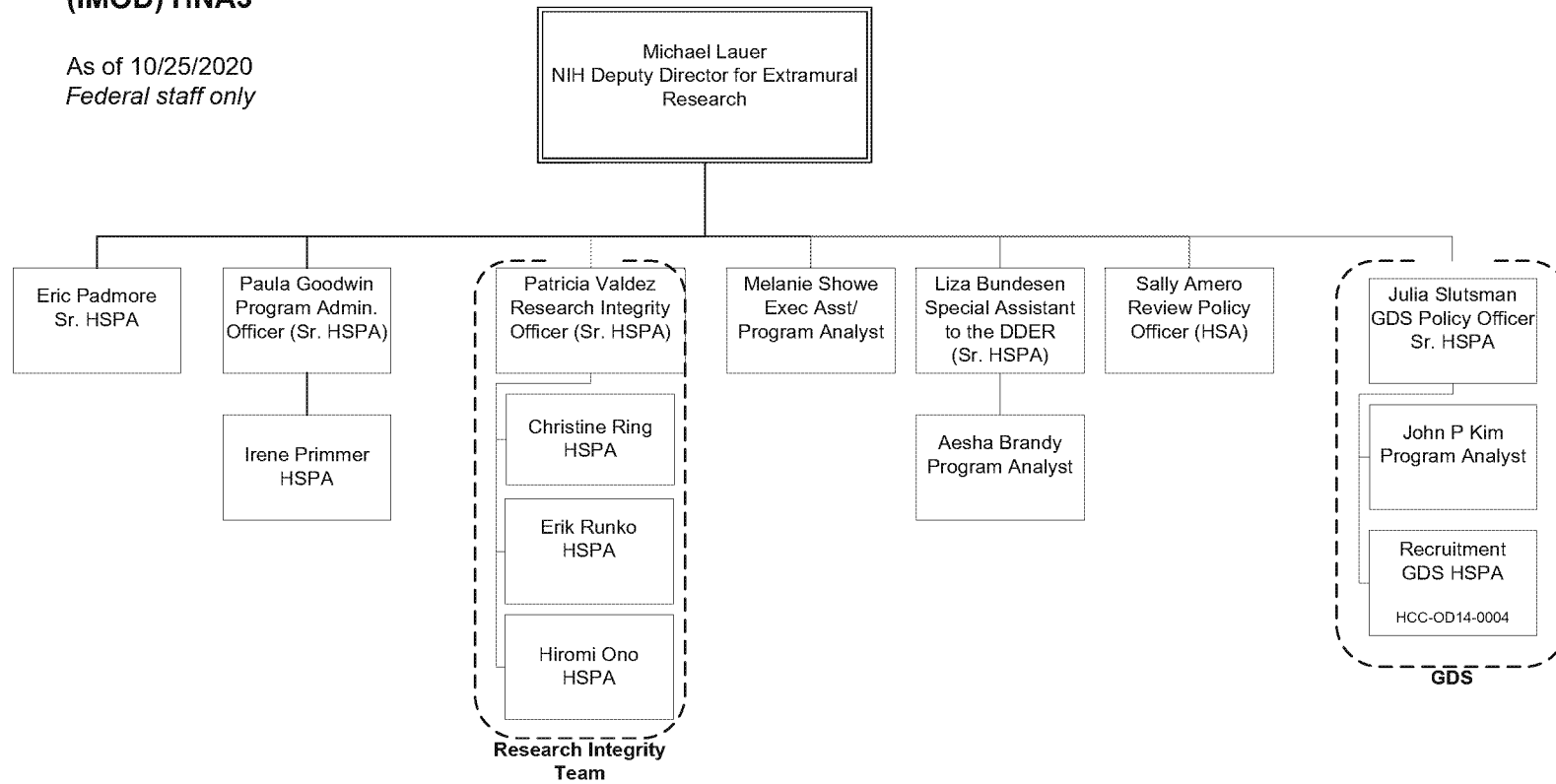
Org Chart as of 10/25/2020

Federal Staff only



OER
Immediate Office of the Director
(IMOD) HNA3

As of 10/25/2020
Federal staff only



SMCO
Marianna Merts
See detailed chart

OPERA
Michelle Bulls
See detailed chart

SEED
Matt McMahon
See detailed chart

DHSR
Pamela Kearney
See detailed chart

NIH Guide
Jose Ruiz
See detailed chart

OLAW
Pat Brown
See detailed chart

ORIS
Sheryl Brining
See detailed chart

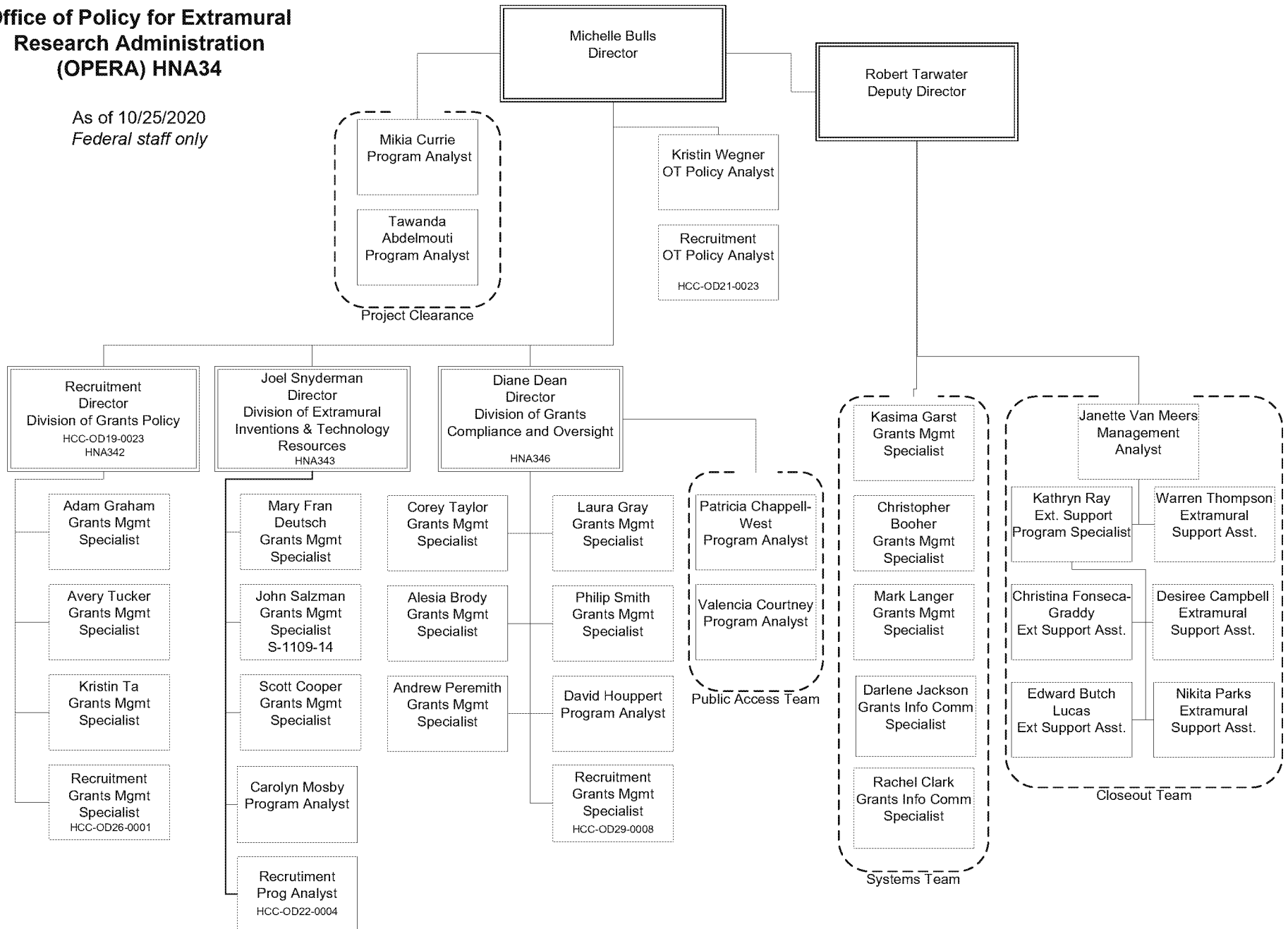
DCO
Megan Columbus
See detailed chart

DBRW
Kay Lund
See detailed chart

eRA
Inna Faenson
See detailed chart

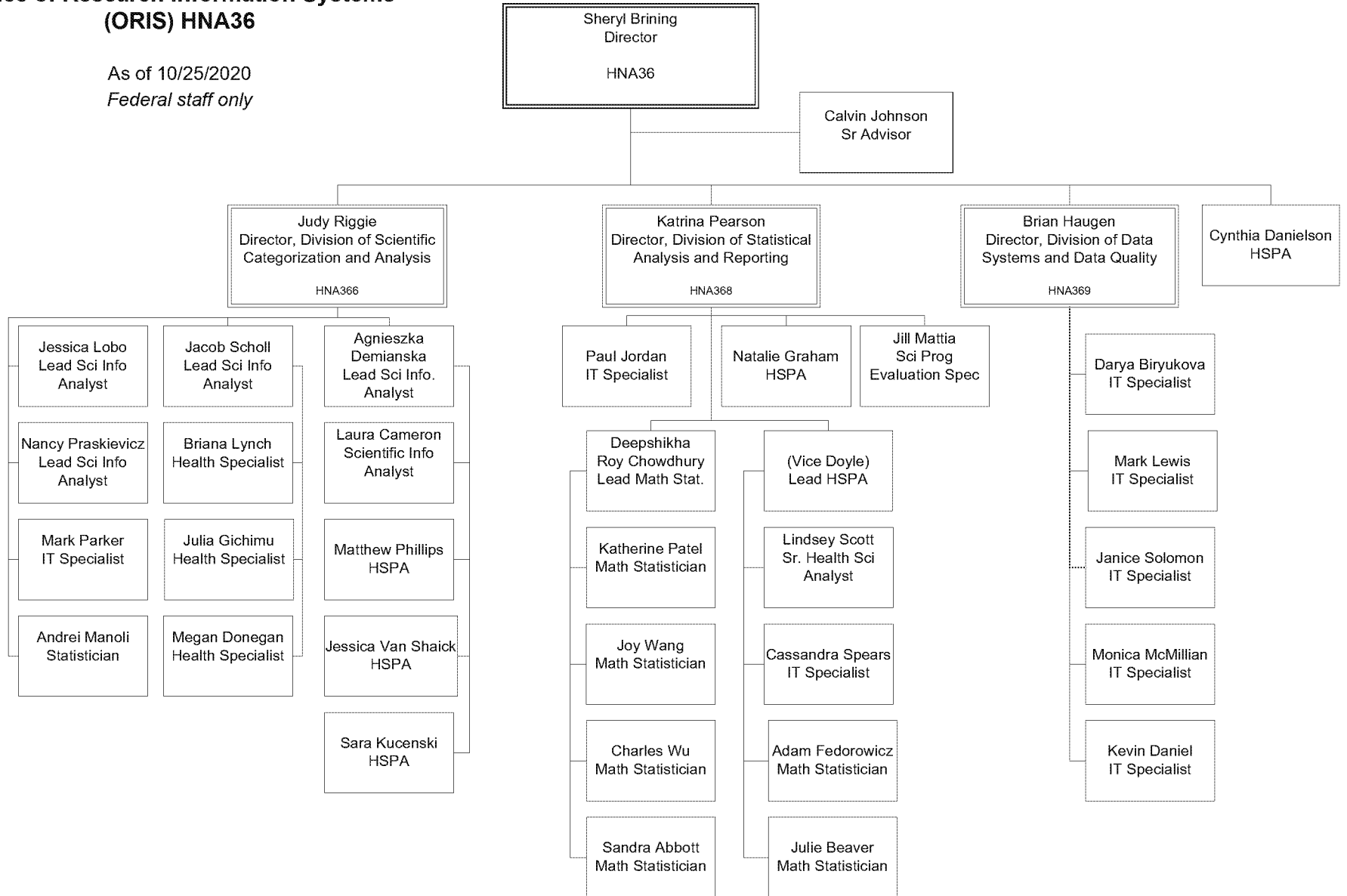
OER
Office of Policy for Extramural
Research Administration
(OPERA) HNA34

As of 10/25/2020
 Federal staff only



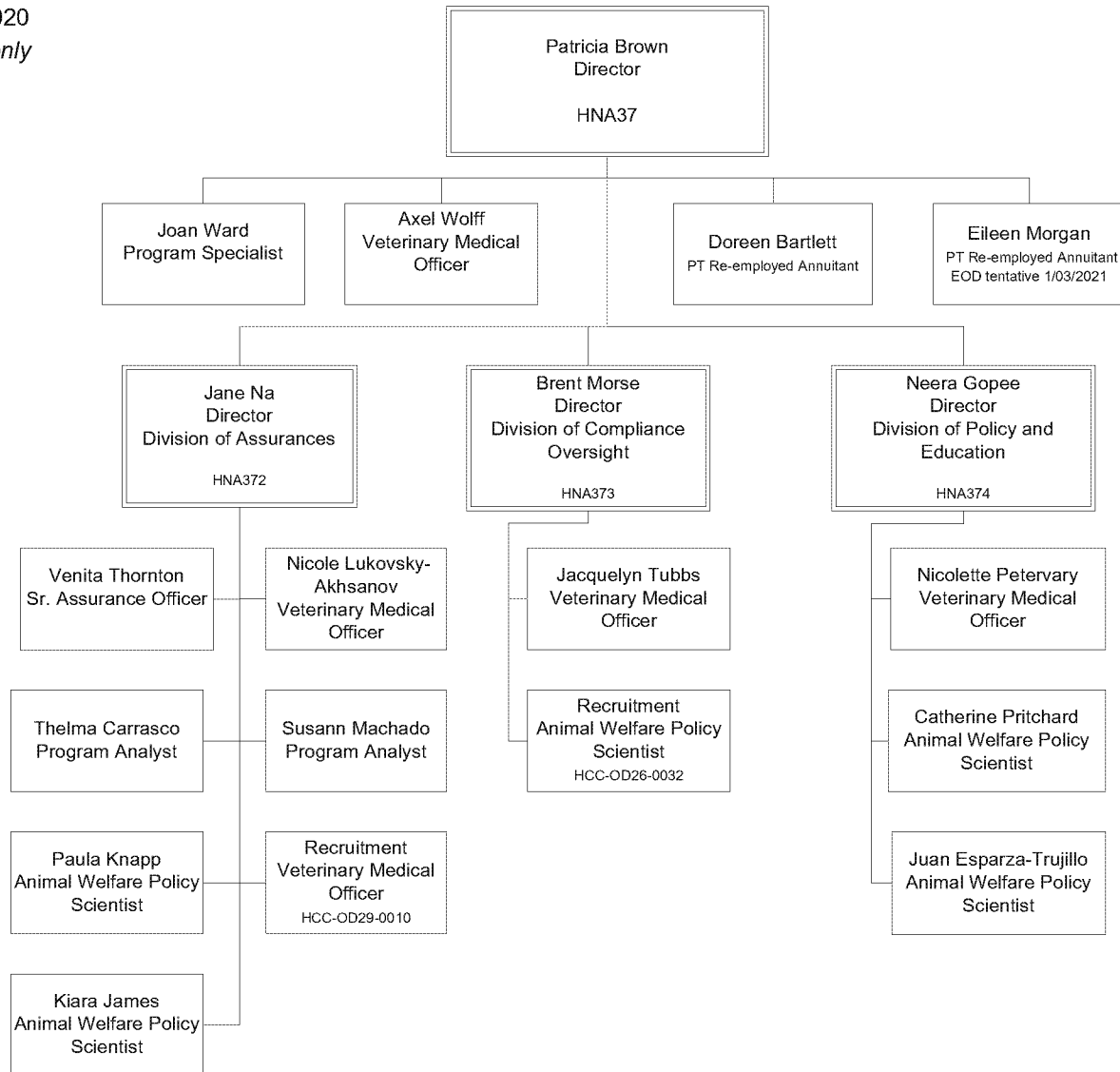
OER
Office of Research Information Systems
(ORIS) HNA36

As of 10/25/2020
Federal staff only



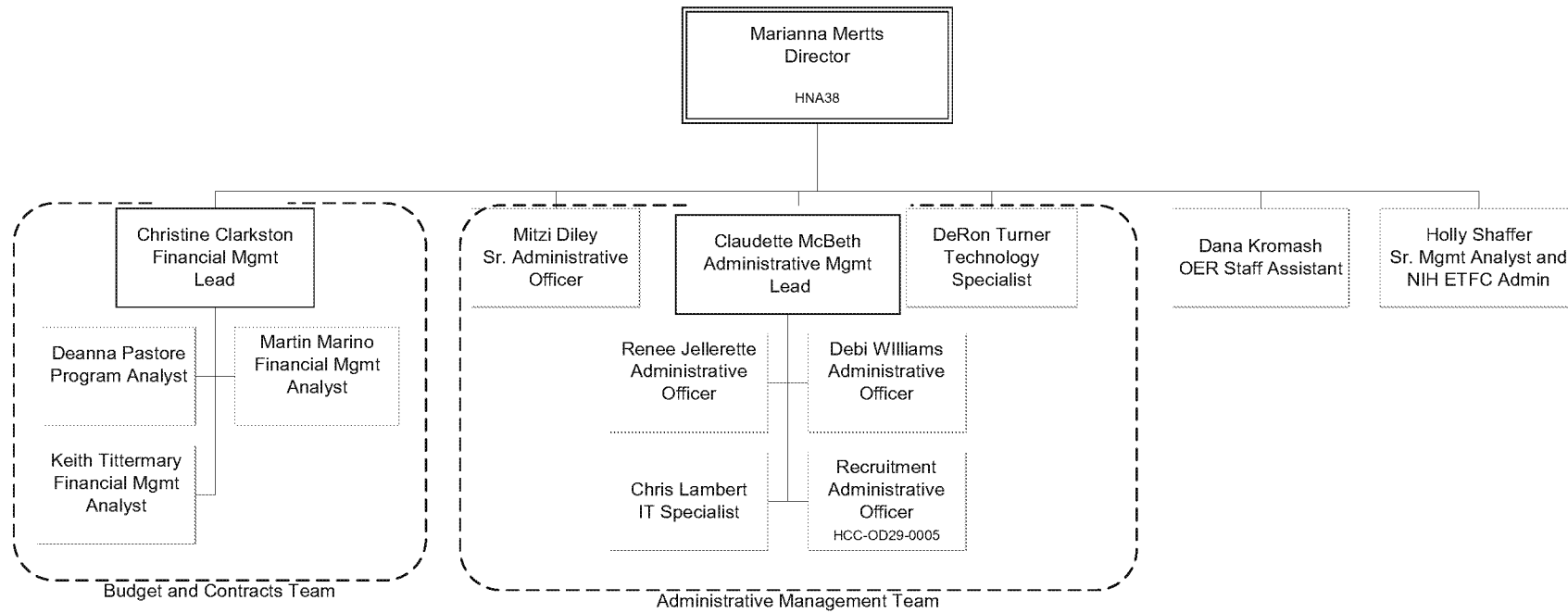
OER
Office of Laboratory Animal Welfare
(OLAW) HNA37

As of 10/25/2020
Federal staff only

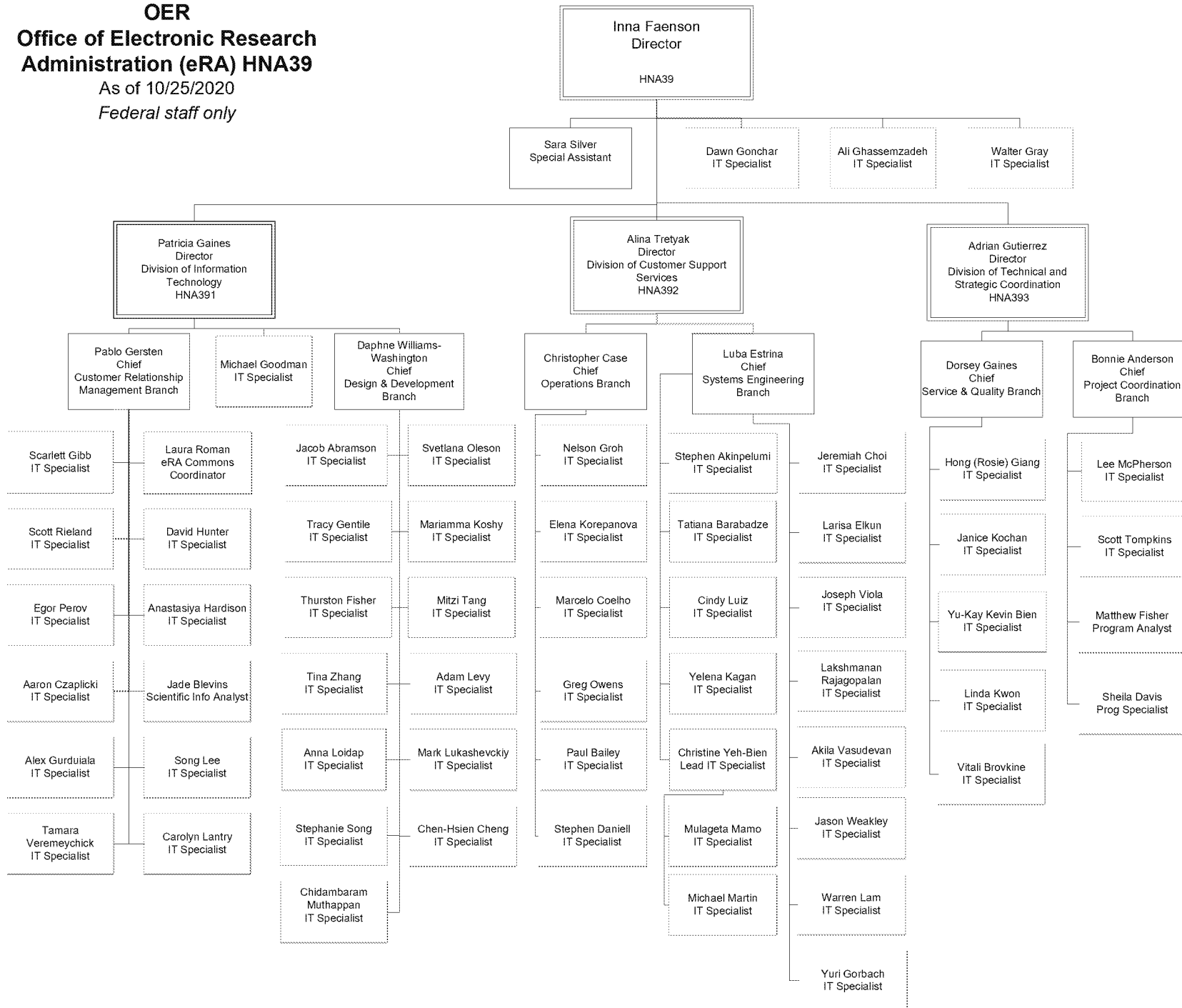


OER
Strategic Management and Contracts Office
(SMCO) HNA38

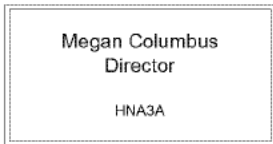
As of 10/25/2020
Federal staff only



OER
Office of Electronic Research
Administration (eRA) HNA39
 As of 10/25/2020
Federal staff only

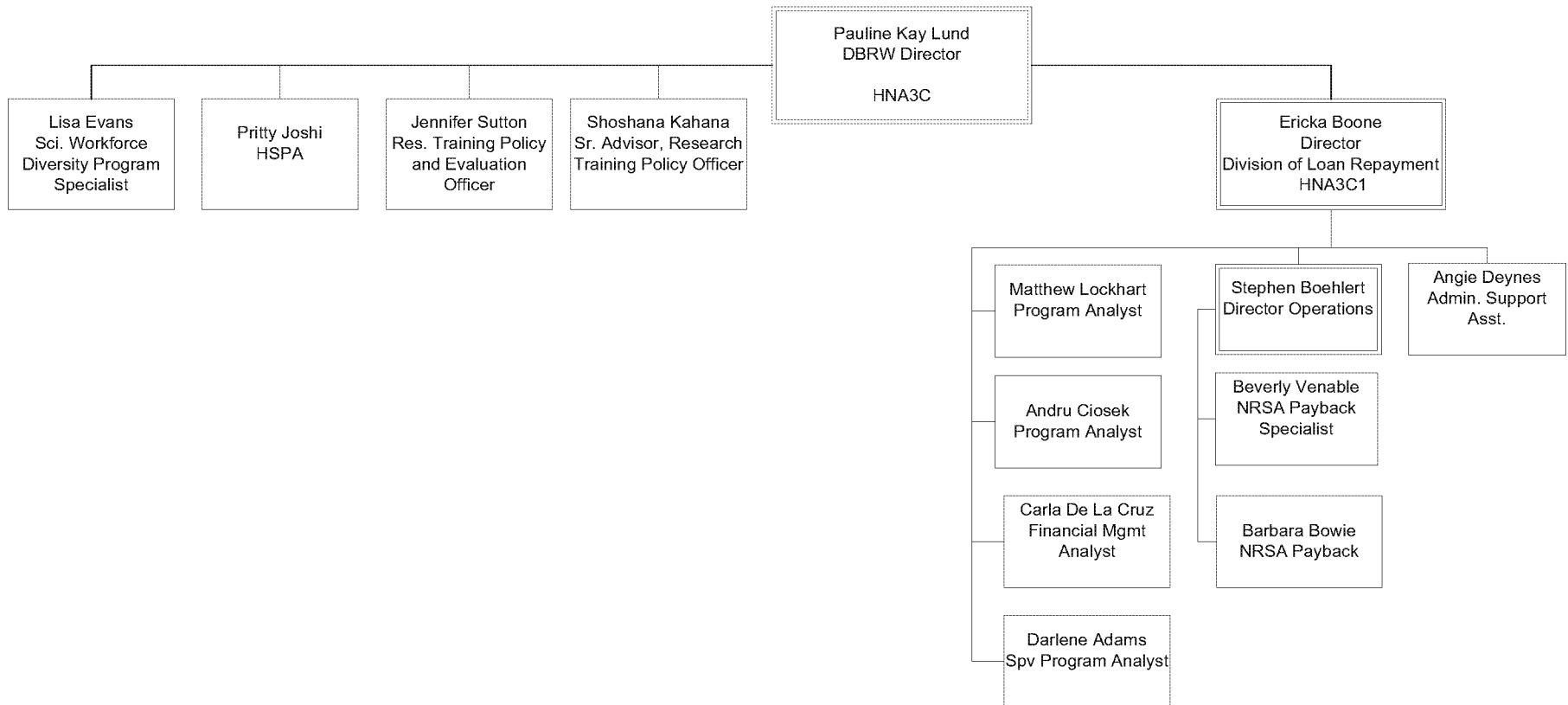


As of 10/25/2020
Federal staff only



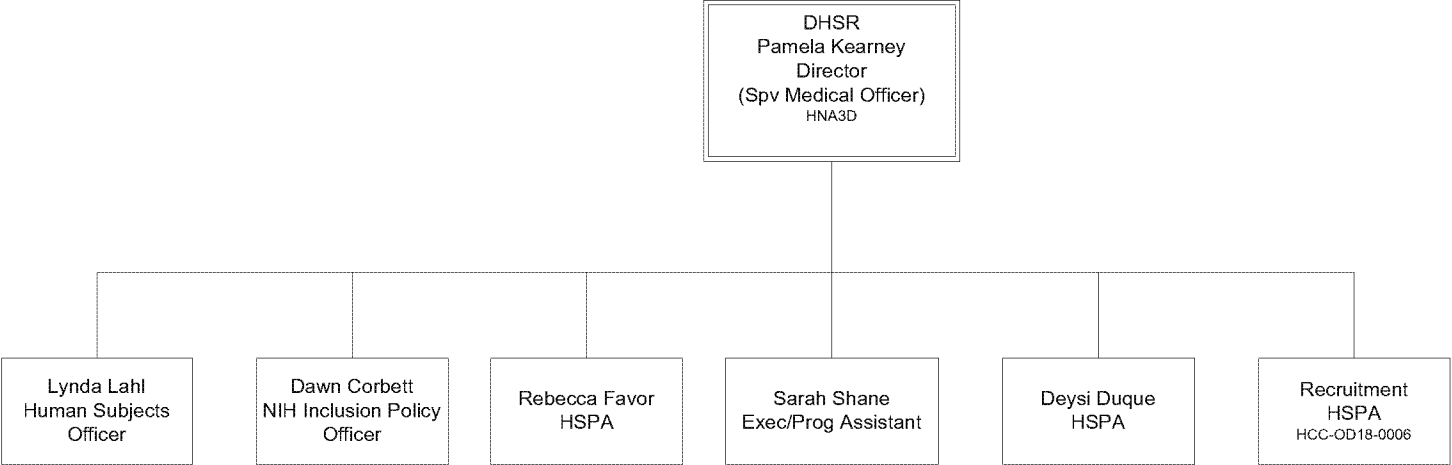
OER
Division of Biomedical Workforce (DBRW)

As of 10/25/2020
Federal staff only



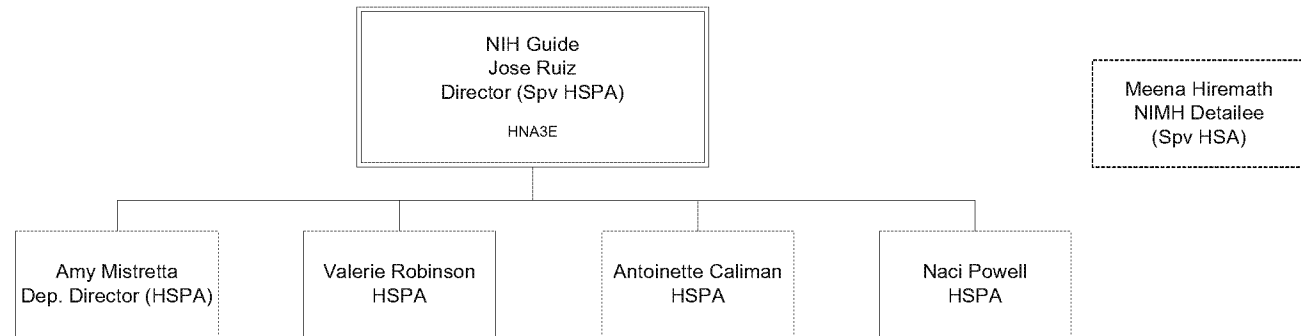
OER
Division of Human Subjects Research (DHSR)
HNA3D

As of 10/25/2020
Federal staff only



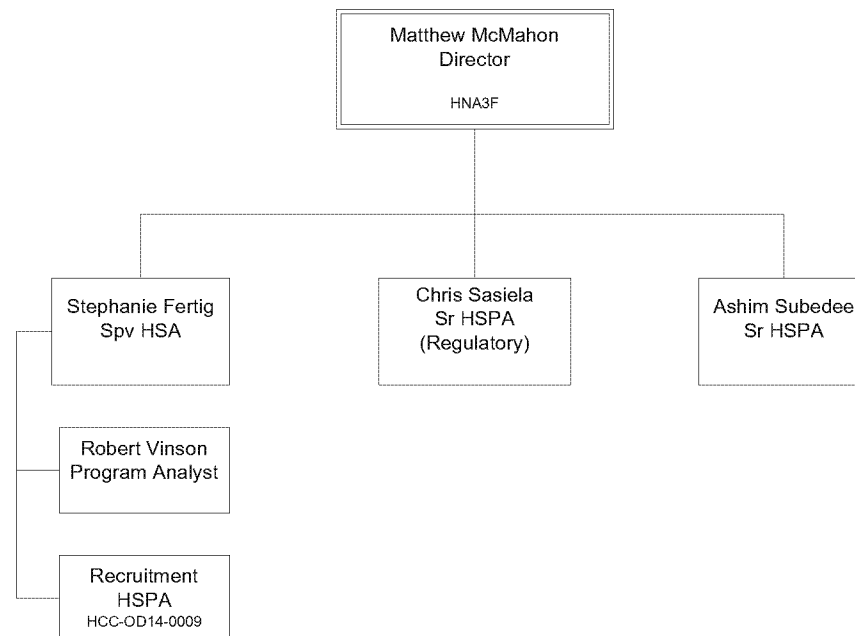
**OER
NIH Guide
HNA3E**

*As of 10/25/2020
Federal staff only*



OER
Small Business Education and
Entrepreneur Development (SEED)
HNA3F

As of 10/25/2020
Federal staff only



MEMORANDUM OF UNDERSTANDING

BETWEEN

THE NATIONAL INSTITUTES OF HEALTH OF THE UNITED STATES OF AMERICA DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

THE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY OF THE UNITED STATES OF AMERICA DEPARTMENT OF COMMERCE

This Memorandum of Understanding (“MOU”) is by and between the National Institutes of Health (“NIH”), an agency of the United States (“U.S.”) Department of Health and Human Services (“DHHS”), and the National Institute of Standards and Technology (“NIST”), an agency of the U.S. Department of Commerce, are referred to herein individually as a Party and collectively as the Parties;

WHEREAS, NIST arranges for the U.S. technical reviews, including assisting with identifying subject matter experts (“SME”) for peer review, of research and development project proposals submitted to the U.S.-Israel Binational Industrial Research and Development (“BIRD”) Foundation, a non-profit self-sustaining grant awarding foundation jointly established through an agreement between the U.S. and Israel governments in 1977 to generate mutually beneficial cooperation between U.S. and Israeli companies in industrial research and development;

WHEREAS, the BIRD Foundation is receiving an increasing number of life science and biomedical project proposals, and NIST has limited access to SMEs to conduct peer review of these projects;

WHEREAS, NIH routinely conducts and arranges for the peer review of biomedical and life sciences research proposals;

WHEREAS, NIST desires NIH’s assistance in identifying biomedical and life sciences experts to conduct peer review for research and development proposals submitted to the BIRD Foundation, and NIH desires to provide such assistance to NIST in fulfillment of its mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability;

WHEREAS, NIH is authorized under Sections 301 and Title IV of the Public Health Service Act to cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, biomedical and behavioral research;

WHEREAS, NIST is authorized under Title 15 United States Code §§ 272(b) and 272(c).

NOW, THEREFORE, the Parties intend to proceed as follows:

1. Responsibilities

A. NIST Responsibilities

NIST arranges the technical reviews, including soliciting SME peer reviewers, for all BIRD Foundation proposals. To find appropriate SME peer reviewers, NIST recruits scientific experts from NIST intramural labs, experts from U.S. Federal Government scientific agencies, and U.S. academia:

- NIST intends to use NIH's public database, RePORTER, to identify potential biomedical and life sciences peer reviewers. RePORTER is an electronic tool that allows users to search a repository of both intramural and extramural NIH-funded research projects from the past 25 years and access publications since 1980. RePORTER contains the names and contact information of potential external peer reviewers.
- NIH intends to facilitate identification of appropriate potential SMEs located from RePORTER and NIH staff, NIST will organize and conduct the peer review of biomedical and life sciences BIRD Foundation proposals.
- NIST will have direct contact with the BIRD Foundation regarding the peer reviewers.

B. NIH Responsibilities

NIH intends to work directly with NIST to facilitate access to appropriate biomedical and life science SME based on individual projects. NIH intends to assist NIST in confirming the reviewers with the most appropriate biomedical subject matter expertise for project proposals using the following strategies:

- Provide NIST with assistance in utilizing RePORTER to locate appropriate external scientific peer reviewers for the applicable subject matter and providing recommendations to NIST on the most appropriate potential external peer reviewers from RePORTER;
- Provide NIST with recommendations on NIH staff that could potentially serve as peer reviewers.

C. Mutual Responsibilities

NIH and NIST intend to jointly establish the NIST-NIH Reviewer Partnership Program to Assist the BIRD Foundation (“Program”) to facilitate peer review support for biomedical and health-related proposals.

- The primary points of contact for the Program are the Office of Extramural Research (“OER”) within NIH and the International and Academic Affairs Office (“IAAO”) within NIST.
- The NIST/IAAO BIRD Foundation point of contact (“POC”) is responsible for communications with the BIRD Foundation Secretariat and with the project proposers.
- NIH/OER intends to facilitate and coordinate assistance from NIH Institutes and Centers in locating appropriate SMEs for peer review and to communicate with the NIST/IAAO POC regarding the same.
- NIST/IAAO intends to begin utilizing NIH’s RePORTER and NIH staff recommendations no later than eight (8) weeks prior to final peer review submissions due date to BIRD Foundation. The NIST/IAAO POC intends to inform OER of all external reviewer sources located and secured through use of RePORTER related to biomedical health-related proposals.

2. Terms of Participation in the Program

The Parties recognize:

- The BIRD Foundation call for proposals occurs twice per year at 6-month intervals, as follows: full proposals are due in April and October. Review periods are March-May and September-November. NIST/IAAO intends to actively use NIH’s RePORTER to identify external SME and seek NIH staff support as SME during this time, without intent to seek direct support.
- All NIH staff and external SME who serve as peer reviewers for BIRD Foundation project proposals must first sign the NIST Confidentiality and Conflict of Interest Agreement for BIRD Foundation proposals. Abstracts from the Executive Summaries may be reviewed in the absence of a signed agreement.
- Full proposals will be available to all peer reviewers no later than 5 business days after the proposals are received by the NIST/IAAO BIRD POC from the BIRD Secretariat. Oversight of this task lies with NIST.
- Written reviews are due to NIST/IAAO BIRD POC no later than 20 business days from the date of the BIRD Foundation Board of Governors meeting for that review cycle. This is approximately a maximum 4-week review period and will be made

explicit in the communications between the NIST/IAAO BIRD POC and peer reviewers. Oversight of this task lies with NIST.

- NIH staff who agree to participate in BIRD Foundation peer review will do so as an official duty without expectation of compensation. NIH staff will prioritize NIH work.
- The NIST/IAAO BIRD POC is responsible for processing the peer reviewers' Confidentiality and Conflict of Interest Agreement for BIRD Foundation proposals, as well as for communicating the results of the reviews to BIRD Foundation.

3. General Provisions

A. Effect of MOU; Conflicts; Compliance.

This MOU does not create any binding obligations under the laws of the United States or under international law. Specific projects and activities under this MOU are subject to the availability of personnel, appropriated funds and other resources. Any differences of opinion relating to activities conducted under this MOU are intended to be resolved through discussions between the Parties. Each Party intends to undertake all activities contemplated by this MOU in accordance with all applicable laws, regulations and policies.

B. Term and Termination.

Activities under this MOU may commence upon signature below and continue for two years from the date of signature. Either Party may discontinue cooperation under this MOU at any time and should endeavor to provide 90 days' written notice to the other Party according to the contact information listed under the applicable Party's signature.

Date activities commence: On the _____ day of _____, 2020.

For the NATIONAL INSTITUTES OF
HEALTH

Michael S. Lauer -S

Digitally signed by Michael S. Lauer -
S
Date: 2020.10.06 17:35:51 -04'00'

Date:

Name: Michael S. Lauer, MD
Title: Deputy Director for Extramural
Research, National Institutes of Health
Department of Health and Human
Services
Phone Number: 301-496-1096
Email Address: Michael.Lauer@nih.gov

For the NATIONAL INSTITUTE OF
STANDARDS AND TECHNOLOGY

JAMES
OLTHOFF

Digitally signed by JAMES
OLTHOFF
Date: 2020.10.08 11:45:37
-04'00'

Date:

Name: James K. Olthoff, PhD
Title: Associate Director for Laboratory
Programs, National Institute of Standards
and Technology
Department of Commerce
Phone Number: 301-975-2300
Email Address: james.olthoff@nist.gov

**Five Eyes Dialogue on Promoting & Protecting the Integrity of the International Research
& Development (R&D) Enterprise**

October 15, 2020 | 3:00 – 5:30 PM EDT

Webex

International science and technology (S&T) cooperation allows us to amplify research and accelerate advances, as it brings together top minds, resources, and facilities to solve some of the world's most pressing challenges. As we seek to deepen cooperation, however, there is a growing need to recognize not only the vast benefits afforded by international partnerships, but also potential risks to the integrity of the global research enterprise. This multi-country dialogue will engage likeminded countries who lead the world in and prioritize R&D in a discussion on “risks to research” and ways to mitigate those risks and align approaches. This forum could also identify opportunities to lower barriers to scientific cooperation among partners who share a commitment to certain research values and principles, including openness, transparency, reciprocity, and merit-based competition. The goal of this dialogue is to foster a network that upholds shared values and principles of research cooperation and models best practices – within and beyond the group – that promote and protect the integrity of the international research system.

Objectives:

- Share cases, experiences, and best practices.
- Reaffirm and reinforce values and principles worldwide, and find means to codify and operationalize them.
- Work to align and harmonize research integrity guidance, policies, and frameworks.

AGENDA

3:00 PM **Welcome** – Jonathan Margolis, Acting Deputy Assistant Secretary, Bureau of Oceans and International Environmental and Scientific Affairs (OES), U.S. Department of State

Opening Remarks – Dr. Kelvin Droegemeier, Director, White House Office of Science and Technology Policy (OSTP)

3:15 PM **Introductions and Country Updates** (10 min per del) (U.S. moderating)

Heads of delegations introduce delegation members and provide timely updates on latest practices, new policies, or thinking on research integrity and security.

In order: United Kingdom, New Zealand, Australia, Canada, United States

4:05 PM Special Project Presentation (Australia)

The Australian Embassy in the United States compiled key efforts from the Five Eyes countries on promoting and protecting the integrity and security of national and international R&D enterprises. This paper may serve as a foundation for further analysis and comparison across the five countries, as we seek to identify best practices, align approaches, and determine next steps.

4:15 PM Focus Topic: Scrutiny and Oversight of International S&T Cooperation (U.S. moderating)

The United States is undertaking a whole-of-government approach to promoting and protecting the integrity of the research enterprise. This includes more closely assessing the scope of international cooperative S&T activities and their benefit to the United States, without compromising national or economic security. U.S. departments and agencies have therefore taken action to evaluate the risks and benefits of engaging certain countries in S&T research. The U.S. government will offer perspectives on and mechanisms for enhancing scrutiny and oversight as a way to maximize the benefits of international S&T cooperation while protecting against exploitation of open, collaborative research. All countries are invited to share their perspectives and similar efforts to date.

- Introduction by the United States (State Department)
- Presentations by U.S. science agencies (5-7 min apiece)
- Discussion – All countries to share perspectives and processes

5:10 PM Next Steps (U.S. moderating)

- Future dialogues – identifying leads for Jan, Apr, Jul, Oct 2021
- Dialogue construct and participation moving forward (e.g., non-government, additional countries, other ministries and agencies, etc.)

5:30 PM Adjourn

PARTICIPANTS

Current as of 10/10/20

AUSTRALIA

Department of Education, Skills, and Employment

Travis Power, Assistant Secretary, International Policy (**lead**)

Georgia Cowie, Assistant Director, Countering Foreign Interference, International Division

Department of Industry, Science, Energy, and Resources

Justin Skelly, Assistant Secretary, National Security Engagement Branch

Department of Home Affairs

TBD

Embassy of Australia in the USA

Ann Bray, Minister Counselor (Industry, Science, Energy, and Resources)

Paul Harris, Counselor, Australian National University

CANADA

Global Affairs Canada (GAC)

Emmanuel Kamarianakis, Director General, Investment, Innovation and Education (**lead**)

Agriculture and Agri-Food Canada

Ian Campbell, Director, Science Coordination and International Engagement

Health Canada

Marc Desjardins, Executive Director, Science Policy Directorate, Strategic Policy Branch

Innovation, Science and Economic Development (ISED)

Sinead Tuite, Senior Director, Digital Research Infrastructure

Natural Resources Canada (NRCan)

Vik Pant, Chief Scientist and Chief Science Advisor to NRCan

Office of the Chief Science Advisor

Luc Gauthier, Chief of Staff

Observer

Embassy of Canada to the USA

Carol Ann Weichel, Science Counsellor

NEW ZEALAND

Ministry of Business, Innovation and Employment

Loveday Kempthorne, PhD, Principal Advisor for International Science (**Lead**)

Marta Mager, Minister Counsellor, Science & Innovation, NZ Consulate General

Ministry of Defence

Hema Sridhar, Chief Advisor Industry and Science

UNITED KINGDOM**Department for Business, Energy & Industrial Strategy (BEIS)**

Mark Ruglys, Head, International Research Collaboration Policy (**lead**)

Siôn Griffiths, Head of Risks and Security to Science and Innovation

Foreign and Commonwealth Office

James Stopford

UK Research and Innovation (UKRI)

TBD

British Embassy in the USA

Chris Dain, Director, U.S. Science & Innovation Network | Regional Head, Americas

Karla Hagan, Senior Science and Innovation Policy Advisor

UNITED STATES**U.S. Department of State**

Jonathan Margolis, Acting Deputy Assistant Secretary for Science, Space, and Health, Bureau of
Oceans and International Environmental and Scientific Affairs (OES) (**lead**)

Reece Smyth, Director, Office of Science and Technology Cooperation (OES/STC)

Megan Frisk, Foreign Affairs Officer, OES/STC

Office of Science and Technology Policy (EOP/OSTP)

Kelvin Droegemeier, Director

Aaron Miles, Principal Assistant Director for National Security and International Affairs

Helena Fu, Senior Policy Advisor

U.S. Department of Agriculture (USDA)

Scott Hutchins, Deputy Under Secretary

Jaime Adams, Senior Advisor for International Affairs, Office of the Chief Scientist

U.S. Department of Energy (DOE)

Stephen Binkley, Principal Deputy Director, Office of Science

Maria DiGiulian, Director, Office of International Science and Technology Collaboration

National Institutes of Health (NIH)

Michael Lauer, Deputy Director for Extramural Research, Office of the Director

Patricia Valdez, Extramural Research Integrity Officer, Office of Extramural Programs

National Science Foundation (NSF)

Samuel Howerton, Deputy Director, Office of International Science and Engineering (OISE)
Bridget Turaga, Foreign Affairs Specialist, OISE

Observers

U.S. Department of State

Lisa Brodey, U.S. Embassy London
Staci Rijal, Acting Team Lead for Asia and Americas, OES/STC

Commentary

How Support of Early Career Researchers Can Reset Science in the Post-COVID19 World

Erin M. Gibson,^{1,12,*} F. Chris Bennett,² Shawn M. Gillespie,³ Ali Deniz Güler,⁴ David H. Gutmann,⁵ Casey H. Halpern,⁶ Sarah C. Kucenas,⁴ Clete A. Kushida,¹ Mackenzie Lemieux,⁷ Shane Liddelow,⁸ Shannon L. Macauley,⁹ Qingyun Li,¹⁰ Matthew A. Quinn,¹¹ Laura Weiss Roberts,¹ Naresha Saligrama,⁵ Kathryn R. Taylor,³ Humsa S. Venkatesh,³ Belgün Yalçın,³ and J. Bradley Zuchero⁶

¹Department of Psychiatry and Behavioral Sciences, Stanford University School of Medicine, Palo Alto, CA 94305, USA

²Department of Psychiatry, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA 19104, USA

³Department of Neurology and Neurological Sciences, Stanford University School of Medicine, Palo Alto, CA 94305, USA

⁴Department of Biology, University of Virginia, Charlottesville, VA 22903, USA

⁵Department of Neurology, Washington University School of Medicine, St. Louis, MO 63110, USA

⁶Department of Neurosurgery, Stanford University School of Medicine, Palo Alto, CA 94305, USA

⁷The Salk Institute for Biological Studies, La Jolla, CA 92037, USA

⁸Neuroscience Institute, NYU School of Medicine, New York, NY 10016, USA

⁹Department of Internal Medicine, Wake Forest School of Medicine, Winston-Salem, NC 27101, USA

¹⁰Departments of Neuroscience and Genetics, Washington University School of Medicine, St. Louis, MO 63110, USA

¹¹Department of Pathology, Section on Comparative Medicine, Wake Forest School of Medicine, Winston-Salem, NC 27517, USA

¹²Lead Contact

*Correspondence: egibson1@stanford.edu

<https://doi.org/10.1016/j.cell.2020.05.045>

The COVID19 crisis has magnified the issues plaguing academic science, but it has also provided the scientific establishment with an unprecedented opportunity to reset. Shoring up the foundation of academic science will require a concerted effort between funding agencies, universities, and the public to rethink how we support scientists, with a special emphasis on early career researchers.

The novel coronavirus, SARS-CoV-2, has placed science at the center of every conversation, amplifying the importance of scientific research to economic stability, healthcare infrastructure, and disaster preparedness. In academic science, recovery from the immediate COVID19 crisis will require departments, universities, private foundations, federal agencies, and the public to work together collaboratively and comprehensively. The goal of recovery should not be to return to “normal” but, rather, to reset. Here, we argue that recovery provides us with the opportunity to address three systemic issues that plague the conduct of research in the twenty-first century, with an emphasis on supporting early career researchers who are the most vulnerable. The strategies needed to ensure stability and success of early career scientists post-COVID19 can be adapted to chip away at the systemic issues affecting the scientific establishment.

Excess Does Not Equal Excellence

Science has changed immensely over the past 50 years. More has become better:

more experiments per paper, more papers per year, more expectations and requirements for grants and tenure, more opinions from reviewers. The scientific community rewards quantity over quality. Most scientists can easily name a seminal paper; many were published long before the 2000s, and many had, at most, a handful of figures. Today, papers are often published with a plethora of supplemental figures that will largely go unread and underappreciated. The desire for “more” results in delays in publication, the awarding of grants, and career advancement for early career researchers; it also stymies creativity and encourages the proliferation of low-quality journals.

Diversification Leads to Discovery

This crisis is exacerbating the well-documented discrimination afflicting academic science (Monroe et al., 2008). Women, parents, and individuals who identify as racial or ethnic minorities leave science, technology, engineering, and math (STEM) fields as early career researchers at an excessively high rate in the best of

times and will undoubtedly suffer more from the present lab closures. The responsibilities of family life disproportionately impact women. A parent who is trying to homeschool their children, manage household duties, and work will have left little time to further their own scientific agenda. Faculty with family responsibilities—women specifically—must be supported. The COVID19 crisis will only highlight the rampant diversity issues plaguing the scientific establishment, many of which begin with the loss of women and minorities during early career stages and may lead to further disenfranchisement of the disadvantaged (Malisch et al., 2020).

Rethink the Fundamentals of Funding

The current model of academic science is heavily reliant upon federal funding, even though agencies such as the National Institutes of Health (NIH) were not built to sustain such expectations. The federal government's funding capacity has significantly diminished as the cost of science has radically increased. The 2019 defense



budget was ~\$685 billion while the 2019 NIH budget was \$39 billion. The COVID19 crisis has clearly amplified that the greatest risk to American life is not war, but disease. Funding is needed at all levels; however, early career researchers should be particularly supported as the consistent trend of shifting funding away from younger researchers has no end in sight (Daniels, 2015).

Ensuring a Durable Future for Academic Science Post-COVID19

Recovery from the immediate COVID19 crisis necessitates a multi-pronged approach including fiscal and non-fiscal strategies to help graduate students, postdoctoral fellows, and early and later career faculty. This pandemic has particularly impacted senior postdoctoral fellows seeking academic faculty positions and early career faculty seeking to establish themselves as independent investigators. Special consideration for these early career researchers is key to overcoming the crisis and strengthening the foundations of academic science. Our action plan proposed below is not an exhaustive list of all possible recommendations for supporting scientists, nor is it inclusive of every academic scientist's specific circumstance. Not all of our suggestions are applicable at every university or institution, as each will have its own unique set of challenges. We acknowledge that monetary support will be limited due to the deteriorating economic situation and drastic loss of revenue from clinical operations for most medical campuses. While the immediate goal of the recommendations is to provide support for scientists from funding agencies, universities, departments, and the public following COVID19, this support also provides solutions to the three major challenges. Solutions to these systemic issues (i.e., *Excess Does Not Equal Excellence*, *Diversification Leads to Discovery*, or *Funding Agencies*) are interwoven across the structure of academic science, allowing us to comprehensively tackle these issues at all levels. Plans for recovery from the COVID19 pandemic must ensure as much continuity as possible in research while improving upon existing infrastructures in order to provide a more inclusive, cohesive, and efficient future for the

next generation of independent scientists.

Funding Agencies Grantsmanship

The resiliency of research is dependent upon the support of funding agencies. Like the broader scientific community, funding agencies will need to adapt their strategies and structure to fit the changing times. Simplification of grant application processes, including fewer supplemental documentations and more implementation of letter-of-intent formats prior to full proposals, could increase efficiency for both the funding agency and researcher. Lab closures will undoubtedly create a void in the preliminary data that are necessary to obtain most awards. Early career researchers who had less time to acquire these data prior to lab shutdowns will be the most affected. Funding agencies could introduce policies and programs targeted at early investigators that require fewer preliminary data (similar to the National Institute of Mental Health [NIMH] Brain Research through Advancing Innovative Neurotechnologies [BRAIN] Initiative R01 or the DP2), reducing the excess in data required for most grants. Grants submitted by graduate students, postdoctoral fellows, and early career faculty who do not have sufficient preliminary data per current standards should be given special consideration. Currently, many of the new funding opportunities by funding agencies, such as the NIH, are geared toward supplements to existing grants or COVID-related research. As there will likely be restrictions or reductions to new funding opportunities in the coming years due to fiscal shortages, faculty with existing grants might help early career faculty by including them in their supplemental applications. Including early career faculty will also foster collaboration and resource sharing, both of which will be vital during this time (*Excess Does Not Equal Excellence* and *Rethink the Fundamentals of Funding*).

Extension of Deadlines, Timelines, and Funding

Numerous funding agencies have already implemented deadline extensions, but deadlines must be further extended for the duration of lab disruptions. It is also imperative that funding agencies extend

early investigator status for grant applications and implement no-cost extensions for currently held grants. Additional bridge funding programs may be especially important for faculty who are between projects or aiming to switch areas of study following the COVID19 crisis.

Universities

Extensions for Tenure: Faculty

Most universities have added one-year extensions to the tenure tracks of early career researchers, but sliding extensions may better support the success of vulnerable academics. Many early career investigators may request extensions during lab closures, but they should also have the ability to go up for tenure early if the opportunity arises. Ensuring the promotion and advancement of marginalized groups such as women, who make up < 30% of STEM faculty, is even more imperative post-COVID19. COVID19-initiated resetting of expectations for the publishing, teaching, mentorship, and service requirements for tenure may not only help minimize the excesses innate to the current tenure structure, but also may help foster environments that can acknowledge implicit biases and keep marginalized groups from disproportionately leaving STEM fields. Tenure expectations for the next generation of early career researchers may need to account for increased variability between faculty that is exacerbated by the COVID19 crisis and allow for more flexibility in the process. This crisis has amplified how the antiquated one-size-fits-all guidelines only encourage the disenfranchisement of women and racial or ethnic minorities (*Diversification Leads to Discovery and Excess Does Not Equal Excellence*).

Trainees

The current crisis will have a dramatic trickle-down effect, and numerous hiring freezes are already in place. Mechanisms to allow postdoctoral fellows or graduate students in their final year to continue in their current positions should be enacted, if necessary, and if labs or universities are able to provide fiscal support. Current closures are also disrupting the ability of many graduate students to complete their rotations. Universities could extend the timeline for rotations and potentially cover graduate students' stipends. Trainees, particularly postdoctoral fellows, may

have limited ability to extend their period of training due to visa restrictions. Universities should coordinate with federal agencies to pursue strategies aimed at extending visa expiration timelines, allowing trainees to complete work that was delayed due to the COVID19 crisis. These mechanisms are needed to assure that we do not lose an entire generation of scientists following the coronavirus crisis.

Curtailment of Applicable Hiring Freezes

Many universities have implemented hiring freezes for faculty and staff for the remainder of the year or beyond. Universities should not limit the ability of early career faculty to hire postdoctoral fellows and staff, however. Restricting early career faculty from hiring technical assistance and lab managers will stymie their ability to generate preliminary data, which will consequently limit grant and paper submissions and delay career advancement. Even a short hiring freeze could have devastating effects on the ability of early career faculty labs to succeed. Allowing early career faculty to continue hiring will also help to ease the bottleneck of graduate students looking for postdoctoral or research scientist positions within the next few years. Hiring freezes at any level will disproportionately affect early career individuals and oversaturate the market with qualified candidates. Permitting ongoing interviews for faculty positions, even if the official hire date is postponed, could alleviate stress on the postdoc population and expedite the hiring process when hiring freezes are lifted. The faculty search process serves as a valuable feedback mechanism for postdoctoral fellows that sometimes has an impact on career path. Halting all hiring and all faculty searches may drive talented postdocs, especially women and members of ethnic or racial minorities, out of academia (*Diversification Leads to Discovery*).

Institutional Funds and Startup Packages

Although universities may curtail spending from institutional funds, special consideration should be given to new and early career faculty. Early career faculty must retain access to their startup packages during this time. Institutional funds should be released for salary support for early career faculty and for all staff, students, and trainees in their labs.

If startup funds are set to expire, the expiration date should be extended. New faculty should be given the funds needed to establish their labs once research activities resume (*Rethink the Fundamentals of Funding*).

Supplementation

The economic toll caused by shelter-in-place will undoubtedly be significant, including the reduction in funding through endowments and charitable giving. We fully acknowledge that monetary supplementation may be difficult for universities following the COVID19 crisis. Any combination of fiscal supplementation with other mechanisms of non-fiscal support should be considered. Universities might implement new or expanded fellowships for postdocs and graduate students, add to existing startup packages for faculty, assist with the purchasing of equipment or expand shared equipment funding, or create subsidies or joint ventures with federal programs similar to unemployment or re-deployment programs. Universities might supplement pay or provide reimbursement for staff, postdoc, and graduate student salaries during the duration of academic closures.

Supplementation: Per Diem Costs

Many universities have per diem policies that differ based on funding source, with reduced per diem costs associated with federal grants. Early career faculty without federal funding have per diem costs double that of other labs. Universities could implement mechanisms to reduce or supplement animal costs that will be accrued during lab closures and when labs reopen and expand their animal colonies (*Rethink the Fundamentals of Funding*).

Supplementation: Childcare Initiatives

Onsite daycare facilities support postdoctoral fellows and faculty with young children. These family care centers are critical to narrowing the gap and slow the attrition of women and parents in science. Universities could work with early childhood education programs to establish or expand daycare and preschool programs, providing free or subsidized childcare for faculty and teaching opportunities for early education majors. Universities might also reach out to current or retired teachers seeking supplemental income (*Diversification Leads to Discovery*).

Supplementation: Access to Technology

Universities should encourage and enable graduate students and postdocs to use this time to learn new computational skills in anticipation of reductions in ability to do work at the bench. Many university-offered computational courses were over-committed during lab closures due to a significant increase in enrollment requests. Universities should make a concerted effort to increase bandwidth and capacity for computational courses. Many free online resources are also available to supplement the acquisition of coding skills.

Departments: Administrative and Teaching Load

Administrative and teaching expectations should be reevaluated during university closures. Departments should reassess administrative and teaching loads, especially for early career faculty whose promotions are contingent upon teaching requirements. This is especially important, since female scientists generally have increased teaching loads and more advisory expectations than male scientists (Gibney, 2017), which could disproportionately delay scientific recovery of female scientists from COVID19 closures (*Diversification Leads to Discovery*).

Mentorship Mental Health

The COVID19 crisis and subsequent lab closures will take an incredible toll on mental health. Early career faculty who have yet to establish themselves or their research independently and postdocs whose future job prospects are now significantly limited will be especially impacted by prolonged lab shutdowns. Department chairs, division leaders, and mentors should do their best to check in with early career faculty and postdocs during this time. Mentoring will be key both during and after this crisis. Establishing scheduled virtual meetings during social distancing and in-person meetings after labs are reopened could help alleviate some mental stress. University mental health resources are also available for anyone who needs support. As students generally contact female faculty about mental health issues more frequently than male

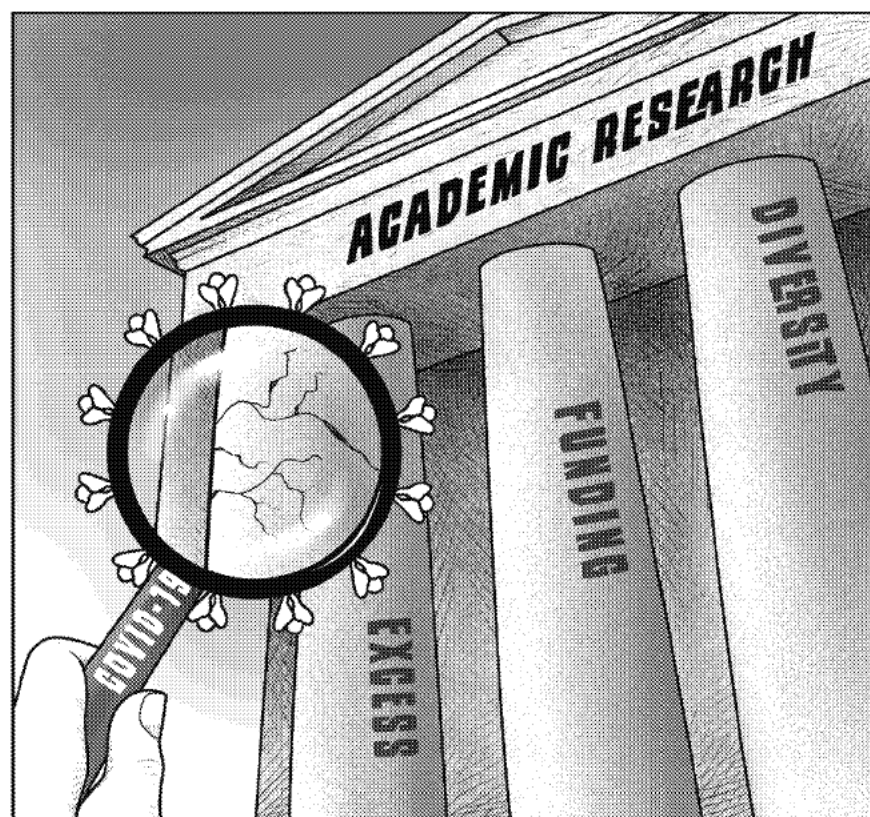


Figure 1. The COVID19 crisis has magnified the systemic issues plaguing academic research. These include the often stifling excess requirements in publication, tenure, and grant processes; the reliance on funding from national agencies that is catered towards senior level researchers; and the lack of diversity in academic research due to the attrition of women and racial or ethnic minorities during early career stages.

faculty (Bennett, 1982), equal encouragement of mentorship from all faculty is essential to not overburdening women faculty during this time (Diversification Leads to Discovery).

Graduate Student Programs

Mentoring graduate students throughout lab closures and after reopening should be strongly encouraged. Those conducting experiments will be most affected by lab closures, and this should be explicitly acknowledged by faculty and mentors. Universities must assure graduate students that graduate programs will be stabilized and that admittance will not be decreased. For many faculty, graduate students are the major workforce of the lab. To ensure that faculty can successfully build and sustain a lab, continued ability to attract graduate students is necessary. This is especially important for new investigators, as getting postdoctoral fellows can be more challenging for newer faculty.

Faculty Mentorship Programs

Once labs are reopened, pairing early career faculty with a later career faculty mentor of an established lab could facilitate more effective research programs and allow for resource sharing. Later career faculty could be incentivized to help early career researchers through reductions in teaching or administrative loads, supplementations to animal care costs, core facility usages, or other means of reimbursement and/or subsidizations. Investment of later career faculty in the success of early career faculty will help to ensure stability and success in the younger generation of independent researchers.

Clinician-Scientists

Faculty who have clinical responsibilities also necessitate special consideration during this time, especially if they are on the front lines. These individuals will not only lose productivity due to lab closures

and curtailment of patient enrollment in clinical trials, they will also have the extra physical and mental stressors of working in the hospital during a crisis. Establishment of protocols to aid clinician-scientists is imperative to ensuring their important contributions to science. Just as senior faculty mentoring will be critical for junior faculty and graduating postdocs to successfully transition to a post-COVID era in the basic sciences, this type of mentorship protocol may be even more critical for clinician-scientists, many of whom do not have doctorates beyond the medical degree.

Public Initiatives

Make Science a National Priority

The current crisis has brought the importance of science and research to the forefront of public life. Not only is science critical for public health decision-making, but a sustained investment in research better positions political leaders to efficiently deploy testing and therapeutic solutions. Capitalizing this momentum is crucial to engaging the public in science and science funding. Providing additional funding sources focused on conveying science to the greater public and stimulating interest in science through educational outreach is critical. Exploiting technology and social media to bring science and research directly to the public will be vital in the post-COVID19 world. Such technology might include mechanisms to allow private citizens to directly invest in science and scientists (Else, 2019; Miller, 2019), including simplified website-based donation platforms or inclusion on election ballots. This is necessary for establishing new funding sources for scientists, potentially supplementing the dearth of funding for early career researchers at federal funding agencies (Rethink the Fundamentals of Funding).

Enhanced Scientific Transparency

The COVID19 crisis has revealed a lack of public understanding about how science is funded, conducted, and reported. The current administration's belief that the NIH is "giving away \$32 billion a year" should be cause for concern (DeYoung et al., 2020). Much of the mistrust evident between the scientific establishment and the general population is rooted in lack of transparency and community

involvement in science. Taking scientists out of the “ivory tower” and increasing accessibility through technology may help to assuage the mistrust that hinders our preparedness in times of crisis. People cannot support what they do not understand. Removing excess requirements in publishing, grantsmanship, and tenure expectations could have the added benefit of creating more time for scientists to interact in the public domain. Scientists must work on building the trust that is imperative to success as a community, and early career scientists are primed to help pave this new future (*Excess Does Not Equal Excellence*).

Conclusions

Beyond the immediate challenges of returning to laboratories and research careers, the COVID19 crisis has exposed some of the underlying weaknesses and problems that permeate the current scientific enterprise (Figure 1). For example, editors are asking reviewers to not request more experiments unless absolutely necessary to validate the core claims of a manuscript during the review process. Most are applauding this effort to minimize excess and calling for its continued implementation even after scientists are able to get back to the bench. All institutions, funding agencies, departments, and members of the scientific

community should speak openly and honestly about the difficulties faced during the current situation. Early career researchers should be involved in the decision-making processes, as they represent the future of science and academic leadership. The COVID19 crisis has provided us with the unique opportunity to reflect upon the present norms and enact change through fiscal and non-fiscal strategies. Our hope is that this pandemic will allow us to chart a new course for science, both academically and socially, and to begin to address the core challenges of research, with a special focus on supporting the next generation of independent scientists.

DECLARATION OF INTERESTS

Dr. Roberts serves as Editor-in-Chief of books for the American Psychiatric Association Publishing Division and as Editor-in-Chief of the journal *Academic Medicine*. Unrelated to this publication, Dr. Roberts serves as an advisor for the Bucksbaum Institute of the University of Chicago Pritzker School of Medicine and owns the small business Terra Nova Learning Systems.

REFERENCES

Bennett, S.K. (1982). Student perceptions of and expectations for male and female instructors: Evidence relating to the question of gender bias in teaching evaluation. *J. Educ. Psychol.* 74, 170–179.

Daniels, R.J. (2015). A generation at risk: young investigators and the future of the biomedical workforce. *Proc. Natl. Acad. Sci. USA* 112, 313–318.

DeYoung, K., Sun, L.H., and Rauhalu, E. (2020). Americans at World Health Organization transmitted real-time information about coronavirus to Trump administration. *The Washington Post*, Available from. https://www.washingtonpost.com/world/national-security/americans-at-world-health-organization-transmitted-real-time-information-about-coronavirus-to-trump-administration/2020/04/19/951c77fa-318c-11ea-9040-68981f4388ed_story.html.

Else, H. (2019). Crowdfunding research flips science's traditional reward model. *Nature*, Available from. <https://www.nature.com/articles/d41586-019-00104-1>.

Gibney, E. (2017). Teaching load could put female scientists at career disadvantage. *Nature*, Available from. <https://www.nature.com/news/teaching-load-could-put-female-scientists-at-career-disadvantage-1.21839>.

Malisch, J.L., Harris, B.N., Sherrer, S.M., Lewis, K.A., Shepherd, S.L., McCarthy, P.C., Spott, J.L., Karam, E.L., Moustaid-Moussa, N., McCrory Calarco, et al. (2020). In the wake of COVID-19, academia needs new solutions to ensure gender equity. *Proceedings of the National Academy of Science*. <https://doi.org/10.1073/pnas.2010636117>.

Miller, Z. (2019). The best platforms for crowdfunding science research. *The Balance: Small Business*, Available from. <https://www.thebalancesmb.com/top-sites-for-crowdfunding-scientific-research-985236>.

Monroe, K., Ozyurt, S., Wrigley, T., and Alexander, A. (2006). Gender Equality in Academia: Bad News from the Trenches, and Some Possible Solutions. *Perspectives on Politics* 6, 215–233.

From: Norris, Andrea (NIH/CIT) [E] (b) (6)
Sent: 10/8/2020 8:02:17 PM
To: Lauer, Michael (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)
Hallett, Adrienne (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6)
Subject: RE: Action: By 12pm, Tuesday, 10/13 - Please provide availability to discuss new OIG audit "NIH Technology Controls and Related Efforts to the Grant Program" (A-18-20-06300)

(b) (5)

From Grants Policy Statement 4.1.9

All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access. This also applies to information associated with NIH grants and contracts. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), 44 U.S.C. 3541 et seq. The applicability of FISMA to NIH recipients applies only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. The recipient retains the original data and intellectual property, and is responsible for the security of this data, subject to all applicable laws protecting security, privacy, and research. If and when information collected by a recipient is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information and any derivative copies as required by FISMA.

Awardee systems and resources are not part of the NIH inventory of systems and we do not extend NIH cybersecurity control requirements to awardee systems. In select cases, we require awardees to submit formal documentation that they have followed Federal and NIST processes for system authorization to operate (All of Us Program, most notably), but these cases are driven by management considerations and not by policy requirements. When I was at NSF, this very same issue came up with the NSF OIG. We sponsored a series of workshops with NSF large grantees – targeted at universities and centers that ran large computational infrastructure like supercomputers, etc. – to build a more connected network across the community (which didn't really exist at that time), talk about cyber best practices, have them share experiences, etc. This was quite some time ago, but it helped with keeping the NSF OIG from pushing NSF to audit or take additional steps with awardees. And it helped with advancing good cyber practices in the community. We may want to consider some variation of this approach here at NIH.

Andrea

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Thursday, October 8, 2020 2:16 PM
To: Tabak, Lawrence (NIH/OD) [E] (b) (6); Hallett, Adrienne (NIH/OD) [E] (b) (6); Schwetz, Tara (NIH/OD) [E] (b) (6); Norris, Andrea (NIH/CIT) [E] (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: FW: Action: By 12pm, Tuesday, 10/13 - Please provide availability to discuss new OIG audit "NIH Technology Controls and Related Efforts to the Grant Program" (A-18-20-06300)

Just FYI ... yet another one ...

From: "Simanich, Sasha (NIH/OD) [E]" (b) (6)
Date: Thursday, October 8, 2020 at 2:03 PM
To: "Bundesen, Liza (NIH/OD) [E]" (b) (6), "Ratliff, Shaun (NIH/OD) [E]" (b) (6)
Cc: "Shannon, Mike (NIH/OD) [E]" <(b) (6)>, "Johnson, Alfred (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6), "Stein, Meredith (NIH/OD) [E]" (b) (6), "Chakraborty, Trisha (NIH/OD) [E]" (b) (6), "Spady, Tyrone (NIH/OD) [E]" (b) (6), "Mackenzie, James (NIH/OD) [E]" (b) (6), "Gonzalez, Itzel (NIH/OD) [E]" (b) (6), "Butler, Benjamin (NIH/OD) [E]" (b) (6), "Showe, Melanie (NIH/OD) [E]" (b) (6)
Subject: Action: By 12pm, Tuesday, 10/13 - Please provide availability to discuss new OIG audit "NIH Technology Controls and Related Efforts to the Grant Program" (A-18-20-06300)

Good Afternoon Dr. Bundesen and Shaun,

The OIG is beginning a new review entitled, *"NIH Technology Controls and Related Efforts to the Grant Program"* (Job code A-18-20-06300) to determine whether NIH has controls in place to ensure grants have appropriate cybersecurity provisions. Please see the attached OIG Notification Letter. OIG has requested an entrance conference to discuss their audit and to get a better understanding of the NIH grants process. This email is to request your availability for two meetings and to share the agenda.

Subject – By 12pm, Tuesday, 10/13 - Please provide your availability for an internal NIH pre-meeting and an entrance conference with the OIG

From – OMA

To – OCIO & OER

Cc – OSP, OCIO, OLPA, OM, OGC

Action 1 – Provide your availability for a 1-hour internal pre-meeting to discuss the attached OIG questions.

- Monday, Oct. 19: 10am-12pm, 2-5pm
- Thursday, Oct. 20: 8am-12pm or 2-3pm

Action 2 – Provide your availability for an entrance conference with the OIG

- Wednesday, Oct. 21: 2-5pm
- Thursday, Oct. 22: 9am-12pm

Action 3 – Provide high level talking points to OIG's questions prior to the internal pre-meeting (date TBD)

Requestor – OIG

Background – The OIG is beginning this work to determine whether NIH has internal controls in place to ensure grants have appropriate cybersecurity provisions.

POCs – Please send comments and any questions to David Fuller (b) (6) and Sasha Simanich (b) (6).

Additional Instructions –

- Please let me know whether additional offices/individuals should be involved in this audit.
- Use the attached Word file to complete the question set with high level talking points

Attachments –

- OIG Notification Letter
- Entrance conference agenda

Thank you,

Sasha Simanich

Audit Liaison, OIG/GAO Review
NIH/OD/OMA/RMAL
6011 Executive Blvd, Suite 108
Rockville, MD 20852-7669

Email: [REDACTED] (b) (6)

From: Mertts, Marianna (NIH/OD) [E] (b) (6)
Sent: 10/14/2020 2:27:52 AM
To: Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: Marianna's 1:1 Agenda 10.14.2020
Attachments: FW: OER org charts; FY21 OER AR Schedule.xlsx; October Deputy Senior Staff Meeting Materials

Hi Mike, please see below agenda items for my 1:1 on Wed 10/14.
Thank you.
Marianna

Marianna 1:1 October 14, 2020

Administrative Items for Small Staff

- OER org charts (see attached email)
- We will send you a full list of admin updates on Thurs evening (as usually)

FY21 Admin Reviews

- Christine will start sending final packages for your review later this week (and continue the next two weeks)
- FY21 OER AR schedule (attached file)
- Retreat on Dec 2, 3, or 9 (3 hrs; virtual) – Melanie is checking small staff's availability

Budget

- Nothing urgent; will have the budget meeting next week and discuss FY21 One-time Funding Requests (as you said -- Nov 5 is too early, but Feb 5 will be after the AR/retreat)
- CR thru Dec 11; 25% of the FY20 funding level; no big/new items while on CR

Staffing

- (b) (5)

Transition/Operations

- **OD Deputy Senior Staff meetings**
 - See attached email for October meeting's materials
 - I attended for Jodi and sent out materials to small staff. Continue or change?
- **Back-up for Melanie for small staff** (handling agenda, Zoom)? Was Dana; can be Claudette and me now.
- Anything else?

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: 10/9/2020 3:49:49 PM
To: Merts, Marianna (NIH/OD) [E] (b) (6)
CC: Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: FW: OER org charts
Attachments: OER Org Charts 10.25.2020.pdf

Flag: Followup

Perfect, Marianna, thanks so much! I'll put this on the agenda for next week's (October 16) Small Staff.

Mike

From: "Merts, Marianna (NIH/OD) [E]" (b) (6)
Date: Friday, October 9, 2020 at 10:09 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: OER org charts

Hi Mike,

As requested – please see attached pdf file with the OER org charts. The charts are as of 10.25.2020 (include new hires who will start during the next two weeks); federal staff only; without GS grades. This can be distributed to small staff. If small staff find this helpful, we can also do a version showing contract staff as well, except for eRA (because they have over 300 contractors).

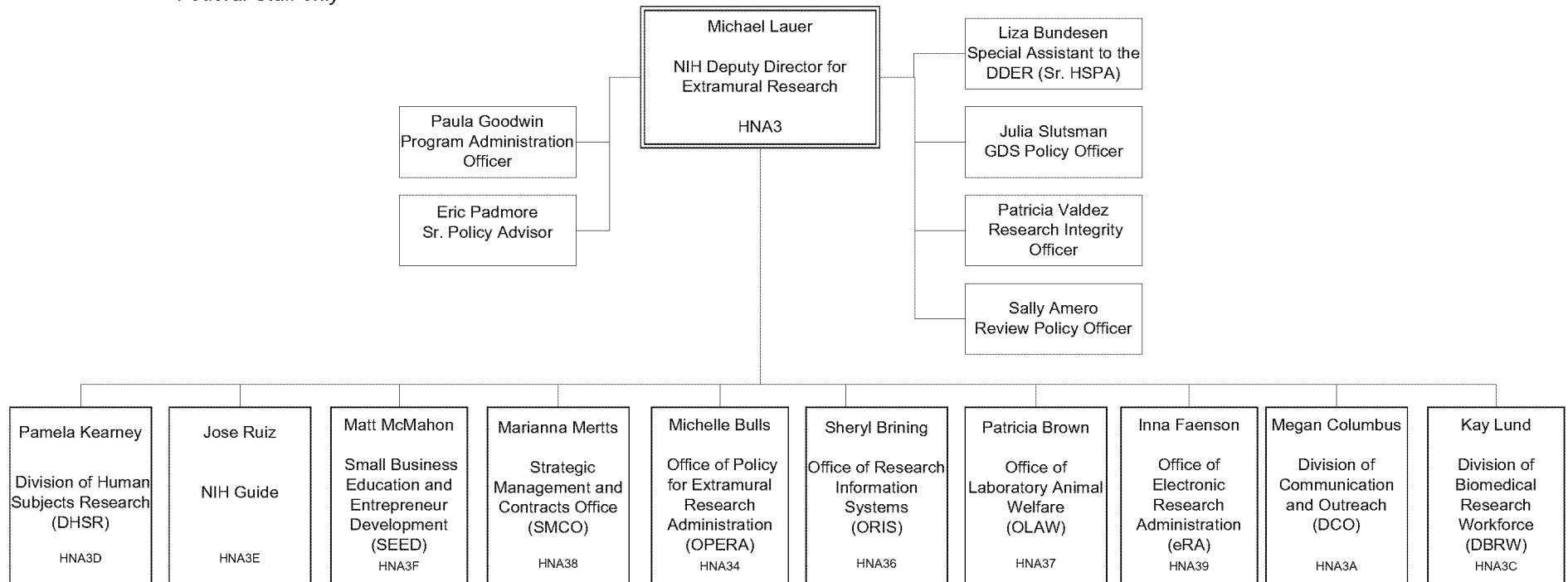
Best,
Marianna

(b) (6) work
(b) (6) cell

Office of Extramural Research (OER)

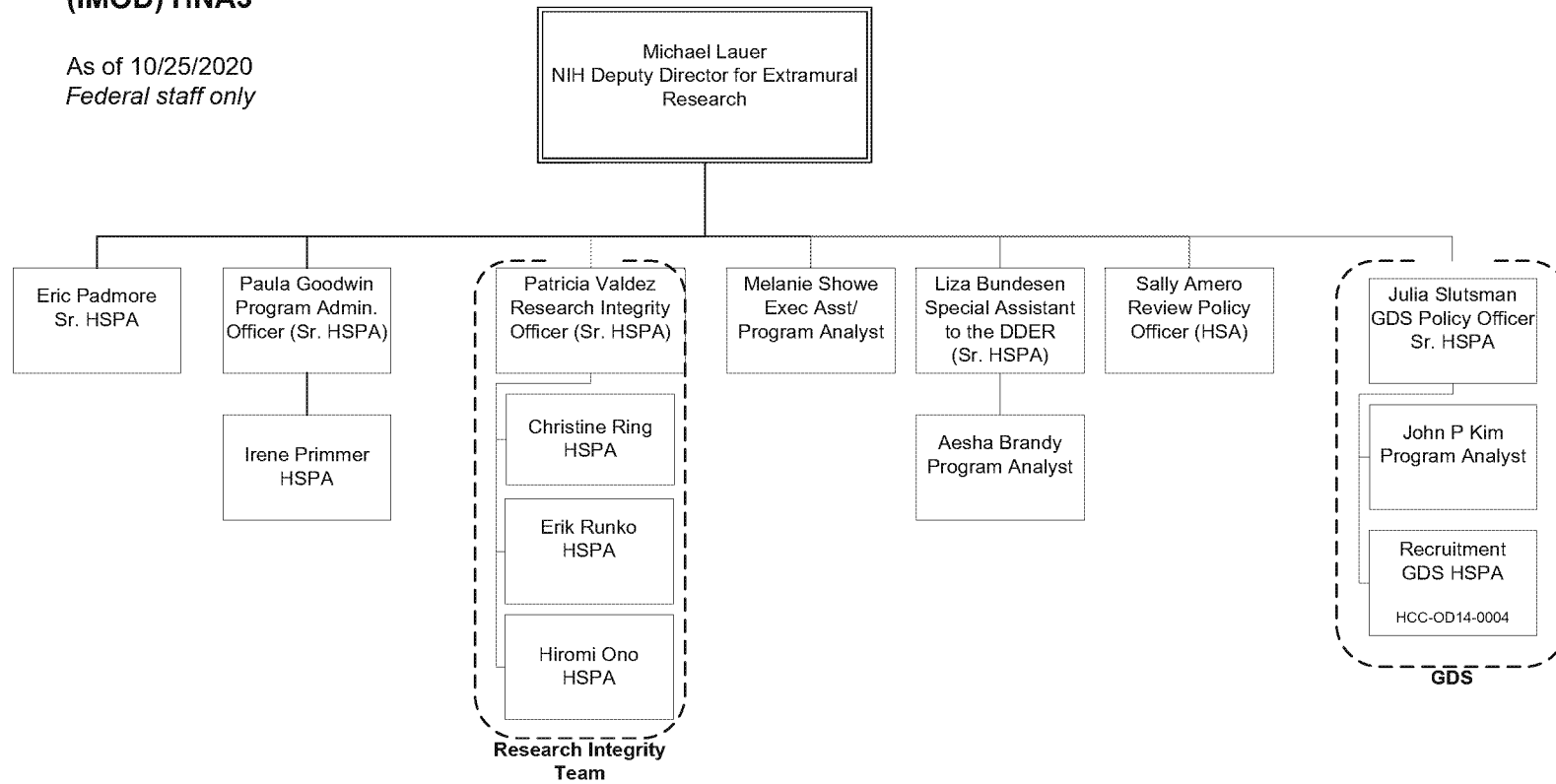
Org Chart as of 10/25/2020

Federal Staff only



OER
Immediate Office of the Director
(IMOD) HNA3

As of 10/25/2020
Federal staff only



SMCO
Marianna Mertts
See detailed chart

OPERA
Michelle Bulls
See detailed chart

SEED
Matt McMahon
See detailed chart

DHSR
Pamela Kearney
See detailed chart

NIH Guide
Jose Ruiz
See detailed chart

OLAW
Pat Brown
See detailed chart

ORIS
Sheryl Brining
See detailed chart

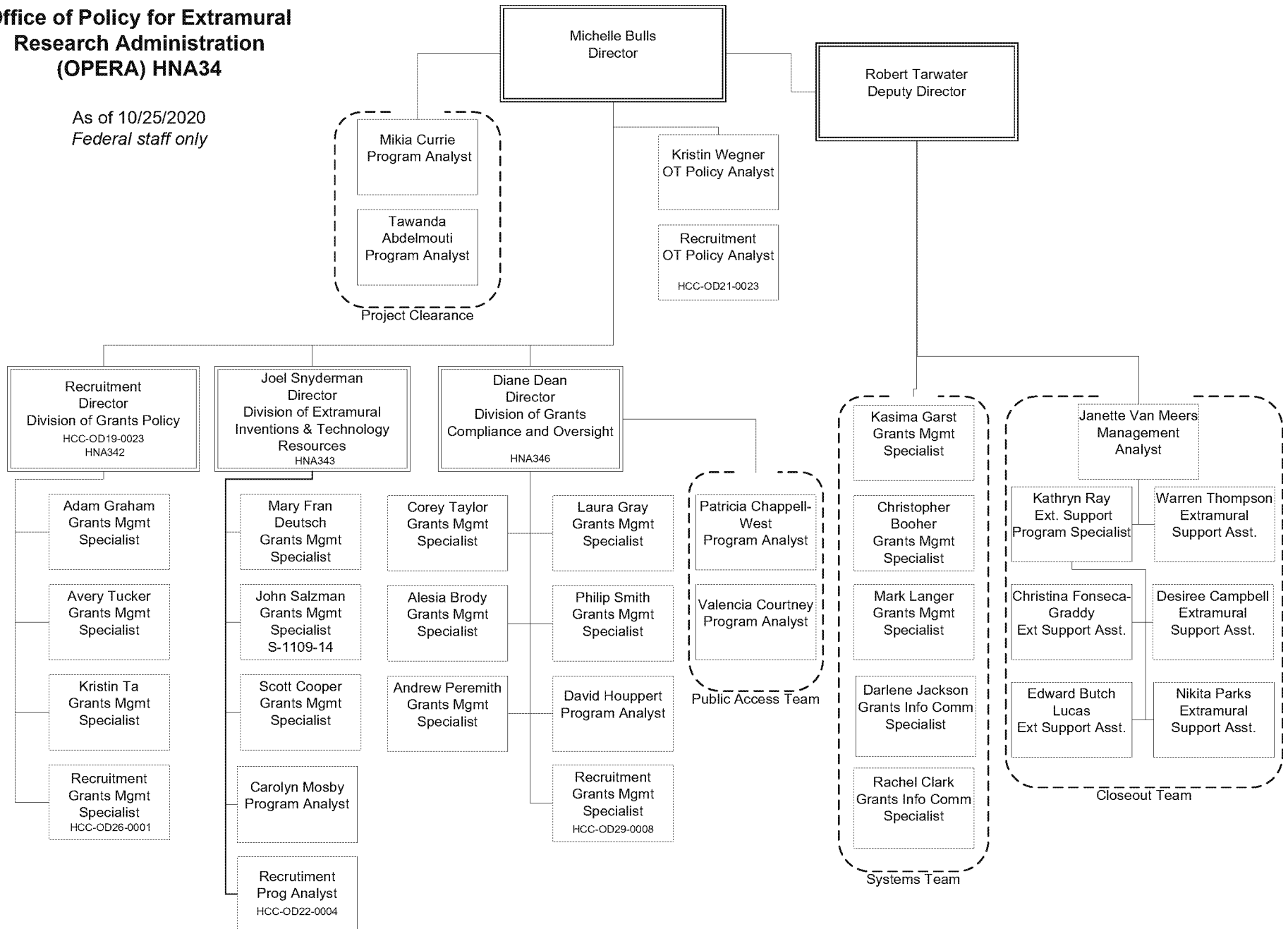
DCO
Megan Columbus
See detailed chart

DBRW
Kay Lund
See detailed chart

eRA
Inna Faenson
See detailed chart

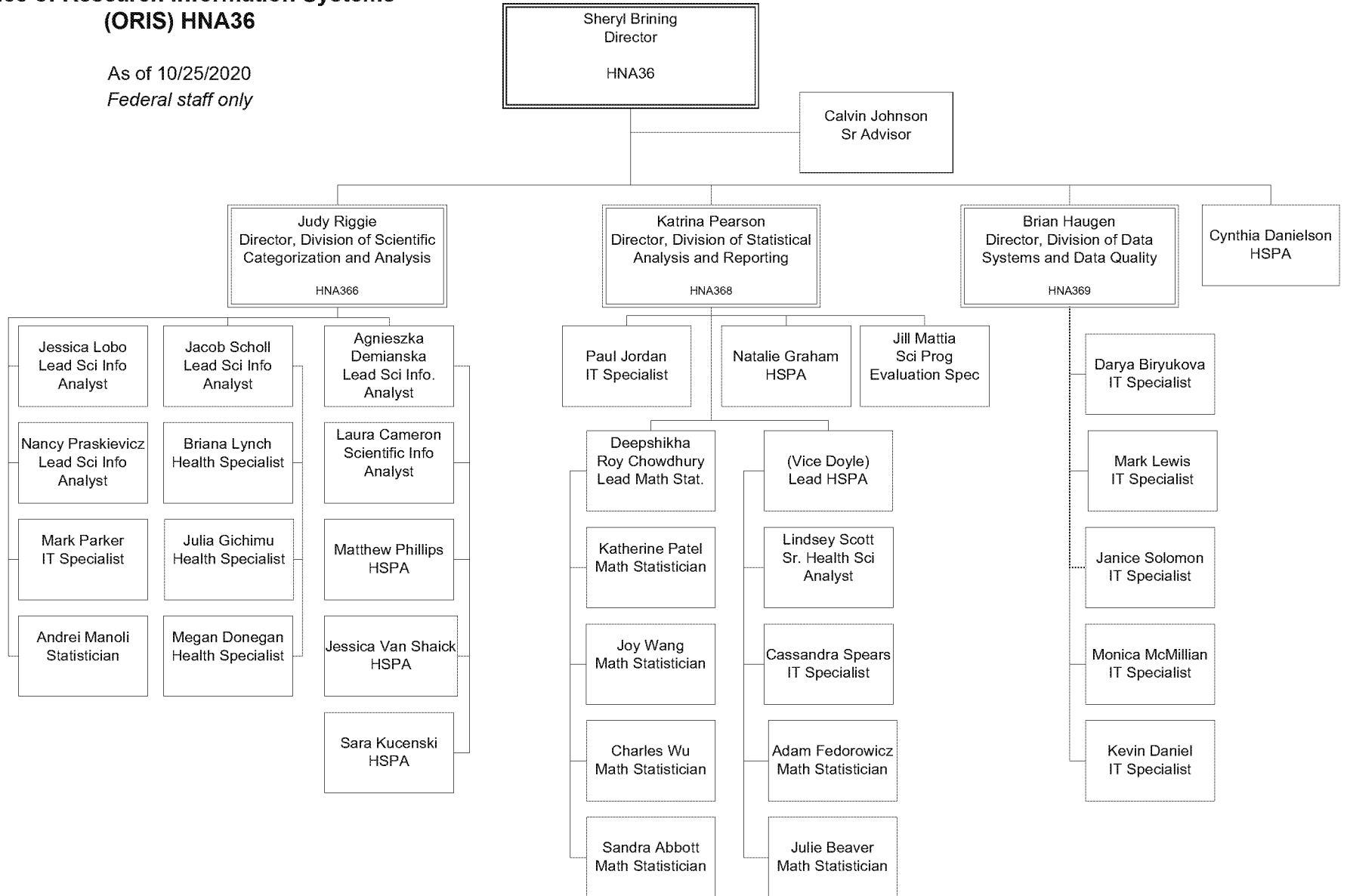
OER
Office of Policy for Extramural
Research Administration
(OPERA) HNA34

As of 10/25/2020
 Federal staff only



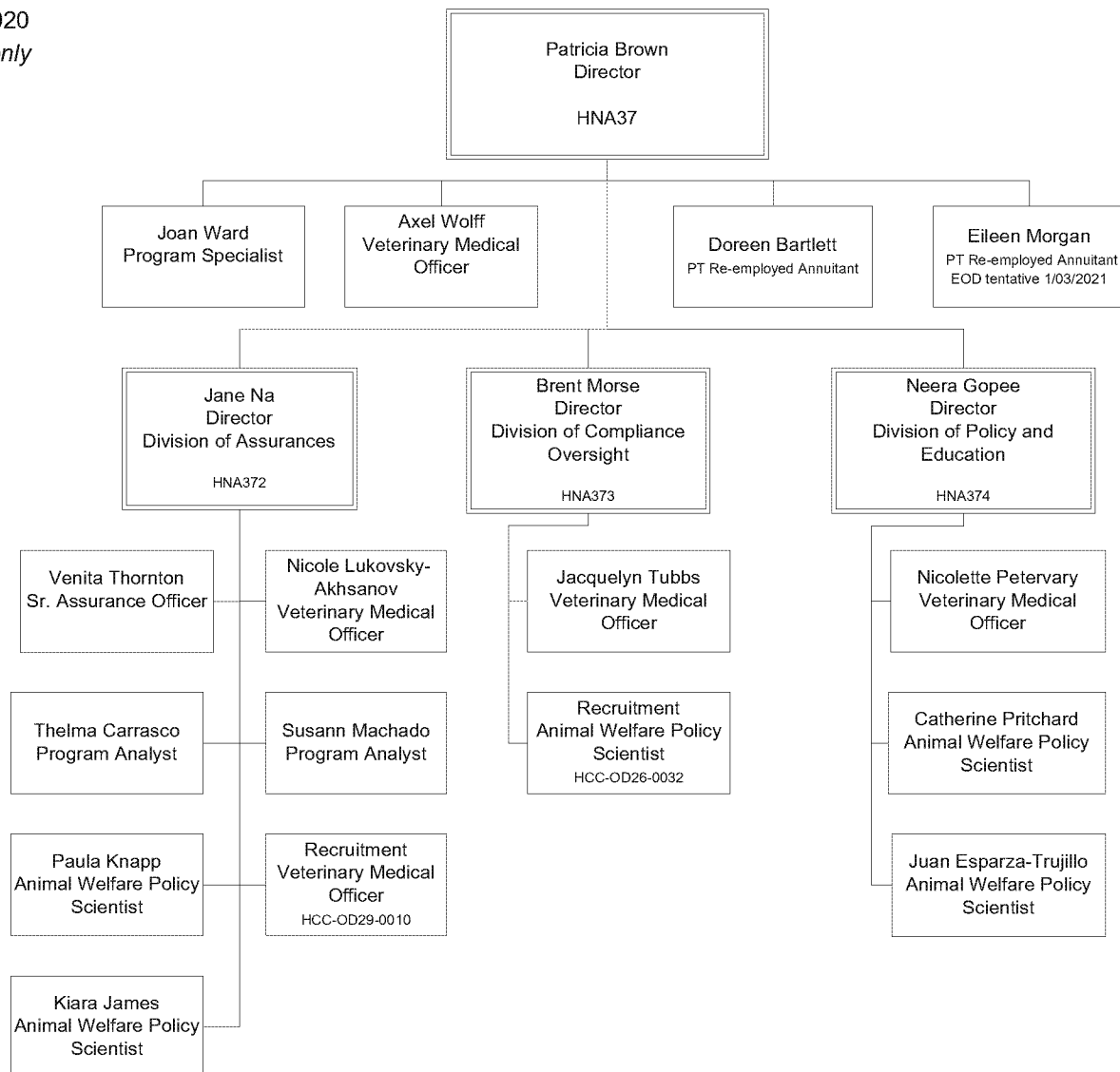
OER
Office of Research Information Systems
(ORIS) HNA36

As of 10/25/2020
Federal staff only



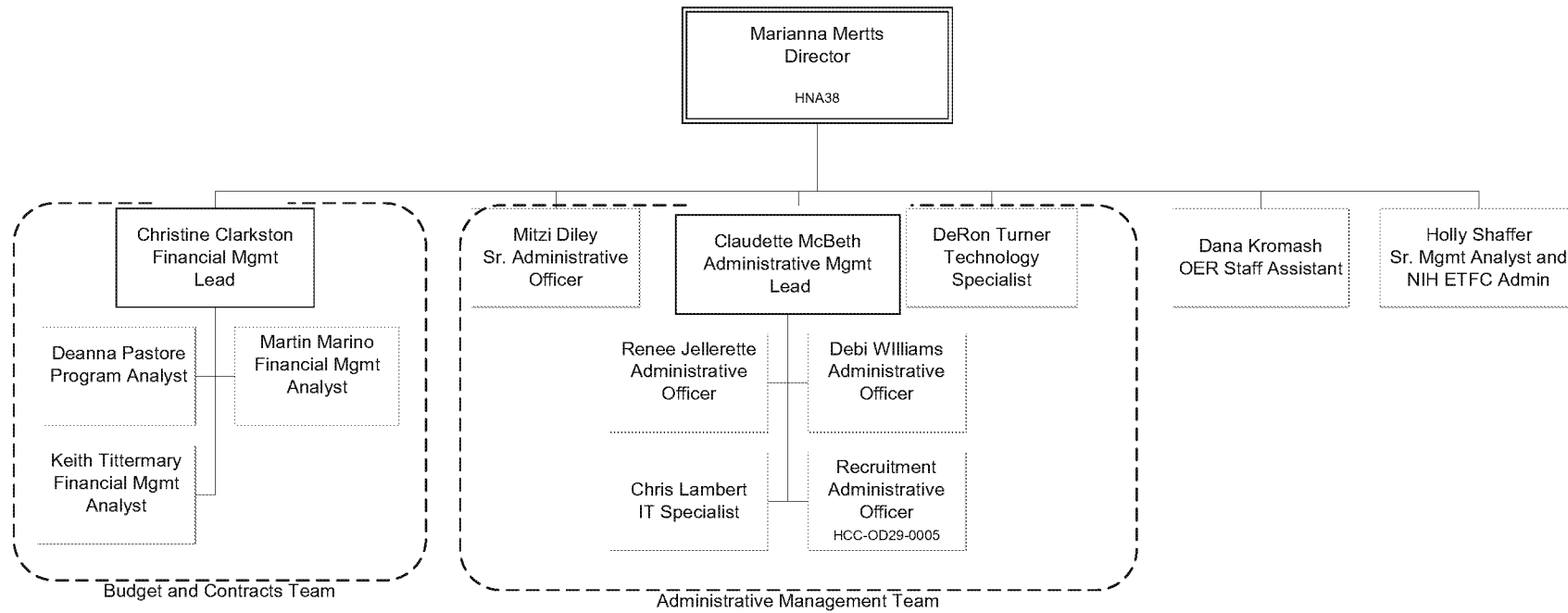
OER
Office of Laboratory Animal Welfare
(OLAW) HNA37

As of 10/25/2020
Federal staff only

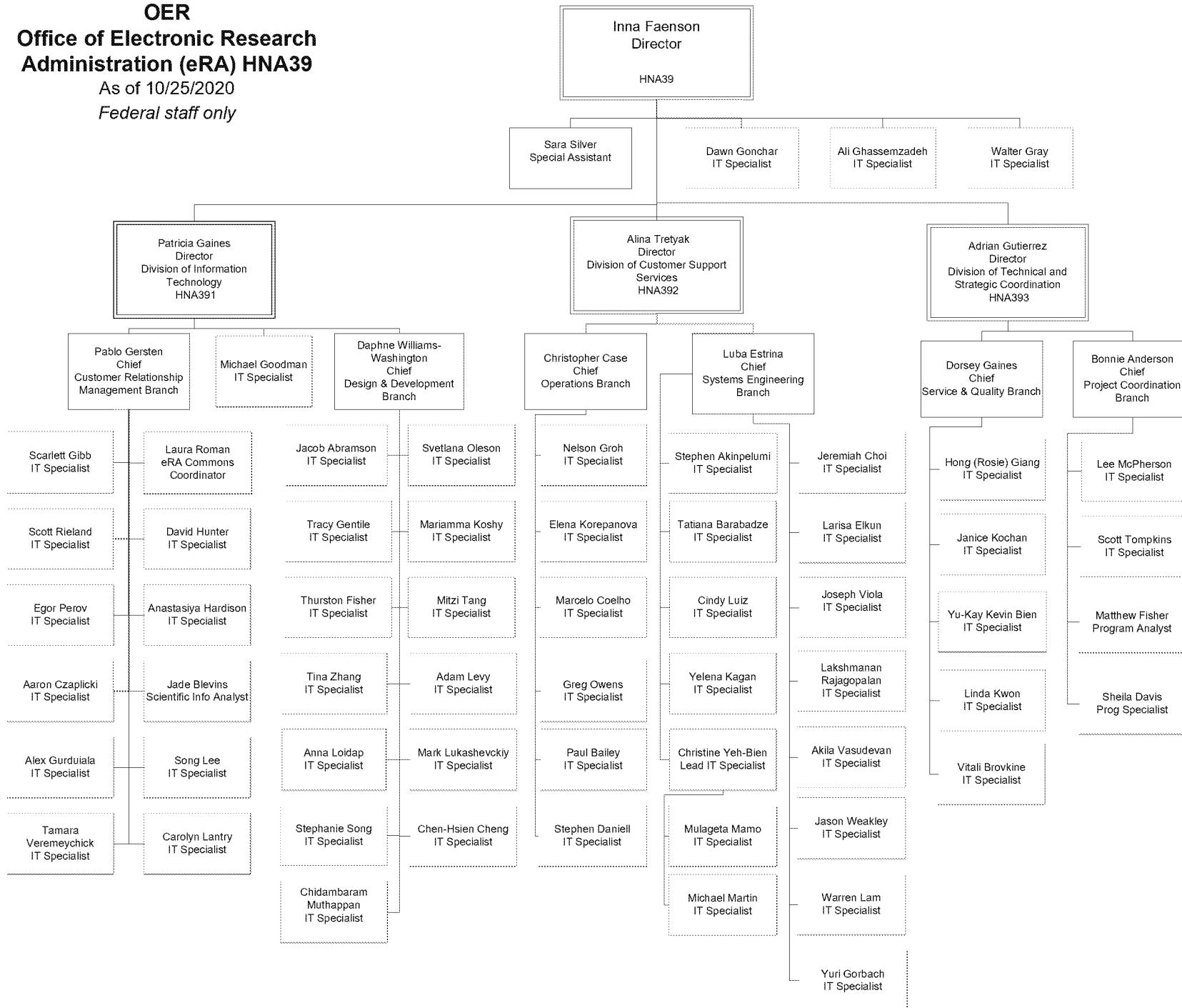


OER
Strategic Management and Contracts Office
(SMCO) HNA38

As of 10/25/2020
Federal staff only

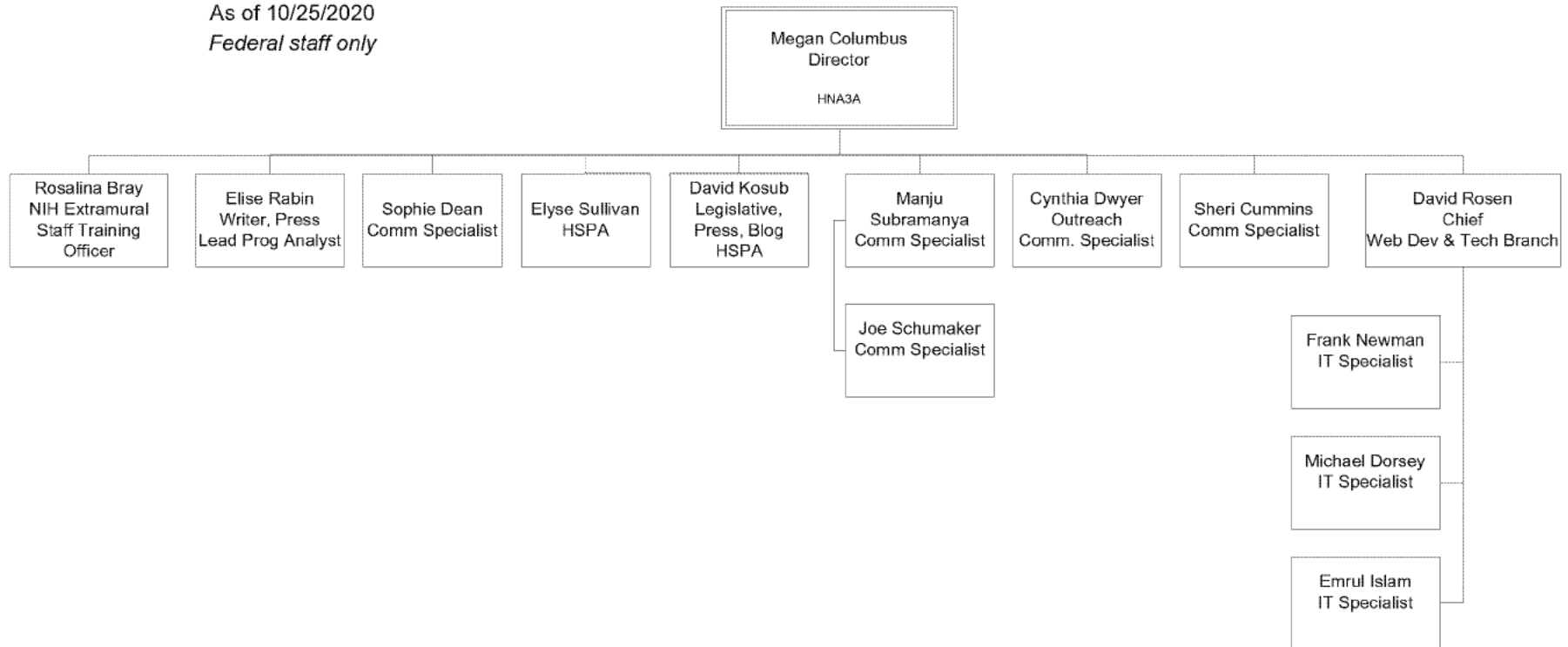


OER
Office of Electronic Research
Administration (eRA) HNA39
 As of 10/25/2020
Federal staff only



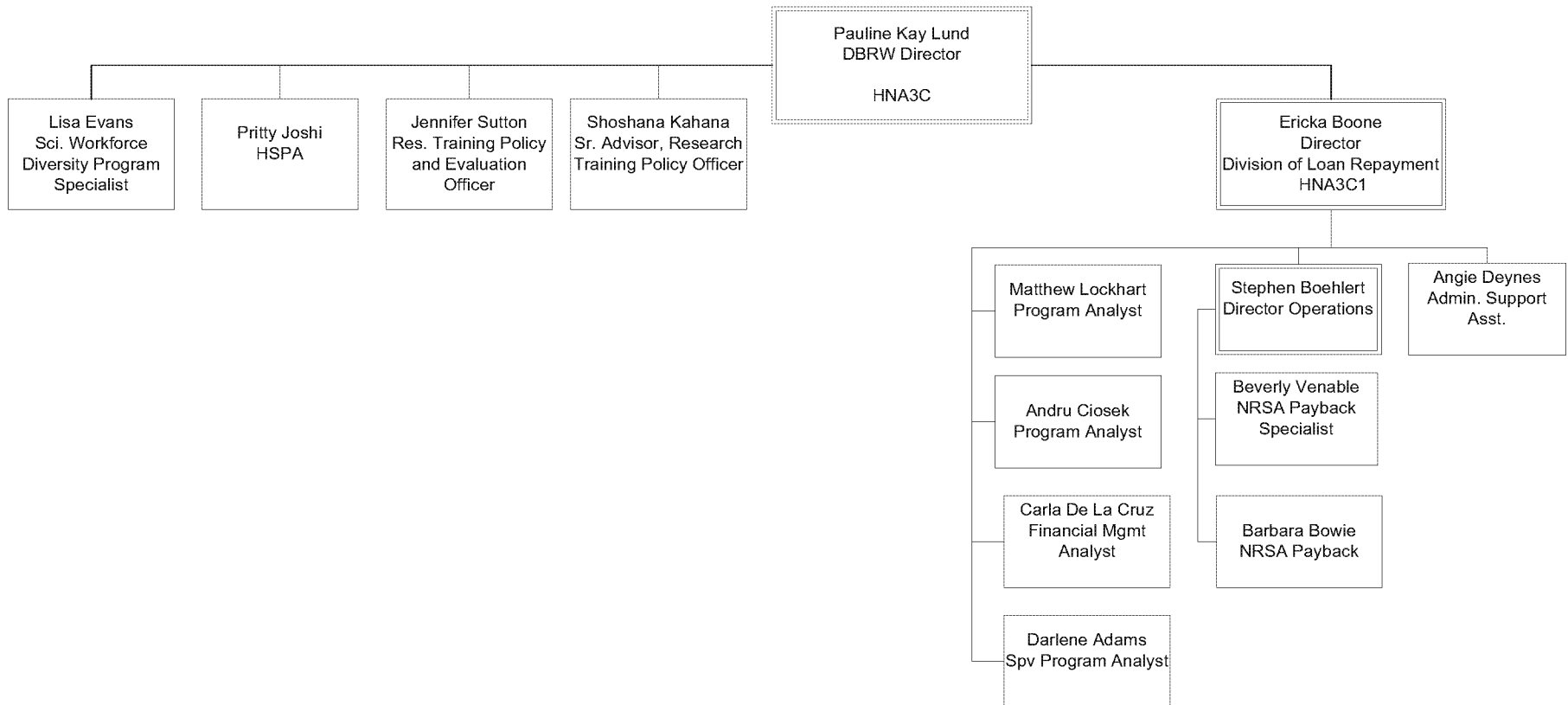
OER
Division of Communication and Outreach
(DCO) HNA3A

As of 10/25/2020
Federal staff only



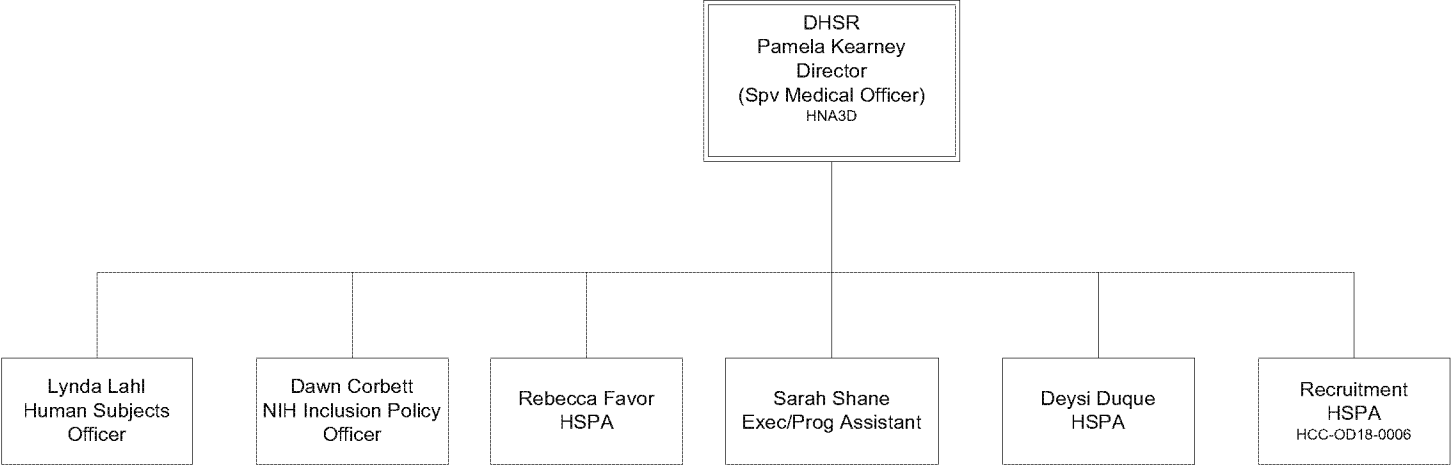
OER
Division of Biomedical Workforce (DBRW)

As of 10/25/2020
Federal staff only



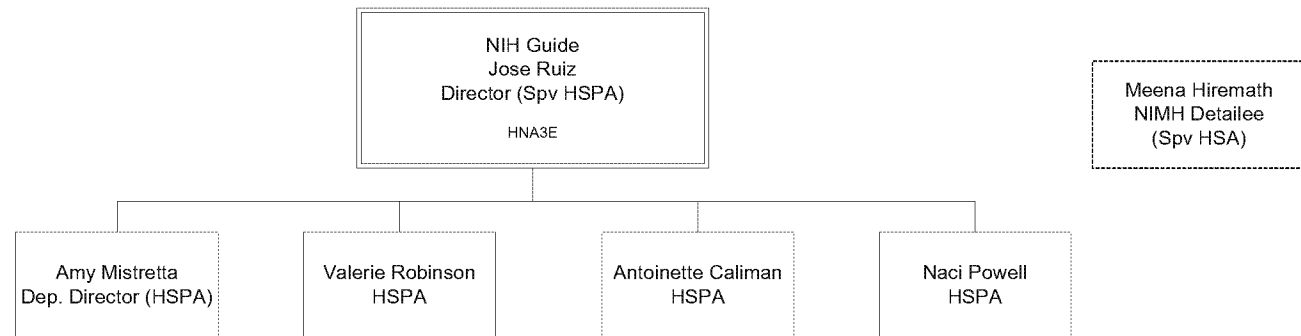
OER
Division of Human Subjects Research (DHSR)
HNA3D

As of 10/25/2020
Federal staff only



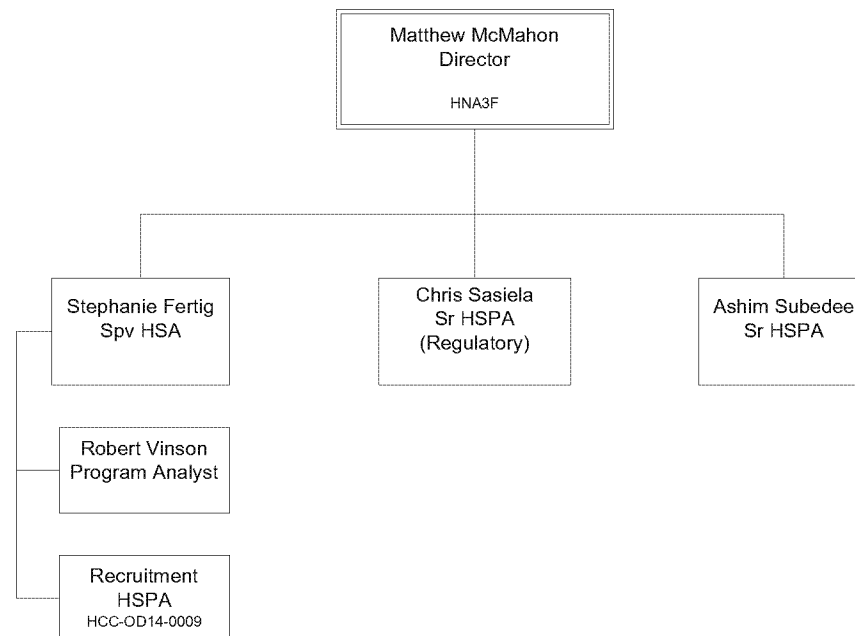
OER
NIH Guide
HNA3E

As of 10/25/2020
Federal staff only



OER
Small Business Education and
Entrepreneur Development (SEED)
HNA3F

As of 10/25/2020
Federal staff only



From: OD Executive Officer [REDACTED] (b) (6)
Sent: 10/13/2020 8:24:57 PM
To: OD Senior Staff Deputies [REDACTED] (b) (6)
Subject: October Deputy Senior Staff Meeting Materials
Attachments: Deputy Senior Staff Meeting--October 2020 Agenda.docx; OD DEPUTY SENIOR STAFF SEPTEMBER MEETING MINUTES.docx; Cyber Security Campaign_NTAG Update Presentation.pptx; NIH OD Workforce COVID19 Impact Survey_10_13_20_Final.pptx

Dear Colleagues,

Attached please find the agenda and materials for tomorrow's Deputy Senior Staff meeting. While this is our Round Robin month, we will be have a presentation on the NIH Technology Availability Guide and Cyber Security Campaign update. In addition, Dr. Charlene LeFauve will provide an overview of the NIH COVID-19 Impact Survey results. Note that materials and additional handouts are also located on the [Deputy Senior Staff SharePoint site](#).

Best

Daria

OD Deputy Senior Staff Meeting Minutes

Deputy Senior Staff Meeting
September 9, 2020
WebEx
10:00 a.m. – 11:00 a.m.

ATTENDEES:

Darla Hayes	ODEO	Janie Kuhn	ODEO
Tara Schwetz	IMOD	Charlene LeFauve	COSWD
Benjamin Butler	OGC	Jennifer Levithan	ODEO
Beth Chandler	OHR	Marianna Mertts	OER
Mike Chang	ORIP	Phil Osborne	OALM
Belinda Cowling	ODEO	Dennis Papula	OCIO
Wilma Cross	ODP	Rachel Pollock	ES
		Pat Porter	ODEO
		Scott Prince	OCPL
John Davis	OFM		
Kathy Farhat-Sabet	ODEO	Cecile Shaya	OB
		Elizabeth Spencer	ORWH
Claire Harris	OFACP	Leah Stroud	ODEO
Jeff Hayden	OMA	Richard Wyatt	OIR
Timothy Holtz	OAR	<u>Guest</u>	
		Kamilah Rashid	IMOD
Christine Hunter	OBSSR	Tonya Lee	
Scott Jackson	OSC		
Robin Kawazoe	DPCPSI	Sheria Washington (Exec Support)	ODEO

The meeting was called to order at 10:00 a.m.

- I. Resources for Families during the COVID-19 Experience- Tonya Lee
 - Division of Amenities and Transportation (DATS) NIH Child and Family Programs Services reached out to working caregivers to get a better sense of what their needs. The main categories were
 - Stress- managing many obligations
 - Workplace flexibility- understanding what's available and what their leadership supports
 - Care for School-age children- Managing virtual classes, while trying to manage their work functions is overwhelming
- II. Hatch Act- Avraham Gross
 - OD Town Hall
- III. Round Robin
 - OHR

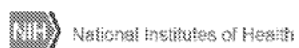
OD Deputy Senior Staff Meeting Minutes

- Health Benefits Elections Open Season is coming up. This season will be entirely virtual. More information will be shared in the coming weeks.
-

NEXT MEETING:

October 14, 2020, 10:00 a.m.–11:00 a.m.
Via WebEx

Protecting Our People and Our Science





The NIH Technology Availability Guide (NTAG)

Presented by the Collaboration Tools Team



National Institutes of Health

Cyber Safety. Protect our People and our Science.

NTAG – Increasing Access to Tools

The NIH Technology Availability Guide (NTAG) is an online list of approved collaboration tools for NIH users. This central source provides clear information on each tool, including its availability and how it is used at the NIH.

Current State

- **Plethora of collaboration tools in use across NIH** without clarity for users on which tools are approved for specific use cases
- Prevalent use of **free web tools** that may not have been evaluated for security
- **Decentralized decision-making** on which tools are permitted and why
- **NIH's digital assets at risk**



Enables Mission-Critical Activities

Provide access to the tools needed to enable mission success



Promotes IT Security

Ensure appropriate IT security practices and mitigate the risk of shadow IT



Protects NIH's Digital Assets

Maintain a robust, risk-based security posture to protect digital assets



Improves Transparency

Improve transparency across the NIH IT landscape



Enables Easy Access

Help staff easily find approved collaboration tools





Saves Money

Capitalize on opportunities for economies of scale and pooled resources



NTAG Tool Categories

NTAG includes the following three categories of tools:

	NIH ENTERPRISE STANDARD	NIH ENTERPRISE ENDORSED	IC ENDORSED
Who approves the technology?	The technology is approved by the NIH CIO for use by NIH staff.	The technology is approved by NIH CIO for IC adoption based on specific use cases.	The technology is approved by the IC Authorizing Official for IC use based on a specific use case. ICs complete the process for onboarding low-risk, high value technology and provide all evaluation artifacts to OCIO as a record. OCIO adds tool to IC Endorsed list.
To whom is the technology available?	The technology is generally available to all NIH staff and provided by CIT or OD (sometimes by an IC).	ICs determine the availability of the technology within their IC.	Artifacts may be shared and used by multiple ICs if the use cases and environment match.
Who is responsible for the technology?	NIH is responsible for the central management, support, licensing, and security of the technology.	The IC serves as the service provider and is responsible for the availability, deployment, management, support, training and security of the technology on behalf of NIH.	Artifacts may be shared and used by multiple ICs if the use cases and environment match.
What is an example?	 Microsoft Teams	 Zoom Zoom for Government	Propose a tool that meets your unique business need!



NTAG Website Features

NTAG Technology Availability Guide (NTAG): Collaboration Technology

NTAG provides a comprehensive list of tools and resources available to researchers and researchers. The guide is organized into categories such as: **Collaboration Technology**, **Security Tools**, **Training Resources**, and **Other Resources**.

The guide is organized into categories such as: **Collaboration Technology**, **Security Tools**, **Training Resources**, and **Other Resources**.

The guide is organized into categories such as: **Collaboration Technology**, **Security Tools**, **Training Resources**, and **Other Resources**.

1 Homepage

- Definitions of categories
- Complete list of tools
- Tool use cases

2 ToolPage

- Detailed tool information
- Contact information
- Links to resources

NTAG: Collaboration Technology Available at NIH

Tool Name	Category	Description
Zoom	Collaboration Technology	Zoom is a cloud-based video conferencing tool that allows researchers to collaborate in real-time. It is available to all NIH researchers and is used for a variety of purposes, including virtual meetings, webinars, and training sessions.
Microsoft Teams	Collaboration Technology	Microsoft Teams is a collaboration platform that integrates chat, video conferencing, and document sharing. It is available to all NIH researchers and is used for a variety of purposes, including virtual meetings, webinars, and training sessions.
Slack	Collaboration Technology	Slack is a collaboration platform that integrates chat, video conferencing, and document sharing. It is available to all NIH researchers and is used for a variety of purposes, including virtual meetings, webinars, and training sessions.

ToolPage

Tool Name: Zoom

Category: Collaboration Technology

Description: Zoom is a cloud-based video conferencing tool that allows researchers to collaborate in real-time. It is available to all NIH researchers and is used for a variety of purposes, including virtual meetings, webinars, and training sessions.

Contact Information: [Contact details for Zoom support]

Links to Resources: [Links to Zoom documentation, training materials, and other resources]

Next Steps

1**VISIT**

Visit the **NTAG homepage** to familiarize yourself with the resource; know what technology can be used securely.

2**PLAN**

Work with your CIO and ISSO to **promote NTAG within your IC**; FAQs, Talking Points and Sample Emails are available.

3**STAY INVOLVED**

Know what tools are used in your IC; Work with your IC ISSO to use the **IC Endorsed process** for onboarding low-risk technology.

Visit NTAG here: <https://sps.nih.gov/sites/ITMC/NTAG/~/SitePages/Home.aspx>

The Collaboration Tools Team

Co-Chairs

- Teresa Booher, OD/OCIO
- Peter Soltys, NINDS
- Ute Reichling, NCI

Team Members

- Carlos Sanchez, OD/EO
- Christine Salaita, OD/OALM
- Dustin Close, OD/OMA
- Marco Demartin, OD/OCIO
- Scott Sloper, OD/OCIO
- Thomas Cooper, NINDS
- Vikas Khator, NIDDK
- John Prue, NIDCR (former member)



Questions?

For more information contact the NTAG mailbox at NTAG@NIH.gov



Cyber Safety Awareness Campaign

Optimize IT Security



National Institutes of Health

Cyber Safety. Protect our People and our Science.

Campaign Objectives

The campaign is structured around the following key objectives:

- **Raise awareness of real-life, cyber-related risks** to our organization and how NIH is affected when cyber safety is not prioritized
- **Integrate cyber-safe behaviors into everyone's roles** to enable a community approach across NIH
- **Inspire NIH staff** to fully embrace the value of cyber-safe behaviors and practice them on a day-to-day basis



"Cyber safety is not solely the responsibility of staff in information technology, security, or privacy functions. **It is the concern of the whole NIH community.**"

Dr. Francis Collins (December 2019)

As you all know, the NIH Cyber Safety Awareness Campaign is an organization-wide initiative under the Optimize IT Security umbrella. And it has become one of the most significant ways that the NIH is helping all staff embrace our cyber-safe roles.

Just to recap, the campaign is focused on

Raising awareness of real-life cyber risks at NIH and the potential consequences of breaches

Integrating cyber-safe behaviors into all of our roles

Inspiring NIH staff to recognize the value of cyber safety and practice cyber-safe behaviors daily

Like Dr. Collin's said in his campaign launch message: "Cyber safety is not solely the responsibility of staff in information technology, security, or privacy functions. It is the concern of the whole NIH community."

Campaign Accomplishments

The Campaign team has made tremendous progress with accomplishing their anticipated outcomes.

24

Stakeholders interviewed for discovery purposes



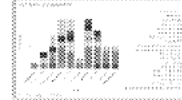
40+

Contributions on 3 IdeaScale challenges with +340 votes



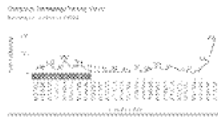
53

Stakeholder meetings to present about cyber safety



1.1k

Unique views on website homepage



159+

Campaign products developed



46

Cyber Champions volunteered to promote cyber safety at NIH



The campaign has been hard at work and our biggest achievement has been our people-centric approach, designing this campaign with the input of stakeholders across NIH who have helped identify priority topics and products. We have crowdsourced ideas from staff, interviewed NIH community stakeholders, and we constantly receive their feedback when presenting the campaign at meetings.

Thanks to this engagement with NIH staff, we have been able to create content, products and resources that are easy to understand, aligned to our NIH mission, and highly relatable so that we can embrace our responsibility towards cyber safety, just like Dr. Collins has encouraged us to do so in the past.

The campaign has used IdeaScale to crowdsource campaign ideas from staff and implement them across the NIH community. As of this month, three IdeaScale challenges have been launched producing over 40 contributions: the first focused on how to learn about cyber-safe behaviors, and the second focused on collecting real-life cyber risk stories. The third challenge just launched and is centered around what kinds of activities the campaign should conduct during National Cybersecurity Awareness Month in October to drive the most awareness/engagement.

Conducted 24 stakeholder interviews to learn about staff's pain points, challenges and behaviors around cyber safety.

53 Meetings with NIH Groups to ensure that the messaging resonates with target audiences

To ensure that everyone is equipped with the information they need to embrace cyber-safe behaviors, the campaign is addressing each of the priority topics identified by stakeholders including:

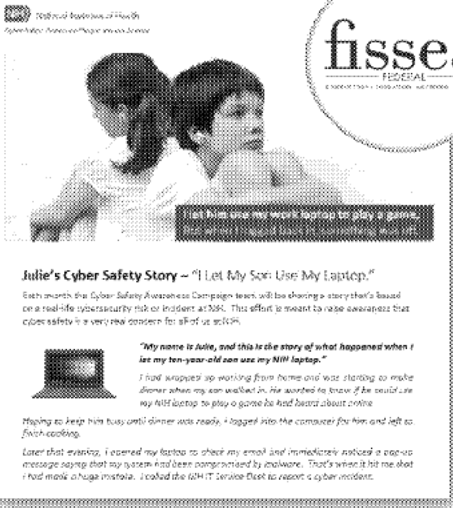
- Cyber-Safe Leadership
- Remote Work
- Sensitive Information
- Acquisitions & Supply
- Phishing
- Collaboration Tools

The campaign created targeted communications products preferred by NIH stakeholders and further disseminated at standing meetings to ensure messaging authenticity as we engage with NIH's diverse stakeholder landscape. These products include:

- Dedicated website
- Engaging Events, like Virtual Cyber Safety Family Day
- Leadership Toolkit
- Cyber Storytelling Emails
- Tips & Tricks
- Cyber Champion Program

An Award-Winning Campaign!

The campaign participated in FISSEA's 2020 Security Awareness and Training Contest and was selected as a winner in the category of **Best Newsletter**.



Julie's Cyber Safety Story – "I Let My Son Use My Laptop."


Each month the Cyber Safety Awareness Campaign team will be sharing a story that's based on a real-life cybersecurity risk or incident at NIH. This effort is meant to raise awareness that cyber safety is a very real concern for all of us at NIH.

"My name is Julie, and this is the story of what happened when I let my ten-year-old son use my NIH laptop."

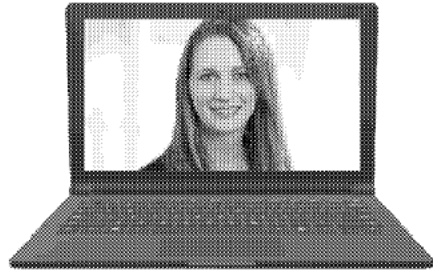
I had woken up working from home and was starting to make dinner when my son walked in. He wanted to know if he could use my NIH laptop to play a game he had heard about online.

Hoping to keep him busy until dinner was ready, I logged into the computer for him and left to finish cooking.

Later that evening, I opened my laptop to check my email and immediately noticed a curious message saying that my system had been compromised by malware. That's when it hit me that I had made a huge mistake. I called the OIT Service Desk to report a cyber incident.



This idea was crowdsourced from staff and has now been taken to a video format.



See all videos on the campaign website:
<https://ocio.nih.gov/infoSecurity/Pages/Sharing.aspx>

Our campaign won an award! We participated in FISSEA's 2020 Security Awareness and Training Contest and NIH was selected as a winner under the category of **BEST NEWSLETTER**.

The Campaign submitted our monthly Cyber Storytelling Newsletter which shares fictionalized scenarios about real-life cyber incidents at the NIH to help staff fully understand the importance of cyber safety and the role they play in protecting the organization from risk. The best part of this recognition, is that this idea of cyber stories was an idea crowdsourced from NIH staff, and it's just a great example of how the campaign turns your ideas into action!

And since our stories have had so much success, we have decided to take them to the big screen and record videos of NIH leaders and staff sharing their experiences with cyber risk. For example, many NIH leaders have been exposed or fallen victim to phishing and spoofing and different types of social engineering. So getting a leader like Dr. Schwetz on video talking about a real instance where this happened, make this story so much more impactful.

Let's take a look... (show video)

What did you all think? We are happy you liked it, so please help us share it to keep spreading cyber safety awareness!

Any questions? Thank you!



So let's jump into talking about our plans for National Cybersecurity Awareness Month!

Objectives for NCSAM

NIH's participation in National Cybersecurity Awareness Month aims to reinforce the broader campaign objectives in the following ways:

- 1 Reinforce year-round cybersecurity awareness and education efforts and help NIH staff move to the next level of cyber safety understanding and commitment** by providing microtrainings in engaging, non-traditional formats such as live panels and games
- 2 Create external alignment with other federal agencies' cybersecurity awareness and education strategies** through collaboration with partners such as CISA and HHS
- 3 Empower Cyber Champions and other NIH staff to own their roles** in protecting our people and our science through cyber safety in order to promote long-term sustainment of campaign impact

As you may know, NCSAM is a national initiative led by the Cybersecurity and Infrastructure Agency (CISA) that is held in October of each year to promote awareness of cyber safety across industries and sectors. NIH's participation in this event will be the culmination of the campaign's efforts over the course of the preceding year

Our goal for National Cyber Safety Awareness Month is to reinforce broader campaign objectives to:

Reinforce cybersecurity awareness so that staff gain understanding and are committed to protecting NIH year-round. As Comms Directors, you have an important role in this objective, which I'll explain in more depth in a few minutes. Create alignment with other federal agencies like HHS and CISA, leveraging CISA's publicly available resources while also partnering with HHS to align our parallel efforts. And finally empower Cyber Champions and NIH staff to own their roles in protecting our people and our science so that cyber safety awareness efforts are promoted long-term.



Activities for NCSAM

Activities cover a wide variety of topics and channels, all focused on creating engaging, accessible touch points with NIH staff that help them understand their own responsibility for cyber safety.

UPCOMING EVENTS & ACTIVITIES

**Cyber Storytelling Videos**

Videos and emails from NIH leaders sharing stories about real-life cyber safety risks and incidents at the NIH

**Virtual Cybersecurity Escape Room**

Virtual escape room experience provided by HHS challenging participants to put their cyber safety knowledge to the test in real-life scenarios

**Panels with NIH and HHS Experts**

A look into the everchanging world of cybersecurity through conversations on securing medical devices, COVID-19-related cyber risks, and more

**Live Cyber Safety Games**

Educational and entertaining virtual sessions featuring interactive activities on encryption, phishing, and other cyber safety topics

**Virtual Cyber Safety Sessions for Families**

The return of the popular Virtual Cyber Safety Family Day event held last May, inviting NIH families to participate in an interactive virtual trivia game



Questions? Email Cybersafety@NIH.gov

The campaign used its people-focused approach to engage stakeholders from a variety of ICs to collect and rank suggestions for the most impactful activities and events to offer during NCSAM. We received feedback from our People and Culture Working Group, NIH Cyber Champions and three different crowdsourcing exercises with a total sample group of over 50 NIH staff members

Staff requested a strong leadership presence, a variety of digital products as well as gamification-driven micro trainings to guide NCSAM awareness efforts. That's why we will have a series of weekly cyber storytelling videos from leaders at the NIH, a virtual cybersecurity escape room sponsored by HHS, panels on cybersecurity with NIH and HHS experts, and live educational cyber safety game sessions including the return of the popular Virtual Cyber Safety Family Day event held last May, inviting NIH families to participate in an interactive virtual trivia game

NCSAM Calendar of Events

The Campaign Team has the following activities and events planned *(all subject to change or evolve)*.

SUN	MON	TUES	WED	THURS	FRI	SAT
KEY:  NIH Activity  HHS Partnership						
	<i>Available on Monday, September 28:</i> <ul style="list-style-type: none"> • Dr. Collins launch email and storytelling video • Updated website • Digital and on-site branding 			1 NIH Leadership Email from Andrea Nonts HHS Kick-Off Email	2	3
4	5 Email from Amber Simco to OCIO	6 NIH Leadership Email from Dr. Lauer with Cyber Video	7 Virtual Event: HHS Hacking Demo	8	9 Virtual Event: NIH Cyber Safety & COVID-19	10
11	12	13 NIH Leadership Email from Dr. Schwetz with Cyber Video	14 Virtual Event: HHS Cybersecurity Self-Service Training	15	16 Virtual Event: NIH Trick or Treat Phishing Game with OCIO	17
18	19 NIH Cyber Champion Forum	20 NIH Leadership Email from Dr. Gottesman with Cyber Video	21 Virtual Event: HHS Briefing on Securing Healthcare Devices	22	23 Virtual Event: Virtual Cyber Safety Family Day	24
25	26	27 NIH Leadership Email from Dr. Johnson with Cyber Video	28 Virtual Event: HHS Cybersecurity Escape Room	29 Fireside Chat: "Ask the CISO: Amber Simco" (Tentative)	30 Virtual Event: NIH Sensitive Info. Game	31 Note: Follow-up email from Andrea Nonts released Mon, November 2

So this is how our activities come together on the calendar for the month of October, packed with a robust series of events designed to bring awareness and education to every community within NIH through a variety of media channels. Its basically Leadership Emails and HHS events at the beginning of the week, and NIH events and interactive games at the end of the week.

We are already half way along the month so we want to ask that you motivate you staff to register on:

Trick or Treat Phishing Game - which we will test people's skills and knowledge around different phishing tactics

Virtual Cyber Safety Family Day - where both parents and kids will be able to learn about cyber safety through a trivia game

Fireside Chat with Amber Simco - where staff have the opportunity will be able to ask our CISO questions around her experience

Sensitive Information Game - where will we go over the basics on encryption and passwords

Registration for events and activities is on the Cyber Safety Awareness Campaign Homepage, hosted on the OCIO website.

How You Can Support?

1

Spread the word about NCSAM so that others can get excited and prepared for upcoming events and activities. We will share resources you can leverage!

(<https://ocio.nih.gov/InfoSecurity/Pages/CyberSafetyLeadership-Toolkit.aspx>)



2

Motivate your staff to register for NCSAM activities and events! And if YOU want to organize a meeting in your office to talk about cyber safety, let us know and we will gladly support your effort with talking points, videos and decks.

Please help the campaign spread the word about all the upcoming NCSAM events and activities. We will share an NCSAM Supporter Toolkit with resources that you can leverage such as Zoom Backgrounds and Email Signatures! We will distribute these to you via email after this meeting.

All information about events will be on our Campaign Website. Please motivate others to register and participate.

On the website you have a Cyber Leadership Page, which hosts talking points if you or your Director want to talk about a specific Cyber Safety topic, or a standard slide deck if you want to give a presentation! If you do send something out, or you get Cyber Safety as a topic on an agenda for a meeting, PLEASE let us know! We are here to support you to deliver the most impactful activities possible.

NIH Workforce COVID-19 Impact Survey

Deputy Senior Staff meeting

October 14, 2020

Charlene E. Le Fauve, Ph.D.

Senior Advisor to the NIH Chief Officer for Scientific Workforce
Diversity



National Institutes of Health

Office of the Director

Scientific Workforce Diversity

Background

- The Goals of the Chief Officer for Scientific Workforce Diversity (COSWD) are:
 - To expand scientific workforce diversity as a field of inquiry
 - Build and implement evidence related to diversity outcomes
 - Understand the role of sociocultural factors in biomedical recruitment and retention
 - Sustain nationwide workforce diversity with seamless career transitions
 - Promote the value of scientific workforce diversity
- COSWD has an **immediate and urgent need to assess the impact of COVID-19** on the biomedical workforce as well as the full NIH staff base, particularly for underrepresented and/or vulnerable populations
- This includes **NIH employees, Fellows, students, and others who support the NIH Intramural Research Program** at NIH campuses across the country

Background – Survey Development and Distribution

- Questions were developed by the **NIH Survey Development Group** and a team from Deloitte Consulting's Survey Research and Analytics Center
- The questions were refined based on past NIH survey experiences
- The web survey was administered from **July 14 to July 28, 2020**
- The following were **invited** to complete the survey:
 - **Federal Employees** (research and administrative staff)
 - **Fellows**
 - **Contractors** (with company permission)
 - **Volunteers**
- All questions were **optional**
- A **51.2% response rate** (16,892 out of 33,013) was achieved

Background – Survey Objectives

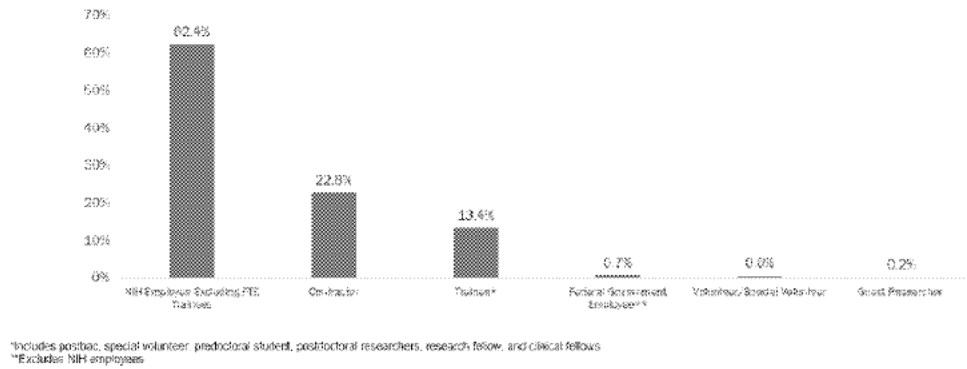
- **Objective 1:** Understand the impact of COVID-19 on the NIH workforce overall
- **Objective 2:** Assess COVID-19's impact on underrepresented and vulnerable populations
- **Objective 3:** Identify groups that may be newly vulnerable due to factors related to COVID-19
- **Objective 4:** Produce findings that will enable the NIH to implement interventions to mitigate COVID-19's impact on the workforce

NIH wide Data

Trainees

- The majority (62.4%) of respondents are NIH employees; the remainder are contractors, trainees, or other

Which of the following best describes your employment mechanism at NIH? (Q1)
n=16,868



Across all of NIH

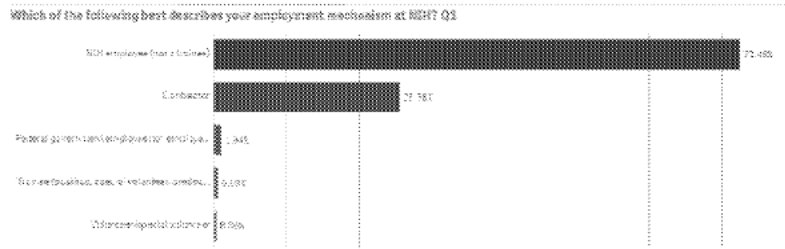
diversity.nih.gov

Response data is from 2,221 participants (OD, all locations)

Office of the Director Data

NIH Role

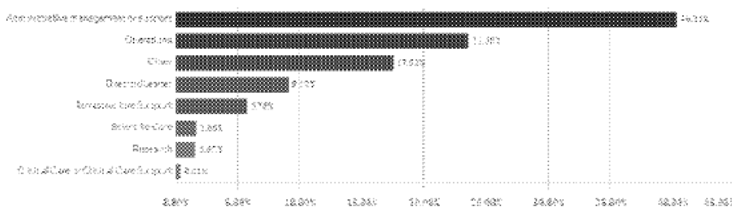
Response data from **2,221** participants, covering all OD locations



72.45% identified as NIH Employee (Not a trainee)

NIH Role and Workplace

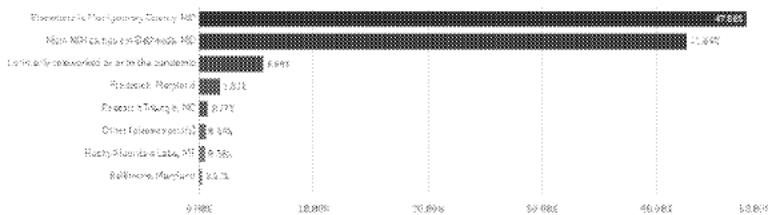
NIH Primary Role



Response data from 2,221 participants, covering all OD locations

63.87 % identified their primary role as either in administrative management, support or Operations.

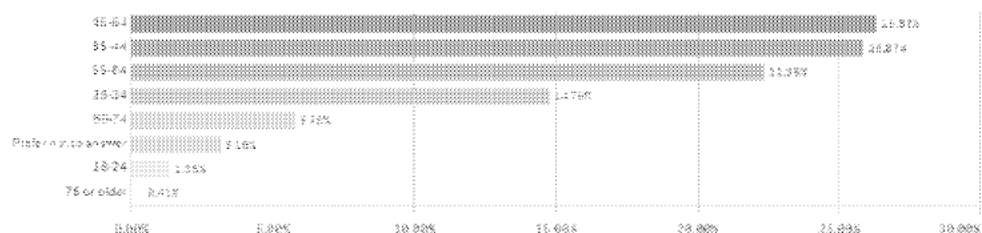
Where is your primary NIH workplace? ODs



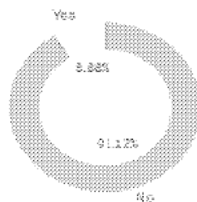
90.52% of the respondents identified their primary NIH physical workplace location to be in Montgomery County, MD (NIH Main campus or elsewhere in the county)

Demographic Information

What is your age? Q9



Do you have a disability? Q11CR



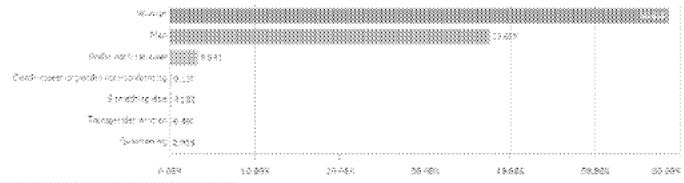
52.19% of the 2,221 respondents is aged 35-54 and 22.35% between 55-64

Demographic Information

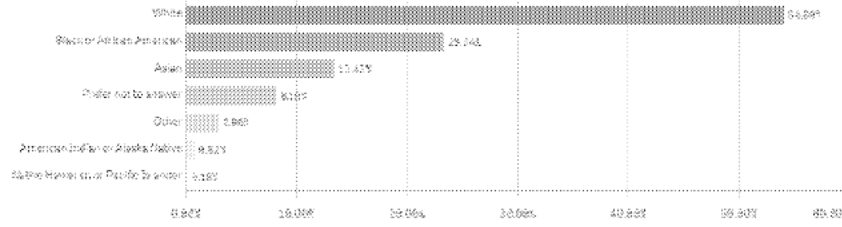
Are you of Hispanic, Latino, or Spanish origin? Q1A.A



What is your gender identity? Q1B.B



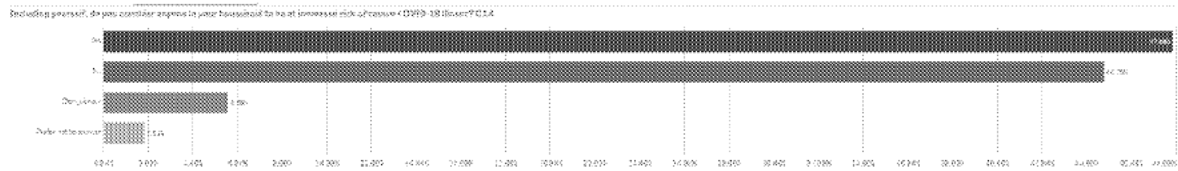
With which race do you most identify? Q1C.BP



58.65 % said their gender identity is a Woman

54.09% most identified their race as White, 23.34% as Black or African American, 8.19% preferred not to answer and 3.96% as Other, American Indian or Alaska Native, or Native Hawaiian or Pacific Islander.

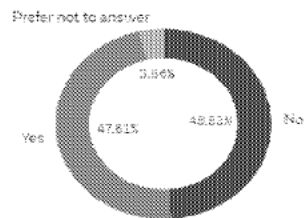
Caretaking Responsibilities



47.88 % of 2,221 participants consider someone in their household to be at increased risk of severe COVID-19 illness

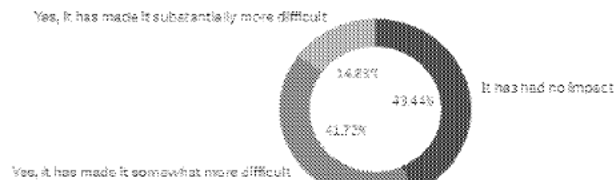
Caretaking Responsibilities

Do you have caretaking responsibilities for individuals who live in your household and/or family members who do not live with you? Q12



47.61 % of the 2,221 participants have caretaking responsibilities.

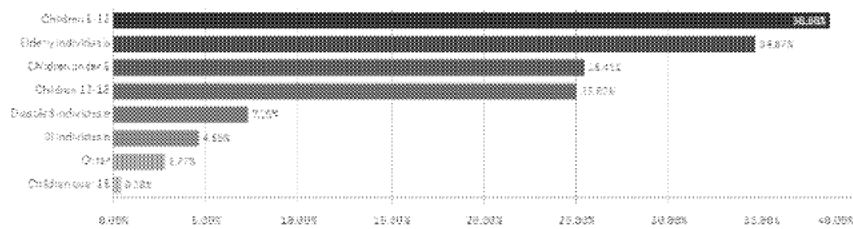
Have your caretaking responsibilities made it more difficult to complete your work responsibilities? Q13C



56.55 % of the 2,221 participants believe caretaking responsibilities affected their work responsibilities.

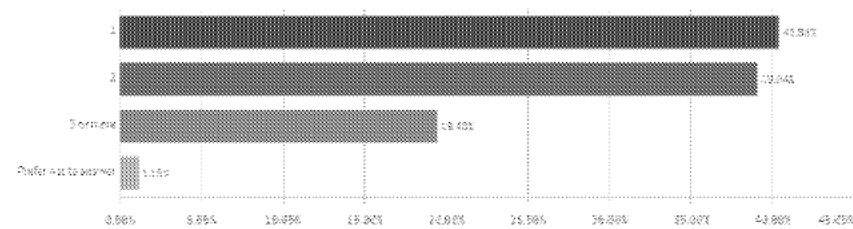
Caretaking Responsibilities

Whom do you provide care for? Q13A



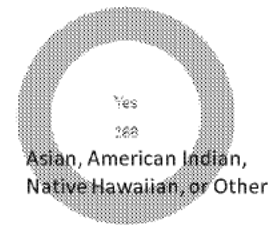
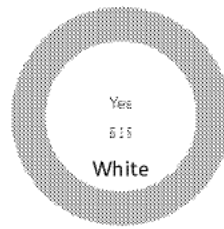
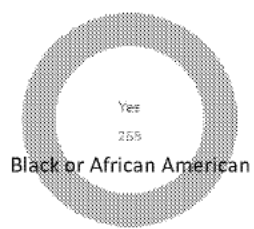
89.11 % provides care for children 18 and under, and 34.67 % for elderly individuals

How many people do you provide care for? Q13B



98.85 % of 2,221 participants said they cared for at least 1 person

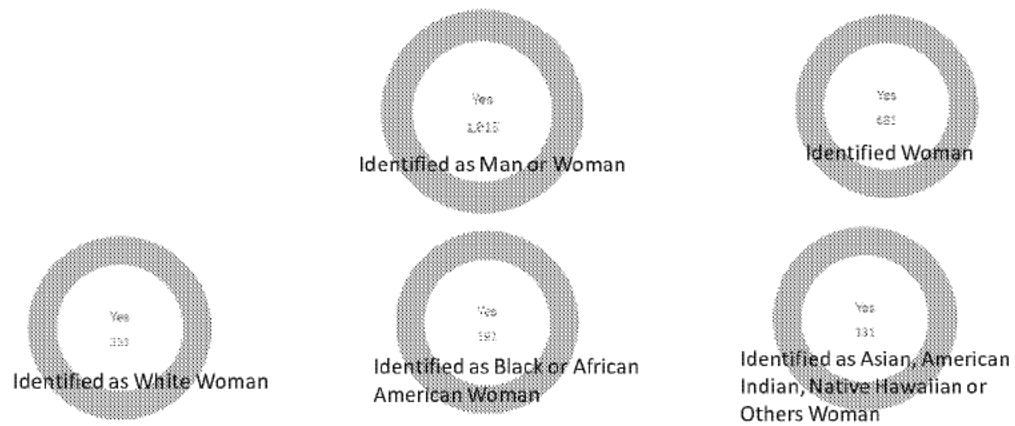
Caretaking Responsibilities



Of 2,221 OD participants, 1,015 identified themselves as either Man or Woman and indicated that they have caretaking responsibilities. 258 identified as Black or African American, 515 as White, and 200 as Asian, American Indian, Native Hawaiian or Other.

Caretaking Responsibilities

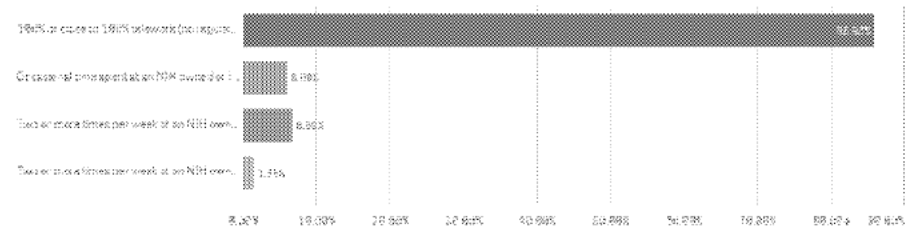
Do you have caretaking responsibilities for individuals who live in your household and/or family members who do not live with you? Q12



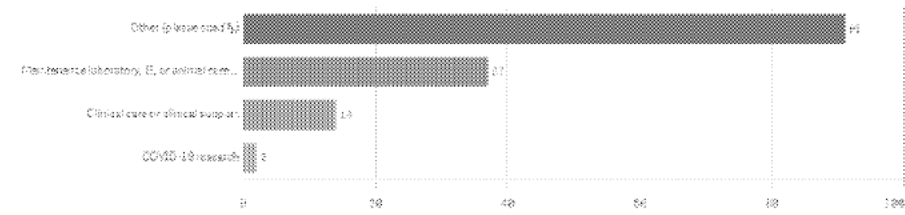
Of 2,221 OD participants, 1,015 identified themselves as either Man or Woman and indicated that they have caretaking responsibilities. 682 were women, of which 192 were Black or African American, 131 were Asian, American Indian, Native Hawaiian or Others

Maximal Telework Experience

What best describes your work status since maximum telework began? Q15A

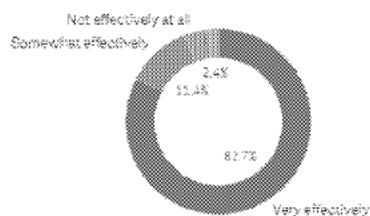


You indicated you work at an NIH building two or more times a week. What is the primary purpose? Q15B



Maximal Telework Experience

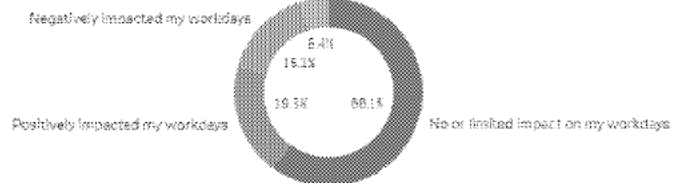
How effectively do you believe your role can be performed at the NIH via telework? Q18



94.1% believe their role can be effectively performed via telework

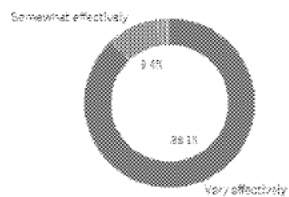
How has being physically separated from co-workers impacted you? Overall it has... Q22

Not applicable (I have been coming to the workplace regularly and interacting with co-workers)



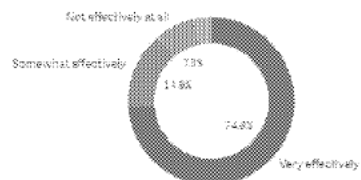
Maximal Telework Experience

How effectively do you believe your role can be performed at the NIH via telework? Q16



N= 1,286
97.5 % of OD women believe
their role can be performed
effectively via telework

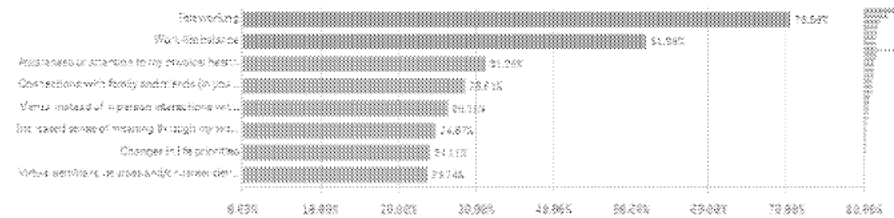
How effectively do you believe your role can be performed at the NIH via telework? Q16



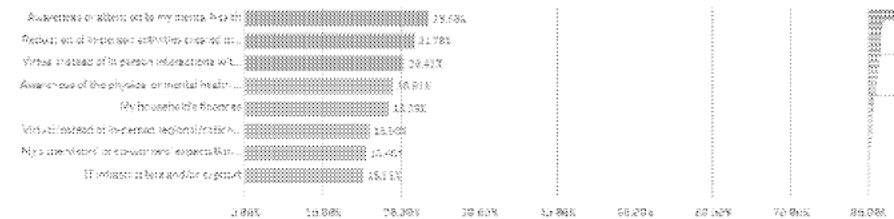
N= 831
88.9 % of OD men believe
their role can be performed
effectively via telework

Pandemic Impact on Productivity

Which, if any, of these factors have had the most positive impact on your productivity? Q24A



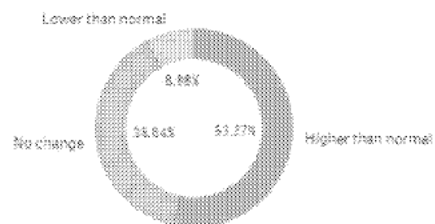
Which, if any, of these factors have had the most positive impact on your productivity? Q24A



Teleworking (70.50%) and Work-life balance (51.96%) were two of the most cited factors that had the most positive impact on respondent's productivity.

Pandemic Impact on Productivity

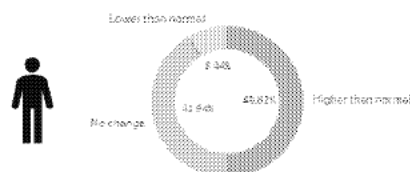
Since the pandemic began in March, on average, how would you rate your overall job productivity? Q23



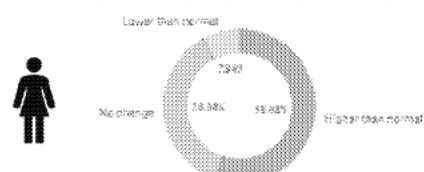
53.27% rated their overall job productivity as higher than normal since the pandemic began in March.

49.62% of men and 55.08% of women found their overall job productivity was higher than normal since the pandemic began in March.

Since the pandemic began in March, on average, how would you rate your overall job productivity? Q23

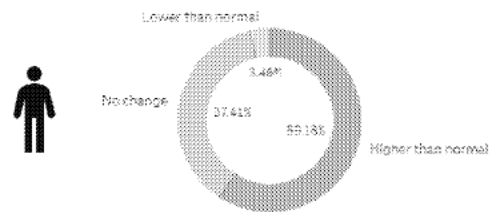


Since the pandemic began in March, on average, how would you rate your overall job productivity? Q23

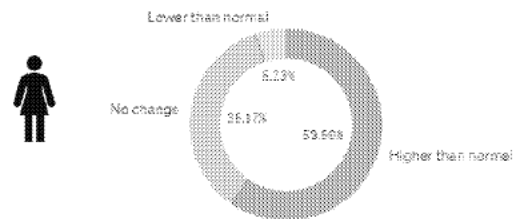


Pandemic Impact on Productivity

Since the pandemic began in March, on average, how would you rate your overall job productivity? Q13



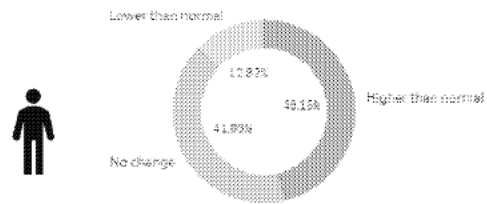
Since the pandemic began in March, on average, how would you rate your overall job productivity? Q12.3



59.18% Black or African-American men and 59.59% Black or African-American women found their overall job productivity was higher than normal since the pandemic began in March.

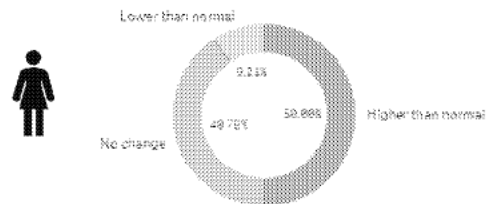
Pandemic Impact on Productivity

Since the pandemic began in March, on average, how would you rate your overall job productivity? Q23



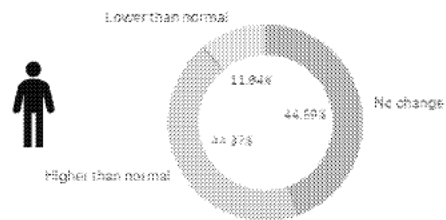
46.15% Hispanic, Latino, or Spanish origin men and 50.00% Hispanic, Latino, or Spanish origin women found their overall job productivity was higher than normal since the pandemic began in March.

Since the pandemic began in March, on average, how would you rate your overall job productivity? Q23

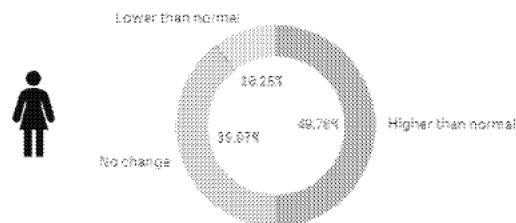


Pandemic Impact on Productivity

Since the pandemic began in March, on average, how would you rate your overall job productivity? Q23



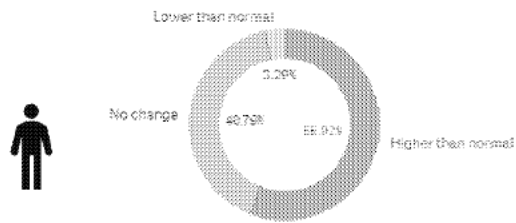
Since the pandemic began in March, on average, how would you rate your overall job productivity? Q23



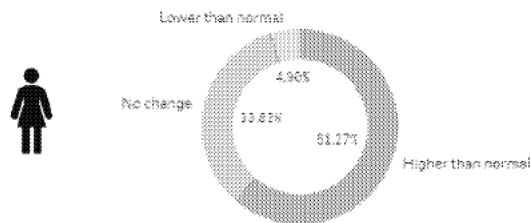
44.59% White men and 49.78% White women found their overall job productivity was higher than normal since the pandemic began in March.

Pandemic Impact on Productivity

Since the pandemic began in March, on average, how would you rate your overall job productivity? Q13



Since the pandemic began in March, on average, how would you rate your overall job productivity? Q13

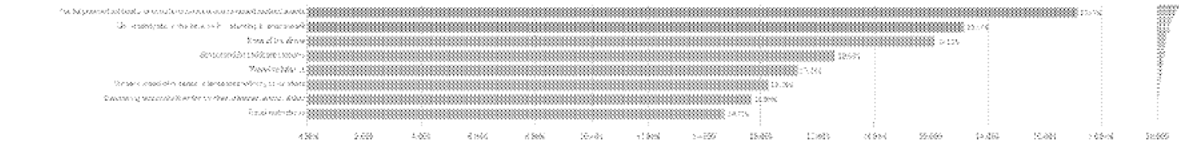


55.92% Asian, American Indian, Native Hawaiian or Other men and 61.27% Asian, American Indian, Native Hawaiian or Other women found their overall job productivity was higher than normal since the pandemic began in March.

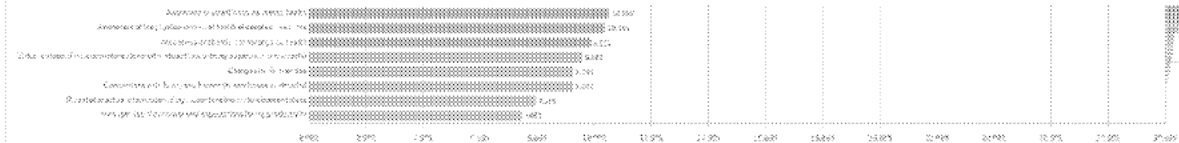
Pandemic Impact on Productivity

The heightened political and social environment due to recent social events (27.17%) and uncertainty about returning to onsite work (23.17%) were two of the most cited factors that had the most negative impact on respondent's productivity

Which, if any, of these factors had the most negative impact on your productivity? Q26b

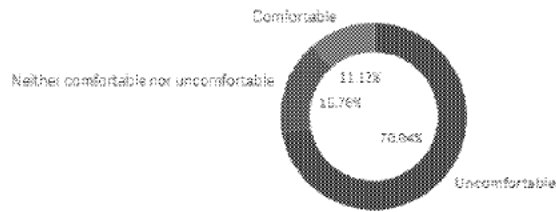


Which, if any, of these factors had the most negative impact on your productivity? Q26b



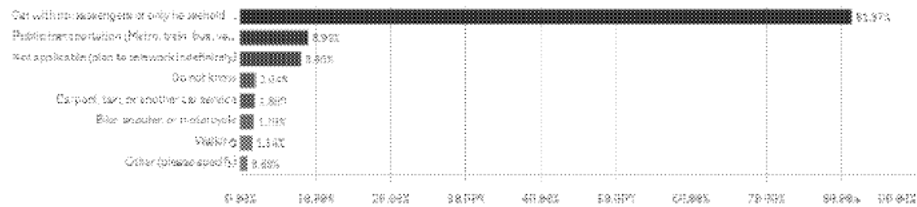
Returning to Work Onsite

How comfortable are you, or how comfortable do you think you will be, returning onsite to your NIH workplace in the context of the COVID-19 pandemic?



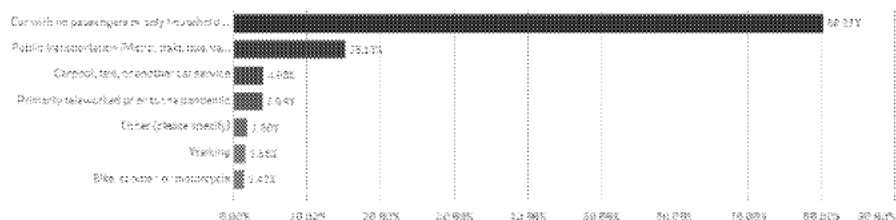
70.04% of the 2,221 participants indicated that they were uncomfortable to return to onsite work; NIH wide = 52.4% were uncomfortable.

How have you been traveling to your NIH workplace during the pandemic, or how do you plan to travel to your NIH workplace following the pandemic?

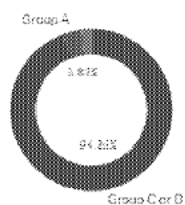


Returning to Work Onsite

Before maximum NIH telework began, how did you travel to your NIH workplace? Please select the method(s) that you used more than once...

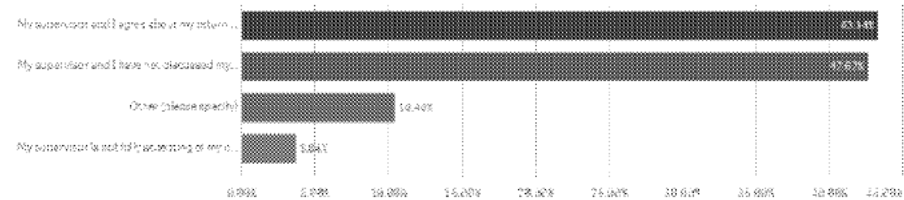


Group Phased Return?

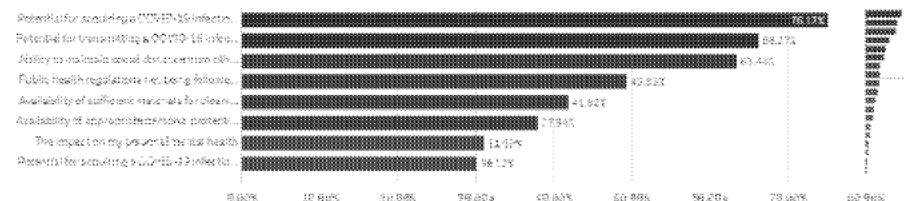


Returning to Work Onsite

How would you describe your communication with your supervisor regarding your NIH workplace status? Q28

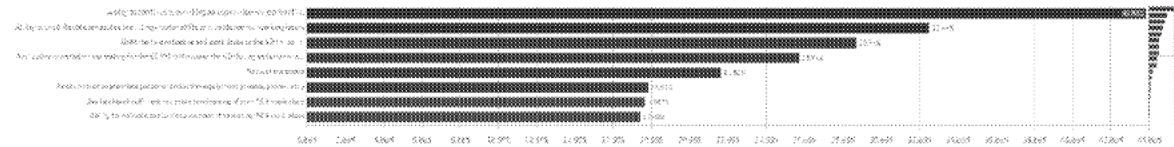
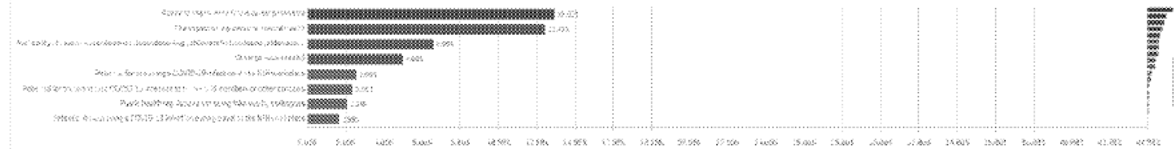


Below are potential concerns one might have about returning onsite to the NIH workplace. Which of the following have the most negative impact on your decision to return to work? Q29



Returning to Work Onsite

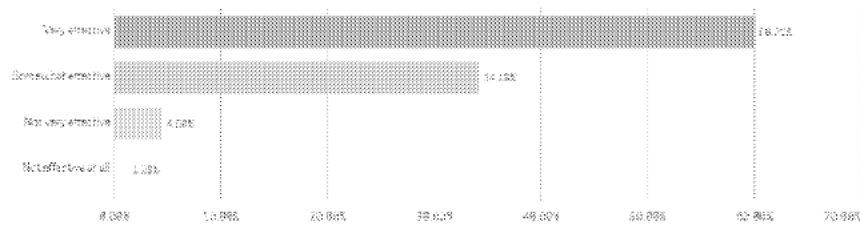
© 2004 The Authors
Journal compilation © 2004 Blackwell Publishing Ltd

[illegible]

76.33 % of 2,221 respondents think that continued telework as appropriate to job function or flexible work schedules are potential benefits of returning onsite to NIH workplace

Communications & Resources

How effective have the communications about personal health and wellness been from the NIH? Q36A



How would you rate the support you've received from your institute and the NIH to remain productive during the COVID-19 pandemic? Q38

89.19% of 2,221 respondents
said they received the support
that they needed from NIH

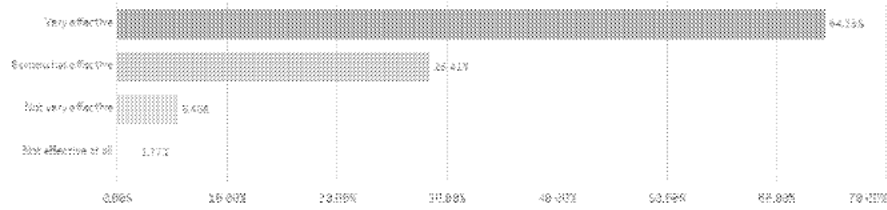
I have received some support, but not enough



I have received the support I needed

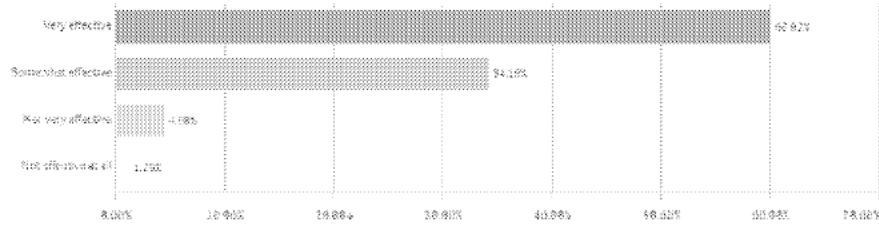
Communications & Resources

How effective have the communications about your work status been from the NIH? Q3B8



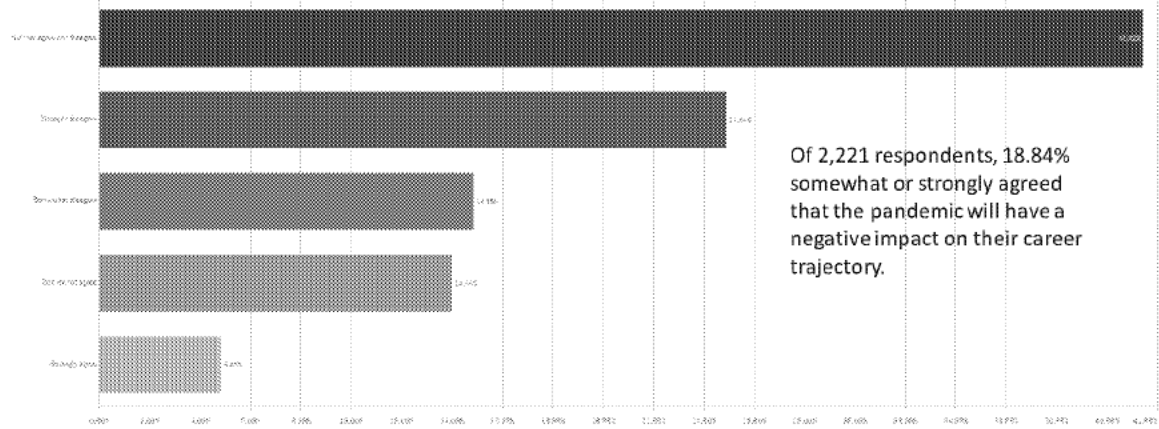
92.76% found communications about work status from NIH as somewhat or very effective and 94.21% found communications about personal health and wellness as somewhat or very effective

How effective have the communications about personal health and wellness been from the NIH? Q3B9A



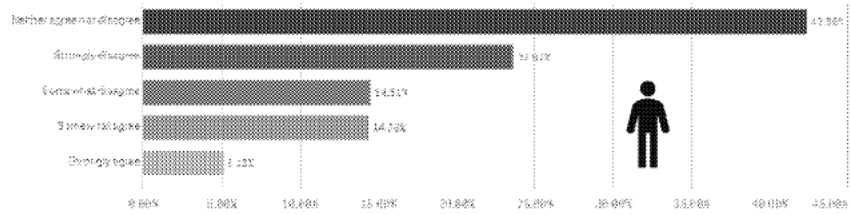
Career Trajectory & Timeline

To what extent do you agree or disagree with the following statement? The pandemic will have a negative impact on my career trajectory. (35)



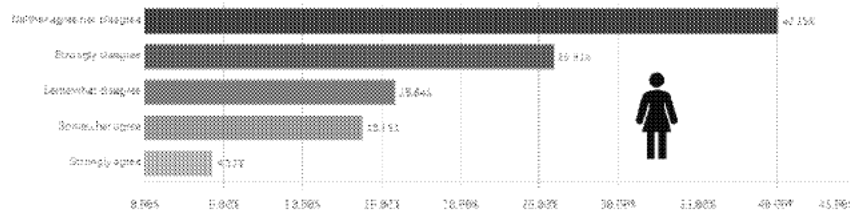
Career Trajectory & Timeline

To what extent do you agree or disagree with the following statement? The pandemic will probably have a negative impact on my career tr...

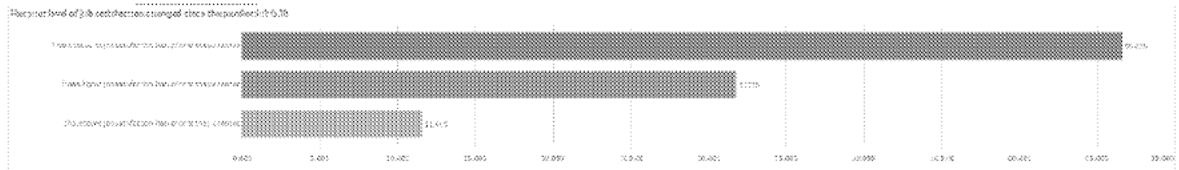


19.51% of those who identified as men somewhat or strongly agreed while 18.12% of those who identified as women somewhat or strongly agreed.

To what extent do you agree or disagree with the following statement? The pandemic will probably have a negative impact on my career tr...



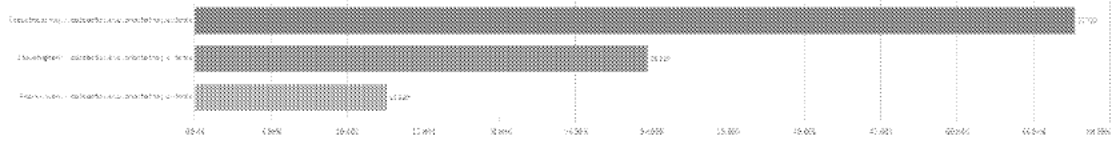
Job Satisfaction



Across OD, 88.39 % of 2,221 participants indicated that they have either the same or increased job satisfaction now than prior to the pandemic.

Job Satisfaction

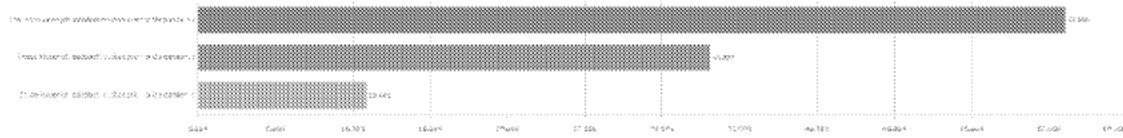
Two-year level of job satisfaction changed since the pandemic? Q38

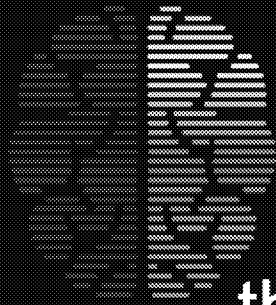


87.42 % of men indicated that they have either the same or increased job satisfaction now than prior to the pandemic.

89.14 % of women indicated that they have either the same or increased job satisfaction now than prior to the pandemic.

Two-year level of job satisfaction changed since the pandemic? Q39





Great minds
think differently ...

@NIH_COSWD



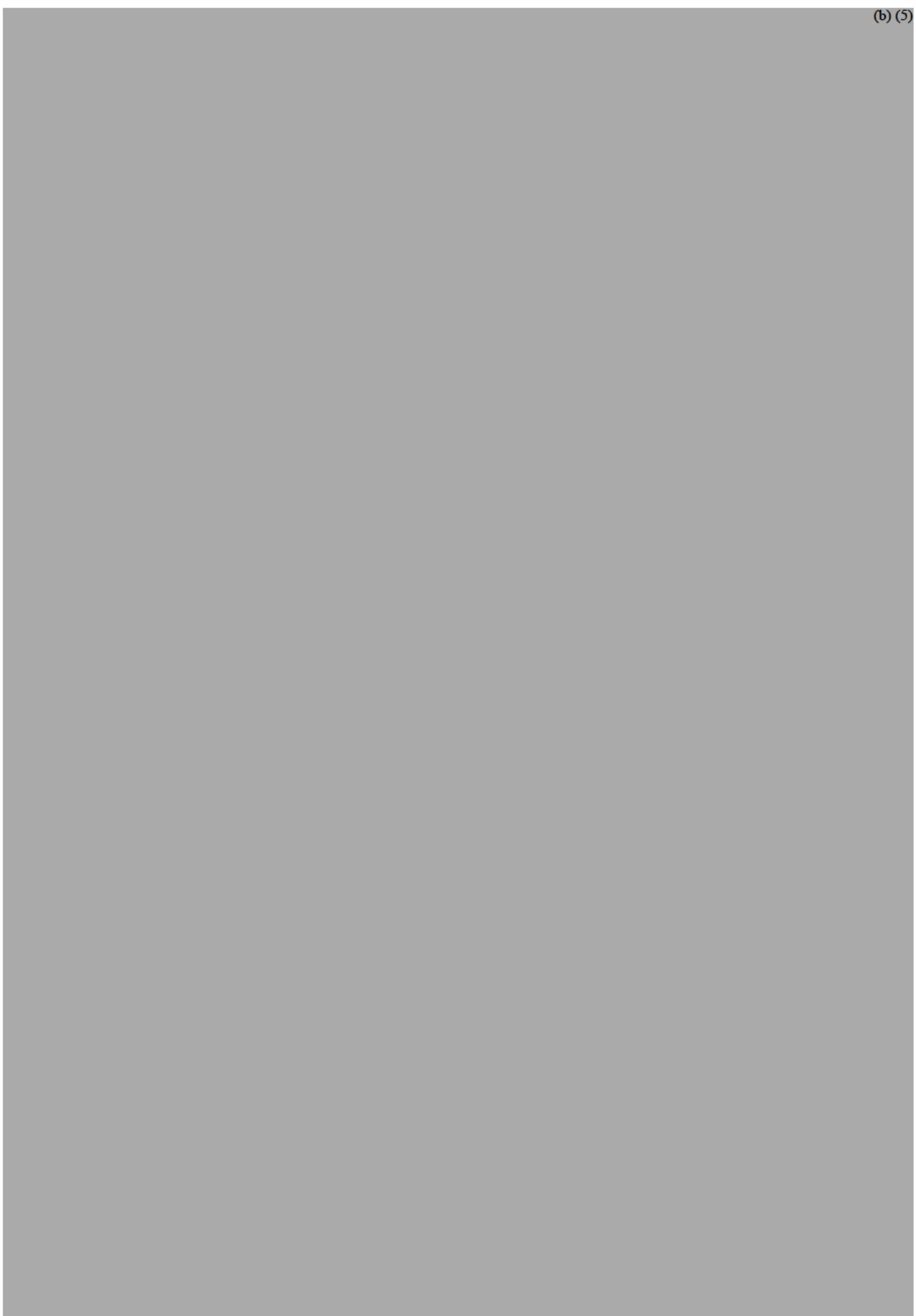
National Institutes of Health
Office of the Director
Scientific Workforce Diversity

Agenda 1 on 1 with Larry Tabak on 10/14/20

Hi Larry – look forward to seeing you at later today (Wednesday). Here's what I have so far:

(b) (5)





(b) (5)

Many thanks!
Best, Mike

A large, dark gray chevron pointing to the right, with a white outline, serving as a background for the title.

FY 2020 CSR Update

Agenda

- Impact of Covid-19
- ENQUIRE Update
- CSR AC Working Group on Simplifying Peer Review
- Bias in Peer Review
- Peer Review Integrity

Agenda

- **Impact of Covid-19**
- ENQUIRE Update
- CSR AC Working Group on Simplifying Peer Review
- Bias in Peer Review
- Peer Review Integrity

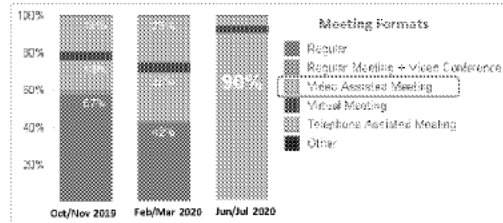
CSR response to covid-19 pandemic

- **Ahead of the curve:** Acquisition of FEDRAMP-certified Zoom platform, 650 licenses in preparation for an emergency. Tested the platform to prepare for adaptation in early/mid 2019
- Most advanced **telework** policy at NIH – enabled 100% of CSR workforce to be virtual with 100% productivity immediately (Mon Mar 16, 2020)
- All **review meetings** virtual with very short notice, relevant security and integrity in place
- **Review Matters** blog on Zoom security to address community concerns re: Zoom-bombing, etc.



Post-pandemic: Future of peer review meetings?

- >600 Zoom meetings Mar-Aug 2020, plus >1000 additional planned Sept 2020 – Mar 2021
- **Forced Experiment:**
 - Zoom vs. older Cisco platform – easier to use
 - Socialization, lowered resistance among staff, reviewers
- **Budgetary savings:** CSR returned \$5M to NIH in FY20, another \$10M slated for early FY21, and more expected later in FY21
- **Data-driven decisions about the future:**
 - objective data re: scoring, recruitment, diversity
 - reviewer/staff surveys re: experience, discussion quality
- **Unlikely to go back to the way it was** – if safe, then some hybrid reality (1-2 times/year virtual)



Agenda

- Impact of Covid-19
- **ENQUIRE Update**
- CSR AC Working Group on Simplifying Peer Review
- Bias in Peer Review
- Peer Review Integrity



Center for
Scientific Review

Search this site...



U.S. Department of Health & Human Services • National Institutes of Health

Welcome to CSR Extranet!

Evaluating Panel Quality in Review (ENQUIRE)

Science changes rapidly. Making sure that study sections change with the science is an ongoing challenge. CSR ENQUIRE integrates data and input from multiple stakeholders to determine whether changes in study section focus or scope are needed to facilitate the identification of high-impact science, with special consideration of emerging science.

- Clusters of study sections are formed based on scientific topics for review via ENQUIRE
- Systematic, data-driven, continuous process – ~50% of CSR study sections are evaluated each year; every study section evaluated every 5 years
- Stakeholder input and involvement – external scientific community, institutional programs at NIH, CSR staff
- Iterative approach – continuous refinement of the process based on experience
- Critical to success – matching external applications and reviewer expertise to redefined scientific scope of study sections

Multiple possible actions follow:

- Change in scientific guidelines
- Merge study sections
- Create new study sections
- Redistribute across existing study sections
- Add emerging areas of science
- Eliminate study sections

Jump to changes for ENQUIRE 2019 clusters:
Healthcare Delivery & Patient Outcomes
GI, Renal, Endocrine Systems
Cardiac, Vascular, and Hematologic Sciences
Functional/Cognitive Neuroscience



Center for
Scientific Review

ENQUIRE 2019 Implementation – 42 study sections



Healthcare Delivery/Patient Outcomes – 9 study sections
(Prioritized due to lowest RCR/publication output metrics)



GI, Renal, Endocrine, Metabolism – 11 study sections
(Prioritized due to concerns regarding peer review integrity)



Functional/Cognitive Neuroscience – 12 study sections
(Prioritized due to CSR Advisory Council recommendation)



Cardiac, Vascular, Hematology – 10 study sections
(Prioritized due to concerns regarding peer review integrity)

- Approved by CSR Advisory Council, March 2020
- Implementation delayed due to covid-19 – from June 5, 2020 to Oct 5, 2020 receipt dates
- New and restructured study section descriptions posted on the web
- Members being reassigned according to expertise need/scientific area realignment - Nov 2020
- First study section meetings of new/restructured committees in Feb 2021



E.g. Restructuring Kidney/Urology Panels

Digestive, Kidney and Endocrinology Study Sections		
<p>Study Sections are organized by organ system and disease area. The following table lists the Study Sections and their respective chairs. The chairs are listed in the order of their current chair's term.</p>		
Study Section	Chair	Term
Physiology and Pathology of the Digestive System	Dr. [Name]	2020-2022
Physiology and Pathology of the Kidney	Dr. [Name]	2020-2022
Physiology and Pathology of the Endocrine System	Dr. [Name]	2020-2022
Physiology and Pathology of the Reproductive System	Dr. [Name]	2020-2022
Physiology and Pathology of the Nervous System	Dr. [Name]	2020-2022
Physiology and Pathology of the Immune System	Dr. [Name]	2020-2022
Physiology and Pathology of the Cardiovascular System	Dr. [Name]	2020-2022
Physiology and Pathology of the Respiratory System	Dr. [Name]	2020-2022
Physiology and Pathology of the Musculoskeletal System	Dr. [Name]	2020-2022
Physiology and Pathology of the Sensory System	Dr. [Name]	2020-2022



Hepato-biliary Pathophysiology Study Section *Revised scope by Oct. 5 grant deadlines and Feb/March 2021 review meetings	DKPP	Digestive Sciences Small Business Activities (SIBR/STTR) Special Emphasis Panel	DKS10 (10)
Kidney Molecular Biology and Gastrointestinal Development Study Section *Ends after October 2020 review meetings	DKMS	Renal and Urological Sciences Small Business Activities (SIBR/STTR) Special Emphasis Panel	DKUS (11)
Systemic Injury by Endocrine/Mental Exposure	SIIR	Urologic and Gastrointestinal Physiology and Pathology Special Emphasis Panel *Ends after Oct/Nov 2020 review meetings	DKUS DKUS (10)
Renal Kidney and Urological Systems Function and Dysfunction *Revised Oct. 5 grant deadlines and Feb/March 2021 review meetings	SIIR	Renal Digestive and Nutrient Physiology and Diseases *Revised with Oct. 5 grant deadlines and Feb/March 2021 review meetings	DKPP
Renal Digestive System Host Defense, Microbial Interactions and Immune and Inflammatory Diseases *Revised with Oct. 5 grant deadlines and Feb/March 2021 review meetings	DKMS		

Ongoing



Basic Sciences – 16 study sections
(prioritized due to #s and formation of MIRA standing panels)

- Cellular Signaling and Regulatory Systems – CSRS
- Biochemistry and Biophysics of Membranes – BBM
- Molecular Genetics B Study Section – MGB
- Macromolecular Structure and Function D – MSFD
- Molecular Genetics A – MGA
- Macromolecular Structure and Function C – MSFC
- Membrane Biology and Protein Processing – MBPP
- Synapses, Cytoskeleton and Trafficking – SYN
- Biophysics of Neural Systems Study Section – BPNS
- Macromolecular Structure and Function B – MSFB
- Prokaryotic Cell and Molecular Biology – PCMB
- Macromolecular Structure and Function A – MSFA
- Molecular and Integrative Signal Transduction – MIST
- Molecular Neuropharmacology and Signaling – MNPS
- Neurotransmitters, Receptors, and Calcium Signaling – NTRC
- Nuclear and Cytoplasmic Structure/Function and Dynamics – NCSD

Coming up (fall 2020)



Epidemiological Sciences – 10-12 study sections
(prioritized due to low RCRs)



Oncological Sciences – 10-12 study sections
(prioritized due to increased numbers, emerging areas)



Center for
Scientific Review

Agenda

- Impact of Covid-19
- ENQUIRE Update
- **CSR AC Working Group on Simplifying Peer Review**
- Peer Review Integrity
- Bias in Peer Review

Simplifying Peer Review Criteria

- Review criteria length and complexity
- Administrative questions for scientific peer reviewers
- Reviewer burden – time spent before and at meeting on answering all disparate questions, fatigue, disenchantment with process, disincentive to review
- CSR AC Working Group, with external scientific community participants, CSR and OER representatives – *Goal: develop plan to simplify peer review criteria to refocus on scientific assessment and reduce reviewer burden*

CSR Advisory Committee Working Group Members

CSR Advisory Council



Jinning Gao, Ph.D.
University of Texas Southwestern
Medical Center



Alfred George, M.D.
Northwestern University



Yasmán Hurd, Ph.D.
Mount Sinai School of Medicine



Deanna Kirovets, Ph.D.
University of California, San Francisco



José López, M.D.
University of Washington



Tonya Palermo, Ph.D.
University of Washington

Ad Hoc



Kevin Corbett, Ph.D.
University of California, San
Diego



Michele Janichins, Ph.D.
University of Rochester
Medical Center



Brooks King-Casas, Ph.D.
Virginia Tech

NIH Staff



Sally Amers, Ph.D.
Office of Extramural Research



Bruce Reed, Ph.D.
Center for Scientific Review

Working Group Timeline

- Jan 16, 2020 – WG Meeting 1
- Jan 31, 2020 - Subgroup meeting 1
- Feb 7, 2020 - Subgroup meeting 2
- Feb 14, 2020 - Subgroup meeting 3
- Feb 18, 2020 – WG Meeting 2
- Feb 27, 2020 – Review Matters Blog
>1200 responses, >8000 views
- March 6, 2020 – WG Meeting 3
- Mar 30, 2020 – Full CSR Advisory Council discussion
- April 7, 2020 – WG report published ([Link](#))

Review Matters

Seeking Your Input on Simplifying Review Criteria



Bruce Bead
Deputy Director
February 27, 2020

Over the past several years we have heard consistent concerns about the complexity of review criteria and a peer review. CSR shares the concern that the current set of standards has the unintended consequence of asking too many questions, thus reducing focus on scientific merit and increasing reviewer burden. Each will make review better, but we worry that the cumulative whole may in fact distract from the main goal of review: experts on the scientific and technical merit of the proposed work.

To address these concerns, CSR has convened a working group of our advisory council, charged with recommending research project grant review criteria that will improve review outcomes and reduce reviewer burden. The group is led by Dr. Patricia A. Hensley and me, and includes some of our council members, other members of the scientific community, and a Policy Officer from the Office of Extramural Research.

We would like to hear your thoughts on the issue. How might review criteria be modified to obtain the scientific merit? You can provide feedback directly to me at bruce.bead@nih.gov, to feedback@csr.nih.gov, or to the working group. Before you fire off that email, though, read on.

First, be aware that current criteria derive from multiple regulations changes that conform to laws and regulations that don't. The Code of Federal Regulations (41 C.F.R. Part 52) requires that research project applications

Working Group Recommendations

1. Reorganize the current five scored review criteria into three scored factors
2. Define each criterion and factor conceptually.
3. Alter templates to focus reviewer attention on score driving factors
4. Clarify reviewer responsibility for evaluating the budget
5. Relieve reviewers of responsibility for most "additional review considerations"
6. Convene an additional workgroup for review criteria for clinical trials applications
[Currently underway: Meeting 1 on 9/3, Meeting 2 during week of 10/5]

Major Recommendation (#1): Restructure review criteria

1. Reorganize the current five scored review criteria into **three scored factors**:

- Should it be done? → **Importance of the science**
- Can it be done well? → **Feasibility and rigor**
- Will it be done? → **Investigators and environment**

Allows for a multi-stage, partially-blinded review process

Agenda

- Impact of Covid-19
- ENQUIRE Update
- CSR AC Working Group on Simplifying Peer Review
- **Bias in Peer Review**
- Peer Review Integrity

Bias in Peer Review

Anonymization Study, Double-blinded reviews

- Anonymization study (2014-2019):
 - No effect on scores of Black applicants
 - Worsens scores of White applicants (significant, small effect size)
 - 20% of the time, reviewers could correctly identify the applicant
 - *publication ready, rejected without peer review by Sci Adv, holding for PLOS One....*

Three takeaways:

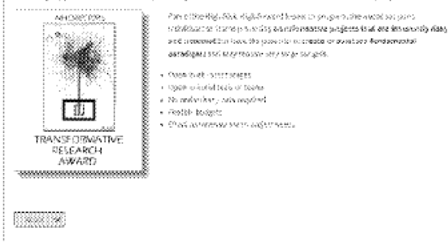
- *Isolating the effect of race in the peer review process is challenging due to secondary, linked variables (e.g. institutional "prestige", investigator "pedigree", Matthew/halo effects, etc.) all tied to racial disparities in opportunity/access.*
- *Anon study (post-submission redaction) not the same as carefully-designed, double-blinded review process*
- *Implicit bias in everyone, including the 18,000 reviewers*

Piloting Multi-Stage Partially Double-Blinded Review

CSR/Common Fund Collaboration (Fall 2020 transformative R01s)

NIH Director's Transformative Research Award

Funding opportunities for exceptionally innovative and successful early research projects



- **Self-redaction** by investigators – no identifiers/institutions
- Phase 1: **Editorial Board** reviews Specific Aims; selects top subset
- Phase 2: **Subject matter experts** evaluate Specific Aims, Abstract, Research Strategy
- Stage 3: **Editorial Board** selects top subset, gives prelim scores, followed by receiving full application with investigator info, meeting with discussion and final scores of all 5 criteria.

CSR will launch bias awareness module for reviewers, SROs *Spring 2021 (before summer 2021 meetings)*

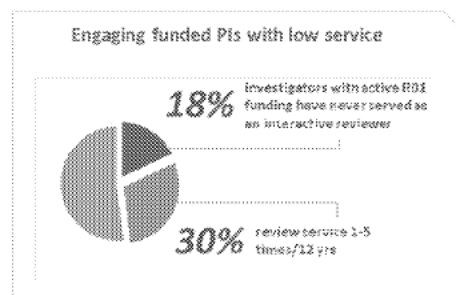
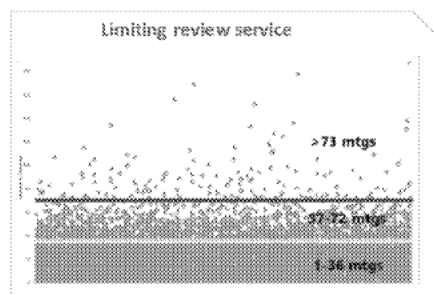
- **Piloted in summer 2020** for NIGMS MIRA reviewers, SROs, POs - collaboration between CSR, NIGMS, and NIH's COSWD
- Based on pilot feedback, CSR is designing multimedia, interactive module for reviewers and SROs –
Planned launch: Apr/May 2021
 - bias awareness in self, in others
 - case studies in review
 - mitigation and bystander strategies in review



RASHID please remove all animation.

Broadening the pool of reviewers

Reviewer "overuse" (undue influence), "underuse"



Broadening the Pool

Early Career Reviewer Program Expanded

Early Career Reviewer (ECR) Program
 The NIH's Early Career Reviewer Program is a voluntary program that allows early career reviewers to provide their expertise and feedback on research proposals. The program is open to all NIH-funded researchers who are currently in the early stages of their careers.

Benefits of the ECR Program:

- Gain valuable experience in reviewing research proposals
- Develop your expertise in a specific research area
- Receive training and support from the NIH
- Contribute to the advancement of science

How to Apply:

Interested researchers should visit the NIH website at <https://www.nih.gov/early-career-reviewer-program> for more information and to apply.

ECR Program Overview:

The ECR program is a voluntary program that allows early career reviewers to provide their expertise and feedback on research proposals. The program is open to all NIH-funded researchers who are currently in the early stages of their careers.

ECR Program Goals:

- To provide early career reviewers with the opportunity to contribute to the advancement of science
- To develop the expertise of early career reviewers in a specific research area
- To gain valuable experience in reviewing research proposals
- To receive training and support from the NIH

ECR Program Benefits:

- Gain valuable experience in reviewing research proposals
- Develop your expertise in a specific research area
- Receive training and support from the NIH
- Contribute to the advancement of science

ECR Program Eligibility:

Interested researchers should visit the NIH website at <https://www.nih.gov/early-career-reviewer-program> for more information and to apply.

- **Sept 2019 CSRAC Working Group Recommendations re: qualifications, usage, consistency, engagement**
- **Sept – Dec 2019:**
 - Database revamped – usable, trackable, accurate
 - CSR SRO Guidance Developed
 - 2 ECRs/standing committee
 - 2 ECRs/SEP with >49 R01/R21
 - 1 ECR/SEP with 25-49 R01/R21
- **940 ECRs recruited in 2020, compared to 575 in 2019**
- **ECR pool is more diverse; 12.1% URM vs. 8.5% for all CSR reviewers in 2020**

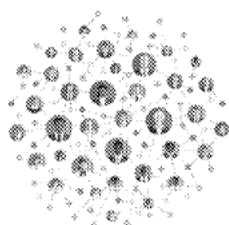
Broadening the Pool

Additional Sources of Reviewer Recommendations

Representatives from scientific societies may create an account and then enter names of recommended reviewers they have vetted.

NIH program staff may recommend scientists for specific study sections, including SBIR panels.

Recommending Potential Reviewers



Scientific Society – Reviewer Recommendations Portal

As for scientific societies that would like to recommend reviewers, when first visiting this portal, a representative from the society should create a user account. After an account is created, users will confirm that you are acting on the society's behalf. After confirmation, you will receive an email inviting you to submit recommendations.

Please carefully vet all recommended reviewers. They should be scientists who are generally willing to serve as reviewers and are listed as experts with integrity in their field. They should have an active research program, command funding, and are currently the principal investigator of an NIH study section or advisory council, are strongly endorsing scientists as recommended reviewers (written from advisory body panels and career stages – e.g., assistant, associate, and full professors).

Please gather the required information (below) before logging into the portal.

Center for Scientific Review

IC: Reviewer Recommendation

27%

Select Division/IRG Study Section

Division: IRG: Study Section:

Add / Update Recommendation → Help → Find the next qualified reviewer. When selecting the typical criteria are: having well established research in the specific field; also a reviewer is able to conduct research in the field they could be a good fit for a review panel. Reviewers should not be paid for their review. Reviewers should not be paid for their review.

Search for Reviewers for SBIR Panels:

First Name: Last Name:

Title: Institution:

Address: Country:

Reviewer category:

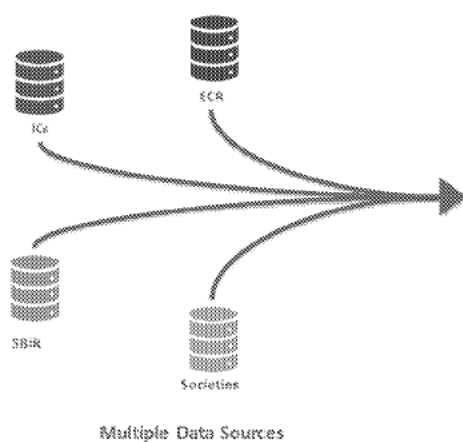
Significant research:

Details of research and your subject expertise:

Submit Recommendation

Broadening the Pool: Aug 2020 Launch of CSR Reviewer Finder

Moving beyond the "mental rolodex" approach to reviewer recruitment



Search: ICR ☐ Society ☐ ECR ☐ PubMed ☐ All

Last Search: Expertise Keyword: Profile ID: Study ID:

Agency for Toxic Substances and Hazardous Waste (ATSDH)
 Society for Toxicology (SOT)
 NIH
 SBR

Search Results (123)

Reviewer Profile	Profile ID	Expertise	State	Study Status	Publication	Institution	Score CV
Steele, Richard	158225	Genetics, molecular biology, toxicology, early development of host-guest in the tropics	TX	IPED	Good	University of Texas	100%
Edin, Jeffrey	166704	NEPHROLOGY, nephrology, nephrology	CA	ACIS	Good	University of California, San Diego	100%
Kramer, John	166702	INFECTIOUS DISEASES	MA	PTIC	Good	Children's Hospital	100%

One interface - user-friendly for SROs

Broadening the pool of reviewers

Reviewer demographics and diversity

Increasing Assistant and Associate Professors

Council	Professor	Associate	Assistant	Other
05/2015	55.5%	29.1%	6.3%	9.1%
05/2020	49.7%	32.2%	10.5%	7.5%

FY 20 Demographics

	%P	%I/AA	%B/AA
All Applicants	34.9%	8.3%	2.6%
Study Section Members	42.8%	13.2%	4.2%
All Reviewers	38.2%	8.5%	2.5%

CURRENT FOCUS

- 1) SRO training, expectations (away from old habits, "mental rolodex")
- 2) SRO resources ("reviewer finder tool" – multiple sources, includes demographic info)
- 3) Increased management oversight of SEPs/ad hoc recruitment

Agenda

- Impact of Covid-19
- ENQUIRE Update
- CSR AC Working Group on Simplifying Peer Review
- Bias in Peer Review
- **Peer Review Integrity**

Launch of Reviewer Integrity Training Module

September 2020



- Designed with input from community regarding actual experiences
- Multimedia, interactive with case studies
- Combination of policy instruction, exercises with increasing levels of complexity, consequences, reporting, tools
- Piloted with ~70 study section
- Launching to all CSR reviewers in Sept 2020
- Trackable

Integrity of the Peer Review Process

What is the NIH Doing?

PRO-ACTIVE MEASURES

- Review Integrity Officer
- Enhanced Reporting – SRO signature
- Enhanced SRO Awareness and Training
- Reviewer/Chair Awareness and Training
- Tighter IT controls
- Outreach to scientific community – culture change

ACTIONS

- Following up on every allegation

Actions have included

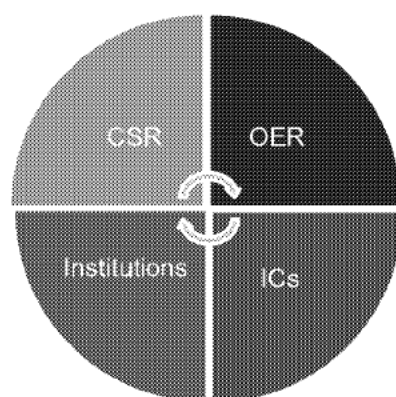
- Deferral or withdrawal of application
- Removal from serving on peer review committees
- Disbanding entire committees
- Notifying the institution of the PI or reviewer which has led to personnel actions

Issues:

- Enhance NIH policy/expectations for grantee institutions [i.e. bring peer review integrity in line with sexual harassment; foreign influence policies]
- Integrity violations, cabals and diversity – ultimate power structures – some DNU's still well-funded, leadership in societies, editors of journals

Coming Next: Strategic Plan for NIH Peer Review Integrity

CSR/OER: Policies, expectations, oversight responsibilities, communications



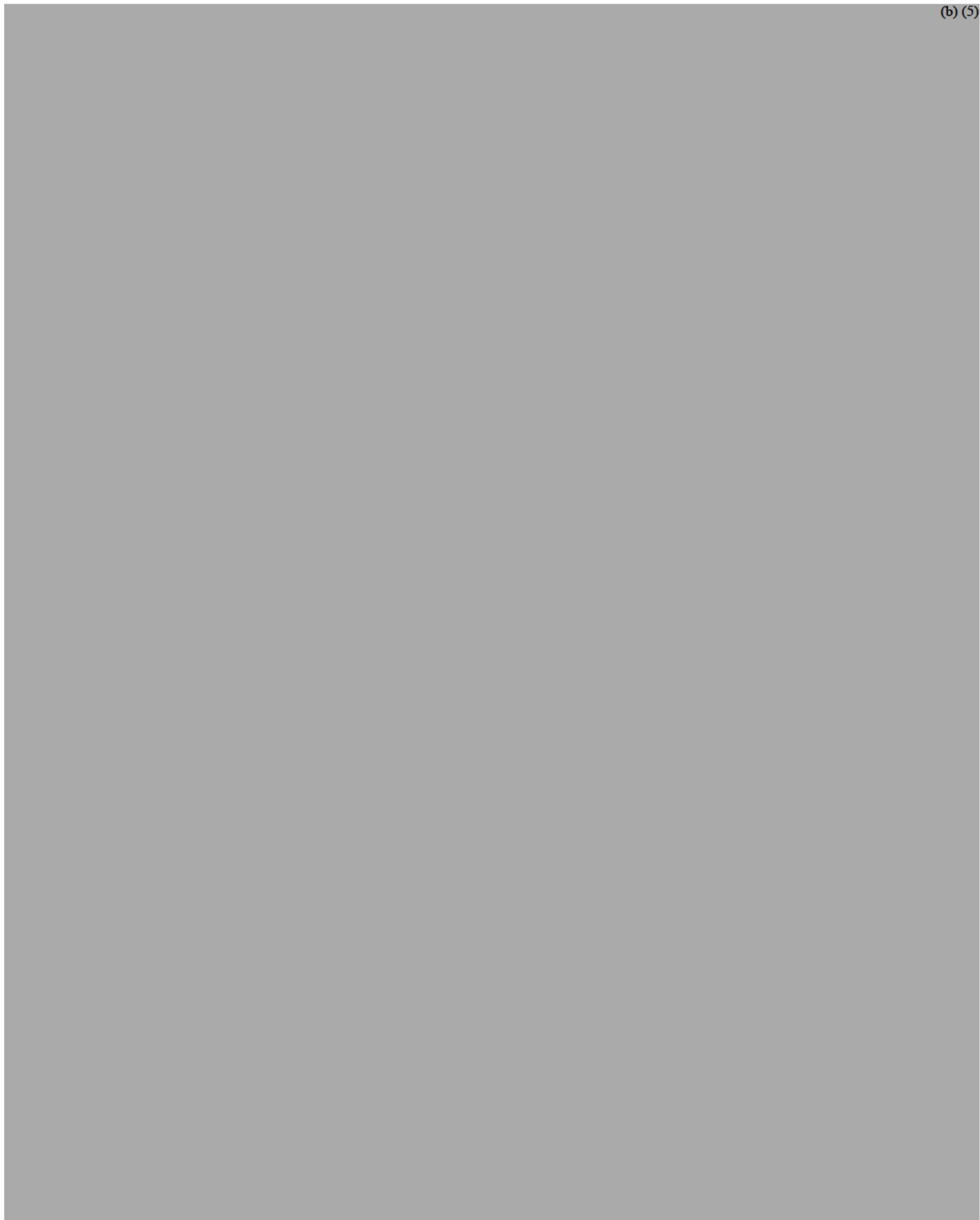


DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

(b) (5)







Options for \$3B supplement for COVID-19 losses
Mike Lauer (OER)

(b) (5)



From: Simanich, Sasha (NIH/OD) [E] (b) (6)
Sent: 10/8/2020 6:03:01 PM
To: Bundesen, Liza (NIH/OD) [E] (b) (6); Ratliff, Shaun (NIH/OD) [E] (b) (6)
CC: Shannon, Mike (NIH/OD) [E] (b) (6); Johnson, Alfred (NIH/OD) [E] (b) (6);
Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6);
Chakraborty, Trisha (NIH/OD) [E] (b) (6); Spady, Tyrone (NIH/OD) [E] (b) (6);
Mackenzie, James (NIH/OD) [E] (b) (6); Gonzalez, Itzel (NIH/OD) [E] (b) (6);
Butler, Benjamin (NIH/OD) [E] (b) (6); Showe, Melanie (NIH/OD) [E] (b) (6)
Subject: Action: By 12pm, Tuesday, 10/13 - Please provide availability to discuss new OIG audit "NIH Technology Controls and Related Efforts to the Grant Program" (A-18-20-06300)
Attachments: OIG Notification Letter (A-18-20-06300).pdf; OIG Entrance Conference Questions (A-18-20-06300).docx

Good Afternoon Dr. Bundesen and Shaun,

The OIG is beginning a new review entitled, *"NIH Technology Controls and Related Efforts to the Grant Program"* (Job code A-18-20-06300) to determine whether NIH has controls in place to ensure grants have appropriate cybersecurity provisions. Please see the attached OIG Notification Letter. OIG has requested an entrance conference to discuss their audit and to get a better understanding of the NIH grants process. This email is to request your availability for two meetings and to share the agenda.

Subject – By 12pm, Tuesday, 10/13 - Please provide your availability for an internal NIH pre-meeting and an entrance conference with the OIG

From – OMA

To – OCIO & OER

Cc – OSP, OCIO, OLPA, OM, OGC

Action 1 – Provide your availability for a 1-hour internal pre-meeting to discuss the attached OIG questions.

- Monday, Oct. 19: 10am-12pm, 2-5pm
- Thursday, Oct. 20: 8am-12pm or 2-3pm

Action 2 – Provide your availability for an entrance conference with the OIG

- Wednesday, Oct. 21: 2-5pm
- Thursday, Oct. 22: 9am-12pm

Action 3 – Provide high level talking points to OIG's questions prior to the internal pre-meeting (date TBD)

Requestor – OIG

Background – The OIG is beginning this work to determine whether NIH has internal controls in place to ensure grants have appropriate cybersecurity provisions.

POCs – Please send comments and any questions to David Fuller (b) (6) and Sasha Simanich (b) (6)

Additional Instructions –

- Please let me know whether additional offices/individuals should be involved in this audit.
- Use the attached Word file to complete the question set with high level talking points

Attachments –

- OIG Notification Letter
- Entrance conference agenda

Thank you,

Sasha Simanich

Audit Liaison, OIG/GAO Review
NIH/OD/OMA/RMAL
6011 Executive Blvd, Suite 108
Rockville, MD 20852-7669

Email: (b) (6)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



September 22, 2020

TO: Meredith Stein
Director, Division of Risk Management and Audit Liaison
National Institutes of Health

FROM: Tamara J. Lilly
Assistant Inspector General for Audit Services

Tamara Lilly

Digitally signed by
TAMARA LILLY
Date: 2020.09.22 13:35:00
-04'00'

SUBJECT: Notice of Audit Start: Audit of National Institutes of Health Information
Technology Controls and Related Efforts to the Grant Program (A-18-20-06300)

Assignment: The objective of our audit is to determine if the National Institutes of Health has controls in place to ensure grants have appropriate cybersecurity provisions.

OIG/OAS Division: Cybersecurity and Information Technology Audit Division (CITAD).

Background and General Description of Work:

The National Institutes of Health (NIH) is the primary Federal agency for conducting and supporting biomedical research to enhance health, lengthen life, and reduce illness and disability. Annually, NIH invests nearly \$39.2 billion in medical research projects on a number of common and rare diseases including cancer, Alzheimer's, diabetes, arthritis, heart ailments, and AIDS.

More than 80 percent of the NIH's funding is awarded through approximately 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every State and around the world. According to NIH's Grants Policy Statement, "All information systems, electronic or hard copy which contain Federal data need to be protected from unauthorized access." Without appropriate cybersecurity provisions and monitoring of grantees, NIH does not have assurance that sensitive data is not at risk, specifically the confidentiality, integrity, and availability of sensitive research data.

Our work will include interviewing key personnel, reviewing applicable Federal regulations, NIST requirements, and industry best practices; grants, policies, procedures, and security documentation, walk-throughs, and selected testing of procedures using automated tools.

Where Work Will Be Performed: National Institutes of Health in Bethesda, Maryland, and select grantees. Due to the COVID-19 pandemic, our work may be completed remotely through the utilization of email, secure teleconferencing, and secure file transfer service(s).

When Work Will Begin: September 2020. We will contact the audit liaison to schedule an entrance conference and submit an initial documentation request list.

Method for Securely Transmitting Audit Information to OAS over the Internet:

When transmitting any audit information to OAS over the Internet, please properly safeguard the information. We request that you use the HHS/OIG Delivery Server, not email or attachments to email. Information transmitted through the HHS/OIG Delivery Server complies with Federal Information Processing Standard (FIPS) 140-2, *Security Requirements for Cryptographic Module*.

We are required to report as a security breach any audit information sent to us that does not meet FIPS 140-2 requirements.

OIG Contacts: Charles Summers, Assistant Director-CITAD, (214) 601-5614
Jarvis Rodgers, Director-CITAD, (202) 836-1183

cc:

Andrea T. Norris
Chief Information Officer

Amy J. Frontz
Deputy Inspector General for Audit Services

OIG Components

GAO

OIG Questions Audit (A-18-20-06300)
NIH Information Technology Controls and Related Efforts to the Grant Program

1. What are the security requirements for grantee(s)?
 - a. The OIG is aware that the NIH web site mentions they are required to meet NIST Standards.
 - b. The OIG is aware that requirements may vary by grant type.
2. Can NIH officials point the OIG to the language in the terms and conditions that contain security requirements for the grantee?
3. What steps does NIH take to ensure grantee(s) meet the security requirements to protect research data, NIH data, etc.?



Raising the NIH Honorarium Rate

Sally Rockey, Ph.D.
NIH Steering Committee
11/5/2009

Purpose

Review recommendations from EAWG on changing honorarium rates for peer reviewers, SGE, other advisors and speakers and recommend next steps or approval

Background

- NIH honorarium has been remained at its current level of \$200/day for many years
- Intramural had been interested in discussing a potential increase to honorarium for speakers and others
- Peer review enhancement had pointed out an increase honorarium as a potential way to incentivize reviewers
- Committee was formed to look at the issue and make recommendations
- Recommendations vetted to Gottesman and EAWG

Honorarium Rate

NIH honorarium rate = \$200/day

- Peer reviewers
 - Fully participating members - \$200/day
 - Other contributing reviewers (10/2009 & 01/2010 Council rounds):
 - \$100/day if submit 1 – 3 written critiques
 - \$200/day if submit 4 or more written critiques
- Special Government Employees (SGE's)
 - Advisory Council members
 - Board of Scientific Counselors members
 - Program Advisory Committee members
- Seminar speakers, guest lecturers
- NIH IRB Panel members

Considerations for Changing Honorary Threshold

- Current level is not at our ceiling of Executive Level IV*
 - 2009 basic rate = \$153,200/annum
 - \$589.23/day (based on 2080 hours/yr, 8 hr/day)
 - 1999 basic rate (Ex. Level IV) = \$118,400/annum
 - 29% increase since 1999
- Any increase will have a major financial impact due to the large number of peer reviewers and future uncertainty in numbers of applications
 - Historical continuous increase in number of applications each year
 - Increase number of applications due to ARRA
- Coordination between extramural and intramural programs

* Delegation of Authority No. 5 – Rates of Compensation (Honoraria) Under Professional Services Orders (12/13/99; updated 11/16/05)

Honorarium Costs for Peer Reviewers

FY2009 – honoraria (extramural) ≈ \$12.68 M

- Does not include ARRA costs
- Includes reviewers for CSR and ICs

Predicted Costs for Peer Reviewers

- Based on total costs (not number of reviewers)
- Assumes current levels of applications

Honorarium Rate	Cost	Estimated Increase
\$200/day	\$12.68 M	-----
\$300/day	≈ \$19.03 M	\$ 6.34 M
\$400/day	≈ \$25.38 M	\$12.68 M
\$500/day	≈ \$31.72 M	\$19.03 M

Honorarium Costs for other advisors (SGE's, etc.)

FY2009 costs - honoraria: ~ \$950,000

- Advisory Councils ≈ \$368,500
- Boards of Scientific Counselors ≈ \$339,600
- Program Advisory Committees ≈ \$245,300

Predicted Costs:

Honorarium Rate	Cost	Estimated increase
\$200/day	\$.950M	-----
\$300/day	\$1.43 M	\$.48 M
\$400/day	\$1.91 M	\$.95 M
\$500/day	\$2.38 M	\$1.43 M

EAWG Discussion:

Honorarium Committee Recommendations Presented to EAWG

- Increase rate *up to* \$400/day in FY2011
- Allow intramural and extramural programs to diverge
- Evaluate for subsequent increases thereafter
- Explore additional incentive stipend based on # applications reviewed/reviewer

Synopsis of EPMC and RPC issues and concerns

Is it the right time to do this considering the economy?

It is long over due!

Stop giving honorarium as it is just a token anyway and it may not provide incentives.

Recommendations from EAWG

1) Increase rate to \$300/day in FY2011 for:

- Fully participating peer reviewers, retain differential scale for other participating reviewers (mail reviewers)
- Special Government Employees
 - Members of Boards of Scientific Counselors
 - Members of Advisory Councils
 - Members of Program Advisory Committees
- Members of NIH IRBs

2) Allow flexible rates *up to* \$400/day in FY2011 for guest speakers and lecturers, but retain exceptions with approval from NIH Deputy Directors

3) Establish periodic evaluation for subsequent increases

Honorarium Rates at other agencies

- AHRQ, EPA = \$200/day
- DHS = \$300/day
- DoE, Army = (up to) \$500/day
- NSF
 - *Ad hoc* reviewers (mail reviewers) – no honorarium
 - Panelists = \$280/travel day; \$480/meeting day (includes honorarium)
- VA = \$200 - \$500
 - Different rates for different branches
 - In branches at \$200/day, the Chair receives additional \$100

DoE: meetings are not established as FACA meetings, and honoraria are not required. However, depending on the discretion of the official running the review, they can provide up to \$500/day honorarium to panelists; mail reviewers do not receive honoraria.

FDA: allowed to pay up to GS15-10 level (\$489.12/day)

Honorarium Rate Committee

Honorarium Committee

Edward Wilgus, OALM - Chair

Sally Amero, OER

Diane Bernal, CSR

Larry Chloupek, IRP

Melanie Keller, CSR

Sherley Mizzell, OALM

Milton Nicholas, OALM

Annette Romanesk, OALM

Mary Smith, OALM

And thanks to:

Cheryl Kitt, CSR

Diane Bernal, CSR

Melanie Keller, CSR

Kevin Laser, CSR

**DRAFT - STANDARD OPERATING
PROCEDURES ELEMENTS FOR NIH
INSTITUTES AND CENTERS MANAGING
CLINICAL TRIALS**

DATE PUBLISHED: OCTOBER (TBD), 2020

VERSION 1.0

(b) (5)

27
28
29
30
31
32
33
34
35
36
37
38
39
40
41

42
43
44
45
46
47
48
49
50
51
52
53
54
55

56
57
58
59

60
61
62
63
64
65
66
67
68
69
70
71
72
73



DRAFT

74

75

76

77

78

79

80

81

82

83

84

85

86

87

88

89

90

91

92

93

94

95

96

97

98

99

100

101

102

103

104

105
106
107
108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132
133
134
135
136
137

138
139
140
141
142
143
144
145
146
147
148
149
150
151
152
153
154
155
156
157
158
159
160
161
162
163
164
165
166
167
168
169
170
171
172
173

174
175
176
177
178
179
180
181
182
183
184
185
186
187
188
189
190
191
192
193
194
195
196
197
198
199
200
201
202
203
204
205
206
207
208

209
210
211
212
213
214
215
216
217
218
219
220
221
222
223
224
225
226
227
228
229
230
231
232
233
234
235
236
237
238
239
240
241
242
243

244
245
246
247
248
249
250
251
252
253
254
255
256
257
258
259

260

261
262
263
264
265
266
267
268
269
270
271
272
273

274
275
276
277
278
279
280
281
282
283
284
285
286
287
288
289
290
291
292
293
294
295
296
297
298
299
300
301
302
303
304
305
306

307
308
309
310
311
312
313
314
315
316
317
318

319
320
321
322
323
324
325
326
327
328
329
330
331
332
333
334
335
336
337
338
339

340
341

342

343
344

345
346
347
348
349
350
351
352
353

354

355
356

357
358

359

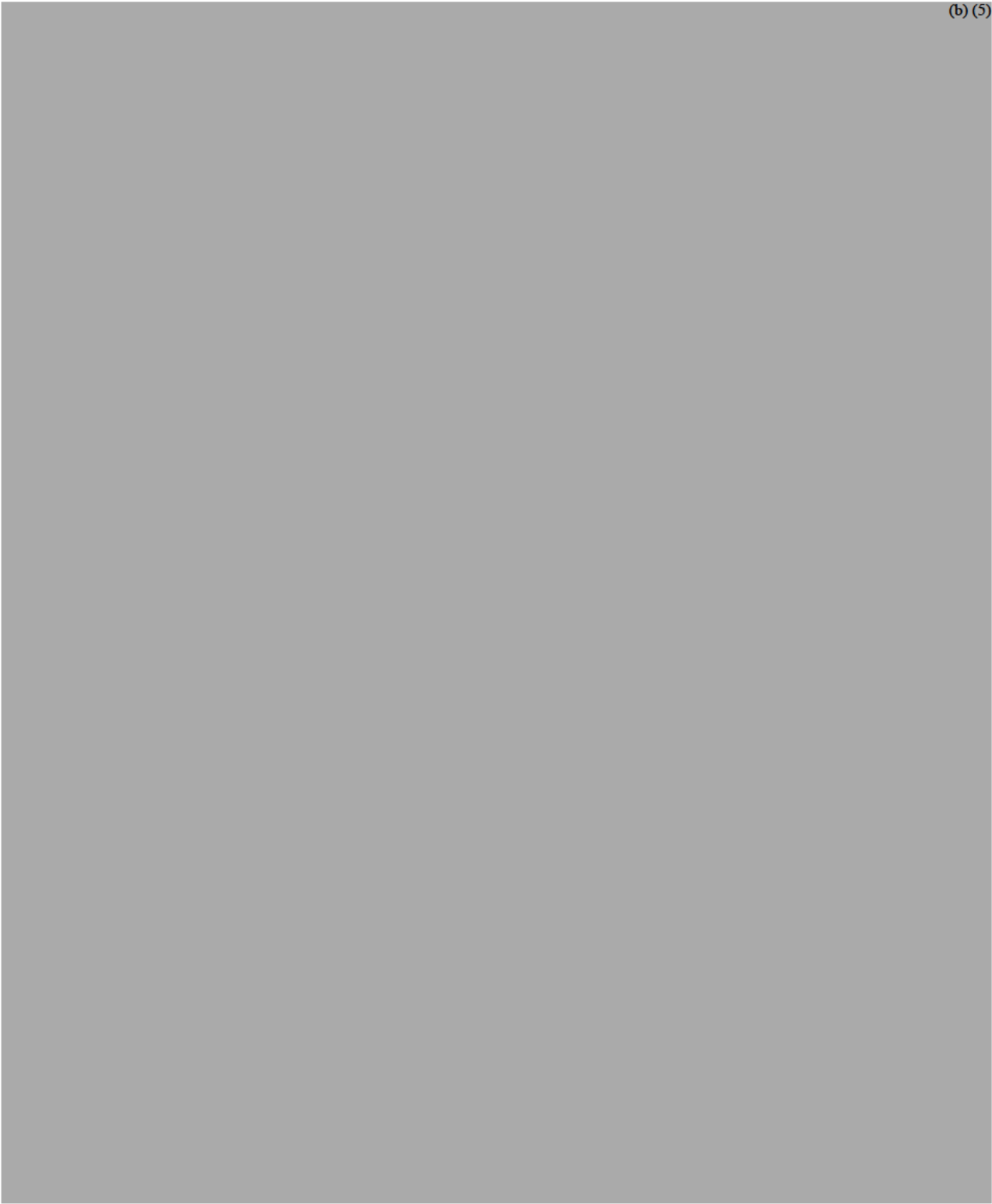
360
361

362
363
364
365

366
367
368
369
370
371
372
373
374
375
376
377
378
379
380
381
382
383
384
385
386
387
388
389
390
391
392
393
394
395
396
397
398
399
400
401

402
403
404
405
406
407
408
409
410
411
412
413
414
415
416
417
418
419
420
421
422
423
424
425
426
427
428
429
430
431
432
433
434
435
436
437

438
439
440
441
442
443
444
445
446
447
448
449
450
451
452
453
454
455
456
457
458
459
460
461
462
463
464
465
466
467
468
469
470
471



DRAFT Communications Plan: Harmonizing Clinical Trials' Standard Operating Procedure (SOP) Elements Across NIH Institutes and Centers

Revised 09/30/2020

(b) (5)

For internal use only



From: Bundesen, Liza (NIH/OD) [E] (b) (6)
Sent: 10/20/2020 3:43:30 PM
To: EPMC Principals (b) (6)
Subject: EPMC Meeting Materials for Tomorrow, Oct. 21, 8:30-9:30 AM, via WebEx
Attachments: EPMC Agenda 10-21-2020.docx; Erin Gibson Cell reset PHS0092867420306784.pdf; Lauer EPMC 10 21 20.pptx; Research_COVID_August2020_COGR_FINAL 10 15 20.pdf

Good morning,

Here are the materials for tomorrow's EPMC meeting.

Date: October 21, 2020

Time: 8:30 to 9:30 AM

Location: WebEx

WebEx link: [Join the meeting](#)

Meeting number: (b) (6)

Meeting password: (b) (6)

Call-in #: 1-650-479-3208

Agenda

Topic: Announcements/updates

- HHS communications with NIH
- Section 889/codified in 2 CFR Part 200.216 Prohibition on certain telecommunications and video surveillance services or equipment.
- Expiration of OMB Memos
- PHS 6031 – NRSA payback forms

Presenter: Michelle Bulls, Director, OER Office of Policy for Extramural Research Administration (OPERA)

Topic: COVID-19, Research Impact, and Considerations for Next Steps

Presenter: Michael Lauer, M.D., NIH Deputy Director for Extramural Research

Regards,
Liza

Commentary

How Support of Early Career Researchers Can Reset Science in the Post-COVID19 World

Erin M. Gibson,^{1,12,*} F. Chris Bennett,² Shawn M. Gillespie,³ Ali Deniz Güler,⁴ David H. Gutmann,⁵ Casey H. Halpern,⁶ Sarah C. Kucenas,⁴ Clete A. Kushida,¹ Mackenzie Lemieux,⁷ Shane Liddelow,⁸ Shannon L. Macauley,⁹ Qingyun Li,¹⁰ Matthew A. Quinn,¹¹ Laura Weiss Roberts,¹ Naresha Saligrama,⁵ Kathryn R. Taylor,³ Humsa S. Venkatesh,³ Belgün Yalçın,³ and J. Bradley Zuchero⁶

¹Department of Psychiatry and Behavioral Sciences, Stanford University School of Medicine, Palo Alto, CA 94305, USA

²Department of Psychiatry, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA 19104, USA

³Department of Neurology and Neurological Sciences, Stanford University School of Medicine, Palo Alto, CA 94305, USA

⁴Department of Biology, University of Virginia, Charlottesville, VA 22903, USA

⁵Department of Neurology, Washington University School of Medicine, St. Louis, MO 63110, USA

⁶Department of Neurosurgery, Stanford University School of Medicine, Palo Alto, CA 94305, USA

⁷The Salk Institute for Biological Studies, La Jolla, CA 92037, USA

⁸Neuroscience Institute, NYU School of Medicine, New York, NY 10016, USA

⁹Department of Internal Medicine, Wake Forest School of Medicine, Winston-Salem, NC 27101, USA

¹⁰Departments of Neuroscience and Genetics, Washington University School of Medicine, St. Louis, MO 63110, USA

¹¹Department of Pathology, Section on Comparative Medicine, Wake Forest School of Medicine, Winston-Salem, NC 27517, USA

¹²Lead Contact

*Correspondence: egibson1@stanford.edu

<https://doi.org/10.1016/j.cell.2020.05.045>

The COVID19 crisis has magnified the issues plaguing academic science, but it has also provided the scientific establishment with an unprecedented opportunity to reset. Shoring up the foundation of academic science will require a concerted effort between funding agencies, universities, and the public to rethink how we support scientists, with a special emphasis on early career researchers.

The novel coronavirus, SARS-CoV-2, has placed science at the center of every conversation, amplifying the importance of scientific research to economic stability, healthcare infrastructure, and disaster preparedness. In academic science, recovery from the immediate COVID19 crisis will require departments, universities, private foundations, federal agencies, and the public to work together collaboratively and comprehensively. The goal of recovery should not be to return to “normal” but, rather, to reset. Here, we argue that recovery provides us with the opportunity to address three systemic issues that plague the conduct of research in the twenty-first century, with an emphasis on supporting early career researchers who are the most vulnerable. The strategies needed to ensure stability and success of early career scientists post-COVID19 can be adapted to chip away at the systemic issues affecting the scientific establishment.

Excess Does Not Equal Excellence

Science has changed immensely over the past 50 years. More has become better:

more experiments per paper, more papers per year, more expectations and requirements for grants and tenure, more opinions from reviewers. The scientific community rewards quantity over quality. Most scientists can easily name a seminal paper; many were published long before the 2000s, and many had, at most, a handful of figures. Today, papers are often published with a plethora of supplemental figures that will largely go unread and underappreciated. The desire for “more” results in delays in publication, the awarding of grants, and career advancement for early career researchers; it also stymies creativity and encourages the proliferation of low-quality journals.

Diversification Leads to Discovery

This crisis is exacerbating the well-documented discrimination afflicting academic science (Monroe et al., 2008). Women, parents, and individuals who identify as racial or ethnic minorities leave science, technology, engineering, and math (STEM) fields as early career researchers at an excessively high rate in the best of

times and will undoubtedly suffer more from the present lab closures. The responsibilities of family life disproportionately impact women. A parent who is trying to homeschool their children, manage household duties, and work will have left little time to further their own scientific agenda. Faculty with family responsibilities—women specifically—must be supported. The COVID19 crisis will only highlight the rampant diversity issues plaguing the scientific establishment, many of which begin with the loss of women and minorities during early career stages and may lead to further disenfranchisement of the disadvantaged (Malisch et al., 2020).

Rethink the Fundamentals of Funding

The current model of academic science is heavily reliant upon federal funding, even though agencies such as the National Institutes of Health (NIH) were not built to sustain such expectations. The federal government's funding capacity has significantly diminished as the cost of science has radically increased. The 2019 defense



budget was ~\$685 billion while the 2019 NIH budget was \$39 billion. The COVID19 crisis has clearly amplified that the greatest risk to American life is not war, but disease. Funding is needed at all levels; however, early career researchers should be particularly supported as the consistent trend of shifting funding away from younger researchers has no end in sight (Daniels, 2015).

Ensuring a Durable Future for Academic Science Post-COVID19

Recovery from the immediate COVID19 crisis necessitates a multi-pronged approach including fiscal and non-fiscal strategies to help graduate students, postdoctoral fellows, and early and later career faculty. This pandemic has particularly impacted senior postdoctoral fellows seeking academic faculty positions and early career faculty seeking to establish themselves as independent investigators. Special consideration for these early career researchers is key to overcoming the crisis and strengthening the foundations of academic science. Our action plan proposed below is not an exhaustive list of all possible recommendations for supporting scientists, nor is it inclusive of every academic scientist's specific circumstance. Not all of our suggestions are applicable at every university or institution, as each will have its own unique set of challenges. We acknowledge that monetary support will be limited due to the deteriorating economic situation and drastic loss of revenue from clinical operations for most medical campuses. While the immediate goal of the recommendations is to provide support for scientists from funding agencies, universities, departments, and the public following COVID19, this support also provides solutions to the three major challenges. Solutions to these systemic issues (i.e., *Excess Does Not Equal Excellence*, *Diversification Leads to Discovery*, or *Funding Agencies*) are interwoven across the structure of academic science, allowing us to comprehensively tackle these issues at all levels. Plans for recovery from the COVID19 pandemic must ensure as much continuity as possible in research while improving upon existing infrastructures in order to provide a more inclusive, cohesive, and efficient future for the

next generation of independent scientists.

Funding Agencies Grantsmanship

The resiliency of research is dependent upon the support of funding agencies. Like the broader scientific community, funding agencies will need to adapt their strategies and structure to fit the changing times. Simplification of grant application processes, including fewer supplemental documentations and more implementation of letter-of-intent formats prior to full proposals, could increase efficiency for both the funding agency and researcher. Lab closures will undoubtedly create a void in the preliminary data that are necessary to obtain most awards. Early career researchers who had less time to acquire these data prior to lab shutdowns will be the most affected. Funding agencies could introduce policies and programs targeted at early investigators that require fewer preliminary data (similar to the National Institute of Mental Health [NIMH] Brain Research through Advancing Innovative Neurotechnologies [BRAIN] Initiative R01 or the DP2), reducing the excess in data required for most grants. Grants submitted by graduate students, postdoctoral fellows, and early career faculty who do not have sufficient preliminary data per current standards should be given special consideration. Currently, many of the new funding opportunities by funding agencies, such as the NIH, are geared toward supplements to existing grants or COVID-related research. As there will likely be restrictions or reductions to new funding opportunities in the coming years due to fiscal shortages, faculty with existing grants might help early career faculty by including them in their supplemental applications. Including early career faculty will also foster collaboration and resource sharing, both of which will be vital during this time (*Excess Does Not Equal Excellence* and *Rethink the Fundamentals of Funding*).

Extension of Deadlines, Timelines, and Funding

Numerous funding agencies have already implemented deadline extensions, but deadlines must be further extended for the duration of lab disruptions. It is also imperative that funding agencies extend

early investigator status for grant applications and implement no-cost extensions for currently held grants. Additional bridge funding programs may be especially important for faculty who are between projects or aiming to switch areas of study following the COVID19 crisis.

Universities

Extensions for Tenure: Faculty

Most universities have added one-year extensions to the tenure tracks of early career researchers, but sliding extensions may better support the success of vulnerable academics. Many early career investigators may request extensions during lab closures, but they should also have the ability to go up for tenure early if the opportunity arises. Ensuring the promotion and advancement of marginalized groups such as women, who make up < 30% of STEM faculty, is even more imperative post-COVID19. COVID19-initiated resetting of expectations for the publishing, teaching, mentorship, and service requirements for tenure may not only help minimize the excesses innate to the current tenure structure, but also may help foster environments that can acknowledge implicit biases and keep marginalized groups from disproportionately leaving STEM fields. Tenure expectations for the next generation of early career researchers may need to account for increased variability between faculty that is exacerbated by the COVID19 crisis and allow for more flexibility in the process. This crisis has amplified how the antiquated one-size-fits-all guidelines only encourage the disenfranchisement of women and racial or ethnic minorities (*Diversification Leads to Discovery and Excess Does Not Equal Excellence*).

Trainees

The current crisis will have a dramatic trickle-down effect, and numerous hiring freezes are already in place. Mechanisms to allow postdoctoral fellows or graduate students in their final year to continue in their current positions should be enacted, if necessary, and if labs or universities are able to provide fiscal support. Current closures are also disrupting the ability of many graduate students to complete their rotations. Universities could extend the timeline for rotations and potentially cover graduate students' stipends. Trainees, particularly postdoctoral fellows, may

have limited ability to extend their period of training due to visa restrictions. Universities should coordinate with federal agencies to pursue strategies aimed at extending visa expiration timelines, allowing trainees to complete work that was delayed due to the COVID19 crisis. These mechanisms are needed to assure that we do not lose an entire generation of scientists following the coronavirus crisis.

Curtailment of Applicable Hiring Freezes

Many universities have implemented hiring freezes for faculty and staff for the remainder of the year or beyond. Universities should not limit the ability of early career faculty to hire postdoctoral fellows and staff, however. Restricting early career faculty from hiring technical assistance and lab managers will stymie their ability to generate preliminary data, which will consequently limit grant and paper submissions and delay career advancement. Even a short hiring freeze could have devastating effects on the ability of early career faculty labs to succeed. Allowing early career faculty to continue hiring will also help to ease the bottleneck of graduate students looking for postdoctoral or research scientist positions within the next few years. Hiring freezes at any level will disproportionately affect early career individuals and oversaturate the market with qualified candidates. Permitting ongoing interviews for faculty positions, even if the official hire date is postponed, could alleviate stress on the postdoc population and expedite the hiring process when hiring freezes are lifted. The faculty search process serves as a valuable feedback mechanism for postdoctoral fellows that sometimes has an impact on career path. Halting all hiring and all faculty searches may drive talented postdocs, especially women and members of ethnic or racial minorities, out of academia (*Diversification Leads to Discovery*).

Institutional Funds and Startup Packages

Although universities may curtail spending from institutional funds, special consideration should be given to new and early career faculty. Early career faculty must retain access to their startup packages during this time. Institutional funds should be released for salary support for early career faculty and for all staff, students, and trainees in their labs.

If startup funds are set to expire, the expiration date should be extended. New faculty should be given the funds needed to establish their labs once research activities resume (*Rethink the Fundamentals of Funding*).

Supplementation

The economic toll caused by shelter-in-place will undoubtedly be significant, including the reduction in funding through endowments and charitable giving. We fully acknowledge that monetary supplementation may be difficult for universities following the COVID19 crisis. Any combination of fiscal supplementation with other mechanisms of non-fiscal support should be considered. Universities might implement new or expanded fellowships for postdocs and graduate students, add to existing startup packages for faculty, assist with the purchasing of equipment or expand shared equipment funding, or create subsidies or joint ventures with federal programs similar to unemployment or re-deployment programs. Universities might supplement pay or provide reimbursement for staff, postdoc, and graduate student salaries during the duration of academic closures.

Supplementation: Per Diem Costs

Many universities have per diem policies that differ based on funding source, with reduced per diem costs associated with federal grants. Early career faculty without federal funding have per diem costs double that of other labs. Universities could implement mechanisms to reduce or supplement animal costs that will be accrued during lab closures and when labs reopen and expand their animal colonies (*Rethink the Fundamentals of Funding*).

Supplementation: Childcare Initiatives

Onsite daycare facilities support postdoctoral fellows and faculty with young children. These family care centers are critical to narrowing the gap and slow the attrition of women and parents in science. Universities could work with early childhood education programs to establish or expand daycare and preschool programs, providing free or subsidized childcare for faculty and teaching opportunities for early education majors. Universities might also reach out to current or retired teachers seeking supplemental income (*Diversification Leads to Discovery*).

Supplementation: Access to Technology

Universities should encourage and enable graduate students and postdocs to use this time to learn new computational skills in anticipation of reductions in ability to do work at the bench. Many university-offered computational courses were over-committed during lab closures due to a significant increase in enrollment requests. Universities should make a concerted effort to increase bandwidth and capacity for computational courses. Many free online resources are also available to supplement the acquisition of coding skills.

Departments: Administrative and Teaching Load

Administrative and teaching expectations should be reevaluated during university closures. Departments should reassess administrative and teaching loads, especially for early career faculty whose promotions are contingent upon teaching requirements. This is especially important, since female scientists generally have increased teaching loads and more advisory expectations than male scientists (Gibney, 2017), which could disproportionately delay scientific recovery of female scientists from COVID19 closures (*Diversification Leads to Discovery*).

Mentorship Mental Health

The COVID19 crisis and subsequent lab closures will take an incredible toll on mental health. Early career faculty who have yet to establish themselves or their research independently and postdocs whose future job prospects are now significantly limited will be especially impacted by prolonged lab shutdowns. Department chairs, division leaders, and mentors should do their best to check in with early career faculty and postdocs during this time. Mentoring will be key both during and after this crisis. Establishing scheduled virtual meetings during social distancing and in-person meetings after labs are reopened could help alleviate some mental stress. University mental health resources are also available for anyone who needs support. As students generally contact female faculty about mental health issues more frequently than male

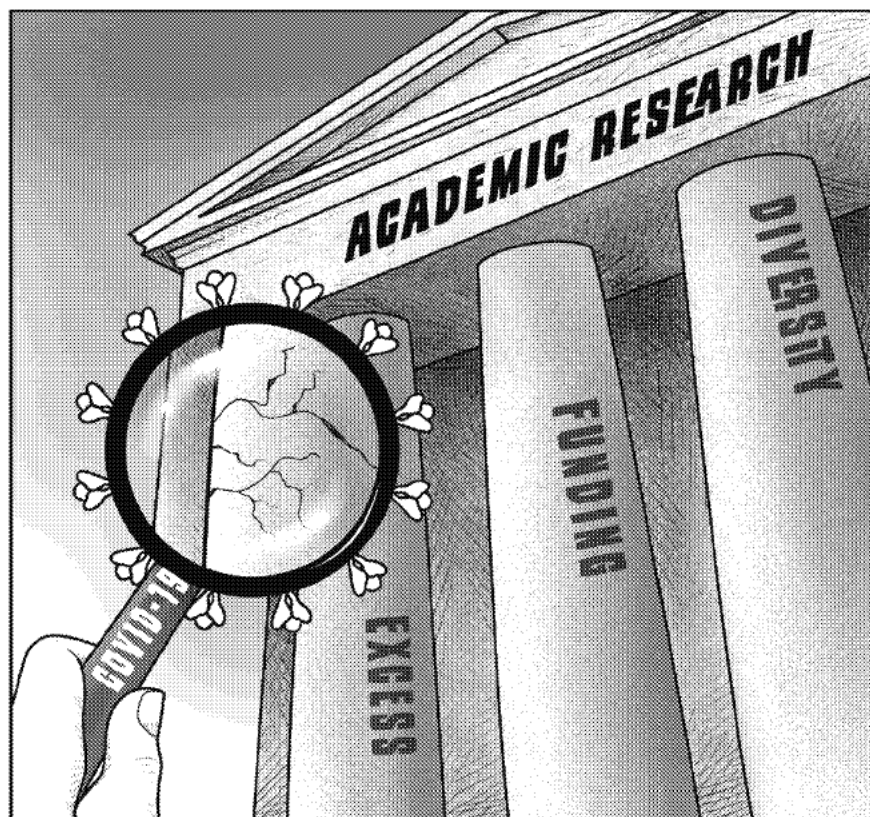


Figure 1. The COVID19 crisis has magnified the systemic issues plaguing academic research. These include the often stifling excess requirements in publication, tenure, and grant processes; the reliance on funding from national agencies that is catered towards senior level researchers; and the lack of diversity in academic research due to the attrition of women and racial or ethnic minorities during early career stages.

faculty (Bennett, 1982), equal encouragement of mentorship from all faculty is essential to not overburdening women faculty during this time (Diversification Leads to Discovery).

Graduate Student Programs

Mentoring graduate students throughout lab closures and after reopening should be strongly encouraged. Those conducting experiments will be most affected by lab closures, and this should be explicitly acknowledged by faculty and mentors. Universities must assure graduate students that graduate programs will be stabilized and that admittance will not be decreased. For many faculty, graduate students are the major workforce of the lab. To ensure that faculty can successfully build and sustain a lab, continued ability to attract graduate students is necessary. This is especially important for new investigators, as getting postdoctoral fellows can be more challenging for newer faculty.

Faculty Mentorship Programs

Once labs are reopened, pairing early career faculty with a later career faculty mentor of an established lab could facilitate more effective research programs and allow for resource sharing. Later career faculty could be incentivized to help early career researchers through reductions in teaching or administrative loads, supplementations to animal care costs, core facility usages, or other means of reimbursement and/or subsidizations. Investment of later career faculty in the success of early career faculty will help to ensure stability and success in the younger generation of independent researchers.

Clinician-Scientists

Faculty who have clinical responsibilities also necessitate special consideration during this time, especially if they are on the front lines. These individuals will not only lose productivity due to lab closures

and curtailment of patient enrollment in clinical trials, they will also have the extra physical and mental stressors of working in the hospital during a crisis. Establishment of protocols to aid clinician-scientists is imperative to ensuring their important contributions to science. Just as senior faculty mentoring will be critical for junior faculty and graduating postdocs to successfully transition to a post-COVID era in the basic sciences, this type of mentorship protocol may be even more critical for clinician-scientists, many of whom do not have doctorates beyond the medical degree.

Public Initiatives

Make Science a National Priority

The current crisis has brought the importance of science and research to the forefront of public life. Not only is science critical for public health decision-making, but a sustained investment in research better positions political leaders to efficiently deploy testing and therapeutic solutions. Capitalizing this momentum is crucial to engaging the public in science and science funding. Providing additional funding sources focused on conveying science to the greater public and stimulating interest in science through educational outreach is critical. Exploiting technology and social media to bring science and research directly to the public will be vital in the post-COVID19 world. Such technology might include mechanisms to allow private citizens to directly invest in science and scientists (Else, 2019; Miller, 2019), including simplified website-based donation platforms or inclusion on election ballots. This is necessary for establishing new funding sources for scientists, potentially supplementing the dearth of funding for early career researchers at federal funding agencies (Rethink the Fundamentals of Funding).

Enhanced Scientific Transparency

The COVID19 crisis has revealed a lack of public understanding about how science is funded, conducted, and reported. The current administration's belief that the NIH is "giving away \$32 billion a year" should be cause for concern (DeYoung et al., 2020). Much of the mistrust evident between the scientific establishment and the general population is rooted in lack of transparency and community

involvement in science. Taking scientists out of the “ivory tower” and increasing accessibility through technology may help to assuage the mistrust that hinders our preparedness in times of crisis. People cannot support what they do not understand. Removing excess requirements in publishing, grantsmanship, and tenure expectations could have the added benefit of creating more time for scientists to interact in the public domain. Scientists must work on building the trust that is imperative to success as a community, and early career scientists are primed to help pave this new future (*Excess Does Not Equal Excellence*).

Conclusions

Beyond the immediate challenges of returning to laboratories and research careers, the COVID19 crisis has exposed some of the underlying weaknesses and problems that permeate the current scientific enterprise (Figure 1). For example, editors are asking reviewers to not request more experiments unless absolutely necessary to validate the core claims of a manuscript during the review process. Most are applauding this effort to minimize excess and calling for its continued implementation even after scientists are able to get back to the bench. All institutions, funding agencies, departments, and members of the scientific

community should speak openly and honestly about the difficulties faced during the current situation. Early career researchers should be involved in the decision-making processes, as they represent the future of science and academic leadership. The COVID19 crisis has provided us with the unique opportunity to reflect upon the present norms and enact change through fiscal and non-fiscal strategies. Our hope is that this pandemic will allow us to chart a new course for science, both academically and socially, and to begin to address the core challenges of research, with a special focus on supporting the next generation of independent scientists.

DECLARATION OF INTERESTS

Dr. Roberts serves as Editor-in-Chief of books for the American Psychiatric Association Publishing Division and as Editor-in-Chief of the journal *Academic Medicine*. Unrelated to this publication, Dr. Roberts serves as an advisor for the Bucksbaum Institute of the University of Chicago Pritzker School of Medicine and owns the small business Terra Nova Learning Systems.

REFERENCES

Bennett, S.K. (1982). Student perceptions of and expectations for male and female instructors: Evidence relating to the question of gender bias in teaching evaluation. *J. Educ. Psychol.* 74, 170–179.

Daniels, R.J. (2015). A generation at risk: young investigators and the future of the biomedical workforce. *Proc. Natl. Acad. Sci. USA* 112, 313–318.

DeYoung, K., Sun, L.H., and Rauhalu, E. (2020). Americans at World Health Organization transmitted real-time information about coronavirus to Trump administration. *The Washington Post*, Available from. https://www.washingtonpost.com/world/national-security/americans-at-world-health-organization-transmitted-real-time-information-about-coronavirus-to-trump-administration/2020/04/19/951c77fa-318c-11ea-9040-68981f4388ed_story.html.

Else, H. (2019). Crowdfunding research flips science's traditional reward model. *Nature*, Available from. <https://www.nature.com/articles/d41586-019-00104-1>.

Gibney, E. (2017). Teaching load could put female scientists at career disadvantage. *Nature*, Available from. <https://www.nature.com/news/teaching-load-could-put-female-scientists-at-career-disadvantage-1.21839>.

Malisch, J.L., Harris, B.N., Sherrer, S.M., Lewis, K.A., Shepherd, S.L., McCarthy, P.C., Spott, J.L., Karam, E.L., Moustaid-Moussa, N., McCrory Calarco, et al. (2020). In the wake of COVID-19, academia needs new solutions to ensure gender equity. *Proceedings of the National Academy of Science*. <https://doi.org/10.1073/pnas.2010636117>.

Miller, Z. (2019). The best platforms for crowdfunding science research. *The Balance: Small Business*, Available from. <https://www.thebalancesmb.com/top-sites-for-crowdfunding-scientific-research-985236>.

Monroe, K., Ozyurt, S., Wrigley, T., and Alexander, A. (2006). Gender Equality in Academia: Bad News from the Trenches, and Some Possible Solutions. *Perspectives on Politics* 6, 215–233.

COVID-19, Research Impact, and Considerations for Next Steps

Michael Lauer, MD

Deputy Director for Extramural Research; Director, Office of Extramural Research
National Institutes of Health

EPMC Virtual Meeting

Wednesday, October 21, 2020

Virtual Meeting

Disclosures: None

THE WALL STREET JOURNAL

This site is for user personal consumption of content. This is not a publication and may contain errors. For more information, please contact your account manager at wsj@wsj.com.

OPINION | COMMENTARY

Medical Research Is Locked Down, Too

Clinical trials grind to a halt as patients are told to stay home and research personnel are redeployed

By Kevin S. Smith

May 4, 2020 5:58 pm ET

I lead clinical trials for medications to treat crippling disorders such as stroke and brain hemorrhages. During the past few months, every one of these studies has come to a grinding halt. The pandemic has thrown clinical trials, the lifeblood of new treatments, into disarray.

STAT

Covid-19 has shuttered scientific labs. It could put a generation of researchers at risk

By Justin Chen

May 4, 2020



Eric Berger/Getty Images



NIH

National Institutes of Health
Office of Extramural Research



**Congressional
Research Service**

Informing the legislative debate since 1914

Effects of COVID-19 on the Federal Research and Development Enterprise

April 10, 2020



NIH

National Institutes of Health
Office of Electronic Products

- Laboratories closed or nearly so
- Communications suboptimal
- Conferences and meetings cancelled or disrupted
- Supply chains interrupted; resources lost
- Widespread financial losses
- Required telework has disparate effects (e.g. childcare)
- Anxiety high, especially for early career investigators

<https://crsreports.congress.gov/product/pdf/R/R46309>

Pharmaceutical & Life Sciences News



Francis Collins, director of the National Institutes of Health, testifies during a Senate panel hearing on May 7, 2020. The hearing is about the impact of COVID-19 on the NIH.

Virus Will Cost NIH \$10 Billion in Lost Research, Director Warns (1)

May 7, 2020 4:00 PM Updated on May 7, 2020 4:20 PM

- NIH's COVID-19 testing efforts: Senate hearing panel on hearing
- \$10 billion in lost research due to COVID-19, says director

Journalist: [Name]
Reporter: [Name]

comment

 Check for updates

Unequal effects of the COVID-19 pandemic on scientists

COVID-19 has not affected all scientists equally. A survey of principal investigators indicates that female scientists, those in the 'bench sciences' and, especially, scientists with young children experienced a substantial decline in time devoted to research. This could have important short- and longer-term effects on their careers, which institution leaders and funders need to address carefully.

Kyle R. Myers, Wei Yang Tham, Yian Yin, Nina Cohodes, Jerry G. Thursby, Marie C. Thursby, Peter Schiffer, Joseph T. Walsh, Karim R. Lakhani and Dashun Wang

Nature Human Behavior, July 15, 2020

<https://www.nature.com/articles/s41562-020-0921-y>

ARE WOMEN PUBLISHING LESS DURING THE PANDEMIC? HERE'S WHAT THE DATA SAY

Early analyses suggest female academics are posting fewer preprints than men, and starting fewer projects.

By Giuliana Viglione

Quarantined with a six-year-old child underfoot, Megan Frederickson wondered how academics were managing to write papers during the COVID-19 pandemic. Lockdowns implemented to stem coronavirus spread meant that, overnight, many households worldwide had become an intersection of work, school and home life. Conversations on Twitter seemed

PREPRINT DROP-OFF

Two separate analyses show that women's posting rate on preprint servers has slowed during the coronavirus pandemic.

All-author analysis

When compared with March and April 2019, the number of male authors on preprints posted to bioRxiv and arXiv has grown faster than the number of female authors in that period this year.

Mar-Apr 2019 ■ Mar-Apr 2020 ■

arXiv: 2019 vs 2020 bioRxiv: 2019 vs 2020

The Virus Moved Female Faculty to the Brink. Will Universities Help?

The pandemic is a new setback for women in academia who already faced obstacles on the path to advancing their research and careers.



Lisa Werner is her lab at Boise State University. Photo credit: The New York Times

Nature, May 28, 2020

<https://media.nature.com/original/magazine-assets/641566-020-01264-9/641566-020-01264-9.pdf>



NIH

National Institutes of Health
Office of Extramural Research

<https://www.nytimes.com/2020/05/28/science/covid-and-women-nature.html>

- Application deadlines, post-submission data
- All peer review remote – through Spring 2021
- Salaries and stipends – until September 30, 2020
- Human subject research, clinical trials
- Animal research, guidance to IACUCs
- Extensions on reporting; flexibility on expenditures
- Accommodations for loss of time, ESI extension



Table 1*: Number of R01-equivalent applications received between May 1 and June 5 in 4 consecutive years.

	Number	All Women (%)	All Men (%)	Other (%)
2017	6398	24.6%	61.7%	11.5%
2018	6481	26.4%	59.8%	11.2%
2019	6171	25.8%	60.9%	10.7%
2020	6799	25.7%	56.8%	14.8%

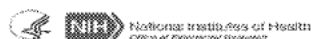
August
2020



Research Impact Under COVID-19

FINANCIAL CRISIS AND THE
"PANDEMIC NORMAL"

Research output has been severely impacted during the COVID-19 pandemic, at home and abroad. The Research Impact Metric (RIM) Model is a novel tool that estimates the impact. The United States is the global leader in research—however, as the financial impact to research approaches the tens of billions of dollars and our global leadership in research is threatened, national security and economic stability are jeopardized. What started as an acute occurrence has become a chronic crisis, and will persist until an effective vaccine is widely available. As we learn to do research under the "Pandemic Normal," a new commitment by Federal leaders, Research institutions, and other stakeholders is imperative.



Cell

Leading Edge

CellPress

Commentary

How Support of Early Career Researchers Can Reset Science in the Post-COVID19 World

Erin M. Gibson,^{1,12,*} F. Chris Bennett,² Shawn M. Gillespie,³ Ali Deniz Güler,⁴ David H. Gutmann,⁵ Casey H. Halpern,⁶ Sarah C. Kucenas,⁴ Clete A. Kushida,⁷ Mackenzie Lemieux,⁷ Shane Liddelow,⁸ Shannon L. Macauley,⁹ Qingyun Li,¹⁰ Matthew A. Quinn,¹¹ Laura Weiss Roberts,¹² Naresha Saligrama,¹³ Kathryn R. Taylor,¹⁴ Humsa S. Venkatesh,¹⁵ Belgin Yalcin,¹⁶ and J. Bradley Zuchero⁶

"The COVID19 crisis has magnified the systemic issues plaguing academic research ... often-stifling excess requirements in publication, tenure, and grant processes; the reliance on funding from national agencies that is catered towards senior level researchers; and the lack of diversity in academic research due to the attrition of women and racial or ethnic minorities during early career stages ... An unprecedented opportunity to reset ... will require a concerted effort between funding agencies, universities, and the public to rethink how we support scientists, with a special emphasis on early career researchers."

 **NIH** National Institutes of Health
Office of Extramural Research

<https://doi.org/10.1016/j.cell.2020.05.045>

Open Mike

Helping connect you with the NIH perspective, and helping connect us with yours

Posted on October 9, 2020 by Mike Lauer

Encouraging Participation in Upcoming NIH Surveys to Identify Impacts of COVID-19 on Extramural Research

NIH has been working diligently to support the extramural research community since the pandemic began in March. We are now preparing to reach out with surveys to gather data on how COVID-19 is impacting our extramural researchers and their institutions. If you receive



Dr. Michael Lauer is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

- Absent unlikely supplemental, answer is “No”
- Most likely supplemental now is only \$3 Billion
- Consideration:

(b) (5)

- Maximize flexibilities we already have

NIH Impact of COVID-19 on Extramural Research Surveys

The NIH wants to understand how COVID-19 is impacting extramural researchers and their institutions to inform policy and program decisions. To achieve this, they are launching two surveys.

NIH Impact of COVID-19 on the Extramural Institutions Survey

- ▶ **Objective:** Understand institutional support for research activities, productivity expectations, and safety measures during COVID-19
- ▶ **Sample:** VPs of Research and equivalent at institutions receiving NIH funding
- ▶ **Invite:** An email from Mike Lauer, NIH's Deputy Director for Extramural Research, with a link to the survey
- ▶ **Timing:** This survey will be open until late October

NIH Impact of COVID-19 on the Extramural Researchers Survey

- ▶ **Objective:** Understand how COVID-19 has impacted researchers at institutions that receive NIH funding
- ▶ **Sample:** Individuals who have logged into eRA Commons in the past 2 years and are identified in the system as having a Scientific Role
- ▶ **Invite:** An email from Qualtrics (noreply@qemailserver.com) with a link to the survey
- ▶ **Timing:** This survey launches October 14 and is open until the end of the month

Both surveys are confidential and run by a third party, who will share only de-identified survey data with NIH. Survey results will be analyzed and reported to leadership in aggregate.

August
2020

COGR

Council On Governmental Relations

Research Impact Under COVID-19

FINANCIAL CRISIS AND THE “PANDEMIC NORMAL”

Research output has been severely impacted during the COVID-19 pandemic, at home and abroad. The Research Impact Metric (RIM) Model is a novel tool that estimates the impact. The United States is the global leader in research—however, as the financial impact to research approaches the tens of billions of dollars and our global leadership in research is threatened, national security and economic stability are jeopardized. What started as an acute occurrence has become a chronic crisis, and will persist until an effective vaccine is widely available. As we learn to do research under the “Pandemic Normal,” a new commitment by Federal leaders, Research institutions, and other stakeholders is imperative.

Released August 25, 2020

Research Impact under COVID-19: Financial Crisis and the “Pandemic Normal”

EXECUTIVE SUMMARY

The COVID-19 pandemic and the subsequent economic downturn have led the country into unprecedented times—consequently, an unprecedented response is needed to safeguard research

and development at colleges, universities, and research organizations across the United States. ***This paper presents a model for estimating research output loss and financial impact, describes the challenges of doing research under the new “Pandemic Normal,” and advocates for renewed commitment and a substantial infusion of new research investment. Federal leaders, research institutions, and all stakeholders must rally around the longstanding Federal Government-Research Institution Partnership.***

Council on Governmental Relations

The Council on Governmental Relations (COGR), established in 1948, is an association of almost 200 leading universities and research institutions and is nationally recognized as the technical expert on a wide range of research policy issues, including how the research funding model works in the United States. For more information on COGR, please visit www.cogr.edu

COGR
Council On Governmental Relations

- The Research Impact Metric (RIM) Model is a novel model that estimates the research output loss and financial impact due to the COVID-19 pandemic and the resultant economic downturn. The initial ramp down, the transition to ramp up, and the uncertainty going forward, have had a dramatic impact on research.

- The RIM model provides important data on the research output loss and financial impact at mission diverse and geographically widespread institutions. The RIM model has shown: 1) research output losses between 20 and 40 percent, 2) financial disinvestment impact in the hundreds of millions of dollars at individual institutions, and 3) potential impact in the tens of billions of dollars across the entire U.S. research enterprise. Without new and sustained investment, our institutions’ and the nation’s research capabilities will be severely weakened.

- Just as importantly, we are at risk of losing a whole cohort of graduate and post-doctoral students seeking training and education at research institutions across the U.S. They are our future scientists, engineers, and innovators, and include researchers from

underrepresented groups, minorities, women, and junior researchers.

- A new “Pandemic Normal” for how research is conducted in our country, as well as globally, has emerged—and inefficiencies are unavoidable. For example, the scope of research promised on a \$1 million award (pre-COVID-19) will now require more than \$1 million to complete. And, the scope of research to be delivered in one year (pre-COVID-19) will now require more than one year. In order to operate effectively and efficiently under the “Pandemic Normal,” new measures such as redefining proposal and budgeting guidelines, eliminating overly-burdensome regulations, and related measures are necessary.
- Understanding the impact and supporting the research enterprise to get through this crisis is paramount to maintaining the global competitiveness, technological leadership, and the economy of the United States.

This paper draws on the expertise and experience of the COGR membership and describes research impact under COVID-19 in the following sections:

- **PART I. INTRODUCTION.** Sets the stage and defines the crisis, including threats to the research enterprise (see page 5).
- **PART II. THE RESEARCH IMPACT METRIC (RIM) MODEL.** Presents key considerations and assumptions, which can be used by institutions to assess/estimate the research impact at an institution, and by others to understand the breadth and depth of impact of the pandemic to the research mission across the country and globally.
- **PART III. THE PANDEMIC NORMAL.** Presents a cautionary tale of how the research community and stakeholders should expect research to unfold until there is a widely available vaccine that allows life to return to normal. Under a “Pandemic Normal,” where physical laboratory access, social distancing, and other new norms around research operations are implemented, the repercussions will be seen in research delivery, program goals and aims, and realistic expectations around research outcomes.
- **PART IV. CASE STUDIES.** Five case studies are presented. These are representative of five diverse research institutions—two privates and three publics, three of which have medical schools, one that is a land-grant institution, and one that has both a medical school and is a land-grant. *These case studies demonstrate that the research output loss and financial impact are real and severe.*
- **PART V. CONCLUSION.** Final thoughts including the need to fully engage the Federal Government-Research Institution Partnership.

- **CONTRIBUTORS AND APPENDICES.** Key Contributors, How Research Operations are Disrupted ([Appendix A](#)), and Research Under the Pandemic – Challenges and Adaptations ([Appendix B](#)).
- **ADDITIONAL RESOURCES.** COGR resources specific to COVID-19’s Impact to Research, including a dedicated web page, agency policy links, FAQs, and more.

PART I. INTRODUCTION

These are unprecedented times. The impact on the research function at research institutions since March 2020 is real, material, and in many cases, severe. Ramp up initiatives are ongoing, but the effort to return to normal functioning has been uneven and the risk of setbacks lurks as the impacts of COVID-19 continue to persist.

This paper introduces a Research Impact Metric (RIM) Model as a tool to demonstrate the impact on research output due to the COVID-19 pandemic for the period March 2020 through February 2021.

The RIM Model can be used as an internal tool to estimate the impact at an institution and also may be used to understand the macro-impact of COVID-19 on the United States’ research enterprise. As the disruptions caused by the COVID-19 pandemic persist, ***it is apparent this is causing a net disinvestment in research and development activities in the United States—in effect, requiring new and significant capital investments to ensure the research enterprise is not irreversibly disrupted.*** Should this investment be forthcoming, the United States can have confidence in its ability to retain its position as the global leader in innovation and discovery.

Institutions are confronted with difficult decisions caused by the COVID-19 pandemic and the subsequent economic downturn. Cost cutting measures are under consideration and being implemented across all functions of research institutions, and difficult decisions rest on institutional policies and federal and state guidance, rules, and regulations. All institutions are impacted economically by the response to COVID-19—public and private, medical and non-medical, rural and urban.

The threats to the United States research enterprise are real and include:

- Inability to achieve original program goals
- Loss of entire research programs
- Loss of the ability for investigators to collaborate across institutions, designated research centers, federal laboratories, and via traditional subrecipient agreements
- Loss of a generation of trained scientists and engineers, as well as researchers in social, behavioral, education disciplines, and the arts—all of whom provide a workforce and education pipeline to meet the needs of academia, government, and industry
- Loss of foreign students and scholars and their major contributions to academia
- Significant slowdowns in discoveries and technological development
- Recurring costs of the “ramp down, ramp up, ramp down” cycle
- Loss of cell lines, animal colonies, and continuity of human subjects trials
- Disruptions in core facilities and centers due to interrupted research
- Fear of the unknown, including loss of employee morale and the persistent uncertainty about current and future employment
- And ultimately, the decrease, not only in volume, but also the quality of research conducted in the United States

The federal government has recognized these threats. For example, the Office of Management and Budget, in collaboration with federal agencies, provided administrative and salary charging flexibilities to protect against furloughs and layoffs that could prevent a quick return to normal research activity.¹ ***However, until the COVID-19 pandemic is definitively controlled, the possibility of shuttering research laboratories and research activity could become a reality.*** The threat of a severely damaged research enterprise should be addressed while there is time to mitigate it by allowing the research function to operate at maximum efficiency and effectiveness under its unique “Pandemic Normal.”

¹ See the March 19 release of OMB M-20-17 “Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus (COVID-19) due to Loss of Operations” and the June 18 release of OMB M-20-26 “Extension of Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus (COVID-19) due to Loss of Operations.”

PART II. THE RESEARCH IMPACT METRIC (RIM) MODEL

The Research Impact Metric (RIM) is a model designed to illustrate the degree to which research output (as a percentage) has been negatively affected under the COVID-19 pandemic. The RIM also captures financial impact, or disinvestment, expressed in dollars.

$$\text{Research Output Loss} = \frac{\text{Research Output Loss due to COVID-19 Emergency Restrictions}}{\text{Research Output under Pre-COVID-19 (Normal) Conditions}}$$

For example, a 30 percent loss indicates that 30 percent of research output is in jeopardy, which means certain program goals and aims may not be achievable in the scheduled time frame—and unless addressed systematically, this 30 percent becomes a permanent loss of research output and productivity. Note, the COVID-19 pandemic has not halted all research, as investigators, research personnel, and institutional leaders have taken significant measures to keep the research engine functioning by maintaining/preserving the most critical and irreplaceable elements.

Despite these heroic efforts, NIH Director Francis Collins, while testifying before Congress on May 7, 2020 stated: “*The estimates are something like \$10 billion of NIH funded-research that is going to disappear because of the way in which this virus has affected everybody requiring this kind of distancing and sending people home.*”² With financial and other pressures on higher education institutions, it is inevitable that output has been and will continue to be lost as the COVID-19 pandemic makes it impossible for research to function according to traditional standards.

The RIM Model presented in this paper captures research impact for all externally sponsored research at the institution. ***However, it can be adapted to a range of disciplines to differentiate between biochemistry, aerospace engineering, computer science, literature/language, and other disciplines.***

² See “*Virus Will Cost NIH \$10 Billion in Lost Research, Director Warns (1)*” (Bloomberg Law) – May 7, 2020

In addition, the model also treats all types of expense categories the same. For example, labor, laboratory supplies, and travel all are assumed to be affected similarly. However, we know the impact on labor and the impact on travel caused by the COVID-19 pandemic are very different—labor continues to be productive at various levels, while the ability to travel has been significantly impaired. ***Though we treat each expense category the same, the model can be adapted to provide differential treatment for various expense categories.***

Other assumptions of the RIM Model include:

- The starting point is the “average” month of financial expenditures for federal and other sponsored research at the institution (Chart A.), prior to the COVID-19 pandemic. This simplifies the model, though more precision (e.g., academic year, summer months, specific expense categories) could be used to determine monthly financial expenditures.
- Four “Negative Impact” scenarios are used: 10 percent, 25 percent, 50 percent, and 80 percent, with 10 percent being the minimal and 80 percent being the most severe. These scenarios are flexible and can be adjusted according to lab circumstances and safety policies and procedures in place at the institution.
- The model also is meant to take into account costs such as cell lines, animal colonies, and human subject participation, which all have been interrupted and result in a real impact on research outcomes. Also included in the model are losses to core facilities.
- Negative impact is based on currently available information, which includes an estimated duration of lab closures to varying degrees that began in March, continued into May and longer, and will persist to varying degrees as institutions continue to ramp up research and work to implement new standards for doing research under COVID-19.

We have taken the high-level approach, which we suggest presents a fair and representative RIM Model for the entire institution. However, the “hypothetical model” presented below could be completed for specific academic disciplines (biochemistry, aerospace engineering, computer science, literature/language, etc.) with differentiated impacts for various expense categories (labor, travel, etc.). The approach taken depends on the needs of the institution—the “hypothetical model” is meant to be an instructive starting point. Actual case studies use the high-level approach and are shown in Part IV.

HYPOTHETICAL INSTITUTION:

Chart A. is premised on Pre-COVID-19 (i.e., FY 2019) average monthly federal and other sponsored research expenditures, by categories of expense (note, including categories of expense is optional)—***most important is to arrive at monthly expenditures.*** The negative impact scenarios are 10 percent (minimal), 25 percent, 50 percent, and 80 percent (most severe).

Chart A. Monthly Negative Impact on Research using Various Scenarios

	Pre-COVID Monthly (millions)	10% Negative Impact	25% Negative Impact	50% Negative Impact	80% Negative Impact
Payroll & Fringe Benefits	20.0	2.0	5.0	10.0	16.0
F&A Reimbursement	10.0	1.0	2.5	5.0	8.0
Subrecipient Payments	7.0	0.7	1.8	3.5	5.6
Other Costs	1.0	0.1	0.3	0.5	0.8
Lab Supplies	1.0	0.1	0.3	0.5	0.8
Recharges	1.0	0.1	0.3	0.5	0.8
FinAid/Tuition Remission	1.0	0.1	0.3	0.5	0.8
Professional Services	0.1	-	-	-	0.1
Capital Equipment	1.0	0.1	0.3	0.5	0.8
Travel	0.2	-	-	0.1	0.1
MONTHLY (millions)	\$42.3	\$4.2	\$10.6	\$21.2	\$33.8
ANNUAL (millions)	\$507.6	\$50.4	\$127.2	\$254.4	\$405.6

In this hypothetical, the institution has average monthly research expenditures (federal and other sponsored) of \$42.3 million, and annual expenditures of \$507.6 million. For example, using a 25 percent negative impact for the entire year, the negative impact would be \$10.6 million monthly and \$127.2 million for the entire year.

In Chart B. below, the negative impact scenarios are entered on a month-by-month basis to model both the known negative impact (e.g., March thru July 2020) and the projected impact going forward (e.g., August 2020 thru February 2021). While Chart B. stops at February 2021, it is becoming increasingly clear that research performance will likely be impacted for much longer.

The results in Chart B. are shown both in terms of dollars and percentage. *The RIM Model calculation demonstrates the research output that has been lost—program goals and aims may not be achievable in the scheduled time frame, or the research may be lost altogether. Unless addressed systematically, this becomes a permanent and irreplaceable loss of research. This critical loss to the continuity of research, ultimately impacts future scientific research workforce development.*

Model #1 in Chart B. presents “Continuous Ramp Up” where there is no significant recurrence of COVID-19 affecting the institution. Model #2 presents “Interrupted Ramp Up” where there is disruption, for example, in November due to a recurrence of COVID-19 affecting the institution. The one-year negative impact to research covers March 2020 through February 2021.

Chart B. Research Impact Metric (RIM) Calculation
Model #1 – Continuous Ramp Up (no significant recurrence of COVID-19)

Month	Negative Impact	10% Negative Impact	25% Negative Impact	50% Negative Impact	80% Negative Impact
March 2020	\$21.2			\$21.2	
April 2020	\$33.8				\$33.8
May 2020	\$33.8				\$33.8
June 2020	\$21.2			\$21.2	
July 2020	\$21.2			\$21.2	
August 2020*	\$10.6		\$10.6		
September 2020*	\$4.2	\$4.2			
October 2020*	\$4.2	\$4.2			
November 2020*	\$4.2	\$4.2			
December 2020*	\$4.2	\$4.2			
January 2021*	\$4.2	\$4.2			
February 2021*	\$4.2	\$4.2			
Disinvestment	\$167.0 M				
Research O/P Loss	32.9%				

Research Output Loss = \$167.0 M / \$507.6 M (annual amount) = 32.9%

**March-July 2020: Actuals. August 2020-February 2020: Projections.*

Chart B. Research Impact Metric (RIM) Calculation
Model #2 – Interrupted Ramp Up (recurrence of COVID-19 in November)

Month	Negative Impact	10% Negative Impact	25% Negative Impact	50% Negative Impact	80% Negative Impact
March 2020	\$21.2			\$21.2	
April 2020	\$33.8				\$33.8
May 2020	\$33.8				\$33.8
June 2020	\$21.2			\$21.2	
July 2020	\$21.2			\$21.2	
August 2020*	\$10.6		\$10.6		
September 2020*	\$4.2	\$4.2			
October 2020*	\$4.2	\$4.2			
November 2020*	\$10.6		\$10.6		
December 2020*	\$21.2			\$21.2	
January 2021*	\$21.2			\$21.2	
February 2021*	\$10.6		\$10.6		
Disinvestment	\$213.8 M				
Research O/P Loss	42.1%				

Research Output Loss = \$213.8 M / \$507.6 M (annual amount) = 42.1%

**March-July 2020: Actuals. August 2020-February 2020: Projections.*

Different approaches may be used for estimating impact, and each approach will be institution-specific. Other methods for estimating impact include surveys to measure campus/facility/lab access, percent of personnel (e.g., faculty, graduate students, post-docs, research scientists) allowed to access facilities (including the time and duration of their access), or a variations on these types of surveys. Most important is to develop sound institutional metrics that demonstrate how research has been impacted by the COVID-19 pandemic.

In summary, the projected annual loss to research output for this hypothetical institution is devastating:

**Research Output Loss and Financial Disinvestment
(March 2020 thru February 2021)**

Annual Research (external)	Output loss (Continuous Ramp Up)	Disinvestment (Continuous Ramp Up)	Output loss (Interrupted Ramp Up)	Disinvestment (Interrupted Ramp Up)
\$507 M	32.9 %	\$167 M	42.1 %	\$214 M

The RIM is demonstrated both by the research output loss (between 32.9 and 42.1 percent) and the financial disinvestment (between \$167 and \$214 million)—*these numbers are alarming for an institutional already reeling from real revenue losses in tuition, state funding, athletics revenue, and housing, food services, and other revenues.*

In addition, we are at risk of losing a whole cohort of graduate and post-doctoral students seeking training and education at research institutions across the U.S. They are our future scientists, engineers, innovators, and include researchers from underrepresented groups, minorities, women, and junior researchers. This would be a devastating loss, and one the nation cannot tolerate. Case Studies are shown in Part IV.

III. THE PANDEMIC NORMAL

While productive and important research has been and will continue to be performed during the COVID-19 pandemic, the initial shutdown of research labs, uneven reopening, implementation of new mandated safety practices, research dependencies through subawards with collaborators who are at different phases of ability to work, and risk of future shutdowns all have contributed to hindering research performance according to traditional standards of efficiency and effectiveness. Approaches such as the RIM Model provide useful quantitative metrics to show the impact to research.

It is understood that, given the unprecedented nature of the COVID-19 pandemic, estimates of research output loss are just that, estimates, which are institution-specific. Still, it is imperative that the research community and policymakers understand the gravity of the situation. In addition

to the RIM Model, institutional surveys can be used to collect data to more fully assess the impact on research. For example, surveys can be conducted on campus/facility/lab access; the percent of personnel (e.g., faculty, graduate students, post-doc / research scientist) allowed to access facilities, including the time and duration of their access; impact on specific populations and how these populations may be disproportionately impacted (i.e., minorities, women, and other under-represented populations), as well as other indicators that can help demonstrate the impact on research.

All of this leads to a discussion of the Pandemic Normal, requiring recognition that how we conduct research is significantly changed, and will be the norm, at least until an effective vaccine is widely available.

What is meant by a “Pandemic Normal” for an institution?

First, with significant projected loss in research output, without both time extensions and funding supplements to recover the loss in research output, most research projects will be unable to meet their original program goals and aims. Scopes of work can be adjusted, retro-actively, and the research that can be completed still provides value and advances the body of knowledge. However, there will be other consequences as well. The careers of academic personnel (faculty, graduate students, post-docs) and at-risk populations (minorities, women, and other under-represented populations) that rely on the outcomes of research (peer-reviewed publications, dissertations) will be negatively impacted.³ The discovery and development of technologies may be delayed. The research community and all stakeholders must be realistic and holistic in assessing the risk to the country in terms of lost research, loss of innovation and discoveries that emerge from research, and ultimately, loss of global competitive advantage.

Second, until the COVID-19 pandemic is definitively controlled, the research community, stakeholders, and the country as a whole must come to terms with the fact that there is a “Pandemic Normal” as it relates to conducting research. In the simplest terms: The scope of research promised on a \$1 million award (pre-COVID-19) will now require more than \$1 million to complete. And, the scope of research to be delivered in one year (pre-COVID-19) will now require more than one year.⁴

³ See “The career cost of COVID-19 to female researchers, and how science should respond” (*Nature*) <https://www.nature.com/articles/d41586-020-02183-x> and “It’s like we’re going back 30 years’: how the coronavirus is gutting diversity in science” (*Nature*) <https://www.nature.com/articles/d41586-020-02288-3>

⁴ See Congressional Research Service Report “Effects of COVID-19 on the Federal Research and Development Enterprise” <https://crsreports.congress.gov/product/pdf/R/R46309>

New standards of research operations will define the Pandemic Normal

These standards include but are not limited to:

- Restricted access to research buildings and research laboratories
- Social distancing within the laboratory
- Staggered shift-scheduling (i.e., 6:00 AM-2:00PM, 2:00 PM-8:00 PM, etc.), and the loss of intellectual stimulation and sharing that comes from working collaboratively
- Additional “down-time” to clean between shifts (and between equipment use cycles) requiring research personnel to clean the space (and equipment) to be in compliance with CDC guidelines
- Adjustment to working with continuous use of PPE where formerly not necessary, along with the associated inefficiencies and costs
- Temporary (or permanent) loss of research personnel who test positive or display COVID-19 symptoms
- Deployment of new health and administrative staff to implement testing and contact tracing, as well as to assure research laboratory compliance with safety policies
- Transition to remote work if a research building or laboratory is shut down
- New and unanticipated day-to-day work disruptions affecting research operations
- Slow or compromised supply chains and associated higher costs
- Reduced lab visitors from visiting scholars and collaborators
- Interruption of or limitations on conducting in-person human subject research
- Discontinuation of conducting artistic and performing arts exhibition with live audiences

These are only a few examples. ***APPENDIX A, HOW RESEARCH OPERATIONS ARE DISRUPTED*** provides additional examples to the above list, and ***APPENDIX B, RESEARCH UNDER THE PANDEMIC – CHALLENGES AND ADAPTATIONS***, provides real life examples of how specific research projects, across various academic disciplines, have been impacted under the Pandemic Normal.

The Pandemic Normal requires the research community, and importantly, ***the research funding agencies***, to rethink how research continues under the Pandemic Normal—and consequently, the monetization of unavoidable inefficiencies which must be captured in evaluating and funding new proposals, both in the scope of work and budgets submitted to the funding agencies.

Proposals, in fact, may also need to include an approximate and well justified “contingency factor,” recognizing the possibility that a facility may need to shut down for a period of time. Such budgeting flexibility could reflect local/regional COVID-19 conditions and would inject more certainty into the research process. If conditions do not hinder research progress, the funds would be retained by the funding agency.

As an example, the Pandemic Normal can be monetized as follows: A graduate student, who cannot readily access the lab as in the past, will take longer to complete the same work, assuming the graduate student is working in shifts and has restricted access under the Pandemic Normal. For dissertation support, typical three-year graduate student support requested on a grant may be extended by an additional semester (or semesters). Assuming a graduate student needs an additional semester for the same quantity of work, the research impact is 1/6th or 16.7%. Additional time may also be required for field work should travel be limited or stopped all together.

Monetization of unavoidable inefficiencies also is relevant with respect to traditional ways of thinking about research infrastructure. Most of an institution’s research infrastructure is captured in the Facilities and Administrative (F&A) cost rate and reimbursement.⁵ This includes the costs of constructing and maintaining technologically advanced research laboratories, protecting human and animal subjects in research, safeguarding the community from dangerous chemicals and biohazard waste, ensuring reliable financial stewardship, providing high-speed data processing and technology, and supporting numerous other compliance and administrative activities that help researchers conduct their research in the least-burdensome environment possible. It is inevitable that the cost of an institution’s research infrastructure will increase as long as the COVID-19 pandemic persists. Any mechanisms that can provide for recovery of these costs will offer welcome relief to research institutions.

In addition, institutional ramp down efforts (after the initial shutdown), ramp up efforts (after it was deemed safe to transition), and the possibility of additional cycles of ramp down / ramp up, each result in new costs. This includes physical modifications to labs (changes to entry points, signage, badge readers, HVAC modifications, Plexiglas barriers, etc.), PPE and sanitizing stations, regular COVID-19 testing protocols, specialized sanitization materials and procedures for sensitive laboratory equipment such as microscopes, staffing (increased security personnel, janitorial and environmental safety, other administrative personnel, etc.), and unanticipated costs that certainly be incurred. Some of these costs will be allowable as direct charges to federal awards and others will be more appropriately classified as F&A (in which case they are not

⁵ See COGR’s 2019 paper, *“Excellence in Research: The Funding Model, F&A Reimbursement, and Why the System Works”* (see: https://www.cogr.edu/sites/default/files/ExcellenceInResearch4_12_19_0.pdf)

recoverable as direct charges). Regardless, this also contributes to the monetization of unavoidable inefficiencies and real costs to be absorbed by the institution.

The Pandemic Normal may also be an opportunity to rethink how federal agencies and research institutions can work together to reduce regulatory burden. Program officers at federal agencies can be empowered to implement a supplement policy, review justifications on a case-by-case basis, and allow for project performance period extensions with funding to offset other inefficiencies. Since this is a systemic inefficiency, an allowance at the proposal stage (until a vaccine is available and we return to an approximation of the old normal) will be a helpful and practical solution.

Finally, one more opportunity under the Pandemic Normal would be, on a case-by-case basis, providing additional stipend support for students whose research requires an extended time period to complete the necessary work, subject to justification. In the education and social science research fields, where access to schools, field stations, or human subjects is restricted, it will be important to allow these researchers more time to complete the same quantity of work. If funding agencies adopt the target date approach for proposal submission deadlines, this would allow more flexibility should researchers face delays due to reduced facility access, graduate student availability, or illness. Allowing for more frequent deadlines can also provide enhanced flexibility and reduce burden on sponsored programs staff and avoid the need for additional personnel.

The Pandemic Normal, while making research a more expensive and challenging endeavor, provides a new opportunity to identify new practices to facilitate research and reduce regulatory burden. A joint commitment by the research funding agencies and the research institutions to implement new and needed practices and flexibilities during the Pandemic Normal would be action taken in the true spirit of the Federal Government-Research Institution Partnership.

IV. CASE STUDIES

The five case studies below, at mission diverse and geographically widespread institutions, represent real-life research institutions in the United States. Using the RIM Model, research output loss and financial disinvestment are shown for the 12-month period, March 2020 through February 2021. ***These case studies demonstrate: 1) research output losses between 20 and 40 percent, 2) financial disinvestment impact in the hundreds of millions of dollars at individual institutions, and 3) potential impact in the tens of billions of dollars across the entire U.S.***

research enterprise. Without new and sustained investment by the federal government and other research sponsors (or until an effective vaccine is found and widely distributed), our institutions’ and the nation’s research capabilities will be severely weakened, and these research output losses will persist.

**Research Output Loss and Financial Disinvestment
(March 2020 thru February 2021)**

Private/ Public	Med School	Land Grant	Annual Research	Output Loss (No Interrupt)	Financial Disinvest (No Interrupt)	Output Loss (November Interrupt)	Financial Disinvest (November Interrupt)
Private	Y		\$900 M	24%	\$218 M	33%	\$296 M
Public	Y		\$409 M	21%	\$88 M	38%	\$153 M
Public		Y	\$150 M	23%	\$34 M	41%	\$61 M
Private	Y		\$670 M	22%	\$145 M	31%	\$206 M
Public	Y	Y	\$1,097 M	18%	\$201 M	28%	\$302 M

No Interrupt. (No significant recurrence of COVID-19)

November Interrupt. (Recurrence of COVID-19 in November)

The RIM Model presented is a macro-model spanning the medical, physical, engineering, social and behavioral sciences, and the humanities at an institution. It can be fine-tuned, depending on the needs of the institution. Regardless of how it is used, it can provide timely and important information to a diverse range of stakeholders.

V. CONCLUSION

This paper presents a model for estimating research output loss and financial impact, describes the challenges of doing research under the new “Pandemic Normal,” and advocates for renewed commitment by federal leaders, research institutions, and all stakeholders to the longstanding Federal Government-Research Institution Partnership. It also raises many new questions and issues around research operations during a pandemic—including effective practices around institutional and research finances, institutional management of research

programs, and funding agency partnership and reducing regulatory burden. All are fluid topics that must be addressed regularly and in more depth under the Pandemic Normal.

What goes without saying is that an unprecedented response is needed to safeguard the United States’ research enterprise and ensure that the United States remains the global leader in research, innovation, and discovery. Research output has been severely impacted under the COVID-19 pandemic and the following are required:

- A new and sustained investment in our institutions’ and the nation’s research capabilities is imperative. The RIM model provides important data on the research output loss and financial impact at mission diverse and geographically widespread institutions. The RIM model shows: 1) research output losses between 20 and 40 percent, 2) financial disinvestment impact in the hundreds of millions of dollars at individual institutions, and 3) potential impact in the tens of billions of dollars across the entire U.S. research enterprise.
- Recognition that without this new research investment, active projects will be unable to achieve original program goals, in some cases causing the loss of an entire research program.
- Further, without this new research investment, the country is at risk of a significant reduction in today’s graduate and post-doc students, who are poised to be the next generation of the world’s best scientists. Particularly at risk for being disproportionately impacted are minorities, women, and other under-represented populations.
- Acceptance of the Pandemic Normal, which means the scope of research promised on a \$1 million award (pre-COVID-19) will now require more than \$1 million to complete. And, the scope of research to be delivered in one year (pre-COVID-19) will now require more than one year. In order to operate effectively and efficiently under the “Pandemic Normal,” new measures such as redefining proposal and budgeting guidelines, eliminating overly-burdensome regulations, and related measures are necessary.

The Case Studies from Part IV. show that the projected research output loss due to the COVID-19 pandemic for the twelve months (March 2020 through February 2021) is in the vicinity of 20 percent for each institution—***and in the less optimistic scenario, research output losses could reach 40 percent, and in terms of financial disinvestment, would exceed hundreds of millions of dollars at individual institutions.***

There is little doubt that the Federal Government-Research Institution Partnership is more important than ever. Global competition (especially, with China) is at a critical juncture and our

global leadership status could be at-risk. Until a vaccine is widely available, research universities and other research performers are facing an existential threat. Not only are research finances tenuous, the uncertainty of tuition status, students returning to campus, and safely operating the institution are real threats. Further, immigration issues hover over our research workforce development, which jeopardizes the top minds from the around the world coming to the United States and contributing their diversity and expertise to the United States research enterprise.

Finally, while the research enterprise may appear vulnerable during the COVID-19 pandemic, the same could be said of the United States research enterprise in 1957 after the launch of Sputnik by the Soviet Union. However, we rallied behind the tenacity of university and academic leaders, the foresight of federal policy experts and lawmakers, and the visionary promise of science and discovery to ensure that the United States would be the global leader in research. With that same commitment to and investment in the nation’s research enterprise, we can thrive and remain the envy of the world.

CONTRIBUTORS

Dr. Tanju Karanfil, Vice President for Research, Clemson University and **Dr. Melur (Ram) Ramasubramanian**, Vice President for Research, University of Virginia, provided the initial conceptual framework for the Research Impact Metric (RIM) Model and analysis on impact to research output loss and financial disinvestment.

James Luther, Associate Vice President of Finance & Research Compliance Officer, Duke University, and **Joe Gindhart**, Associate Vice Chancellor for Finance and Sponsored Projects, Washington University (Jim as a former Chair and Joe as the current Chair of the COGR Costing and Financial Compliance Committee), provided a financial compliance lens to the paper.

Cindy Hope, Director, Academic Contracts and Grants Administration, Georgia Institute of Technology (and also a former Chair of the COGR Costing and Financial Compliance Committee) provided editorial support.

Dr. Sheila Lischwe, Director of Office of Sponsor Programs, and **Meghan Mullaney**, Director of Data Analytics in Research Division, both from Clemson University, provided editorial support.

Wendy Streitz, COGR President, **Toni Russo**, COGR Policy Analyst, and **David Kennedy**, COGR Vice President and Director of Costing and Financial Compliance, provided the COGR support for the paper.

CONTACT: The Council on Governmental Relations
1200 New York Avenue NW, Suite 460
Washington D.C. 20005
202-289-6655
www.cogr.edu
wstreitz@cogr.edu, trusso@cogr.edu, dkennedy@cogr.edu

ADDITIONAL RESOURCES

COGR's FAQs and Resources on COVID-19's Impact to Federal Awards
<https://www.cogr.edu/cogrs-faqs-and-resources-covid-19s-impact-federal-awards>

COGR's Webinar Series on COVID-19 (Available upon request to COGR Members Only)
<https://www.cogr.edu/cogrs-webinar-series-covid-19>

Furlough Programs and Implications for Financial Research Compliance (COGR) May 2020. https://www.cogr.edu/sites/default/files/COGR_Furlough_UPDATED_May2020.pdf

Funding Programs and Implications for Financial Research Compliance (Addendum to Finances of Research Universities – June 2014) (COGR) July, 2020.
https://www.cogr.edu/sites/default/files/COGR_Funding_July1_2020.pdf

Institutional and Agency Responses to COVID-19 and Additional Resources (COGR)
<https://www.cogr.edu/institutional-and-agency-responses-covid-19-and-additional-resources>

Institutional Resources on Ramping Up and Reopening (COGR)
<https://www.cogr.edu/institutional-resources-ramping-and-reopening>

APPENDIX A. HOW RESEARCH OPERATIONS ARE DISRUPTED

During Shut Down

- Idle time caused by shutdown of campus
- Loss of productivity due to remote status
- Loss of productivity for cored facilities and shared resources
- Cancelled travel

Re-Opening

- Restart and Replacement
 - Reestablishing cell lines and animal models
 - Purchasing replacement reagents for those that have expired
 - Inability to work at previous level of efficiency (due to remote status, etc.)
 - Recruiting/training new support staff/students/post-docs if people are no longer available to work in the lab
 - Replacement of donated PPE
 - Loss of labor related to visiting students/staff to labs
 - Loss of productivity for cores and shared resources
- Return to work issues
 - Immuno-compromised people staying at home
 - Slowed return to work due to day-care/school closures
 - Delayed research due to faculty/staff unable to travel and/or stuck in other states/countries
- Other
 - Delayed supply chain
 - Termination of industry and service agreements

Infrastructure

- Lab reconfiguration to operate safely with COVID
- Increased lab costs (or research inefficiencies) related to required density issues
- Lack of PPE to enable research labs to open
- Purchase and implementation of HVAC, air sanitization, increased house-keeping/sanitization requirements
- The “unknowns” related to stalled/stopped research building renovation & construction
- Redirection of entire strategic focus to “operating in a COVID world” and associated opportunity cost
- COVID testing

- Addition of sanitizing stations to building entry/labs, etc. and managing access
- Additional administrative support for management of COVID oversight
- Retesting/calibrating equipment
- Need for increased infrastructure to support remote work access

Pandemic Normal

- Clinical Research:
 - Reduced efficiency for enrolling subjects because people are concerned about coming into clinic for clinical trial
 - Inability to enroll subjects for clinical studies
 - Reenrolling human subjects for trials that were paused
- Return to work issues
 - Immuno-compromised people staying at home
 - Slowed return to work due to day-care/school closures
 - Shift scheduling to accommodate 24 hour shifts
 - Need for ramp-down due to reoccurrence of COVID outbreak

APPENDIX B. RESEARCH UNDER THE PANDEMIC – CHALLENGES AND ADAPTATIONS

Included is a small cross-section of research and activity interrupted by the COVID-19 pandemic. In some cases, the research can be adapted, and the work continues. In other cases, the research completed to-date is at-risk of being lost in its entirety. In all cases, while the challenges to continue the work are significant, passionate and dedicated investigators and research personnel are pursuing new and creative avenues to advance the science and ensure that the hope and promise of life-changing discoveries moves forward and continues to benefit the nation.

Interruptions in Research with At-Risk Teens. A statewide early literacy intervention has operated continuously for a more than decade for at-risk students. In 2019-2020, a group of 750 students completed the intervention and were tested. These students were scheduled to have been tested again at the end of the academic year to determine if gains assessed mid-year held. This assessment could not be completed due to the closing of public schools. A second cohort of 750 students began receiving intervention services mid-year. No initial assessment data were collected from these students due to school closures. These data have been reported annually to school district and state level stakeholders and are used to refine intervention protocols. Researchers have worked through the summer to problem solve virtual data collection. While data collection was interrupted in 2019-2020, procedures will be modified and adjusted depending on the school format used during 2020-2021.

NSF-Advancing Informal STEM Learning (AISL) Program. The pandemic impacted an ongoing NSF-AISL program in three ways: 1) Inability to implement the planned intervention during this time as travel to community sites has been suspended, 2) As a result of the sites closing their doors, the investigators have been unable to maintain consistent contact with community partners; investigators are unclear if employees at these sites are furloughed, no longer employed, or unable to respond for other reasons, and 3) Investigators have had to adjust their timeline for program implementation and data collection, which has led to adjusting the functions of a graduate student who is being funded by this project.

Face-to-face Patient Research and Diabetes Research. Research on the effect of performing exercise on a diabetic patient’s blood sugar level after eating is a face-to-face event between patient and researcher. The blood specimen is tested, and observations are made of the exercise performed. Research was halted as the face-to-face research with patients was discontinued as a COVID prevention strategy. This research could not be accomplished as a virtual patient visit because the special machine for the blood sugar testing would need to be brought to the location and one-on-one supervision provided.

Research on End-of-life Conversations with the Elderly. Initially, this research was conceptualized as a face-to-face interaction between the patient, provider, and family members. As the disruption due to COVID-19 approached five months, research re-design came under discussion and the focus for this research has been adapted to emphasize virtual interaction between the patient, provider, and family members. The patient is supported in decisions as the family hears first-hand of their wishes and conceptualizing of novel methods of holding serious conversations about wishes at the end of life take place.

Craniofacial Morphology Research on Children. The purpose of the study is to provide a quantitative assessment of the craniofacial morphology associated with a rare congenital syndrome using 3D images of children’s faces that have been diagnosed with the disorder. The primary data collection was to occur at the biannual family conference scheduled for July 2020 in Orlando, FL. The family conference was postponed for at least one year and therefore data collection at the conference could not occur. While some images were able to be collected from clinics and regional conferences, the family conference was an opportunity for hundreds of children with the rare disorder to be in the same place at the same time. Hopefully, the conference will occur next summer, and the data collection will be able to happen then.

Clinical Trial Enrollment (applicable to thousands of projects). Many NIH sponsored clinical trials may take months or years to enroll research subjects due to the nature of the research being conducted. In some cases, these subjects have had routine visits, blood draws, and other in-person interactions for extended periods. COVID has reduced/eliminated the ability to continue these in-person visits, which could mean the loss of these subjects and/or material impact on the quality of the data being collected. Ultimately, this could mean that enrollment would have to start over, setting the project back by months or years, while also jeopardizing the necessary rigor and reproducibility standards.

Graduate Student Research Career and Thesis (affecting thousands and thousands of individuals). Many graduate students receive funding directly from federal sponsors in support of their developing academic and research careers. In many instances, travel to a field site is a critical component of their fellowship. Many of these support awards have limited funding and duration; if a graduate student was planning to travel during this past spring, their entire research thesis could be materially impacted causing them to adjust the thesis objectives materially (or not be able to complete their work). The end result could mean that the student requires an additional full year of financial support to conduct the project.

Support of Undergraduates in Research. Students, both graduate and undergraduate, provide important research support. In one example, undergraduates are critical to interaction with puppies in their early development to better understand their ability to function as service dogs in

various roles such as PTSD support, bomb detection and assistance to disabled persons. This predictive analysis is based on a significant investment of time and personnel and lapses in interaction can have detrimental impact on the research outcomes. Support by undergraduates is critical to the research outcomes but is also an important opportunity for most students in their developing academic and research careers. Further, with the absence of undergraduates, many labs that rely on them as critical resources may have to have more senior staff (graduate students, postdocs, technicians) to take on the undergraduates' roles on projects.

Research on Cognitive Aging, Child Development, Brain Function, and Clinical Psychology (applicable to thousands of projects). Many research projects involving human participants have been delayed significantly as a result of COVID. Laboratories had to pause their research programs at a time that is often when the most significant phase of data collection occurs.

Global Health Research on Pregnancy Outcomes. COVID-19 has impacted health research abroad because travel for the researchers has been significantly impacted, and researchers abroad have been unable to work at their labs or with study subjects. Longitudinal studies of pregnancy outcomes in several studies have been interrupted since March. Researchers have been able to get some information from cell phone interviews of the subjects, but key data such as birth weights have been lost. Some of this longitudinal data, unfortunately, will be unrecoverable.

Study of Earthquakes in Chile. The investigator and a student were scheduled to travel to Argentina and Chile to recover several seismographs, retrieve the data, and pack them to be returned to a collaborating institution in April-May. They were unable to go, so \$800K of equipment and project data is unavailable at this time.

Seasonal Travel and Malaria Research. There are various research studies that require the research team to be on site at the early seasonal onset of a disease. One example of this is malaria. If the team cannot be onsite for this critical time period, it could mean that the research is stalled for an entire year.

USDA and Food Research. Finally, investigators funded by the USDA work on a seasonal basis to engage in innovative food and plant research, which benefits the nation and the world by enhancing the world food supply. This research, dependent on the planting and harvest seasons, will continue to be at risk as travel and other disruptions caused by the COVID-19 pandemic persist and affect the normal flow of research and innovation.

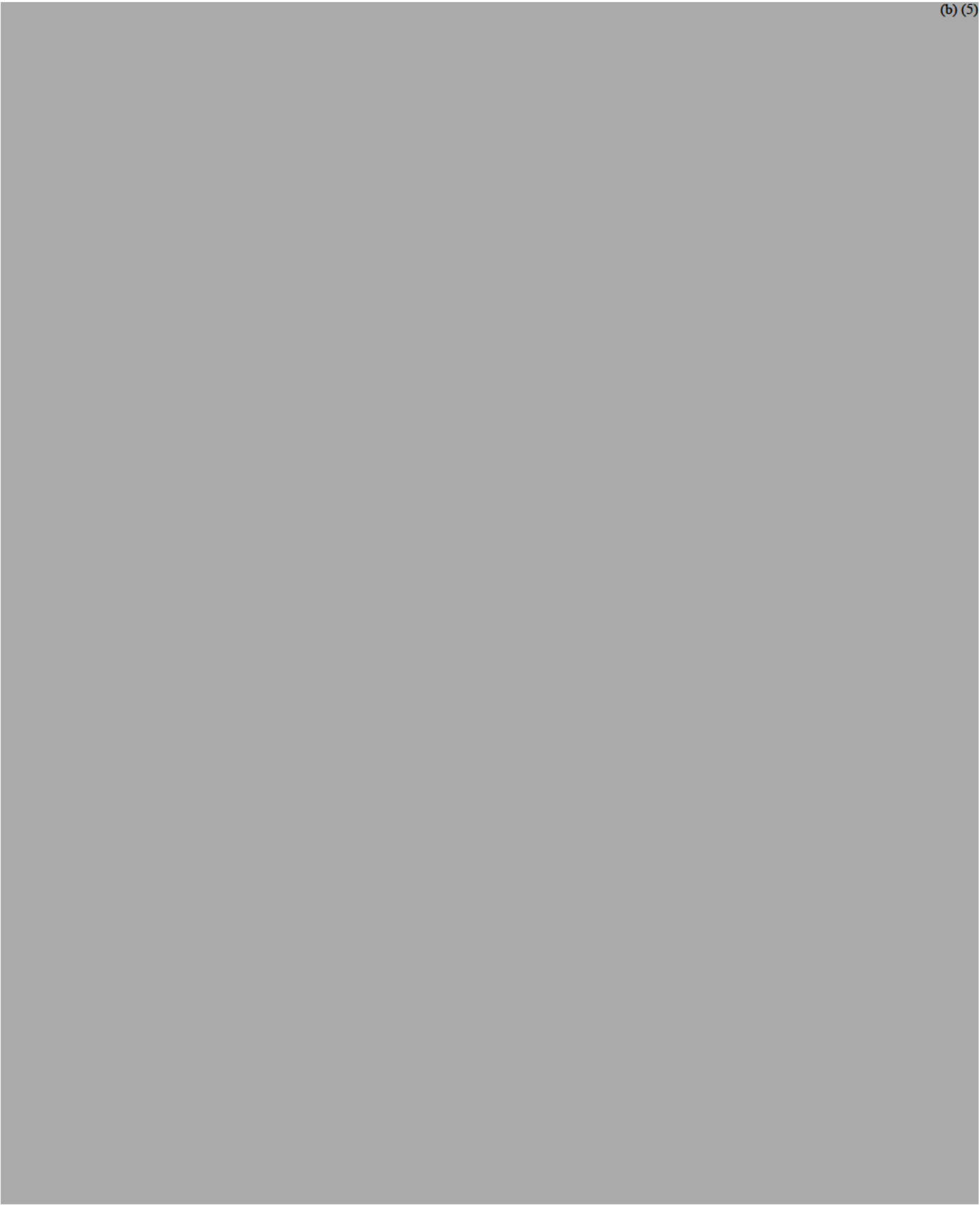


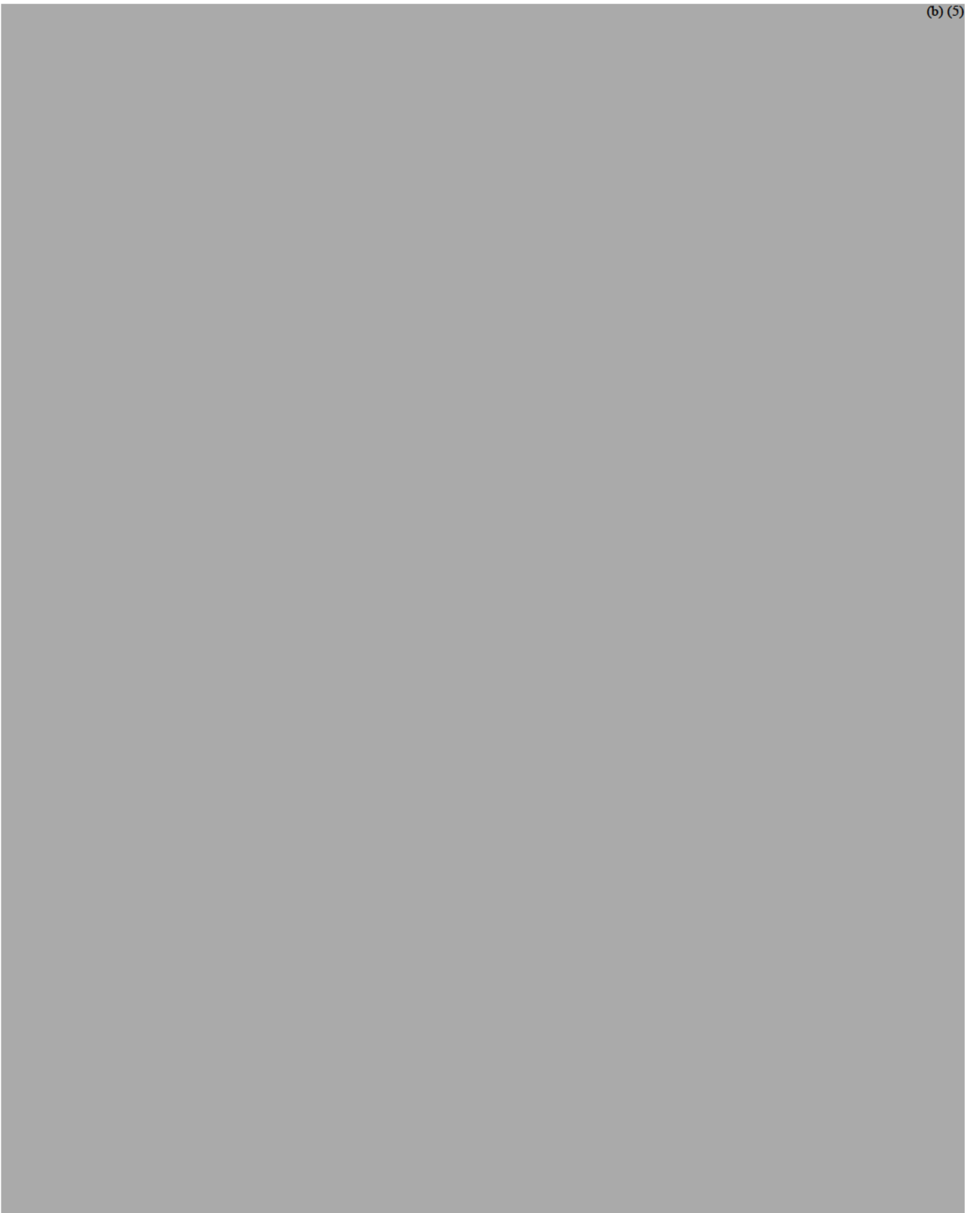
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

(b) (5)







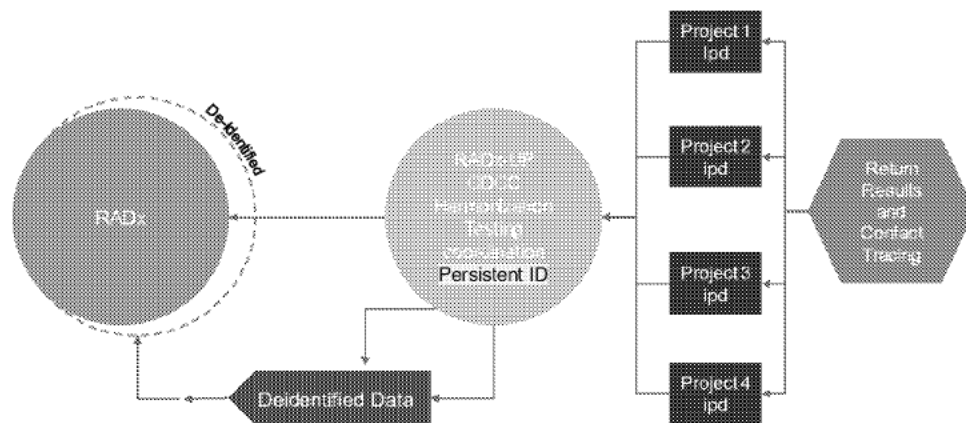
Persistent ID:
How?: UUID, Hash Encryption
Why?: anonymize, combine, connect

Patti Brennan

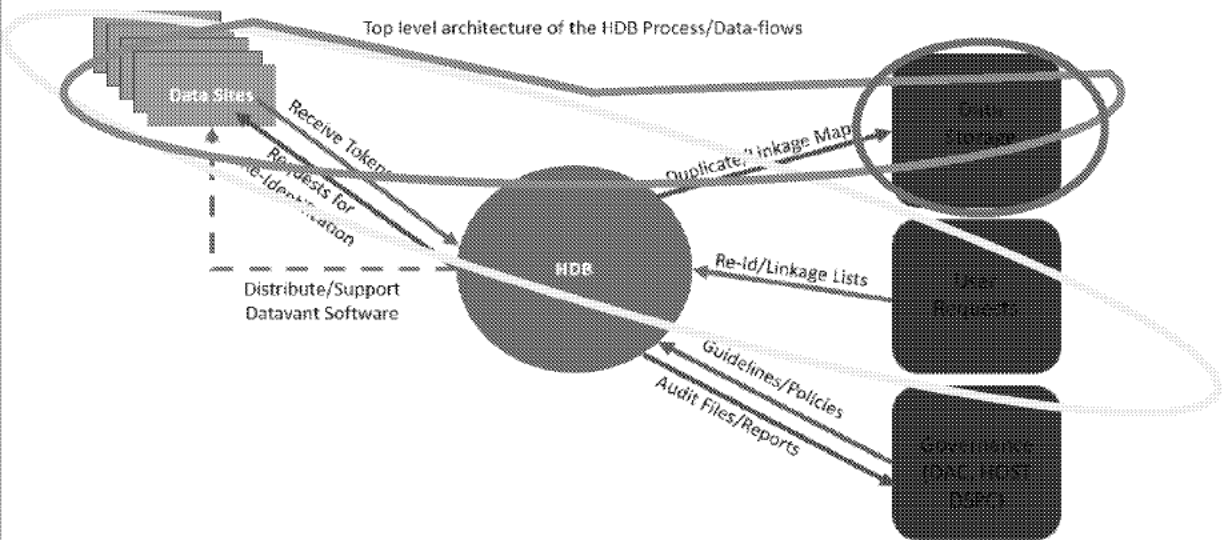
RADx UP Governance Committee

10.15.20

RADx UP Program



Honest Data Broker



Honest Data Broker

