

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

COMMONWEALTH OF
MASSACHUSETTS, *et al.*,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of Health and Human
Services, *et al.*,

Defendants.

Civil Action No. 1:25-cv-10814-WGY

AMERICAN PUBLIC HEALTH
ASSOCIATION; IBIS REPRODUCTIVE
HEALTH; INTERNATIONAL UNION,
UNITED AUTOMOBILE, AEROSPACE,
AND AGRICULTURAL IMPLEMENT
WORKERS (UAW); BRITTANY
CHARLTON; KATIE EDWARDS; PETER
LURIE; and NICOLE MAPHIS,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH;
JAY BHATTACHARYA, in his official
capacity as Director of the National Institutes
of Health; UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES; and ROBERT F.
KENNEDY, JR., in his official capacity as
Secretary of the United States Department of
Health and Human Services,

Defendants.

Civil Action No. 1:25-cv-10787-WGY

NOTICE OF FILING UPDATED CERTIFICATION

Please take notice that Defendants are filing an updated Certification of the Administrative record, as discussed with Plaintiffs in the above-captioned case (“State Plaintiffs”) and disclosed to Plaintiffs in the related case, *APHA, et al. v. NIH, et al.*, No. 25-cv-10787 (“APHA Plaintiffs”), and documents associated with that certification.

Pursuant to this Court’s order, Defendants produced the Certified Administrative Record for phase one of the above-captioned proceeding on June 2, 2025.

After producing the record, Defendants realized that three documents had been unintentionally omitted. The evening of June 5, 2025, State Plaintiffs also requested the addition of certain other documents and asked why the record did not include grant-specific termination documents for certain entries on their Excel spreadsheet. *See* Ex. A. The next day, Defendants agreed to add all documents requested by State Plaintiffs, answered Plaintiffs’ questions, and disclosed the documents that had been unintentionally omitted on June 2, 2025. *Id.* Defendants included counsel for the APHA Plaintiffs on their email. *Id.*

Defendants sought to file the attached updated certification before filing their opening brief on June 9, 2025, but technical issues in the filing process prevented the filing. Accordingly, that day, Defendants provided a copy of the filing and all attachments by email to State Plaintiffs and APHA Plaintiffs.

The certification was signed before State Plaintiffs filed their motion to complete the record. To avoid argument in this notice of filing, Defendants will respond to State Plaintiffs’ motion to complete the record at the pretrial conference scheduled for June 12, 2025, at 11:00 am, or in a filing before 6:00 pm on June 12, 2025, as proposed by the parties on May 29, 2025 in their Proposed Schedule for Further Proceedings, Doc No.

113, and adopted by the Court on June 3, 2025, *see* Doc No. 119, whichever the Court prefers.

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General

LEAH B. FOLEY
United States Attorney

YAAKOV M. ROTH
Principal Deputy Assistant Attorney General,
Civil Division

KIRK T. MANHARDT
Director

MICHAEL J. QUINN
Senior Litigation Counsel

Dated: June 11, 2025

/s/ Thomas W. Ports, Jr.
Trial Attorney
THOMAS W. PORTS, Jr. (Va. Bar No. 84321)
Trial Attorney
U.S. Department of Justice
Civil Division
Corporate/Financial Section
P.O. Box 875
Ben Franklin Stations
Washington D.C. 20044-0875
Tel: (202) 307-1105
Email: thomas.ports@usdoj.gov

ANUJ KHETARPAL
Assistant U.S. Attorney
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3658
anuj.khetarpal@usdoj.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: June 11, 2025

/s/ Thomas W. Ports, Jr.
Thomas W. Ports, Jr.

From: [Ports, Thomas \(CIV\)](#)
To: [Cedrone, Gerard \(AGO\)](#); [Khetarpal, Anuj \(USAMA\)](#)
Cc: [Jessie Rossman](#); [Olga Akselrod](#); [Lisa Mankofsky](#); [Kenneth Parreno](#); [Suzanne Schlossberg](#); [Kirschner, Adam](#); [Hughes, Andrew \(ATG\)](#); [Arslanian, Vanessa \(AGO\)](#); [Brown, Rachel \(AGO\)](#); [Daniel Ambar](#); [Dirks, Katherine \(AGO\)](#); [Emilio Varanini](#); [Hilary Chan](#); [Luh, James](#); [Kathleen Boergers](#); [Ketakee Kane](#); [Kundl, Jak \(AGO\)](#); [Lockhart, Phoebe \(AGO\)](#); [Meredith Trueblood](#); [Drezner, Michael](#); [Neli, Palma](#); [Nimrod, Elias](#); [Pappavaselio, Chris \(AGO\)](#); [Slater, Allyson \(AGO\)](#); [Sophia TonNu](#); [Teresa ReedDippo](#); [tyler.roberts](#)
Subject: RE: NIH Litigation -- Issues with Administrative Record
Date: Friday, June 6, 2025 2:22:00 PM
Attachments: [NIH GRANTS_004252.pdf](#)
[NIH GRANTS_004253.pdf](#)

Hi Jerry,

Thank you again for your email. We will file a certification of the administrative record, with corrections. We conducted our own review and found that additional documents NIH intended to include in the record did not get Bates stamped and produced on June 2. We're not entirely sure why, other than the rush to produce and the technical issues that I raised with you on our phone call the afternoon of June 2. Please find specific responses to your points below, and three additional documents that we'll include with the forthcoming certification.

1. You are correct, in the expedited time allowed to compile the administrative record NIH did not have time to create an index of all documents. NIH still does not have time. The relevant staff is compiling the APHA record on an equally expedited timeline, in addition to their other responsibilities. If you have documents in mind that require a title or date to understand, or where a title/date is relevant to APA review, please let me know those documents and I'll check with NIH.
2. NIH is working on an index of documents that were not terminated or failed to renew, and we will include this as part of the certification.
3. Please find NIH's response for each identified entry below:
 - a. T34GM136497 – When plaintiffs filed their complaint this grant was active. When NIH collected documents for the AR, there was no grant-specific termination or non-renewal document to include in the record.
 - b. U19AI171292 – When plaintiffs filed their complaint this grant had been terminated. Three days later, NIH reinstated the grant and it was active through the end of the project period. We will add the termination document and the re-instatement document.
 - c. T32GM144876 – When plaintiffs filed their complaint this grant was active. When NIH collected documents for the AR, there was no grant-specific termination or non-renewal document to include in the record.
 - d. R25DA051338 – When plaintiffs filed their complaint this grant was active. When NIH collected documents for the AR, there was no grant-specific termination or non-renewal document to include in the record.
 - e. 1T32GM140951-01 – When plaintiffs filed their complaint this grant was active. When NIH collected documents for the AR, there was no grant-specific termination or non-renewal document to include in the record.
 - f. 1R01GM151687-01 – When plaintiffs filed their complaint this grant was active. When

NIH collected documents for the AR, there was no grant-specific termination or non-renewal document to include in the record.

- g. 75N94023C00001 – This is a non-grant contract. On May 28, 2025, defendants informed plaintiffs that plaintiffs' Excel included non-grant contracts and requested additional information. Plaintiffs did not respond. Accordingly, there is no grant termination record for this entry.
 - h. 3R01CA190558-07S1 – When plaintiffs filed their complaint this grant was active. When NIH collected documents for the AR, there was no grant-specific termination or non-renewal document to include in the record.
 - i. 1T34GM154615-01 – When plaintiffs filed their complaint this grant was active. When NIH collected documents for the AR, there was no grant-specific termination or non-renewal document to include in the record.
4. NIH intended to include responses to administrative appeals. One document inadvertently omitted between collection and production was a response to an appeal, dated May 27, 2025. It is attached. The NIH collection of appeal documents occurred on May 27, 2025 thus NIH did not collect the response document that you forwarded (dated May 28) because it did not yet exist. We will add the document that you forwarded.
5. That is a typo that we will correct.

Finally, attached please find additional documents that are part of the record. The certification will also include a copy of the 2024 NIH Policy Statement, but we have not attached that because the file is large and has already been filed on the docket. We wanted to send you these documents as soon as possible, while NIH completes the index of documents that were not terminated or failed to renew and finalizes a certification.

Please do let us know if you identify any other documents that plaintiffs believe were inadvertently omitted.

Best,
Tom

Tom Ports
Trial Attorney
U.S. Department of Justice
202.717.7336

From: Ports, Thomas (CIV)

Sent: Thursday, June 5, 2025 9:49 PM

To: Cedrone, Gerard (AGO) <Gerard.Cedrone@mass.gov>; Khetarpal, Anuj (USAMA) <Anuj.Khetarpal@usdoj.gov>

Cc: Jessie Rossman <jrossman@aclum.org>; Olga Akselrod <oakselrod@aclu.org>; Lisa Mankofsky <lmankofsky@cspinet.org>; Kenneth Parreno <kenneth.parreno@protectdemocracy.org>; Suzanne Schlossberg <sschlossberg@aclum.org>; Kirschner, Adam <akirschner@oag.state.md.us>; Hughes,

Andrew (ATG) <andrew.hughes@atg.wa.gov>; Arslanian, Vanessa (AGO) <Vanessa.Arsanian@mass.gov>; Brown, Rachel (AGO) <Rachel.Brown@mass.gov>; Daniel.Ambar <Daniel.Ambar@doj.ca.gov>; Dirks, Katherine (AGO) <katherine.dirks@mass.gov>; Emilio.Varanini <Emilio.Varanini@doj.ca.gov>; Hilary Chan <Hilary.Chan@doj.ca.gov>; Luh, James <JLuh@oag.state.md.us>; Kathleen.Boergers <Kathleen.Boergers@doj.ca.gov>; Ketakee.Kane <Ketakee.Kane@doj.ca.gov>; Kundl, Jak (AGO) <Jak.Kundl@mass.gov>; Lockhart, Phoebe (AGO) <Phoebe.Lockhart@mass.gov>; Meredith Trueblood <Meredith.Trueblood@doj.ca.gov>; Drezner, Michael <mdrezner@oag.state.md.us>; Neli.Palma <Neli.Palma@doj.ca.gov>; Nimrod.Elias <Nimrod.Elias@doj.ca.gov>; Pappavaselio, Chris (AGO) <Chris.Pappavaselio2@mass.gov>; Slater, Allyson (AGO) <Allyson.Slater@mass.gov>; Sophia TonNu <Sophia.TonNu@doj.ca.gov>; Teresa.ReedDippo <Teresa.ReedDippo@doj.ca.gov>; tyler.roberts <tyler.roberts@atg.wa.gov>
Subject: RE: NIH Litigation -- Issues with Administrative Record

Hi Jerry,

Thank you for your email. I'll confer with NIH as soon as possible and plan to get back to you tomorrow.

Best,
Tom

Tom Ports
Trial Attorney
U.S. Department of Justice
202.717.7336

From: Cedrone, Gerard (AGO) <Gerard.Cedrone@mass.gov>
Sent: Thursday, June 5, 2025 5:50 PM
To: Ports, Thomas (CIV) <Thomas.Ports@usdoj.gov>; Khetarpal, Anuj (USAMA) <Anuj.Khetarpal@usdoj.gov>
Cc: Jessie Rossman <jrossman@aclum.org>; Olga Akselrod <oakselrod@aclu.org>; Lisa Mankofsky <lmankofsky@cspinet.org>; Kenneth Parreno <kenneth.parreno@protectdemocracy.org>; Suzanne Schlossberg <sschlossberg@aclum.org>; Kirschner, Adam <akirschner@oag.state.md.us>; Hughes, Andrew (ATG) <andrew.hughes@atg.wa.gov>; Arslanian, Vanessa (AGO) <Vanessa.Arsanian@mass.gov>; Brown, Rachel (AGO) <Rachel.Brown@mass.gov>; Daniel.Ambar <Daniel.Ambar@doj.ca.gov>; Dirks, Katherine (AGO) <katherine.dirks@mass.gov>; Emilio.Varanini <Emilio.Varanini@doj.ca.gov>; Hilary Chan <Hilary.Chan@doj.ca.gov>; Luh, James <JLuh@oag.state.md.us>; Kathleen.Boergers <Kathleen.Boergers@doj.ca.gov>; Ketakee.Kane <Ketakee.Kane@doj.ca.gov>; Kundl, Jak (AGO) <Jak.Kundl@mass.gov>; Lockhart, Phoebe (AGO) <Phoebe.Lockhart@mass.gov>; Meredith Trueblood <Meredith.Trueblood@doj.ca.gov>; Drezner, Michael <mdrezner@oag.state.md.us>; Neli.Palma <Neli.Palma@doj.ca.gov>; Nimrod.Elias <Nimrod.Elias@doj.ca.gov>; Pappavaselio, Chris (AGO) <Chris.Pappavaselio2@mass.gov>; Slater, Allyson (AGO) <Allyson.Slater@mass.gov>; Sophia TonNu <Sophia.TonNu@doj.ca.gov>; Teresa.ReedDippo <Teresa.ReedDippo@doj.ca.gov>; tyler.roberts <tyler.roberts@atg.wa.gov>

Subject: [EXTERNAL] NIH Litigation -- Issues with Administrative Record

Tom, Anuj:

I'm writing to raise several issues related to the administrative record.

First, we request that defendants produce an index of documents in the AR. At our conference on Monday, you articulated defendants' position that there was not enough time to prepare an index in advance of the June 2 production. Without waiving any objection to the failure to provide an index on June 2, we request that defendants promptly produce an index that identifies at least the title, date, and associated Bates numbers for each document in the record. Such an index is particularly necessary given the presence in the record of undated documents and/or documents whose identity is not apparent on their face.

Second, defendants' Designation and Certification of Administrative Record, ECF No. 118-1, states that "over 100 entries correspond to grants that are either not terminated or have not failed to renew, including a grant issued by the Agency for Healthcare Research and Quality. Accordingly, there is no grant termination record for those entries." We request that defendants promptly produce an index of those "over 100 entries," identifying which ones defendants assert were "not terminated" and which one defendants assert "have not failed to renew."

Third, we've noticed that the record does not contain termination letters for certain projects that plaintiffs listed on the spreadsheet produced to the court in May. So far we have identified four University of Maryland–Baltimore County grants (T34GM136497, U19AI171292, T32GM144876, R25DA051338), five Rutgers projects (1T32GM140951-01, 1R01GM151687-01, 75N94023C00001 3R01CA190558-07S1), and one TCNJ project (1T34GM154615-01) in this category. Can you please explain the discrepancy? To the extent it was an oversight, we request that defendants supplement the record to include the missing documents.

Fourth, the administrative record includes a number of administrative appeals, but no decisions on those administrative appeals. To the extent the agency has acted on any of the administrative appeals in the record (see, for example, the attached, which resolves the administrative appeal appearing at NIH_GRANTS_002290 et seq.), they should be included in the record. We request that defendants promptly supplement the record as appropriate.

Fifth, there appears to be a material typo in the Designation and Certification of Administrative Record. The document states, at paragraph 7, that "[t]he complete administrative record for 'Challenged Directives 3 and 4, the Lauer Memos' consists of the documents with Bates range NIH_GRANTS_000032 - NIH_GRANTS_003824." Looking at the ARs you produced, we believe it should read "[t]he complete administrative record for 'Challenged Directives 3 and 4, the Lauer Memos' consists of the documents with Bates range **NIH_GRANTS_000006 - NIH_GRANTS_000032**." The Lauer memoranda appear in the 000006–00032 page range, and that page range is not otherwise described in the certification as it stands right now. We request that

defendants file a corrected certification.

I am available at your convenience to meet and confer about any of these issues. We are continuing our cross-check of the record reserve the right to raise any additional issues that become apparent in due course.

Thanks,
Jerry

Gerard J. Cedrone

Deputy State Solicitor

Massachusetts Attorney General's Office

One Ashburton Place, Boston, MA 02108

(617) 963-2282 | gerard.cedrone@mass.gov

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 25-cv-10814

COMMONWEALTH OF
MASSACHUSETTS, *et al.*,
Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of Health and Human
Services, *et al.*,

Defendants.

UPDATED CERTIFICATION OF ADMINISTRATIVE RECORD

I, Raymond Jacobson, Ph.D., hereby declare and certify as follows:

1. I am employed by the National Institutes of Health (NIH) and serve as the Director, Division of Receipt and Referral, of the Center for Scientific Review (CSR). I have held this position since December 2024 and have been employed by NIH in various capacities since 2009.

2. As the Director, Division of Receipt and Referral, I oversee the Division of Receipt and Referral's functions regarding the receipt and scientific referral of grant applications submitted to NIH and other HHS agencies. In that capacity, I oversee and supervise the NIH staff that compiled the administrative records in this case.

3. NIH produced the Administrative Record in this case on June 2, 2025. Doc No. 118.

4. Three documents that are part of the administrative record were mistakenly omitted from that production. Those documents are attached, bear Bates ranges

NIH_GRANTS_003825 - NIH_GRANTS_004254, and are part of the administrative record in this case. NIH provided notice of these additions to plaintiffs in this case and in the related case on June 6, 2025.

5. Additionally, on June 5, 2025, Plaintiffs requested that NIH update the

administrative record to include an index of grants that they identified but that NIH had not terminated and that had not failed to renew. NIH agreed, and indexes are attached.

6. The attached document, labeled Exhibit A, contains a list of 90 entries from the spreadsheet Plaintiff provided on May 13 pursuant to a court order ("Plaintiffs' Spreadsheet"). Doc No. 109. NIH did not terminate the grant agreements associated with

these entries, and they did not fail to renew during any project period before or after Plaintiffs sued.

7. The attached document, labeled Exhibit B, contains a list of 28 entries from

Plaintiffs' Spreadsheet that are not a grant, a contract, or another transaction.

8. The attached document, labeled Exhibit C, contains a list of 7 entries from

Plaintiffs' Spreadsheet. These entries are not grants issued by NIH. Six of them are non-grant contracts. And one of them, 5R01HS028024-03, is a grant issued by the Agency for

Healthcare Research and Quality.

9. Also on June 5, 2025, Plaintiffs informed NIH of a grant termination that had

been omitted from the Administrative Record (U19A1171292). When plaintiffs filed their

complaint this grant had been terminated. Three days later, NIH reinstated the grant and it

was active through the end of the project period. NIH agreed to add the termination letter and the reinstatement to the record. They are attached and bear Bates numbers

NIH_GRANTS_004255 - NIH_GRANTS_004269.

10. Also on June 5, 2025, Plaintiffs informed NIH of an appeal decision that issued after NIH collected documents for the administrative record. NIH agreed to add that document. It is attached and bears Bates number NIH_GRANTS_004270.

11. Finally, on June 5, 2025, Plaintiffs notified NIH of a typo that NIH agreed to correct, as follows: The complete administrative record for “Challenged Directives 3 and 4, the Lauer Memos” consists of the documents with Bates range NIH_GRANTS_000006 - NIH_GRANTS_000031.

In accordance with 28 U.S.C. § 1746 I hereby certify and declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information and belief.

Executed on June 9, 2025 at Bethesda, MD.

/s/Raymond Jacobson

Raymond Jacobson, Ph.D.

Exhibit A

No.	Entry Identification
1.	2R25MH067127-21
2.	2T32AR007175-47
3.	1P20CA290477-01
4.	1P20CA290477-01
5.	5R01EY034973-02
6.	5R25AG078149-03
7.	5R25MH084565-14
8.	5T32AG052354-09
9.	5R01DK134723-02
10.	5R01HD109158-02
11.	R01AR082816
12.	R37AR061402
13.	3R01MD018265-03S1
14.	5R01AA026302-09
15.	5R01GM086858-17
16.	5R01NS123263-03
17.	5R01NS128277-02
18.	5R35GM149542-03
19.	5R01DK106399-09
20.	1F32GM154469-01
21.	5R01EY018839-16
22.	5R01EY032861-03
23.	5R35NS132160-02
24.	5R01AI148300-05
25.	5R01GM144446-04
26.	5R01HG002385-24
27.	5R01HG010632-06
28.	5R01HL112808-13
29.	5R01HL146500-06
30.	5R01HL155990-04
31.	5R01HL156808-04
32.	5R01HL158667-04
33.	5R01MH126040-03
34.	5R01NS058721-15
35.	5R01NS101354-07
36.	5R01NS120218-04
37.	5R21HG013504-02 [Should be 1R21HG013504-01]
38.	5R24GM141156-05
39.	5R35GM122451-07

40.	5R01DK138948-02 [Should be 1R01DK138948-01]
41.	1K76AG088411-01
42.	1R01MH137799-01
43.	5K01AG071798-05 [Should be -04]
44.	5K01AG073533-04
45.	5K08AG083050-02
46.	5K23AG072035-04
47.	5K23AG076960-03
48.	5K23EY034893-02
49.	5P2CHD042828-24
50.	5P50HD112034-02
51.	5P51OD010425-64
52.	5R01AA030750-03
53.	5R01AG073244-04
54.	5R01AI145486-07
55.	5R01AI158861-04
56.	5R01AI161019-05
57.	5R01DK123104-05
58.	5R01DK128346-04
59.	5R01DK133527-02
60.	1F31CA288086-01
61.	1F31HL170757-01A1
62.	1P30AG086635-01
63.	1P30AG086635-01
64.	1R01AG075734-01A1
65.	5R01EY021482-15
66.	5R01EY031312-05
67.	5R35NS122110-04
68.	5T32AG000212-32
69.	5T32AG049663-08
70.	5U01NS120836-04
71.	5U54AI170792-03
72.	5UM1AI164560-04
73.	1R35GM153309-02
74.	5U19AI077439-18
75.	R25GM056637
76.	5P01AG002132-43
77.	5P01AI091580-14
78.	5P01NS083513-10

79.	5P30ES030284-05
80.	5R01AI175614-03
81.	5R01AR080034-04
82.	5R01MD016071-05
83.	5U2CDK135074-03
84.	K24DA042720-08
85.	5R25GM086304-14
86.	5R01DK133645-04
87.	5K99GM147825-02
88.	1F31GM151860-01A1
89.	T34GM136497
90.	K99GM145410-02

Exhibit B

No.	Entry Identification Number
1.	15042sc
2.	18X107CF8
3.	71505-00 11
4.	71541-00 12
5.	7F515-00 04
6.	7K001-00 01
7.	Award Account Not Established
8.	Award Account Not Established
9.	Award Account Not Established
10.	GG011322-01
11.	SUBK00023583
12.	2(GG019236-01)
13.	21X184F7
14.	30008154-04
15.	41393-00 22
16.	42133-00 05
17.	42135-00 04
18.	42189-00 01
19.	42200-00 02
20.	42201-00 02
21.	42218-00 02
22.	42239-00 01
23.	42246-00 01
24.	42250-00 01
25.	42433-00 02
26.	42435-00 02
27.	42445-00 01
28.	5116689 amendment 4

Exhibit C

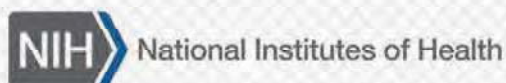
No.	Entry Identification Number
1.	75N93024D00018
2.	75N94023C00001
3.	75N95019D00031
4.	75N95022F00001 / 75N95019D00031
5.	75N95023Q00445
6.	75N95024P00617
7.	5R01HS028024-03



NIH GRANTS POLICY STATEMENT

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH



APRIL 2024

INTRODUCTION

The *National Institutes of Health Grants Policy Statement* (NIHGPS) is intended to make available to NIH recipients, in a single document, the policy requirements that serve as the terms and conditions of NIH grant awards. These terms and conditions apply not only to the recipients of NIH Grant Awards, but also flow down to any subawards as well as to subrecipients unless specified otherwise in the regulation or the terms and conditions of the specific NIH award (see "Consortium Agreements" on page IIB-114).

This document also is designed to be useful to those interested in NIH grants by providing information about NIH, its organization, its staff and its grants process. The NIHGPS is available [online](#). This version includes many links within the document as well as links to some web resources outside of this document. Users are strongly encouraged to use the on-line version of this document to benefit from these links.

NIHGPS ORGANIZATION

The NIHGPS has three parts, which allows general information, application information, and other types of reference material to be separated from legally binding terms and conditions:

- **Part I: NIH Grants General Information.** Part I (chapters 1 and 2) contains a glossary defining commonly used terms and abbreviations used throughout the document; describes NIH and its relationship to other organizations within the Department of Health and Human Services (HHS); specifies recipient, NIH, and other HHS staff responsibilities and outlines the grant application and review processes.
- **Part II: Terms and Conditions of NIH Grant Awards.** Part II (chapters 3-19) includes generally applicable terms and conditions (Part IIA). This part also specifies the terms and conditions that apply to particular types of grants, recipients, and activities that differ from, supplement, or elaborate on the standard terms and conditions (Part IIB). These requirements, in separate chapters, pertain to multiple PD/PI applications and awards; construction, modernization and major alteration and renovation grants; research training grants and fellowships; career development awards; modular applications and awards; conference grants, consortium agreements; grants to foreign and international organizations (and grants with substantial foreign components awarded to domestic organizations), grants to Federal institutions and payments to Federal employees; grants to for-profit organizations; and research patient care activities.
- **Part III: Points of Contact.** Part III (chapter 20) lists pertinent offices with their contact information.

CONVENTIONS

Certain conventions are followed throughout this document. The term "grant" is used to mean both grants and cooperative agreements; however, for clarity, certain sections mention both grants and cooperative agreements. The term "recipient" generally is used to refer to recipients of grants and cooperative agreements. "NIH" may be used in this document to refer to the entire organization or to its component organizations, or else to contrast an action by NIH, including actions by its ICs, with an action by a recipient or other organization. A reference to "Part II (IIA or IIB)" or "Part III" without further elaboration means the corresponding part of the NIHGPS.

SUPERSESSION

The NIHGPS was originally published with an effective date of October 1, 1998. It was subsequently revised several years thereafter with the turn of each new fiscal year (October). This revision of the NIHGPS is an update of the December, 2022 publication. It applies to all NIH grants and cooperative agreements for budget periods beginning on or after October 1, 2023. This version incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the GPS from December, 2022. An explanation of the major changes to the NIHGPS since the previous edition is included in the *NIH Guide for Grants and Contracts* notice announcing the reissuance of the NIHGPS.

ADDITIONAL INFORMATION

The Office of Policy for Extramural Research Administration (OPERA) develops and maintains this document. Changes in statutes, regulations, or policies that take effect before the next revision of the NIHGPS will be published separately in the *NIH Guide for Grants and Contracts*. Recipients are responsible for reviewing the [NIH Guide for Grants and Contracts](#) for changes and for implementing them, as appropriate. Subscribe to the *NIH Guide for Grants and Contracts* Listserv at <http://grants.nih.gov/grants/guide/listserv.htm>.

TABLE OF CONTENTS

1 GLOSSARY	I-1
1.1 Abbreviations	I-1
1.2 Definition of Terms	I-7
2 THE NATIONAL INSTITUTES OF HEALTH AS A GRANT-MAKING ORGANIZATION	I-44
2.1 Roles and Responsibilities	I-44
2.1.1 NIH and HHS Staff	I-44
2.1.2 Recipient Staff	I-45
2.2 eRA Commons	I-47
2.2.1 eRA Commons Registration	I-47
2.2.1.1 eRA Commons Registration for the Organization	I-48
2.2.1.2 eRA Commons Registration for the PD/PI	I-48
2.2.1.3 eRA Commons Registration for Other Individuals Participating in NIH Application and Research Performance Progress Reports	I-49
2.3 Application Information and Processes	I-49
2.3.1 Support Mechanisms	I-49
2.3.2 Eligibility	I-50
2.3.3 Types of Award Instruments	I-50
2.3.4 Types of Applications	I-50
2.3.5 Types of Notices of Funding Opportunities (NOFOs)	I-51
2.3.5.1 Other Funding-Related Notices	I-53
2.3.6 Legal Implications of Applications	I-53
2.3.7 Policies Affecting Applications	I-54
2.3.7.1 Direct Cost Limitations for Applications That Include Consortium/Contractual F&A Costs	I-54
2.3.7.2 Requirements for Submitting Unsolicited Applications Requesting \$500,000 or More in Direct Costs	I-54
2.3.7.3 Resubmission of Unfunded RFA Applications	I-55
2.3.7.4 Resubmission of an Unfunded Application	I-55
2.3.7.5 New Investigators and Early Stage Investigators	I-56
2.3.7.6 Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance	I-56
2.3.7.7 Post-Submission Grant Application Materials	I-57
2.3.7.8 SAM Registration and Unique Entity Identifier (UEI) Requirements	I-60
2.3.7.9 Graduate Student Compensation	I-61
2.3.7.10 NIH Data Management and Sharing and Genomic Data Sharing	I-62
2.3.7.11 Human Fetal Tissue from elective abortions	I-62
2.3.7.12 Biographical Sketches (Biosketches)	I-62
2.3.8 Application Forms	I-62
2.3.9 Application Receipt Information and Deadlines	I-63
2.3.9.1 Electronic Submission Requirements	I-63
2.3.9.2 Late Applications	I-64
2.3.9.3 Continuous Submission for Appointed Members of NIH Federal Advisory Committees	I-64
2.3.9.4 Similar, Essentially Identical, or Identical Applications	I-65
2.3.9.5 Application Non-conformity	I-65
2.3.9.6 Natural Disasters and Other Emergencies	I-66
2.3.10 Fraud, Waste and Abuse of NIH Grant Funds	I-66

2.3.11 Availability and Confidentiality of Information	I-68
2.3.11.1 Availability of Information	I-68
2.3.11.2 Confidentiality of Information	I-68
2.3.12 Protecting Sensitive Data and Information Used in Research	I-71
2.4 The Peer Review Process	I-71
2.4.1 Initial Review	I-71
2.4.1.1 Responsibilities	I-71
2.4.1.2 Overall Impact	I-72
2.4.1.3 Scored Review Criteria	I-72
2.4.1.4 Additional Review Criteria	I-73
2.4.1.5 Additional Review Considerations	I-73
2.4.2 Appeals of Initial Scientific Review	I-74
2.4.3 National Advisory Council or Board Review	I-75
2.4.4 Disposition of Applications	I-76
2.5 Completing the Pre-Award Process	I-77
2.5.1 Just-in-Time Procedures	I-77
2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement	I-80
2.5.3 Determining Applicant Organization Eligibility	I-80
2.5.4 Determining Eligibility of Individuals	I-81
2.5.5 Cost Analysis and Assessment of Management Systems	I-82
3 OVERVIEW OF TERMS AND CONDITIONS	IIA-1
3.1 Federalwide Standard Terms and Conditions for Research Grants	IIA-2
4 PUBLIC POLICY REQUIREMENTS, OBJECTIVES AND OTHER APPROPRIATION MANDATES	IIA-3
4.1 Public Policy Requirements and Objectives	IIA-3
4.1.1 Animal Welfare Requirements	IIA-10
4.1.1.1 Animal Welfare Assurance Requirements	IIA-11
4.1.1.2 Verification of IACUC Approval	IIA-12
4.1.1.3 Consortia	IIA-12
4.1.1.4 Foreign Recipients and Foreign Performance Sites	IIA-13
4.1.1.5 Reporting to OLAW	IIA-13
4.1.2 Civil Rights Protections	IIA-14
4.1.2.1 Civil Rights Act of 1964	IIA-14
4.1.2.2 Educational Amendments of 1972	IIA-14
4.1.2.3 Rehabilitation Act of 1973	IIA-14
4.1.2.4 Age Discrimination Act of 1975	IIA-15
4.1.2.5 Limited English Proficiency	IIA-15
4.1.3 Clinical Trials Registration and Reporting in ClinicalTrials.gov Requirement	IIA-15
4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information	IIA-15
4.1.3.2 Food and Drug Administration Amendments Act (FDAAA)	IIA-17
4.1.3.3 Good Cause Extension (GCE) Request Requirements	IIA-17
4.1.4 Confidentiality	IIA-19
4.1.4.1 Certificates of Confidentiality	IIA-19
4.1.4.2 Confidentiality of Alcohol and Substance Use Patient Records	IIA-21
4.1.4.3 Confidentiality of Patient Records: Health Insurance Portability and Accountability Act	IIA-21
4.1.5 Controlled Substances	IIA-21
4.1.6 Debarment and Suspension	IIA-21

4.1.7 Drug-Free Workplace	IIA-23
4.1.8 Federal Funding Accountability and Transparency Act (FFATA)	IIA-23
4.1.9 Federal Information Security Management Act	IIA-24
4.1.10 Financial Conflict of Interest	IIA-24
4.1.11 Fly America Act	IIA-27
4.1.12 Health and Safety Regulations and Guidelines	IIA-28
4.1.13 Human Stem Cell Research	IIA-28
4.1.13.1 Human Pluripotent Stem Cell Research Prohibited with NIH Funding	IIA-29
4.1.14 Human Fetal Tissue Research	IIA-29
4.1.14.1 Research on Transplantation of Human Fetal Tissue	IIA-30
4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions	IIA-31
4.1.15 Human Subjects Protections	IIA-32
4.1.15.1 Federalwide Assurance Requirements	IIA-34
4.1.15.2 Certification of IRB Approval	IIA-35
4.1.15.3 Reporting to Funding Agency and OHRP	IIA-36
4.1.15.4 OHRP Oversight	IIA-36
4.1.15.5 Education in the Protection of Human Research Participants	IIA-36
4.1.15.6 Data and Safety Monitoring	IIA-36
4.1.15.7 Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects	IIA-37
4.1.15.8 Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation	IIA-38
4.1.15.9 Good Clinical Practice Training for NIH Recipients Involved in NIH-fun- ded Clinical Trials	IIA-39
4.1.15.10 NIH Policy on the Use of a Single Institutional Review Board for Multi- Site Research	IIA-40
4.1.16 Investigational New Drug Applications/Investigational Device Exceptions	IIA-40
4.1.17 Lobbying Prohibition	IIA-41
4.1.18 Metric System	IIA-42
4.1.19 Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education	IIA-42
4.1.20 National Environmental Policy Act	IIA-42
4.1.21 Nondelinquency on Federal Debt	IIA-43
4.1.22 President's Emergency Plan for AIDS Relief (PEPFAR) Program	IIA-43
4.1.22.1 PEPFAR Agreements	IIA-43
4.1.22.2 PEPFAR Agreements Between the U.S. Government and Foreign Non- Governmental Organizations (NGOs)	IIA-44
4.1.23 Pro-Children Act of 1994	IIA-45
4.1.24 Public Health Security	IIA-46
4.1.24.1 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents)	IIA-46
4.1.24.1.1.1 Select Agent Awards to U.S. Institutions	IIA-46
4.1.24.1.1.2 Select Agent Awards to Foreign Organizations and Inter- national Organizations	IIA-46
4.1.24.1.1.3 Select Agent Awards to U.S. Institutions with Foreign Sub- components	IIA-47
4.1.24.2 Dual Use Research of Concern	IIA-47

4.1.24.3 Agents Regulated Under the Chemical Weapons Convention	IIA-48
4.1.25 Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees	IIA-48
4.1.26 Research Involving Recombinant or Synthetic Nucleic Acid Molecules	IIA-49
4.1.26.1 Scope and Availability	IIA-49
4.1.26.2 Institutional Biosafety Committee	IIA-49
4.1.26.3 Investigators and Institutional Staff	IIA-50
4.1.27 Research Misconduct	IIA-50
4.1.28 Seat Belt Use	IIA-51
4.1.29 Smoke-Free Workplace	IIA-52
4.1.30 Standards of Conduct	IIA-52
4.1.31 Text Messaging While Driving	IIA-52
4.1.32 Trafficking in Persons	IIA-53
4.1.33 USA Patriot Act	IIA-53
4.1.34 Responsibility/Qualification Information in SAM.gov	IIA-53
4.1.35 Mandatory Disclosures	IIA-54
4.1.36 Never Contract with the Enemy	IIA-54
4.1.37 Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment	IIA-55
4.2 Appropriation Mandates	IIA-55
4.2.1 Acknowledgment of Federal Funding	IIA-55
4.2.2 Dissemination of False or Deliberately Misleading Information	IIA-56
4.2.3 Gun Control	IIA-56
4.2.4 Human Embryo Research and Cloning Ban	IIA-56
4.2.5 Lobbying—Appropriation Prohibition	IIA-56
4.2.6 Promotion or Legalization of Controlled Substances	IIA-57
4.2.7 Restriction on Abortion Funding	IIA-57
4.2.8.1 Exceptions to Restrictions on Abortions	IIA-57
4.2.9 Restriction on Distribution of Sterile Needles	IIA-57
4.2.10 Salary Cap/Salary Limitation	IIA-58
4.2.10 Restriction of Pornography on Computer Networks	IIA-58
4.2.11 Restriction on Disclosure of Political Affiliation for Federal Scientific Advisory Committee Candidates	IIA-58
5 THE NOTICE OF AWARD	IIA-59
5.1 Notice of Award Notification	IIA-61
5.2 Associated Applications and/or Awards	IIA-61
5.3 Funding	IIA-61
5.4 Budget	IIA-62
5.5 Additional Terms and Conditions	IIA-63
6 PAYMENT	IIA-64
6.1 Smartlink II/ACH	IIA-64
6.2 Cash Request	IIA-64
6.3 Interest Earned on Advances of Grant Funds	IIA-65
6.4 Improper Payments Elimination and Recovery Improvement Act	IIA-65
7 COST CONSIDERATION	IIA-66
7.1 General	IIA-66
7.2 The Cost Principles	IIA-66
7.3 Direct Costs and Facilities and Administrative Costs	IIA-67

7.4 Reimbursement of Facilities and Administrative Costs	IIA-68
7.5 Cost Transfers, Overruns, and Accelerated and Delayed Expenditures	IIA-71
7.6 Allocation of Costs and Closely Related Work	IIA-72
7.7 Applicable Credits	IIA-72
7.8 Services Provided by Affiliated Organizations	IIA-72
7.9 Allowability of Costs/Activities	IIA-73
7.9.1 Selected Items of Cost	IIA-74
8 ADMINISTRATIVE REQUIREMENTS	IIA-103
8.1 Changes in Project and Budget	IIA-103
8.1.1 NIH Standard Terms of Award	IIA-103
8.1.1.1 Carryover of Unobligated Balances from One Budget Period to Any Sub- sequent Budget Period	IIA-104
8.1.1.2 Cost-Related Prior Approvals	IIA-105
8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds	IIA-106
8.1.1.4 Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement	IIA-107
8.1.1.5 Direct Charging Salaries of Administrative and Clerical Staff	IIA-107
8.1.1.6 Supplemental Compensation under Written Institutional Policy for IHEs ..	IIA-107
8.1.1.7 Intra-IHE Faculty Consulting that Exceed a Faculty Member's Base Salary, Under Certain Conditions.	IIA-107
8.1.2 Prior Approval Requirements	IIA-107
8.1.2.1 Additional No-cost Extension or Extension Greater Than 12 Months or Late Notification of Initial No-Cost Extension	IIA-109
8.1.2.2 Alterations and Renovations	IIA-109
8.1.2.3 Capital Expenditures	IIA-109
8.1.2.4 Carryover of Unobligated Balances	IIA-109
8.1.2.5 Change in Scope	IIA-110
8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Per- sonnel Named in the NoA	IIA-112
8.1.2.7 Change of Recipient Organization	IIA-113
8.1.2.8 Change in Recipient Organizational Status	IIA-117
8.1.2.9 Deviation from Award Terms and Conditions, including Restrictions in the NoA	IIA-118
8.1.2.10 Foreign Component Added to a Grant to a Domestic or Foreign Organ- ization	IIA-118
8.1.2.11 Provide Subawards Based on Fixed Amounts	IIA-119
8.1.2.12 Need for Additional NIH Funding without Extension of Budget and Pro- ject Period	IIA-119
8.1.2.13 Need for Additional NIH Funding with Extension of the Final Budget Period of a Project Period	IIA-120
8.1.2.14 Pre-Award Costs	IIA-120
8.1.2.15 Rebudgeting of Funds from Trainee Costs	IIA-120
8.1.2.16 Rebudgeting of Funds Between Construction and Non-construction Work	IIA-120
8.1.2.17 Retention of Research Grant Funds When a Career Development Award is Issued	IIA-120
8.1.3 Requests for Prior Approval	IIA-121
8.2 Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources	IIA-121

8.2.1 Rights in Data (Publication and Copyrighting)	IIA-122
8.2.2 NIH Public Access Policy	IIA-123
8.2.3 Sharing Research Resources	IIA-123
8.2.3.1 Policy for Data Management and Sharing (DMS Policy)	IIA-124
8.2.3.2 Genomic Data Sharing (GDS) Policy	IIA-126
8.2.3.3 Sharing Model Organisms	IIA-126
8.2.4 Inventions and Patents	IIA-127
8.2.5 Interim Research Products	IIA-135
8.3 Management Systems and Procedures	IIA-136
8.3.1 Financial Management System Standards	IIA-136
8.3.2 Program Income	IIA-137
8.3.2.1 Reporting Program Income	IIA-137
8.3.2.2 Sale of Real Property, Equipment, and Supplies	IIA-138
8.3.2.3 Royalties and Licensing Fees from Copyrights, Inventions, and Patents ...	IIA-139
8.3.3 Property Management System Standards	IIA-139
8.3.3.1 Real Property	IIA-140
8.3.3.2 Equipment and Supplies	IIA-140
8.3.4 Procurement System Standards and Requirements	IIA-142
8.3.4.1 General	IIA-142
8.3.4.2 Approval Requirements	IIA-142
8.3.4.3 Contracting with Small Businesses, Minority-Owned Firms, and Women's Business Enterprises	IIA-143
8.3.4.4 Domestic Preferences for Procurements	IIA-143
8.4 Monitoring	IIA-143
8.4.1 Reporting	IIA-144
8.4.1.1 Non-Competing Continuation Progress Reports	IIA-144
8.4.1.2 Streamlined Non-Competing Award Process	IIA-145
8.4.1.3 Progress Reports for Multiyear Funded Awards	IIA-147
8.4.1.4 Final Research Performance Progress Report (F-RPPR)	IIA-147
8.4.1.5 Financial Reports	IIA-147
8.4.1.6 Invention Reporting	IIA-150
8.4.1.7 Financial Conflict of Interest Reports	IIA-150
8.4.1.8 NIH Disclosure Requirements	IIA-151
8.4.2 Record Retention and Access	IIA-151
8.4.3 Audit	IIA-152
8.5 Specific Award Conditions and remedies for noncompliance (specific award con- ditions and Enforcement Actions)	IIA-154
8.5.1 Specific Award Conditions: Modification of the Terms of Award	IIA-155
8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Ter- mination, and Withholding of Support	IIA-155
8.5.3 Other Enforcement Actions	IIA-157
8.5.4 Recovery of Funds	IIA-157
8.5.5 Debt Collection	IIA-157
8.6 Closeout	IIA-158
8.6.1 Final Federal Financial Report	IIA-158
8.6.2 Final Research Performance Progress Report	IIA-159
8.6.3 Final Invention Statement and Certification	IIA-159
8.6.4 Submission of Closeout Documents	IIA-159
8.7 Grant Appeals Procedures	IIA-160

9 MULTIPLE PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR APPLICATIONS AND AWARDS	IIB-2
9.1 General	IIB-2
9.2 Applicability	IIB-2
9.3 Application Requirements	IIB-2
9.4 Application Review and Award	IIB-4
9.5 Post-Award Administration	IIB-4
10 CONSTRUCTION, MODERNIZATION, OR MAJOR ALTERATION AND RENOVATION OF RESEARCH FACILITIES	IIB-6
10.1 General	IIB-6
10.1.1 Eligibility	IIB-7
10.1.2 Notices of Funding Opportunity	IIB-7
10.1.3 Application Review and Award	IIB-7
10.1.4 Title to Site	IIB-8
10.1.5 Matching Requirement	IIB-8
10.2 Procurement Requirements for Construction Services	IIB-9
10.2.1 General	IIB-9
10.2.2 Liquidated Damages	IIB-10
10.3 Contracting Methods	IIB-10
10.3.1 Design-Bid-Build	IIB-10
10.3.2 Alternate Contracting Methods	IIB-10
10.3.2.1 Construction Manager	IIB-10
10.3.2.2 Design-Build Services	IIB-11
10.3.2.3 Guaranteed Maximum Price	IIB-12
10.4 Design Documentation Requirements	IIB-12
10.4.1 Minimum Design Requirements for Construction, Modernization and Major A&R	IIB-13
10.5 Equal Opportunity and Labor Standards	IIB-13
10.5.1 Equal Employment Opportunity	IIB-14
10.5.2 Nonsegregated Facilities	IIB-14
10.5.3 Labor Standards	IIB-14
10.5.3.1 Contract Work Hours and Safety Standards	IIB-14
10.5.3.2 Disposition of Unclaimed Wages	IIB-15
10.6 Real Property Management Standards	IIB-15
10.6.1 General	IIB-15
10.6.2 Notice of Federal Interest	IIB-16
10.6.3 Insurance Requirements	IIB-16
10.6.4 Use of Facility and Disposition	IIB-17
10.6.5 Real Estate Appraisals	IIB-18
10.7 Allowable and Unallowable Costs and Activities	IIB-18
10.8 Administrative Requirements	IIB-20
10.8.1 Prior Approval Requirements	IIB-20
10.8.2 Alteration and Renovation Projects Under Non-construction Grants	IIB-21
10.9 Closeout	IIB-22
10.10 Public Policy Requirements	IIB-23
10.10.1 Executive Orders	IIB-26
11 RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARDS	IIB-31
11.1 General	IIB-31

11.1.1 Background	IIB-31
11.1.2 Nondiscrimination	IIB-31
11.2 Individual Fellowships	IIB-31
11.2.1 General	IIB-31
11.2.2 Eligibility	IIB-32
11.2.2.1 Research Areas	IIB-32
11.2.2.2 Research Training Program	IIB-32
11.2.2.3 Degree Requirements	IIB-32
11.2.2.4 Citizenship	IIB-33
11.2.2.5 Sponsorship	IIB-33
11.2.2.6 NIH Employees & Other Federal Sponsorship (Federal Fellows)	IIB-34
11.2.2.7 Individuals on Active Military Duty	IIB-34
11.2.3 Application Requirements and Due Dates	IIB-35
11.2.3.1 Application	IIB-35
11.2.3.2 eRA Commons Registration	IIB-35
11.2.3.3 ORCID iDs	IIB-35
11.2.3.4 Letters of Reference	IIB-35
11.2.3.5 Responsible Conduct of Research	IIB-36
11.2.3.6 Concurrent Applications	IIB-38
11.2.3.7 Receipt Dates	IIB-38
11.2.4 Review	IIB-38
11.2.4.1 Overall Impact	IIB-38
11.2.4.2 Scored Review Criteria	IIB-38
11.2.4.3 Additional Review Criteria	IIB-39
11.2.4.4 Additional Review Considerations	IIB-39
11.2.4.5 Secondary Level of Review	IIB-39
11.2.5 Notification of Action	IIB-39
11.2.6 Period of Support	IIB-40
11.2.7 Full-Time and Part-Time Training	IIB-41
11.2.8 Initiation of Support	IIB-41
11.2.8.1 Process	IIB-41
11.2.8.2 Payment	IIB-42
11.2.9 Allowable and Unallowable Costs	IIB-42
11.2.9.1 Pre-award Costs	IIB-42
11.2.9.2 Stipends	IIB-42
11.2.9.3 Stipend Levels	IIB-43
11.2.9.4 Institutional Allowance	IIB-43
11.2.9.5 Tuition and Fees	IIB-44
11.2.9.6 Travel to Foreign Training Sites	IIB-45
11.2.9.7 Childcare Costs	IIB-45
11.2.9.8 Employee Benefits	IIB-45
11.2.9.9 Rebudgeting of Funds	IIB-46
11.2.10 Supplementation of Stipends, Compensation, and Other Income	IIB-46
11.2.10.1 Stipend Supplementation	IIB-46
11.2.10.2 Compensation	IIB-46
11.2.10.3 Other Income: Concurrent Benefits	IIB-47
11.2.10.4 Other Income: Educational Loans or GI Bill	IIB-47
11.2.10.5 Other Income: NIH Loan Repayment Program	IIB-47
11.2.10.6 Taxability of Stipends	IIB-47
11.2.10.7 Form 1099	IIB-47
11.2.11 Reporting Requirements	IIB-48

11.2.11.1 Activation Notice	IIB-48
11.2.11.2 Payback Agreement	IIB-48
11.2.11.3 Termination Notice	IIB-48
11.2.11.4 Consecutive Support	IIB-49
11.2.11.5 Progress Reports	IIB-49
11.2.11.6 Financial Reporting	IIB-49
11.2.12 Changes in the Project	IIB-49
11.2.13 Other Terms and Conditions	IIB-50
11.2.13.1 Leave	IIB-50
11.2.13.2 Termination	IIB-51
11.2.13.3 Publications and Sharing of Research Results	IIB-51
11.2.13.4 Copyright	IIB-51
11.2.13.5 Inventions and Patents	IIB-51
11.2.13.6 Disposition of Professional Fees	IIB-52
11.2.13.7 Public Policy Requirements and Objectives	IIB-52
11.2.13.8 Applicability of NIH Standard Terms of Award	IIB-53
11.3 Institutional Research Training Grants	IIB-53
11.3.1 General	IIB-53
11.3.2 Eligibility	IIB-53
11.3.2.1 Applicant Eligibility	IIB-53
11.3.2.2 Research Areas	IIB-53
11.3.2.3 Training Program Director/Principal Investigator(s)	IIB-54
11.3.2.4 Research Training Program	IIB-54
11.3.2.5 Degree Requirements	IIB-55
11.3.2.6 Citizenship	IIB-56
11.3.3 Application Requirements and Due Dates	IIB-57
11.3.3.1 Application	IIB-57
11.3.3.2 Due Dates	IIB-57
11.3.3.3 Special Program Considerations	IIB-57
11.3.3.4 Recruitment Plan to Enhance Diversity	IIB-58
11.3.3.5 Training in the Responsible Conduct of Research	IIB-61
11.3.4 Review	IIB-63
11.3.4.1 Overall	IIB-63
11.3.4.2 Overall Impact	IIB-63
11.3.4.3 Scored Review Criteria	IIB-63
11.3.4.4 Additional Review Criteria	IIB-63
11.3.4.5 Additional Review Considerations	IIB-64
11.3.4.6 National Advisory Council Review	IIB-64
11.3.5 Notification of Action	IIB-64
11.3.6 Period of Support	IIB-64
11.3.6.1 Training Grants	IIB-64
11.3.6.2 Trainees	IIB-64
11.3.6.3 Kirschstein-NRSA Limitations	IIB-65
11.3.7 Initiation of Support	IIB-66
11.3.8 Allowable and Unallowable Costs	IIB-66
11.3.8.1 Pre-Award Costs	IIB-66
11.3.8.2 Stipends	IIB-67
11.3.8.3 Trainee Tuition and Fees	IIB-67
11.3.8.4 Training-Related Expenses	IIB-68
11.3.8.5 Trainee Travel Costs	IIB-68
11.3.8.6 Short-Term Training Costs	IIB-69

11.3.8.7 Employee Benefits	IIB-69
11.3.8.8 Facilities and Administrative Costs	IIB-69
11.3.9 Rebudgeting of Funds	IIB-69
11.3.10 Stipend Supplementation, Compensation, and Other Income	IIB-70
11.3.10.1 Stipend Supplementation	IIB-70
11.3.10.2 Compensation	IIB-70
11.3.10.3 Other Income: Concurrent Benefits	IIB-70
11.3.10.4 Other Income: Educational Loans or GI Bill	IIB-71
11.3.10.5 Other Income: NIH Loan Repayment Program	IIB-71
11.3.10.6 Taxability of Stipends	IIB-71
11.3.10.7 Form 1099	IIB-71
11.3.11 Carryover Authority	IIB-71
11.3.12 Program Income	IIB-72
11.3.13 Reporting Requirements	IIB-72
11.3.13.1 Statement of Appointment (Form PHS 2271)	IIB-72
11.3.13.2 Payback Agreement (Form PHS 6031)	IIB-73
11.3.13.3 Termination Notice (Form PHS 416-7)	IIB-73
11.3.13.4 Research Performance Progress Reports	IIB-73
11.3.13.5 Federal Financial Report (FFR)	IIB-73
11.3.14 Closeout	IIB-74
11.3.15 Changes in the Project	IIB-74
11.3.16 Other Terms and Conditions	IIB-74
11.3.16.1 Leave	IIB-74
11.3.16.2 Termination	IIB-75
11.3.16.3 Publications and Sharing of Research Results	IIB-75
11.3.16.4 Copyright	IIB-76
11.3.16.5 Inventions and Patents	IIB-76
11.3.16.6 Disposition of Professional Fees	IIB-76
11.3.16.7 Public Policy Requirements and Objectives	IIB-76
11.4 Payback Requirements	IIB-77
11.4.1 General	IIB-77
11.4.2 Implementation	IIB-77
11.4.3 Payback	IIB-78
11.4.3.1 Service Payback	IIB-78
11.4.3.2 Financial Payback	IIB-79
11.4.3.3 Extensions of Payback	IIB-80
11.4.3.4 Waiver	IIB-81
11.4.4 Certification of Payback Activities	IIB-81
11.4.4.1 Annual Payback Activities Certification (Form PHS 6031-1)	IIB-81
11.4.4.2 Annual Certification	IIB-81
11.4.4.3 Change of Address	IIB-82
11.4.4.4 Breaks in Kirschstein-NRSA Support	IIB-82
11.4.4.5 National Health Service Corps	IIB-82
12 RESEARCH CAREER DEVELOPMENT ("K") AWARDS	IIB-83
12.1 General	IIB-83
12.1.1 Background	IIB-83
12.2 Types of Career Development Awards	IIB-83
12.2.1 General	IIB-83
12.2.2 Individual Mentored Career Development Awards	IIB-83
12.2.2.1 Mentor	IIB-84

12.2.3 Career Transition Awards	IIB-84
12.2.3.1 K22	IIB-84
12.2.3.2 Pathway to Independence Award (K99/R00)	IIB-84
12.2.4 Individual Non-mentored (Independent) Career Development Awards	IIB-86
12.2.5 Institutional Scientist Development Programs	IIB-86
12.3 Eligibility	IIB-86
12.3.1 Eligible Institutions	IIB-87
12.3.2 Eligible Individuals	IIB-87
12.3.3 Degree Requirements	IIB-87
12.3.4 Citizenship	IIB-87
12.3.5 Type of Appointment	IIB-88
12.3.5.1 Temporary Adjustments to the Full-Time Institutional Appointment Requirement	IIB-88
12.3.6 Level of Effort	IIB-89
12.3.6.1 Mentored CDAs	IIB-89
12.3.6.2 Concurrent Support	IIB-90
12.3.6.3 Non-mentored CDAs	IIB-91
12.3.6.4 Temporary Adjustments to the Percent Effort Requirement	IIB-91
12.3.7 Prior Research Support	IIB-92
12.4 Application Requirements and Due Dates	IIB-92
12.4.1 Application	IIB-92
12.4.1.1 Letters of Reference	IIB-93
12.4.1.2 Concurrent Applications	IIB-93
12.4.1.3 Environment and Institutional Commitment to the Candidate	IIB-93
12.4.1.4 Training in the Responsible Conduct of Research	IIB-94
12.4.1.5 Budget	IIB-95
12.4.1.6 Submission Dates	IIB-96
12.5 Review	IIB-96
12.5.1 Overall Impact	IIB-96
12.5.2 Scored Review Criteria	IIB-96
12.5.3 Additional Review Criteria	IIB-97
12.5.4 Additional Review Considerations	IIB-97
12.6 Notification of Action	IIB-97
12.7 Period of Support	IIB-97
12.8 Allowable and Unallowable Costs	IIB-98
12.8.1 Salaries and Fringe Benefits	IIB-98
12.8.2 Research Development Support Costs	IIB-99
12.8.3 Proposal Preparation Costs	IIB-99
12.8.4 Facilities and Administrative Costs	IIB-99
12.9 Rebudgeting of Funds	IIB-99
12.10 Carryover Authority	IIB-99
12.11 Reporting Requirements	IIB-100
12.11.1 Progress Reports	IIB-100
12.11.2 Federal Financial Report	IIB-100
12.11.3 Closeout	IIB-100
12.11.4 Post Closeout Evaluation	IIB-100
12.12 Changes in the Project	IIB-100
12.12.1 Temporary Off-Site Career Development Experience	IIB-101
12.13 Other Terms and Conditions	IIB-101
12.13.1 Leave	IIB-101

12.13.1.1 Unpaid Leave	IIB-102
12.13.2 Statement of Appointment—Institutional CDAs Only	IIB-102
12.13.3 Early Termination	IIB-102
12.13.4 Other Income: Generation and Disposition of Professional Fees	IIB-103
13 MODULAR APPLICATIONS AND AWARDS	IIB-104
13.1 General	IIB-104
13.2 Applicability	IIB-104
13.3 Application Requirements	IIB-104
13.3.1 Budget	IIB-104
13.4 Application Review and Award	IIB-105
13.5 Post-Award Administration	IIB-105
14 SUPPORT OF SCIENTIFIC MEETINGS (CONFERENCE GRANTS)	IIB-106
14.1 General	IIB-106
14.2 Applicability	IIB-106
14.3 Definitions	IIB-106
14.4 Eligibility	IIB-107
14.5 Application Requirements	IIB-107
14.6 Public Policy Requirements and Objectives	IIB-107
14.6.1 The United States Hotel and Motel Fire Safety Act of 1990	IIB-107
14.6.2 Guideline on the Inclusion of Underrepresented Populations	IIB-107
14.6.3 Plans to Promote Safe Environments at Conferences	IIB-108
14.7 Application Review	IIB-109
14.8 Funding	IIB-109
14.9 Acknowledgment of Funding Source and Disclaimer	IIB-110
14.10 Allowable and Unallowable Costs	IIB-110
14.10.1 Allowable Costs	IIB-110
14.10.2 Unallowable Costs	IIB-111
14.11 Administrative Requirements	IIB-112
14.11.1 Intellectual Property: Publications, Copyright, and Public Disclosure	IIB-112
14.11.2 Reporting and Record Retention	IIB-112
14.11.2.1 Progress/Final Report	IIB-112
14.11.2.2 Federal Financial Report	IIB-113
15 CONSORTIUM AGREEMENTS	IIB-114
15.1 General	IIB-114
15.2 Administrative and Other Requirements	IIB-115
15.2.1 Written Agreement	IIB-115
15.2.2 Public Policy Requirements and Objectives	IIB-117
15.2.3 Allowable and Unallowable Costs	IIB-118
15.2.4 Approval Authorities	IIB-118
15.2.5 Tangible Personal Property	IIB-118
15.2.5.1 Exempt Property	IIB-118
15.2.5.2 Nonexempt Property	IIB-118
15.2.6 Audit	IIB-119
16 GRANTS TO FOREIGN ORGANIZATIONS, INTERNATIONAL ORGANIZATIONS, AND DOMESTIC GRANTS WITH FOREIGN COMPONENTS	IIB-120
16.1 General	IIB-120
16.2 Eligibility	IIB-120

16.3 Application Review	IIB-121
16.4 Public Policy Requirements and Objectives	IIB-121
16.5 Funding and Payment	IIB-122
16.6 Allowable and Unallowable Costs	IIB-123
16.7 Administrative Requirements	IIB-123
16.7.1 Changes in Project and Budget	IIB-124
16.7.2 Change in Scope	IIB-124
16.7.3 Change of Recipient Organization	IIB-124
16.7.4 Audit	IIB-124
16.7.5 Reporting and Record Retention	IIB-124
17 GRANTS TO FEDERAL INSTITUTIONS AND PAYMENTS TO FEDERAL EMPLOYEES UNDER GRANTS	IIB-125
17.1 General	IIB-125
17.2 Eligibility	IIB-125
17.3 VA-University Affiliations	IIB-125
17.4 Public Policy Requirements and Objectives	IIB-126
17.5 Payment	IIB-126
17.6 Allowable and Unallowable Costs	IIB-126
17.7 Administrative Requirements	IIB-129
17.7.1 Equipment Accountability	IIB-129
17.7.2 Procurement Requirements	IIB-129
17.7.3 Intellectual Property	IIB-129
17.7.4 Reporting Requirements	IIB-129
18 GRANTS TO FOR-PROFIT ORGANIZATIONS	IIB-130
18.1 General	IIB-130
18.2 Eligibility	IIB-130
18.3 Allowable and Unallowable Costs	IIB-130
18.3.1 Cost Principles	IIB-130
18.3.2 Facilities and Administrative Costs (Indirect Costs)	IIB-130
18.3.3 Profit or Fee	IIB-130
18.4 Administrative Requirements	IIB-130
18.4.1 Equipment Accountability	IIB-131
18.4.2 Intellectual Property	IIB-131
18.4.3 Program Income	IIB-131
18.4.4 Operating Authorities	IIB-131
18.4.5 Audit	IIB-131
18.4.6 Labor Distribution Requirements for For-Profit Organizations	IIB-132
18.5 Small Business Innovation Research and Small Business Technology Transfer Programs	IIB-132
18.5.1 NIH Fast-Track Application Process	IIB-134
18.5.2 Eligibility	IIB-134
18.5.2.1 Place of Performance	IIB-136
18.5.2.2 Change in Organization Size & Change of Recipient Institution Actions	IIB-136
18.5.2.3 Minimum Level of Effort	IIB-137
18.5.2.4 Multiple Program Director/Principal Investigator Applications and Awards	IIB-137
18.5.3 Public Policy Requirements and Objectives	IIB-138
18.5.4 Allowable Costs and Fee	IIB-138

18.5.4.1 Program Levels (Total Costs)	IIB-138
18.5.4.2 Profit or Fee	IIB-138
18.5.4.3 Facilities and Administrative Costs (Indirect Costs)	IIB-139
18.5.5 Administrative Requirements	IIB-139
18.5.5.1 Market Research	IIB-139
18.5.5.2 Intellectual Property	IIB-140
18.5.5.3 Data Sharing	IIB-143
18.5.5.4 SBIR Life Cycle Certification	IIB-143
18.5.5.5 STTR Life Cycle Certification	IIB-145
18.5.5.6 Final RPPR	IIB-147
18.5.5.7 Phase II Data Collection Requirement for Government SBIR Reporting Database	IIB-147
19 RESEARCH PATIENT CARE COSTS	IIB-149
19.1 General	IIB-149
19.2 Definitions	IIB-149
19.3 Policy	IIB-150
19.4 Allowable Costs	IIB-150
19.4.1 Computing Research Patient Care Costs	IIB-151
19.4.2 Facilities and Administrative Costs	IIB-151
19.4.3 Special Procedures for Certain Hospitals	IIB-151
19.4.3.1 Recipients	IIB-151
19.4.3.2 Consortium Participants/Contractors under Grants	IIB-152
19.4.4 Financial Responsibilities	IIB-152
19.5 Program Requirements	IIB-152
19.6 Post-Award Requirements	IIB-153
20 INSTITUTES AND CENTERS	III-1
20.1 Other NIH Offices	III-5
20.2 Other HHS Government Offices	III-10

PART I: NIH GRANTS—GENERAL INFORMATION

This part contains a glossary defining terms and abbreviations commonly used throughout the NIHGPS; describes NIH and its relationship to other organizations within HHS; specifies recipient, NIH, and other HHS staff responsibilities; and outlines the grant application and review processes.

1 GLOSSARY

The glossary lists acronyms and other abbreviations used in the NIHGPS. The glossary also defines terms commonly used throughout the NIHGPS. The definitions may be amplified and additional definitions may be found throughout this document and in source documents, such as applicable statutes and grants administration regulations. This is the only location in the NIHGPS where these terms are defined. If an abbreviation used in the NIHGPS is unfamiliar, the reader should consult this list for its meaning.

1.1 ABBREVIATIONS

Exhibit 1: Abbreviation and full language of acronyms used in the Grants Policy Statement

Abbreviation	Full Meaning of Abbreviation
A&R	Alteration and Renovation
ACF	Administration for Children and Families
ACH	Automated Clearinghouse
ACL	Administration for Community Living
AHRQ	Agency for Healthcare Research and Quality
AIA	American Institute of Architects
AoA	Administration on Aging
AOR	Authorized Organization Representative
APAC	Annual Payback Activities Certification
AREA	Academic Research and Enhancement Award
ASHRAE	American Society of Heating, Refrigeration and Air Conditioning Engineers
BSO	Biological Safety Officer
CAS	Cost Allocation Services
CDA	Career Development Award
CDC	Centers for Disease Control and Prevention
CF	Common Form (previously known as Standard Form)
CFR	Code of Federal Regulations

Abbreviation	Full Meaning of Abbreviation
CGMO	Chief Grants Management Officer
CM	Construction Manager
CMS	Centers for Medicare and Medicaid Services
CoC	Certificate of Confidentiality
COR	Career Opportunities in Research Education and Training Program
CSR	Center for Scientific Review
DAB	Departmental Appeals Board
DCGP	Division of Central Grants Processing, OER, NIH
DCIS	Departmental Contracts Information System
DEA	Drug Enforcement Administration
DEITR	Division of Extramural Inventions & Technology Resources, OPERA, OER, NIH
DES	Department of Engineering Services, NIH
DFAS	Division of Financial Advisory Services, NIH
DGCO	Division of Grants Compliance and Oversight, OPERA, OER, NIH
DGP	Division of Grants Policy, OPERA, OER, NIH
DGSI	Division of Grants System Integration, OPERA, OER, NIH
DNA	Deoxyribonucleic acid
DoC	Department of Commerce
DoD	Department of Defense
DoL	Department of Labor
DPI	Division of Program Integrity, OMA, NIH
DRR	Division of Receipt and Referral, CSR
DSMB	Data and Safety Monitoring Board
EA	Environmental Assessment
FFR	Federal Financial Report
EIN	Entity Identification Number
EIS	Environmental Impact Statement
EO	Executive Order
eRA	Electronic Research Administration
ESI	Early Stage Investigator

Abbreviation	Full Meaning of Abbreviation
eSNAP	Electronic Streamlined Non-competing Award Process
F&A	Facilities and Administrative (costs)
FAC	Federal Audit Clearinghouse
FAIN	Federal Award Identification Number
FAR	Federal Acquisition Regulation
FCOI	Financial Conflict of Interest
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDP	Federal Demonstration Partnership
FEMA	Federal Emergency Management Agency
FFATA	Federal Funding Accountability and Transparency Act
FFR	Federal Financial Report (SF425)
FIC	Fogarty International Center
FICA	Federal Insurance Contributions Act
FOI	Freedom of Information
FOIA	Freedom of Information Act
FTR	Federal Travel Regulation
FWA	Federalwide Assurance
GAAP	Generally Accepted Accounting Principles
GAGAS	Generally Accepted Government Accounting Standards
GeMCRIS	Genetic Modification Clinical Research Information System
GMO	Grants Management Officer
GMP	Guaranteed Maximum Price
GMS	Grants Management Specialist
GPO	Government Printing Office
GSA	General Services Administration
GWAS	Genome-wide Association Studies
hESC	Human Embryonic Stem Cells
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act

Abbreviation	Full Meaning of Abbreviation
HPSL	Health Professional Student Loan
HRSA	Health Resources and Services Administration
HVAC	Heating, Ventilating, and Air Conditioning
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IBS	Institutional Base Salary
IC	Institute or Center
IDE	Investigational Device Exception
IHE	Institutions of Higher Education
IHS	Indian Health Service
IND	Investigational New Drug
IPA	Intergovernmental Personnel Act
IPF	Institutional Profile File
IR&D	Independent Research and Development
IRB	Institutional Review Board
IRG	Integrated Review Group
IRS	Internal Revenue Service
IVF	In vitro Fertilization
K award	Career Award
Kirschstein-NRSA	Ruth L. Kirschstein National Research Service Award
LWOP	Leave Without Pay
MARC-U*STAR	Maximizing Access to Research Careers Undergraduate Student Training in Academic Research Program
MOU	Memorandum of Understanding
MTDC	Modified Total Direct Cost
NCATS	National Center for Advancing Translational Sciences
NCT	National Clinical Trial
ND	Not Discussed
NEARC	National External Audit Review Center, OIG
NEI	National Eye Institute

Abbreviation	Full Meaning of Abbreviation
NEPA	National Environmental Policy Act
NFI	Notice of Federal Interest
NFPA	National Fire Protection Association
NHSC	National Health Service Corps
NICHD	<i>Eunice Kennedy Shriver</i> National Institute for Child Health and Human Development
NIDCR	National Institute of Dental and Craniofacial Research
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIH MSID	NIH manuscript submission reference number
NIHGPS	National Institutes of Health Grants Policy Statement
NIMH	National Institute of Mental Health
NINR	National Institute on Nursing Research
NLM	National Library of Medicine
NoA	Notice of Award
NOFO	Notice of Funding Opportunity
NTIS	National Technical Information Service
OASH	Office of the Assistant Secretary for Health
OCR	Office for Civil Rights, HHS
OER	Office of Extramural Research, NIH
OFCCP	Office of Federal Contract Compliance Programs, DoL
OFM	Office of Financial Management, NIH
OHRP	Office for Human Research Protections, HHS
OIG	Office of the Inspector General
OIR	Office of Intramural Research, NIH
OLAW	Office of Laboratory Animal Welfare, NIH
OMA	Office of Management Assessment, NIH
OMB	Office of Management and Budget
ONR	Office of Naval Research
OPERA	Office of Policy for Extramural Research Administration, OER, NIH
ORI	Office of Research Integrity, HHS

Abbreviation	Full Meaning of Abbreviation
OSC	Other Significant Contributor
P.L.	Public Law
PA	Program Announcement
PAR	Program Announcement with Special Review Criteria and/or Special Receipt Dates
PD/PI	Program Director/Principal Investigator
pdf	portable document format
PHS	Public Health Service
PII	Personally Identifiable Information
PMC	PubMed Central
PMCID	PubMed Central Identification/reference number
PMS	Payment Management System, Payment Management Service, HHS
PO	Program Official
PSC	Payback Service Center, NIH, or Program Support Center, HHS
PTE	Pass-through Entity
R&D	Research and Development
R&R	Research and Related
RePORT	Research Portfolio Online Reporting Tool
RFA	Request for Applications
RFP	Request for Proposals
ROTC	Reserve Officer Training Corps
RPPR	Research Performance Progress Report
S&W	Salaries and Wages
SAM	System for Award Management
SAMHSA	Substance Abuse and Mental Health Services Administration
SBA	Small Business Administration
SBC	Small Business Concern
SBIR	Small Business Innovation Research Program
SEP	Special Emphasis Panel
SEVIS	Student and Exchange Visitor Information System
SF	Standard Form

Abbreviation	Full Meaning of Abbreviation
SF424(R&R)	Standard Form 424 for Research and Research-Related (R&R)
SII	Successor-In-Interest
SNAP	Streamlined Non-competing Award Process
SO	Signing Official
SPOC	State Single Point of Contact
SRG	Scientific Review Group
SRO	Scientific Review Officer
STTR	Small Business Technology Transfer Program
TVPA	Trafficking Victims Protection Act
U.S.	United States
U.S.C.	United States Code
USCIS	United States Citizenship and Immigration Services
USDA	United States Department of Agriculture
USPS	United States Postal Service
VA	Department of Veterans Affairs
VAMC	VA Medical Center
VANPC	VA-Affiliated Non-Profit research Corporation
VAT	Value Added Tax
VHA	Veterans Health Administration
WIC	Women, Infants and Children

1.2 DEFINITION OF TERMS

Exhibit 2: Definitions of terms used in the Grants Policy Statement

Term	Definition
Acquisition cost	The cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.
Activity code	A 3-character code used to identify a specific category of extramural research activity, applied to financial assistance mechanisms. NIH uses three funding mechanisms for extramural research awards: grants, cooperative agreements and contracts. Within each funding mechanism, NIH uses 3-character activity codes (e.g., F32, K08, P01, R01, T32, etc.) to differentiate the wide variety of research-related programs NIH supports. A comprehensive list of activity codes is on the Activity Code Search Results webpage .
Additive alternative	A use of program income earned during or after the project period that permits income that is generated under a grant to be added to funds committed to the project by the Federal awarding agency and recipient and used to further eligible project or program objectives. (See definitions for deductive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Administrative supplement	A request for (or the award of) additional funds during a current project period to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer reviewed and approved project.
Advance payment	A payment that a Federal awarding agency or pass through entity makes by any appropriate payment mechanism, including a predetermined payment schedule, before the non-Federal entity disburses the funds for program purposes.
Allocation	The process of assigning a cost, or a group of costs, to one or more cost objective(s), in reasonable proportion to the benefit provided or other equitable relationship. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate cost objectives. For additional information, see Cost Considerations—The Cost Principles .

Term	Definition
Allowable cost	A cost incurred by a recipient that is: (1) reasonable for the performance of the award; (2) allocable; (3) in conformance with any limitations or exclusions set forth in the Federal cost principles applicable to the organization incurring the cost or in the NoA as to the type or amount of cost; (4) consistent with regulations, policies, and procedures of the recipient that are applied uniformly to both federally supported and other activities of the organization; (5) accorded consistent treatment as a direct or indirect cost; (6) determined in accordance with generally accepted accounting principles; and (7) not included as a cost in any other federally supported award (unless specifically authorized by statute). For additional information on each, see Cost Considerations—The Cost Principles .
Alteration and renovation	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major or minor is made by the NIH Program Official. See definition for Modernization.
Applicable clinical trial	Applicable clinical trial is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements in FDAAA.
Animal Welfare Assurance	The Animal Welfare Assurance is part of the required documentation to receive an award for organizations involved in live, vertebrate animal activity conducted or supported by the Public Health Service (PHS). The Animal Welfare Assurance enumerates the organization's commitment to compliance with the PHS Policy on Humane Care and Use of Laboratory Animals and other incorporated laws and policies.
Applicable credit	Those receipts that offset or reduce direct or indirect costs. Typical examples of such transactions include purchase discounts, rebates, or allowances; recoveries or indemnities on losses, insurance refunds; and adjustments of overpayments or erroneous charges.
Application	A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions. (See Application Information and Processes for detailed information about the application process, including an explanation of the types of applications).
Application type code	A single-digit code identifying the type of application received and processed. Application type codes include the following: 1=New; 2=Renewal; 3=Revision; 4=Extension; 5=Non-Competing Continuation; 6=Change of Organization Status (Successor-In-Interest); 7=Change of Recipient or Training Institution; 8=Change of Institute or Division (Type 5 transfer to another NIH IC); 9=Change of Institute or Division (Type 2 transfer to another NIH IC).
Appropriation Act	The statute that provides the authority for Federal agencies to incur obligations to and make payments out of the U.S. treasury for specified purposes.

Term	Definition
Assistance listing number	A unique number assigned to identify a Federal Assistance Listing, formerly known as the CFDA number.
Assistance listing program title	The title that corresponds to the Federal Assistance Listings Number. Formerly known as the CFDA program title.
Assurance	A certification by an applicant, normally included with the application or State plan, indicating that the entity is in compliance with, or that it will abide by, a particular requirement if awarded a Federal grant.
Audit finding	Deficiencies which an auditor is required by 2 CFR Part 200.516(a) and to report in the schedule of findings and questioned costs.
Audit resolution	The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings (that is, questioned costs).
Authorized organization representative	The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. This individual is equivalent to the signing official in the eRA Commons, i.e., holds the SO Role.
Award	The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.
Awarding IC	NIH IC responsible for the award, administration, and monitoring of grant supported activities.
Budget	The financial plan for the project or program that the Federal awarding agency or pass-through entity approves during the Federal award process or in subsequent amendments to the Federal award. It may include the Federal and non-Federal share or only the Federal share, as determined by the Federal awarding agency or pass through entity. The approved budget specified in the NoA may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the recipient in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.
Budget period	The time interval from the start date of a funded portion of an award to the end date of that funded portion (usually 12 months) during which recipients are authorized to expend the funds awarded, including any funds carried forward or other revisions. NIH award project periods (periods of performance) are typically divided by budget periods for budgetary and funding purposes. See Project Period . See Period of Performance .

Term	Definition
Capital assets	Tangible or intangible assets used in operations having a useful life of more than one year which are capitalized in accordance with GAAP. Capital assets include: (1) Land, buildings (facilities), equipment, and intellectual property (including software) whether acquired by purchase, construction, manufacture, lease-purchase, exchange, or through capital leases; and (2) Additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations or alterations to capital assets that materially increase their value or useful life (not ordinary repairs and maintenance).
Capital expenditures	Expenditures to acquire capital assets or expenditures to make additions, improvements, modifications, replacements, rearrangements, reinstallations, renovations, or alterations to capital assets that materially increase their value or useful life. (See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Capital Expenditures).
Carryover	Unobligated Federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried forward to another budget period to cover allowable costs of that budget period (whether as an offset or additional authorization). Obligated, but unliquidated, funds are not considered carryover.
Change in scope	An activity whereby the objectives or specific aims identified in the approved grant application are significantly changed by the recipient after award. GMO prior approval is required for a change in scope to be allowable under an award. See Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Change of Scope for additional information.
Change of PD/PI	A process, usually initiated by the recipient, whereby the federally approved PD/PI is replaced by another individual, with the approval of the GMO.
Change of recipient organization	Transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment).
Chief Grants Management Officer	The Grants Management Officer within an awarding agency who is the principal Grants Officer in the Institute or Center. The Chief Grants Management Officer provides leadership to an organizational component that is responsible for the business and fiscal management of an IC's grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each IC has a CGMO.
Claim	Depending on the context, either: (1) A written demand or written assertion by one of the parties to a Federal award seeking as a matter of right: (i) The payment of money in a sum certain; (ii) The adjustment or interpretation of the terms and conditions of the Federal award; or (iii) Other relief arising under or relating to a Federal award. (2) A request for payment that is not in dispute when submitted.

Term	Definition
Clinical research	Research with human subjects that is: 1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies. 2) Epidemiological and behavioral studies. 3) Outcomes research and health services research Studies falling under 45 CFR Part 46.101(b)(4) (the “Common Rule” prior to July 19, 2018 and 45 CFR Part 46.104(d) 4) (the “Revised Common Rule” effective July 19, 2018, Exemption 4) are not considered clinical research by this definition.

Term	Definition
Clinical trial	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. • See 45 CFR Part 46, Subpart A, referred to as the “Revised Common Rule” definition of research at 45 CFR Part 46.102(l). Pre-2018, see 45 CFR Part 46, Subpart A, referred to as the “Common Rule” definition of research at 45 CFR Part 46.102(d) • See Revised Common Rule definition of human subject at 45 CFR Part 46.102(e)(1). See Common Rule definition of human subject at 45 CFR Part 46.102(f) • The term “prospectively assigned” refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial. • An <i>intervention</i> is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and treatment, prevention, and diagnostic strategies. • A <i>health-related biomedical or behavioral outcome</i> is defined as the pre-specified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and well-being or quality of life. Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases: Phase I. Tests a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). Phase II. Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety. Phase III. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely.

Term	Definition
	Phase IV. Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
Closeout	The process by which the Federal awarding agency or pass-through entity determines that all applicable administrative actions and all required work of the Federal award have been completed and takes actions as described in 2 CFR Part 200.344.
Cluster of programs	A grouping of closely related programs that share common compliance requirements. The types of clusters of programs are research and development (R&D), student financial aid (SFA), and other clusters. “Other clusters” are as defined by OMB in the compliance supplement or as designated by a state for Federal awards the state provides to its subrecipients that meet the definition of a cluster of programs. When designating an “other cluster,” a state must identify the Federal awards included in the cluster and advise the subrecipients of compliance requirements applicable to the cluster, consistent with 2 CFR Part 200.332(a). A cluster of programs must be considered as one program for determining major programs, as described in 2 CFR Part 200.518, and, with the exception of R&D as described in 2 CFR Part 200.501(c), whether a program-specific audit may be elected.
Code of Federal Regulations	The codified regulations of the Federal government based on the final agency regulations published in the Federal Register.
Cognizant agency for audit	The Federal agency designated to carry out the responsibilities as described in 2 CFR Part 200.513. The cognizant agency for audit is not necessarily the same as the cognizant agency for indirect costs. A list of cognizant agencies for audit may be found at the FAC web site.
Cognizant agency for indirect costs	The Federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals developed under this part on behalf of all Federal agencies. The cognizant agency for indirect cost is not necessarily the same as the cognizant agency for audit. For assignments of cognizant agencies see the following: (1) For IHEs: 2 CFR Part 200, Appendix III, C.11. (2) For non-profit organizations: 2 CFR Part 200, Appendix IV, C.2. (3) For state and local governments: 2 CFR Pt 200, Appendix V, F.1. (4) For Indian tribes: 2 CFR Pt 200, Appendix VII, D.1.
Co-Investigator	An individual involved with the PD/PI in the scientific development or execution of a project. The Co-Investigator (collaborator) may be employed by, or be affiliated with, the applicant/recipient organization or another organization participating in the project under a consortium agreement. A Co-Investigator typically devotes a specified percentage of time to the project and is considered senior/key personnel . The designation of a Co-Investigator, if applicable, does not affect the PD/PI's roles and responsibilities as specified in the NIHGPS, nor is it a role implying multiple PD/PI.

Term	Definition
Competitive revision	A request for (or the award of) additional funds during a current project period to support new or additional activities which are not identified in the current award that reflect an expansion of the scope of the grant-approved activities. Competitive revisions require peer review.
Competitive segment	The initial project period recommended for support (up to 5 years) or each extension of a project period resulting from a renewal award.
Compliance Supplement	Appendix XI to 2 CFR Part 200. See Section 93 for HHS Agency Program Requirements.
Component	For the purposes of applications and progress reports, a component is a distinct, reviewable part of a multi-project application or progress report for which there is a business need to gather detailed information identified in the Notice of Funding Opportunity (NOFO). Components typically include general information (component organization, project period, project title, etc.), performance sites, personnel, and budget. The NOFO defines the construction and naming convention for the application; the funded application defines the construction and naming convention for the progress report. Components may also be referred to as “cores” or “projects.” Note, for RPPR Question G.9, the term “foreign component” is distinct from “component” as defined here. However, a “foreign component” may also be a “component” in the RPPR. (See definition of foreign component for more information).
Computing devices	Machines used to acquire, store, analyze, process, and publish data and other information electronically, including accessories (or “peripherals”) for printing, transmitting and receiving, or storing electronic information. See also “supplies” and “information technology systems.”
Conference (domestic or international)	A symposium, seminar, workshop, or any other organized and formal meeting, whether conducted face-to-face or via the Internet, where individuals assemble (or meet virtually) to exchange information and views or explore or clarify a defined subject, problem, or area of knowledge, whether or not a published report results from such meeting.
Conference grant	A grant whose purpose is to support activities related to the conduct of a conference(s) or defined set of conference-related activities.
Conflict of interest	Conflict of Interest is a cross-cutting issue that affects many policy areas such as peer review, financial conflict of interest, and responsible conduct of research. There are different uses of this term throughout this document. It generally means that a competing personal interest could affect, or could appear to affect, an individual’s judgment or could cause the individual’s impartiality to be questioned. Conflicts of Interest (actual or potential) may arise in the objective review process or in other activities or phases of the financial assistance process. See also Financial Conflict of Interest for a specific definition covering that policy area.

Term	Definition
Consortium agreement	A formalized agreement whereby a research project is carried out by the recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. These agreements typically involve a specific level of effort from the consortium organization's PD/PI and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. The relationship between the recipient and the collaborating organizations is considered a subaward relationship. (See Consortium Agreements chapter in IIB).
Construction	Construction of a new building structure or facility, including the installation of fixed equipment, which provides space not presently available. It excludes the purchase of land and ancillary improvements, for example, parking lots or roads. The construction of shell space is not allowable as a construction activity since shell space does not provide usable space for research activities). See Construction chapter in IIB.
Consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, recipients and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants also include firms that provide professional advice or services. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Consultant Services).
Contact PD/PI	When multiple PD/PIs are designated, NIH requires that the applicant organization identify one of the PD/PIs as the Contact PD/PI to serve as a primary point of contact. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. See Multiple PI chapter in IIB for additional information.
Contract	A legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. The term as used in 2 CFR Part 200 does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward. See Subaward .
Contractor	An entity that receives a contract. See contract .

Term	Definition
Cooperative agreement	A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302–6305: (1) Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or pass through entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal government or pass-through entity’s direct benefit or use; (2) Is distinguished from a grant in that it provides for substantial involvement between the Federal awarding agency or pass-through entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. (3) The term does not include: (i) development agreement as defined in 15 U.S.C. 3710a; or (ii) An agreement that provides only: (A) Direct United States Government cash assistance to an individual; (B) A subsidy; (C) A loan; (D) A loan guarantee; or (E) Insurance.
Cost allocation plan	Central service cost allocation plan or public assistance cost allocation plan.
Cost objective	A program, function, activity, award, organizational subdivision, contract, or work unit for which cost data are desired and for which provision is made to accumulate and measure the cost of processes, products, jobs, capital projects, etc. A cost objective may be a major function of the non-Federal entity, a particular service or project, a Federal award, or an indirect (Facilities & Administrative (F&A)) cost activity, as described in 2 CFR Part 200, Subpart E—Cost Principles.
Cost overrun	Any amount charged in excess of the Federal share of costs for the project period (competitive segment).
Cost principles	The government-wide principles established under 2 CFR Part 200 for determining the allowable costs incurred by non-Federal entities under Federal awards. The principles are for the purpose of cost determination and are not intended to identify the circumstances or dictate the extent of Federal Government participation in the financing of a particular program or project. The principles are designed to provide that Federal awards bear their fair share of cost recognized under these principles except where restricted or prohibited by statute. In the case of hospitals, they follow the cost principles in 2 CFR Part 200, Appendix IX, “Hospital Cost Principles.” In the case of for-profit organizations, there are no cost principles specifically applicable; the cost principles for for-profit organizations are set forth in the FAR (48 CFR Part 31.2). See Cost Considerations—The Cost Principles for additional details.
Cost sharing	See matching or cost sharing definition.
Cost sharing or matching alternative	An alternative use of program income whereby income accrued during the period of grant support may be used to satisfy a cost sharing or matching requirement. (See also definitions for additive alternative and deductive alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Cost-type contract	A contract or subcontract under a grant in which the contractor or subcontractor is paid on the basis of the allowable costs it incurs, with or without a fee.

Term	Definition
Data and safety monitoring plan	For each NIH-supported clinical trial, NIH requires a data and safety monitoring plan that will provide oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial. A detailed data and safety monitoring plan must be submitted to the applicant's IRB and subsequently to the awarding IC for approval prior to the accrual of human subjects.
Data Management	The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.
Data Management and Sharing Plan (DMS Plan)	A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.
Data Sharing	The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.
Debarment and suspension	The actions taken by a debarring official in accordance with OMB guidance at 2 CFR Part 180, "Non-procurement Debarment and Suspension," as implemented by HHS in 2 CFR Part 376, to exclude a person or organization from participating in grants and other non-procurement awards government-wide. If debarred or suspended, the person or organization may not receive financial assistance (under a grant, cooperative agreement, or subaward, or contract under a grant) for a specified period of time. Debarments and suspensions carried out pursuant to 2 CFR Part 376 are distinct from post-award suspension action by an awarding agency. (See also Public Policy Requirements and Objectives—Debarment and Suspension).
Debt collection	The process of collecting funds owed by recipients to the Federal government, which, under grants, generally are owed as a result of formal cost disallowances.
Debt instrument	A document used to record a legal obligation of one party to pay a financial obligation to another in accordance with predetermined terms and conditions.
Deductive alternative	An alternative for the use of program income earned during the period of grant support under which allowable costs of the project or program to be paid by the Federal government are offset by the amount of the program income. (See also definitions for additive alternative and cost sharing or matching alternative and Administrative Requirements—Management Systems and Procedures—Program Income).
Departmental Grants Appeals Board	The independent office established in the Office of the Secretary with delegated authority from the Secretary to review and decide certain disputes between recipients of HHS funds and HHS awarding agencies under 45 CFR Part 16 and to perform other review, adjudication and mediation services as assigned.

Term	Definition
Deviation	A departure on a single-case or class basis from a regulatory or policy requirement. A single-case deviation represents a request for waiver or exception sought for one grant only that arises on a case-by-case basis. A class deviation involves more than one grant for which the same type of deviation action is being requested.
Direct costs	Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
Disallowed costs	Those charges to a Federal award that the Federal awarding agency or pass-through entity determines to be unallowable, in accordance with the applicable Federal statutes, regulations, or the terms and conditions of the Federal award.
Discretionary Award	An award in which NIH, in keeping with its statutory authority to exercises judgment (“discretion”), selects the recipient and/or the amount of funding through a competitive process. Generally, NIH awards are discretionary. See Non-Discretionary Award .
Domestic organization	A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.
Early Stage Investigator	An individual who is classified as a New Investigator and is within 10 years of completing their terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). See definition of New Investigator .
Entity Identification Number	A three-part coding scheme of 12 characters used in PMS to identify organizations and individuals. The first character identifies the recipient as an organization or an individual. The next nine characters are the Employer Identification Number. The last two characters are a suffix to provide distinction between organizational entities that are assigned a single EIN and those that have more than one. (Also known as Payment System Identifier.)
Equipment	Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or \$5,000. (See also capital assets , computing devices , general purpose equipment , information technology systems , special purpose equipment , and supplies).
eRA Commons	The Electronic Research Administration (eRA) Commons is a virtual meeting place where NIH extramural recipient organizations, recipients, and the public can receive and transmit information about the administration of biomedical and behavioral research. The eRA Commons is divided into both unrestricted and restricted portions that provide for public and confidential information, respectively.

Term	Definition
Expanded authorities	A standard term of all NIH awards to allow recipients several flexibilities to waive the requirement for prior approval for specified actions. NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances for certain awards. (see Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award).
Expenditure report	Means: (1) For non-construction grants, the SF-425 Federal Financial Report (FFR) (or other OMB-approved equivalent report); (2) for construction grants, the SF-271 “Outlay Report and Request for Reimbursement” (or other OMB-approved equivalent report)
Expenditures	Charges made by a non-Federal entity to a project or program for which a Federal award was received. 1. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. 2. For reports prepared on a cash basis, expenditures are the sum of: i. Cash disbursements for direct charges for property and services; ii. The amount of indirect expense charged; iii. The value of third-party in-kind contributions applied; and iv. The amount of cash advance payments and payments made to subrecipients. 3. For reports prepared on an accrual basis, expenditures are the sum of: i. Cash disbursements for direct charges for property and services; ii. The amount of indirect expense incurred; iii. The value of third-party in-kind contributions applied; and iv. The net increase or decrease in the amounts owed by the non-Federal entity for: A. Goods and other property received; B. Services performed by employees, contractors, sub-recipients, and other payees; and C. Programs for which no current services or performance are required such as annuities, insurance claims, or other benefit payments.
Facilities and Administrative (F&A) costs (or indirect costs)	Necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective, and not readily assignable to the cost objectives specifically benefitted, without effort disproportionate to the results achieved. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of F&A (indirect) costs. F&A (indirect) cost pools must be distributed to benefitted cost objectives on bases that will produce an equitable result in consideration of relative benefits derived.
Federal agency	An “agency” as defined at 5 U.S.C. 551(1) and further clarified by 5 U.S.C. 552 (f).

Term	Definition
Federal Audit Clearinghouse (FAC)	The clearinghouse designated by OMB as the repository of record where non-Federal entities are required to transmit the reporting packages required by Subpart F—Audit Requirements of 2 CFR Part 200 Subpart F – Audit Requirements. The mailing address of the FAC is Federal Audit Clearinghouse, Bureau of the Census, 1201 E. 10th Street, Jeffersonville, IN 47132. Any future updates to the location of the FAC may be found at the Federal Audit Clearinghouse web site .
Federal award	Depending on the context, in either paragraph (1) or (2) of this section: (1)(i) The Federal financial assistance that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 2 CFR Part 200.101; or (ii) The cost-reimbursement contract under the Federal Acquisition Regulations that a non-Federal entity receives directly from a Federal awarding agency or indirectly from a pass-through entity, as described in 2 CFR Part 200.101. (2) The instrument setting forth the terms and conditions. The instrument is the grant agreement, cooperative agreement, other agreement for assistance covered in paragraph (2) of Federal financial assistance , or the cost-reimbursement contract awarded under the Federal Acquisition Regulations. (3) Federal award does not include other contracts that a Federal agency uses to buy goods or services from a contractor or a contract to operate Federal government owned, contractor operated facilities (GOCOs). (4) See also definitions of Federal financial assistance , grant agreement , and cooperative agreement .
Federal award date	The date when the Federal award is signed by the authorized official of the Federal awarding agency.
Federal Award Identification Number	A unique number assigned to a financial assistance award to assist recipients in correctly reporting subawards. The public can use the FAIN and the Assistance listing number together to find one accurate result when searching online in such databases as USASpending.gov and FSRS. The FAIN can be found on the notice of award. NIH implements the FAIN by deriving it from the core elements of the grant number. For example, the FAIN for 1R01HL654321-01 would be R01HL654321.
Federal awarding agency	The Federal agency that provides a Federal award directly to another entity. See also Awarding IC .
Federal Demonstration Partnership	A cooperative initiative among some Federal agencies, including NIH, selected organizations receiving Federal funding for research, and certain professional associations. Its efforts include demonstration projects intended to simplify and standardize Federal requirements in order to increase research productivity and reduce administrative costs.

Term	Definition
Federal financial assistance	1. Federal financial assistance means assistance that non-Federal entities receive or administer in the form of: i. Grants; ii. Cooperative agreements; iii. Non-cash contributions or donations of property (including donated surplus property); iv. Direct appropriations; v. Food commodities; and vi. Other financial assistance (except assistance listed in paragraph (b) of this section). 2. For 2 CFR Part 200.202 and 2 CFR Part 200 Subpart F, federal financial assistance also includes assistance that non-Federal entities receive or administer in the form of: i. Loans; ii. Loan Guarantees; iii. Interest subsidies; and iv. Insurance. 3. Federal financial assistance does not include amounts received as reimbursement for services rendered to individuals as described in 2 CFR Part 200.502(h) and (i).
Federal institution	A Cabinet-level department or independent agency of the executive branch of the Federal government or any component organization of such a department or agency. For the purposes of this document, this term is used in the context of a Federal institution as a recipient. See also Awarding IC .
Federal interest	For purposes 2 CFR Part 200.330 or when used in connection with the acquisition or improvement of real property, equipment, or supplies under a Federal award, the dollar amount that is the product of the: (1) Federal share of total project costs; and (2) Current fair market value of the property, improvements, or both, to the extent the costs of acquiring or improving the property were included as project costs.
Federal program	1. All Federal awards which are assigned a single number in the Assistance listings. 2. When no Assistance listing number is assigned, all Federal awards to non- Federal entities from the same agency made for the same purpose should be combined and considered one program. 3. Notwithstanding paragraphs (1) and (2) of this definition, a cluster of programs. The types of clusters of programs are: i. Research and development (R&D); ii. Student financial aid (SFA); and iii. “Other clusters,” as described in the definition of Cluster of Programs.

Term	Definition
Federal share	The portion of the total project costs that are paid by Federal funds.
Federalwide Assurance	The Federalwide Assurance is the only type of assurance of compliance accepted and approved by OHRP for institutions engaged in nonexempt research involving human subjects conducted or supported by HHS. Under a FWA, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR Part 46 , as well as the terms of assurance .
Fee	An amount, in addition to actual, allowable costs, paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as profit. (See Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs—Allowable Costs and Fee—Profit or Fee).
Financial conflict of interest	A financial conflict of interest exists when the recipient's designated official(s) reasonably determines that an investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. See 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought and Public Policy Requirements and Objectives—Financial Conflict of Interest .
Foreign component	The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are: • collaborations with investigators at a foreign site anticipated to result in co-authorship; • use of facilities or instrumentation at a foreign site; or • receipt of financial support or resources from a foreign entity. Foreign travel for consultation is not considered a foreign component. (See Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components chapter in IIB).

Term	Definition
Foreign organization	An entity that is: 1. A public or private organization located in a country other than the United States and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance; 2. A private nongovernmental organization located in a country other than the United States that solicits and receives cash contributions from the general public; 3. A charitable organization located in a country other than the United States that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entities organized primarily for religious purposes; or 4. An organization located in a country other than the United States not recognized as a <i>Foreign Public Entity</i>.
Foreign public entity	(1) A foreign government or foreign governmental entity; (2) A public international organization, which is an organization entitled to enjoy privileges, exemptions, and immunities as an international organization under the International Organizations Immunities Act (22 U.S.C. 288–288f); (3) An entity owned (in whole or in part) or controlled by a foreign government; or (4) Any other entity consisting wholly or partially of one or more foreign governments or foreign governmental entities.
For-profit organization	An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners. A for-profit organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons. (Also see definition for small business concern).
Full-time appointment	The number of days per week and/or months per year representing full-time effort at the applicant/recipient organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.
General purpose equipment	Equipment which is not limited to research, medical, scientific or other technical activities. Examples include office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles. See also " Equipment " and "Special Purpose Equipment."
Generally Acceptable Accounting Principles (GAAP)	The meaning specified in accounting standards issued by the Government Accounting Standards Board (GASB) and the Financial Accounting Standards Board (FASB).

Term	Definition
Generally Accepted Government Auditing Standards (GAGAS)	Also known as the Yellow Book, generally accepted government auditing standards issued by the Comptroller General of the United States, which are applicable to financial audits.
Grant number	A grant number is a unique identifier for a grant composed of the application type code, activity code, Institute code, 6-digit serial number, support year and /or suffix code for the support year of the grant, or other information, such as a supplement (S1), resubmission (A1), or a fellowship's institutional allowance. In Federalwide systems (e.g., USASpending.gov, FFATA/FSRS) the Federal Award Identifier Number (FAIN) is used to identify grants for Federalwide implications. Similar to the NIH Grant Number, the FAIN consists of the activity code, Institute code, and 6-digit serial number. Sample Grant Number: 1 R01 AI 123456-01 A1 S1 Sample FAIN: R01 AI 654321
Grant or grant agreement	A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302, 6304: 1. Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or passthrough entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal awarding agency or passthrough entity's direct benefit or use; 2. Is distinguished from a cooperative agreement in that it does not provide for substantial involvement between the Federal awarding agency or passthrough entity and the non-Federal entity in carrying out the activity contemplated by the Federal award. 3. Does not include an agreement that provides only: i. Direct United States Government cash assistance to an individual; ii. A subsidy; iii. A loan; iv. A loan guarantee; or v. Insurance. See also Cooperative Agreement.

Term	Definition
Grants Management Officer	An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. GMOs are delegated the authority from the CGMO to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH IC that awards grants has one or more GMOs with responsibility for particular programs or awards. See also Chief Grants Management Officer definition.
Grants Management Specialist	An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to recipients; and administering grants after award.
Grants.gov	Grants.gov has been designated by the Office of Management and Budget as the single access point for all grant programs offered by 26 Federal grant-making agencies. It provides a single interface for agencies to announce their grant opportunities and for all applicants to find and apply for those opportunities.
Grant-supported project or activity	Those activities specified or described in a grant application or in a subsequent submission that are approved by an NIH IC for funding, regardless of whether Federal funding constitutes all or only a portion of the financial support necessary to carry them out.
Honoraria	Payments given in support of professional services for the purpose of conferring distinction or to symbolize respect, esteem, or admiration. In other words, if the service is related to research oversight, research supervision, co-authoring research papers, then the payments are not honoraria but considered research funding.
Hospital	A facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state. Also includes a non-profit or for-profit hospital or a medical care provider component of a non-profit organization (for example, a foundation).
Human Fetal Tissue	Human Fetal Tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as NIH guidance. See also Human Fetal Tissue from Elective Abortion .

Term	Definition
Human subject	Revised Common Rule (45 CFR Part 46, effective July 19, 2018): A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Pre-2018 Common Rule (45 CFR Part 46, effective July 19, 2018): A living individual about whom an investigator (whether professional or student) conducting research: (i) Data through intervention or interaction with the individual; or (ii) Identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals. (See Public Policy Requirements and Objectives—Human Subjects Protections).
Impact score	The impact score is the rating which is assigned to an individual application by an SRG and designates the reviewers' assessment of scientific and technical merit of the application. For research projects, this is defined as the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of established review criteria. The impact score is one mechanism by which the SRG makes a recommendation to the funding component concerning the application's scientific and technical merit. Impact scores may be numeric (10 – 90) or alphabetical (ND, for example).
Improper payment	(1) Any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and (2) Includes any payment to an ineligible party, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except for such payments where authorized by law), any payment that does not account for credit for applicable discounts, and any payment where insufficient or lack of documentation prevents a reviewer from discerning whether a payment was proper.

Term	Definition
Indian tribe (or “federally recognized Indian tribe”)	Any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)). See annually published Bureau of Indian Affairs list of Indian Entities Recognized and Eligible to Receive Services.
Indirect costs	See facilities and administrative costs definition.
Information technology systems	Computing devices, ancillary equipment, software, firmware, and similar procedures, services (including support services), and related resources. See also computing devices and equipment .
Innovation	Something new or improved, including research for (1) development of new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For the purposes of PHS programs, an example of innovation would be new medical or biological products for improved value, efficiency, or costs.
Institute or Center	The NIH organizational component responsible for a particular grant program or set of activities. The terms “NIH IC,” or “awarding IC” are used throughout this document to designate a point of contact for advice and interpretation of grant requirements and to establish the focal point for requesting necessary prior approvals or changes in the terms and conditions of award.
Institutional Animal Care and Use Committee	The <i>PHS Policy on Humane Care and Use of Laboratory Animals</i> incorporates the <i>U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training</i> , and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the institution's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). IACUC review and approval is required for all PHS supported activities involving live vertebrate animals prior to funding.
Institutional base salary	The annual compensation paid by an organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties for the applicant/recipient organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds. (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Salaries and Wages).
Institutional Review Board (IRB)	An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction.

Term	Definition
Institutions of Higher Education (IHEs)	IHE is defined at 20 U.S.C. 1001.
Intangible property	Property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership (whether the property is tangible or intangible).
Intergovernmental Personnel Act (IPA)	The Intergovernmental Personnel Act Mobility Program provides for the temporary assignment of personnel between the Federal Government and state and local governments, colleges and universities, Indian tribe (or "federally recognized Indian tribe" governments, federally funded research and development centers, and other eligible organizations. The goal of the Intergovernmental Personnel Act mobility program is to facilitate the movement of employees, for short periods of time, when this movement serves a sound public purpose.
Internal control over compliance requirements for Federal awards	A process implemented by a non-Federal entity designed to provide reasonable assurance regarding the achievement of the following objectives for Federal award: 1. Transactions are properly recorded and accounted for, in order to: i. Permit the preparation of reliable financial statements and Federal reports; ii. Maintain accountability over assets; and iii. Demonstrate compliance with Federal statutes, regulations, and the terms and conditions of the Federal award; 2. Transactions are executed in compliance with: i. Federal statutes, regulations, and the terms and conditions of the Federal award that could have a direct and material effect on a Federal program; and ii. Any other Federal statutes and regulations that are identified in the Compliance Supplement; and 3. Funds, property, and other assets are safeguarded against loss from unauthorized use or disposition.
Internal controls	A process, implemented by a non-Federal entity, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: (1) Effectiveness and efficiency of operations; (2) Reliability of reporting for internal and external use; and (3) Compliance with applicable laws and regulations.
International organization	An organization that identifies itself as international or intergovernmental and has membership from, and represents the interests of, more than one country, without regard to whether the headquarters of the organization and location of the activity are inside or outside of the United States.

Term	Definition
Invention reporting	The requirement pursuant to 37 CFR Part 401 that recipients of contracts, grants or cooperative agreements fully disclose any subject inventions made during the performance of work under a funding agreement in order to protect the Federal government's rights.
Investigational new drug	A new drug or biological drug that is used in a clinical investigation.
Investigator-initiated research	Research funded as a result of an investigator, on their own, submitting a research application in response to Parent Announcements only. Also known as unsolicited research.
IPF number	Institutional Profile File (IPF) number is a unique number used by NIH for tracking/reporting awards to recipient institutions.
Just-in-Time	NIH policy allows the submission of certain elements of a competing application to be deferred until later in the application process, after review when the application is under consideration for funding. Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by NIH. Through this module, institutions can electronically submit the information that is requested after the review, but before award. See Completing the Pre-Award Process—Just-In-Time Procedures for additional information.
Liquidated damages	An amount defined in a contract and chargeable against funds due to the contractor for each day the contractor fails to complete the project beyond the contract completion date.
Local government	Any unit of government within a state, including a: (1) County; (2) Borough; (3) Municipality; (4) City; (5) Town; (6) Township; (7) Parish; (8) Local public authority, including any public housing agency under the United States Housing Act of 1937; (9) Special district; (10) School district; (11) Intrastate district; (12) Council of governments, whether or not incorporated as a nonprofit corporation under state law; and (13) Any other agency or instrumentality of a multi-, regional, or intra-state or local government.
Major A&R	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants. See "Modernization" on page I-32.
Matching or cost sharing	The portion of project costs not paid by Federal funds (unless otherwise authorized by Federal statute). This may include the value of allowable third-party in-kind contributions, as well as expenditures by the recipient.
Mechanism	Extramural awards are divided into three types of financial assistance: <i>grants</i> , <i>cooperative agreements</i> and <i>contracts</i> . A mechanism is the type of funded application or transaction used by NIH. Within each mechanism NIH includes programs . Programs can be further refined by specific activity codes .

Term	Definition
Merger	A legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for the recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change will apply.
Metadata	Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).
Micro-purchase	A purchase of supplies or services using simplified acquisition procedures, the aggregate amount of which does not exceed the micro-purchase threshold. Micro-purchases comprise a subset of a non-Federal entity's small purchases. Micro-purchase threshold means the dollar amount at or below which a non-Federal entity may purchase property or services using micro-purchase procedures (see § 2 CFR Part 200.320). Generally, the micro-purchase threshold for procurement activities administered under Federal awards is not to exceed the amount set by the FAR at 48 CFR Part 2, Subpart 2.1, unless a higher threshold is requested by the non-Federal entity and approved by the cognizant agency for indirect costs (For NIH DCA for non-profits or DFAS for for-profit organizations).
Minor A&R	Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. See "Modernization" on the next page. Minor A&R is not an allowable activity or cost under grants to individuals or grants for limited purposes, such as grants in support of scientific meetings (conference grants). Routine maintenance and repair of the organization's physical plant or its equipment is not considered A&R; these types of costs are typically treated as F&A costs.

Term	Definition
Modernization	Modernization. Alteration, renovation, remodeling, improvement, expansion or repair of, or completion of shell space in an existing building (whether for storage or for human occupancy), necessary to make the building suitable for use for the purposes of a particular program. Modernization is distinct from construction in that it leaves the existing structure in place. This can range from updating flooring to replacing everything except for the existing mainframe and foundations. When the primary purpose of the award is to modernize biomedical research facilities, the grant cannot support the conduct of any research. Alteration and renovation (A&R) activities are considered as modernization activities and are typically supported under research grants where the primary purpose for the grant is other than construction or modernization. The determination of whether proposed A&R is major, or minor is made by the NIH Program Official. Major A&R is an unallowable activity or cost under foreign grants and foreign components in domestic grants. Examples of activities of Major A&R are as follows: • A structural change (e.g., to the foundation, roof, floor or exterior load-bearing walls of a facility, or extension of an existing facility) to increase the floor area and/or change the function and purpose of a facility Examples of activities of Minor A&R are as follows: • Changes to physical characteristics (interior dimensions, surfaces, and finishes); internal environments (temperature, humidity, ventilation, and acoustics); or utility services (plumbing, electricity, gas, vacuum, and other laboratory fittings); • Installation of fixed equipment (including casework, fume hoods, large autoclaves, biological safety cabinets); • Replacement, removal, or reconfiguration of interior non-load bearing walls, doors, frames, or windows in order to place equipment in a permanent location; • Making unfinished shell space suitable for purposes other than human occupancy, such as storage of pharmaceuticals; or • Alterations to meet requirements for accessibility by physically disabled individuals.
Modified Total Direct Cost (MTDC)	All direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and subawards up to the first \$25,000 of each subaward (regardless of the period of performance of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of \$25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.

Term	Definition
Modular application	A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review of the application, award, and post-award administration.
Monitoring	A process whereby the programmatic and business management performance aspects of a grant are assessed by reviewing information gathered from various required reports, audits, site visits, and other sources.
Name change	An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.
New Investigator	A PD/PI who has not previously competed successfully as a PD/PI for a substantial NIH independent research award is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains their status as a New Investigator. A complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at http://grants.nih.gov/grants/new_investigators/#definition . See also the definition of Early Stage Investigator .
No-cost extension	An extension of time to a project period and/or budget period to complete the work of the grant under that period, without additional Federal funds or competition. See NIH Standard Terms of Award and Prior Approval Requirements .
Non-competing continuation application/award	A financial assistance request (in the form of an application or progress report) or resulting award for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applicants.
Non-Discretionary Award	An award made by NIH to specific recipients in accordance with statutory, eligibility and compliance requirements, in which NIH has no ability to exercise judgement. The award amount could be determined specifically or by formula. NIH does not typically make non-discretionary awards. See "Discretionary Award" on page I-19.
Non-Federal entity	A state, local government, Indian tribe, institution of higher education (IHE), or nonprofit organization that carries out a Federal award as a recipient or sub-recipient.
Non-Federal share	When cost sharing or matching is required as a condition of an award, the portion of allowable project/program costs not borne by the Federal government.
Non-profit organization	Any corporation, trust, association, cooperative, or other organization, not including IHEs, that: (1) Is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; (2) Is not organized primarily for profit; and (3) Uses net proceeds to maintain, improve, or expand the operations of the organization.

Term	Definition
Notice of Award	The official, legally binding document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: 1. notifies the recipient of the award of a grant; 2. contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and, 3. provides the documentary basis for recording the obligation of Federal funds in the NIH accounting system.
Notice of Funding Opportunity (NOFO)	A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. NIH Notices of Funding Opportunities may also be known as program announcements, requests for applications, notices of funding availability, solicitations, or other names as described in 2 CFR 200.204,) depending on the Agency and type of program. Notices of Funding Opportunities can be found at grants.gov and in the NIH Guide for Grants and Contracts.
Obligations	When used in connection with a non- Federal entity's utilization of funds under a Federal award, obligations means orders placed for property and services, contracts and subawards made, and similar transactions during a given period that require payment by the non- Federal entity during the same or a future period.
Office of Management and Budget (OMB)	The Executive Office of the President, Office of Management and Budget.
Offset	IC or awarding agency approval/authorization of the use of unobligated grant funds remaining from a prior budget period to support grant activities of the current budget period. An offset does not change the current budget period authorized amount of funding but does reduce the amount of current fiscal year funds provided to support the authorized award amount.
Open Researcher and Contributor Identifiers (ORCID iDs)	Unique, persistent digital identifiers that distinguish individual investigators and can be used to connect researchers with their contributions to science over time and across changes of name, location, and institutional affiliation. These free identifiers are assigned and maintained by the non-profit organization ORCID.
Organization	A generic term used to refer to an Institution of Higher Education or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.
Other Significant Contributors	Individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition.

Term	Definition
Other support	Includes all resources made available to researcher or senior key personnel in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. Other support does not include training awards, prizes, start-up support from the US based institution, or gifts. (note: Gifts are resources provided where there is no expectation of anything (e.g., time, services, specific research activities, money, etc.) in return).
Oversight agency for audit	The Federal awarding agency that provides the predominant amount of funding directly (direct funding) (as listed on the schedule of expenditures of Federal awards, see 2 CFR Part 200.510(b)) to a non-Federal entity unless OMB designates a specific cognizant agency for audit.. When the direct funding represents less than 25 per-cent of the total Federal expenditures (as direct and subawards) by the non-Federal entity, then the Federal agency with the predominant amount of total funding (direct and subawards) is the designated cognizant agency. When there is no direct funding, the Federal awarding agency which is the predominant source of pass-through funding must assume the oversight responsibilities. The duties of the oversight agency for audit and the process for any reassignments are described in 2 CFR Part 200.513(b).
Parent announcement	Broad NOFO enabling applicants to electronically submit an investigator-initiated grant application for a specific activity code, e.g., Research Project Grant (Parent R01) .
Participant support costs	Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects. For the purposes of Kirschstein-NRSA programs and Education Grants (e.g., R25), this term does not apply. NIH will continue to use the terms trainees, trainee-related expenses, and trainee travel for those programs.
Pass-through entity	A non- Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program (see 2 CFR 200.1).
Payback	Requirement that the recipient of a NRSA postdoctoral fellowship engage in qualified health-related research, health-related research training, or health-related teaching activities for a length of time equal to the period of NRSA support received. Only the first year of training incurs a payback obligation. In general, payback activity must involve at least 20 hours per week and be conducted over 12 consecutive months; special exceptions may be considered on a case-by-case basis. See Ruth L. Kirschstein National Research Service Awards—Pay-back for additional information.
Payment Management System	The HHS centralized grants payment system operated by the Payment Management Service, Program Support Center. Most HHS (and some other Federal government agencies') recipients receive grant payments through this system.

Term	Definition
Peer review	The two-stage process that involves the consistent application of standards and procedures that produce fair, equitable, timely, and objective examinations of applications based on an evaluation of scientific or technical merit or other relevant aspects of the application. The review is performed by experts (Peer Reviewers) in the field of endeavor for which support is requested. Peer review is intended to provide guidance and recommendations to the NIH individuals responsible for making award decisions.
Period of performance	The total estimated time interval between the start of an initial Federal award and the planned end date, which may include one or more funded portions, or budget periods. Identification of the period of performance (project period) in the Federal award does not commit the awarding agency to fund the award beyond the currently approved budget period. The period of performance for NIH awards is noted on the Notice of Award. See "Project period" on page I-38 as well as "Budget period" on page I-10.
Person months	The metric for expressing the effort (amount of time) PD/PI(s), faculty and other senior/key personnel devote to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year, academic year, and/or summer term; and the organization's definition of such. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment.
Personal property	Property of any kind except real property. It may be tangible, having physical existence, or intangible, such as copyrights, patents, or securities.
Personally Identifiable Information (PII)	Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public web sites, and university listings. This type of information is considered to be Public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual.
Phase III clinical trial	As defined by NIH, a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included. (See clinical trial definition).

Term	Definition
Pre-award costs	Any cost incurred prior to the beginning date of the project period or the initial budget period of a competitive segment (under a multi-year award), in anticipation of the award and at the applicant's own risk, for otherwise allowable costs.
Prior approval	Written approval by an authorized HHS official, e.g., a designated IC GMO, evidencing prior consent before a recipient undertakes certain activities or incurs specific costs (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).
Profit	See definition for fee .
Program	A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs that carry out their missions through the award of grants or cooperative agreements to other organizations.
Program Director/Principal Investigator	The individual(s) designated by the applicant organization/recipient to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the official(s) at the applicant organization/recipient, or as appropriate, to a collaborating organization for the proper conduct of the project, program, or activity including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI.
Program income	Gross income earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance except as provided in 2 CFR Part 200.307(f). (See Period of performance .) Program income includes but is not limited to income from fees for services performed, the use or rental of real or personal property acquired under Federal awards, the sale of commodities or items fabricated under a Federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See 2 CFR Part 200.307, 45 CFR Part 200.307, 2 CFR Part 200.407 and 35 USC §§ 200-212 for inventions made under Federal awards. (See Administrative Requirements—Management Systems and Procedures—Program Income).
Program Official/Program Officer/Project Officer	The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant or cooperative agreement.

Term	Definition
Progress report	Periodic, usually annual, report submitted by the recipient and used by NIH to assess progress and, except for the final progress report of a project period, to determine whether to provide funding for the budget period subsequent to that covered by the report. This report may also be called the non-competing continuation progress report.
Project period	The total time for which Federal support of a project has been programmatically approved as shown in the NoA; however, it does not constitute a commitment by the Federal government to fund the entire period. The total project period comprises the initial competitive segment, any subsequent competitive segments resulting from a renewal award(s), and extensions. See "Period of performance" on page I-36. Also see "Budget period" on page I-10.
Project/performance site	Location(s) of where the work described in the research plan will be conducted.
Property	Real property or personal property.
Protected Personally Identifiable Information (Protected PII)	An individual's first name or first initial and last name in combination with any one or more of types of information, including, but not limited to, social security number, passport number, credit card numbers, clearances, bank numbers, biometrics, date and place of birth, mother's maiden name, criminal, medical and financial records, educational transcripts. This does not include PII that is required by law to be disclosed. (See Personally Identifiable Information (PII)).
Questioned cost	A cost that is questioned by the auditor because of an audit finding: 1. Which resulted from a violation or possible violation of a statute, regulation, or the terms and conditions of a Federal award, including for funds used to match Federal funds; 2. Where the costs, at the time of the audit, are not supported by adequate documentation; or 3. Where the costs incurred appear unreasonable and do not reflect the actions a prudent person would take in the circumstances.
Real property	Land, including land improvements, structures and appurtenances thereto, but excludes moveable machinery and equipment.
Recipient	An entity, usually but not limited to non-Federal entities, that receives a Federal award directly from a Federal awarding agency. The term recipient does not include subrecipients nor consortiums of the award. See Non-Federal entity .
Renewal application	An application requesting additional funding for a period subsequent to that provided by a current award. Renewal applications compete for funds with all other peer reviewed applications, and must be developed as fully as though the applicant is applying for the first time. The previous NIH term was "competing continuation."

Term	Definition
Renewal award	An award made subsequent to an expiring Federal award for which the start date is contiguous with, or closely follows, the end of the expiring Federal award. A renewal award's start date will begin a distinct period of performance.
Research & Development (R&D)	All research activities, both basic and applied, and all development activities that are performed by HHS award recipients. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. "Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.
Research Administrator	The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. See also Roles and Responsibilities—Recipient Staff.
Research misconduct	Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. 1. Fabrication is making up data or results and recording or reporting them. 2. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. 3. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. 4. Research misconduct does not include honest error or honest differences of opinion.
Research patient care costs	Costs of routine and ancillary services provided by hospitals to participants in research protocols.
Responsible party	Responsible party is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to refer to the entity or individual who is responsible under FDAAA for registering a clinical trial and submitting clinical trial information to ClinicalTrials.gov .
Resubmission application	An application that has been previously submitted, but was not funded, and is being resubmitted for new consideration. Applicants must make significant changes to the application and can only resubmit once the summary statement is available from review of the first submission. Applicants must apply and undergo peer review. Additional policies on resubmissions can be found in the applicable Application Instruction Guide. The previous NIH term was "revision." A resubmission has a suffix in its application identification number, e.g., A1.

Term	Definition
Revision application	As defined in the Federalwide SF424 (R&R): An application that proposes a change in 1) the Federal Government's financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of the existing award. Note in general for NIH applicants, #2 would not require the submission of another application. NIH recipients use revision applications to request an increase in support in a current budget period for expansion of the project's approved scope or research protocol. Applicants must apply and undergo peer review. The previous NIH term was "competing supplemental." NOTE: The former NIH term "revision," is now "resubmission". A revision has a suffix in its application identification number; e.g., S1.
Scientific Data	The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.
Scientific Review Group (SRG)	A peer review committee group of primarily non-government experts (peer reviewers), qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review, to evaluate and give expert advice on the scientific and technical merit of the applications. No more than one-fourth of the members of any SRG may be Federal employees, as noted in 42 CFR Part 52(h).
Scientific Review Officer (SRO)	The NIH official who serves as the designated Federal officer having legal responsibility for managing the peer review meeting, the procedures for evaluating the applications assigned to the SRG and the determinations and management of conflicts of interest, as noted in 42 CFR Part 52(h).
Scope of work	The aims, objectives, and purposes of a grant; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the grant's objectives. This includes the research or training plan included with the original grant application, along with any approved modifications.
Senior/Key Personnel	The PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel.

Term	Definition
Significant rebudgeting	A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by more than 25 percent of the total costs awarded. Significant rebudgeting is one indicator of change in scope.
Simplified acquisition threshold	The dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures in order to expedite the purchase of items costing less than the simplified acquisition threshold. The simplified acquisition threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1. (See also Micro-purchase .)
Small business concern	A business that is independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the SBA at 13 CFR Part 121.
Special purpose equipment	Equipment which is used only for research, medical, scientific, or other technical activities. Examples of special purpose equipment include microscopes, x-ray machines, surgical instruments, and spectrometers. See also Equipment and General purpose equipment .
State	Any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any agency or instrumentality thereof exclusive of local governments.
State government	The government of any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any U.S. territory or possession, or any agency or instrumentality of a State exclusive of local governments. For purposes of NIH grants, federally recognized Indian tribal governments generally are considered State governments. State institutions of higher education and State hospitals are not considered State governments for HHS's general administrative requirements for grants and the NIHGPS.
Stipend	A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual's living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract. The term includes consortium agreements.

Term	Definition
Subrecipient	A non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency. The term includes consortium participants.
Subsidiary	An entity in which more than 50 percent of the entity is owned or controlled directly by a parent corporation or through another subsidiary of a parent corporation.
Successor-in-interest	Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
Supplies	All tangible personal property other than those described in Equipment. A computing device is a supply if the acquisition cost is less than the lesser of the capitalization level established by the non-Federal entity for financial statement purposes or \$5,000, regardless of the length of its useful life. See Computing devices and Equipment .
Suspension of award activities	An action by the NIH awarding IC requiring the recipient to cease all activities on the award pending corrective action by the recipient. It is a separate action from suspension under HHS regulations (2 CFR Part 376) implementing Executive Orders 12549 and 12689. (See Public Policy Requirements and Objectives—Debarment and Suspension and Administrative Requirements—Enforcement Actions).
Termination	The ending of a Federal award, in whole or in part at any time prior to the planned end of period of performance.
Terms and conditions of award	All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The NoA may include both standard and specific award conditions that are considered necessary to attain the grant's objectives, facilitate post-award administration of the grant, conserve grant funds, or otherwise protect the Federal government's interests.
Third-party in-kind contributions	The value of non-cash contributions (i.e., property or services) that: (1) Benefit a federally assisted project or program; and (2) Are contributed by non-Federal third parties, without charge, to a non-Federal entity under a Federal award.
Total costs	The total allowable costs (both direct costs and F&A costs) incurred by the recipient to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the recipient to satisfy a matching or cost-sharing requirement.
Uniform Administrative Requirements ("Uniform Guidance")	The administrative requirements, cost principles and audit requirements for Federal awards to non-Federal entities as set forth in Part 200 of CFR Title 2 (Grants and Agreements), also referred to as "Uniform Guidance".

Term	Definition
Unique Entity Identifier (UEI)	The identifier assigned by the System for Award Management (SAM) to uniquely identify business entities.
United States	The 50 States, territories, and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.
Unliquidated obligations	For financial reports prepared on a cash basis, obligations incurred by the non-Federal entity that have not been paid (liquidated). For reports prepared on an accrual expenditure basis, these are obligations incurred by the non-Federal entity for which an expenditure has not been recorded.
Unobligated balance	The amount of funds authorized under a Federal award that the non-Federal entity has not obligated. The amount is computed by subtracting the cumulative amount of the non-Federal entity's unliquidated obligations and expenditures of funds under the Federal award from the cumulative amount of the funds that the Federal awarding agency or pass-through entity authorized the non-Federal entity to obligate.
Withholding of support	A decision by NIH not to make a non-competing continuation award within the current competitive segment.

2 THE NATIONAL INSTITUTES OF HEALTH AS A GRANT-MAKING ORGANIZATION

NIH is the steward of medical and behavioral research for the Nation. Its [mission](#) is 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. NIH operates under the general policy guidance of the Department in carrying out its mission, which is accomplished through the conduct and support of biomedical and behavioral research, research training, research infrastructure, and communications. These efforts take place intramurally (primarily at NIH) and extramurally (through grants, cooperative agreements, and contracts awarded to institutions of higher education, governmental organizations, non-profit research organizations, for-profit organizations, and individuals). NIH also works closely with other HHS components and other Federal departments and agencies. HHS components include SAMHSA, FDA, CDC, IHS, AHRQ, HRSA, ACF, ACL, OASH, and CMS, among others.

The rules that govern grants and cooperative agreements detailed at 2 CFR Part 200, and in certain cases further codified through HHS regulation, provide the framework for the terms and conditions of NIH awards, as specified in "Part II: Terms and Conditions of NIH Grant Awards" on page IIA-1.

NIH is organized into ICs, which have their own mission and functions, separate appropriations, and statutory authorities. The ICs that award grants and their points of contact are listed in [Part III](#). Although the ICs operate under the same general grant process and requirements, applicants and recipients need to be aware of differences that may exist. This information may be obtained from NIH IC staff. The policies generally applicable to NIH grants are set forth in the NIHGPS.

2.1 ROLES AND RESPONSIBILITIES

NIH, as a Federal grantor agency, is responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively and in compliance with applicable rules and regulations. NIH seeks to ensure integrity and accountability in its grant award and administration processes by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for recipient organizations.

The following subsections highlight the major functions and areas of responsibility of Federal and recipient staffs. NIH recognizes that additional staff members in a number of different organizations may be involved in grant-related activities; however, this section details only the major participants representing the Federal government and the recipient. The responsibilities of CSR and IC staff members, who are involved only in the initial review phase of the peer review process, are described in [The Peer Review Process—Initial Review—Responsibilities](#). The responsibilities of other offices, such as OHRP, are described in Part II as applicable.

2.1.1 NIH and HHS Staff

The roles and responsibilities of NIH and HHS participants are as follows:

- **Grants Management Officer.** The GMO whose name appears in the NoA is the NIH official responsible for the business management and other non-programmatic aspects of the award. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to applicants and recipients, including interpretation of grants administration policies and provisions; and administering and closing out grants. The GMO works closely with their counterparts in other NIH ICs and with the designated PO. The GMO is the focal point for receiving and acting on requests for NIH prior approval or for changes in the terms and conditions of award, and is the only NIH official authorized to obligate NIH to the expenditure of Federal funds or to change the funding, duration, or other terms and conditions of award. A Chief Grants Management Officer is the principal GMO who provides leadership to an organizational component that is responsible for the business and fiscal management of the ICs grant portfolio. Generally, the CGMO will have the authority to appoint and exercise line authority over one or more GMOs. At NIH each awarding component has a CGMO.
- **Grants Management Specialist.** The GMS whose name appears in the NoA is an agent of the GMO and is assigned responsibility for the day-to-day management of a portfolio of grants.
- **Program Official.** The PO is responsible for the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, development of research and research training programs to meet the IC's mission; coordination with CSR/IC SROs; and post-award administration, including review of progress reports, participation in site visits, and other activities complementary to those of the GMO. The PO and the GMO work as a team on many of these activities.
- **Scientific Review Officer.** SROs are health science administrators who manage the activities of SRGs, including CSR study sections. The SRO is responsible for conduct of the SRG in accordance with applicable laws, regulations, and policies. For the SRG for which they are responsible, the SRO reviews applications for completeness and conformity to requirements, ensures that adequate numbers of reviewers with appropriate expertise are available for application review, assigns applications to individual reviewers as discussion leaders and for preparation of written critiques, manages conflicts of interest and confidentiality, and serves as the overall point of contact with applicants during the initial phase of the peer review process, i.e., until the conclusion of the SRG meeting.
- **Other NIH, HHS and Federal Agency Staff.** In addition to the GMO and PO, the recipient may be required to interact with other NIH or HHS staff members or offices with respect to its organization-wide systems and/or individual transactions. These include the office responsible for negotiating F&A costs and research patient care rates, typically the cognizant CAS office, ONR, or DFAS; OIG; OHRP; ORI; OLAW; and OPERA. Staff members in these offices generally coordinate with the GMO, but they are responsible for discrete areas of specialization and are not required to channel their communications with the recipient through the GMO. Part III includes a list of these organizations and their addresses and telephone numbers. ONR is the cognizant agency for negotiation of F&A costs for some NIH recipients.

2.1.2 Recipient Staff

Overall responsibility for successfully implementing an NIH grant is a shared responsibility of the PD/PI (s), the AOR, and the Research Administrator. As key members of the grant team, they respectively lead the scientific and administrative aspects of the grant. While communications can be conducted with Research Administrators and other institutional staff, NIH staff members conduct official business only

with the designated PD/PI(s) and AORs. The roles and responsibilities of recipient participants are as follows:

- **Authorized Organization Representative.** The AOR is the designated representative of the recipient organization in matters related to the award and administration of its NIH grants, including those that require NIH approval. The AOR should ascertain and assure that the materials the applicant organization are submitting on behalf of the PD/PI are the original work of the PD/PI and have not been used by other individuals in the preparation and submission of a similar grant application. In signing a grant application, this individual certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. This individual's signature on the grant application further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the grant-supported project or activities resulting from the application. (Also see [Legal Implications of Applications](#).) This individual also is responsible to NIH for ensuring that the organization complies with applicable Federal laws and regulations, including required certifications and assurances, its application, and the terms and conditions of individual awards. For applications submitted electronically through Grants.gov, the signature of the AOR is documented as part of the electronic submission process and is authenticated through the Grants.gov registration process. In the eRA Commons, this individual holds the Signing Official role. Although NIH requires that the recipient organization designate such an official, NIH does not specify the organizational location or full set of responsibilities for this official.
- **Program Director/Principal Investigator.** A PD/PI is an individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the award. The applicant organization may designate multiple individuals as PD/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the recipient organization or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. The presence of more than one identified PD/PI on an application diminishes neither the responsibility nor the accountability of any individual PD/PI.

When a single PD/PI is designated, that individual is not required to be an employee of the applicant organization. However, because the grant, if awarded, is made to the organization, the applicant organization must have a formal written agreement with the PD/PI that specifies an official relationship between the parties even if the relationship does not involve a salary or other form of remuneration. If the PD/PI is not an employee of the applicant organization, NIH will assess whether the arrangement will result in the organization being able to fulfill its responsibilities under the grant, if awarded.

When multiple PD/PIs are designated, NIH requires identification of one PD/PI who will be designated as the Contact PD/PI. This person is responsible for communication between the PD/PIs and NIH. Serving as Contact PD/PI confers no special authorities or responsibilities within the project team. The Contact PD/PI must meet all eligibility requirements for PD/PI status. They are not required to be an employee of the applicant organization. However, as with the single PD/PI model, if the Contact PD/PI is not an employee, the applicant organization must have a formal written agreement with the Contact PD/PI that specifies an official relationship between the parties. This same principle applies to all PD/PIs at the applicant organization; e.g., they need not be employees; however, the applicant organization must have a formal written agreement in place.

When multiple PD/PIs are involved at different organizations, only the Contact PD/PI is required to have the official relationship with the applicant organization. PD/PIs in the leadership team at other organizations must have a documented relationship with a consortium organization, but need not be employees. Any consortium agreement must address the unique aspects to these individuals holding the PD/PI role. For additional information, see [NIHGPS Section 9](#) Multiple Program Director/Principal Investigator Applications and Awards.

PD/PIs are members of the recipient team responsible for ensuring compliance with the financial and administrative aspects of the award. They work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support of research findings in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements. NIH encourages PD/PIs to maintain contact with the NIH PO with respect to the scientific aspects of the project and the GMO/GMS concerning the business and administrative aspects of the award. The [NIH staff contacts list](#) includes contact information for NIH grants management and program staff at each IC.

- ***Research Administrator.*** The Research Administrator acts as a local agent of the AOR and/or PD/PIs providing day-to-day grant-related support. Depending on the structure of the organization, this individual can be located centrally or within an organizational component such as a Department.

2.2 ERA COMMONS

eRA Commons is an online interface where grant applicants, recipients and Federal staff at NIH and grantor agencies can conduct their research administration business electronically as well as access and share administrative information relating to research grants. While applicants use Grants.gov to find and apply for grants; the eRA Commons retrieves the application or proposal information from Grants.gov, compiles it into a consistent application format and then makes it available to applicants and NIH staff for electronic research administration purposes.

Access to the eRA Commons is vital for all steps in the NIH grant administration process. Following application submission, the eRA Commons becomes the primary site for accessing grant information such as Institute/Center assignments, review outcomes, Summary Statements, and Notices of Award. The eRA Commons also provides electronic business processes such as Internet Assisted Review, submission of Just-In-Time material, submission of electronic SNAP progress reports (eSNAP), submission of notification of extensions without funds, and submission of Closeout documents. Appropriate user roles are assigned to registered individuals depending on the responsibilities assigned to them by the recipient organization.

2.2.1 eRA Commons Registration

An organization and PD/PI(s) must complete a **one-time** registration in the Commons. Institutional/organizational officials are responsible for registering PD/PI(s) in the eRA Commons. PD/PI(s) should work with their AOR (also known as the Signing Official in the eRA Commons) to determine their institutional/organizational process for registration.

IMPORTANT: Organizations registering in the eRA Commons for the first time should allow 2-4 weeks to complete the registration process.

2.2.1.1 eRA Commons Registration for the Organization

Prospective applicant organizations should also see [Legal Implications of Applications](#) before beginning the eRA Commons registration process.

Organizations may verify their current registration status by running the [“Commons Registered Organizations” query](#). This query can be run without logging into the Commons. The resulting list includes organization name and location and the NIH-assigned IPF Code that has been stored in the institutional profile for that organization.

To register an Organization in the eRA Commons an AOR should follow the procedures found on the [Register in eRA Commons page](#).

Once an organization is registered, information in the Institutional Profile can be maintained through the Commons.

During this registration process, NIH may make a preliminary assessment of applicant organization eligibility. Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH may deny registration if an organization is determined ineligible. Note, acceptance of an organization’s registration in the Commons does not mean an organization is an acceptable recipient for a particular program. That assessment will be made by the NIH awarding component prior as part of the pre-award process. See [Determining Applicant Organization Eligibility](#) for additional information.

Foundations that represent already existing recipient organizations, or a newly formed consortium where the consortium members are already individually recognized as NIH recipient organizations present unique and complex situations and should contact the [Systems Policy Branch, OPERA](#) before attempting to separately register as a new applicant organization.

2.2.1.2 eRA Commons Registration for the PD/PI

The individual(s) designated as the PD/PI(s) on the application must also be registered in the Commons. The PD/PI(s) must hold a PI eRA Commons role **and** be affiliated with the applicant organization. **The initial registration must be done by an AOR who has the SO role in the Commons or other authorized accounts administrators at the organization.** However, after the initial registration process is complete, it becomes the responsibility of each individual to maintain the information in their personal profile.

Designating the PI role in the eRA Commons provides the individual with the administrative authority needed to see pertinent information regarding an application (e.g., summary statements, scores, electronic submission status, etc.). The PI role within the eRA Commons is necessary to complete the grant application process, to view the impact score and summary statement (the SO role also has this capability), and if an award is made, to complete required post-award actions such as submission of a progress report. The PD/PI may delegate certain authorities to other individuals.

Users should only have one PD/PI eRA Commons account. If the PD/PI has already been registered in eRA Commons by an organization other than the organization submitting an application, a separate eRA Commons registration with the submitting organization is not necessary. However, the submitting organization must take steps to affiliate the individual with that organization so that the individual can view and access data records for those applications.

For more information on the features of the eRA Commons, including links to resources such as user guides and frequently asked questions, see the [eRA Commons webpage](#).

2.2.1.3 eRA Commons Registration for Other Individuals Participating in NIH Application and Research Performance Progress Reports

Any individual with an Undergraduate, Graduate Student, and/or Postdoctoral Role who participates in a NIH-funded project for at least one person month or more should also be registered in the eRA Commons and should verify that all Personal Information located within the Personal Profile tab in the eRA Commons System is accurate. This is required regardless of whether salary is actually charged to the project. For graduate students supported on a particular research grant, this could include project roles of graduate research assistant or graduate student. For postdoctoral individuals supported on a particular research grant, this could include project roles such as Postdoctoral Associate and other similar Postdoctoral positions.

When an individual is assigned the Undergraduate, Graduate Student, or Postdoctoral Role in the Commons, responses to certain data items in the Personal Profile tab will be required to meet NIH reporting requirements to Congress included in the NIH Reform Act, P.L. 109-482. The Commons user name ID for those with an Undergraduate, Graduate Student, or Postdoctoral Role is not required at the time of application submission, but will be required as part of the Research Performance Progress Report (RPPR).

For individuals at the postdoctoral level, this requirement is already in effect and progress reports will not be accepted if the Commons ID is not provided. For individuals at the undergraduate and graduate student levels, a Commons ID is required with RPPRs. The Undergraduate and Graduate Student Roles have been added to the Commons to accommodate this requirement; recipients are encouraged to begin registering these individuals now.

Note, the Graduate Student and Postdoctoral eRA Commons Roles should NOT be used for individuals submitting Individual Fellowships; the PD/PI role is used for those submissions. Nor should they be used for individuals supported on institutional training grants and reported using xTrain; the Trainee Role must continue to be used for those individuals.

In addition to the above roles, a Commons ID is required at the time of submission for sponsors in fellowship applications, component leads on multi-project applications, candidates for support under Research Supplements to Promote Diversity in Health-Related Research (Diversity Supplements), and primary mentors on career development applications. A Commons ID is also required at the time of application submission for all individuals listed on the R & R Senior / Key Person Profile (Expanded) Form; the requirement applies to Senior/Key Personnel as defined in NIHGPS Section 1.2 as well as Other Significant Contributors (OSCs). For other roles a Commons ID is strongly encouraged, but currently optional, for all other project personnel. A general Commons Role of Project Personnel is available for those not assigned other Commons Roles.

2.3 APPLICATION INFORMATION AND PROCESSES

This section provides an overview of NIH's grant support mechanisms, types of entities eligible to receive grants, types of applications, types of funding opportunities, legal implications of applications, policies affecting application preparation and submission, application forms, application receipt information and deadlines, fraud, waste and abuse of NIH grant funds, and availability and confidentiality of application information.

2.3.1 Support Mechanisms

NIH ICs award grants under multiple programs and subprogram initiatives and use a variety of support mechanisms. NIH grants may be distinguished by purpose, type of recipient, amount, or other

characteristics. One method NIH uses to differentiate the various support mechanisms is an activity coding that indicates the category and specific form of support (e.g., R01, F32, P01, R43). The applicability of requirements may vary for different activity codes. Some of the distinctions also are significant for purposes of applying Part II. NIH ICs may vary in the way they use specific activity codes; not all ICs accept applications for all types of grant programs and may apply specialized eligibility criteria. See a [comprehensive list of activity codes](#) on NIH's web site.

2.3.2 Eligibility

In general, NIH grants may be awarded to organizations that are domestic or foreign, public or private, or non-profit or for-profit. Eligible organizations include governments, including Federal institutions, institutions of higher education, other non-profit organizations, hospitals, and, in rare occasions, individuals (see [Completing the Pre-Award Process—Determining Applicant Organization Eligibility](#)). Any special criteria for applicant eligibility or requirements concerning the qualifications of the PD/PI or other staff or participants will be specified in the NOIFO, program guidelines, or other publicly available documents. Part IIB includes information on fellow and trainee eligibility.

2.3.3 Types of Award Instruments

NIH uses several different extramural award instruments in support of its mission. The Federal Grant and Cooperative Agreement Act of 1977 (P.L. 95-224) distinguishes financial assistance between contracts, cooperative agreements and grants. The NIHGPS requirements apply to grants and cooperative agreements. Both grants and cooperative agreements are financial assistance instruments.

The grant instrument is used to administer awards that do not require NIH involvement beyond standard agency monitoring and stewardship. Under a cooperative agreement, NIH expects to be substantially involved in carrying out the project. Grants are used both for investigator-initiated research and for more targeted research. Cooperative agreements generally do not result from investigator-initiated applications. However, NIH may apply terms and conditions that differ from those in the NIHGPS consistent with the nature of its involvement under cooperative agreements.

2.3.4 Types of Applications

In the NIH grants process, five types of applications are used most frequently. The first four application types described below are considered “competing” because, through the peer review process, the application must compete for available funding with other applications.

- **New Application (Type 1).** A request for financial assistance for a project or activity that is not currently receiving NIH support and must compete for support. A new application is being submitted for the first time.
- **Renewal (Type 2).** A request for additional funding for a period subsequent to that provided by a current award. A renewal application competes with all other applications and must be fully developed as though the applicant is applying for the first time.

- ***Revision (Type 3).*** A request for an increase in support in a current budget period for expansion of the project's approved scope or research protocol. The request may specify budgetary changes required for the remainder of the project period as well as for the current budget period. Applications for revisions are not appropriate when the sole purpose is to restore awards to the full SRG-recommended level if they were administratively reduced by the funding agency. A revision application should not be submitted until after the original application has been awarded and may not extend beyond the term of the current award period. A revision application must have the same title as the currently funded grant. (A Type 3 prefix also refers to a request/award for a non-competing administrative supplement [see [Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements—Need for Additional NIH Funding without Extension of Budget and Project Period.](#)]).
- ***Resubmission (suffix -A1).*** An unfunded application that the applicant has modified following initial review and resubmitted for new consideration. Before a resubmission application can be submitted, the PD/PI must have received the summary statement from the previous review. A resubmission application may be submitted for any of the three preceding types of applications provided an appropriate NOFO is available. See [Application Information and Processes—Policies Affecting Applications](#) for other policies affecting Resubmissions. NIH allows only one resubmission application.
- ***Non-Competing Continuation Progress Report (Type 5).*** A non-competing progress report is required to continue support of a PHS grant for the second or subsequent budget period within an approved competitive segment (see [Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports](#)).

In addition to the list above, NIH periodically uses a pre-application (also known as a “white paper” or “précis”) to facilitate certain approaches or economies, such as reducing burden on the applicant community, for a funding opportunity. Pre-applications are generally used in combination with a competing application in a 2-phase process. Pre-applications do not result in an award; the end result is the opportunity to submit to the subsequent phase of a particular program. Successful applicants to the pre-application phase are notified of the opportunity to submit to the subsequent phase. In addition to the pre-application, NIH may use an application process for prospective applicants to request access to an NIH research resource. This process also does not result in an award; the end result is permission to access a resource. NIH uses the numbers shown in parentheses as prefixes to distinguish the application types and any resulting awards (e.g., 5R0198765-02 is a non-competing continuation progress report).

2.3.5 Types of Notices of Funding Opportunities (NOFOs)

Most applications submitted to NIH under the categories of research and research training (including fellowships) are investigator-initiated. NIH accepts applications on the application due dates noted on the submission schedule. NIH generally reviews applications in three review cycles per year; however any variations in schedule will be noted in the NOFO. Some ICs review applications for Institutional National Research Service Awards (T32) only once a year; such information is generally found in a particular NOFO. The schedules for submission, review, and award of investigator-initiated applications are available on [the NIH standard due dates web page](#).

Notice of Notice of Funding Opportunity (NOFO). In accordance with 2 CFR 200.204, NOFO is an umbrella term for a publicly available document in which NIH makes known its intentions to award "Discretionary Award" on page I-19, usually as a result of competition for funds. Each NOFO includes a solicitation identifier, will outline the program goals and objectives, and will include information to allow prospective applicants to determine whether the entity is eligible to apply. All applications must be electronically submitted in response to a NOFO.

NIH NOFOs primarily fall into the categories of Program Announcements, (PAs), which include Parent Announcements, and Requests for Applications (RFAs). While individual announcements will continue to carry an announcement number reference to [PA](#) or [RFA](#), all announcements are [NOFOs](#). NOFO is the general term is used to reference any type of funding announcement. NIH uses the PA and RFA references in the actual announcement number to distinguish between the various types of announcements.

- **Parent Announcement.** Electronic submission of applications requires that applications must be associated with a specific NOFO. Therefore, NIH omnibus/broad parent announcements are provided for applicants to submit investigator-initiated (unsolicited) applications. Responding to such an omnibus or umbrella parent NOFO ensures that the correct application package is used and enables NIH to receive the application from [Grants.gov](#). This process in no way diminishes the interest of [NIH ICs](#) in investigator-initiated, unsolicited research grant applications. Parent announcements are NIH-wide, but some ICs may limit their participation; therefore, prospective applicants should check the announcement to determine IC participation. For institute-specific opportunities in a particular area of science, search the *NIH Guide for Grants and Contracts*.
- **Program Announcement (PA).** A PA is a formal statement about a new or ongoing extramural activity or program. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or program, and/or invite applications for grant support. Most applications in response to PAs may be submitted to a standing submission date and are reviewed with all other applications received at that time using standard peer review processes. NIH may also make funds available through PARs (PAs with special receipt, referral, and/or review considerations) and PASSs (PAs with set-aside funds).

ICOs issuing PARs or PASSs may now choose to describe within the NOFO criteria that would make an application non-responsive to the PAR/PAS. Only applications to PARs and PASSs that include non-responsive criteria will be evaluated by the ICOs upon receipt for non-responsiveness. These non-responsive criteria will be listed in the Funding Opportunity Description section (Part 2, Section 1). Those applications that are deemed non-responsive will be withdrawn from review.

PAs may be used for any support mechanism other than construction awards. Unless otherwise specified in the PA, new applications (and associated renewal and revision applications) submitted in response to PAs are treated as investigator-initiated. PAs also are used to annually solicit applications for the SBIR and STTR programs. Those applications must be received by the dates specified in the PA.

- **Request for Applications (RFA).** An RFA is a formal statement that solicits grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. An RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, whether cost sharing is required, and the application submission date(s). For cooperative agreements, the RFA will describe the responsibilities and obligations of NIH and recipients as well as joint responsibilities and obligations. Applications submitted in response to an RFA are usually reviewed by an SRG specially convened by the awarding component that issued the RFA.

All applications involving one or more clinical trials must be submitted through a NOFO specifically designed for clinical trials. NIH will not process applications that propose one or more clinical trials if the NOFO (Part 2, Section 2) indicates clinical trials are “Not Allowed.” Applications that propose clinical trials, including applications with a mix of trial and non-trial aims or a combination of clinical and non-clinical studies, must be submitted to NOFOs designated as clinical trial “Optional” or “Required”.

All NIH NOFOs are published in the [NIH Guide for Grants and Contracts](#) and on Grants.gov under Search Grants (<https://www.grants.gov/web/grants/search-grants.html>). NIH may develop areas of high

priority or special research interest and use a special announcement to stimulate submission of applications in those areas. These NOFOs are also published in the *NIH Guide for Grants and Contracts*.

2.3.5.1 Other Funding-Related Notices

Notice of Intent to Publish (NOITP). The purpose of an NOITP is to alert the extramural research community of an upcoming funding opportunity.

Request for Information (RFI). The purpose of an RFI is to alert the extramural research community to a request for comments on a specific issue. A RFI does not include reminders, extensions, or clarifications to RFIs.

2.3.6 Legal Implications of Applications

An applicant must be an eligible entity and must submit a complete application in accordance with established receipt (deadline) dates in order to be considered for support. The signature of an AOR on the application certifies that the organization will comply with all applicable assurances and certifications referenced in the application. The applicant organization is responsible for verifying conformity with the most current guidelines for all administrative, fiscal, and scientific information in the application, including the F&A cost (indirect cost) rate. The AOR's signature further certifies that the applicant organization has the ability to provide appropriate administrative and scientific oversight of the project and agrees to be fully accountable for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from the application. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

Applicants for and recipients of NIH grant funds, whether such funds are received through a grant, indirectly under a contract or consortium agreement, or by a fiscal agent acting on another organization's behalf, or as student assistance under a training grant, are responsible for and must adhere to all applicable Federal statutes, regulations, and policies, including income tax regulations. Questions concerning the applicability of income tax regulations to grant funds should be directed to the IRS. The applicant also is expected to be in compliance with applicable State and local laws and ordinances.

Applicants may be required to provide proof of organizational eligibility (such as proof of non-profit status), trainee or fellow eligibility and citizenship, or other eligibility information. Applications also must demonstrate compliance (or intent to comply), through certification or other means, with a number of public policy requirements. The more significant of the public policy requirements for the purpose of peer review are those concerning research involving human subjects; inclusion of genders, members of minority groups, and individuals across the lifespan in clinical research; and research involving live vertebrate animals. Part II details public policy requirements and cost and administrative policies.

Affiliate organizations and other similar administrative organizations

There are times when an institution desires to use an affiliate organization, such as a Foundation or other similar organization to provide administrative services for NIH grants. These situations are often complex and each situation is unique when determining which organization is the appropriate applicant institution. Foundations, particularly those associated with institutions already recognized as NIH recipient organizations, should contact the [Division of Grants Systems Integration, OPERA](#) before attempting to separately register as an applicant organization.

Similarly, when new consortiums are formed where the consortium members are already separately recognized as NIH recipient organizations, DGSI/OPERA should be contacted before attempting to

separately register as a new applicant organization. [See NIHGPS Section 7.8 Services Provided by Affiliated Organizations.](#)

2.3.7 Policies Affecting Applications

Application information to be submitted typically includes a project description, budget and budget justification, biographical sketches of senior/key personnel, and other information specified in the application instructions, in the announcement, and/or in program guidelines, if any. Applicants should consult the cost principles and general administrative requirements for grants pertaining to their organizational type in order to prepare the budget and complete other parts of the application. This section describes NIH policies that affect application preparation and/or submission. Specific details on application content are addressed in application instructions and specific NOFOs. Any significant change to the application post-submission must be reported immediately to the appropriate NIH official.

2.3.7.1 Direct Cost Limitations for Applications That Include Consortium/Contractual F&A Costs

For NOFOs that include a direct cost limit, NIH policy excludes consortium/contractual F&A when determining if an applicant is in compliance with the direct cost limitation. This policy extends to all solicited and investigator-initiated applications and to all active announcements (Request for Applications and Program Announcements), involving consortium/contractual F&A costs, regardless of budget amount or budget format (e.g., modular and non-modular). While consortium F&A costs may be requested and awarded, applicants should not consider these costs when determining if a budget exceeds a direct cost limit.

This policy impacts eligibility to submit a modular budget. The modular budget format is used for applications requesting \$250,000 or less in direct costs per year. Consortium/contractual F&A costs are not factored into this direct cost limit; however, they may be requested in addition to the \$250,000.

This policy also impacts applications requesting a budget of \$500,000 direct costs or more for any year. These applications require prior approval from Institute/Center staff; however, the limit is exclusive of any consortium F&A costs. It does not affect any specific NOFO that includes a total cost limit.

This policy does not affect the SBIR and STTR programs since the statutory budget guidelines are based on total costs, not direct costs.

2.3.7.2 Requirements for Submitting Unsolicited Applications Requesting \$500,000 or More in Direct Costs

Any applicant requesting \$500,000 or more in direct costs (excluding consortium F&A costs) in any one budget period is required to contact the IC PO, in writing or by telephone, as early as possible during development of the application but no later than 6 weeks or as specified in the NOFO before submission for prior approval. If staff is contacted less than six weeks before submission, there may be insufficient time to make a determination about assignment prior to the intended submission date. If the requested dollars are significantly greater than \$500,000, then approval should be sought even earlier. This requirement applies to a single grant application, whether a new, renewal, revision, or resubmission application, under any NIH support mechanism; it also applies to a group of applications, such as those for clinical trial networks, meeting the \$500,000 threshold in the aggregate even if no single application in the group requests that much.

This policy does not apply to applications submitted in response to RFAs or to other announcements that include specific budgetary limits. However, any such application must be responsive to budgetary limits

specified or NIH will administratively withdraw the application and it will not be reviewed or considered for funding.

The PD/PI must include a cover letter with the application identifying the PO contacted and the IC that has agreed to accept assignment of the application. CSR will accept such applications for review only if an IC has agreed to accept the application for consideration and the applicant submits with its application a cover letter to that effect with the name of the authorizing program staff member and IC affiliation (see [The Peer Review Process](#)). An application subject to this policy that does not include the required information in the cover letter will be administratively withdrawn and will not be reviewed or considered for funding.

2.3.7.3 Resubmission of Unfunded RFA Applications

This policy applies to all activity codes that might be solicited via an RFA and to instances where there is a change in activity code. Unless a particular NOFO states that resubmissions from an RFA may be submitted, unfunded applications should be submitted as **new** applications if the grant applications fall into the following categories:

1. Applications that were originally submitted in response to an RFA and now submitted as an investigator-initiated application.
2. Applications that were originally submitted as investigator-initiated applications and subsequently submitted in response to an RFA.
3. Applications that were originally submitted using one grant activity code and subsequently submitted using a different grant activity code (for example, an application that was originally an R01 and is now submitted as an R21).

The new application must be submitted on the scheduled due dates for new applications and follow all instructions that apply to new applications. Do not include an Introduction describing the changes and improvements made; do not mark text to indicate the changes and do not mention prior review anywhere in the application (including the cover letter). In these cases the reviewers will not be provided with the previous summary statement.

2.3.7.4 Resubmission of an Unfunded Application

An unfunded competing application (A0) may be resubmitted for future funding opportunities. These applications are referred to as a resubmission application (A1). NIH will only accept a single resubmission (A1) application. NIH will accept a new (A0) application following an unsuccessful resubmission (A1) application or a prior A0 application. The subsequent new application need not demonstrate substantial changes in scientific direction compared to previously reviewed submissions, and must not contain an introduction to respond to the critiques from the previous review. NIH's policy for accepting overlapping applications remains in effect: NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that NIH will not review:

1. a new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
2. a resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
3. an application that has substantial overlap with another application pending appeal of initial peer review (see Section [2.3.9.4](#) below)

NIH policy allows a 37 month window for one resubmission (A1) following the submission of a new, renewal, or revision application (A0 application). The initial submission of a new, renewal or revision

application constitutes the starting point for the 37 month policy. After 37 months, NIH views a submission as a new application, regardless of whether an unsuccessful resubmission (A1) was submitted during the 37 month period.

Submission to a different NOFO under review at the same time is not sufficient to make an application new. (There are exceptions for applications following an RFA or changing activity code. See [Resubmission of Unfunded RFA Applications](#) above). The new application must be submitted on the [scheduled due dates for new applications](#). It must not include an Introduction describing the changes and improvements made; and the text must not be marked to indicate the changes.

2.3.7.5 New Investigators and Early Stage Investigators

The NIH is committed to identifying and attracting new biomedical researchers and will continue to explore novel ways to encourage early transition to independence. NIH has implemented a number of policies specific to New Investigators, and in particular the category of New Investigator called Early Stage Investigator.

New Investigator. In general, a PD/PI is considered a New Investigator if they have not previously competed successfully as PD/PI for a substantial NIH independent research award. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. See definitions section for additional information and references.

Early Stage Investigator (ESI). An ESI is a New Investigator who has completed their terminal research degree or end of post-graduate clinical training (i.e., completing medical residency, whichever is later, within the past 10 years at the time of application submission and who has not previously competed successfully as a PD/PI for a substantial NIH independent research award. Extensions of the end of ESI eligibility date may be requested following the procedures documented on the Early Stage Investigator Extensions page on the NIH Grants & Funding website. Please note an investigator will retain their ESI status if they receive smaller research grants, training, infrastructure, and career awards appearing on this list.

The NIH intends to support New Investigators at success rates comparable to those for established investigators submitting new applications. ESIs should comprise a majority of the New Investigators supported. Where possible, New Investigator applications will be clustered during review. The applications will be given special consideration during peer review and at the time of funding. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator.

NIH New Investigator policies are limited to applications for traditional research project grant (R01) support. Accordingly, NIH strongly encourages New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding. To determine New Investigator and ESI status, NIH relies on the data entered by the individual in their eRA Commons Profile, therefore it is important that PD/PIs verify the accuracy of their personal profiles. Particularly key for ESIs are the terminal research degree and end date of residency data fields. ESI status and end of eligibility date also appear in the eRA Commons profile for the individual.

2.3.7.6 Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance

The applicant organization is required to secure and retain a unique signature and dated assurance from the PD/PI for each submitted application, prior to submitting an application to the NIH. This assurance must be available to the NIH or other authorized DHHS or Federal officials upon request. Such an assurance must include at least the following certifications: 1) that the information submitted within the application is true, complete and accurate to the best of the PI's knowledge; 2) that any false, fictitious, or

fraudulent statements or claims may subject the PI to criminal, civil, or administrative penalties; and 3) that the PI agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application. If multiple PIs are proposed in an application, this assurance must be retained for all named PIs.

For individual Fellowship applications, this assurance requirement applies to the individual fellow and the sponsor. Such an assurance must include at least the following certifications: (1) that the information submitted within the application is true, complete and accurate to the best of the Fellow's and Sponsor's knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Fellow and Sponsor to criminal, civil, or administrative penalties; (3) that the Sponsor will provide appropriate training, adequate facilities, and supervision if a grant is awarded as a result of the application; (4) that the Fellow has read the [Ruth L. Kirschstein National Research Service Award Payback](#) and will abide by the Assurance if an award is made; and (5) that the award will not support residency training. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

2.3.7.7 Post-Submission Grant Application Materials

Post-submission of application materials is not required. Adding materials to reviewer workload may be counterproductive, so applicants should carefully consider the need to send post-submission materials. For materials that are submitted after the initial grant application submission but prior to initial peer review, NIH will only accept such materials resulting from unforeseen administrative issues. This policy does not modify the Just-in-Time requirements or any other requests for additional information after the initial peer review.

Allowable Post-Submission Materials for All Applications

For all research and research-related applications, individual fellowship, and individual career development awards, acceptable materials include:

- Citations of issued patents
- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution [e.g., Program Director/Principal Investigator (PD/PI) moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Special submission procedures are required for videos.

- Other post-submission materials specified in the NOFO for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application, which must include only:**
 - List of authors and institutional affiliations
 - Title of the article
 - Journal or citation (if available)

Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the Notice of Funding Opportunity (NOFO) for which the application was submitted or a special Guide Notice.

Additional Materials for Certain Applications

Preliminary Data NIH will accept preliminary data as post-submission material for Type 1 R01, R21, or R03 applications, including resubmissions, if the NOFO used for submission allows preliminary data in the application.

Institutional Training and Training-related Grants (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2): in addition to the materials for All Applications above, news—since the training grant application was submitted—of:

- A trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- A faculty member's promotion, funding, or publications; and
- The addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).
- Lists of publications for Training Grant are allowed. Follow the page limits in the NIH Table of Page Limits.

Individual Fellowship (F-Series) and Individual Career Development Award (K-series) Applications: in addition to the materials for All Applications listed above:

- New information on the Sponsor/Mentor funding, limited to the project title, funding source (e.g., NIH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
- News of change in Mentor(s) or other Senior/Key Persons specified in the original application.

Applications submitted to Requests for Applications (RFAs): the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

Conference Grant Applications (R13, U13): a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively, the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

Any other types of post-submission materials are not likely to be accepted.

Requirements for Submitting Post-Submission Materials

All post-submission materials must conform to NIH policies on font size, margins, and paper size as referenced in the applicable application instructions.

- Any specified formats (e.g., budgets, biographical sketches) and page limits referenced in the applicable application instructions apply.
- If post-submission material is not required on a specific format page and does not have a specified page limit, each explanation or letter is limited to one page.
- If the application has multiple components (subprojects or cores), each subproject or core is allowed explanations or letters, but each explanation or letter is limited to one page.

Post-submission materials must be received by the NIH Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. Post-submission materials will not be accepted if fewer than 30 calendar days remain before the peer review meeting, unless specifically stated otherwise in the NOFO for which the application was submitted or in a special Guide Notice.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the post-submission materials may originate from the PD/PI, Contact PD/PI, or organizational officials, the AOR must send the materials directly to the SRO or must send their concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a copy to the AOR will not be accepted.

Post-submission materials **can only** be submitted as a PDF attachment, except for video submissions. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check their application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

Non-traditional Application Materials

NIH will accept only videos as non-traditional application materials. No devices or other media will be accepted unless specified in the Notice of Funding Opportunity (NOFO). However, videos may include demonstrations of devices and other items as listed below. These guidelines may be superseded by instructions in specific NOFOs.

The only acceptable content for videos is demonstrations of devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time; or demonstrates movement or change.

- Examples of acceptable content include unusual interventions or surgical procedures, prototype model use, visualization of 3-D structures or structural changes in molecules or cells, software or database demonstrations, educational materials or video games.
- Examples of unacceptable content include virtual tours of laboratories, equipment in place, platform presentations, advertisements, commercials, or PowerPoint presentations [unless requested by the Scientific Review Officer (SRO) in lieu of a site visit].

Application requirements. Videos may only be submitted as post-submission materials and not embedded in or linked from the application materials unless expressly instructed to do so in the funding opportunity instructions. The application must be structured at the time of submission to indicate that a video will be submitted subsequently. The cover letter submitted with the application must include information about the intent to submit a video; if this is not done, a video will not be accepted. Key images/"stills" and a brief description of each video must be included within the page limits of the research strategy. Sufficient descriptive information must be provided within the research strategy to understand the information presented in the video, as not all reviewers may be able to access the video, depending on technological constraints.

When human subjects or personally identifiable information is represented in a video, the applicant organization is responsible for ensuring that human subjects have been consented and protected appropriately. Submission through the Authorized Organizational Representative (AOR) certifies acceptance of this responsibility.

Video formats. Multiple videos may be submitted per application but their aggregate length must not exceed 2 minutes for single-project applications and 5 minutes for multi-component applications.

Post-submission videos can be submitted as an mp4, mov, avi, or wmv video format with a maximum file size of 25 MB. This material can be submitted via e-mail and it will be uploaded to the grant folder by the SRO.

Closed captioning is not required when narration is present. However, captioning is recommended as an optional component of the video to assist reviewers evaluating the application.

Limitations. Video files containing unacceptable content or exceeding the time or size limits will not be accepted. Applications submitted with hyperlinks to videos or with videos embedded in the research strategy will be considered in violation of page limits and the application will be withdrawn before review.

[Additional information on post-submission videos can be found on the NIH Format Attachments webpage.](#)

Note: Due to technological constraints, the NIH cannot guarantee that reviewers will be able to view videos.

Video submission. If the submission requirements have been met (see above), videos will be accepted by the SRO managing the review. After the assignment of the application to a review group is visible in the eRA Commons, the applicant should contact the SRO for that review group to discuss logistics for submission of any videos.

As with all other post-submission materials, videos must be received by the SRO one month (30 calendar days) prior to the peer review meeting or as otherwise specified in the NOFO. Videos will not be accepted if fewer than 30 calendar days remain before the peer review meeting.

Concurrence from the Authorized Organization Representative (AOR) of the applicant organization is required. Although the video may originate from the Program Director/Principal Investigator (PD/PI), Contact PD/PI for multiple PD/PI applications, or organizational officials, the AOR must send the materials directly to the SRO, or must send their concurrence to the PD/PI who will forward the materials and concurrence to the SRO. A communication from the PD/PI only or with a “cc” to the AOR will not be accepted.

The opportunity to submit additional materials should not be a means of circumventing submission deadlines, page limitations, or content requirements and should not substantially enhance, alter or add to the originally submitted application.

After the initial peer review phase is completed, the Chief GMO of the IC is the NIH official responsible for accepting additional materials. Most of the material submitted after peer review can be submitted as part of the Just-in-Time process.

2.3.7.8 SAM Registration and Unique Entity Identifier (UEI) Requirements

All applicant organizations must register in the System for Award Management (SAM), in accordance with Appendix I to 2 CFR Part 200(D).(3.), and always maintain the registration with current information at all times during which such organizations have an application under consideration for funding by NIH and, if an award is made, until a final financial report is submitted or the final payment is received,

whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. SAM is the central repository for common government-wide certifications and representations required of NIH applicants and recipients. Additional information about registration procedures may be found at the [SAM.gov internet site](https://sam.gov).

A Unique Entity Identifier (UEI) is issued as part of the SAM.gov registration process. The UEI must be provided on application forms; the same UEI must be used for all registrations, as well as on the grant application.

2.3.7.9 Graduate Student Compensation

The maximum amount NIH will award for the support of a graduate student on a research grant or cooperative agreement is tied to the National Research Service Award (NRSA) zero-level stipend for postdoctoral fellows in effect at the time the grant award is issued on the Federal award date. Stipend levels are updated periodically in conjunction with an NIH annual appropriation and are published in the NIH Guide for Grants and Contracts. Consistent with cost principles for Institutions of Higher Education (IHEs) described in [2 CFR Part 200.431\(j\)](#) and [200.466](#), the compensation of graduate students supported by research grants must be reasonable. The amount provided for compensation includes salary or wages, fringe benefits, and tuition remission.

These guidelines apply to graduate students at the recipient institution who are supported by NIH research grants and cooperative agreements and not to individuals supported by NRSA training grants and fellowships. NIH has separate appropriations to support research training under the NRSA authorization at Section 487 of the Public Health Service Act.

The stipends provided to recipients of NRSA support offset the cost-of-living during the period of training and are not considered equivalent to salaries or other forms of compensation provided to individuals supported on research grants. Nevertheless, the entry-level postdoctoral NRSA stipend provides a useful benchmark for an award amount that approximates a reasonable rate of compensation for graduate students. Expected future increases in NRSA stipends, to adjust for inflation, should permit annual increases in the maximum award for such individuals.

For all new and competing grant and cooperative agreement awards, the NIH will provide reasonable amounts for graduate compensation, consistent with the requested budget for the position(s) and up to the currently effective NRSA zero postdoctoral stipend level. NIH staff will review the compensation requested for graduate students on competing and cooperative agreement applications for which a detailed budget is submitted. NIH will neither request nor accept budgets for those applications using a modular budget format solely for the purpose of reviewing graduate student compensation. However, applicants should use this policy when estimating the number of modules.

When submitting detailed budgets that request support for a graduate student, recipients are reminded to request actual institutional-based compensation and to provide information justifying the requested compensation level. If this information is not provided, NIH staff will obtain this information from the institution's business office for any request that appears excessive.

NIH Institutes and Centers will review the requested compensation level and, if considered reasonable, will award the actual amount requested, up to a maximum equal to the NRSA zero level postdoctoral stipend. Revised budgets submitted solely to adjust requested levels for graduate students will not be accepted.

Institutions may continue to rebudget funds to charge more than the awarded amount provided that OMB cost principles requiring reasonable compensation are observed. In general, graduate student com-

pensation will not be considered reasonable if in excess of the amount paid to a first-year postdoctoral scientist at the same institution performing comparable work.

2.3.7.10 NIH Data Management and Sharing and Genomic Data Sharing

NIH issued the Data Management and Sharing (DMS) policy to promote the sharing of scientific data. Sharing scientific data accelerates biomedical research discovery, in part, by enabling validation of research results, providing accessibility to high-value datasets, and promoting data reuse for future research studies. Applicant projects that generate scientific data are subject to the DMS Policy. Additionally, if applicable, genomic data sharing considerations must be submitted with the application. Please refer to Section 8.2.3.1 Policy for Data Management and Sharing (DMS Policy) for more information.

2.3.7.11 Human Fetal Tissue from elective abortions

For competing grant applications proposing the use of Human Fetal Tissue (HFT) from elective abortions NIH requires applicants to address HFT requirements by providing a justification of the use of HFT, details regarding procurement and costs, and information about how the applicant will use HFT. These additional requirements can be found in the application instructions and must be met within existing applicable page limits.

Applications that do not address all of the required information, including the detailed budget, will be administratively withdrawn and not reviewed.

2.3.7.12 Biographical Sketches (Biosketches)

NIH requires submission of a biographical sketch (also referred to as biosketch) for each proposed senior/key personnel and other significant contributor.

Applicants and recipients are required to submit biosketches in 1) competing applications for all types of grant programs; 2) in progress reports when new senior/key personnel or other significant contributors are identified; and 3) to support prior approval requests for changes in senior/key personnel status and changes of recipient organization.

NIH staff and peer reviewers utilize the biosketch to ensure that individuals included on the applications are equipped with the skills, knowledge, and resources necessary to carry out the proposed research. Applications containing one or more biosketches that do not conform to the required format may be withdrawn.

See the [NIH Biosketch page](#) for format pages, instructions and the [NIH disclosure table](#).

2.3.8 Application Forms

Exhibit 3 lists the required application forms for competing applications, which vary by support mechanism. These forms and associated instructions are available on the [NIH Forms and Format Pages](#).

Exhibit 3. Required Forms for Competing Applications

Application Title	Form Number	Use
SF424 (R&R) Application Guide for NIH and Other PHS Agencies	SF424 (R&R)	The SF424 (R&R) form set, combined with PHS 398 components, is used for electronic submission.
SF424 (R&R) Individual Fellowship Application Guide for NIH and AHRQ	SF424 (R&R) and PHS 416-1	The SF424 (R&R) form set, combined with a PHS Fellowship Supplemental form component, is used for electronic submission of individual fellowship applications. The PHS 416-1 may be used for e-mail form submissions of a change of sponsoring recipient organization application.
Application for a Public Health Service Grant	PHS 398	Form PHS 398 is used for paper submission for those programs that have not yet transitioned to electronic submission.

The NIH competing applications now require electronic application submission. Questions about application forms and instructions may be directed to [DGS/OPERA, OER, NIH](#); see Part III for contact information.

2.3.9 Application Receipt Information and Deadlines

The NIH generally requires electronic submission of all competing and administrative supplement applications. Applicants should carefully read instructions in the NOFO and the application guide to determine submission requirements. The NOFO will either provide unique application deadlines or refer to NIH's [standard due dates](#).

NIH expects all applications to be submitted on time. Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances and limited to two weeks past the due date. If an application is submitted late, a cover letter explaining the reasons for the delay must be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Only DRR, CSR has the authority to accept a late application; however, contacting DRR in advance will not influence the acceptance of a late application. The NIH policy on late applications is stated in the applicable application instructions. Also see Late Applications below.

2.3.9.1 Electronic Submission Requirements

NIH requires electronic submission of:

- All competing (Type 1, Type 2) and administrative supplement (Type 3) applications;
- All Research Performance Progress Reports (RPPRs), including interim and final RPPRs (submitted electronically through the eRA Commons RPPR module);
- Change of recipient organization (Type 7) and successor-in-interest (Type 6) applications (may be submitted electronically via email).

All applications, regardless of the NOFO type, must be successfully submitted electronically to Grants.gov on or before 5:00 p.m. local time (of the applicant organization) on the appropriate date listed in the funding opportunity.

If an application due date falls on a weekend, it will be extended to the following Monday; any time the date falls on a Federal holiday, the due date will be extended to the following business day. The application will be on time if it is submitted on or before the following business day.

Questions about application forms and instructions may be directed to DGS/OPERA, OER, NIH; see Part III for contact information.

2.3.9.2 Late Applications

There is a two week window of consideration after the application due date, during which time NIH might consider accepting a late application (see details below). When the application due date falls on a weekend or Federal holiday, and is extended to the next business day, the window of consideration for late submission of applications will be calculated from that business day. Acceptance of late applications will be made on a case-by-case basis, dependent upon the explanation provided in a cover letter submitted with the application.

Generally, when an applicant organization is closed due to natural disaster or other emergency situation, applications must include a cover letter indicating the reasons for the delay. In general, the delay should not exceed the time period that the applicant organization is closed, unless otherwise notified by the agency. Additional information can be found on the NIH Extramural Response to Natural Disasters and Other Emergencies webpage.

NIH will not consider accepting late applications under the following circumstances:

- Submissions to RFAs that must be reviewed on a compressed time line and that have declared, in the Application Due Date field, “No late applications will be accepted for this Funding Opportunity”.
- Submissions to any NOFOs (RFAs, PAs, PARs, PASSs) after the two-week window of consideration.

Please be aware that any reasons for late submission must be in relation to the individual(s) with the PD/PI role on the application. For multiple PD/PI (MPI) applications, the reasons may apply to any or all of the PD/PIs. This accommodation does not apply to co-Investigators, project leaders in a multi-component application, or other Key Persons listed in an application (unless they also have MPI status).

Examples of acceptable and unacceptable reasons for submission of a late application can be found in the [NIH Submission Policies](#) web page.

The windows of time for consideration of late applications have been carefully chosen so that the late applications can be processed with the cohort of on-time applications.

Late applications are evaluated on an individual basis considering the reasons provided. Contacting the [Division of Receipt and Referral, Center for Scientific Review \(CSR\)](#), NIH in advance will not influence the acceptance of a late application. Additional information on submission of electronic applications can be found in the applicable SF424 (R&R) Application Guide.

2.3.9.3 Continuous Submission for Appointed Members of NIH Federal Advisory Committees

Continuous Submission allows eligible members of NIH Federal Advisory Committees to submit applications for certain grant activity codes after the standard due date, until last day of the receipt period for each Advisory Council Round.

PD/PI individuals serving as appointed members of the following categories of NIH Federal Advisory Committees are eligible:

- Chartered NIH Initial/Integrated Review Groups (IRGs),
- NIH Boards of Scientific Counselors,
- NIH Advisory Boards or Councils,
- NIH Program Advisory Committees.

Eligibility begins on the date the appointment becomes active and continues for six weeks after the official date of retirement from appointed committee service. Thus, if retirement from appointed service occurs on June 30, continuous submission is permitted until August 16th of that year.

Continuous submission eligibility can be viewed in the reviewer's eRA Commons Personal Profile, in the Reviewer Information section.

eRA Commons users with account administration roles (e.g., SO – Signing Official, AO – Administrative Official, AA – Account Administrator, BO – Business Official) can check an investigator's eligibility using the Advanced Search feature in the Admin module.

Under Continuous Submission, applications received after the Advisory Council Round continuous submission period end dates will be assigned to the next Advisory Council Round, as described on the NIH Continuous Submission website. Please direct any continuous submission issues, including Grants.gov rejection messages, to the eRA Service Desk.

See [NIH Continuous Submission website for details and procedures.](#)

2.3.9.4 Similar, Essentially Identical, or Identical Applications

Simultaneous submissions of identical applications to one or more components of the PHS are not allowed, and the NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization for the same receipt date. This includes derivative or multiple applications that propose to develop a single product, process, or service that, with non-substantive modifications, can be applied to a variety of purposes. Likewise, identical or essentially identical grant applications submitted by different applicant organizations will not be accepted for the same receipt date. Applicant organizations should ascertain and assure that the materials they are submitting on behalf of the principal investigator are the original work of the principal investigator and have not been used elsewhere in the preparation and submission of a similar grant application. Applications to the NIH are grouped by scientific discipline for review by individual Scientific Review Groups and not by disease or disease state. The reviewers can thus easily identify multiple grant applications for essentially the same project. In these cases, application processing may be delayed, or the application(s) may not be reviewed.

Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award (K02) proposing essentially identical research in an application for an individual research project; or 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.

2.3.9.5 Application Non-conformity

Applicants are reminded that non-conformity with application requirements can have serious consequences. NIH may withdraw any application identified during the receipt, referral and review process that does not conform with the instructions in the SF424 (R&R) Application Guide, the Notice of Funding Opportunity, and relevant NIH Guide Notices.

Some **examples** of how this policy is applied to NIH applications *include but are not limited to*:

- Applications containing biosketches that do not conform to the required format may be withdrawn.
- Applications that do not conform to the page limit requirements because inappropriate materials have been included in other parts of the application may be withdrawn.
- Applications submitted as new but containing elements of a resubmission or renewal application that do not conform with the resubmission policy and may be withdrawn.
- Applications submitted after 5 PM local (applicant organization) time on the application due date may be withdrawn.

It is important to remember that these are just examples, and that all requirements specified in the SF424 (R&R) Application Guide, the Notice of Funding Opportunity, and relevant NIH Guide Notices are to be followed. Questions about application requirements can be directed to NIH "[Grants Info](#)" or the [Division of Receipt and Referral](#).

If an application is withdrawn because it does not conform to the application preparation and submission instructions, a letter will be placed in the eRA Commons Status page for that application.

2.3.9.6 Natural Disasters and Other Emergencies

For major disasters impacting many organizations, NIH will coordinate with other HHS components and Federal agencies (such as FEMA and OMB), as well as with state, local, and institutional representatives, to develop any additional response. NIH will consider such issues as whether a Federal Disaster is declared; the severity of damage inflicted; the length of time an organization may be required to close or that is required for recovery; the impact on investigators, human research subjects, and animal subjects; and the overall impact on the community.

Late applications due to natural disasters or other emergency situations are subject to the late application policy found in NIHGPS Section 2.3.9.2.1.

NIH responses to specific events will be issued in the form of an NIH Guide Notice published in the NIH Guide to Grants and Contracts.

2.3.10 Fraud, Waste and Abuse of NIH Grant Funds

Any individual who becomes aware of the existence (or apparent existence) of fraud, waste, or abuse related to NIH grants or grant funds should consider contact:

- Your institution's Office of Sponsored Research, Compliance Office, or other responsible office,
- The NIH CGMO listed in the NoA for the IC that funded the grant,
- The [DGCO/OPERA/OER](#).

In addition, allegations of criminal offenses should be reported to the Department of Health and Human Services, [OIG Hotline](#).

The OIG has authority within HHS to conduct criminal investigations. The HHS OIG maintains a post office box and a toll-free hotline for receiving information from individuals concerning fraud, waste, or abuse under HHS grants and cooperative agreements. The identity of the caller is kept confidential, and callers are not required to give their names. The address and telephone number of the [OIG](#) and the [OIG hotline](#) are included in Part III.

Further allegations of non-criminal misuse of grant funds, and recipient conflict of interest should be reported to the [NIH OMA](#).

OMA provides a centralized management survey and review capability to promote program integrity, conducts appraisals of alleged incidents of waste, fraud, and abuse and has lead responsibility for cases received through the Office of Inspector General (OIG) Hotline that are referred to NIH for action. OMA has no authority to undertake criminal investigations. OMA refers all allegations of criminal offenses to the OIG for investigation. The address and telephone number for the [OMA, DPI](#) are included in Part III.

False statements involving falsified, fabricated, or plagiarized information identified during research misconduct proceedings should be reported to the [NIH Extramural Research Integrity Officer](#).

Examples of fraud, waste, and abuse that should be reported include, but are not limited to, embezzlement, misuse, or misappropriation of grant funds or property, and false statements, whether by organizations or individuals. Other examples include theft of grant funds for personal use; using funds for non-grant-related purposes; theft of federally owned property or property acquired or leased under a grant; charging the Federal government for the services of “ghost” individuals; charging inflated building rental fees for a building owned by the recipient; submitting false financial reports; and submitting false financial data in bids submitted to the recipient (for eventual payment under the grant).

The Federal government may pursue administrative, civil, or criminal action under a variety of statutes relating to fraud and making false statement or claims. Part II includes administrative and other remedies the Federal government may use if a recipient deliberately withholds information or submits fraudulent information or does not comply with applicable requirements. Even if a grant is not awarded, the applicant may be subject to penalties if the information contained in or submitted as part of an application, including its certifications and assurances, is found to be false, fictitious, or fraudulent.

The Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 et seq., provides for the administrative imposition by HHS of civil penalties and assessments against any person who knowingly makes false, fictitious, or fraudulent claims to the Federal government for money, including money representing grants, loans, or benefits. A civil penalty of not more than \$5,500 may be assessed for each such claim. If a grant is awarded and payment is made on a false or fraudulent claim, an assessment of not more than twice the amount of the claim, up to \$150,000, may be made in lieu of damages. Regulations established by HHS at 45 CFR Part 79 specify the review process for imposing civil penalties and assessments, including hearing and appeal rights.

The Criminal False Claims Act, 18 U.S.C. 287, and 18 U.S.C. 1001, provides for criminal prosecution of a person who knowingly makes or presents any false, fictitious, or fraudulent statements or representations or claims against the United States. Violations of these statutes carry a maximum sentence of five and eight years imprisonment, respectively.

The Civil False Claims Act, 31 U.S.C. 3729(a), provides for imposition of penalties and damages by the United States, through civil litigation, against any person who knowingly makes a false or fraudulent claim for payment, makes or uses a false record or false statement to get a false claim paid or approved, or conspires to defraud the Federal government to get a false claim paid. A “claim” includes any request or demand for money or property made to the United States or to a contractor, recipient, or other recipient, if the Federal government provides or will reimburse any portion of the funds claimed. Civil penalties of \$5,500 to \$11,000 may be imposed for each false claim, plus damages of up to three times the amount of the damages the government sustains because of the violation, and the costs of any civil action brought to recover such penalties and damages.

NIH also may administratively recover misspent grant funds pursuant to the authorities contained in 2 CFR Part 200.

2.3.11 Availability and Confidentiality of Information

2.3.11.1 Availability of Information

Except for certain types of information that may be considered proprietary or private information that cannot be released, most grant-related information submitted to NIH by the applicant or recipient in the application or in the post-award phase is considered public information and, once an award is made, is subject to possible release to individuals or organizations outside NIH. The statutes and policies that require this information to be made public are intended to foster an open system of government and accountability for governmental programs and expenditures and, in the case of research, to provide information about federally funded activities.

NIH routinely places information about awarded grants, including project title, the name of the PD/PI, and the project description, on the [RePORT Web site](#). For funded research grant applications, NIH also sends the project description provided by an applicant to the DoC's NTIS. NTIS disseminates scientific information for classification and program analysis. The public may obtain the project descriptions from RePORT or request them from NTIS. Other information may be released case by case as described in this subsection.

Several policies require acknowledgment of support and a disclaimer for publications, inventions, and other research products, as provided in [Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources](#) and elsewhere in the NIHGPS.

2.3.11.2 Confidentiality of Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets, information that is commercial or financial, or information that is privileged or confidential, the pages containing that information should be identified as specified in the application instructions.

When such information is included in the application, it is furnished to the Federal government in confidence, with the understanding that the information will be used or disclosed only for evaluation of the application. The information contained in an application will be protected by NIH from unauthorized disclosure, consistent with the need for peer review of the application (including the agreement by peer reviewers and Advisory Council members to the NIH confidentiality and nondisclosure rules); and the requirements of the FOIA and Privacy Act (5 U.S.C. 552 as discussed below). However, if a grant is awarded as a result of or in connection with an application, the Federal government has the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Federal government's right to use the information if it is obtained without restriction from another source.

2.3.11.2.1 Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a (as amended), and its implementing regulations (45 CFR Part 5b) provide certain safeguards for information about individuals maintained in a system of records (i.e., information may be retrieved by the individual's name or other identifying information). These safeguards include the rights of individuals to know what information about them is maintained in Federal agencies' files (hard copy or electronic) and how it is used, how they may obtain access to their records, and how to correct, amend, or request deletion of information in their records that is factually incorrect.

The NIH maintains application and grant records as part of a system of records as defined by the [Privacy Act: NIH 09-25-0225](#).

This system of record provides guidance on requirements for the management of applicable grant records in NIH's possession and include appropriate routine uses of such information. It also includes requirements for safeguarding the records and for record retention and disposal.

Parties other than PD/PIs may request the release of Privacy Act grant records. Such requests are processed under FOIA. For example, information requested by co-investigators in grant applications is released to them only when required under FOIA because they have no right of access under the Privacy Act. When releasing information about an individual to a party other than the subject of the file, NIH will balance the individual's right to privacy with the public's right to know as provided by the FOIA.

Records maintained by recipients ordinarily are not subject to the requirements of 45 CFR Part 5b.

2.3.11.2.2 The Freedom of Information Act

The Freedom of Information Act, 5 U.S.C. 552, and implementing HHS regulations (45 CFR Part 5) require NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information. These policies and regulations apply to information in the possession of NIH. Generally, NIH cannot require recipients or contractors under grants to permit public access to their records. An exception related to certain research data is described in this subsection.

NIH generally will release the following types of records pursuant to a FOIA request:

- Funded applications and funded progress reports, including award data.
- Final reports that have been transmitted to the recipient organization of any audit, survey, review, or evaluation of recipient performance.

NIH generally will withhold the following types of records or information in response to a FOIA request:

- Pending competing grant applications
- Unfunded new, renewal, and revision applications
- Financial information pertaining to project personnel, such as institutional base salary information
- Information pertaining to an individual, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
- Predecisional opinions in interagency or intraagency memorandums or letters expressed by Federal government officers, employees, or consultants
- Evaluative portions of site visit reports and peer review summary statements, including impact scores
- Trade secrets and commercial, financial, and otherwise intrinsically valuable items of information that are obtained from a person or organization and are privileged or confidential
- Information which, if released, would adversely affect the competitive position of the person or organization
- Patent or other valuable commercial rights of the person or organization

Applicants are instructed to identify proprietary information at the time of submission of an application. If, after receiving a FOIA request, NIH has substantial reason to believe that information in its records could reasonably be considered exempt from release, the appropriate NIH FOI office will notify the applicant or recipient, through the PD/PI, before the information is released. In the case of multiple PD/PI's the Contact PD/PI will be notified and is responsible for coordinating any response to the notice.

Multiple responses to the notice will not be accepted. If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA. The PD/PI will be given five (5) working days to identify potentially patentable or commercially valuable information that the PD/PI believes should not be disclosed. Any such submission must be specific as to the nature and type of commercial harm that will result if the requested information is released. Submissions that merely state in general terms that the grant application or portions should not be released will not be honored. If the PD/PI does not respond within that time period, the grant will be prepared for release in accordance with applicable FOIA policies and released to the requester. If the PD/PI does identify commercial or proprietary information an NIH official will review that response. After NIH consideration of the response, the PD/PI and recipient will be informed if NIH does not agree with the PD/PI's position. If a document contains both disclosable and non-disclosable information, the non-disclosable information will be redacted and the balance of the document will be disclosed.

The HHS regulations implementing FOIA provide that only the NIH FOI Officer may deny requests for information. Requests for information, the release of which is believed to be exempt under FOIA, are referred to the NIH FOI Officer along with written documentation of the rationale for nondisclosure. If the NIH FOI Officer determines that the requested information is exempt from release under FOIA, the requester may appeal that determination to the Deputy Assistant Secretary for Public Affairs (Media), HHS. Additional information on the FOIA process is available at the [NIH FOI Office Web site](#).

2.3.11.2.3 Release of Research Data

NIH handles requests for the release of research data by certain types of recipients as FOIA requests. The term “research data” is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings. It does not include preliminary analyses; drafts of scientific papers; plans for future research; peer reviews; communications with colleagues; physical objects (e.g., laboratory samples, audio or video tapes); trade secrets; commercial information; materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal; information that is protected under the law (e.g., intellectual property); personnel and medical files and similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy; or information that could be used to identify a particular person in a research study.

As required by 2 CFR Part 200.315, recipients that are institutions of higher education, hospitals, or non-profit organizations must release research data first produced in a project supported in whole or in part with Federal funds that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., regulations and administrative orders). If the data are publicly available, NIH directs the requester to the public source. Otherwise, the IC FOI coordinator handles the request, consulting with the affected recipient and the PD/PI. This requirement also provides for assessment of a reasonable fee to cover recipient costs and (separately) the NIH costs of responding.

This requirement to release research data does not apply to for-profit organizations or to research data produced by State or local governments. However, if a State or local governmental recipient contracts with an IHE, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to the disclosure requirement.

Additional information is available on the [NIH scientific data sharing website](#). Additional information is available on the [Data Management & Sharing Policy Overview web page](#). (Also see [Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources](#).)

2.3.12 Protecting Sensitive Data and Information Used in Research

Recipients of NIH funds have a vital responsibility to protect sensitive and confidential data as part of proper stewardship of federally funded research, and take all reasonable and appropriate actions to prevent the inadvertent disclosure, release or loss of sensitive personal information. NIH advises that personally identifiable, sensitive, and confidential information about NIH-supported research or research participants not be housed on portable electronic devices. If portable electronic devices must be used, they should be encrypted to safeguard data and information. These devices include laptops, tablets, mobile devices, CDs, disc drives, flash drives, etc. Researchers and institutions also should limit access to personally identifiable information through proper access controls such as password protection and other means. Research data should be transmitted only when the security of the recipient's systems is known and is satisfactory to the transmitter. See also [Public Policy Requirements and Objectives—Federal Information Security Management Act](#).

2.4 THE PEER REVIEW PROCESS

NIH policy is intended to ensure that applications for funding submitted to NIH are evaluated on the basis of a process that is fair, equitable, timely, and conducted in a manner that strives to eliminate bias. Competing applications for NIH grants and cooperative agreements, including renewals and revisions, are subject to peer review as required by sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006 and 21st Century Cures Act. The peer review system used by NIH, often referred to as the “dual review system,” is based on two sequential levels of review for each application—initial review by an IRG or SRG, and a second level of review for scientific merit by the IC National Advisory Council/Board.

The NIH peer review process has evolved over the years to accommodate increasingly collaborative and multi-disciplinary research, changes in workload, resource constraints, and recommendations of various scientific and professional groups. However, the underlying basis for the system—to provide a fair and objective review process in the overall interest of science—has not changed. Information concerning NIH's peer review process may be found at [NIH's web site](#) or Peer Review Policies and Practices on the NIH [Grants & Funding web site](#).

2.4.1 Initial Review

2.4.1.1 Responsibilities

The DRR in the CSR receives all competing grant applications submitted to NIH, whether the peer review will be conducted by CSR or by an IC. The primary determining factors in whether CSR or an IC will be responsible for the peer review are the announcement type, the support mechanism, and/or the program. In general, CSR is responsible for the initial review of research project grant applications (including NIH Research Enhancement Award applications), Kirschstein-NRSA individual fellowship applications, and SBIR/STTR applications, while the ICs handle the initial review of applications that have Institute-specific features such as conference grant applications, applications resulting from RFAs, and program project and center grant applications. CSR also may review other types of applications at an IC's request.

When the IC is responsible for the initial review, CSR reviews the application for completeness and staff in the soliciting IC review the application for responsiveness to the RFA/PAR/PAS, if applicable. The scientific review office in that IC coordinates the initial technical review for scientific merit and prepares the summary statements.

CSR Referral Officers, who are senior health scientist administrators with both research and scientific review experience, assign each application to one or more ICs for potential funding and to an IRG or SRG for initial review of the scientific merit of the application. These assignments are made on the basis of the application's contents, the referral guidelines, and any written request by the applicant organization (accompanying the application) for a specific study section or IC assignment.

SRGs, including CSR study sections, are organized by scientific discipline or current research areas and are managed by health scientist administrators functioning as SROs. Generally, study sections are chartered groups composed of formally appointed members serving multiyear terms, to which the SRO often adds temporary members or other additional reviewers. Ad hoc SEPs are formed to review applications that cannot be reviewed by a standing review group or study section because they require special expertise or involve other special circumstances.

SRGs, whether study sections or SEPs, are primarily composed of non-federal scientists who have expertise in relevant scientific disciplines and are actively engaged in research. NIH's conflict-of-interest and confidentiality of information requirements for reviewers are intended to promote an unbiased review process by minimizing even the appearance of a conflict of interest and by restricting the use of privileged application information.

Applicants are notified by e-mail that their application has been received and that they can find information about the application's SRO, SRG, and IC assignments in eRA Commons. At this time, applicants may request reconsideration of the SRG and IC assignment. Applicants also are notified by e-mail to check eRA Commons for any change in the application's SRG or IC assignment, as well as a change in Council date. Once the assignment process is completed, the SRO, not the PO, is the primary contact for communication with the applicant until the summary statement is released. An applicant organization may withdraw an application from consideration at any time during the review process. A request to withdraw an application must be signed by the PD/PI and an AOR, and submitted to the SRO.

In preparation for the initial review, SROs review applications to determine whether they are complete and conform to administrative requirements. For each reviewable application, they then assign (from among the standing and temporary members) at least three reviewers to write a critique of the application, provide initial scores, and to be prepared to discuss the application in detail.

Following the initial review, the SRO prepares a summary statement for most applications reviewed. The summary statement includes the reviewers' written comments, and, for scored applications, a summary of the discussion, and an impact score. Summary statements are then simultaneously provided to the IC's program staff, Advisory Councils, the PD(s)/PI(s), and applicant institution's Authorized Organization Representative.

2.4.1.2 Overall Impact

The SRG assesses overall impact in the determination of scientific and technical merit; overall impact is defined based on the different types of applications. When considering applications for research grants and cooperative agreements, reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five scored review criteria, and additional review criteria (as applicable for the project proposed). All the criteria, weighted as appropriate for each application or as described in the NOFO, will be considered when assigning the overall impact score.

2.4.1.3 Scored Review Criteria

The goals of NIH-supported research are to advance the understanding of biological systems, improve the control of disease, enhance health, and reduce illness and disability. For research grant applications, and most other types of applications, reviewers evaluate the overall impact to reflect their assessment of

the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, taking into account, among other pertinent factors: Significance, Investigator(s), Innovation, Approach, and Environment. These scored review criteria may not be applicable for some types of applications. When these criteria are not applicable, the NOFO will include the specific review criteria.

Reviewers will consider each of the five criteria below in the determination of scientific and technical merit, and determine a separate score for each. An application does not need to be strong in all categories to be evaluated likely to have a major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

The NOFO should be consulted for additional information describing each of the scored review criteria.

2.4.1.4 Additional Review Criteria

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- Diversity Plan (for Conference Grant Applications)
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan.
- Vertebrate Animals
- Biohazards
- Resubmission Applications
- Renewal Applications
- Revision Applications

The NOFO should be consulted for additional information describing each of the relevant additional review criteria.

2.4.1.5 Additional Review Considerations

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and Reviewers should not consider these items in providing an overall impact score.

- Provision of Family Care Facilities (for Conference Grant Applications)
- Applications from Foreign Organizations
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

The NOFO should be consulted for additional information describing each of the relevant additional review considerations.

Although the review criteria are intended for use primarily with investigator-initiated research project grant applications (e.g., R01 and P01), including those in response to PAs, to the extent reasonable, the criteria also will form the basis of the review of solicited applications and research related activities. However, for some activities (e.g., construction grants), the use of these criteria may not be feasible. Applications also may be reviewed against other pertinent factors as stated in NOFOs.

2.4.2 Appeals of Initial Scientific Review

To preserve and underscore the fairness of the NIH peer review process, NIH has established a peer review appeal system to provide applicants the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was procedurally flawed. The NIH policy for appeals of initial peer review does not apply to appeals of the technical evaluation of Research and Development contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT awards. In addition, NIH will not review a resubmission application when an appeal of initial peer review is pending on the original application. As stated in the Notice of Funding Opportunity, appeals of initial peer review outcome will not be accepted for applications in response to an RFA.

An appeal is a written communication from a Program Director/Principal Investigator (PD/PI) and/or applicant institution that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw or perceived flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence from the Authorized Organization Representative (AOR).

An applicant who is concerned about procedural aspects related to the completed initial peer review of their application first should consider the comments in the summary statement, and then should contact the appropriate NIH Program Official (PO). Following discussion of concerns with the PO, if the PD/PI and/or an official of the applicant organization wishes to appeal the outcome of the initial peer review process, an appeal letter must be submitted, either in hard copy or electronically, to the PO. The appeal letter must display concurrence from the AOR of the applicant organization for the application. Although the content of the appeal letter may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the letter directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and AOR concurrence to the PO. A communication from the PD/PI or official of the applicant organization (other than the AOR) only or with a “cc” to the AOR will not be accepted. The PO will send the PD/PI and/or institutional official, and AOR, an acknowledgement letter within 10 days of receipt of the appeal letter.

An appeal letter will be accepted only if the letter 1) describes the flaws in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers.
- Conflict of interest, as specified in regulation at [42 CFR Part 52h.5 “Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects”](#), on the part of one or more non-Federal peer reviewers.
- Lack of appropriate expertise within the SRG.

- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal letter, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

If review staff and program staff do not support the appeal, or do not agree on its merit, the PD/PI and/or an institutional official (not necessarily the AOR) may elect to withdraw the appeal letter. The request to withdraw an appeal letter must be submitted either in hard copy or electronically to the PO, and must display concurrence from the AOR of the applicant organization for the application. Although the content of the request may originate from the PD/PI, Contact PD/PI for multiple PD/PI applications, or an organizational official(s) (not necessarily the AOR), the AOR must send the request directly to the PO, or must send their concurrence to the PD/PI who will forward the materials and their concurrence to the PO. A communication from the PD/PI or institutional official (other than the AOR) only or with a “cc” to the AOR will not be accepted.

If review staff and program staff do not support the appeal, or do not agree on its merit, and the appeal letter is not withdrawn, the appeal letter will be made available to Council. The IC may not deny the PD/PI or applicant organization the opportunity to have an appeal letter made available to Council. Only two outcomes are possible following consideration of an appeal letter by Council:

- The Council may concur with the appeal, and recommend that the application be re-reviewed.
- The Council may concur with the SRG's recommendation and deny the appeal. Although factual errors or other issues may be evident, the Council may determine that these factors were unlikely to alter the final outcome of the SRG and deny the appeal. No action by the Council is equivalent to concurrence with the SRG's recommendation and denial of the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

The Executive Secretary for the Council will communicate the Council recommendation concerning an appeal to the PD/PI, AOR, and NIH staff with a need to know. If the appeal letter was received by the IC deadline, the PD/PI and AOR will receive a written explanation of the resolution no later than 30 calendar days after the Council meeting. If the appeal letter was received after the IC deadline, the Executive Secretary will provide, no more than 30 calendar days after the date when the appeal letter was received, a written explanation of the IC's plan for making the appeal available to Council.

If the Council recommended that the application be re-reviewed, the original application will be re-reviewed without additional materials or modifications. The application may be re-reviewed by the same or a different SRG, depending on the flaws in the original review process that led to the appeal. In most cases, the re-review will entail re-assignment to a subsequent review round and delay in the final funding decision. The outcome of the re-review is final and cannot be appealed again.

On occasion, and for specific circumstances, the NIH may suspend temporarily the policy and process for handling appeals of NIH initial peer review. Such decisions will be announced in NIH Guide Notices and/or the relevant Notice of Funding Opportunity when they are issued in the [NIH Guide for Grants and Contracts](#).

2.4.3 National Advisory Council or Board Review

Summary statements for those applications recommended for further consideration are presented to the assigned IC National Advisory Council or Board (hereafter “Council”) for use in the second level of

review. Council members include senior scientists with broad experience and members of the public with general knowledge of, and interest in, the IC's mission. The Council reviews applications not only for scientific and technical merit, as judged by the SRG, but also for relevance to the IC's programs and priorities. The Council may concur with the SRG's recommendation, may decide not to recommend an application on the basis of program or policy considerations, or may recommend deferral of an application and refer it back to the SRG for re-review.

In addition, Council members will receive a list of competing applications that will be considered for funding from PD/PIs that meet the threshold for Special Council Review. These are investigators who currently receive \$2 million or more in total costs (inclusive of direct and indirect) per year of NIH funding to support Research Project Grants. Council members will be asked to recommend consideration of funding for applications that afford a unique opportunity to advance research which is both highly promising and distinct from the other funded projects from the PD/PI. This does not represent a cap to NIH funding.

With very limited exception, an application may not be considered for funding unless it has received a favorable recommendation by both the SRG and the Council. For some applications (e.g., Kirschstein NRSA Fellowship applications) the second level of review is conducted by senior level IC staff.

2.4.4 Disposition of Applications

All incomplete applications, non-compliant applications, and applications determined to be non-responsive to NOFO requirements will not be reviewed. If the NOFO remains open with subsequent submission dates, the applicant may resubmit a corrected or complete version of an investigator-initiated application for consideration in the next review cycle. An application may resubmit one application may be submitted for an appropriate due date up to 37 months after the application due date of the initial application, provided the NOFO allows resubmission applications. Any application on the same topic proposed as a resubmission more than 37 months from the initial receipt date will not be accepted; it must be formatted and submitted as a new application.

For complete, compliant and responsive applications, following the initial scientific peer review, the summary statement will be available to the PD/PI and AORs of the applicant organization with the Signing Official (SO) user role in the eRA Commons. Applicants just receiving their summary statements should consult the NIH Next Steps page for detailed guidance. If an application does not result in funding, there may be an opportunity to respond to the reviewers' comments and resubmit the application, provided the NOFO allows resubmission applications. Applicants seeking advice beyond that available online may want to contact the NIH Program Officer listed at the top of the summary statement.

The IC Director or designee is the official who has the authority to make final award decisions from among those applications receiving a favorable initial review and Council recommendation. If an application has been recommended for further consideration but is not expected to be funded in the current cycle, the application may be held by NIH for one or more additional cycles and will compete with other applications submitted for that cycle. If an application is unsuccessful, the applicant may subsequently submit one revised version of the application (referred to as a resubmission) for review in a future cycle.

Some of the ICs publish paylines as part of their [funding strategies](#) to guide applicants on their likelihood of receiving funding. Application scores can only be compared against the payline for the fiscal year when the application will be considered for funding, which is not necessarily the year when it was submitted. At the beginning of fiscal years when the agency awaits an actual budget, there may be a delay of several months to determine paylines. If the application is assigned to an IC that does not announce a payline, the Program Officer listed at the top of the summary statement may be able to provide guidance on the likelihood of funding.

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The process leading to an award, including the business management review performed by the GMO, is described in [Completing the Pre-Award Process](#) below.

For unsuccessful applicants, the NIH will send a centralized, automated correspondence to the applicant organizations to notify them of NIH's intent not to fund the indicated applications.

The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any NIH or HHS official or board.

2.5 COMPLETING THE PRE-AWARD PROCESS

Following the peer review process, applications that an IC may fund are reviewed for a number of other considerations. These include, as applicable, alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements. The applicant may be asked to submit additional information (such as other support or verification of IACUC approval) or to undertake certain activities (such as negotiation of an F&A cost rate) in anticipation of an award. However, such requests by NIH do not guarantee that an award will be made. Following review of all applicable information, the IC will determine whether an award can be made, if specific award conditions are required, and what level of funding is appropriate.

Although these reviews and determinations occur before NIH makes a new award, recipients must continue to comply with eligibility and public policy requirements and maintain adequate management systems throughout the period of support. The pre-award process for non-competing continuation awards is a streamlined version of this process, including an assessment of progress (see [Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports](#)).

2.5.1 Just-in-Time Procedures

NIH uses Just-in-Time procedures for certain programs and award mechanisms (each NOFO will include specific guidance on the use). These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include other support information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure. (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.)

Applicants will be notified (primarily by e-mail) when Just-in-Time information is needed. This notification is not a Notice of Award nor should it be construed to be an indicator of possible funding. Applicants should only submit this information when requested. Information must be submitted electronically using the Just-in-Time feature in the eRA Commons. In some circumstances the GMO may ask for information in addition to the descriptions below, e.g., if the application involves hESCs and the applicant did not identify a hESC from the NIH Registry in the application.

The requirement for applicants to verify the accuracy and validity of all administrative, fiscal, and programmatic information extends to information submitted through the Just-in-Time process. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award. This includes items such as Other Support changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PI(s) or any Senior/Key Personnel; or any changes in the use or approval of vertebrate animals or

human subjects. Similar to the NIH public policy requirements, applicants are responsible for establishing and maintaining the necessary processes to monitor its compliance and informing NIH of any problems or concerns. Failure to address changes to Just-in-Time submissions prior to award does not diminish the applicant's responsibility to address changes post-award by submitting a prior approval request to NIH in accord with Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award.

Other Support. Information on other active and pending support will be requested as part of the Just-in-Time procedures. Other support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes:

- Resources and/or financial support from all foreign and domestic entities that are available to the researcher. This includes but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.). Institutional resources, such as core facilities or shared equipment that is made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources.
- Consulting agreements, when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities and the activities fall outside of their appointment at the applicant or recipient institution.
- In-kind contributions, e.g., office/laboratory space, equipment, supplies, or employees or students supported by an outside source. If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, the recipient must provide reasonable estimates.

Other support does not include training awards, prizes, or gifts. Gifts are resources provided where there is no expectation of anything (e.g., time, services, specific research activities, money, etc.) in return. An item or service given with the expectation of an associated time commitment is not a gift and is instead an in-kind contribution and must be reported as Other Support.

Reporting of other support is required for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Each PD/PI or other senior/key personnel must electronically sign their respective Other Support form prior to submission. This signature certifies that the statements are true, complete, and accurate. Information on Other Support is not specifically requested for Program Directors, training faculty, and other individuals involved in the oversight of training grants since applicable information is collected in other sections of a training grant application. It is also not requested for individuals categorized as Other Significant Contributors.

Recipients are expected to establish and maintain effective internal controls (e.g. policies and procedures) to ensure that individuals designated in applications as senior/key personnel fully disclose all Other Support information to their institution as soon as it becomes known. When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the recipient must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

For Other Support submissions that include foreign activities and resources, recipients are required to submit copies of contracts, grants, or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution as supporting documentation. If they are not in English, recipients must provide translated copies. This does not include personal service contracts, or employment contracts for fellows supported by foreign entities.

The supporting documentation must be provided as part of the Other Support PDF following the Other Support Format page. See NIH Other Support page for forms, instructions, and other resources.

IC scientific program and grants management staff will review this information before award to ensure the following:

- Sufficient levels of effort are committed to the project.
- There is no scientific, budgetary, or commitment overlap.
 - Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.
 - Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.
 - Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application.
 - Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the IC with the applicant and the PD/PI at the time of award.
- Only funds necessary for the approved project are included in the award.
- Any foreign resources that meet the definition of a foreign component have received appropriate prior approval.

See [NIH Other Support](#) for format page, instructions and the [NIH disclosure table](#).

Certification of IRB Approval. If the proposed project involves human subjects research, a certification to NIH that all non-exempt research involving human subjects has been reviewed and approved by an appropriate IRB must be submitted. Pending or expired approvals are not acceptable. See Public Policy Requirements/Human Subjects for additional information.

Verification of IACUC Approval. If the proposed project involves research with live vertebrate animals, verification of the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable. See Public Policy Requirements/Animal Welfare for additional information.

Human Subjects Research Education Requirement. If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted. See Public Policy Requirements/Human Subjects/Education in the Protection of Human Research Participants for additional information.

Human Embryonic Stem Cells (hESCs). If the proposed project involves hESCs and the applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line(s) should be included in the Just-in-Time submission.

Genomic Data Sharing Institutional Certification. If the proposed project involves research subject to the Genomic Data Sharing policy for the generation of human genomic data (including within the Data Management and Sharing Plan, as applicable), investigators must submit an Institutional Certification,

or, in some cases, a Provisional Institutional Certification. Institutional certification forms and directions for completing them are available on the NIH GDS Data Sharing website. This certification must be submitted as a “Genome Data Sharing Certification” file in the eRA Commons Just-in-Time module.

SBIR Foreign Disclosure Form. For SBIR and STTR competing applications, applicants must submit the Required Disclosure of Foreign Affiliations or Relationships to Foreign Countries form. See NIH SBIR and STTR Foreign Disclosure requirements for more information. This form must be submitted as an “SBIR STTR Foreign Disclosure Form” file in the eRA Commons Just-in-Time module.

SBIR Funding Agreement Certification. For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification described in Section 2.18 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://grants.nih.gov/grants/forms/manage_a_small_business_award.htm. This should be submitted as an “Other Upload” in the eRA Commons Just-in-Time module.

STTR Funding Agreement Certification. For STTR applicants, provide only upon request the STTR Funding Agreement Certification described in Section 2.19 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://grants.nih.gov/grants/forms/manage_a_small_business_award.htm. This should be submitted as an “Other Upload” in the eRA Commons Just-in-Time module.

My Bibliography Report of Publications. For renewal applicants to research training programs, a My Bibliography Report of Publications arising from work conducted by trainees while supported by the training grant will be collected in the Interim/Final Research Performance Progress Report.

Other Information Requested by the Awarding IC. NIH IC’s may also request additional Just-in-Time information on a case-by-case basis, such as revised budgets or changes to the human subjects or vertebrate animals sections of the application. If required, these changes must be submitted as an “Other Upload” file in the eRA Commons Just-In-Time module.

2.5.2 Submitting Revised Project Summary/Abstracts, Specific Aims, and/or Public Health Relevance Statement

When requested by NIH as part of the pre-award process, PD/PIs and the AOR should discuss potential changes in scope with NIH PO and revise the Project Summary/Abstract, Specific Aims, and/or Public Health Relevance sections of their application as appropriate. Once all issues are resolved, applicants should e-mail a document with final versions of the revised sections to the IC-designated e-mail address (normally a Program Official, Grants Management Official, or centralized e-mail box) as a single Microsoft Word file only. Be reminded that all revised application information submitted to the NIH must be approved by an AOR. Applicants should use [this template](#). The template includes specific headings that must be used for each section. All three headings must be included in the document that is submitted even if a particular section had no changes from the previous submission. If there are no changes for a section include the header but leave the text area blank to ensure appropriate processing of this information by NIH’s electronic systems.

2.5.3 Determining Applicant Organization Eligibility

All applicant organizations must complete the one-time eRA Commons registration process ([see NIHGPS 2.2.1 eRA Commons Registration](#)) prior to submitting any application (paper or electronic) to the NIH. During the registration process, NIH may make a preliminary assessment of applicant organization eligibility. In an effort to streamline the registration requirements and reduce the administrative

burden (i.e., time between registration submission and NIH's final determination), NIH urges potential applicants to consider the following eligibility considerations:

- What is the nature of the research and business that your organization performs and how does that fit within the NIH mission?
- Is your organization professionally responsible for the research?
- How many people are in your organization?
- Are the researchers employed by your organization?
- Where will the proposed research physically be conducted?
- Can you identify a Notice of Funding Opportunity that you would apply for?
- Has your organization applied to and/or been directly funded by any other Federal agency?

Applicants should be prepared to establish their eligibility to receive and administer all awards (that are applied for), and NIH reserves the right to deny registration if an organization is determined not to be an appropriate applicant for a particular NOFO. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information.

NIH awards may be made only to eligible applicants. Continued funding is dependent on the recipient's continued eligibility. In general, domestic or foreign, public or private, non-profit or for-profit organizations and individuals are eligible to receive NIH grants. However, on the basis of statutory, regulatory, or published policy limitations, under certain programs or types of awards, NIH may limit eligibility to, or exclude from eligibility, classes or types of entities. Examples are limitations on the participation of foreign entities, and programs under which only small businesses are eligible applicants. The determination of eligibility includes verification of the applicant's status. The applicant may be required to provide proof of its status by submitting documentation; otherwise, the AOR's signature on the application certifies that the applicant is eligible to apply for and receive an award (e.g., a small business applying under the SBIR or STTR programs).

In addition to reviewing organizational eligibility, NIH may consider other factors relating to the applicant's ability to responsibly handle and account for Federal funds and to carry out the project. These factors include the applicant's intended role in the project, the location where the project will be performed, the role of the PD/PI in the project, and the PD/PI's employment and citizenship status. Although some of these same considerations are reviewed as part of the peer review, NIH's concern at this stage in the process is making an award to a legal entity that will be accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. NIH will not make an award to an applicant that does not have a substantive role in the project and would simply serve as a conduit for another entity.

2.5.4 Determining Eligibility of Individuals

It is the responsibility of the applicant organization to select the individuals who have the appropriate expertise to manage the scientific and administrative aspects of the project. The eligibility of these individuals to complete the project will be evaluated during peer review and at the IC level by grants management and program staff.

The GMO will verify whether the proposed PD/PI or other senior/key personnel are debarred or suspended from participation in Federal assistance programs (see [Public Policy Requirements and Objectives—Debarment and Suspension](#) for certification requirements).

Generally, PD/PIs and other personnel supported by NIH research grants are not required to hold any particular educational degree, and are not required to be U.S. citizens. However, some NIH programs/mechanisms have a citizenship requirement. Any citizenship requirement will be stated in the NOFO. In these cases, individuals are required to have the appropriate citizenship status when the award is made rather than when the application is submitted. For example, under most career development awards or Kirschstein-NRSA individual fellowships, the individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence at the time of award.

NIH requires the applicant to determine that individuals' visas will allow them to remain in this country long enough for them to be productive on the research project, but NIH does not provide guidance on or assess the different types of visas. NIH expects recipient organizations to have policies, consistently applied regardless of the source of funds, to address this area. If a grant is awarded and an individual's visa will not allow a long enough stay to be productive on the project, NIH may terminate the grant (see [Administrative Requirements—Changes in Project and Budget](#) and [Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support](#)).

The eligibility requirements for trainees and additional eligibility requirements for fellows are addressed in [Ruth L. Kirschstein National Research Service Awards](#) chapter in IIB.

In the post-award phase, NIH monitors changes in recipient and project status to ensure they meet legal and programmatic requirements and takes actions necessary to protect the Federal government's interests.

2.5.5 Cost Analysis and Assessment of Management Systems

The GMO will ensure that a cost analysis is performed on any application that requires a detailed budget. Cost analysis involves obtaining cost breakdowns, validating cost data, evaluating specific elements of cost, and examining data to determine the necessity for, and the reasonableness and allowability of, the costs included in the application budget. The extent of cost analysis will depend on the type of funding instrument and award mechanism, the complexity of the project, prior experience with the applicant, and other factors. Information on the applicable cost principles and on allowable and unallowable costs under NIH grants is provided in the [Cost Considerations](#) chapter.

The amount of NIH funding is based on reasonable and allowable costs consistent with the principles of sound cost management, considering IC priorities (e.g., program relevance), constraints on the growth of average grant costs, and available funds.

In addition to considering the specific information provided in the application, the GMO determines the adequacy of the applicant's financial and business management systems that will support the expenditure of and accountability for NIH funds. When an applicant has had no prior Federal grants or cost-reimbursement contracts, the GMO may review the applicant's financial management and other management systems before award, or within a reasonable time after award, to determine their adequacy and acceptability. For an applicant with prior NIH or other Federal cost-reimbursement awards, the GMO may review recent audit reports and other relevant available information to determine whether the applicant's management systems meet the standards established in 2 CFR Part 200. The GMO will advise the applicant if additional information is required. Based on the results of the review results, the GMO will determine the need for any corrective action and may impose specific award conditions on the award.

PART II: TERMS AND CONDITIONS OF NIH GRANT AWARDS

Subpart A: General

3 OVERVIEW OF TERMS AND CONDITIONS

Part II includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards. Subpart A (IIA) includes those terms and conditions that apply, in general, to NIH awards. Subpart B (IIB) either expands on IIA coverage or specifies additional or alternate terms and conditions for particular types of awards, recipients, or activities.

These terms and conditions are not intended to be all-inclusive. All awards or a specified subset of awards also may be subject to additional requirements, such as those included in executive orders and appropriations acts.

[NIH recipients are responsible for complying with all requirements of the Federal award.](#) NIH grants awards are based on the application submitted to, and approved by, the NIH and are subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in the NoA.
- The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in [appropriations acts](#). This also includes any recent legislation.
- 2 CFR Part 200.
- The NoA including all terms and conditions cited on the document or attachments.

Notice of requirements not specified in the NIHGPS generally will be provided in the NoA, but such notice is not required for the award to be subject to the requirements of pertinent statutes and regulations. An individual award also may contain award-specific terms and conditions. For example, the GMO may include terms or conditions necessary to address concerns about an applicant's management systems.

Program and administrative policies and the terms and conditions of individual awards are intended to supplement, rather than substitute for, governing statutory and regulatory requirements. Thus, the requirements of the NIHGPS apply in addition to governing statutory and regulatory requirements not cited herein, and award-specific terms apply in addition to the requirements of the NIHGPS.

This NIHGPS is an aid to the interpretation of statutory and regulatory requirements. These terms and conditions are intended to be compliant with governing statutes and the requirements of 2 CFR Part 200, as modified by previously approved waivers and deviations. However, in the case of a conflict, the statutes and regulations govern.

If there is a perceived conflict between or among these three categories of requirements—statutory and regulatory requirements, the terms and conditions in the NIHGPS, and award-specific terms and conditions—or if the recipient has other questions concerning award terms and conditions, the recipient

should request written clarification from the GMO. This may be done at any time; however, if the inclusion of the term or condition would cause the recipient not to accept the award or to be unable to comply, the question should be raised before funds are requested from the HHS payment system. By drawing funds from the HHS payment system, the recipient agrees to the terms and conditions of the award.

3.1 FEDERALWIDE STANDARD TERMS AND CONDITIONS FOR RESEARCH GRANTS

In order to create greater consistency in the administration of Federal research awards, all Federal research agencies now utilize a standard core set of administrative terms and conditions on research and research-related awards that are subject to 2 CFR Part 200, to the extent practicable. The core set of administrative requirements for participating Federal research agencies and other pertinent documents are posted on the [National Science Foundation's web site](#). Recipients are encouraged to review the companion documents which include a Prior Approval Matrix, National Policy Requirement Matrix, Subaward Requirement Matrix, and Agency-Specific Requirements. NIH implementation of these Federalwide research terms and conditions is also known as the "NIH Standard Terms of Award".

See [Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award](#) for more details.

4 PUBLIC POLICY REQUIREMENTS, OBJECTIVES AND OTHER APPROPRIATION MANDATES

NIH grants are subject to requirements intended to ensure that recipient organizations handle their Federal awards responsibly. Recipients are required to adopt and enforce policies that minimize the opportunity for improper financial gain on the part of the organization, its employees, and organizations and individuals whom they may collaborate, and that limit the potential for research results to be tainted by possible financial or other gain. In addition, NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.

This chapter addresses public policy requirements, objectives, and other appropriation mandates applicable to NIH awards. The term “public policy” indicates that the requirement is based on social, economic, or other objectives or considerations that may be attached to the expenditure of Federal funds by recipients, subrecipients, and contractors, in general, or may relate to the expenditure of Federal funds for research or other specified activities.

In addition to cross-cutting requirements that some or all Federal agencies must apply to their grant programs, NIH recipients and subrecipients are subject to requirements contained in the HHS annual appropriations act that apply to the use of NIH grant funds, applicable provisions in other Federal agencies’ appropriations acts, including Treasury, and other Federal statutes. Some of those requirements are included here in a separate section titled Appropriation Mandates since they have been included in the appropriations acts for several years with little or no change. Those requirements may be changed or other requirements may be added in the future.

The public policy requirements, objectives, and appropriation mandates listed in Exhibit 4 apply to all NIH awards with exceptions as noted.

4.1 PUBLIC POLICY REQUIREMENTS AND OBJECTIVES

NIH intends to uphold high ethical, health, and safety standards in both the conduct of the research it funds and the expenditure of public funds by its recipients. The public policy requirements specified in this section set many of those standards. NIH will not accept forms or other documentation bearing generic departmental signatures or their electronic equivalent (e.g., Department of Sponsored Research). All forms and documentation submitted to NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information. The signature of the AOR on the application certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced (and, in some cases, included) in the application instructions. The policies, certifications and assurances listed in this section may or may not be applicable to the project, program, or type of applicant organization. Requirements / objectives are listed in alphabetical order.

As noted in this section, some requirements may necessitate the submission of a separate document (e.g., human subjects assurance, certification of IRB approval or institutional exemption, civil rights assurance). Applicants and recipients should take particular note of these requirements (for example, see specific sections on [Human Subjects Protections](#) and [Civil Rights Protections](#)), the absence or inadequacy of which may delay an award or render an applicant ineligible for award.

The recipient is responsible for: 1) establishing and maintaining the necessary processes to monitor its compliance and that of its employees, consortium participants, and contractors with these requirements; 2) taking appropriate action to meet the stated objectives; and, 3) informing NIH of any problems or concerns.

If a grant is awarded on the basis of false or misrepresented information, or if a recipient does not comply with these public policy requirements, NIH may take any necessary and appropriate action, including using any of the remedies described in [Administrative Requirements—Enforcement Actions](#) or other available legal remedies.

Exhibit 4 contains information to help the recipient determine what public policy requirements, objectives and appropriations mandates apply to its activities and whether a requirement should be included in a consortium agreement or a contract for routine goods or services under the grant (see [Glossary](#) in Part I for definitions). The exhibit distinguishes between these types of transactions under a grant and indicates (by “Y” for Yes or “NA” for Not Applicable) whether a given requirement normally would apply. However, even if the exhibit indicates that a requirement is not applicable that requirement potentially could be applicable in a specific situation, e.g., if a contract under a grant involves research activity. Therefore, this exhibit should be used as general guidance only. The recipient should consult the terms and conditions of its award and should contact the GMO if it has any question concerning the applicability of a particular public policy requirement or objective.

Exhibit 4 also indicates where, in the NIHGPS, the individual public policy requirements, objectives and appropriation mandates are covered in more detail. The recipient should also consult its attorney, as appropriate, regarding particular questions about the governing statute or regulation as applied to its specific circumstances. Other cited policies or documents may provide additional information.

In addition to the requirements addressed in this section, there are applicable NIH administrative requirements outlined in the [Administrative Requirements](#) chapter.

Some programs may have special requirements and are covered in IIB.

Exhibit 4. Public Policy Requirements, Objectives and Appropriation Mandates *

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Military Recruiting and ROTC Program Access to Institutions of Higher Education 4.1.19	Y	N	N
Seat Belt Use 4.1.28	Y	NA	NA
Labor Standards under Federally Assisted Construction 10.5.3	Y (Construction Grants and major A&R Contracts Exceeding \$100,000)	NA	Y
Smoke-Free Workplace 4.1.29	Y	NA	NA
Drug-Free Workplace 4.1.7	Y	NA	NA

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Flood Disaster Protection Act of 1973 — Flood Insurance 10.10.1	Y (Construction grants only)	NA	NA
National Environmental Policy Act of 1969 (including Public Disclosure) 4.1.20 and 10.10.1	Y	NA	NA
Intergovernmental Review of Federal Programs under EO 12372 10.10.1	Y (Construction grants only)	NA	NA
Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 10.10.1	Y	NA	NA
Standards of Conduct 4.1.30	Y	NA	NA
Federal Funding Accountability and Transparency Act (FFATA) 4.1.8 and 8.4.1.5.5	Y	NA If under \$30,000	NA If under \$30,000
President's Emergency Plan for AIDS Relief (PEPFAR Program) 4.1.22	Y	Y	Y
Nondelinquency on Federal Debt 4.1.21	Y	Y	NA
National Historic Preservation Act of 1966 — Archaeological and Historic Preservation Act of 1974 10.10.1	Y (Construction Grants; any award involving major or minor A&R, or any work resulting in physical changes to real property)	Y	Y
Lead-Based Paint Poisoning Prevention Act 10.10.1	Y (Construction grants only)	Y	Y
Investigational New Drug Applications/Investigational Device Exceptions 4.1.16	Y	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Inclusion of Women/Minorities as Subjects in Clinical Research 4.1.15.8	Y	Y	NA
Metric System 4.1.18 and 10.10	Y	Y	Y
Lobbying (Appropriation Mandate) 4.2.6	Y	Y	Y
Limited English Proficiency 4.1.2.5	Y	Y	NA
Pro-Children Act of 1994 4.1.23	Y	Y	Y
Safe Drinking Water Act 10.10.1	Y (Construction grants only)	Y	Y
Salary Limitation/Cap (Appropriation Mandate) 4.2.10	Y	Y	NA
Restriction on Distribution of Sterile Needles (Appropriation Mandate) 4.2.9	Y	Y	Y
Select Agents (see Public Health Security & Bioterrorism Preparedness and Response Act) 4.1.24.1.1	Y	Y	Y
USA Patriot Act 4.1.33	Y	Y	Y
U.S. Flag Air Carriers 7.9.1	Y	Y	Y
Text Messaging While Driving 4.1.31	Y	Y	Y
Restriction on Abortions & Exceptions (Appropriation Mandates) 4.2.8 & 4.2.8.1	Y	Y	Y
Wild and Scenic Rivers Act of 1968 10.10.1	Y (Construction grants only)	Y	Y
Protection of Wetlands (EO 11990) 10.10.1	Y (Construction grants only)	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Promotion or Legalization of Controlled Substances (Appropriation Mandate) 4.2.7	Y	Y	Y
Public Health Security and Bio-terrorism Preparedness and Response Act (Select Agents) 4.1.24.1.1	Y	Y	Y
Research Misconduct 4.1.27	Y	Y	NA
Research Involving Recombinant or Synthetic Nucleic Acid Molecules 4.1.26	Y	Y	Y
Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees 4.1.25	Y	Y	NA
Inclusion of Individuals Across the Lifespan as Participants in Research 4.1.15.7	Y	Y	NA
Copeland Act, when required by statute 10.10.1	Y (Construction grants only)	Y	Y
Controlled Substances 4.1.5	Y	Y	Y
Conservation of Petroleum and Natural Gas (EO 12185) 10.10.1	Y (Construction grants only)	Y	Y
Data and Safety Monitoring 4.1.15.6	Y	Y	Y
Dual Use Research of Concern 4.1.24.2	Y	Y	Y
Dissemination of False or Deliberately Misleading Information (Appropriation Mandate) 4.2.3	Y	Y	Y
Davis-Bacon Act, when required by statute 10.10.1	Y (Construction grants only)	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Confidentiality of Alcohol and Drug Abuse Patient/Client Records 4.1.4.2	Y	Y	Y
Architectural Barriers Act of 1968 10.10	Y (Construction grants and any grant involving major A&R)	Y	Y
Animal Welfare 4.1.1	Y	Y	Y
Acknowledgment of Federal Funding (Appropriation Mandate) 4.2.1	Y	Y	NA
Certificates of Confidentiality 4.1.4.1	Y	Y	Y
Coastal Zone Management Act of 1972 10.10	Y (Construction grants only)	Y	Y
Clinical Trials.gov 4.1.3	Y	Y	NA
Clean Air and Clean Water Act 10.10.1	Y (Construction grants only); for contracts exceeding \$100,000	Y	Y
Earthquake Hazards Reduction Act of 1977 and Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction (EO 12699) 10.10	Y (Construction grants only)	Y	NA
Human Subjects Protections 4.1.15	Y	Y	Y
Gun Control 4.2.4	Y	Y	Y
Fly America Act 4.1.11	Y	Y	Y
Hotel and Motel Fire Safety Act of 1990 14.6.1	Y (Conference Grants Only)	Y	Y

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Human Fetal Tissue Research (Including Transplantation Research) 4.1.14	Y	Y	Y
Human Stem Cell Research 4.1.13	Y	Y	Y
Human Embryo Research and Cloning Ban (Appropriation Mandate) 4.2.5	Y	Y	Y
Health and Safety Regulations and Guidelines 4.1.12	Y	Y	Y
Endangered Species Act of 1973 10.10.1	Y (Construction grants only)	Y	Y
Equal Employment Opportunity 10.5	Y (Construction grants and any grant involving major A&R)	Y	NA If under \$10,000
Financial Conflict of Interest 4.1.10	Y (NA to Phase I of the SBIR/STTR programs and to Federal institutions)	Y	NA
Federal Information System Security Management Act 4.1.9	Y	Y	Y
Age Discrimination Act of 1975 4.1.2.4	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Civil Rights Act of 1964 (Title VI) 4.1.2.1	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Health Insurance Portability and Accountability Act (HIPAA) 4.1.4.3	Y (if a covered entity)	Y (if a covered entity)	Y (if a covered entity)

Requirement, Objective, or Appropriation Mandate	Recipient	Subaward/Subrecipient	Contractor under Grant (routine goods/services)
Debarment and Suspension 4.1.6	Y (NA to certain foreign organizations)	Y (NA to certain foreign organizations)	Y If contract equals or exceeds \$25,000 (NA to certain foreign organizations)
Education Amendments of 1972 (Title IX) 4.1.2.2	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Rehabilitation Act of 1973 (section 504) 4.1.2.3 and 10.10.1	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)	Y (NA to foreign and international organizations)
Lobbying (Federalwide Certification) 4.1.17	Y (Certification required if total costs expected to exceed \$100,000)	Y (Certification required if greater than \$100,000 only)	Y (Certification required on contracts greater than \$100,000 only)
Trafficking in Persons 4.1.32	Y (Private entities)	Y (Private entities)	NA
Never Contract with the Enemy 4.1.36	Y	Y	Y
Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment 4.1.37	Y	Y	Y

* NA: A designation of NA in this table indicates that a particular requirement does not apply to an otherwise eligible recipient, consortium participant, or contractor or may not apply because the type of activity covered is one not normally performed by such an entity.

Please note that the core set of National Policy Requirements for participating Federal research agencies is maintained by the National Science Foundation and is [posted on Research Terms and Conditions website](#).

4.1.1 Animal Welfare Requirements

The *Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) requires that an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at the time of award for all organizations involved in PHS-conducted or supported activities involving live vertebrate animals. This requirement includes organizations that are award

recipients and organizations that serve as performance sites where animal activities will be conducted. Recipient organizations must establish appropriate policies and procedures to ensure the humane care and use of animals and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.

The PHS Policy incorporates the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training*, and requires the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals. An Institutional Animal Care and Use Committee (IACUC) appointed by the Chief Executive Officer or designee, is federally mandated to oversee the organization's animal program, facilities, and procedures (Public Law 99-158, Sec. 495). Organizations in foreign countries must also comply with the PHS Policy on Humane Care and Use of Laboratory Animals or may provide evidence to the PHS (i.e. NIH) that acceptable standards for the humane care and use of the animals in PHS-conducted or supported activities will be met per Section II of the PHS Policy.

The PHS Policy defines "animal" as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or related purposes.

Applications from organizations proposing the use of animals are incomplete if they do not thoroughly address the use of vertebrate animals required in the Research Plan of the application. If the involvement of animals is not yet known and cannot be described in the application at the time of application, the applicant should provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to conducting any animal activities the recipient must submit to the NIH awarding IC for prior approval the detailed information about the use of animals as required in the Research Plan of the application and meet the Assurance and IACUC approval requirements of the PHS Policy.

Noncompeting and competing awards are prohibited from using NIH funds to procure cats from USDA Class B dealers. The procurement of cats may only be from USDA Class A dealers or other approved legal sources.

NIH funds may not be used to procure or support the use of dogs from Class B dealers. Dogs used in NIH-supported research may only be from USDA Class A dealers or other approved legal sources. Any costs incurred in violation of this policy are unallowable and will be subject to a cost disallowance.

No activities with live vertebrate animals may begin and no costs for activities with live vertebrate animals may be charged to NIH if there is not a valid Animal Welfare Assurance and IACUC approval of the activity.

The PHS Policy does not supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research. All recipient organizations are required to comply, as applicable, with the regulations (9 CFR, Subpart A) issued by the U.S. Department of Agriculture under the Animal Welfare Act, as amended, 7 U.S.C. 2131 et seq., and other Federal statutes and regulations relating to animals.

4.1.1.1 Animal Welfare Assurance Requirements

An Animal Welfare Assurance is the document submitted by an institution assuring institutional compliance with the PHS Policy. OLAW is responsible for requesting, negotiating, approving or disapproving, and, as necessary, restricting or withdrawing approval of Assurances.

When an applicant institution does not have an Animal Welfare Assurance, the Authorized Organization Representative's signature on the application constitutes declaration that the institution will submit an Assurance when requested by OLAW. Upon such request, the institution shall prepare the Assurance as instructed by OLAW and in accordance with the PHS Policy, and the authorized IACUC shall review

those components of the application related to the care and use of animals. Except in certain circumstances, the Assurance must be submitted to and approved by OLAW in order for the IC to award the grant. No activities with live vertebrate animals may be conducted and no costs for activities with live vertebrate animals may be charged to NIH grants in the absence of a valid Assurance on file with OLAW.

Organizations where live, vertebrate animal work is performed onsite (i.e., serve as an animal performance site) must have an approved Domestic or Foreign Assurance. If the pass-through entity does not have an approved Domestic or Foreign Assurance and the animal activities will be conducted at an Assured institution named as a performance site, the recipient must obtain an Interinstitutional Assurance from OLAW. Under the Interinstitutional Assurance, the recipient and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance.

4.1.1.2 Verification of IACUC Approval

NIH will delay an award for research involving live vertebrate animals until the recipient organization and all performance sites are operating in accordance with approved Animal Welfare Assurances and the recipient has provided verification of IACUC approval of those sections of the application that involve use of vertebrate animals. IACUC approval must have been granted not more than three years prior to the budget period start date to be valid; however, IACUCs may determine that continuing review on a more frequent basis is appropriate.

Verification of IACUC approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with approved Assurances may wish to proceed with IACUC review for those applications that have not yet received IACUC approval and that appear to be in a fundable range.

It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC. The applicant verifies that there is congruence between the application and the IACUC-approved protocol when it provides the IACUC approval date.

No costs for activities with live vertebrate animals may be charged to NIH grants if there is not a valid IACUC approval.

4.1.1.3 Consortia

Under consortium (subaward) agreements in which the recipient collaborates with one or more other organizations, the recipient, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the recipient as specified in the NIHGPS (see [Consortium Agreements](#) chapter in IIB). The animal welfare requirements that apply to recipients also apply to consortium participants and sub-projects.

The primary recipient is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. The approval of more than one IACUC is not required if the recipient and performance site(s) have Assurances; the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted.

The recipient is further responsible for complying with NIH prior approval requirements related to the addition of sites not included in the approved application (see [Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements](#)).

The list of domestic and foreign organizations with a PHS approved animal welfare assurance is available on OLAW's [website](#). The list of organizations with approved assurances is available at The OLAW web site posts a list of [domestic institutions](#) and [foreign institutions](#) with approved assurances.

4.1.1.4 Foreign Recipients and Foreign Performance Sites

Foreign recipients that will perform live, vertebrate animal activity onsite must provide OLAW with an Animal Welfare Assurance for Foreign Institutions. This constitutes institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the [International Guiding Principles for Biomedical Research Involving Animals](#). IACUC approval is not required of foreign recipients; however, OLAW encourages foreign recipients to use the standards in the *Guide for the Care and Use of Laboratory Animals*.

When the recipient is a domestic institution and animal performance sites are foreign (i.e., domestic grant with a foreign component), the IACUC approval requirement applies. Accordingly, the recipient remains responsible for animal activities conducted at the foreign site and must provide verification of IACUC approval (i.e., certification that the activities as conducted at the foreign performance site are acceptable to the recipient). The recipient IACUC may accept, as its own, the approval of a foreign organization's animal welfare committee or oversight body;; however, the recipient IACUC remains responsible for the review. Additionally, the foreign animal performance site must obtain an Animal Welfare Assurance for Foreign Institutions as described in the preceding paragraph.

4.1.1.5 Reporting to OLAW

Reporting requirements under the PHS Policy include an annual report to OLAW describing any change in the institution's program for animal care and use as described in the Assurance, changes in IACUC membership, and the dates the IACUC conducted its semiannual evaluations of the institution's program and facilities. The IACUC, through the institutional official signing the Assurance, must promptly report any serious or continuing noncompliance with the PHS Policy, serious deviations from the Guide for the Care and Use of Laboratory Animals, and any IACUC suspensions.

Charges to NIH grant awards for the conduct of live vertebrate animal activities during periods of time that the terms and conditions of the grant award are not upheld are not allowable. Specific situations under which charges are not allowable are:

1. The conduct of animal activities in the absence of a valid Animal Welfare Assurance on file with OLAW.
2. The conduct of animal activities in the absence of a valid IACUC approval of the activities. Absence of IACUC approval includes failure to obtain IACUC approval, expiration, or suspension of IACUC approval.

Instances of serious noncompliance with section IV.F.3. of the PHS Policy, such as those mentioned above, are to be reported to OLAW and the IC supporting the grant award. In cases where charges have been made for unauthorized animal activities, appropriate adjustments must be made to the grant to remove those charges. NIH requires that reports contain a certification that no unallowable costs were charged to NIH grant funds during a period of noncompliance. If such a certification cannot be made, a detailed accounting of unallowable charges made to each affected grant should be included with the

report. If a detailed accounting has not been completed at the time of reporting, a date when it will be provided should be included.

NIH expects recipients to continue to maintain and care for animals during periods when animal activities are conducted in the absence of a valid Animal Welfare Assurance and/or IACUC approval. ICs may allow expenditure of NIH grant funds for maintenance and care of animals on a case-by-case basis. Consultation with the IC is encouraged regarding questions concerning allowable costs.

Information about the PHS Policy, Animal Welfare Assurances, and other relevant topics is available on the OLAW [website](#).

4.1.2 Civil Rights Protections

Recipients are required to administer NIH-funded projects in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy, and comply with applicable conscience protections.

Before NIH may make an award to a domestic organization, the AOR must certify, by means of the signature on the application, that the organization has on file with the HHS OCR a one-time Assurance of Compliance with the statutes described in this subsection. The Assurance, HHS Form 690, is filed for the organization and is not required for each application. If the application has been recommended for funding and the applicant organization does not have an Assurance of Compliance on file, it will receive the required form and instructions for completion and submission from the awarding IC. The HHS Form 690 also is available from GrantsInfo@nih.gov or by telephone at 301-435-0714.

Domestic organizations that receive funding from recipients (including consortium participants and contractors under grants) rather than directly from NIH, also are required to file an HHS 690. The applicant/recipient is responsible for determining whether those organizations have the required Assurance on file and, if not, ensuring that it is filed with OCR. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity, The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS.

4.1.2.1 Civil Rights Act of 1964

Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 80.

4.1.2.2 Educational Amendments of 1972

Title IX of the Education Amendments of 1972 provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any educational program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 86.

4.1.2.3 Rehabilitation Act of 1973

Section 504 of the Rehabilitation Act of 1973, as amended, provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the physical or mental impairment, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any

program or activity receiving Federal financial assistance. These requirements pertain to the provision of benefits or services as well as to employment. The HHS implementing regulations are codified at 45 CFR Parts 84 and 85.

4.1.2.4 Age Discrimination Act of 1975

The Age Discrimination Act of 1975 prohibits discrimination on the basis of age in any program or activity receiving Federal financial assistance. The HHS implementing regulations are codified at 45 CFR Part 91.

4.1.2.5 Limited English Proficiency

EO 13166, August 11, 2000, requires recipients receiving Federal financial assistance to take steps to ensure that people with limited English proficiency can meaningfully access health and social services. A program of language assistance should provide for effective communication between the service provider and the person with limited English proficiency to facilitate participation in, and meaningful access to, services. The obligations of recipients are explained on the [Limited English Proficiency \(LEP\) page of the HHS website.](#)

4.1.3 Clinical Trials Registration and Reporting in ClinicalTrials.gov Requirement

4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

For grant applications that request support for the conduct of a clinical trial, the NIH Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded recipients and investigators conducting clinical trials, funded in whole or in part by NIH, will ensure that their clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting. The purpose of the policy is to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Disseminating this information supports NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health. For basic experimental studies with humans (BESH) NIH continues to expect registration and results reporting, but with the additional flexibility to register and report results on alternative publicly available platforms. This flexibility is only applicable to BESH studies submitted to Notices of Funding Opportunities designated as “basic experimental studies with humans” in the title and is available until September 24, 2023.

This policy is complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11, hereinafter referred to as the regulation.

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including applicable clinical trials subject to the regulation. All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov according to the timelines described in the regulation.

This policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Applicants seeking NIH funding for clinical trials will be required to submit a plan that will address how the expectations of this policy will be met. Recipients and investigators conducting clinical trials funded

in whole or in part by NIH are required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.

The signature of the AOR on the grant application or progress report form certifies that, for any clinical trials funded under the NIH award, the recipient and all investigators are in compliance with the recipient's clinical trial information dissemination plan.

Responsibilities of recipients and investigators will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the recipient is the responsible party, the recipient will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the recipient is not the responsible party, the recipient will coordinate with the responsible party to ensure that all regulatory requirements are met.
3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the recipient will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Recipients of NIH funding conducting non-exempt research involving human subjects research subject to the revised Common Rule and conducting a clinical trial as defined in 45 CFR Part 46.102(b) should be aware that for each funded trial, one IRB-approved consent form must be posted on a designated public federal website in accordance with 45 CFR Part 46.116(h). The forms must be posted on a designated public federal website after recruitment closes and no later than 60 days after the last study visit by any subject, as required by the protocol. More information about these requirements is available [on Posting Clinical Trial Informed Consent Forms webpage](#).

- **NIH-funded recipients using an English-language informed consent form to enroll participants may either:**

Submit an IRB-approved English-language informed consent form to ClinicalTrials.gov. Documents that are uploaded to ClinicalTrials.gov should be uploaded in accordance with [these instructions](#). ClinicalTrials.gov does not currently support upload of non-English documents. Or:

Submit an IRB-approved informed consent form to Regulations.gov following the instructions in the paragraph below. NIH recipients submitting informed consent forms to Regulations.gov must maintain a copy of their Regulations.gov receipt and tracking number and make it available to NIH upon request.

- **NIH-funded recipients using only non-English informed consent forms to enroll participants:**

Submit an IRB-approved informed consent form to Docket ID: HHS-OPHS-2018-0021 on the Regulations.gov website in accordance with [guidance issued by the Office for Human Research Protections](#). NIH recipients submitting informed consent forms to Regulations.gov must maintain a copy of their Regulations.gov receipt and tracking number and make it available to NIH upon request.

Institutions submitting documents to either ClinicalTrials.gov or Regulations.gov must protect participant privacy in accordance with applicable federal, state, and local laws and regulations (e.g., the HIPAA Privacy Rule, Certificates of Confidentiality) and any applicable terms of their NIH award.

Each NIH-funded clinical trial should have only one entry in ClinicalTrials.gov that contains its registration and results information. Recipients need not and should not create a separate record of the applicable clinical trial to comply with this policy.

4.1.3.2 Food and Drug Administration Amendments Act (FDAAA)

Applicants and recipients should familiarize themselves with the requirements of 42 U.S.C. 282(j), also known as Sec. 801 of Public Law 110-85 (the FDA Amendments Act of 2007 or FDAAA), as implemented in regulation by 42 CFR Part 11, with respect to registration and results reporting requirements that apply to certain clinical trials. Of particular note is that, in general, results of applicable clinical trials are due not later than 12 months after the primary completion date. If this date occurs after the period of performance has ended, results reporting is still required in accordance with FDAAA and the terms and conditions of grant award.

The signature of the AOR on the grant or progress report form certifies that, for applicable clinical trials funded in whole or part by the award, the responsible party has made all registration and results submissions required by 42 CFR Part 11.

4.1.3.3 Good Cause Extension (GCE) Request Requirements

Section 402(j) of the Public Health Service Act (PHS Act) and the Final Rule for Clinical Trials Registration and Results Information establish requirements and deadlines for the submission of clinical trial results information for Applicable Clinical Trials (ACTs). In general, the standard submission deadline for clinical trials results information is no later than 1 year after the primary completion date. However, in rare instances, a good cause extension (GCE) request may be sought for the following categories of trials:

- ACTs that are subject to the Final Rule (42 CFR 11.42).
- NIH Clinical trials subject to the complementary policy in Section 4.1.3.1.

Therefore, GCE requests must be submitted through the ClinicalTrials.gov Protocol Registration and Results System (PRS) prior to (i.e., the day before) the standard submission deadline or granted extended deadline. Late submissions, or requests submitted outside of the PRS, will not be accepted. If NIH determines the request does not constitute “good cause,” the GCE request will be denied. If the request is denied, the responsible party must either (1) submit clinical trial results information by the later of the date on which clinical trial results information would otherwise be due, or 30 calendar days after the date that the PRS GCE denial notification was issued by NIH; or (2) submit an appeal.

Special Considerations for NIH Recipients

For NIH-funded and supported clinical trials, recipients should be aware that any GCE request could impact other aspects of the grant award. Therefore, the submission of a “Request for an Extension for Good Cause” does not constitute a prior approval request submission (e.g., No Cost Extension and Carry-over).

Each GCE request must include

1. a complete description of the reason(s) why clinical trial results information cannot be provided according to the deadline, with sufficient detail to justify good cause for the extension and to allow for the evaluation of the request; and
2. an estimated date on which the clinical trial results information will be submitted.

Extension requests will be evaluated on a case-by-case basis using the following general criteria to support a determination of “good cause.” These include, but are not limited to:

General Criteria:

1. The circumstances and their leading to the GCE request, including steps the responsible party is taking to mitigate the impact of those circumstances.
2. The extent to which the factors underlying the GCE request are outside of the responsible party's control.
3. 3. What steps will be taken during the requested extension, why they are necessary to mitigate the circumstances leading to the GCE request, and whether the requested submission date is commensurate with the explanation provided in the request.
4. 4. Whether information is internally consistent with relevant data element definitions and is consistent with information provided in other sections of the study record.
5. 5. The number of, and explanations for, previous GCE request(s), and the proposed reporting deadline in previous requests.

General Formatting Criteria and Considerations:

1. The request must be in English.
2. Acronyms and abbreviations should be spelled out, with the acronym or abbreviation provided in parentheses immediately after, at least the first time they are used in the request.
3. The responsible party should not include specific personal health information in the request.

Sufficient detail should be provided, including the steps that will be taken to meet the estimated submission date, a description of mitigating steps to avoid future delay, and any other information needed to address the criteria listed above. Requests that do not provide sufficient information may be denied.

More than one GCE request may be submitted for the same ACT or NIH Clinical Trial after a previous GCE request was granted. When a GCE is granted, the results submission deadline is updated to align with the approved extension. Any subsequent GCE request must be submitted prior to the granted extended deadline.

Appeals

Responsible parties or Recipients, as appropriate, may appeal denied GCE requests or the NIH-identified earlier deadline specified in a granted extension request. An appeal must provide an explanation of the reason(s) why the initial decision to deny the GCE request or grant the GCE request with a shorter deadline than requested should be overturned or revised, with sufficient detail to allow for the evaluation of the appeal. Responsible parties or Recipients, as appropriate, should provide further elaboration of the grounds for the request or highlight factors that justify an extension. The appeal should only address why the initial decision was incorrect; new bases for an extension request should not be presented for the first time in an appeal and will not be considered.

Only one appeal may be submitted for a denied GCE request. The appeal must be submitted via the PRS not later than 30 calendar days after the date that the PRS notification was issued by NIH. NIH will provide an electronic notification to the responsible party or recipient, as appropriate, communicating the determination of whether the appeal is granted or denied.

If the appeal is granted, the responsible party or recipient, as appropriate, has until the extended date specified in the electronic notification to submit clinical trial results information. If NIH denies the appeal of a denied GCE request, the responsible party or recipient, as appropriate, must submit clinical trial results information by the later of the date on which clinical trial results information would otherwise be due, or 30 calendar days after the electronic notification denying the appeal was sent by NIH.

The GCE request review and decision notification process can be found on the NIH Good Cause Extension website.

4.1.4 Confidentiality

4.1.4.1 Certificates of Confidentiality

In keeping with Section 301(d) of the PHS Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255, and as enacted December 13, 2016 Certificates of Confidentiality (Certificates) are issued automatically to any NIH funded investigators or institutions engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected.

At the time of enactment, all NIH-funded and conducted research that was commenced or ongoing on or after December 13, 2016 was deemed to be issued a Certificate and was therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act. Per the PHS Act, subsection 301(d)(1), the Certificates protect identifiable, sensitive information collected and all copies, in perpetuity.

Institutions and their investigators are responsible for determining whether research they conduct is subject to the requirement and therefore issued a Certificate. Certificates issued in this manner will not be issued as a separate document.

For the purposes of this Policy, NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR Part 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

Recipient Responsibilities

To determine if the requirement applies to research conducted or supported by NIH, investigators will need to ask, and answer the following question:

- Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer the following questions:

- Does the research involve Human Subjects as defined by 45 CFR Part 46?
- Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
- If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
- Does the research involve the generation of individual level, human genomic data?

If the answer to any one of these questions is yes, then the requirement will apply to the research and therefore, in accordance with subsection 301(d) of the Public Health Service Act, the recipient of the Certificate shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

As set forth in [NIHGPS Chapter 8.3](#), recipients conducting NIH supported research applicable to the Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award.

Recipients of Certificates are required to ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate issued by the Policy, understand they are also subject to the requirements of subsection 301(d) of the Public Health Service Act. In accordance with [NIHGPS Chapter 15.2.1](#), recipients are also responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sensitive information protected by a Certificate issued by the Policy understand they are also subject to subsection 301(d) of the Public Health Service Act.

For studies in which informed consent is sought, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by the Policy.

Information on CoCs is available on the NIH Web site at Grants and Funding's Certificates of Confidentiality (CoC) webpage.

4.1.4.2 Confidentiality of Alcohol and Substance Use Patient Records

Section 543 of the PHS Act, as implemented in 42 CFR Part 2, requires that records of substance abuse patients be kept confidential except under specific circumstances and purposes. These protections differ from those available to patients under HIPAA and are intended to ensure that a patient in a substance or alcohol use program is not made more vulnerable than a similar patient who does not seek treatment. The covered records are any information, written or not, of a patient who has applied for or been given diagnosis or treatment for substance or drug use at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as a substance or drug user in order to determine that individual's eligibility to participate in a program. This includes records of the identity, diagnosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, training, treatment, rehabilitation, or research, which is conducted under an NIH grant. Except as authorized under a court order, no patient record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient. The regulations also describe procedures to allow for nonvoluntary disclosure of certain information by persons engaged in research on mental health, including research on the use and effect of alcohol and other psychoactive substances.

4.1.4.3 Confidentiality of Patient Records: Health Insurance Portability and Accountability Act

HHS issued the final version of the "Standards for Privacy of Individually Identifiable Health Information"—the Privacy Rule—on August 14, 2002. The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information. It is administered and enforced by OCR, HHS.

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and the recipient organization. The [OCR web site](#) provides information on the Privacy Rule, including the complete text of the regulation and a set of decision tools for determining whether a particular entity is subject to the rule. An educational booklet, Protecting Health Information in Research: Understanding the HIPAA Privacy Rule, is available through OCR's web site. That web site also includes other educational materials including information specific to grants.

4.1.5 Controlled Substances

If controlled substances are proposed to be administered as part of a research protocol or if research is to be conducted on the substances themselves, applicants/recipient must ensure that the DEA requirements, including registration, inspection, and certification, as applicable, are met. Regional DEA offices can supply forms and information concerning the type of registration required for a particular substance for research use. The main registration office in Washington, DC may be reached at 800-882-9539. Information also is available from the National Institute on Drug Abuse at 301-443-6441.

4.1.6 Debarment and Suspension

HHS regulations published in 2 CFR Part 376 implement the government-wide debarment and suspension system guidance (2 CFR Part 180) for HHS' non-procurement programs and activities. "Non-

procurement transactions” include, among other things, grants, cooperative agreements, scholarships, fellowships, and loans. NIH implements the HHS Debarment and Suspension regulations as a term and condition of award. Accordingly, recipients of NIH grants (“primary covered transactions”), including sponsoring institutions for Kirschstein-NRSA individual fellowships, are required to determine whether it or any of its principals (as defined in [2 CFR Part 180.995](#) and [2 CFR Part 376.995](#)) is excluded or disqualified from participating in a covered transaction (i.e., grant or cooperative agreement) prior to entering into the covered transaction, i.e., prior to the drawdown of funds which signals acceptance of the grant award. Recipients may decide the method and frequency by which this determination is made and may check excluded parties in [SAM](#), although checking SAM is not required.

Prior to the drawdown of funds for each grant award, recipients must report to the funding IC if the recipient or any of its principals:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 CFR Part 180.800(a) or had a civil judgment for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses listed in 2 CFR Part 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years or default.

Disclosure of unfavorable information by recipients under this requirement will not necessarily cause NIH to deny participation in the grant. NIH will consider the information when determining whether to enter into the covered transaction. NIH will also consider any additional information or explanation that recipients elect to submit with the disclosed information. However, if it is later determined that a recipient failed to disclose information that it knew at the time it accepted the NIH grant award, NIH may (a) terminate the transaction for material failure to comply with the terms and conditions of the award or (b) pursue any other available remedies, including suspension and debarment.

Recipients must immediately report to the NIH funding IC if at any time during the project period, including periods of no-cost extension, they discover that they (a) failed to disclose information prior to the drawdown of funds or (b) due to changed circumstances the recipient or any of its principals for the grant now meet the reporting criteria.

“Lower tier” transactions (e.g., consortiums, subcontracts, consultants, collaborators, and contractors that require the provision of goods or services that will equal or exceed \$25,000) also are subject to the HHS regulations. Prior to entering into a lower tier covered transaction with a participant (as defined in [2 CFR Part 180.980](#)), recipients must verify that the person (as defined in [2 CFR Part 180.985](#)) is not excluded or disqualified. Recipients may not enter into any transaction with a person who is disqualified from that transaction unless an exception under the disqualifying statute, Executive Order, or regulation has been obtained from HHS.

Recipients must require participants at the next lower tier to (a) comply with the HHS Debarment and Suspension regulations as a condition of participation in the transaction and (b) pass the requirement to comply with the HHS Debarment and Suspension regulations to each person involved in the covered transaction at the next lower tier. Likewise, before entering into such a transaction lower tier participants and contractors under grants (where the contract requires the provision of goods or services that will equal or exceed \$25,000) must report to the recipient if it or any participants are presently excluded or disqualified.

Recipients also are required to assure compliance for each trainee under a Kirschstein-NRSA institutional research training grant, or other similar NIH-supported institutional training grant, before their appointment.

Organizations or individuals that are suspended, debarred, or voluntarily excluded from eligibility cannot receive NIH grants, be paid from NIH grant funds, whether under a primary or lower-tier transaction (including trainees on NIH-supported training grants), or otherwise participate during the period of suspension, debarment, or exclusion. Because individuals who have been debarred, suspended, declared ineligible, or voluntarily excluded from covered transactions may not receive Federal funds for a specified period, charges made to NIH grants for such individuals (e.g., salary) are unallowable.

4.1.7 Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (41 U.S.C. § 701 et seq.) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the application, the AOR agrees that the recipient will provide a drug-free workplace and will comply with the requirement to notify NIH if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. Government wide requirements for Drug-Free Workplace for Financial Assistance are found in 2 CFR Part 182; HHS implementing regulations are set forth in 2 CFR Part 382.400. All recipients of NIH grant funds must comply with the requirements in Subpart B (or Subpart C if the recipient is an individual) of Part 382. Foreign applicants and recipients may be exempted from the drug-free workplace requirements of 2 CFR Part 182 based on a documented finding by the NIH awarding IC that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government.

4.1.8 Federal Funding Accountability and Transparency Act (FFATA)

Public Law 109-282, the [Federal Funding Accountability and Transparency Act of 2006](#) as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible web site, [USASpending.gov](#). The Web site includes information on each Federal financial assistance award and contract over \$30,000, including such information as:

1. The name of the entity receiving the award
2. The amount of the award
3. Information on the award including [FAIN](#), transaction type, funding agency, etc.
4. The location of the entity receiving the award
5. A unique identifier of the entity receiving the award; and
6. Names and compensation of highly-compensated officers (as applicable)

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: 1) information on executive compensation when not already reported through the Central Contractor Registry; and 2) similar information on all subawards/subcontracts/consortiums over \$30,000. Information on the recipient reporting requirement for this law can be found in [Monitoring—Reporting—Financial Reports—Recipient Reporting of Subrecipient Data for FFATA](#).

Full text of the award term is available at [2 CFR Part 170](#).

4.1.9 Federal Information Security Management Act

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.

4.1.10 Financial Conflict of Interest

NIH requires recipient institutions (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." (FCOI Regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements. FCOI requirements are aligned with [42 CFR Part 50--Subpart F](#) and the overarching goal for reporting is to promote and encourage transparency in order to avoid distorting NIH funding decisions; NIH staff consider reports in light of other disclosures, e.g. other support, biographical sketch data, and foreign components, etc., and provide a holistic approach to award and risk management principles.

The requirements under the 2011 revised regulation promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the PD/PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants. These requirements do not apply to Federal employees or Federal agencies. Federal agencies have their own set of rules governing FCOI for employees. When submitting a grant application, the signature of the AOR certifies the applicant Institution's compliance with the requirements of the FCOI regulations, including that:

1. There is in effect at the Institution an up-to-date, written and enforced administrative process to identify and manage FCOI with respect to all research projects for which NIH funding is sought or received;
2. The Institution shall promote and enforce Investigator compliance with the regulation's requirements including those pertaining to disclosure of Significant Financial Interests (SFI);
3. The Institution shall identify and manage FCOIs and provide initial and ongoing FCOI reports to NIH;
4. When requested, the Institution will promptly make information available to the NIH/HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI;
5. The Institution must fully comply with the requirements of the regulation.

When the Institution determines that an FCOI exists (see #3 above), the Institution must report to the NIH awarding IC through the submission of an initial and annual FCOI report using the eRA Commons FCOI Module. The initial FCOI report will include the following information:

- Grant number and PD/PI or Contact PD/PI if the grant is awarded under the multiple PI model;
- Name of Investigator (if different from the PD/PI) with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the FCOI (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
- Value of the financial interest \$0-4,999; \$5,000-9,999; \$10,000-19,999; amounts between \$20,000-100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000 or a statement that a value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan, including:
 1. Role and principal duties of the conflicted Investigator in the research project;
 2. Conditions of the management plan;
 3. How the management plan is designed to safeguard objectivity in the research project;
 4. Confirmation of the Investigator's agreement to the management plan;
 5. How the management plan will be monitored to ensure Investigator compliance; and
 6. Other information as needed.

The annual FCOI report must be submitted to NIH through the eRA Commons FCOI Module each year within a competitive segment or until the Institution reports that the FCOI no longer exists. The annual FCOI report will include the following information:

- Status of the FCOI
- Changes to the management plan, if applicable

The Institution must enter into a formal written agreement, signed and agreed to by the recipient and each consortium participant and/or subrecipient. The agreement must establish whether the FCOI policy of the recipient Institution or that of the subrecipient will apply to subrecipient Investigators and in either case, the agreement must include required significant financial interest disclosure, review, and FCOI reporting timelines to ensure compliance with the FCOI regulations. Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the recipient Institution in sufficient time to allow the recipient Institution to report the FCOI to NIH to meet its reporting obligations. (See [Consortium Agreements, 15.2.1 Written Agreement](#).)

NIH will not support any agreement that does not meet the minimum requirements. If a subrecipient is unwilling to accept the requirements of the written agreement by signing the agreement, then the agreement cannot be issued. NIH reserves the right to request copies of the written agreement and relevant supporting documentation as needed as part of its oversight responsibilities. Failure to provide requested documentation may lead to remedies for noncompliance and potential enforcement actions (See 8.5, Specific Award Conditions and remedies for noncompliance).

The Institution will make certain information available concerning identified FCOI held by senior/key personnel as defined in the regulation via a publicly accessible web site or by a written response to any

requestor within five business days of a request and update such information as specified in the regulation.

Each Institution shall maintain an up-to-date, written, enforced policy on FCOI that complies with the regulation, and make the policy available via a publicly accessible web site. NIH funded recipients are required to submit their publicly accessible FCOI policy to NIH via the eRA Commons Institution Profile (IPF) Module (IPF Module). The information is provided on an institutional level as part of an institution's IPF, rather than on a grant-specific level, so it is not necessary to submit the FCOI policy with each grant application.

The Institution must require each Investigator to disclose their (and their spouse and dependent children) domestic and foreign SFIs that are related to their Institutional responsibilities to the Institution's designated official(s).

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education and foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000). Institutions are strongly encouraged to review their FCOI policy and make any necessary changes to ensure Investigators fully understand their disclosure responsibilities.

The Institution must require each Investigator (including subrecipient Investigators) to complete training prior to engaging in NIH-supported research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an Investigator noncompliant with the Institution's FCOI policy or management plan.

As described in the regulation, examples of how FCOIs might be managed include but are not limited to, the following:

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- Disclosure of FCOI directly to human subjects research participants;
- Monitoring of research by independent reviewer(s);
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of SFIs (e.g., sale of an equity interest)
- Severance of relationships that create FCOIs.

The information above is only a sample of the regulatory requirements found in 42 CFR Part 50--Subpart F. Applicants and recipients must review the regulation in its entirety to ensure compliance with all of the requirements. Resources applicable to FCOI, including Frequently Asked Questions, etc. can be found on [the NIH Financial Conflict of Interest website](#).

4.1.11 Fly America Act

The Fly America Act (49 U.S.C. 40118) generally provides that foreign air travel funded by Federal government money may only be conducted on U.S. flag air carriers. A "U.S. flag air carrier" is an air carrier that holds a certificate under 49 U.S.C. 41102 but does not include a foreign air carrier operating under a permit. There are limited circumstances under which use of a foreign-flag air carrier is permissible.

These circumstances are outlined below:

1. **Airline "Open Skies" Agreement.** A foreign flag air carrier may be used if the transportation is provided under an air transportation agreement between the United States and a foreign government, which the Department of Transportation has determined meets the requirements of the Fly America Act. For example, in 2008, the U.S. entered into an "Open Skies" Agreement with the European Union (EU). This Agreement gives European Community airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the U.S. government, when the transportation is between a point in the United States and any point in a Member State or between any two points outside the United States.

The U.S.-EU Open Skies Agreement was [amended](#) effective June 24, 2010. GSA issued [Guidance](#) October 6, 2010. Pursuant to the amendment, federal contractors and recipients (not U.S. Government employees) need not be concerned about city-pair contract fares. However, contractors and recipients must check with the airline to ensure that the airline is covered by the U.S.-EU Open Skies agreement which may change periodically.

Additionally, pursuant to the amendment, EU airlines are no longer limited to flying passengers between points in the United States and points in the EU. Instead, EU airlines are authorized to transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the U.S.-EU Open Skies Agreement. This includes flights that originate, arrive, or stop in the European Union. For additional information, please see [GSA Bulletin FTR 11-02](#). For information on other "open skies" agreements in which the United States has entered, refer to the [Fly America Act page](#) on GSA's website

2. **Involuntary Rerouting.** Travel on a foreign-flag carrier is permitted if a U.S.-flag air carrier involuntarily reroutes the traveler via a foreign-flag air carrier, notwithstanding the availability of alternative U.S.-flag air carrier service.
3. **Travel To and From the U.S.** Use of a foreign-flag air carrier is permissible if the airport abroad is: (a) the traveler's origin or destination airport, and use of U.S.-flag air carrier service would extend the time in a travel status by at least 24 hours more than travel by a foreign-flag air carrier; or (b) an interchange point, and use of U.S.-flag air carrier service would increase the number of aircraft changes the traveler must make outside of the U.S. by two or more, would require the traveler to wait four hours or more to make connections at that point, or would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.
4. **Travel Between Points Outside the U.S.** Use of a foreign-flag air carrier is permissible if: (a) travel by a foreign-flag air carrier would eliminate two or more aircraft changes en route; (b) travel by a U.S.-flag air carrier would require a connecting time of four hours or more at an overseas interchange point; or (c) the travel is not part of the trip to or from the U.S., and use of a U.S.-flag air carrier would extend the time in a travel status by at least six hours more than travel by a foreign-flag air carrier.

5. ***Short Distance Travel.*** For all short distance travel, regardless of origin and destination, use of a foreign-flag air carrier is permissible if the elapsed travel time on a scheduled flight from origin to destination airport by a foreign-flag air carrier is three hours or less and service by a U.S.-flag air carrier would double the travel time.

4.1.12 Health and Safety Regulations and Guidelines

Recipients are responsible for meeting applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- 29 CFR Part 1910.1030, Blood borne pathogens; 29 CFR Part 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in [29 CFR Part 1910](#).
- Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available at on [CDC's Strengthening Lab Safety webpage](#).
- Prudent Practices for Safety in Laboratories (2011), National Research Council, National Academies Press, 500 Fifth Street, NW, Lockbox 285, Washington, DC 20055 (ISBN 978-0-309-13864-2).

Recipient organizations are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines. However, if requested by the awarding IC, recipients should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.

4.1.13 Human Stem Cell Research

Under Executive Order 13505 NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. [NIH Guidelines on Human Stem Cell Research](#), implement the Executive Order. The Guidelines apply to the expenditure of NIH funds for research using hESCs and certain uses of induced pluripotent stem cells.

For the purpose of NIH Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos.

NIH recipients may use hESCs that have been approved by NIH in accord with NIH Guidelines and are posted on the [NIH Human Embryonic Stem Cell Registry](#), or may establish eligibility of specific cell lines for NIH funding by submitting a [Request for Human Embryonic Stem Cell Line to be Approved](#)

[for Use in NIH Funded Research](#) (NIH Form 2890). Prior to the use of NIH funds, applicants and recipients must provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs to be used are listed on the NIH Registry and will be used in accordance with any restrictions associated with the line as cited on the Registry. If a specific line from the NIH Registry cannot be identified at the time of submission, the applicant/recipient must provide a strong justification why one cannot be identified at that time and a certification that one from the NIH Registry will be used.

DHHS regulations for Protection of Human Subjects, [45 CFR Part 46](#), Subpart A, establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. When research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 CFR Part 46, Subpart A.

In addition, 45 CFR Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 CFR Part 46.102(f). The HHS [Office for Human Research Protections](#) (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult [OHRP guidance](#).

4.1.13.1 Human Pluripotent Stem Cell Research Prohibited with NIH Funding

The following uses of hESCs, even if derived from embryos donated in accordance with NIH Guidelines and listed on the NIH Registry, or human induced pluripotent stem cells, are prohibited:

- Research in which hESCs or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
- Research involving the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line.

In addition, the derivation of stem cells from human embryos is prohibited in NIH funded research by the annual appropriations ban on funding of human embryo research known as the Dickey Wicker Amendment. NIH funding for research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is also prohibited.

NIH will also not fund research in which human pluripotent cells are introduced into non-human vertebrate animal pre-gastrulation stage embryos.

4.1.14 Human Fetal Tissue Research

Human fetal tissue is defined as tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion or stillbirth. This definition does not include established human fetal cell lines.

Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) set forth specific requirements and prohibitions on research involving human fetal tissue. Research involving human fetal tissue is also subject to the HHS Regulations for the Protection of Human Subjects. 45 C.F.R. 46.204 and 46.206 may be specifically relevant.

The scientific and ethical challenges associated with research utilizing human fetal tissue make it imperative that researchers and their organizations be fully aware of and in compliance with the Federal requirements. When an application involving human fetal tissue research is submitted to NIH, the AOR's signature certifies that researchers using these tissues are in compliance with the PHS Act. The statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. The term "valuable consideration" is a concept similar to profit and does not include reasonable payment for costs associated with the collection, processing, preservation, storage, quality control, or transportation of these tissues. Violation of this statute carries criminal penalties that apply to both those that supply and those that acquire human fetal tissue.

Current federal laws and regulations require informed consent for research involving the transplantation of human fetal tissue and for research with human fetal material associated with information that can identify a living individual. Most states require informed consent for the use of fetal tissue in research. Accordingly, NIH expects informed consent to have been obtained from the donor for any NIH-funded research using human fetal tissue.

When obtaining primary human fetal tissue for research purposes, NIH expects recipients to maintain appropriate documentation.

4.1.14.1 Research on Transplantation of Human Fetal Tissue

Sections 498A and 498B contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions:

- The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:
 - for therapeutic transplantation research,
 - without any restriction regarding the identity of individuals who may receive the transplantation, and
 - without the donor knowing the identity of the recipient.
- The attending physician must sign a statement that they have:
 - obtained the tissue in accordance with the donor's signed statement and
 - fully disclosed to the donor their intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.
- In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that they:
 - obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
 - did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
 - performed the abortion in accordance with applicable State and local laws.

- The PD/PI must sign a statement certifying that they are aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information.
- The PD/PI must certify in writing that they have had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the AOR that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

In addition, FDA has jurisdiction over fetal cells and tissues intended for use in humans and requests that investigators contact them to determine whether any planned or ongoing clinical research would require submission of an IND application. Additional information and FDA contact information is available on [FDA's Safety & Availability \(Biologics\)](#) webpage.

4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions

For the purposes of this section, HFT from elective abortions is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following:

- human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.
- animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.
- derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.
- any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

- The definition of research involving HFT from elective abortions does not include the following:
 - human fetal primary or secondary cell cultures, if cells were not derived from an elective abortion
 - already-established (as of June 5, 2019) human fetal cell lines (e.g., induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines).
 - derivative products from human fetal tissue or cells (e.g., DNA, RNA, protein) if not derived from elective abortion.
 - human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi if not derived from elective abortion.
 - human fetal cells present in maternal blood or other maternal sources
 - human embryonic stem cells or human embryonic cell lines.
 - research on transplantation of HFT for therapeutic purposes (because of the statutory provision(s) addressing such research)."

NIH requires additional documentation of the use of HFT from elective abortions in research, as NIH does with other research materials and models, to ensure that it is utilized for research only when scientifically justifiable, and in the least amount possible to achieve the scientific outcomes. NIH requires applicants to provide detailed information addressing the use of HFT in applications/proposals and reports. These requirements are designed to enable NIH to assess whether extramural research applicants and recipients are adequately assuring compliance with all applicable laws and HHS/NIH policies concerning the acquisition and use of HFT obtained from elective abortion.

NIH requires applicants to address HFT requirements by providing a justification of the use of HFT, details regarding procurement and costs, and information about how the applicant will use HFT. These additional requirements must be met within existing applicable page limits.

The addition of research involving HFT from elective abortions to a funded NIH grant project is considered an indicator of a change in scope and, due to the additional information required, such changes will require the submission of a competing revision application. Competing revision applications must include all required information, as described below. Administrative supplements to add HFT research will not be allowed. Complex grant mechanisms that include centers/cores with discretionary funds will not be allowed to expand existing HFT funding or to add HFT funded activities, including pilot projects.

Training awards and individual fellowships may not propose research using HFT. In addition, grant mechanisms that include centers with discretionary funds and Other Transaction Authority may not be used to support HFT research.

4.1.15 Human Subjects Protections

The HHS regulations for the protection of human subjects, in 45 CFR Part 46, implement Section 491(a) of the PHS Act and provide a framework, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by NIH or other HHS components.

The HHS regulations state that institutions (whether domestic or foreign) that are engaged in nonexempt research involving human subjects research and institutional boards (IRBs) reviewing research that is subject to the HHS regulations must comply with the regulations at 45 CFR 46 (Revised Common Rule §46.101(a) and Pre-2018 Common Rule §46.101(a)). Recipient institutions "engaged" in human subjects research must provide written assurance that it will comply with the regulatory requirements (Revised Common Rule §46.103(a) and Pre-2018 Common Rule §46.103(a)). The recipient institution provides written assurance by obtaining a Federalwide Assurance (FWA) with the HHS Office for Human Research Protections (OHRP) and establishing appropriate policies and procedures for the protection of human subjects (Revised Common Rule §46.108(a)(3) & (4) and Pre-2018 Common Rule §46.103(b) (4) & (5)). An institution is engaged in human subjects research if:

1. the institution's employees or agents intervene or interact with human subjects for research purposes;
2. the institution's employees or agents obtain individually identifiable private information or identifiable biospecimens about human subjects for research purposes; or
3. the institution receives a direct HHS award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.

The OHRP's document entitled [Engagement of Institutions in Human Subjects Research](#) provides additional guidance on "engagement".

The HHS regulations at Subparts B, C, and D include additional protections for specific populations as follows:

1. pregnant women, human fetuses and neonates (45 CFR Part 46, Subpart B);
2. prisoners (45 CFR Part 46, Subpart C); and
3. children (45 CFR Part 46, Subpart D).

Certain research activities are exempt from regulatory requirements for an FWA and IRB oversight (Revised Common Rule 46.104(d) and Pre-2018 Common Rule 46.101(b)). [OHRP guidance](#) states that institutions must adopt clear procedures under which the IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations. NIH will review the materials submitted by the institution, including the PHS Human Subjects Clinical Trials Information Form of the application, to determine if it can concur with the institution that the proposed activities are covered by the regulations or are in one or more exempt category. For research potentially subject to an exemption, this includes reviewing which category of exemption applies. NIH's review does not relieve the institution of any of its regulatory responsibility to accurately make and implement correct determinations about the research for the entirety of the project or otherwise speak for regulatory entities within HHS.

Unless all research activities meet the criteria for one or more exemptions from 45 CFR Part 46, research involving human subjects may only be conducted under an HHS award if the organization has a current OHRP approved FWA and provides certification that an Institutional Review Board (IRB) registered with OHRP has reviewed and approved the proposed activity in accordance with the HHS regulations.

In accepting an award that supports human subjects research, the recipient institution assumes responsibility for all research conducted under the award, including protection of human subjects at all participating and consortium sites. The recipient institution also assumes responsibility for ensuring that all institutions under the award engaged in nonexempt research involving human subjects have a current, approved FWA and must obtain certification of approval by an IRB registered with OHRP, of all nonexempt research involving human subjects before research may begin. When consultants are performing

research involving human subjects on NIH-funded projects, the consultant's institution must obtain an FWA.

The [The Human Subjects page of the NIH Grants & Funding website](#) contains additional information and Frequently Asked Questions that are available to help investigators understand how these Federal requirements apply to their research.

Applications will be considered incomplete if they do not address the involvement of human subjects in the PHS Human Subjects and Clinical Trials Information Form of the application. If human subjects research is anticipated within the period of the award but definite plans for involvement of human subjects cannot be described in the application (referred to as "delayed onset human subjects research" in the NIH grant application instructions), applicants must provide a detailed explanation of why it is not possible to develop definite plans. Prior to the involvement of human subjects the recipient must submit to the NIH awarding IC for prior approval either (1) detailed information as required in the PHS Human Subjects and Clinical Trials Information Form of the application, and meet the FWA and IRB certification requirements, or (2) if all of the research meets the criteria for one or more exemptions, identification of which exemptions(s) is/are applicable to the research, and a justification for the exemption with sufficient information about the involvement of human subjects to allow a determination that the claimed exemption is appropriate. Typically, recipients that are part of large clinical research networks or consortia that plan to add new protocols after the award must follow the awarding IC's procedures for approval of new protocols. Institutions with award mechanisms that allow them to select new projects, typically small future research projects (e.g., pilot projects), for support by their NIH award are responsible for ensuring that the selected projects follow all relevant regulations and policies including those governing the involvement of human subjects in research, including prior approval from the IRB if applicable. They must follow the awarding IC's procedures for prior approval of new protocols and updating the IC on the status of funded projects in annual progress reports which are typically described in the NOFO and/or NoA.

Recipients may not draw funds from the payment system, request funds from the paying office, or make obligations against Federal funds for research involving human subjects at any site engaged in nonexempt research for any period not covered by both an FWA and IRB approval consistent with 45 CFR Part 46. Costs associated with IRB review of human research protocols are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.

The use of autopsy materials is governed by applicable State and local law and is not regulated by 45 CFR Part 46.

4.1.15.1 Federalwide Assurance Requirements

The Federalwide Assurance (FWA) commits the organization to compliance with the requirements set forth in 45 CFR Part 46, and the Terms of Assurance. Each institution that is engaged in HHS supported human subjects research must be covered by an FWA approved by OHRP.

When an applicant organization proposes nonexempt research involving human subjects and does not have an FWA, the AOR signature on the application constitutes declaration that the organization will comply with 45 CFR Part 46 and proceed to obtain an FWA. The NIH awarding component will place a restriction in the NoA so that no human subjects research may be conducted under the award until the FWA and certification of IRB review and approval (or certification of institutional determination of exemption, if applicable) have been obtained and accepted by NIH.

Each recipient institution must file its own FWA even if the organization does not operate its own IRB and designates another IRB for that purpose. IRBs must be registered with OHRP before the IRB may be designated on an FWA as reviewing proposed research for the FWA-holding institution.

Organizations that will serve as additional performance sites that are engaged in nonexempt research involving human subjects under the award must obtain an FWA, or, under specified circumstance, may be covered by the recipient's FWA in accordance with the OHRP's Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement.

It is the recipient organization's responsibility to ensure that all sites engaged in research involving human subjects are covered by an appropriate FWA and have IRB approval consistent with 45 CFR Part 46. It also is the recipient's responsibility to comply with NIH prior approval requirements related to the addition of sites not included in the approved application (see [Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements](#)). A list of organizations with approved assurances is available at the [OHRP web site](#).

No individual may receive NIH grant funds for nonexempt research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an FWA or the individual makes other arrangements with OHRP.

Detailed information concerning FWAs is available on the [OHRP web site](#).

4.1.15.2 Certification of IRB Approval

Recipients must provide a certification to NIH that all nonexempt research involving human subjects has been reviewed and approved by an appropriate IRB, consistent with 45 CFR Part 46 and OHRP guidance. NIH-funded sites in the United States cannot rely on a non-US IRB; therefore, NIH will not accept an approval from a non-US IRB. The date of final IRB approval is the date that all protocols in the proposed research application received IRB review and approval (i.e., the date of the last protocol approval). When human subjects research is anticipated within the period of the award but definite plans for involvement of human subjects cannot be described in the application or proposal (referred to as "delayed onset human subjects research"), prior to the involvement of human subjects in nonexempt research, the recipient must submit to the NIH awarding IC for prior approval (1) detailed information as required in the Human Subjects and Clinical Trials Information Form of the application, as well as the certification and date of final IRB approval. Note that NIH requires the date of final IRB approval; conditional IRB approval is not sufficient. According to OHRP, in the case of IRB approval with conditions, IRB approval only becomes effective when the IRB has approved all information submitted in response to their conditions.

Certification of IRB approval may be filed at any time before award in accord with Just-in-Time procedures, unless required earlier by the IC. Therefore, following peer review and notification of impact score/percentile, applicant organizations with OHRP FWAs may wish to proceed with IRB review for those protocols that have not yet received IRB approval and that apply to applications in a fundable range.

Under no circumstances may NIH-supported nonexempt research involving human subjects be initiated prior to obtaining IRB approval and providing the final IRB approval date to NIH. NIH will not allow any funds to be used by recipients where a certification and an IRB approval date has not been provided to the funding IC.

Recipients are also reminded that any changes to study protocols that have been subject to peer review, as well as the addition of new study protocols, require the prior approval of the NIH awarding Institute or Center consistent with [Section 8.1.2.5](#) of the NIHGPS. Such requirements are also generally described in the Notice of Funding Opportunity and/or the Notice of Award.

4.1.15.3 Reporting to Funding Agency and OHRP

Under the HHS regulations, recipient institutions must establish and follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and NIH of any unanticipated problem involving risks to subjects or others or any serious or continuing noncompliance with 45 CFR Part 46 or IRB requirements or determinations; and any suspension or termination of IRB approval (revised Common Rule 45 CFR Part 46.108(a)(4) and pre-2018 Common Rule 45 CFR Part 46.103(b)(5)). Any IRB suspension or termination of approval must include a statement of the reasons for the IRB's action and must be reported promptly to the investigator, appropriate institutional officials, and NIH (45 CFR Part 46.113). Recipient institutions must also file incident reports promptly with OHRP of unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 45 CFR Part 46 or with the requirements or determinations of the IRB, and suspension or termination of IRB approval. See Guidance on Reporting Incidents to OHRP for more information.

4.1.15.4 OHRP Oversight

OHRP has regulatory responsibility for oversight of recipient compliance with the HHS human subjects regulations. In carrying out this responsibility, OHRP evaluates all written allegations or indications of non-compliance with the HHS regulations it receives from any source. All compliance oversight evaluations are predicated on the HHS regulations and the organization's assurance of compliance. Any corrective actions imposed as a result of a compliance oversight evaluation are intended to remedy identified non-compliance and prevent reoccurrence. Because each case is different, OHRP tailors corrective actions to foster the best interest of human research subjects and, to the extent possible, of the organization, research community, and HHS. Most compliance oversight evaluations and resultant corrective actions are resolved at the OHRP level. However, OHRP may recommend actions to be taken by other HHS officials.

Information about the FWA submission process and about OHRP activities related to oversight and compliance, as well as copies of the human subjects regulations, may be obtained from OHRP at the address shown in Part III or from the [OHRP home page](#).

4.1.15.5 Education in the Protection of Human Research Participants

Before funds are awarded for competing applications involving human subjects, applicants must submit documentation that all senior/key personnel involved in human subjects research have received training in the protection of human subjects. Senior/key personnel include all individuals responsible for the design or conduct of the study, including senior/key personnel of all sites involved in research activities. This documentation should be included in the cover letter signed by the AOR that accompanies the description of other support, IRB and IACUC approval, and other information submitted prior to funding in accordance with Just-in-Time procedures. For non-competing continuation awards, the description of education for new senior/key personnel should be part of the progress report submitted as a prerequisite to award. Additional information about this education requirement is available on the [Training & Resources – Human Subjects page of the NIH Grants & Funding website](#).

4.1.15.6 Data and Safety Monitoring

The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. NIH policies on data and safety monitoring specify that the level and frequency of monitoring should be commensurate with the risks, nature, and complexity of the clinical trial, and are in addition to any monitoring requirements imposed by FDA. There are a number of options for monitoring clinical trials including, but not limited to, monitoring by a/an:

- PD/PI (required),
- IRB (required),
- Independent individual/safety officer,
- Designated medical/research monitor,
- Internal committee or board with explicit guidelines,
- DSMB (required for multi-site trials).

Applications that include clinical trials must include a general description of the data and safety monitoring plan. The description of the data and safety monitoring plan in competing applications will be reviewed by the SRG. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It must describe the entity that will be responsible for monitoring how adverse events will be reported to the IRB and NIH and, when appropriate, how NIH Guidelines and FDA regulations for INDs and IDEs will be satisfied.

A detailed monitoring plan must be included as part of the research protocol, be submitted to the IRB, and be reviewed and approved by the NIH awarding IC prior to the accrual of human subjects. The awarding IC may specify the reporting requirements for adverse events, which are in addition to the annual report to the IRB. The clinical trial monitoring function is above and beyond that traditionally provided by IRBs; however, the IRB must be cognizant of the procedures used by clinical trial monitoring entities and the monitor must provide periodic reports to investigators for transmittal to the IRB.

NIH specifically requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials also may use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.

For multi-site Phase I and II trials, investigators should organize a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and the IRBs of participating sites. The frequency of summary reports will depend on the nature of the trial. Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and II clinical trials. However, such plans always should be evaluated for appropriateness for the particular investigation.

All multi-site trials with DSMBs are expected to forward summary reports of adverse events to each responsible IRB so they can address as appropriate to their responsibility reports related to the site. Recipients should address questions on this subject to the NIH PO.

Further information concerning these requirements is found on the [NIH Human Subjects Research website](#) and in the SF424 (R&R) application instructions, [see section G.500 – PHS Human Subjects and Clinical Trials Information](#).

4.1.15.7 Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

For all competing grant applications, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR Part 46 as well as with other pertinent federal laws and regulations.

Applications or proposals for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. Applications must include a description

of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the recipient / offeror must provide an acceptable justification for the exclusion.

Scientific review groups at NIH will assess each application as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project, in addition to evaluating the plans for conducting the research in accord with these provisions. NIH staff will monitor implementation of this policy during the development, review, award and conduct of research; and manage the NIH research portfolio to comply with the policy.

NIH recipients must submit data on participant age at enrollment in progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided to NIH in progress reports.

Ongoing, non-competing awards and competing applications submitted prior to January 25, 2019, will not be expected to comply with this policy until the recipient submits a competing renewal application. For these projects, the previous policy on the inclusion of children ([NOT-98-024](#)) continues to apply.

4.1.15.8 Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation

NIH-conducted and supported Clinical research must conform to the [NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research](#) in accord with Public Health Service Act sec. 492B, 42 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations be included in NIH-conducted or supported clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the NIH IC Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an IC Director based on a compelling rationale and justification.

Cost is not an acceptable reason for exclusion except when the research would duplicate existing data. Women of childbearing potential should not be routinely excluded from participation in clinical research. The policy applies to research subjects of all ages in NIH-supported clinical research studies (see definition of clinical research). The inclusion of individuals on the basis of sex/gender, race, and ethnicity must be addressed in developing a research design appropriate to the scientific objectives of the study. A proposed outreach program for recruiting should also be included. When an NIH-defined Phase III clinical trial is proposed, investigators must consider whether clinically important sex/gender, racial, and/or ethnic differences in the intervention effect are to be expected and plan the research accordingly. When registering in Clinicaltrials.gov, applicable clinical trials as defined in 42 C.F.R. Part 11, that are also NIH-defined Phase III clinical trials must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the [NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research](#). For applicable clinical trials that are also NIH-defined Phase III clinical trials, submissions of results to Clinicaltrials.gov must include results of valid analyses by sex/gender and race/ethnicity, as required based on prior evidence.

Investigators must also collect and annually report information on sex/gender, race, and ethnicity in clinical research studies. The OMB minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant projects are described in [OMB Directive No. 15](#). The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards include five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. There are two categories for ethnicity: "Hispanic or Latino," and "Not Hispanic or Latino."

For more information on policies and procedures related to inclusion: [Inclusion Procedures](#)

4.1.15.9 Good Clinical Practice Training for NIH Recipients Involved in NIH-funded Clinical Trials

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP), consistent with principles of the [International Conference on Harmonization \(ICH\) E6 \(R2\)](#).

The principles of GCP help assure the safety, integrity, and quality of clinical trials. GCP provides a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors and monitors. GCP addresses elements related to the design, conduct and reporting of clinical trials.

GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. The principles were developed in 1996 by the ICH in collaboration with representatives from the European Union, Japan, and the United States. The U.S. Food and Drug Administration (FDA) requires GCP compliance for studies conducted under an investigational new drug application or investigational device exemption.

GCP describes the responsibilities of investigators, sponsors, monitors and IRBs in the conduct of clinical trials. Compliance with GCP provides assurance that the rights, safety and well-being of human subjects are protected, that clinical trials are conducted in accordance with approved plans with rigor and integrity, and that data derived from clinical trials are reliable.

GCP training complements other required training on protections for human research participants. Since June 2000, the NIH Extramural Research Program has required training on protections for human research participants for all NIH-funded investigators and individuals responsible for the design or conduct of NIH funded research involving human subjects.

The GCP policy applies to NIH-funded investigators and clinical trial site staff who are responsible for the conduct, management and oversight of [NIH-funded clinical trials](#). GCP training includes the Principles of ICH GCP found in Section 2 of ICH E6. GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. Acceptable GCP courses include the [NIAID GCP Learning Center website](#) and [National Drug Abuse Treatment Clinical Trials Network](#). Completion of GCP training will demonstrate that individuals have attained the fundamental knowledge of clinical trial quality standards for designing, conducting, recording and reporting trials that involve human research participants. GCP training should be refreshed at least every three years in order remain current with regulations, standards and guidelines. Recipients of GCP training are expected to retain documentation of their training, and make it available to NIH upon request.

For purposes of Good Clinical Practice training the following definitions apply:

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical trial staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and

collect and record information from research participants. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

4.1.15.10 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

NIH requires sites located in the United States engaged in NIH-funded, multi-site research conducted at more than one domestic site to rely upon approval by a single Institutional Review Board (sIRB) as required by the Revised Common Rule (rCR) at 45 CFR Part 46.114 and NIH sIRB Policy, including projects supported by career development (K) and fellowship (F) awards with initial IRB approval on or after January 20, 2020. NIH expects the domestic sites in NIH-funded, multi-site studies to rely on a US sIRB (located in the United States). Foreign sites participating in NIH-funded, multi-site studies will not be expected to use a single IRB.

NIH applicants whose research is subject to the sIRB requirements must provide the name of the sIRB during the Just-in-Time period, before the award is issued. If, in delayed-onset research, an sIRB has not yet been identified, the recipient will provide the name of the sIRB to the funding NIH Institute/Center (IC) prior to initiating the multi-site research study/project.

The applicant may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study/project by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, as described in Chapter 7 (Cost Consideration) and in case of for-profit organizations the Federal Acquisition Regulation (FAR) 31.302 (Direct Costs) and FAR 31.203 (Indirect Costs).

Recipients are responsible for ensuring that authorization agreements are in place. Copies of authorization agreements and other necessary documentation should be maintained to document compliance, as needed. As appropriate, recipients are responsible for ensuring that a mechanism for communication between the sIRB and participating sites is established.

All sites participating in multi-site research studies/projects subject to the sIRB requirements are expected to rely on an sIRB to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR Part 46. Participating sites are responsible for meeting all other regulatory obligations.

NIH sIRB policy does not prohibit participating sites from also reviewing the research under the applicable regulatory framework. This additional review, even if performed by the institution's IRB, is not the regulatory review of the research as that responsibility still remains with the sIRB. If this approach is taken, NIH funds may not be used to pay for the cost of the duplicate review.

4.1.16 Investigational New Drug Applications/Investigational Device Exceptions

To be eligible for NIH funding, all clinical research involving investigational drugs and devices, or other products regulated by the FDA, must comply with all applicable FDA requirements, including those for INDs, IDEs, and human subjects protections. Among other provisions, FDA regulations for human subjects protections are published in 21 CFR Parts 50 and 56 with additional standards found in Parts 312 and 812.

When applicable, the sponsor of the IND/IDE, whether NIH, a recipient, or a third party, is legally responsible for meeting the FDA requirements for sponsors. If the sponsor is also the PI, then the sponsor will need to satisfy FDA's requirements for sponsor-investigators. If the IND/IDE sponsor is a third party, such as a pharmaceutical company or research organization under contract to a recipient or to a

pharmaceutical company, the legal responsibility for monitoring the clinical trial and reporting to FDA rests with the sponsor rather than the recipient. This generally will be the case for larger, multi-site clinical trials. If the recipient is the IND/IDE holder, commonly referred to as an “investigator-initiated IND/IDE,” the recipient or the investigator serves as the sponsor and assumes the legal responsibility. In any case, the recipient is ultimately responsible to NIH for ensuring compliance with the applicable requirements for protection of human subjects, including compliance with FDA’s requirements.

Following the filing of an IND, FDA has a 30-day period in which to review it. FDA may allow the IND to proceed or may defer approval of the IND until changes it deems acceptable are made. FDA also may order a clinical trial to be suspended or terminated, at any time, based on information it receives about that clinical trial.

When NIH funds any part of a clinical study involving an IND or an IDE, NIH must be knowledgeable about any significant communications with FDA concerning the study. The recipient organization must report certain types of FDA communications to the NIH awarding IC within 72 hours of receiving a copy of, or upon being informed of, the FDA communication (through the PD/PI or another person acting on behalf of the recipient), whichever occurs first. This notification requirement applies to any of the following communications from FDA with the sponsor of the IND or IDE:

- Warning letters (whether sent to the recipient or to the for-profit sponsor)
- Notices of Initiation of Disqualification Proceedings and Opportunity to Explain
- Notice of Opportunity for Hearing
- Notice of Disqualification
- Consent Agreements
- Clinical hold letters that pertain to breaches of good manufacturing practices, good clinical practices, or other major issue requiring significant changes in the protocol.

The notification should be made in writing, but also may be done by telephone if a written notice would delay the notification. It should include a statement of the action taken or contemplated and the assistance needed to resolve the situation. These requirements apply to the recipient even if the recipient or the NIH-funded PD/PI is the sponsor. Failure to comply with this requirement may result in NIH imposing a corrective and/or enforcement action (see [Administrative Requirements—Enforcement Actions](#)). FDA communications are considered grant-related records for purposes of retention and access (see [Administrative Requirements—Monitoring—Record Retention and Access](#)).

4.1.17 Lobbying Prohibition

Recipients of Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, “Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions,” from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments. These requirements are implemented for HHS in 45 CFR Part 93, which also describes types of activities, such as legislative liaison activities and professional and technical services, which are not subject to this prohibition under certain circumstances.

Applicants for NIH awards are required to certify and disclose that they:

- have not made, and will not make, such a prohibited payment;
- used or will use non-appropriated funds if they have made or agreed to make such payment; and

- will include these requirements in consortium agreements and contracts under grants that will exceed \$100,000 and obtain necessary certifications from those consortium participants and contractors.

Certifications and disclosures must be filed at the times prescribed in the regulations based on the expected total costs.

The signature of the AOR on the application serves as the required certification of compliance for the applicant organization. Disclosure reporting is addressed in [Administrative Requirements—Monitoring—Reporting](#).

See also Appropriation Public Policy Requirements Mandates [Lobbying—Appropriation Prohibition](#) for additional restrictions.

4.1.18 Metric System

Consistent with EO 12770 (July 25, 1991), Metric Usage in Federal Government Programs, measurement values in applications and recipient-prepared reports, publications, and other grant-related documents should be in metric. See [Construction Grants](#) chapter in IIB for requirements for metric usage in construction activities.

4.1.19 Military Recruiting and Reserve Officer Training Corps Program Access to Institutions of Higher Education

Section 588 of the National Defense Authorization Act of 1995, amended (10 U.S.C. §983), precludes NIH grant awards to institutions of higher education that DoD determines have an anti-Reserve Officer Training Corps (ROTC) policy or practice (regardless of when implemented) that either prohibits or, in effect, prevents the Secretary of Defense from gaining entry to campuses or access to students or information for military recruiting. DoD publishes each determination of ineligibility in the Federal Register as well as publishing, once every 6 months, a list of all currently ineligible schools. If DoD determines that an institution is ineligible during an ongoing project period, NIH will suspend support of current and future grant awards as provided in [Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support](#). Funding eligibility may be restored on the basis of new information provided by DoD.

4.1.20 National Environmental Policy Act

All NIH grants, whether or not they include construction or major A&R activities, are subject to the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended. This Act requires Federal agencies to consider the reasonably foreseeable environmental consequences of all grant-supported activities. As part of NIH's implementation of this Act, recipients are required to promptly notify NIH of any reasonably foreseeable impacts on the environment from grant-supported activities, or certify that no such impacts will arise upon receipt of a grant award. In addition, NIH has determined that most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment unless any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below:

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.

3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous waste, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

This requirement is in addition to other public policy requirements for grants for construction and alteration and renovation activities discussed more fully in the Construction chapter — [Construction, Modernization, or Major Alteration and Renovation of Research Facilities—Public Policy Requirements](#).

4.1.21 Nondelinquency on Federal Debt

The Federal Debt Collection Procedures Act of 1990 (Act), 28 U.S.C. 3201(e), provides that an organization or individual that is indebted to the United States, and has a judgment lien filed against it, is ineligible to receive a Federal grant. NIH cannot award a grant unless the AOR of the applicant organization (or individual in the case of a Kirschstein-NRSA individual fellowship) certifies, by means of their signature on the application, that the organization (or individual) is not delinquent in repaying any Federal debt. If the applicant discloses delinquency on a debt owed to the Federal government, NIH may not award the grant until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed. In addition, once the debt is repaid or satisfactory arrangements made, NIH will take that delinquency into account when determining whether the applicant would be a responsible NIH grant recipient.

Anyone who has been judged to be in default on a Federal debt and who has had a judgment lien filed against them should not be listed as a participant in an application for an NIH grant until the judgment is paid in full or is otherwise satisfied. No funds may be used for or rebudgeted following an award to pay such an individual. NIH will disallow costs charged to awards that provide funds to individuals in violation of this Act.

These requirements apply to all types of organizations and awards, including foreign grants.

4.1.22 President's Emergency Plan for AIDS Relief (PEPFAR) Program

4.1.22.1 PEPFAR Agreements

Specific terms and conditions concerning prostitution and sex trafficking apply to all grants awarded under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program. These are:

- A. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.
- B. The following definitions apply for purposes of this provision:
 - 1. “Commercial sex act” means any sex act on account of which anything of value is given to or received by any person.
 - 2. “Prostitution” means procuring or providing any commercial sex act and the “practice of prostitution” has the same meaning.
 - 3. “Sex trafficking” means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.
- C. The Recipient must insert this provision, which is a standard provision, in all subawards or subcontracts.
- D. This provision includes express terms and conditions of the award and any violation of it is grounds for unilateral termination of the award by NIH prior to the end of its term.

4.1.22.2 PEPFAR Agreements Between the U.S. Government and Foreign Non-Governmental Organizations (NGOs)

Additional requirements regarding the opposition to prostitution and sex trafficking may be applied to grants awarded under PEPFAR and issued to foreign Non-Governmental Organizations (NGOs) directly supported by or subrecipients of U.S. public or private NGOs. Subject to the United States Supreme Court’s decision in *Agency for International Development, et al., v. Alliance for Open Society International, Inc., et al.*, 133 S. Ct. 2321 (2013) and subsequent proceedings, the terms and conditions for such agreements with foreign NGOs may include the following:

- A. The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

- B.
1. Except as provided in (B)(2) and (B)(3), by accepting this award or any subaward, a non-governmental organization or public international organization recipient / sub-recipient agrees that it is opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children. Any enforcement of this clause is subject to *Agency for International Development, et al., v. Alliance for Open Society International, Inc., et al.*, 133 S. Ct. 2321 (2013) and subsequent proceedings.
 2. The following organizations are exempt from (B)(1): the Global Fund to Fight AIDS, Tuberculosis and Malaria; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.
 3. Contractors and subcontractors are exempt from (B)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.
 4. Notwithstanding section (B)(3), not exempt from (B)(1) are recipients, subrecipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any subaward, or procurement contract or subcontract by:
 - i. Providing supplies or services directly to the final populations receiving such supplies or services in host countries;
 - ii. Providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or
 - iii. Providing the types of services listed in FAR 37.203(b)(1)-(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).
- C. The following definitions apply for purposes of this provision:
1. "Commercial sex act" means any sex act on account of which anything of value is given to or received by any person.
 2. "Prostitution" means procuring or providing any commercial sex act and the "practice of prostitution" has the same meaning.
 3. "Sex trafficking" means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).
- D. The recipient shall insert this provision, which is a standard provision, in all subawards, procurement contracts or subcontracts.
- E. This provision includes express terms and conditions of the award and any violation of it shall be grounds for termination of the award by NIH prior to the end of its term.

4.1.23 Pro-Children Act of 1994

Public Law 103-227, Title X, Part C, Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, imposes restrictions on smoking in facilities where federally funded children's services are provided. NIH grants are subject to these requirements only if they meet the Act's specified coverage. The Act specifies that smoking is prohibited in any indoor facility (owned, leased, or contracted for) used for the routine or regular provision of kindergarten, elementary, or secondary education or library

services to children under the age of 18. In addition, smoking is prohibited in any indoor facility or portion of a facility (owned, leased, or contracted for) used for the routine or regular provision of federally funded health care, day care, or early childhood development (Head Start) services to children under the age of 18. The statutory prohibition also applies if such facilities are constructed, operated, or maintained with Federal funds. The statute does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, portions of facilities used for inpatient substance or alcohol treatment, or facilities where Women, Infants and Children (WIC) coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1,000 per violation and/or the imposition of an administrative compliance order on the responsible entity.

Because of the nature of NIH programs and funding, individual transactions, rather than entire programs, may be subject to these requirements. The signature of the AOR will indicate the intent to comply. Any questions concerning the applicability of these provisions to an NIH grant should be directed to the GMO.

4.1.24 Public Health Security

4.1.24.1 Public Health Security and Bioterrorism Preparedness and Response Act (Select Agents)

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. 201, is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the U.S. homeland or other criminal acts. The Act was implemented, in part, through regulations published by HHS and USDA at 42 CFR Part 73, 9 CFR Part 121 and 7 CFR Part 331 or commonly referred to as "Select Agent Regulations." Copies of these regulations are available [here](#), or can be obtained from CDC, 1600 Clifton Road, MS A-46, Atlanta, GA 30333; telephone: 404-718-2000.

Research involving select agents and recombinant or synthetic nucleic acid molecules also is subject to *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. *NIH Guidelines* apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecule research.

4.1.24.1.1 Select Agents

4.1.24.1.1.1 Select Agent Awards to U.S. Institutions

Domestic recipients who conduct research involving select agents or toxins (see Section 3 and 4 of 42 CFR Part 73 and 9 CFR Part 121 and Section 3 of 7 CFR Part 331) must maintain a registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.

4.1.24.1.1.2 Select Agent Awards to Foreign Organizations and International Organizations

Foreign Organizations and International Organizations who conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must provide information satisfactory to NIH that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all

select agent work sponsored by NIH funds before using these funds for any work directly involving select agents. Recipients must be willing to address the following key elements appropriate for their institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

4.1.24.1.1.3 Select Agent Awards to U.S. Institutions with Foreign Subcomponents

Recipients who conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must complete registration with CDC (or USDA, depending on the agent) before using NIH funds for any work directly involving the select agent at the U.S. institution. No funds can be used for research involving select agents if the final registration certificate is denied. Before using NIH funds for any work directly involving the select agents at a foreign subrecipient, the U.S. recipient must provide information from the foreign organization satisfactory to NIH that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by these funds. Recipients must be willing to address the following key elements appropriate for the foreign organization: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the select agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73 are followed. If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to NIH that your work does not now nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

4.1.24.2 Dual Use Research of Concern

On September 24, 2014, the Federal government issued a policy for the oversight of life sciences [“Dual Use Research of Concern” \(DURC\)](#). DURC is defined as life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. Despite its value and benefits, some research may be misused for harmful purposes. The fundamental aim of this oversight policy is to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

The DURC policy applies to recipient institutions and its investigators in the United States that receive Federal funding for life sciences research and that conduct or sponsor research involving one or more of the 15 agents or toxins listed in the policy and to foreign recipients that receive Federal funding to conduct or sponsor research involving one of these 15 agents or toxins. Institutions must establish an Institutional Review Entity (IRE) which must review research involving these agents or toxins to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR), as required by the U.S. Government’s DURC Policy, to serve as an internal resource for issues regarding compliance with and implementation of the requirements for the oversight of research that falls within the scope of the DURC policy role. The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.

For research that may be considered DURC, NIH will work collaboratively with the institution and investigators to develop a risk mitigation plan, which may be implemented through a term of award and that NIH must approve. For example, NIH may request that institutions periodically review a project for its DURC potential, propose any modifications to the risk mitigation plan, and share any resulting manuscripts with their Program Official prior to submitting the manuscript to a journal.

4.1.24.3 Agents Regulated Under the Chemical Weapons Convention

The United States is one of 175 States Parties to the Chemical Weapons Convention (CWC), which prohibits the development, production, stockpiling, and use of chemical weapons (CW). The CWC does not prohibit production, processing, consumption, or trade of related chemicals for peaceful purposes, but it does establish a verification regime to ensure such activities are consistent with the object and purpose of the treaty.

NIH researchers engaged in activities involving these chemicals, especially Schedule 1 chemicals, may be required to submit declarations and/or reports to the Bureau of Industry and Security (BIS) and may be subject to inspection by the Organization for the Prohibition of Chemical Weapons, which administers the CWC. In addition, trade in certain chemicals with States not Party to the CWC may be prohibited or subject to an export license and or end-use certificate.

Schedule 1 chemicals include, but are not limited to, the toxic chemicals sarin, soman, tabun, VX, sulfur mustards, Lewisites, saxitoxin, ricin, and nitrogen mustards. More information about the U.S. CWC, including complete lists of Schedule 1, 2, and 3 chemicals under the CWC may be found at on the [U.S. Chemical Weapons Convention website](#). Federal regulations that apply to the CWC are 15 CFR CHAPTER VII, SUBCHAPTER B, PARTS 710-722, SUBCHAPTER C, PARTS 730-774; 22 CFR CHAPTER I, PART 103, PARTS 120-130. These CRFs and other applicable safety standards issued by the Department of Commerce and Department of State are available on the [Chemical Weapons Conventions Regulations webpage](#).

4.1.25 Reporting and Assurance Requirements for Institutions Receiving Awards for Training of Graduate Students for Doctoral Degrees

As required by Section 403C of the Public Health Service Act, each institution receiving an NIH award for the training of graduate students for doctoral degrees must provide information on completion rates and time to degree to all applicants to doctoral programs supported by NIH training awards. Specifically, institutions must provide applicants with the following information for the programs to which they apply:

- The percentage of students admitted for study who successfully attain a doctoral degree, and
- The average time (not including any leaves of absence) between the beginning of graduate study and the receipt of a doctoral degree.

Institutions **affected** by this Assurance and information disclosure requirement are doctoral degree granting institutions that receive any of the following institutional training grant awards or cooperative agreements from NIH for the doctoral training of graduate students:

- D43, TU2, T15, T32, T37, T90, U2R, U90, and U54/TL1

Institutions are **not affected** by this requirement if they:

- Receive only individual NIH fellowship awards.
- Provide training only to undergraduate or master's level students supported through one of the activity codes listed above.
- Provide only short-term training to doctoral-level health professional students through one of the activity codes listed above.
- Receive an award for one or more of the activity codes for doctoral training of graduate students, but do not confer doctoral degrees themselves (e.g., teaching hospitals).
- Receive an institutional training grant award for doctoral training of graduate students from a Public Health Service Agency other than NIH.

In complying with this Assurance and information disclosure requirement, institutions may decide how best to present the required information to applicants and may wish to consider consolidating data by department or broad program to which candidates apply, or providing additional information in order to provide context.

Recipients with awards for any of the activity codes listed above are also required to provide corresponding information on trainees supported by each of their awards when submitting a renewal application or RPPR.

4.1.26 Research Involving Recombinant or Synthetic Nucleic Acid Molecules

4.1.26.1 Scope and Availability

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (April 2019 or latest revision) apply to all research projects (NIH-funded and non-NIH-funded) that involve recombinant or synthetic nucleic acid molecules and are conducted at or sponsored by an organization that receives NIH support for recombinant or synthetic nucleic acid molecules.

According to *NIH Guidelines*, recombinant and synthetic nucleic acid molecules are defined as (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). *NIH Guidelines* apply to both basic and clinical research studies.

Failure to comply with these requirements may result in suspension or termination of an award for recombinant or synthetic nucleic acid molecule research at the organization, or a requirement for NIH prior approval of any or all recombinant or synthetic nucleic acid molecule projects at the organization. The recipient should carefully review *NIH Guidelines* in its entirety to ensure compliance with all of the requirements for projects involving recombinant or synthetic nucleic acid molecules.

Research involving recombinant or synthetic nucleic acid molecules and select agents also is subject to pertinent CDC and USDA regulations, 42 CFR Part 73, Select Agents and Toxins; and 7 CFR Part 331 and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins.

4.1.26.2 Institutional Biosafety Committee

Each organization that conducts research involving recombinant or synthetic nucleic acid molecules, including contractors under grants, must have policies and procedures to ensure compliance with NIH

Guidelines and must establish a standing IBC. The IBC is required to review experiments involving recombinant or synthetic nucleic acid molecules to ensure that the procedures, project, personnel, and facilities are adequate and in compliance with NIH Guidelines. Section IV of NIH Guidelines specifies the composition of IBCs. A roster of the IBC members and biosketches for each member must be submitted to NIH. At a minimum, the roster should indicate the name of each IBC member, as well as which IBC members are serving as the chairperson, contact person, and, as applicable, experts in biosafety or plant, animal, or human experimentation. Biosketches should include a description of the occupation and professional qualifications of each member. Organizations can register their IBC with NIH on-line by utilizing the [IBC Registration Management System \(RMS\)](#).

4.1.26.3 Investigators and Institutional Staff

Section IV of *NIH Guidelines* also specifies the roles and responsibilities of PIs, biological safety officers (BSOs) and recipient institutions with respect to the safe conduct and oversight of recombinant or synthetic nucleic acid molecules. Investigators, laboratory staff, BSOs, and institutional officials should read and be aware of their duties and expected biosafety practices, as described by *NIH Guidelines*.

4.1.27 Research Misconduct

Title 42 CFR Part 93, PHS Policies on Research Misconduct (the “PHS regulation”), Subpart C, “Responsibilities of Institutions” specifies recipient responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file an Assurance of Compliance with the HHS Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity. Research misconduct is defined by Subpart A of 42 CFR Part 93 as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Subpart D, “Responsibilities of the U.S. Department of Health and Human Services,” specifies that [ORI](#) has responsibility for addressing research integrity and misconduct, monitors institutional investigations of research misconduct and facilitates the responsible conduct of research through education, preventive, and regulatory activities.

To be eligible for PHS funding, domestic and foreign institutions must have approved assurances and required renewals on file with ORI. The responsible institutional official must assure on behalf of the institution that the institution (1) has written policies and procedures in compliance with 42 CFR Part 93 for inquiring into and investigating allegations of research misconduct in PHS-supported research and (2) complies with its own policies and procedures and the requirements of 42 CFR Part 93. In addition, recipient institutions must foster a research environment that promotes the responsible conduct of research. Domestic and foreign subrecipient institutions must also maintain an assurance by submitting form PHS-6315 to ORI. An institution establishes an assurance when an official signs the face-page (SF 424 (R&R) or PHS 398) of the grant application form or when the institution files a separate assurance form. Once established, institutions maintain their assurance by filing the Annual Report on Possible Research Misconduct (between January 1 and April 30 each year), submitting their policy for responding to allegations of research misconduct for review when requested by ORI, revising their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and complying with the PHS regulation.

As stated throughout the NIHGPS, the recipient has primary responsibility for ensuring that it is conducting its NIH-funded project in accordance with the approved application and budget and the terms and conditions of the award. The recipient must carry out its responsibilities with extra care where research misconduct has been found or where a research misconduct investigation has been initiated, as specified in 42 CFR Part 93, Subpart C. The recipient must report promptly to ORI any decision to initiate an investigation of research misconduct.

The regulations specify the timing of an institutional investigation, related reporting to ORI, notice to the respondent, custody of records, documentation, opportunity for respondent to comment on the report, and the components on a final institutional investigative report.

If a misconduct investigation is initiated, the recipient must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and live vertebrate animals, provide reports to ORI, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate. ORI staff members are available to provide technical assistance to any institution that is responding to an allegation of research misconduct involving PHS funds. NIH IC staff members are available to provide guidance and to work with recipient institutions to protect funded projects from the adverse effects of research misconduct.

The recipient institution's engagement with ORI as provided in 42 CFR Part 93 does not substitute for its engagement with NIH to ensure ongoing compliance with the terms and conditions of award. When the recipient institution finds, learns of, or suspects research misconduct that impacts or might impact the conduct or performance of an NIH-supported project(s), whether at the recipient organization or at a third-party subrecipient organization, the recipient must work with NIH to assess the effect on the ability to continue the project, as originally approved by NIH. If the recipient institution determines that a change of scope or a change of PD/PI or other senior/key personnel is required, the institution must promptly obtain approval from the NIH funding Institute or Center Grants Management Officer. When a recipient institution finds, learns, or suspects that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research, including but not limited to, applications for funding and progress reports, or published research or research products supported by NIH funds, NIH has a need to know this information, and the institution must immediately provide information on the affected research to the [NIH Office of Extramural Research – Research Integrity](#) (OER-RI), in a manner consistent with the ORI confidentiality provision at, 42 CFR Part 93.108. The final institutional investigation report must be submitted to ORI, as outlined in Subpart C of 42 CFR Part 93.

NIH retains the authority to provide oversight regarding the management of grants and cooperative agreements. Accordingly, NIH may take action(s) to protect the health and safety of the public, including research participants, to promote the integrity of the PHS supported research and research process, and to conserve public funds. When a recipient fails to comply with the terms and conditions of award, NIH may take one or more enforcement actions including disallowance of costs, withholding of further support, or suspension or termination of the grant. These actions are described in [Administrative Requirements—Enforcement Actions](#).

Where research misconduct has affected data validity or reliability, ORI or NIH may request that the recipient and its employee/collaborator authors submit a correction or retraction of the data to a journal, publish the corrected data, or both. If the recipient does not comply, NIH may invoke its rights, under 2 CFR Part 200.315, to access the data (including copyrightable material developed under the award), and may then have the data reviewed, and notify the journal.

4.1.28 Seat Belt Use

Pursuant to EO 13043 (April 16, 1997), Increasing the Use of Seat Belts in the United States, NIH encourages recipients to adopt and enforce on-the-job seat belt policies and programs for their employees when operating vehicles, whether organizationally owned or rented or personally owned.

4.1.29 Smoke-Free Workplace

NIH strongly encourages recipients to provide smoke-free workplaces and to promote the nonuse of tobacco products. NIH defines the term “workplace” to mean office space (including private offices and other workspace), conference or meeting rooms, corridors, stairways, lobbies, rest rooms, cafeterias, and other public spaces.

4.1.30 Standards of Conduct

NIH requires recipients to establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business, or other ties. These safeguards must be reflected in written standards of conduct. Except as provided below, NIH does not require a recipient to establish separate standards of conduct if it maintains such standards for its non-grant-supported activities, as long as those standards are consistent with State and local laws and cover, at a minimum, expected conduct in regard to financial interests, gifts, gratuities and favors, nepotism, and such other areas as political participation and bribery. The standards also must do the following:

- Address the conditions under which outside activities, relationships, or financial interests are proper or improper.
- Provide for advance notification of outside activities, relationships, or financial interests to a responsible organizational official.
- Include a process for notification and review by the responsible official of potential or actual violations of the standards.
- Specify the nature of penalties that the recipient may impose. These penalties would be in addition to any penalties that NIH or a cognizant Federal agency may impose for infractions that also violate the terms or conditions of award.

The recipient is not required to submit its general standards of conduct to NIH for review or approval. However, a copy must be made available to each of its officers, each employee and consultant working on the grant-supported project or activity, each member of the governing board, if applicable, and, upon request, to NIH. The recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, the recipient is required to notify the NIH of an identified financial conflict of interest (FCOI) by submitting the FCOI report to NIH via the eRA Commons FCOI Module (see 4.1.10, Financial Conflict of Interest). If a suspension or separation action is taken by a recipient against a PD/PI or other senior/key personnel under an NIH grant, the recipient must request prior approval of the proposed replacement as specified in [Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements](#).

The recipient must promptly report issues involving potential criminal violations, such as misappropriation of Federal funds, to the [HHS OIG](#).

4.1.31 Text Messaging While Driving

Executive Order 13513 (E.O. 13513) requires each Federal agency to encourage contractors, sub-contractors, and grant and cooperative agreement recipients and subrecipients to adopt and enforce policies that ban text messaging while driving company-owned or -rented vehicles or Government Owned Vehicles, or while driving Personally Owned Vehicles when on official Government business or when performing any work for or on behalf of the Government.

To further the requirement of encouraging such policies, NIH encourages recipients to consider new rules and programs, reevaluate existing programs to prohibit text messaging while driving, and conduct education, awareness, and other outreach for employees about the risks associated with texting while driving. These initiatives should encourage voluntary compliance with the recipient agency's text messaging policy while off duty.

For the purposes of this policy and pursuant to E.O. 13513, the following definitions apply:

- a. "Texting" or "Text Messaging" means reading from or entering data into any handheld or other electronic device, including for the purpose of SMS texting, e-mailing, instant messaging, obtaining navigational information, or engaging in any other form of electronic data retrieval or electronic data communication.
- b. "Driving" means operating a motor vehicle on an active roadway with the motor running, including while temporarily stationary because of traffic, a traffic light or stop sign, or otherwise. It does not include operating a motor vehicle with or without the motor running when one has pulled over to the side of, or off, an active roadway and has halted in a location where one can safely remain stationary.

4.1.32 Trafficking in Persons

This government-wide award term implements Section 106 (g) of the Trafficking Victims Protection Act (TVPA) of 2000, as amended (22 U.S.C. 7104), located at 2 CFR Part 175.A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance. A Final Notice is expected to be issued in the future; however, HHS agencies have implemented this award term based on the Interim Final Guidance.

In accordance with the statutory requirement, in each agency award under which funding is provided to a private entity, section 106(g) of the TVPA, as amended, requires the agency to include a condition that authorizes the agency to terminate the award, without penalty, if the recipient or a subrecipient —

- a. Engages in severe forms of trafficking in persons during the period of time that the award is in effect;
- b. Procures a commercial sex act during the period of time that the award is in effect; or
- c. Uses forced labor in the performance of the award or subawards under the award.

4.1.33 USA Patriot Act

The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act) (P.L. 107-56) amends 18 U.S.C. 10 and provides criminal penalties for possession of any biological agent, toxin, or delivery system of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The Act also establishes restrictions on access to specified materials. "Restricted persons," as defined by the Act, may not possess, ship, transport, or receive any biological agent or toxin that is listed as a select agent (see [Public Health Security and Bioterrorism Preparedness and Response Act](#) in this section).

4.1.34 Responsibility/Qualification Information in SAM.gov

NIH award recipients are subject to the reporting requirements established by Public Law 112-239, National Defense Authorization Act for Fiscal Year 2013 and provided in Appendix XII to 2 CFR Part 200, NIH recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000

must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semi-annual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system. Full reporting requirements and procedures are found in Appendix XII to 2 CFR Part 200.

4.1.35 Mandatory Disclosures

Consistent with 2 CFR Part 200.113, NIH applicants and recipients must disclose, in a timely manner, in writing to the NIH awarding IC and the HHS Office of Inspector General (OIG) all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially impacting the federal award. Subrecipients must disclose, in a timely manner, in writing to the pass-through entity and the HHS OIG all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the NIH awarding IC and to the HHS OIG at the following address:

NIH CGMO listed on the NoA for the IC that funded the grant (See [Part III: Points of Contact 20 INSTITUTES AND CENTERS](#))

AND

U.S. Department of Health and Human Services

Office of Inspector General

ATTN: Mandatory Grant Disclosures, Intake Coordinator

330 Independence Avenue, SW, Cohen Building

Room 5527

Washington, DC 20201

URL: <https://oig.hhs.gov/fraud/report-fraud/index.asp>

(Include "Mandatory Grant Disclosures" in the subject line")

Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or

Email: MandatoryGranteeDisclosures@oig.hhs.gov

Failure to make required disclosures can result in any of the remedies described in 2 CFR Part 200.339. Remedies for noncompliance and [Administrative Requirements – Enforcement Actions](#), including [suspension or debarment](#) (See 2 CFR Part 180 and 376, 31 U.S.C.3321 and [Public Policy Requirements and Objectives— Debarment and Suspension](#)), as necessary and appropriate.

4.1.36 Never Contract with the Enemy

Federal awarding agencies and recipients are subject to the regulations implementing Never Contract with the Enemy in 2 CFR Part 183. The regulations in 2 CFR Part 183 affect covered contracts, grants and cooperative agreements that are expected to exceed \$50,000 within the period of performance, are

performed outside the United States and its territories, and are in support of a contingency operation in which members of the Armed Forces are actively engaged in hostilities.

4.1.37 Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment

Recipients and subrecipients are prohibited from expending loan or grant funds to: (1) Procure or obtain; (2) Extend or renew a contract to procure or obtain; or (3) Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Public Law 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

(i) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

(ii) Telecommunications or video surveillance services provided by such entities or using such equipment.

(iii) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

COVERED FOREIGN COUNTRY means the People's Republic of China.

In implementing the prohibition under section 889 of the NDAA, subsection (f), paragraph (1), heads of executive agencies administering loan, grant, or subsidy programs shall prioritize available funding and technical support to assist affected businesses, institutions, and organizations as is reasonably necessary for those affected entities to transition from covered communications equipment and services, to procure replacement equipment and services, and to ensure that communications service to users and customers is sustained.

4.2 APPROPRIATION MANDATES

The following statutory provisions limit the use of funds on NIH grants, cooperative agreements, and contract awards. These are provided separately in this section since they are subject to change annually based on specific appropriation language that restricts the use of grant funds. References to "Act" in these sections refer to the governing HHS annual appropriation Act. A list of Appropriation Mandates applicable to each fiscal year can be found on the [OER web site](#).

4.2.1 Acknowledgment of Federal Funding

In accordance with [Public Law 101-166](#), Section 511, known as the Steven's Amendment, all HHS recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Recipients are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and (2) the dollar amount of the total costs financed by nongovernmental sources, only for NIH programs that require cost-sharing.

4.2.2 Dissemination of False or Deliberately Misleading Information

None of the funds made available in the governing appropriations Act may be used to disseminate information that is deliberately false or misleading.

4.2.3 Gun Control

NIH funds may not be used, in whole or in part, to advocate or promote gun control.

4.2.4 Human Embryo Research and Cloning Ban

NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term “human embryo or embryos” includes any organism not protected as a human subject under 45 CFR Part 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. Furthermore, per the NIH Director’s Statement of April 28, 2015, NIH will not fund any use of gene-editing technologies in human embryos.

In addition to the statutory restrictions on human fetal research under subsection 498(b) of the PHS Act, by Presidential memorandum of March 4, 1997, NIH is prohibited from using Federal funds for cloning of human beings.

4.2.5 Lobbying—Appropriation Prohibition

NIH appropriated funds may not be used, other than for normal and recognized executive-legislative relationships for publicity or propaganda purposes, for the preparation, distribution, or use of a kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State legislature or local legislature itself or designed to support or defeat any proposed or pending regulation administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself. No part of any governing appropriation act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government. No part of any governing appropriation Act shall be used for any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control, except as described above. Also see [Public Policy Requirements and Objectives—Lobbying Prohibition](#), [Appropriation Mandates—Gun Control](#) and [Cost Considerations—Allowability of Costs and Activities](#).

4.2.6 Promotion or Legalization of Controlled Substances

Recipients are prohibited from knowingly using appropriated funds to support activities that promote the legalization of any drug or other substance included in Schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act, 21 U.S.C. 812 except for normal and recognized executive-congressional communications. This limitation does not apply if the recipient notifies the GMO that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage (see also [4.1.5 Controlled Substances](#)).

4.2.7 Restriction on Abortion Funding

NIH appropriated funds and funds in any trust fund to which funds are appropriated in the governing appropriation Act may not be spent for any abortion. None of the funds appropriated in the governing appropriation Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion. The term “health benefits coverage” means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

4.2.8.1 Exceptions to Restrictions on Abortions

- A. The limitations established in the preceding section shall not apply to an abortion —
 - 1. If the pregnancy is the result of an act of rape or incest; or
 - 2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.
- B. Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State’s or locality’s contribution of Medicaid matching funds).
- C. Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State’s or locality’s contribution of Medicaid matching funds).
- D.
 - 1. None of the funds appropriated to NIH may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.
 - 2. In this subsection, the term “health care entity” includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

4.2.9 Restriction on Distribution of Sterile Needles

NIH appropriated funds may not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. However, this limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health

department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law

4.2.10 Salary Cap/Salary Limitation

None of the funds appropriated in the governing appropriation Act for NIH (the Act), shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of that prescribed in the Act. Applications and proposals with categorical direct cost budgets reflecting direct salaries of individuals in excess of the rate prescribed in the Act will be adjusted in accordance with the legislative salary limitation. Current and historical information on the applicable salary cap for each fiscal year is on the [Salary Cap Summary](#) page of the NIH Grants & Funding website.

4.2.10 Restriction of Pornography on Computer Networks

“(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.”

4.2.11 Restriction on Disclosure of Political Affiliation for Federal Scientific Advisory Committee Candidates

Section 515 of the FY2014 Consolidated Appropriations Act included an additional legislative mandate regarding this requirement:

“None of the funds made available in this Act may be used to request that a candidate for appointment to a Federal scientific advisory committee disclose the political affiliation or voting history of the candidate or the position that the candidate holds with respect to political issues not directly related to and necessary for the work of the committee involved.”

5 THE NOTICE OF AWARD

The Notice of Award (NoA) is the legal document issued to notify the recipient that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is issued for the initial budget period and each subsequent budget period in the approved project period. The NoA reflects any future-year commitments. A revised NoA may be issued during a budget period to affect an action resulting in a change in the period or amount of support or other change in the terms and conditions of award. NIH will not issue a revised NoA to reflect a recipient's post-award rebudgeting. Until an IC has issued the NoA for the initial award, any costs incurred by the applicant for the project are incurred at its own risk (see [Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Pre-Award \(Pre-Agreement\) Costs](#) for NIH policy on the allowability of pre-award costs).

Notice of Award Page One

Effective October 1, 2020, HHS implemented a standardized page one of the NoA that serves as the first page of every HHS NoA for all discretionary awards. The standardized page one incorporates the following data elements:

- HHS Operating Division
 - Federal Award Identification Number
 - Federal Award Date
- Recipient Information
 - Recipient Name
 - Congressional District of Recipient
 - Payment System Identifier (also known as Entity Identification Number)
 - Employer Identification Number
 - Data Universal Numbering System
 - Recipient's Unique Entity Identifier
 - Project Director or Principal Investigator
 - Authorized Official
- Federal Agency Information
 - Awarding Agency Contact Information
 - Program Official Contact Information
- Federal Award Information
 - Award Number
 - Unique Federal Award Identification Number
 - Statutory Authority
 - Federal Award Project Title
 - Assistance Listing Number (formerly / also known as CFDA Number)

- Assistance Listing Program Title (formerly / also known as CFDA program title)Name
- Award Action Type
- Is this Award R&D?
- Summary Federal Award Financial Information
 - Budget Period Start and End Date
 - Total Amount of Federal Funds Obligated by this Action
 - Direct Cost Amount
 - Indirect Cost Amount
 - Authorized Carryover
 - Offset
 - Total Amount of Federal Funds Obligated this Budget Period
 - Total Approved Cost Sharing or Matching, where applicable
 - Total Federal and Non-Federal Approved this Budget Period
 - Project Period Start and End Date
 - Total Amount of the Federal Award, including Approved Cost Sharing or Matching, this Project Period
- Authorized Treatment of Program Income
- Grants Management Officer Signature
- Remarks

Remainder of the NIH NoA

Additionally, the remainder of the NIH NoA sets forth pertinent information about the grant in Section I (Award Data), Section II (Payment Information), and Sections III and IV (Applicable Terms and Conditions of Award). This additional information, includes, but not limited to, the following:

- Cumulative budget approved by the NIH awarding IC
- Amount of anticipated future-year commitments (if applicable)
- Names of the cognizant IC PO, GMO, and GMS
- Indirect cost rate for the Federal award (including if the de minimis rate is charged per 2 CFR Part 200.414)
- Applicable terms and conditions of award, either by reference or inclusion
- Federal award performance goals (as required by the periodic report in the RPPR or in the final RPPR when applicable)
- Any restriction on the use of funds

Note: If applicable, section III of the NoA will also reference an institution's participation in the current phase of the Federal Demonstration Partnership (FDP).

As specified in the NoA, all awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 2 CFR Part 200. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

A recipient indicates acceptance of an NIH award and its associated terms and conditions by drawing or requesting funds from the designated HHS payment system or office. If the recipient cannot accept the award, including the legal obligation to perform in accordance with its provisions, it should notify the GMO immediately upon receipt of the NoA. If resolution cannot be reached, the GMO will void the grant. NIH’s determination of applicable terms and conditions of award or a GMO’s denial of a request to change the terms and conditions is discretionary and not subject to appeal (post-award appeal rights are discussed in [Administrative Requirements—Grant Appeals Procedures](#)). Once the award is accepted by the recipient, the contents of the NoA are binding on the recipient unless and until modified by a revised NoA signed by the GMO.

5.1 NOTICE OF AWARD NOTIFICATION

NIH notifies the recipient organization via e-mail when an award has been issued-i.e., on the Federal award date. In order to allow for the e-mail notification of the NoA, recipient organizations must register a valid e-mail address in the NoA E-mail field in the eRA Commons Institutional Profile once the initial eRA Commons registration process is complete. Organizations are encouraged to use a unique e-mail address that is not specific to an individual in order to avoid communication problems when personnel change. It is the responsibility of the recipient organization to maintain a current and accurate e-mail address for NoAs. NIH will not distribute NoAs other than through this system-generated e-mail notification process. Recipients that do not maintain a current NoA notification e-mail address will be responsible for accessing NoAs via the eRA Common.

On the Federal award date, the NoA is made available to recipient officials and corresponding PD/PIs in the eRA Commons through the Status module. The eRA Commons is the official repository for the NoA document.

In addition to e-mail notifications, there is a public query [Quick Query – Search for an Issued NoA](#) available on the [eRA web site](#) to generate a list of awards issued to an organization over a selected period. The organization’s Institution Profile File (IPF) Number is required in order to use the query.

5.2 ASSOCIATED APPLICATIONS AND/OR AWARDS

For some special initiatives a project or program may be funded by multiple awards that are associated with the others through specific terms and conditions. These terms include any reporting requirements that would need to be coordinated in future years. When multiple awards are issued for a particular project/program at different institutions, the coordination required among the recipient institutions administering the awards will be documented in the specific terms and conditions.

5.3 FUNDING

For most grants, NIH uses the project period system of funding. Under this system, projects are programmatically approved for support in their entirety but are funded in annual increments called budget

periods. The length of an initial project period (competitive segment) or of any subsequent competitive segment is determined by the NIH awarding IC based on:

- any statutory or regulatory requirements,
- the length of time requested by the applicant to complete the project,
- limitation on the length of the project period recommended by the peer reviewers,
- the awarding IC's programmatic determination of the frequency of competitive review desirable for managing the project, and
- NIH funding principles.

The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. NIH policy limits each competitive segment to a maximum of 5 years (exclusive of non-competing extensions). A single award covering the entire period of support generally is used only if the project is solely for construction or modernization of real property, if the total planned period of support will be less than 18 months, or if the project is awarded under a special support mechanism.

The initial NoA provides funds for the project during the first budget period. Budget periods usually are 12 months long; however, shorter or longer budget periods may be established for compelling programmatic or administrative reasons. The NoA that documents approval of a project period that extends beyond the budget period for which funds are provided (including anticipated levels of future support) expresses NIH's intention to provide continued financial support for the project. The amounts shown for subsequent years represent projections of future funding levels based on the information available at the time of the initial award. Such projected levels of future support are contingent on satisfactory progress, the availability of funds, and the continued best interests of the Federal government. They are not guarantees by NIH that the project will be funded or will be funded at those levels and create no legal obligation to provide funding beyond the ending date of the current budget period as shown in the NoA.

Recipients are required to submit an annual progress report as a prerequisite to NIH approval and funding of each subsequent budget period (non-competing continuation award) within an approved project period (see [Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Report](#)). A decision to fund the next budget period will be formalized by the issuance of the NoA indicating the new budget period and the amount of new funding. The NoA also will reflect any remaining future-year commitments. NIH may decide to withhold support for one or more of the reasons cited in [Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support](#). A recipient may appeal this decision only if the withholding was for the recipient's failure to comply with the terms and conditions of a previous award (see [Administrative Requirements—Grant Appeals Procedures](#)).

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31 of the fifth fiscal year after the year of availability. This provision may limit the availability of funds for carryover. It may also limit or eliminate the authority to extend the final budget period when an entire project period is funded by a single award (e.g., multiyear funded awards).

5.4 BUDGET

Each NoA sets forth the amount of funds awarded. The amount may be shown either as a categorical (line item) budget or as an amount for total direct costs (not broken down by category) and an amount

for F&A costs, if applicable. Modular awards represent a type of award made without a categorical budget (see [Modular Applications and Awards](#) chapter in IIB). The recipient has certain rebudgeting flexibility within the overall amount awarded (see [Administrative Requirements—Changes in Project and Budget](#)). The recipient may be required to provide matching funds under construction awards as specified in [Construction Grants—Matching](#) in IIB as well as under other NIH programs or awards if specified in the Notice of Funding Opportunity.

5.5 ADDITIONAL TERMS AND CONDITIONS

In addition to, or in lieu of, the standard terms and conditions of award specified in the NIHGPS, NIH may use terms and conditions for program-specific or award-specific reasons. For example, if, on the basis of a recipient's application or other available information, the GMO finds—at the time of award or at any time subsequent to award—that the recipient's management systems and practices are not adequate to ensure the appropriate stewardship of NIH funds or to achieve the objectives of the award, the GMO may impose special, more restrictive terms and conditions on the award in accordance with applicable regulations including 42 CFR Part 52.9 and 2 CFR Part 200.339 and 45 CFR Part 75.371. For example, NIH could require a recipient to obtain prior approval for expenditures that ordinarily do not require such approval or to provide more frequent reports. In addition to closer monitoring, NIH may assist the recipient in taking any necessary corrective action.

6 PAYMENT

The PMS is a centralized grants payment and cash management system, operated by HHS PSC, PMS. HHS grant payments may be made by one of several advance payment methods, including SMARTLINK II/ACH, cash request, or by cash request on a reimbursement basis, as specified in the NoA and as described in this chapter. Payments under NIH grants generally are made as advance payments. NIH grant payments are made by PMS, operated by PSC, in accordance with Department of the Treasury and OMB requirements, as implemented by 2 CFR Part 200.305. These requirements are intended to minimize the time elapsing between the transfer of funds from the Federal government and disbursement by a recipient. Therefore, although the grant may be financed by advance payments, the intent is that recipients draw funds on an as-needed basis—specifically, no more than 3 business days before the funds are needed.

All Federal funds deposited by PMS in a recipient's bank account as an unrestricted advance payment should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the next workday after receipt of the funds. The potential for excessive Federal cash on hand exists each time a recipient does not disburse Federal funds in this manner. The recipient is responsible for determining when the Federal funds have been deposited into its bank account for each drawdown, ensuring that the funds are fully disbursed by the close of business the next workday after they are received, and immediately returning all undisbursed Federal funds to PMS.

The Treasury and OMB policies also establish accountability for interest earned on advances of grant funds and provide for use of the reimbursement method if cash management requirements are not met. Advances made by recipients to consortium participants and contractors under grants must conform to substantially the same standards of timing and amount that govern advances to the recipient.

Operational guidance for recipients is provided through a training CD from PSC. Inquiries regarding drawdown requests, cash management rules, and the disbursement of funds through the Federal Financial Report (SF 425) should be directed to [PSC/PMS](#) (see Part III).

6.1 SMARTLINK II/ACH

The SMARTLINK II/ACH method of advance payment makes direct deposit of funds to a recipient's bank account and requires recipients to have Internet access to submit a request for funds to PMS. SMARTLINK II/ACH provides funds the day following the request with direct deposit using the Federal Reserve Bank's (Richmond, Virginia) ACH process.

6.2 CASH REQUEST

Recipients not eligible for an unrestricted advance of funds by SMARTLINK II/ACH must submit a cash request, usually monthly. The cash request may be on either an advance or reimbursement basis, as specified by the NIH awarding IC. Cash requests are used when a recipient's cash management must be closely monitored (for example, recipients whose financial management systems do not meet the standards specified in 2 CFR Part 200.302) or under programs where reimbursement financing is appropriate. A recipient also may be converted from an unrestricted advance payment method to a cash request basis if, during post-award administration, the GMO determines that a recipient is not complying with the cash management requirements or other requirements of the award, including the submission of complete and timely reports (see [Administrative Requirements—Monitoring—Reporting](#) and [Administrative Requirements—Enforcement Actions—Modification of the Terms of Award](#)).

If the cash request is for an advance payment, the recipient may request grant funds from PMS monthly on the basis of expected disbursements during the succeeding month and the amount of Federal funds already on hand. A request for reimbursement may be submitted more often, if authorized. For timely receipt of cash, a recipient must submit the request through the awarding IC early enough for it to be forwarded to PMS at least 2 weeks before the cash is needed. PMS makes payment to the recipient electronically through the ACH process upon receipt of the approved payment request from the awarding IC.

6.3 INTEREST EARNED ON ADVANCES OF GRANT FUNDS

Except as provided in 2 CFR Part 200.305(b)(8), any NIH recipient subject to the requirements of 2 CFR Part 200 that receives advance payments must maintain those advances in an interest-bearing account.

Recipients are expected to promptly return any funds not spent within three business days. As provided in 2 CFR Part 200.305(b)(9) subject to the requirements of 2 CFR Part 200 and to the extent required by law, interest earned on Federal advance payments deposited in interest-bearing accounts must be remitted annually to the Department of Health and Human Services, Payment Management System, Rockville, MD 20852. Interest amounts up to \$500 per year may be retained by the non-Federal entity for administrative expense.

6.4 IMPROPER PAYMENTS ELIMINATION AND RECOVERY IMPROVEMENT ACT

The Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) (PL 112-248), signed into law on January 10, 2013, established the Do Not Pay Initiative to reduce improper payments or awards. Improper payments occur when funds go to the wrong recipient, the recipient receives the incorrect amount of funds (including overpayments and underpayments), documentation is not available to support a payment, or the recipient uses funds in an improper manner. Incorrect amounts are overpayments or underpayments that are made to eligible recipients (including inappropriate denials of payment or service, any payment that does not account for credit for applicable discounts, payments that are for an incorrect amount, and duplicate payments). When an agency's review is unable to discern whether a payment was proper as a result of insufficient or lack of documentation, this payment should also be considered an improper payment. When establishing documentation requirements for payments, agencies should ensure that all documentation requirements are necessary and should refrain from imposing additional burdensome documentation requirements. Interest or other fees that may result from an underpayment by an agency are not considered an improper payment if the interest was paid correctly. These payments are generally separate transactions and may be necessary under certain statutory, contractual, administrative, or other legally applicable requirements.

HHS has implemented provisions of IPERIA through integrating use of the Do Not Pay system into the current payment processes managed by the PMS, HHS.

7 COST CONSIDERATION

7.1 GENERAL

Cost considerations are critical throughout the life cycle of a grant. An applicant's budget request is reviewed for compliance with the governing cost principles and other requirements and policies applicable to the type of recipient and the type of award. Any resulting award will include a budget that is consistent with these requirements.

NIH anticipates that, because of the nature of research, the recipient may need to modify its award budget during performance to accomplish the award's programmatic objectives. Therefore, NIH provides some flexibility for recipients to deviate from the award budget, depending on the deviation's significance to the project or activity. More significant post-award changes require NIH prior approval. Prior approval requirements and authorities are discussed in [Administrative Requirements—Changes in Project and Budget](#).

During post-award administration, the GMO, or a GMO designee, monitors expenditures for conformance with cost policies. The GMO's monitoring includes, among other things, responding to prior approval requests and reviewing progress reports, audit reports, and other periodic reports. The GMO also may use audit findings as the basis for final cost adjustments (see [Administrative Requirements—Closeout](#)).

This chapter addresses the general principles underlying the allowability of costs, differentiates direct costs from F&A costs, and highlights a number of specific costs and categories of cost for NIH applicants and recipients. It is not intended to be all-inclusive and should be used as a supplement to the applicable cost principles.

7.2 THE COST PRINCIPLES

In general, NIH grant awards provide for reimbursement of actual, allowable costs incurred and are subject to Federal cost principles. The cost principles establish standards for the allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or F&A costs, and set forth allowability and allocability principles for selected items of cost. Applicability of a particular set of cost principles depends on the type of organization (regardless whether domestic or foreign) making the expenditure. For example, a for-profit organization collaborating with a university recipient would be subject to the cost principles for for-profit organizations, while the university would be subject to the cost principles for Institutions of Higher Education (IHEs).

The cost principles are set forth in HHS regulations at 2 CFR Part 200, Subpart E. For-profit organizations are subject to the cost principles located at 48 CFR Part 31.2 Federal Acquisition Regulation.

The cost principles apply to all NIH award instruments, award mechanisms, and special programs and authorities, including modular awards and awards under SNAP with one exception: they do not apply to Kirschstein-NRSA individual fellowship awards. The allowable use of funds under those awards is included in [Ruth L. Kirschstein National Research Service Awards](#) in IIB.

Recipients may use their own accounting systems, policies, and procedures to implement the cost principle requirements as long as they meet the standards prescribed in 2 CFR Part 200.302 for financial management systems.

The cost principles address four tests to determine the allowability of costs. The tests are as follows:

- **Reasonableness (Including Necessity).** A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost was made. The cost principles elaborate on this concept and address considerations such as whether the cost is of a type generally necessary for the organization's operations or the grant's performance, whether the recipient complied with its established organizational policies in incurring the cost or charge, and whether the individuals responsible for the expenditure acted with due prudence in carrying out their responsibilities to the Federal government and the public at large as well as to the organization.
- **Allocability.** A cost is allocable to a specific grant, function, department, or other component, known as a cost objective, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable to a grant if it is incurred solely in order to advance work under the grant; it benefits both the grant and other work of the institution, including other grant-supported projects; or it is necessary to the overall operation of the organization and is deemed to be assignable, at least in part, to the grant. A cost is allocable as a direct cost to a grant if it is incurred solely in order to advance work under the grant or meets the criteria for closely related projects determination (see [Cost Considerations—Allocation of Costs and Closely Related Work](#)).
- **Consistency.** Recipients must be consistent in assigning costs to cost objectives. Costs may be charged as either direct costs or F&A costs, depending on their identifiable benefit to a particular project or program, but all costs must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding.
- **Conformance.** This test of allowability—conformance with limitations and exclusions as contained in the terms and conditions of award, including those in the cost principles—varies by the type of activity, the type of recipient, and other characteristics of individual awards. [Cost Considerations—Allowability of Costs/Activities](#) provides information common to most NIH grants and, where appropriate, specifies some of the distinctions if there is a different treatment based on the type of grant or recipient. IIB contains additional information on allowability of costs for particular types of grants, recipients, and activities.

These four tests apply regardless of whether the particular category of costs is one specified in the cost principles or one governed by other terms and conditions of an award. These tests also apply regardless of treatment as a direct cost or an F&A cost. The fact that a proposed cost is awarded as requested by an applicant does not indicate a determination of allowability.

7.3 DIRECT COSTS AND FACILITIES AND ADMINISTRATIVE COSTS

Direct costs are any cost that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned (allocated) to such activities relatively easily with a high degree of accuracy. Direct costs may include, but are not limited to, salaries, travel, equipment, and supplies directly supporting or benefiting the grant-supported project or activity. If directly related to a specific award, certain costs that otherwise would be treated as indirect costs may also be considered direct costs.

Most organizations also incur costs for common or joint objectives that cannot be readily identified with an individual project or program. These are referred to as indirect costs, also called Facilities and Administrative costs (F&A). Facilities operation and maintenance costs, depreciation, and administrative

expenses are examples of costs that usually are treated as F&A costs. The organization is responsible for the management and accounting of costs consistently and must not include costs associated with its F&A rate as direct costs. Note, the term [facilities and administrative costs](#) and the term [indirect costs](#) may be used interchangeably to determine applicable policies. For NIH purposes, including the NIHGPS, these costs will be referred to as F&A costs; however, other documents or non-NIH entities may refer to them as [indirect costs](#).

Project costs consist of the allowable direct costs directly related to the performance of the grant plus the allocable portion of the allowable F&A costs of the organization, less applicable credits (as described below and in the cost principles).

The amount NIH awards for each budget period will reflect the total approved budget for the grant, including direct costs and, if applicable, F&A costs. (SBIR and STTR awards also may include a fee as specified in [Grants to For-Profit Organizations—Small Business Innovation Research and Small Business Technology Transfer Programs](#) in IIB.) If a recipient waives reimbursement of full F&A costs, NIH will either not award F&A costs or will award only partial F&A costs, as appropriate. The NIH award amount shown in the NoA constitutes NIH's maximum financial obligation to the recipient under that award.

7.4 REIMBURSEMENT OF FACILITIES AND ADMINISTRATIVE COSTS

For grant programs that can provide F&A cost reimbursement, NIH will generally not provide F&A costs unless the recipient has established an F&A cost rate covering the applicable activities and period of time, except for awards under which F&A costs are reimbursed at a fixed rate.

In addition, NIH will not require a recipient to establish an F&A rate if the organization's total operations consist of a single grant-supported project or if the organization appropriately and consistently treats all costs as direct costs to projects and accounts for them as such. In the latter case, the GMO must be satisfied that the organization's accounting system can adequately identify and support all costs as direct costs to the project. This includes being able to identify and segregate costs on the basis of a process that assigns costs commensurate with the benefits provided to individual projects (see [Administrative Requirements—Management Systems and Procedures—Financial Management System Standards](#)).

F&A rates are negotiated by CAS, DFAS in the Office of Acquisition Management and Policy, NIH (responsible for negotiating F&A cost rates for for-profit entities receiving awards from HHS), or other agency with cognizance for F&A/indirect cost rate (and other special rate) negotiation. If an applicant is advised by the GMO of the need to establish a rate, the GMO will indicate the responsible office to be contacted.

F&A cost proposals must be prepared in accordance with the applicable cost principles and guidance provided by the cognizant office or agency for indirect costs and must conform to cost policies in the NIHGPS. Further information concerning the establishment of F&A rates and the reimbursement of F&A costs may be obtained from [DCA](#) or [DFAS](#) (see Part III). CAS should be consulted to determine the need to submit a Disclosure Statement (DS-2) pursuant to the requirements of 2 CFR Part 200, Subpart E-Cost Principles.

Consistent with 2 CFR Part 200.414(f), any non-Federal entity, including for-profit organizations, that does not have a current negotiated (including provisional) F&A rate, except for those non-Federal entities described in 2 CFR Part 200, Appendix VII, Section D(1)(b) and 45 CFR Part 75, Appendix VII may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. No documentation is required to justify the 10% de minimis indirect cost rate. As described in 2

CFR Part 200.403 and 45 CFR Part 75.403, costs must be consistently charged as either indirect or direct costs but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.

If a subrecipient already has a negotiated indirect cost rate established with their cognizant agency for indirect cost, the negotiated rate must be used. If no approved rate exists, the pass-through entity must determine the appropriate rate in collaboration with the subrecipient, which is either: the negotiated indirect cost rate between the pass-through entity and the subrecipient; which can be based on a prior negotiated rate between a different PTE and the same subrecipient. If basing the rate on a previously negotiated rate, the pass-through entity is not required to collect information justifying this rate but may elect to do so; or the de minimis indirect cost rate. The pass-through entity must not require use of a de minimis indirect cost rate if the subrecipient has a Federally approved rate. Subrecipients can elect to use the cost allocation method to account for indirect costs. The cost principles are designed to provide that Federal awards bear their fair share of costs recognized under these principles. (See 2 CFR 200.100(c) and 45 CFR Part 75.100). Pass-through entities may, but are not required, to negotiate a rate with a proposed subrecipient that asks to do so. If the consortium is with a for-profit entity, such as a small business, the organization must have an established F&A cost rate before they can charge F&A costs. The default small business rate of 40 percent is only applicable to SBIR and STTR applications.

Regardless of the type of recipient, the rate(s) in effect at the beginning of the competitive segment will be used to determine the amount budgeted for F&A costs for each year of the competitive segment. If the rate agreement does not extend to the end of the project period, the last rate in effect will be used to establish the total cost commitment for any remaining future years. NIH generally will not award additional F&A costs beyond those calculated in the approved budget.

F&A costs awarded may be subject to upward or downward adjustment, depending on the type of rate negotiated and recipient type. Generally, recipients may rebudget between direct and F&A costs (in either direction) without NIH prior approval, provided there is no change in the scope of the approved project. F&A cost reimbursement on grants to IHEs is based on the rates used in the award, which are not subject to adjustment in reimbursement except for the establishment of permanent rates when a provisional rate was used for funding (See 2 CFR 200 Appendix III Section C(7)(b)). Therefore per 2 CFR 200 Appendix III IHEs may not rebudget from direct costs to accommodate a rate increase if the F&A costs provided for a period were based on negotiated (final, fixed or predetermined) rates rather than provisional rates (See 2 CFR 200 Appendix III Section C(7)(a)). For recipients other than IHEs, F&A cost reimbursement is based on the negotiated F&A rate agreement consistent with the time period when the cost is incurred, except if F&A costs were limited or not provided. F&A costs are subject to downward adjustment if the proposal that served as the basis for the negotiation included unallowable costs.

Some grants require negotiation of project costs annually, e.g., clinical trials. For these awards, the policies pertain to each year of support rather than to a multiyear competitive segment.

Once NIH awards a grant, it is not obligated to make any supplemental or other award for additional F&A costs or for any other purpose. There are limited circumstances under which the GMO may award F&A costs where none were previously awarded or may increase the amount previously awarded. If an award does not include an amount for F&A costs because the applicant or recipient did not submit a timely F&A cost proposal and the recipient subsequently establishes a rate, the GMO may amend the award to provide an appropriate amount for F&A costs if the amendment can be made using funds from the same Federal fiscal year in which the award was made. However, the amount will be limited to the F&A costs applicable to the period after the date of the recipient's F&A cost proposal submission. This provision does not affect local governmental agencies that are not required to submit their F&A (indir-

ect) cost proposals to the Federal government. They may charge F&A costs to NIH grants based on the rate computations they prepare and keep on file for subsequent Federal review.

If funds are available, a GMO may amend an award to provide additional funds for F&A costs, but only under the following circumstances:

- NIH made an error in computing the award. This includes situations in which a higher rate than the rate used in the grant award is negotiated and the date of the rate agreement for the higher rate is before 1 calendar month prior to the beginning date of the grant budget period.
- NIH restores funds previously recaptured as part of a recipient's unobligated balance.
- The recipient is eligible for additional F&A costs associated with additional direct costs awarded for the supplementation or extension of a project.

NIH does not reimburse indirect costs under the following classes of awards:

- **Fellowships.** F&A costs will not be provided on Kirschstein-NRSA individual fellowships or similar awards for which NIH funding is in the form of fixed amounts or is determined by the normal published tuition rates of an institution and for which the recipient is not required to account on an actual cost basis.
- **Construction and Modernization.** F&A costs will not be provided on construction or modernization grants.
- **Grants to Individuals.** F&A costs will not be provided on awards to individuals.
- **Grants to Federal Institutions.** F&A costs will not be provided on grants to Federal institutions.
- **Grants in Support of Scientific Meetings (Conference Grants).** F&A costs will not be provided under grants in support of scientific meetings.
- **Endowment Grants.** F&A costs will not be provided for endowment grants.

NIH limits the amounts included in the F&A base for the following type of costs:

- **Genomic Arrays (GA)** are a high-throughput genetic analysis technology which enables the study of genetic variation and gene expression at high resolution. Approaches such as genome-wide association and gene expression profiling often depend upon manufactured products known as microarrays or bead arrays. These tools are exceptional among laboratory supplies in that they are almost always procured from a commercial source; have a relatively high unit cost and are often utilized in large numbers. The treatment of the costs for purchase of GA as "supplies" in these specialized award budgets at high levels of usage would result in the application of F&A cost recovery that is disproportionate to the actual administrative burden associated with the relatively high cost of the procurement of these GA. Accordingly, for purposes of budgeting for and award of high volume purchases of GA in excess of \$50,000 per year, the standard treatment of these resources as supplies in determining the F&A base of an award will be non-applicable. Instead, the requested and reimbursed costs for GA will utilize as a surrogate the concept of subcontracts (consortium/contractual cost). Therefore, for each budget year, the first \$50,000 of GA will be treated as "supplies", and any GA in excess of \$50,000 (for high volume requirements) will use as a surrogate the budgeting and reimbursement concept utilized for subcontracts (consortium/contractual cost), providing consistent budgeting, accounting and reimbursement of these costs.

NIH provides F&A costs without the need for a negotiated rate under the following classes of awards:

- **Research Training and Education Grants (e.g., R25), and K Awards.** F&A costs under Kirschstein-NRSA institutional research training grants, educational and K awards will be budgeted and reimbursed at a rate of 8 percent of modified total direct costs, exclusive of tuition and fees, expenditures for equipment, and consortiums in excess of \$25,000. State, local, and Indian tribes (or "federally recognized Indian tribes") may receive full F&A cost reimbursement under NIH Kirschstein-NRSA institutional research training grants and K awards. For this policy, State universities or hospitals are not considered governmental agencies.
- **Grants to Foreign Organizations and International Organizations.** With the exception of the American University of Beirut and the World Health Organization, which are eligible for full F&A cost reimbursement, F&A costs under grants to foreign and international organizations will be funded at a fixed rate of 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000. These funds are paid to support the costs of compliance with federal requirements. Some examples of NIH compliance requirements are the protection of human subjects (including the required education in the protection of human research participants), animal welfare, invention reporting, other post-award reporting requirements, financial conflict of interest and research misconduct. Note, these are just a few representative examples of compliance requirement; this list is not all inclusive. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of \$25,000. These funds are paid to support the costs of compliance with federal requirements. NIH will not support the acquisition of or provide for depreciation on any capital expenses (facilities) or the normal general operations of foreign and international organizations. Therefore, these expenses may not be requested as a direct cost; however, equipment is an allowable direct cost. *Other items normally treated as F&A costs (e.g., rent) may be requested as direct costs and will be evaluated by NIH for allow-ability.*

7.5 COST TRANSFERS, OVERRUNS, AND ACCELERATED AND DELAYED EXPENDITURES

Cost transfers to NIH grants by recipients, consortium participants, or contractors under grants that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the recipient, consortium participant, or contractor. An explanation merely stating that the transfer was made "to correct error" or "to transfer to correct project" is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.

Recipients must maintain documentation of cost transfers, pursuant to 2 CFR Part 200.337, and must make it available for audit or other review (see [Administrative Requirements—Monitoring—Record Retention and Access](#)). The recipient should have systems in place to detect such errors within a reasonable time frame; untimely discovery of errors could be an indication of poor internal controls. Frequent errors in recording costs may indicate the need for accounting system improvements, enhanced internal controls, or both. If such errors occur, recipients are encouraged to evaluate the need for improvements and to make whatever improvements are deemed necessary to prevent reoccurrence. NIH also may require a recipient to take corrective action by imposing additional terms and conditions on an award(s).

The GMO monitors recipient expenditure rates under individual grants within each budget period and within the overall project period. The funding that NIH provides for each budget period is based on an assessment of the effort to be performed during that period and the recipient's associated budget, including the availability of unobligated balances. Although NIH allows recipients certain flexibilities with respect to rebudgeting (see [Administrative Requirements—Changes in Project and Budget](#)), NIH expects the rate and types of expenditures to be consistent with the approved project and budget and may question or restrict expenditures that appear inconsistent with these expectations.

The GMO may review recipient cash drawdowns to determine whether they indicate any pattern of accelerated or delayed expenditures. Expenditure patterns are of particular concern because they may indicate a deficiency in the recipient's financial management system or internal controls. Accelerated or delayed expenditures may result in a recipient's inability to complete the approved project within the approved budget and period of performance. In these situations, the GMO may seek additional information from the recipient and may make any necessary and appropriate adjustments.

7.6 ALLOCATION OF COSTS AND CLOSELY RELATED WORK

When salaries or other activities are supported by two or more sources, issues arise as to how the direct costs should be allocated among the sources of support. In general, a cost that benefits two or more projects or activities in proportions that can be determined without undue effort or cost should be allocated to the projects on the basis of the proportional benefit. A cost that benefits two or more projects or activities in proportions that cannot be determined because of the interrelationship of the work involved may be allocated or transferred to the benefiting projects on any reasonable basis as long as the costs charged are allowable, allocable, and reasonable under the applicable cost principles and the recipient's financial management system includes adequate internal controls (for example, no one person has complete control over all aspects of a financial transaction).

7.7 APPLICABLE CREDITS

The term [applicable credits](#) refers to those receipt or negative expenditure types of transactions that operate to offset or reduce direct or F&A cost items. Typical examples are purchase discounts, rebates or allowances, recoveries or indemnities on losses, and adjustments for overpayments or erroneous charges. Additional information concerning applicable credits is included in the cost principles.

Applicable credits to direct charges made to NIH grants must be treated as an adjustment on the recipient's FFR, whether those credits accrue during or after the period of grant support. (See [Administrative Requirements—Monitoring—Reporting](#) and [Administrative Requirements—Closeout—Final Federal Financial Reports](#).) The NIH awarding IC will notify the recipient of any additional actions that may be necessary.

7.8 SERVICES PROVIDED BY AFFILIATED ORGANIZATIONS

A number of universities and other organizations have established closely affiliated, but separately incorporated, organizations to facilitate the administration of research and other programs supported by Federal funds. Such legally independent entities are often referred to as "foundations," although this term does not necessarily appear in the name of the organization. Sometimes, the parent organization provides considerable support services, in the form of administration, facilities, equipment, accounting, and other services, to its foundation, and the latter, acting in its own right as an NIH recipient, includes the cost of these services in its F&A proposal.

Costs incurred by an affiliated, but separate, legal entity in support of a recipient foundation are allowable for reimbursement under NIH grants only if at least one of the following conditions is met:

- The affiliated organization is charged for, and is legally obligated to pay for, the services provided by the parent organization.
- The affiliated organizations are subject to State or local law that prescribes how Federal reimbursement for the costs of the parent organization's services will be expended and requires that a State or local official acting in their official capacity approves such expenditures.
- There is a valid written agreement between the affiliated organizations whereby the parent organization agrees that the recipient foundation may retain Federal reimbursement of parent organization costs. The parent organization may either direct how the funds will be used or permit the recipient foundation that discretion.

If none of the above conditions are met, the costs of the services provided by the parent organization to the recipient foundation are not allowable for reimbursement under an NIH grant. However, the services may be acceptable for cost-sharing (matching) purposes.

Foundations that represent already existing recipient organizations should contact [DGP, OPERA](#) before attempting to become a separately recognized applicant organization.

7.9 ALLOWABILITY OF COSTS/ACTIVITIES

The governing cost principles address selected items of cost, some of which are mentioned in this section for emphasis. This section is not intended to be all-inclusive. The cost principles should be consulted for the complete explanation of whether or not a cost is allowed.

This section also includes NIH-specific requirements concerning costs and activities. The allowability of costs under specific NIH awards may be subject to other requirements specified in the program legislation, regulations, or the specific terms and conditions of an award, which take precedence over the general discussion provided here. Specific program requirement may also be covered in other sections of the NIHGPS. Applicants or recipients that have questions concerning the allowability of particular costs should contact the GMO.

If a cost is allowable, it is allocable as either a direct cost or an F&A cost, depending on the recipient's accounting system. For some costs addressed in this section, the text specifies whether the cost is usually a direct cost or an F&A cost.

Unless otherwise indicated in the NoA, an award based on an application that includes specific information concerning any costs or activities that require NIH prior approval constitutes the prior approval for those costs or activities. The recipient is not required to obtain any additional approval for those costs/activities. Post-award requests to incur costs or undertake activities requiring prior approval that are not described in the approved application are subject to the requirements in [Administrative Requirements—Changes in Project and Budget](#).

Consortium participants and contractors under grants are subject to the requirements of the cost principles otherwise applicable to their type of organization and to any requirements placed on them by the recipient to be able to comply with the terms and conditions of the NIH grant.

The cost principles do not address profit or fee. NIH policy allows the payment of fee on SBIR/STTR grants (see [Grants to For-Profit Organizations](#) chapter in IIB) but NIH will not provide profit or fee to any other type of recipient under any other grant program or support mechanism. A fee may not be paid by a recipient to a consortium participant, including a for-profit organization. However, a fee (profit)

may be paid to a contractor providing routine goods or services under a grant in accordance with normal commercial practice.

7.9.1 Selected Items of Cost

Exhibit 5: Selected Items of Cost

The table presents specific items that may or may not be included in the cost portion of grants

Items	Explanation of Allowable Costs
Advertising and Public Relations	1. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television, direct mail, exhibits, electronic or computer transmittals, and the like. 2. The only allowable advertising costs are those which are solely for: a. The recruitment of personnel required by the non-Federal entity for performance of a Federal award (See also 2 CFR Part 200.463); b. The procurement of goods and services for the performance of a Federal award; c. The disposal of scrap or surplus materials acquired in the performance of a Federal award except when non-Federal entities are reimbursed for disposal costs at a predetermined amount; or d. Program outreach and other specific purposes necessary to meet the requirements of the Federal award. 3. The term “public relations” includes community relations and means those activities dedicated to maintaining the image of the non- Federal entity or maintaining or relations with the community or public at large or any segment of the public. 4. The only allowable public relations costs are: a. Costs specifically required by the Federal award; b. Costs of communicating with the public and press pertaining to specific activities or accomplishments which result from performance of the Federal award (these costs are considered necessary as part of the outreach effort for the Federal award); or c. Costs of conducting general liaison with news media and government public relations officers, to the extent that such activities are limited to communication and liaison necessary to keep the public informed on matters of public concern, such as notices of funding opportunities, financial matters, etc. 5. Unallowable advertising and public relations costs include the following: a. All advertising and public relations costs other than as specified in paragraphs (2) and (4) of this section; b. Costs of meetings, conventions, convocations, or other events related to other activities of the entity (see also 2 CFR Part 200.432), including: i. Costs of displays, demonstrations, and exhibits; ii. Costs of meeting rooms, hospitality suites, and other special facilities used in conjunction with shows and other special events; and

Items	Explanation of Allowable Costs
	iii. Salaries and wages of employees engaged in setting up and displaying exhibits, making demonstrations, and providing briefings; c. Costs of promotional items and memorabilia, including models, gifts, and souvenirs; d. Costs of advertising and public relations designed solely to promote the non-Federal entity
Alcoholic Beverages	Unallowable as an entertainment expense, but allowable if within the scope of an approved research project.
Alteration and Renovation	Individual A&R projects that are treated as direct costs and that are determined to be minor be subject to the A&R policies specified in this exhibit and in the Construction Grants chapter, as applicable. Individual A&R projects determined to be A&R will be subject to the requirements specified in the Construction Grants chapter. Routine maintenance and repair of the organization's physical plant or equipment, which is allowable and is ordinarily treated as an F&A cost, is not considered A&R for purposes of applying this policy. Certain allowable costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, may be considered either equipment costs or A&R costs, depending on the recipient's accounting system. A&R costs are not allowable under grants to individuals, and grants in support of scientific meetings (conference grants). In all other cases, these costs are allowable unless the program legislation, implementing regulations, program guidelines, or other terms and conditions of the award specifically exclude such activity. The A&R must be consistent with the following criteria and documentation requirements: • The building has a useful life consistent with program purposes and is architecturally and structurally suitable for conversion to the type of space required. • The A&R is essential to the purpose of the grant-supported project. • The space involved will be occupied by the project. • The space is suitable for human occupancy before A&R work is started except where the purpose of the A&R is to make the space suitable for some purpose other than human occupancy, such as storage. • If the space is rented, evidence is provided that the terms of the lease are compatible with the A&R proposed and cover the duration of the project period.

Items	Explanation of Allowable Costs
	• If the A&R will affect a site listed in (or eligible for inclusion in) the National Register of Historic Places, the requirements specified in “Preservation of Cultural and Historic Resources” have been followed. Work necessary to obtain an initial occupancy permit for the intended use is not an allowable A&R cost. A recipient may rebudget up to 25 percent of the total approved budget for a budget period into A&R costs without NIH prior approval unless such rebudgeting would result in a change in scope. If the rebudgeting will result in the addition of a major A&R project, NIH will consider the rebudgeting to be a change in scope, and the recipient must submit to the NIH awarding IC the documentation specified in the Construction Grants chapter for prior approval of A&R projects above that dollar level. Under foreign grants or foreign components under domestic grants, major A&R is unallowable. Minor A&R is generally allowable on grants made to foreign organizations or to the foreign component of a domestic grant, unless prohibited by the governing statute or implementing program regulations.
Animals	Allowable for the acquisition, care, and use of experimental animals, contingent upon compliance with the applicable requirements of the PHS Policy on Humane Care and Use of Laboratory Animals (see Public Policy Requirements and Objectives—Animal Welfare). If the recipient operates an animal resource facility, charges for use of the facility should be determined in accordance with the Cost Analysis and Rate Setting Manual for Animal Resource Facilities (PDF, 32 MB) — May 2000.
Audiovisual Activities	Allowable for the production of an audiovisual. “Audiovisual” means any product containing visual imagery, sound, or both, such as motion pictures, films, videotapes, live or recorded radio or television programs or public service announcements, slide shows, filmstrips, audio recordings, multimedia presentations, or exhibits where visual imagery, sound, or both are an integral part. “Production” refers to the steps and techniques used to create a finished audiovisual product including, but not limited to, design, layout, scriptwriting, filming or taping, fabrication, sound recording, and editing. A recipient with in-house production capability must determine whether it would be more efficient and economical to use that capability or to contract for the production of an audiovisual. If an audiovisual intended for members of the general public (i.e., people who are not researchers or health professions personnel or who are not directly involved in project activities as employees, trainees, or participants such as volunteers or patients) is produced under an NIH grant-supported project, the recipient must submit two copies of the finished product along with its annual or final progress report (see Administrative Requirements—Monitoring—Reporting and Administrative Requirements—Closeout). The costs of such copies are allowable project costs. Audiovisuals produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, such as the following:

Items	Explanation of Allowable Costs
	The production of this [type of audiovisual (motion picture, television program, etc.)] was supported by Grant No. _____ from [name of NIH awarding IC]. Its contents are solely the responsibility of [name of recipient organization] and do not necessarily represent the official views of [name of NIH awarding IC].
Audit Services	1. A reasonably proportionate share of the costs of audits required by, and performed in accordance with, the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507), as implemented by requirements of 2 CFR Part 200, are allowable. However, the following audit costs are unallowable: a. Any costs when audits required by the Single Audit Act and Subpart F— Audit Requirements of 2 CFR Part 200 have not been conducted or have been conducted but not in accordance therewith; and b. Any costs of auditing a non- federal entity that is exempted from having an audit conducted under the Single Audit Act and Subpart F—Audit Requirements of 2 CFR Part 200 because its expenditures under Federal awards are less than \$750,000 during the non- Federal entity's fiscal year. 2. The costs of a financial statement audit of a non-Federal entity that does not currently have a Federal award may be included in the indirect cost pool for a cost allocation plan or indirect cost proposal. 3. Pass-through entities may charge Federal awards for the cost of agreed-upon-procedures engagements to monitor subrecipients (in accordance with Subpart D of 2 CFR Part 200.331 through 200.333) which are exempted from the requirements of the Single Audit Act and Subpart F of 2 CFR Part 200. This cost is allowable only if the agreed-upon-procedures engagements are: a. Conducted in accordance with GAGAS attestation standards; b. Paid for and arranged by the pass-through entity; and c. Limited in scope to one or more of the following types of compliance requirements: activities allowed or unallowed; allowable costs/cost principles; eligibility; and reporting.
Bad Debts	Bad debts (debts which have been determined to be uncollectable), including losses (whether actual or estimated) arising from uncollectable accounts and other claims, are unallowable. Related collection costs, and related legal costs, arising from such debts after they have been determined to be uncollectable are also unallowable. (See also 2 CFR Part 200.428).

Items	Explanation of Allowable Costs
Bonding	1. Bonding costs arise when the Federal awarding agency requires assurance against financial loss to itself or others by reason of the act or default of the non-Federal entity. They arise also in instances where the non-Federal entity requires similar assurance, including: bonds as bid, performance, payment, advance payment, infringement, and fidelity bonds for employees and officials. 2. Costs of bonding required pursuant to the terms and conditions of the Federal award are allowable. 3. Costs of bonding required by the non-Federal entity in the general conduct of its operations are allowable as an indirect cost to the extent that such bonding is in accordance with sound business practice and the rates and premiums are reasonable under the circumstances.
Books and Journals	Allowable. If an organization has a library, books and journals generally should be provided as part of normal library services and treated as F&A costs.
Building Acquisition	Unallowable unless building acquisition or construction is specifically authorized by program legislation and is provided for in the NoA. For real property acquired with NIH grant support, the cost of title insurance may be charged to the grant in proportion to the Federal share of the acquisition cost. Filing fees for recording the Federal interest in the real property in appropriate records of the applicable jurisdiction also may be charged to the grant. (Also see Construction Grants—Allowable and Unallowable Costs and Activities in IIB).
Capital Expenditures	See Equipment and Other Capital Expenditures .
Child care Costs	Allowable if incurred to assist individuals to participate as subjects in research projects. Such costs also may be allowable as a fringe benefit for individuals working on a grant-supported project (see Fringe Benefits and Travel Costs in this exhibit). NRSA Fellowship Grants may also be allowed to incur these costs (see 11.2.9.7 for specific eligibility criteria).
Collection of Improper Payments	The costs incurred by a non-Federal entity to recover improper payments are allowable as either direct or indirect costs, as appropriate. Amounts collected may be used by the non-Federal entity in accordance with cash management standards set forth in 2 CFR Part 200.305. (See Improper Payment).
Communications	Allowable. Such costs include local and long-distance telephone calls, express mail, and postage, and usually are treated as F&A costs.
Conference Grant Costs	See Support of Scientific Meetings (Conference Grants) chapter in IIB for allowability of costs for scientific meetings (conferences).
Consortium Agreements/ Contracts under Grants	Allowable to carry out a portion of the programmatic effort or for the acquisition of routine goods or services under the grant. Such arrangements may require NIH approval as specified in Administrative Requirements—Changes in Project and Budget . (See also Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for policies that apply to the acquisition of routine goods and services and the Consortium Agreements chapter in IIB for policies that apply to recipient collaboration with

Items	Explanation of Allowable Costs
	other organizations in carrying out the grant-supported research).
Construction	Allowable only when program legislation specifically authorizes new construction, modernization, or major A&R, and NIH specifically authorizes such costs in the NoA. When authorized, construction activities may include construction of a new facility or projects in an existing building that are considered to be construction, such as relocation of exterior walls, roofs, and floors; attachment of fire escapes; or completion of unfinished shell space to make it suitable for human occupancy (see Construction Grants chapter in IIB).
Consultant Services	See Professional Services and Salaries and Wages/Intra-IHE Consulting .
Contingency Provisions	Unallowable. Payments made by the NIH awarding IC to the non-Federal entity's "contingency reserve" or any similar payment made for events the occurrence of which cannot be foretold with certainty as to the time or intensity, or with an assurance of their happening, are unallowable under non-construction grants. Contingency funds do not include pension funds, self-insurance funds, and normal accruals (also see Reserve Funds in this exhibit). (See also Construction Grants—Allowable and Unallowable Costs and Activities in IIB concerning contingency funds under construction grants).
Customs and Import Duties	Allowable under grants to domestic organizations when performance will take place entirely within the United States, its possessions, or its territories, or when foreign involvement in the project is incidental to the overall grant-supported project. Charges may include consular fees, customs surtaxes, value-added taxes, and other related charges. (See Taxes in this exhibit).
Depreciation or Use Allowances	Allowable. Such costs usually are treated as F&A costs. Depreciation or use charges on equipment or buildings acquired under a federally supported project are not allowable.
Donor Costs	Allowable as payment to volunteers or research subjects who contribute blood, urine samples, and other body fluids or tissues that are specifically project-related. Donor costs are not considered a research patient care expense (see the Research Patient Care Costs chapter in IIB). Also see Incentive Costs in this exhibit.
Drugs	Allowable if within the scope of an approved research project. Project funds may not be used to purchase drugs classified by FDA as "ineffective" or "possibly effective" except in approved clinical research projects or in cases where there is no alternative other than therapy with "possibly effective" drugs.
Dues or Membership Fees	Allowable as an F&A cost for organizational membership in business, professional, or technical organizations or societies. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds. See also Membership, Subscription, and Professional Activity costs .

Items	Explanation of Allowable Costs
Entertainment Costs	Costs of entertainment, including amusement, diversion, and social activities and any associated costs are unallowable, except where specific costs that might otherwise be considered entertainment have a programmatic purpose and are authorized either in the approved budget for the Federal award or with prior written approval of the NIH awarding IC.
Equipment and Other Capital Expenditures	The following rules of allowability must apply to equipment and other capital expenditures: 1. Capital expenditures for general purpose equipment, buildings, and land are unallowable as direct charges, except with the prior written approval of the NIH awarding IC or pass-through entity. 2. Capital expenditures for special purpose equipment are allowable as direct costs, provided that items that relate to a change in scope (which may be indicated by a unit cost of \$25,000 or more) have the prior written approval of the NIH awarding IC or pass-through entity. 3. Capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life are unallowable as a direct cost except with the prior written approval of the NIH awarding IC, or pass-through entity. See Depreciation for rules on the allowability of depreciation on buildings, capital improvements, and equipment. See also Rental Costs of Real Property and Equipment. 4. When approved as a direct charge pursuant to items (1) through (3) above, capital expenditures will be charged in the period in which the expenditure is incurred, or as otherwise determined appropriate and negotiated with the NIH awarding IC. 5. The unamortized portion of any equipment written off as a result of a change in capitalization levels may be recovered by continuing to claim the otherwise allowable depreciation on the equipment, or by amortizing the amount to be written off over a period of years negotiated with the Federal cognizant agency for indirect cost. 6. Cost of equipment disposal. If the non-Federal entity is instructed by the NIH awarding IC to otherwise dispose of or transfer the equipment the costs of such disposal or transfer are allowable. See also Capital Expenditures, Equipment, Special Purpose Equipment, General Purpose Equipment, Acquisition Cost, and Capital Assets.
Federal (U.S. Government) Employees	See Grants to Federal Institutions and Payments to Federal Employees under Grants—Allowable and Unallowable Costs in IIB for the allowability of payments made to, or on behalf of, Federal employees under NIH grants, including grants to Federal institutions.
Fines, Penalties, Damages and Other Settlements	Costs resulting from non-Federal entity violations of, alleged violations of, or failure to comply with, Federal, state, tribal, local or foreign laws and regulations are unallowable, except when incurred as a result of compliance with specific provisions of the Federal award, or with prior written approval of the NIH awarding IC.

Items	Explanation of Allowable Costs
Fringe Benefits	Fringe benefits are allowances and services provided by employers to their employees as compensation in addition to regular salaries and wages. Fringe benefits include, but are not limited to, the costs of leave (vacation, family related, sick or military), employee insurance, pensions, and unemployment benefit plans. Except as provided elsewhere in 2 CFR Part 200, Subpart E, the costs of fringe benefits are allowable provided that the benefits are reasonable and are required by law, non-Federal entity-employee agreement, or an established policy of the non-Federal entity. For policies applicable to tuition remission for students working on grant-supported research projects, see Fringe Benefits / IHE Tuition/Tuition Remission in this exhibit. See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Allowable and Unallowable Costs—Tuition and Fees and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs—Trainee Tuition and Fees in IIB for the allowability of tuition costs for fellows and trainees.
Fringe Benefits / IHE Tuition/Tuition Remission	Tuition remission and other forms of compensation paid as, or in lieu of, wages to students under research grants are allowable, provided the following conditions are met: 1. The individual is conducting activities necessary to the Federal award. 2. Tuition remission and other support are provided, in accordance with established institutional policy, of the IHE and consistently provided in a like manner to students in return for similar activities conducted under Federal awards as well as other activities. 3. During the academic period, the student is enrolled in an advanced degree program at a non-Federal entity or affiliated institution and the activities of the student in relation to the Federal award are related to the degree program. 4. The tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary work. 5. It is the IHE's practice to similarly compensate students under Federal awards as well as other activities Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages are subject to reporting requirements in 2 CFR Part 200.430(i). NIH will determine the allowability and reasonableness of such compensation under a grant on the basis of 2 CFR Part 200, Subpart E. The maximum amount NIH will award for compensation of a graduate student receiving support from a research grant is the zero-level Kirschstein-NRSA stipend in effect when NIH issues the grant award (see current levels posted at http://grants.nih.gov/training/nrsa.htm). Payments made for educational assistance (e.g., scholarships, fellowships, and student aid costs) may not be paid from NIH research grant funds even when they would appear to benefit the research project.

Items	Explanation of Allowable Costs
Fringe Benefits / Insurance	Allowable. Insurance usually is treated as an F&A cost. In certain situations, however, where special insurance is required as a condition of the grant because of risks peculiar to the project, the premium may be charged as a direct cost if doing so is consistent with organizational policy. Medical liability (malpractice) insurance is an allowable cost of research programs at all types of recipients only if the research involves human subjects. If so, the insurance must be treated as a direct cost and must be assigned to individual grants based on the manner in which the insurer allocates the risk to the population covered by the insurance. See also Reserve Funds. The cost of insuring equipment, whether purchased with project funds or furnished as federally owned property, normally should be included in F&A costs but may be allowable as a direct cost if this manner of charging is the normal organizational policy. Health insurance for trainees and fellows is addressed in the Ruth L. Kirschstein National Research Service Awards chapter in IIB.
Fringe Benefits / Pension Plan Costs	Pension plan costs which are incurred in accordance with the established policies of the non-Federal entity are allowable, provided that: 1. Such policies meet the test of reasonableness. 2. The methods of cost allocation are not discriminatory. 3. For entities using accrual-based accounting, the cost assigned to each fiscal year is determined in accordance with GAAP. 4. The costs assigned to a given fiscal year are funded for all plan participants within six months after the end of that year. However, increases to normal and past service pension costs caused by a delay in funding the actuarial liability beyond 30 calendar days after each quarter of the year to which such costs are assignable are unallowable. Non-Federal entity may elect to follow the “Cost Accounting Standard for Composition and Measurement of Pension Costs” (48 CFR Part 9904.412). 5. Pension plan termination insurance premiums paid pursuant to the Employee Retirement Income Security Act (ERISA) of 1974 (29 U.S.C. 1301–1461) are allowable. Late payment charges on such premiums are unallowable. Excise taxes on accumulated funding deficiencies and other penalties imposed under ERISA are unallowable. 6. Pension plan costs may be computed using a pay-as-you-go method or an acceptable actuarial cost method in accordance with established written policies of the non-Federal entity. a. For pension plans financed on a pay-as-you-go method, allowable costs will be limited to those representing actual payments to retirees or their beneficiaries.

Items	Explanation of Allowable Costs
	b. Pension costs calculated using an actuarial cost-based method recognized by GAAP are allowable for a given fiscal year if they are funded for that year within six months after the end of that year. Costs funded after the six month period (or a later period agreed to by the cognizant agency for indirect costs) are allowable in the year funded. The cognizant agency for indirect costs may agree to an extension of the six month period if an appropriate adjustment is made to compensate for the timing of the charges to the Federal government and related Federal reimbursement and the non-Federal entity's contribution to the pension fund. Adjustments may be made by cash refund or other equitable procedures to compensate the Federal government for the time value of Federal reimbursements in excess of contributions to the pension fund. c. Amounts funded by the non- Federal entity in excess of the actuarially determined amount for a fiscal year may be used as the non- Federal entity's contribution in future periods. d. When a non-Federal entity converts to an acceptable actuarial cost method, as defined by GAAP, and funds pension costs in accordance with this method, the unfunded liability at the time of conversion is allowable if amortized over a period of years in accordance with GAAP. e. The Federal government must receive an equitable share of any previously allowed pension costs (including earnings thereon) which revert or inure to the non-Federal entity in the form of a refund, withdrawal, or other credit.
Fringe Benefits / <u>Severance Pay</u>	1. Severance pay, also commonly referred to as dismissal wages, is a payment in addition to regular salaries and wages, by non-Federal entities to workers whose employment is being terminated. Costs of severance pay are allowable only to the extent that in each case, it is required by: a. law, b. employer-employee agreement, c. established policy that constitutes, in effect, an implied agreement on the non- Federal entity's part, or d. circumstances of the particular employment. 2. Costs of severance payments are divided into two categories as follows:

Items	Explanation of Allowable Costs
	a. Actual normal turnover severance payments must be allocated to all activities; or, where the non-Federal entity provides for a reserve for normal severances, such method will be acceptable if the charge to current operations is reasonable in light of payments actually made for normal severances over a representative past period, and if amounts charged are allocated to all activities of the non- Federal entity. b. Measurement of costs of abnormal or mass severance pay by means of an accrual will not achieve equity to both parties. Thus, accruals for this purpose are not allowable. However, the Federal government recognizes its obligation to participate, to the extent of its fair share, in any specific payment. Prior approval by the Federal awarding agency or cognizant agency for indirect cost, as appropriate, is required. 3. Costs incurred in certain severance pay packages which are in an amount in excess of the normal severance pay paid by the non-Federal entity to an employee upon termination of employment and are paid to the employee contingent upon a change in management control over, or ownership of, the non-Federal entity's assets, are unallowable. 4. Severance payments to foreign nationals employed by the non-Federal entity outside the United States, to the extent that the amount exceeds the customary or prevailing practices for the non-Federal entity in the United States, are unallowable, unless they are necessary for the performance of Federal programs and approved by the NIH awarding IC. 5. Severance payments to foreign nationals employed by the non-Federal entity outside the United States due to the termination of the foreign national as a result of the closing of, or curtailment of activities by, the non-Federal entity in that country, are unallowable, unless they are necessary for the performance of Federal programs and approved by the NIH awarding IC.
Fundraising and Investment Management Costs	1. Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred to raise capital or obtain contributions are unallowable. Fund raising costs for the purposes of meeting the Federal program objectives are allowable with prior written approval from the Federal awarding agency. (See also Proposal Costs). 2. Costs of investment counsel and staff and similar expenses incurred to enhance income from investments are unallowable except when associated with investments covering pension, self-insurance, or other funds which include Federal participation allowed by 2 CFR Part 200. 3. Costs related to the physical custody and control of monies and securities are allowable.

Items	Explanation of Allowable Costs
	4. Both allowable and unallowable fund raising and investment activities must be allocated as an appropriate share of indirect costs under the conditions described in 2 CFR Part 200.413.
Genomic Arrays	Allowable as a direct cost, but with specialized treatment of F&A reimbursement for costs exceeding \$50,000 in each budget year. See Cost Considerations-Reimbursement of Facilities and Administrative Costs for more information.
Hazardous Waste Disposal	Allowable; usually treated as an F&A cost.
Honoraria	Unallowable when the primary intent is to confer distinction on, or to symbolize respect, esteem, or admiration for, the recipient of the honorarium. A payment for services rendered, such as a speaker's fee under a conference grant, is allowable.
Hospitalization	See Research Patient Care in this exhibit.
Incentive Costs	Incentive payments to volunteers or patients participating in a grant-supported project or program are allowable. Incentive payments to individuals to motivate them to take advantage of grant-supported health care or other services are allowable if within the scope of an approved project. See Salaries and Wages/Incentive Compensation in this exhibit for incentive payments to employees.
Indemnification	Absent express statutory authority, unallowable if the indemnification would result in liability that is indefinite, indeterminate or potentially unlimited. In those rare cases where authority does allow this cost, it would be reflected in the NoA.
Independent Research and Development Costs	Independent research and development is research and development which is conducted by an organization, and which is not sponsored by Federal or non-Federal awards, contracts, or other agreements. Independent research and development shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development. The cost of independent research and development, including their proportionate share of indirect costs, are unallowable.
Intellectual Property (Invention, Copyright, Patent, or Licensing Costs)	Unallowable as a direct cost unless specifically authorized on the grant award. May be allowable as F&A costs, provided they are in accordance with 2 CFR Part 200.448 and are included in the negotiation of F&A cost rates.
Interest	Allowable as an F&A cost for certain assets as specified in 2 CFR Part 200.449 . Unallowable for hospitals. (2 CFR Part 200, Appendix IX, I.o.). (See Payment—Interest Earned on Advances of Grant Funds).
IRB or IACUC Costs	Costs associated with IRB review of human research protocols, or IACUC review of animal research protocols, are not allowable as direct charges to NIH-funded research unless such costs are not covered by the organization's F&A rate.
Laboratory Directed Research &	NIH awards to DOE laboratories will not include the proportionate share of F&A costs for Laboratory Directed Research & Development (LDRD) in accordance

Items	Explanation of Allowable Costs
Development	with the MOU with the Department of Energy dated June 18, 1998, although NIH will not restrict the DOE laboratory contractors from recovering LDRD costs within the total funding included in an award. In addition, DOE has agreed to waive the Overhead Rate on all NIH grant awards to DOE laboratory contractors.
Leave	Allowable for employees as a fringe benefit (see Fringe Benefits in this exhibit). See Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Other Terms and Conditions—Leave and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Other Terms and Conditions—Leave in IIB for NIH policy on leave for fellows and trainees.
Legal Services	Allowable. Generally treated as an F&A cost but, subject to the limitations described in the applicable cost principles, may be treated as a direct cost for legal services provided by individuals who are not employees of the recipient organization. Before a recipient incurs legal costs that are extraordinary or unusual in nature, the recipient should make an advance agreement regarding the appropriateness and reasonableness of such costs with the GMO. Legal costs incurred in defending or prosecuting claims, whether equitable or monetary, including administrative grant appeals, are generally unallowable charges to NIH grant-supported projects, except as expressly permitted in the 2 CFR Part 200.
Library Services	General library support is not allowable as a direct cost but may be included in the recipient's F&A pool. However, such services are allowable as a direct cost when specifically required for the conduct of the project and when identifiable as an integral part of the grant-supported activity (e.g., in those programs designed to develop and support such services).
Lobbying	Generally unallowable, in accordance with 2 CFR Part 200.450, including costs of lobbying activities to influence the introduction, enactment, or modification of legislation by the U.S. Congress or a State legislature. Under certain circumstances, costs associated with activities that might otherwise be considered "lobbying" that are directly related to the performance of a grant may be allowable. The recipient should obtain an advance understanding with the GMO if it intends to engage in these activities. Unallowable for State and Local governments and for-profit organizations. (Also see Public Policy Requirements and Objectives—Lobbying Prohibition , Appropriation Mandates – Lobbying – Appropriation Prohibition , and Administrative Requirements—Monitoring—Reporting concerning lobbying restrictions, the required certification, and reporting).
Maintenance and Repair Costs	Costs incurred for utilities, insurance, security, necessary maintenance, janitorial services, repair, or upkeep of buildings and equipment (including Federal property unless otherwise provided for) which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are allowable. Costs incurred for improvements which add to the permanent value of the buildings and equipment or appreciably prolong their intended life must be treated as capital expenditures (see 2 CFR

Items	Explanation of Allowable Costs
	Part 200.439 and 45 CFR Part 75.439). These costs are only allowable to the extent that they are not paid through rental or other agreements.
Materials and Supplies Costs, including Costs of Computing Devices.	1. Costs incurred for materials, supplies, and fabricated parts necessary to carry out a Federal award are allowable. 2. Purchased materials and supplies must be charged at their actual prices, net of applicable credits. Withdrawals from general stores or stockrooms should be charged at their actual net cost under any recognized method of pricing inventory withdrawals, consistently applied. Incoming transportation charges are a proper part of materials and supplies costs. 3. Materials and supplies used for the performance of a Federal award may be charged as direct costs. In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award. 4. Where federally-donated or furnished materials are used in performing the Federal award, such materials will be used without charge.
Meals	Allowable for subjects and patients under study, or where specifically approved as part of the project activity, provided that such charges are not duplicated in participants' per diem or subsistence allowances, if any. When certain meals are an integral and necessary part of a meeting or conference (i.e., a working meal where business is transacted), grant funds may be used for such meals only when consistent with terms of award. Recurring business meetings, such as staff meetings, should not be broadly considered as meetings for the primary purpose of disseminating technical information in order to justify charging meals or refreshment costs to grants.
Membership, Subscription, and Professional Activity Costs	1. Costs of the non-Federal entity's membership in business, technical, and professional organizations are allowable as an F&A cost. 2. Costs of the non-Federal entity's subscriptions to business, professional, and technical periodicals are allowable. 3. Costs of membership in any civic or community organization are allowable with prior approval by the NIH awarding IC or pass-through entity. 4. Costs of membership in any country club or social or dining club or organization are unallowable. 5. Costs of membership in organizations whose primary purpose is lobbying are unallowable. See also Lobbying. 6. Payment of dues or membership fees for an individual's membership in a professional or technical organization is allowable as a fringe benefit or an employee development cost, if paid according to an established organizational policy consistently applied regardless of the source of funds.

Items	Explanation of Allowable Costs
Moving	See Recruitment Costs , Relocation Costs , and Transportation Costs in this exhibit.
Nursery Items	Allowable for the purchase of items such as toys and games to allow patients to participate in research protocols.
Overtime	See Salaries and Wages/Extra Service Pay (Overtime) in this exhibit.
Participant Support Costs	Only allowable when identified in specific NOFOs.
Pre-Award (Pre-Agreement) Costs	Allowable. A recipient may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs: • are necessary to conduct the project, and • would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award. Pre-award costs must be charged to the initial budget period of the award, unless otherwise specified by NIH. Recipients may incur pre-award costs before the beginning date of a non-competing continuation award without regard to the time parameters stated above. The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the recipient's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. Pre-Award Costs are generally not applicable to training grants or fellowships. See respective sections for Individual Fellowships and Institutional Training Grants in the Ruth L. Kirschstein National Research Service Award chapter in IIB for additional information.
Professional Services Costs	1. Costs of professional and consultant services rendered by persons who are members of a particular profession or possess a special skill, and who are not officers or employees of the non-Federal entity, are allowable, subject to paragraphs (b) and (c) below when reasonable in relation to the services rendered and when not contingent upon recovery of the costs from the Federal government. In addition, legal and related services are limited under 2 CFR Part 200.435.

Items	Explanation of Allowable Costs
	2. In determining the allowability of costs in a particular case, no single factor or any special combination of factors is necessarily determinative. However, the following factors are relevant: a. The nature and scope of the service rendered in relation to the service required. b. The necessity of contracting for the service, considering the non-Federal entity's capability in the particular area. c. The past pattern of such costs, particularly in the years prior to Federal awards. d. The impact of Federal awards on the non-Federal entity's business (i.e., what new problems have arisen). e. Whether the proportion of Federal work to the non-Federal entity's total business is such as to influence the non-Federal entity in favor of incurring the cost, particularly where the services rendered are not of a continuing nature and have little relationship to work under Federal awards. f. Whether the service can be performed more economically by direct employment rather than contracting. g. The qualifications of the individual or concern rendering the service and the customary fees charged, especially on non-federally funded activities. h. Adequacy of the contractual agreement for the service (e.g., description of the service, estimate of time required, rate of compensation, and termination provisions). 3. In addition to the factors in paragraph (b) above, to be allowable, retainer fees must be supported by evidence of bona fide services available or rendered. Recipients, consortium participants, and contractors under grants are encouraged to obtain written reports from consultants unless such a report is not feasible given the nature of the consultation or would not be useful. Documentation maintained by the receiving organization should include the name of the consulting firm or individual consultant; the nature of the services rendered and their relevance to the grant-supported activities, if not otherwise apparent from the nature of the services; the period of service; the basis for calculating the fee paid (e.g., rate per day or hour worked or rate per unit of service rendered); and the amount paid. This information may be included in the consultant's invoice, in the report, or in another document. See Grants to Federal Institutions and Payments to Federal Employees under Grants chapter in IIB for allowable costs associated with consultant payments to Federal employees and the circumstances of allowability. See Salaries and Wages/Intra-IHE Consulting.
Profit or Fee	Except for grants awarded under the SBIR/STTR programs, under an NIH grant, no profit or fee will be provided to a for-profit organization, whether as a recipient or as a consortium participant. A profit or fee under a grant is not a cost, but is an

Items	Explanation of Allowable Costs
	amount in excess of actual allowable direct and F&A costs. In accordance with normal commercial practice, a profit/fee may be paid to a contractor under an NIH grant providing routine goods or services to the recipient.
Proposal Costs	Proposal costs are the costs of preparing bids, proposals, or applications on potential Federal and non-Federal awards or projects, including the development of data necessary to support the non-Federal entity's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect (F&A) costs and allocated currently to all activities of the non-Federal entity. No proposal costs of past accounting periods will be allocable to the current period.
Public Relations Costs	See Advertising and Public Relations .
Publication and Printing Costs	1. Publication costs for electronic and print media, including distribution, promotion, and general handling are allowable. If these costs are not identifiable with a particular cost objective, they should be allocated as indirect costs to all benefiting activities of the non-Federal entity. 2. Page charges for professional journal publications are allowable where: a. The publications report work supported by the Federal government; and b. The charges are levied impartially on all items published by the journal, whether or not under a Federal award. If charged to the award, these costs must be charged to the final budget period of the award, unless otherwise specified by NIH c. The non-Federal entity may charge the Federal award before closeout for the costs of publication or sharing of research results if the costs are not incurred during the period of performance of the Federal award. Publications and journal articles produced under an NIH grant-supported project must bear an acknowledgment and disclaimer, as appropriate, as provided in Administrative Requirements—Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources.
Rearrangement and Reconversion Costs	See Alteration and Renovation costs .

Items	Explanation of Allowable Costs
Recruiting Costs	1. Subject to paragraphs (2) and (3) of this section, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of “help wanted” advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees, are allowable to the extent that such costs are incurred pursuant to the non-Federal entity’s standard recruitment program. Where the non-Federal entity uses employment agencies, costs not in excess of standard commercial rates for such services are allowable. 2. Special emoluments, fringe benefits, and salary allowances incurred to attract professional personnel that do not meet the test of reasonableness or do not conform with the established practices of the non-Federal entity, are unallowable. 3. Where relocation costs incurred incident to recruitment of a new employee have been funded in whole or in part as a direct cost to a Federal award, and the newly hired employee resigns for reasons within the employee's control within 12 months after hire, the non-Federal entity will be required to refund or credit the Federal share of such relocation costs to the Federal government. See also Relocation Costs of Employees. 4. Short-term, travel visa costs (as opposed to longer-term, immigration visas) are generally allowable expenses that may be proposed as a direct cost. Since short-term visas are issued for a specific period and purpose, they can be clearly identified as directly connected to work performed on a Federal award. For these costs to be directly charged to a Federal award, they must: a. Be critical and necessary to conduct the project; b. Be allowable under the applicable cost principles; c. Be consistent with the non-Federal entity’s cost accounting practices and non-Federal entity policy; and d. Meet the definition of “direct cost” as described in the applicable cost principles. Project funds may not be used for a prospective trainee’s travel costs to or from the recipient organization for the purpose of recruitment. However, other costs incurred in connection with recruitment under training programs, such as advertising, may be allocated to a grant-supported project according to the provisions of the applicable cost principles (also see Travel, Relocation Costs, and Visa Costs in this exhibit).
Registration Fees (for Symposiums and Seminars)	Allowable if necessary to accomplish project objectives.

Items	Explanation of Allowable Costs
Relocation Costs of Employees	Allowable—in other than change of recipient organization situations—when such costs are incurred incidental to a permanent change of duty assignment (for an indefinite period or for a stated period of no less than 12 months) for an existing employee working on a grant-supported project, or when a new employee is recruited for work on the project, provided that the move is for the recipient's benefit rather than the individual's and that payment is made according to established organizational policies consistently applied regardless of the source of funds. Relocation costs may include the cost of transporting the employee and their family, dependents, and household goods to the new location and certain expenses associated with the sale of the former home. If relocation costs have been incurred in connection with the recruitment of a new employee, whether as a direct cost or an F&A cost, and the employee resigns for reasons within their control within 12 months after hire, the recipient must credit the grant account for the full cost of the relocation charged to the grant. When there is a change in the recipient organization, the personal relocation expenses of the PD/PI and others moving from the original recipient to the new recipient are not allowable charges to NIH grants (see Administrative Requirements—Changes in Project and Budget—Prior Approval Requirements).
Rental or Lease of Facilities and Equipment	Allowable subject to the limitations below. Rental costs are allowable to the extent that the rates are reasonable at the time of the decision to lease in light of such factors as rental costs of comparable property, if any; market conditions in the area; the type, life expectancy, condition, and value of the property leased; and available alternatives. Because of the complexity involved in determining the allowable amount under certain types of leases, recipients are encouraged to consult the GMO before entering into leases that will result in direct charges to the grant project. In general, the rental costs for facilities and equipment applicable to each budget period should be charged to that period. However, see Administrative Requirements—Management Systems and Procedures—Procurement System Standards and Requirements for an exception to this general rule. Rental costs under leases that create a material equity in the leased property, as defined in 2 CFR Part 200 Subpart E, are allowable only up to the amount that would be allowed had the recipient purchased the property on the date the lease agreement was executed. This would include depreciation or use allowances, maintenance, taxes, and insurance, but would exclude unallowable costs. When a recipient transfers property to a third party through sale, lease, or otherwise, and then leases the property back from that third party, the lease costs that may be charged to NIH projects generally may not exceed the amount that would be allowed if the recipient continued to own the property. Rental costs under “less-than-arms-length” leases are allowable only up to the amount that would be allowed under 2 CFR Part 200, Subpart E had title to the property been vested in the recipient. A less-than-arms-length lease is one in which one party to the lease agreement is able to control or substantially influence the actions of the other. Such leases include, but are not limited to, those between divisions of an organization; between organizations under

Items	Explanation of Allowable Costs
	common control through common officers, directors, or members; and between an organization and its directors, trustees, officers, or key employees (or the families of these individuals), directly or through corporations, trusts, or similar arrangements in which they hold a controlling interest.
Research Patient Care	The costs of routine and ancillary services provided by hospitals to individuals, including patients and volunteers, participating in research programs are allowable. Incurrence of patient care costs if not previously approved by NIH and rebudgeting additional funds into, or rebudgeting approved amounts out of, the research patient care costs category may be considered a change in scope and require prior approval by the NIH awarding IC. Routine services include the regular room services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made. Ancillary services are those special services for which charges customarily are made in addition to routine services, e.g., x-ray, operating room, laboratory, pharmacy, blood bank, and pathology. See the Research Patient Care Costs chapter in IIB for NIH policy concerning reimbursement of these costs. The following otherwise allowable costs are not classified as research patient care costs: items of personal expense such as patient travel; consulting physician fees; and any other direct payments to individuals, including inpatients, outpatients, subjects, volunteers, and donors. Such costs should be included in the "Other Expenses" category of the grant budget.
Reserve Funds	Contributions to a reserve fund for self-insurance are allowable as specified in the governing cost principles (also see Fringe Benefits/Insurance and Contingency Provisions in this exhibit).
Salaries and Wages / <u>IHEs — Part-time faculty</u>	Charges for work performed on Federal awards by faculty members having only part-time appointments will be determined at a rate not in excess of that regularly paid for part-time assignments.
Salaries and Wages / <u>IHEs — Periods outside the academic year</u>	1. Except as specified for teaching activity in paragraph (2) below, charges for work performed by faculty members on Federal awards during periods not included in the base salary period will be at a rate not in excess of the IBS. 2. Charges for teaching activities performed by faculty members on Federal awards during periods not included in IBS period will be based on the normal written policy of the IHE governing compensation to faculty members for teaching assignments during such periods.
Salaries and Wages / <u>IHEs — Sabbatical Leave Costs</u>	Sabbatical leave costs may be included in a fringe benefit rate or in the organization's F&A rate. Salary may be charged directly to a project for services rendered to the project by individuals while they are on sabbatical leave, provided the salary is proportional to the service rendered and is paid according to established organizational policies applicable to all employees regardless of the source of funds. Sabbatical leave paid by an individual's employer, in combination with other compensation (e.g., partial salary from an NIH grant), may not exceed 100 percent of that individual's regular salary from their

Items	Explanation of Allowable Costs
	organization.
<u>Salaries and Wages / Standards for Documentation of Personnel Expenses</u>	Salary and wage amounts charged to grant-supported projects for personal services must be based on an adequate payroll distribution system that documents such distribution in accordance with Federal Cost Principles and consistently applied institutional policy and practices. See 2 CFR Part 200.430(i).
Salaries and Wages	Allowable. Compensation for personal services covers all amounts, including fringe benefits, paid currently or accrued by the organization for employee services rendered to the grant-supported project. Compensation costs are allowable to the extent that they are reasonable, conform to the established policy of the organization consistently applied regardless of the source of funds, and reasonably reflect the percentage of time actually devoted to the NIH-funded project. Direct salary is exclusive of fringe benefits and F&A costs. This salary guidance does not apply to consultant payments or to contracts for routine goods and services but it does apply to consortium participants (see the Consortium Agreements chapter in IIB). Salaries of federal employees with permanent appointments are unallowable except in certain circumstances (see the Grants to Federal Institutions and Payments to Federal Employees Under Grants chapter in IIB).
<u>Salaries and Wages / Extra Service Pay (Overtime)</u>	Extra Service Pay normally represents overload compensation, subject to institutional compensation policies for services above and beyond IBS. Where extra service pay is a result of Intra-IHE consulting, it is subject to the reasonableness standards for Salaries and Wages above. It is allowable if all of the following conditions are met: 1. The non-Federal entity establishes consistent written policies which apply uniformly to all faculty members, not just those working on Federal awards. 2. The non-Federal entity establishes a consistent written definition of work covered by IBS which is specific enough to determine conclusively when work beyond that level has occurred. This may be described in appointment letters or other documentations. 3. The supplementation amount paid is commensurate with the IBS rate of pay and the amount of additional work performed. 4. The salaries, as supplemented, fall within the salary structure and pay ranges established by and documented in writing or otherwise applicable to the non-Federal entity. 5. The total salaries charged to Federal awards including extra service pay are subject to the Standards of Documentation as described in Salaries and Wages/IHEs.
<u>Salaries and Wages / Institutions of higher education (IHEs)</u>	Certain conditions require special consideration and possible limitations in determining allowable personnel compensation costs under Federal awards. Allowable activities: Charges to Federal awards may include reasonable amounts for activities contributing and directly related to work under an agreement, such as delivering special lectures about specific aspects of the

Items	Explanation of Allowable Costs
	ongoing activity, writing reports and articles, developing and maintaining protocols (human, animals, etc.), managing substances/chemicals, managing and securing project-specific data, coordinating research subjects, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences.
<u>Salaries and Wages / Intra-IHE Consulting</u>	Intra-IHE consulting by faculty is assumed to be undertaken as an IHE obligation requiring no compensation in addition to IBS. However, in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the faculty member is in addition to their regular responsibilities, any charges for such work representing additional compensation above IBS are allowable provided that such consulting arrangements are specifically provided for in the Federal award or approved in writing by the NIH awarding IC. Recipients, consortium participants, and contractors under grants that want to be able to charge employee consulting costs to grant-supported projects must establish written guidelines permitting such payments regardless of the source of funding and indicating the conditions under which the payment of consulting fees to employees is proper. Under no circumstances may an individual be paid as a consultant and an employee under the same NIH grant. Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be documented in writing, on a case-by-case basis, by the head of the organization (or their designee) incurring the costs – i.e., the recipient organization, consortium participant, or contractor. If the designee is personally involved in the project, the authorization may be given only by the head of the recipient organization, consortium participant, or contractor. This authorization must include a determination that the required conditions are present and that there is no apparent or actual conflict of interest.
<u>Salaries and Wages / Nonprofit Organizations</u>	For compensation to members of nonprofit organizations, trustees, directors, associates, officers, or the immediate families thereof, determination should be made that such compensation is reasonable for the actual personal services rendered rather than a distribution of earnings in excess of costs. This may include director's and executive committee member's fees, incentive awards, allowances for off-site pay, incentive pay, location allowances, hardship pay, and cost-of-living differentials.
<u>Salaries and Wages / Professional Activities outside of the Non-Federal Entity</u>	Unless an arrangement is specifically authorized by an NIH awarding IC, a non-Federal entity must follow its written non-Federal entity-wide policies and practices concerning the permissible extent of professional services that can be provided outside the non-Federal entity for non-organizational compensation. Where such non-Federal entity-wide written policies do not exist or do not adequately define the permissible extent of consulting or other non-organizational activities undertaken for extra outside pay, the Federal government may require that the effort of professional staff working on Federal awards be allocated between: 1. Non-Federal entity activities, and

Items	Explanation of Allowable Costs
	2. Non-organizational professional activities. If the NIH awarding IC considers the extent of non-organizational professional effort excessive or inconsistent with the conflicts-of-interest terms and conditions of the Federal award, appropriate arrangements governing compensation will be negotiated on a case-by-case basis.
Salaries and Wages / <u>Special Considerations</u>	Special considerations in determining allowability of compensation will be given to any change in a non-Federal entity's compensation policy resulting in a substantial increase in its employees' level of compensation (particularly when the change was concurrent with an increase in the ratio of Federal awards to other activities) or any change in the treatment of allowability of specific types of compensation due to changes in Federal policy.
Salaries and Wages / <u>Unallowable Costs</u>	1. Costs which are unallowable under other sections of these principles must not be allowable under this section solely on the basis that they constitute personnel compensation. 2. The allowable compensation for certain employees is subject to a ceiling in accordance with statute. For the amount of the ceiling for cost reimbursement contracts, the covered compensation subject to the ceiling, the covered employees, and other relevant provisions, see 10 U.S.C. 2324(e)(1)(P), and 41 U.S.C. 1127 and 4304(a)(16). For other types of Federal awards, other statutory ceilings may apply.
Salaries and Wages / <u>Incentive Compensation</u>	Incentive compensation to employees based on cost reduction, or efficient performance, suggestion awards, safety awards, etc., is allowable to the extent that the overall compensation is determined to be reasonable and such costs are paid or accrued pursuant to an agreement entered into in good faith between the non-Federal entity and the employees before the services were rendered, or pursuant to an established plan followed by the non-Federal entity so consistently as to imply, in effect, an agreement to make such payment.
Salaries and Wages / <u>Overtime Premiums</u>	Premiums for overtime generally are allowable; however, such payments are not allowable for faculty members at institutions of higher education. If overtime premiums are allowable, the categories or classifications of employees eligible to receive overtime premiums should be determined according to the formally established policies of the organization consistently applied regardless of the source of funds.
Salaries and Wages / <u>Payments for Dual Appointments</u>	For investigators receiving compensation from the institution (recipient/contractor) and separately organized clinical practice plans, compensation from such sources may be included in the institutional base salary (IBS) budgeted and charged to NIH sponsored agreements if all of the following criteria are met: • Clinical practice compensation must be set by the institution. * • Clinical practice activity must be shown on the institution's payroll or salary appointment forms and records approved by the institution. • Clinical practice compensation must be paid through or at the direction of the institution.

Items	Explanation of Allowable Costs
	• Clinical practice activity must be included and accounted for in the institution's effort reporting and/or payroll distribution system. • The institution must assure that all financial reports and supporting documents associated with the combined IBS and resulting charges to NIH grants are retained and made available to Federal officials or their duly authorized representatives consistent with the requirements of 2 CFR Part 200.430. * "Set by the institution" means the recipient/contractor institution must be in a position to document and certify that the specified amount of clinical practice compensation is being paid in essentially the same manner as other specified amounts of the committed IBS (compensation) of the investigator. Further, this requires that the IBS not vary based on the specific clinical services provided by investigator within the periods for which total IBS is certified by the recipient institution.
Salaries and Wages / <i>Support from Multiple Grants</i>	See Cost Considerations—Allocation of Costs and Closely Related Work .
Selling and Marketing Costs	Costs of selling and marketing any products or services of the non-Federal entity (unless allowed under 2 CFR Part 200.421) are generally not allowable, except as direct costs, with prior approval by the NIH awarding IC when necessary for the performance of the Federal award.
Service Charge	Allowable. The costs to a user of organizational services and central facilities owned by the recipient organization, such as central laboratory, technology infrastructure fees, computer services and next generation computing/communication costs, are allowable provided that they are not covered by F&A costs. They must be based on organizational fee schedules consistently applied regardless of the source of funds.
Specialized Service Facilities	1. The costs of services provided by highly complex or specialized facilities operated by the non-Federal entity, such as computing facilities, wind tunnels, and reactors are allowable, provided the charges for the services meet the conditions of either paragraphs (b) or (c) of this section, and, in addition, take into account any items of income or Federal financing that qualify as applicable credits under 2 CFR Part 200.406. 2. The costs of such services, when material, must be charged directly to applicable awards based on actual usage of the services on the basis of a schedule of rates or established methodology that: a. Does not discriminate between activities under Federal awards and other activities of the non-Federal entity, including usage by the non-Federal entity for internal purposes, and

Items	Explanation of Allowable Costs
	b. Is designed to recover only the aggregate costs of the services. The costs of each service must consist normally of both its direct costs and its allocable share of all indirect (F&A) costs. Rates must be adjusted at least biennially, and must take into consideration over/under applied costs of the previous period(s). c. Where the costs incurred for a service are not material, they may be allocated as indirect (F&A) costs. d. Under some extraordinary circumstances, where it is in the best interest of the Federal government and the non-Federal entity to establish alternative costing arrangements, such arrangements may be worked out with the Federal cognizant agency for indirect costs.
Stipends	Allowable as cost-of-living allowances for trainees and fellows only under Kirschstein-NRSA individual fellowships and institutional research training grants. These payments are made according to a preestablished schedule based on the individual's experience and level of training. A stipend is not a fee-for-service payment and is not subject to the cost accounting requirements of the cost principles. Additional information, including NIH policy on stipend supplementation, is included in Ruth L. Kirschstein National Research Service Awards—Individual Fellowships—Supplementation of Stipends, Compensation, and Other Income—Stipend Supplementation and Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Stipend Supplementation, Compensation, and Other Income—Stipend Supplementation in IIB. Stipends are not allowable under research grants even when they appear to benefit the research project. See Fringe Benefits / IHE Tuition/Tuition Remission in this exhibit.
Subject Costs	See Research Patient Care and Donor Costs in this exhibit.
Taxes	For nonprofit organizations and IHEs: 1. In general, taxes which the non-Federal entity is required to pay and which are paid or accrued in accordance with GAAP, and payments made to local governments in lieu of taxes which are commensurate with the local government services received are allowable, except for: a. Taxes from which exemptions are available to the non-Federal entity directly or which are available to the non-Federal entity based on an exemption afforded the Federal government and, in the latter case, when the NIH awarding IC makes available the necessary exemption certificates, b. Special assessments on land which represent capital improvements, and c. Federal income taxes.

Items	Explanation of Allowable Costs
	2. Any refund of taxes, and any payment to the non-Federal entity of interest thereon, which were allowed as Federal award costs, will be credited either as a cost reduction or cash refund, as appropriate, to the Federal government. However, any interest actually paid or credited to a non-Federal entity incident to a refund of tax, interest, and penalty will be paid or credited to the Federal government only to the extent that such interest accrued over the period during which the non-Federal entity has been reimbursed by the Federal government for the taxes, interest, and penalties.
Termination or Suspension Costs	Unallowable except as follows. If a grant is terminated or suspended, the recipient may not incur new obligations after the effective date of the termination or suspension and must cancel as many outstanding obligations as possible (see Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support). NIH will allow full credit to the recipient for the Federal share of otherwise allowable costs if the obligations were properly incurred by the recipient before suspension or termination—and not in anticipation of it—and, in the case of termination, are not cancelable. The GMO may authorize other costs in, or subsequent to, the notice of termination or suspension.
Trailers and Modular Units	Allowable only if considered equipment as provided below. A “trailer” is defined as a portable vehicle built on a chassis that is designed to be hauled from one site to another by a separate means of propulsion and that serves, wherever parked, as a dwelling or place of business. A “modular unit” is a prefabricated portable unit designed to be moved to a site and assembled on a foundation to serve as a dwelling or a place of business. The determination of whether costs to acquire trailers or modular units are allowable charges to NIH grant-supported projects depends on whether such units are classified as real property or equipment. The classification will depend on whether the recipient’s intended use of the property is permanent or temporary. A trailer or modular unit is considered real property when the unit and its installation are designed or planned to be installed permanently at a given location so as to seem fixed to the land as a permanent structure or appurtenance thereto. Units classified as real property may not be charged to an NIH grant-supported project unless authorizing legislation permits construction or acquisition of real property and the specific purchase is approved by the NIH awarding IC. A trailer or modular unit is considered equipment when the unit and its installation are designed or planned to be used at any given location for a limited time only. Units classified as equipment may be charged to NIH grant-supported projects only if the terms and conditions of the award do not prohibit the purchase of equipment and NIH prior approval is obtained, as appropriate. A trailer or modular unit properly classified as real property or as equipment at the time of acquisition retains that classification for the life of the item, thereby determining the appropriate accountability requirements under 2 CFR Part 200.439 or 200.465, as applicable.

Items	Explanation of Allowable Costs
Trainee Costs	Allowable only under predoctoral and postdoctoral training grants. (See Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Allowable and Unallowable Costs in IIB for detailed information).
Transportation Costs	Costs incurred for freight, express, cartage, postage, and other transportation services relating either to goods purchased, in process, or delivered, are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the materials received cannot readily be made, inbound transportation cost may be charged to the appropriate indirect (F&A) cost accounts if the non-Federal entity follows a consistent, equitable procedure in this respect. Outbound freight, if reimbursable under the terms and conditions of the Federal award, should be treated as a direct cost.
Travel	Allowable as a direct cost where such travel will provide direct benefit to the project.
Travel/ <u>Employees</u>	Consistent with the organization's established travel policy, these costs for employees working on the grant-supported project may include associated per diem or subsistence allowances and other travel-related expenses, such as mileage allowances if travel is by personal automobile. Domestic travel is travel performed within the recipient's own country. For U.S. and Canadian recipients, it includes travel within and between any of the 50 States of the United States and its possessions and territories and also travel between the United States and Canada and within Canada. Foreign travel is defined as any travel outside of Canada and the United States and its territories and possessions. However, for an organization located outside Canada and the United States and its territories and possessions, foreign travel means travel outside that country. In all cases, travel costs are limited to those allowed by formally established organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used. For-profit recipients' allowable travel costs may not exceed those established by the FTR, issued by GSA, including the maximum per diem and subsistence rates prescribed in those regulations. This information is available at http://www.gsa.gov. If a recipient organization has no established travel policy, those regulations will be used to determine the amount that may be charged for travel costs. Recipients are strongly encouraged to take advantage of discount fares for airline travel through advance purchase of tickets if travel schedules can be planned in advance (such as for national meetings and other scheduled events). Recipients must comply with the requirements of the Fly America Act (49 U.S.C. 40118) which generally provides that foreign air travel funded by Federal funds may only be conducted on U.S. flag air carriers and under applicable Open Skies Agreements. For additional information regarding the Fly America Act and its exceptions, see Public Policy Requirements and Objectives—Fly America Act. Applicants and recipients should consult application instructions to determine how to budget for travel costs under specific mechanisms and for certain types of

Items	Explanation of Allowable Costs
	travelers, because they are not all required to be budgeted as travel (e.g., research subjects).
<u>Travel/Research Patients</u>	If research patient care is an approved activity of the grant-supported project, the costs of transporting individuals participating in the research protocol to the site where services are being provided, including costs of public transportation, are allowable. The purchase of motor vehicles for this purpose also may be allowable. (See also Research Patient Care in this exhibit).
Value Added Tax (VAT)	Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay in country is an allowable expense under Federal awards. Foreign tax refunds or applicable credits under Federal awards refer to receipts, or reduction of expenditures, which operate to offset or reduce expense items that are allocable to Federal awards as direct or indirect costs. To the extent that such credits accrued or received by the non-Federal entity relate to allowable cost, these costs must be credited to the NIH awarding IC either as costs or cash refunds. If the costs are credited back to the Federal award, the non-Federal entity may reduce the Federal share of costs by the amount of the foreign tax reimbursement, or where Federal award has not expired, use the foreign government tax refund for approved activities under the Federal award with prior approval of the NIH awarding IC. For many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site.
Visa Costs (including short-term travel visa costs)	Generally, allowable direct cost as part of recruiting costs on an NIH grant, as long as the institution has an employee/employer relationship with the individual. Visa costs may also be allowable when identified in specific NOFOs or when within the scope of an approved research project. Visa renewal costs for employees is not a recruiting cost and would not be an allowable charge to a grant. Expedited processing fees are generally unallowable unless and until they become part of standard processing fees. Fraud prevention and detection fees are allowable if they are required fees. Department of Homeland Security SEVIS Form I-901 is a required fee and is allowable. See also Recruiting Costs in this exhibit.

8 ADMINISTRATIVE REQUIREMENTS

8.1 CHANGES IN PROJECT AND BUDGET

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities. The recipient-initiated changes that may be made under the recipient's authority and the changes that require NIH approval are outlined below and, with respect to particular types of awards, activities, or recipients, in Subpart IIB. In addition, individual awards may restrict recipients' authorities to make budget and project changes without NIH prior approval. If NIH approval is required, it must be requested of, and obtained in writing from, the awarding IC GMO in advance of the change or obligation of funds as specified later in this chapter under [Requests for Prior Approval](#).

Recipients are required to notify NIH of developments that have a significant impact on the award-supported activities as soon as they become known. This includes significant changes to Other Support (e.g. new appointments or affiliations) that occur during the award. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

Changes in project or budget resulting from NIH-initiated actions are discussed in other sections of this chapter.

8.1.1 NIH Standard Terms of Award

Federal administrative requirements allow agencies to waive certain cost-related and administrative prior approvals; these are known as expanded authorities. In 2001, NIH extended expanded authorities to all NIH awards except for the provision to automatically carry over unobligated balances. Certain award instruments, grant programs, and types of recipients are routinely excluded from the authority to automatically carry over unobligated balances. This includes centers (P50, P60, P30, and others); cooperative agreements (U); Kirschstein-NRSA institutional research training grants (T); non-Fast Track Phase 1 SBIR and STTR awards (R43 and R41); clinical trials (regardless of activity code); and awards to individuals.

One or more of these authorities may be overridden by a specific term or condition of the award. Recipients must review the NoA to determine if a particular authority is withheld for a specific grant.

Recipients must exercise proper stewardship over Federal funds and ensure that costs charged to awards are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds. NIH may disallow the costs if it determines, through audit or otherwise, that the costs do not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

Several authorities have specific deadlines for submission of reports or for timely notification to the NIH awarding IC. Recipients should be aware that any consistent pattern of failure to adhere to those deadlines for reporting or notification will be grounds for excluding that recipient from a specific authority.

Exhibit 6. Summary of NIH Standard Terms of Award

Recipient Authorities as NIH Standard Terms of Award	Exceptions
Carryover of unobligated balances from one budget period to any subsequent period	Centers (P50, P60, P30 and others), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials, and awards to individuals, or if the NoA indicates otherwise.
Cost-related prior approval changes, including research patient care costs and equipment	The cost would result in a change of scope.
Extension of final budget period of a project period without additional NIH funds (no-cost extension)	The recipient has already exercised its one-time authority to extend the award for up to 12 months; the NIH awarding IC has previously extended the project period; and/or a project is multi-year for 5 years (i.e., the entire 5-year project period is funded by a single award).
Transfer of performance of substantive programmatic work to a third party (by consortium agreement)	The transfer would be to a foreign component or it would result in a change in scope.
Direct charge the salaries of administrative and clerical staff if conditions in 2 CFR Part 200.413 are met and the charges also meet the criteria for allowable costs described in 2 CFR Part 200.403.	
Direct charge payments of Incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) 2 CFR Part 200.430. Such activities must be specifically provided for in the Federal award budget.	
Include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member's base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member's regular departmental load.	

8.1.1.1 Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period

Recipients should be aware that there is a difference between unliquidated obligations and unobligated balances. Unliquidated obligations are commitments of the recipient and are considered to be obligations and, therefore, should not be reported as unobligated balances.

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority, or if prior approval is required by the NIH awarding IC. Note the authority to automatically carry over unobligated balances includes the authority to carryover from one competitive segment to another.

Automatic carryover of unobligated balances applies to all awards except centers (P50, P60, P30, other), cooperative agreements (U), Kirschstein-NRSA institutional research training grants (T), non-Fast Track Phase I SBIR and STTR awards (R43 and R41), clinical trials (regardless of activity code), and awards to individuals. For these grants, carryover of unobligated balances requires NIH awarding IC prior approval unless otherwise noted in the NoA. Other awards may be excluded from this authority through a specific term or condition in the NoA.

For awards under SNAP (see [Administrative Requirements—Monitoring—Reporting—Streamlined Non-Competing Award Process](#) for applicability), funds are automatically carried over to the subsequent budget period. However, the recipient will be required to indicate, as part of the grant's progress report, whether any estimated unobligated balance (including prior-year carryover) is expected to be greater than 25 percent of the current year's total approved budget. The total approved budget amount includes current year and any carryover from prior years of the project period. If the unobligated balance is greater than 25 percent of the total approved budget, the recipient must provide an explanation and indicate plans for expenditure of those funds within the current budget year.

For awards that require an annual FFR, the amount to be carried over must be specified under item 12, "Remarks."

For both SNAP and non-SNAP, when a recipient reports a balance of unobligated funds in excess of 25 percent of the total amount awarded for the budget period, plus any approved carryover of funds from a prior year(s), the GMO will review the circumstances resulting in the balance to ensure that these funds are necessary to complete the project, and may request additional information from the recipient, including a revised budget, as part of the review.

If the GMO determines that some or all of the unobligated funds are not necessary to complete the project, the GMO may restrict the recipient's authority to automatically carry over unobligated balances in the future, use the balance to reduce or offset NIH funding for a subsequent budget period, or use a combination of these actions. The GMO also may indicate whether the balance may be carried forward to a budget period other than the succeeding one. The GMO's decision about the disposition of the reported unobligated balance will be reflected in the terms and conditions of the NoA.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30th, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit the availability of funds for carryover.

8.1.1.2 Cost-Related Prior Approvals

NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope.

8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds

The recipient may extend the final budget period of the previously approved project period one time for a period of up to 12 months beyond the original completion date shown in the NoA if:

- no term of award specifically prohibits the extension,
- no additional funds are required to be obligated by the NIH awarding IC, and
- the project's originally approved scope will not change.

Such an action affirms that additional work remains to be completed on the project and that resources are available to continue to support the project, or that additional time is needed to provide for an orderly closeout. The fact that funds remain at the completion date of the grant is not, in itself, sufficient justification for an extension without additional funds.

With the exception of grant programs that have an effort requirement, or where terms and conditions prohibit such reductions, NIH will not require prior approval for the reduction in effort for Senior/Key personnel named in the NOA. The recipient is reminded that active awards must have a measurable level of effort.

Recipients must use the eRA Commons No-Cost Extension feature to electronically notify NIH that they are exercising their one-time authority to extend without funds the completion date of an award. This extension feature becomes available to the recipient 90 days before the project period end date. Extensions may be up to 12 months beyond the final budget period end date. In the eRA Commons, this notification can be made up to the last day of the current project end date. An e-mail notification is automatically sent to the GMO. No further action by the recipient is required.

Notifications may not be submitted via e-mail or fax. If a no-cost extension notification is submitted late, the eRA Commons No-Cost Extension feature cannot be used. Instead, the extension notification becomes a request and that requires the approval of the IC GMO. Recipients who miss the window (or opportunity) to extend the grant in eRA Commons must submit a written prior approval request to the NIH awarding IC for consideration. (See [Administrative Requirements—Prior Approval Requirements](#) for extension requiring additional funds.)

In extending the final budget period of the project period through this process, the recipient agrees to update all required certifications and assurances, including but not limited to those pertaining to human subjects and vertebrate animals, in accordance with applicable regulations and policies. Recipients are reminded that all terms and conditions of the award apply during the extension period.

Recipients may not extend project periods that were previously extended by the NIH awarding IC. Any additional project period extension requires NIH prior approval. (See [Administrative Requirements—Prior Approval Requirements](#) for extensions requiring additional funds.)

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the quarterly cash transaction report (using the FFR) no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit or eliminate this authority to extend the final budget period when an entire project period is funded by a single award (e.g., multiyear funded awards).

The provisions in this subsection do not apply to fellowship awards.

8.1.1.4 Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement

Prior approval by the NIH awarding IC is not required to transfer the performance of already peer reviewed programmatic work unless the activity constitutes a change in scope or results in the transfer of substantive programmatic work to a foreign component.

8.1.1.5 Direct Charging Salaries of Administrative and Clerical Staff

The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:

1. Administrative or clerical services are integral to a project or activity;
2. Individuals involved can be specifically identified with the project or activity;
3. Such costs are explicitly included in the budget; and
4. The costs are not also recovered as indirect costs.

Such charges must also meet the criteria for allowable costs described in 2 CFR Part 200.403.

NIH prior approval is not required to rebudget funds for this direct cost item post-award. Prior approval is only required when additional funds are being requested for such a position.

8.1.1.6 Supplemental Compensation under Written Institutional Policy for IHEs

IHEs may direct charge payments of incidental activities for which supplemental compensation is allowable under written institutional policy (at a rate not to exceed the institutional base salary) and not include them in the records described in 2 CFR Part 200.430. Such activities must be specifically provided for in the Federal award budget.

8.1.1.7 Intra-IHE Faculty Consulting that Exceed a Faculty Member's Base Salary, Under Certain Conditions.

IHEs may include charges for Intra-IHE faculty consulting on sponsored agreements that exceed a faculty member's base salary, but only in unusual cases where: (a) consultation is across departmental lines or involves a separate or remote operation; and (b) the consulting work is in addition to the faculty member's regular departmental load.

8.1.2 Prior Approval Requirements

This section describes the activities and/or expenditures that require NIH prior approval. NIH prior approval requirements are summarized in Exhibit 7, which is provided for guidance only. For the prior approval requirements specified in the exhibit, approval is required whether or not the change has a budgetary impact. The circumstances under which prior approval is required also are summarized in the exhibit.

Recipients also should consult Subpart IIB for prior approval requirements that apply to specific mechanisms, types of grants, and types of recipients.

Any question about the need for prior approval for an activity or cost under a specific NIH award should be directed to the GMO.

Exhibit 7. Summary of Actions Requiring NIH Prior Approval

NIH prior approval is required for	Under the following circumstances
Additional no-cost extension, extension greater than 12 months, or late notification of initial no-cost extension (8.1.2.1)	All instances.
A&R (8.1.2.2)	Rebudgeting into A&R costs that would exceed 25 percent of the total approved budget for a budget period. If rebudgeting would not meet this threshold but would result in a change in scope. Addition of a Major single A&R project.
Capital expenditures (construction, land, or building acquisition) (8.1.2.3)	All instances. Also, any proposals to convey, transfer, assign, mortgage, lease, or in any other manner encumber real property acquired with NIH grant funds.
Carryover of unobligated balances (8.1.2.4)	If the NoA indicates that the recipient does not have the authority to automatically carry over unobligated balances.
Change in scope (8.1.2.5)	All instances.
Change in status of the PD/PI or senior/key personnel named in the NoA (8.1.2.6)	A significant change in the status including but not limited to withdrawal from the project; absence for any continuous period of 3 months or more; reduction of the level of effort devoted to project by 25 percent or more from what was approved in the initial competing year award.
Change of recipient organization (8.1.2.7)	All instances.
Change of recipient organization status (8.1.2.8)	All instances.
Deviation from award terms and conditions (8.1.2.9)	All instances. Includes undertaking any activities disapproved or restricted as a condition of the award.
Foreign component added to a grant to a domestic or foreign organization (8.1.2.10)	All instances.
Make subawards based on fixed amounts (8.1.2.11)	All instances
Need for additional NIH funding (8.1.2.12 and 8.1.2.13)	All instances, including extension of a final budget period of a project period with additional funds.
Pre-award costs (8.1.2.14)	More than 90 days before effective date of the initial budget period of a new or competing continuation award; always at the recipient's own risk.

NIH prior approval is required for	Under the following circumstances
Rebudgeting funds from trainee costs (8.1.2.15)	All instances.
Rebudgeting of funds between construction and non-construction work (8.1.2.16)	All instances.
Retention of research grant funds when CDA awarded (8.1.2.17)	All instances.

8.1.2.1 Additional No-cost Extension or Extension Greater Than 12 Months or Late Notification of Initial No-Cost Extension

The [NIH Standard Terms of Award](#) provide the recipient the authority to extend the final budget period of a previously approved project period one time for a period of up to 12 months beyond the original completion date down in the NoA. Any additional project period extension beyond the initial extension of up to 12 months requires NIH prior approval. The request should include a description of the project activities that require support during the extension and a statement about the funds available to support the extension. Further any late notification of the initial no-cost extension provided by the NIH Standard Terms of Award also requires prior approval.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. In order for NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period.

8.1.2.2 Alterations and Renovations

NIH prior approval is required if a recipient wishes to rebudget more than 25 percent of the total approved budget for a budget period into A&R costs. NIH prior approval also is required for lesser rebudgeting into A &R costs if the rebudgeting would result in a change in scope. If rebudgeting results in the addition of a Major A&R project, NIH will consider the rebudgeting to be a change in scope. (See the [Construction Grants](#) chapter in IIB for documentation requirements for Major A&R projects).

8.1.2.3 Capital Expenditures

Capital expenditures for land or buildings require NIH prior approval. In addition, real property acquired with NIH grant funds may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient without the written prior approval of the NIH awarding IC or its successor organization.

8.1.2.4 Carryover of Unobligated Balances

The NoA will include a term and condition to indicate the disposition of unobligated balances. The term and condition will state whether the recipient has automatic carryover authority or if prior approval is

required by the NIH awarding IC. When NIH prior approval is required, the AOR should submit a request to the GMO that includes at a minimum the following information:

- A detailed budget by direct cost category with the F&A cost information (base and rate) for the proposed use of the carryover funds. If personnel costs are requested, include a detailed breakdown of personnel costs, including base salary, salary requested and effort to be spent on the project during the extension. In general, carryover action requiring prior approval will be approved using the F&A rate that was in effect at the time the initial funds were awarded for the year to which the funds are being carried over. For example, if the carryover is approved from year -01 to year -03, the F&A rate used to calculate the revised -03 year award will be the rate used to initially calculate year -03. However, actual expenditures will still be based on the rate applicable when the cost is incurred.
- A scientific justification for the use of funds.
- The reason for the unobligated balance.

8.1.2.5 Change in Scope

In general, the PD/PI may make changes in the methodology, approach, or other aspects of the project objectives. However, the recipient must obtain prior approval from the NIH awarding IC for a change in scope. A change in scope is a change in the direction, aims, objectives, purposes, or type of research training, identified in the approved project. The recipient must make the initial determination of the significance of a change and should consult with the GMO as necessary.

Potential indicators of a change in scope include, but are not limited to, the following:

- Change in the specific aims approved at the time of award.
- Substitution of one animal model for another.
- Change from the approved use of live vertebrate animals.

- Change from the approved involvement of human subjects that would result in an increased risk. This includes:
 - An addition or change that would result in changing the overall human subjects or clinical trial designation of the award;
 - From non-human subjects research to research involving human subjects (exempt or non-exempt);
 - From exempt to non-exempt research involving human subjects; or
 - From “No Clinical Trial” to “Includes a Clinical Trial.” Requests for this change must be submitted to a clinical trial NOFO as a competitive revision. See NIH definition of [clinical trial](#) and [2.3.5 — Types of Notices of Funding Opportunity](#).
 - The new inclusion of subject populations that are covered by additional regulatory protections under 45 CFR Part 46 subparts B, C or D (pregnant women, human fetuses, and neonates; prisoners; or children).
 - Any change to the study protocol that would increase the risk level for subjects including physical, psychological, financial, legal or other risks. This could include the addition of a new study population that would be at higher risk from existing research procedures, the addition of new study procedures that are greater than minimal risk, any modification of existing study procedures that would increase overall risk, or the addition of a new clinical study or a new clinical trial intervention arm not originally proposed that is greater than minimal risk.
 - New information indicating a higher level of risk to participants than previously recognized for a study intervention, procedure, or pharmacological treatment.
- Shift of the research emphasis from one disease area to another.
- A clinical hold by FDA under a study involving an IND or an IDE.
- Application of a new technology, e.g., changing assays from those approved to a different type of assay.
- Transfer of the performance of substantive programmatic work to a third party through a consortium agreement, by contract, or any other means. If the third party is a foreign component, NIH prior approval is always required.
- Change in other senior/key personnel not specifically named in the NoA (see [Change in Status, Including Absence, of PD/PI and Other Senior/Key Personnel Named in the NoA](#) below for requirements for NIH approval of alternate arrangements for or replacement of named senior/key personnel).
- [Significant rebudgeting](#), whether or not the particular expenditure(s) require prior approval. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established for the budget period by 25 percent or more of the total costs awarded. For example, if the award budget for total costs is \$200,000, any rebudgeting that would result in an increase or decrease of more than \$50,000 in a budget category is considered significant rebudgeting. The base used for determining significant rebudgeting excludes the effects of prior-year carryover balances but includes competing and non-competing supplements. Significant rebudgeting does not apply to modular grants.
- Incurrence of research patient care costs if costs in that category were not previously approved by NIH or if a recipient desires to rebudget additional funds beyond those approved into or rebudget funds out of the research patient care category.

- Purchase of a unit of equipment exceeding \$25,000.

8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA

The recipient is required to submit a prior approval request to the GMO if:

- There is a significant change in the status of the PD/PI or other Senior/Key Personnel specifically named in the NoA including but not limited to withdrawing from the project entirely, being absent from the project during any continuous period of 3 months or more, or reducing time devoted to the project by 25 percent or more from the level that was approved at the time of initial competing year award (for example, a proposed change from 40 percent effort to 30 percent or less effort or in calendar months a change from 4.8 to 3.6 calendar months). Reductions are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more. Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level. Selecting **Yes** in the RPPR constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request.
- There is a change from a multiple PD/PI model to a single PD/PI model.
- There is a change from a single PD/PI model to a multiple PD/PI model.
- There is a change in the number or makeup of the PD/PIs on a multiple PD/PI award.

NIH must approve any alternate arrangement proposed by the recipient, including any replacement of the PD/PI or senior/key personnel named in the NoA, and the addition of any new PD/PIs.

The request for prior approval of any additional or substitute PD/PIs or Senior/Key Personnel named in the NoA, or change from a multiple PD/PI model to a single PD/PI model, must be submitted promptly, and must be accompanied by a strong scientific justification related to the scientific project, including any proposed changes in scope, the biographical sketch of any new individuals proposed and other sources of support, and any budget changes resulting from the proposed change. A new or revised Leadership Plan is required if the request is to change from a single PD/PI model to a multiple PD/PI model, or to change the number or makeup of the PD/PIs on a multiple PD/PI award. The Commons ID must be provided for any new PD/PIs.

In addition, because NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research, the request for approval should include mention as to whether change(s) in PD/PI or Senior/Key Personnel is related to concerns about safety and/or work environments (bullying, retaliation, or hostile working conditions). NIH recipient institutions are required to notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions. Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must be submitted to NIH through the dedicated web form, [Inform NIH About Harassment or Discrimination Concerns](#). All required notifications must include, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action(s) taken, and any anticipated impact on the NIH-funded award(s). If it is determined that the concerns shared with NIH will impact the PD/PI or senior key personnel's ability to continue as the scientific lead of the project, NIH will require prior approval for a replacement PD/PI or senior key official.

NIH will, in turn, be better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight.

If the arrangements proposed by the recipient, including the qualifications of any proposed replacement, are not acceptable to the NIH awarding IC, the grant may be suspended or terminated. If the recipient wishes to terminate the project because it cannot make suitable alternate arrangements, it must notify the GMO, in writing, of its wish to terminate, and NIH will forward closeout instructions.

The requirement to obtain NIH prior approval for a change in status pertains only to those personnel NIH designates in the NoA regardless of whether the applicant organization designates others as senior/key personnel for its own purposes.

8.1.2.7 Change of Recipient Organization

NIH prior approval is required for the transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the completion date of the approved project period (competitive segment). A change of recipient organization may be accomplished under most NIH grants if any of the following conditions are met:

- The original recipient has agreed to relinquish responsibility for an active project before the completion date of the approved project period. This includes any proposed change of recipient as a result of a PD/PI on a research project transferring from one organization to another organization. The project under the same PD/PI may be supported at a new organization for a period up to the remainder of the previously approved project period in an amount not to exceed that previously recommended for direct costs (plus applicable F&A costs) for the remaining period.
- A non-competing continuation award that is within an approved project period has been withheld because of the recipient's actions (see [Administrative Requirements—Enforcement Actions—Suspension, Termination, and Withholding of Support](#)).

A request for change of recipient organization should include mention as to whether the change in recipient institution is related to concerns about safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions) involving the PD/PI. NIH recipient institutions are required to notify NIH when individuals identified as PD/PI or other Senior/Key personnel in an NIH notice of award are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment, bullying, retaliation or hostile working conditions. Notification must be provided by the Authorized Organization Representative within 30 days of the removal or disciplinary action and must be submitted to NIH through a dedicated web form. All required notifications must include, at a minimum, the name of the Authorized Organization Representative submitting the notification, the name of the individual of concern, a description of the concerns, the action(s) taken, and any anticipated impact on the NIH-funded award(s). If it is determined that the concerns shared with NIH will impact the PD/PI or senior key personnel's ability to continue as the scientific lead of the project, NIH will require prior approval for a replacement PD/PI or senior key official.

NIH will, in turn, be better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight.

NIH expects both the relinquishing and applicant organizations to disclose whether a Change of Recipient Organization is occurring within the context of an ongoing or recent investigation of misconduct of any kind, including but not limited to professional misconduct or research misconduct.

A change of recipient that involves the transfer of a grant to or between foreign organizations or international organizations also must be approved by the IC's Advisory Council or Board.

A grant to an individual may not be transferred.

A successor-in-interest or a name change is not considered a change of recipient (see [Change in Recipient Organizational Status](#) below).

A change of recipient organization may involve the transfer of equipment purchased with grant funds. The transfer may be accomplished as part of the original recipient's relinquishment of the grant; otherwise, NIH reserves the right to transfer title to equipment to the new organization as indicated in [Administrative Requirements—Management Systems and Procedures—Property Management System Standards](#).

A change of recipient request normally will be permitted only when all of the permanent benefits attributable to the original grant can be transferred, including equipment purchased in whole or in part with grant funds. In reviewing a request to transfer a grant, NIH will consider whether there is a continued need for the grant-supported project or activity and the impact of any proposed changes in the scope of the project. NIH will also consider the length of time, the percentage of funds, and the amount of work remaining in the project period. A change may be made without peer review, provided the PD/PI plans no significant change in research objectives and the facilities and resources at the new organization will allow for successful performance of the project. If these conditions or other programmatic or administrative requirements are not met, the NIH awarding IC may require peer review or may disapprove the request and, if appropriate, terminate the award.

A change of recipient organization request must be made before the anticipated start date at the new organization and preferably several months in advance. Failure to provide timely notification may result in disapproval of the request or significant delays in processing. Recipients are encouraged to discuss any potential issues with the awarding IC(s) prior to submitting a change of recipient organization request. If requesting a transfer in the middle of a budget period or at the end of the Federal fiscal year, recipients should contact the awarding IC for IC-specific guidance on the timing and preparation of the change of institution application.

A request for a change of recipient organization must be submitted to the GMO. The original institution must include an Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant (PHS 3734) (relinquishing statement). The relinquishing statement may be submitted in paper or electronically via the eRA Commons. Final FFR Expenditure Data and a Final Invention Statement are due to NIH from the relinquishing organization no later than 120 days after the end of NIH support of the project. Final FFR Expenditure Data should not be submitted until the original institution has received a revised NoA for the relinquished grant.

The proposed new recipient institution must provide the GMO with a change of institution application which may be submitted using the PHS 398 or PHS 416-1 paper application forms, or electronically via Grants.gov using the [Parent Announcement](#). If the original award was the result of a modular application and the recipient will submit a paper change of institution application, the modular procedures apply to the request for change of recipient. If the original award was the result of a modular application and the recipient will submit an electronic change of institution application, the recipient may submit a detailed budget or streamlined-detailed budget (as described in the NOFO).

The paper application from the proposed new recipient institution should include, at a minimum, the following:

- PHS 398 Face page
- Budget pages (current and future years). (Under awards resulting from modular applications, the application should include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.) Budgets should not exceed the direct costs (plus applicable F&A costs) previously recommended for any budget period. For transfers in the middle of a budget period, the budget for the initial year may be based on the total costs relinquished only if the recipient has been instructed to do so by the awarding IC. For these applications, recipients will also need to include the Other Project Information and the Senior/Key Personnel components.
- Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel.
- If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- Updated “other support” page(s), if necessary.
- Resources page, including probable effect of the move on the project.
- Checklist page
- Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
- Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of this list in the transfer application from the new organization indicates its acceptance of title to that equipment).

The electronic application from the proposed recipient institution should include, at a minimum, the following:

- SF 424 (R&R) Cover Component
- SF 424 (R&R) Project Performance Site Location(s)
- SF 424 (R&R) Other Project Information:
 - Certification of IRB/IACUC approval, including OHRP and OLAW assurance numbers, if applicable.
 - Facilities and Other Resources, including probable effect of the move on the project.
 - Detailed list of any equipment purchased with grant funds to be transferred to the new organization (inclusion of the list in the transfer application from the new organization indicates its acceptance of title to that equipment).
- SF 424 (R&R) Senior/Key Person Profile:
 - Updated biographical sketches for the PD/PI and existing senior/key personnel and biographical sketches for any proposed new senior/key personnel, and updated “other support” page(s) as necessary.

- Budget pages applicable for activity code (current and future years). If the budget for the original award was submitted in a modular format, use the R&R Detailed Budget form for all electronic applications. Recipients may either complete all of the fields in the R&R Detailed Budget as appropriate or complete only the costs for the PD/PI (Section A), and include the remainder of the direct costs under Section F (Other Direct Costs) Items 8-17, and Section H (Indirect Costs). (For awards resulting from modular applications, include narrative budget information for the current budget period, including total direct cost and the basis for computing F&A costs and, if applicable, future budget periods.) Budgets should not exceed the direct costs previously recommended for direct costs (plus applicable F&A costs) for any budget period. For transfers during the course of a budget period, the budget for the initial year may be based on the total costs relinquished only if the recipient has been instructed to do so by the awarding IC.
- PHS 398 Research Plan
 - If transferring on the anniversary date, include the progress report for the current year including a statement regarding the goals for the upcoming year. For all transfer applications include also a statement indicating whether the overall research plans/aims have changed from the original submission, and, if so, provide updated information.
- PHS 398 Cover Page Supplement
- PHS 398 Checklist

And, as applicable:

- PHS Training Budget Form
- PHS 398 Career Development Award Supplemental Form
- PHS 398 Research Training Program Form
- PHS Human Subjects and Clinical Trial Information Form
- SBIR/STTR Information

NIH may request additional information necessary to accomplish its review of the request. Acceptance of a relinquishing statement by NIH does not guarantee approval of a transfer application for the continued funding of a project.

NIH will accomplish a change of recipient organization by issuing a revised NoA to the original recipient reflecting the revised budget/project period end dates, deletion of any future-year support, and deobligation of remaining funds, if applicable. (A deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as determined from the relinquishing statement or the available balance in PMS, whichever is less.)

Concurrently, the new recipient will receive the NoA reflecting the direct cost balance reported on the relinquishing statement plus applicable F&A costs, if funds are available. If the change of recipient organization occurs on the anniversary date of the project, the NoA to the new recipient will reflect the previously committed direct cost level plus applicable F&A costs if funds are available. If the change of recipient organization occurs during the course of the budget period, the policy of the awarding IC will determine if the NoA to the new recipient will reflect the direct cost relinquished by the former recipient plus applicable F&A costs or the total costs relinquished by the former recipient. This amount is subject to change as a result of the closeout of the original grant and may be adjusted downward.

A recipient may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs before the beginning date of a transfer award. The recipient may do so only if those costs are necessary to conduct the project and would not require prior approval if incurred under an awarded grant. For the purposes of pre-award costs, transfers are treated like non-competing continuation awards.

Therefore, the pre-award costs incurred are not limited to 90 days prior to the beginning date of the initial budget period of that transferred award to the new recipient organization.

8.1.2.8 Change in Recipient Organizational Status

Recipients must give NIH advance notice of the following types of change in organizational status (not a [change of recipient organization](#) as described above):

- **Merger.** Legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of NIH grants, the procedures for recognizing a successor-in-interest will apply. When the action does not involve the transfer of NIH grants, the procedures for recognizing a name change normally will apply.
- **Successor-in-Interest (SII).** Process whereby the rights to and obligations under an NIH grant(s) are acquired incidental to the transfer of all of the assets of the recipient or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
- **Name Change.** Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a recipient.

Advance notification is required to ensure that the recipient remains able to meet its legal and administrative obligations to NIH, and payments are not interrupted.

Recipients are encouraged to contact the GMO of the lead NIH awarding IC to explain the nature of the change in organizational status and receive guidance on whether it will be treated as a name change or SII. The lead awarding IC ordinarily will be the IC with which the organization has the most NIH grants. NIH reserves the right to review the material provided, seek clarification or additional information, and make an independent determination.

A recipient's formal request for a change in organizational status should be submitted to NIH as soon as possible so that NIH can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For a SII, a letter signed by the AORs of the current recipient (transferor) and the successor-in-interest (transferee) must be sent to the lead NIH awarding IC, following consultation with the GMO of that awarding IC. The letter must include the following:

- Stipulate that the transfer will be properly affected in accordance with applicable law.
- Indicate that the transferor relinquishes all rights and interests in all of the affected grants.
- Request that the awarding IC(s) modify its (their) records to reflect the transferee as the recipient of record.
- State the effective date of the transfer.
- Provide the transferee's EIN. If EIN is new, include completed Form W-9.
- Include verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance).

- Include a list of all affected NIH grants (active and pending) with the following information for each:
 - Complete grant number (e.g., 5 R01 GM 12345-04).
 - Name(s) of PD/PI(s).
 - Current budget period and project period.
 - The total direct costs (as originally recommended) plus applicable F&A costs for each remaining budget period. If the SII will occur during a budget period rather than on the anniversary date, the transferor also must provide estimated levels of current-year direct and F&A costs remaining as of the SII effective date. The estimate may be reported on the PHS 3734 (Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant), which may be submitted on paper or electronically through the eRA Commons, or may be itemized by grant number as an attachment to the letter. When an SII occurs during a budget period, the deobligation of funds will be based on the estimated grant expenditures through the relinquishment date, as reported on the relinquishing statement or the available balance in PMS, whichever is less.
- Include a complete face page (PHS 398) for each affected grant showing the transferee as the applicant organization. Each face page must be signed by an AOR at the transferee organization.
- Include a copy of the current negotiated F&A rate agreement for the transferee.

Recipients may choose to submit an electronic application for a successor-in-interest request to satisfy the requirement for the face page(s), confirmation of the transferee's EIN, verification of the transferee's compliance with applicable requirements (e.g., research misconduct assurance of compliance), and Relinquishing Statement. The electronic application is submitted via Grants.gov using the [Parent Announcement](#).

In order to be recognized as the SII, the "new" (transferee) organization must meet each grant program's eligibility requirements; except for grants awarded under the SBIR/STTR programs. See [Small Business Innovation Research and Small Business Technology Transfer Programs—Eligibility](#) in IIB for additional guidance. Upon review and acceptance of this information, NIH will revise the NoA(s) to show the transferee as the recipient of record.

For name changes, the recipient's written notification to the lead NIH awarding IC must include the effective date of the change. Revised face pages are not required for name changes because name changes are reported and processed with the next award action (e.g., non-competing continuation award).

8.1.2.9 Deviation from Award Terms and Conditions, including Restrictions in the NoA

NIH prior approval is required for any deviation from terms or conditions stated or referenced in the NoA, including those in the NIHGPS. This includes undertaking any activities disapproved or restricted as a condition of the award.

8.1.2.10 Foreign Component Added to a Grant to a Domestic or Foreign Organization

Adding a foreign component under a grant to a domestic or foreign organization requires NIH prior approval.

8.1.2.11 Provide Subawards Based on Fixed Amounts

With NIH prior approval, a pass-through entity may provide subawards based on fixed amounts (as defined in 2 CFR Part 200.201), to which the following conditions apply:

1. The Fixed amount subaward is negotiated using the cost principles (or other pricing information) as a guide. The pass-through entity may use fixed amount subawards if the project scope has specific measurable goals and objectives and if adequate cost, historical, or unit pricing data is available to establish a fixed amount subaward based on a reasonable estimate of actual cost. Payments are based on meeting specific requirements of the subaward. Accountability is based on performance and results. Except in the case of termination before completion of the subaward, there is no governmental review of the actual costs incurred by the non-Federal entity in performance of the subaward. Some of the ways in which the fixed amount subaward may be paid include, but are not limited to:
 - a. In several partial payments, the amount of each agreed upon in advance, and the “milestone” or event triggering the payment also agreed upon in advance, and set forth in the subaward;
 - b. On a unit price basis, for a defined unit or units, at a defined price or prices, agreed to in advance of performance of the subaward and set forth in the subaward; or,
 - c. In one payment at subaward completion.
2. A fixed amount subaward cannot be used in programs which require mandatory cost sharing or match.
3. The non-Federal entity must certify in writing to the pass-through entity at the end of the subaward that the project or activity was completed or the level of effort was expended. If the required level of activity or effort was not carried out, the amount of the subaward must be adjusted.
4. Periodic reports may be established for each fixed amount subaward.
5. Changes in principal investigator, project leader, project partner, or scope of effort must receive the prior written approval of the pass-through entity.

When considering the use of a fix amount subaward, note the distinction between a fixed-amount subaward and a fixed-rate agreement.

In a fixed amount subaward, the total value of the award is negotiated upfront. This requires the pass-through entity to know both the unit price and the total number of units that will be provided. In a fixed-rate agreement, while there is a negotiated cost per unit, e.g. per patient cost in a clinical trial (or participant in a non-Clinical Trial Human Subjects Study), the total amount of the award may be unknown when the agreement is created. Since this type of agreement is based on a “fixed rate” as opposed to a “fixed amount” as defined by 2 CFR Part 200.201, prior approval is not required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with [Transfer of the Performance of Substantive Programmatic Work to a Third Party by Means of a Consortium Agreement](#).

8.1.2.12 Need for Additional NIH Funding without Extension of Budget and Project Period

A request for additional funding for a current budget period to meet increased costs that are within the scope of the approved application, but that were unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted, is a non-competing

supplemental application. Such requests must be submitted electronically, for both single and multi-project awards, and are not required to compete with other applications for funding. Other recipient-initiated requests for supplemental funding during a current budget period are considered to change the scope of the approved project and may be required to compete for funding with other applications. When calculating the award for additional funds, NIH will 1) prorate funding if the requested budget is adjusted at the time of award, and 2) use the institution's current F&A rate; i.e., the rate in effect when the new funding is provided.

8.1.2.13 Need for Additional NIH Funding with Extension of the Final Budget Period of a Project Period

A request for a non-competing extension of the final budget period of a project period with a minimal amount of additional funds should be submitted to the GMO, in writing, at least 30 days before the project period is scheduled to expire. Such requests usually are for a period of up to 12 months and must be either for work that remains to be completed on the project or to permit orderly phase-out of project activities for which there will be no further NIH support. Resources must be available to continue to support the project. The request must specify the proposed revised ending date and must include justification for both the extension and the additional funds requested. Special justification will be required for an extension that would exceed 12 months. NIH will not approve such requests if the primary purpose of the proposed extension is to permit the use of unobligated balances of funds. All terms and conditions of the award apply during the extended period.

All Federal agencies are required by 31 U.S.C. §1552(a) to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. For NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, recipients must report disbursements on the FFR no later than August 31st of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision may limit NIH's ability to further extend the final budget period with funding.

8.1.2.14 Pre-Award Costs

See [Cost Considerations—Selected Items of Cost—Pre-Award \(Pre-Agreement\) Costs](#).

8.1.2.15 Rebudgeting of Funds from Trainee Costs

The rebudgeting of amounts previously awarded for trainee costs (stipends, tuition, and fees) to other categories of expense requires NIH prior approval. This excludes trainee travel, which NIH does not consider to be a trainee cost, and training-related expenses (see [Ruth L. Kirschstein National Research Service Awards—Institutional Research Training Grants—Rebudgeting of Funds](#) in IIB).

8.1.2.16 Rebudgeting of Funds Between Construction and Non-construction Work

Under awards that provide for both construction and non-construction work, NIH prior approval is required to transfer funds between the two types of work.

8.1.2.17 Retention of Research Grant Funds When a Career Development Award is Issued

Funds budgeted under an NIH grant for an individual's salary and fringe benefits, but available as a result of receiving a K award for that individual, may not be used for any other purpose without NIH prior approval.

8.1.3 Requests for Prior Approval

All requests for NIH awarding IC prior approval must be made in writing (including submission by e-mail) to the GMO no later than 30 days before the proposed change, and signed by the AOR. If the request is e-mailed, it must provide evidence of the AOR's approval; a cc to the AOR is not acceptable. A request by a subrecipient for prior approval will be addressed in writing to the recipient. The recipient will promptly review such request and shall approve or disapprove the request in writing. A recipient will not approve any budget or project revision which is inconsistent with the purpose or terms and conditions of the Federal-award to the recipient. If the revision, requested by the subrecipient would result in a change to the recipient's approved project which requires Federal prior approval, the recipient will obtain the awarding IC's approval before approving the subrecipient's request. Failure to obtain required prior approval from the appropriate awarding IC may result in the disallowance of costs, termination of the award, or other enforcement action within NIH's authority. While the PD/PI signature is no longer required as part of the submission to NIH, the recipient must secure and retain such a signature for each prior approval request and make it available to NIH or other authorized DHHS or Federal officials upon request. When multiple PD/PIs are recognized for a particular grant, this requirement applies to all PD/PIs. (See [Policies Affecting Applications-Program Director/Principal Investigator, Individual Fellowship and Sponsor Assurance](#)).

E-mail requests must be clearly identified as prior approval requests, must reflect the complete grant number in the subject line, and should be sent by the AOR to the GMO that signed the NoA. Contact information is provided on each NoA and is also available in the eRA Commons. E-mail addresses for NIH staff can be also obtained from the [NIH Enterprise Directory](#). E-mail requests must include the name of the recipient, the name of the initiating PD/PI, the PD/PI's telephone number, fax number, and e-mail address, and comparable identifying information for the AOR.

The GMO will review the request and provide a response to the AOR indicating the final disposition of the request, with copies to the PD/PI and to the cognizant NIH PO. Only responses provided by the GMO are considered valid. Recipients that proceed on the basis of actions by unauthorized officials do so at their own risk, and NIH is not bound by such responses.

Whenever recipients contemplate rebudgeting or other post-award changes and are uncertain about the need for prior approval, they are strongly encouraged to consult, in advance, with the GMO.

Under a consortium agreement or contract, the prior approval authority usually is the pass-through entity. However, the pass-through entity may not approve any action or cost that is inconsistent with the purpose or terms and conditions of the NIH grant. If an action by a consortium participant will result in a change in the overall grant project or budget requiring NIH approval, the pass-through entity must obtain that approval from NIH before giving its approval to the consortium participant.

8.2 AVAILABILITY OF RESEARCH RESULTS: PUBLICATIONS, INTELLECTUAL PROPERTY RIGHTS, AND SHARING RESEARCH RESOURCES

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also [Availability and Confidentiality of Information—Confidentiality of Information—Access to Research Data](#) in Part I for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, apply.

As long as recipients abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR Part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the recipient to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources “research tools” may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

8.2.1 Rights in Data (Publication and Copyrighting)

In general, recipients own the rights in data resulting from a grant-supported project. Specific terms and conditions of the award may indicate alternative rights, e.g., under a cooperative agreement or based on specific programmatic considerations as stated in the applicable RFA. Except as otherwise provided in the terms and conditions of the award, any publications, data, or other copyrightable works developed under an NIH grant may be copyrighted without NIH approval. For this purpose, “data” means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other technical research data.

Rights in data also extend to students, fellows, or trainees under awards whose primary purpose is educational, with the authors free to copyright works without NIH approval. In all cases, NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes. Data developed by a consortium participant also is subject to this policy.

As a means of sharing knowledge, NIH encourages recipients to arrange for publication of NIH-supported original research in primary scientific journals. Recipients also should assert copyright in scientific and technical articles based on data produced under the grant where necessary to effect journal publication or inclusion in proceedings associated with professional activities.

Journal or other copyright practices are acceptable unless the copyright policy prevents the recipient from making copies for its own use (as provided in 2 CFR Part 200.315). The disposition of royalties and other income earned from a copyrighted work is addressed in [Administrative Requirements—Management Systems and Procedures—Program Income](#).

All recipients must acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid invitations, and other documents describing projects or programs funded in whole or in part with Federal money. Each publication, press release, or other document about research supported by an NIH grant must include:

- 1) An acknowledgment of NIH grant support such as:

“Research reported in this [publication, release] was supported by [name of the Institute, Center, or other funding component] of the National Institutes of Health under grant number [specific NIH grant number in this format: R01GM012345].”

2) A disclaimer that says:

“The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

If the recipient plans to issue a press release about research supported by an NIH grant, it should notify the NIH funding component in advance to allow for coordination. See <http://www.nih.gov/news/media/contacts.htm> for media contact information.

Publications resulting from work performed under an NIH grant-supported project must be included as part of the annual or final progress report submitted to the NIH awarding IC (see [Administrative Requirements—Monitoring—Reporting—Non-Competing Continuation Progress Reports](#) and [Administrative Requirements—Closeout—Final Reports—Final Progress Report](#)). When publications are available electronically, the URL or the PMCID number must be provided. If not available electronically, one copy of the publication may be provided along with the progress report. See also [NIH Public Access Policy](#) below for additional requirements for publications resulting from NIH funded research.

8.2.2 NIH Public Access Policy

The NIH Public Access Policy implements Division F, Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009). The policy ensures that the public has access to the published results of NIH funded research at the [NIH NLM PMC](#), a free digital archive of full-text biomedical and life sciences journal literature. Under the policy NIH-funded investigators are required by Federal law to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The author's final peer-reviewed manuscript is defined as the final version accepted for journal publication on or after 4/7/2008, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this policy. Applicants citing articles in NIH applications, proposals, and progress reports that fall under the policy, were authored or co-authored by the applicant and arose from NIH support must include the PMCID or NIHMS ID. The NIHMSID may be used to indicate compliance with the Public Access Policy in applications and progress reports for up to three months after a paper is published. After that period, a PMCID must be provided to demonstrate compliance.

This policy applies to all peer-reviewed articles resulting from research supported in whole or in part with direct costs from NIH, including research grant and career development awards, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, SBIR/STTR awards, and NIH intramural research studies.

Additional information can be found at: <http://publicaccess.nih.gov/>.

8.2.3 Sharing Research Resources

Investigators conducting biomedical research frequently develop unique research resources. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can

impede the advancement of further research. Therefore, when these resources are developed with NIH funds and the associated research findings have been accepted for publication, or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. At the same time NIH recognizes the rights of recipients and contractors to elect and retain title to subject inventions developed with federal funding pursuant to the Bayh-Dole Act. See the [Office of Extramural Research, Division of Extramural Inventions & Technology Resources \(DEITR\), Intellectual Property Policy page](#).

Program staff are responsible for overseeing resource sharing policies and for assessing the appropriateness and adequacy of any proposed resource sharing plans.

NIH has published a set of principles and guidelines known as the NIH Research Tools Policy for funding recipients and the biomedical community. These serve as a reference for identifying an appropriate strategy for disseminating and sharing research tools. The NIH Research Tools Policy webpage explains these principles and guidelines in more detail and provides suggestions on implementation.

For recipients working with biological materials, NIH has a policy for allowing NIH funding recipients to retain and license biological materials for which patent protection might not be pursued. To learn more, read "NIH Procedures for Handling Non-election of Title to Patentable Biological Materials".

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding IC, the recipient also must provide a copy of documents or a sample of any material developed under an NIH grant award. The recipient may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see [Administrative Requirements—Management Systems and Procedures—Program Income](#)).

To facilitate the availability of unique or novel materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories and should ensure that those entities distribute them in a way that is consistent with the above referenced [NIH Research Tools Policy webpage](#). Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

8.2.3.1 Policy for Data Management and Sharing (DMS Policy)

The NIH Policy for Data Management and Sharing (DMS Policy) applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants or other funding agreements regardless of NIH funding level or funding mechanism. The DMS Policy does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities. A list of NIH activity codes subject to the DMS Policy is available on the NIH website, and the applicability of the DMS Policy will be specified in each NIH NOFO.

Applicants must submit a DMS Plan in each competitive grant application, and outline DMS costs in the appropriate cost categories in the budget (see NIH Application Guide for detailed instructions). DMS Plans should explain how scientific data generated by research projects will be managed and which of these scientific data and accompanying metadata will be shared. If DMS Plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), DMS Plans should be

updated by researchers and reviewed by the NIH ICO during regular reporting intervals or sooner. DMS Plans from NIH-funded or conducted research may be made publicly available and should not include proprietary or private information. Costs associated with data management and data sharing are subject to Federal cost principles for the reimbursement of actual costs that are allowable, allocable, reasonable, and consistently treated as described in NIHGPS Section 7.2 The Cost Principles.

Under the NIH DMS Policy, NIH expects researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared. Shared scientific data must be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first.

Consistent with 2 CFR 200.403 and the NIHGPS Section 7.4, budget requests must not include infrastructure costs that are included in institutional overhead (e.g., Facilities and Administrative costs) or costs associated with the routine conduct of research. Costs associated with collecting or otherwise gaining access to research data (e.g., data access fees) are considered costs of doing research and should not be included in scientific data management and sharing budgets. Costs may not be double charged or inconsistently charged as both direct and indirect costs.

Applicants may request data management and sharing costs that are allowable and reasonable when associated with (1) Curating data and developing supporting documentation, including formatting data according to accepted community standards; de-identifying data; preparing metadata to foster discoverability, interpretation, and reuse; and formatting data for transmission to and storage at a selected repository for long-term preservation and access. (2) Local data management considerations, such as unique and specialized information infrastructure necessary to provide local management and preservation (e.g., before deposit into an established repository). (3) Preserving and sharing data through established repositories, such as data deposit fees necessary for making data available and accessible. For example, if a DMS Plan proposes preserving and sharing scientific data for 10 years in an established repository with a deposition fee, the cost for the entire 10-year period must be paid prior to the end of the period of performance. If the DMS Plan proposes deposition to multiple repositories, costs associated with each proposed repository may be included.

Generally, DMS Plans are not considered during peer review, unless the NOFO identifies data sharing as integral to the project. DMS Plans will undergo programmatic assessment by NIH staff following peer review. ICs may request additional information at Just-in-Time in order to meet expectations for data management and data sharing in support of programmatic priorities or to expand the utility of the scientific data generated from the research.

Once approved, the DMS Plan will become a Term and Condition of the NOA, and failure to comply may result in an enforcement action, including additional special terms and conditions or termination of the award, and may affect future funding decisions. In accordance with NIHGPS Section 8.1.1 NIH Standard Terms of Award, recipients must obtain prior approval to make changes to the previously approved DMS Plan (e.g. change in scientific direction, change in repository, or change in the timeline). All prior approval requests must be submitted in the eRA Prior Approval Module (see NIH Application Guide).

All allowable Data Management and Sharing costs in budget requests must be incurred (e.g., curation fees, data repository fees) during the performance period, even for scientific data and metadata preserved and shared beyond the award period.

Recipients are required to provide updates on the activities described in the DMS plan as part of the annual RPPR, and the IC will use this information to assess compliance with the previously approved DMS Plan.

For additional information and resources, [see the NIH Scientific Data Sharing website](#).

8.2.3.2 Genomic Data Sharing (GDS) Policy

The NIH Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports NIH's mission and facilitates the translation of research results into knowledge, products, and procedures that improve human health.

The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. For the purposes of the GDS Policy, the genome is the entire set of genetic instructions found in a cell and large-scale genomic data include GWAS, single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. [Supplemental Information to the GDS Policy](#) provides examples of genomic research projects that are subject to the Policy and the timeline for submission and sharing of data from such projects.

All applications, regardless of the amount requested, proposing research that will generate large-scale genomic data, are expected to describe plans for sharing genomic data in the DMS Plan submitted with the application, and not in a separate GDS Plan or at Just-in-Time, consistent with the changes described in 8.2.3.1 Policy for Data Management and Sharing. For guidance on development a DMS plan that meets the requirements of the DMS plan that meets the requirements of the GDS policy, see the [NIH Scientific Data Sharing](#) website.

Investigators who wish to use cloud computing for storage and analysis will need to indicate in their Data Access Request (DAR) that they are requesting permission to use cloud computing and identify the cloud service provider or providers that will be employed. They also will need to describe how the cloud computing service will be used to carry out their proposed research.

As with data stored in institutional systems, the institution's signing official, Program Director/Principal Investigator, IT Director, and any other personnel approved by NIH to access the data are responsible for ensuring the protection of the data. The institution, not the cloud service provider, assumes responsibility for any failure in the oversight of using cloud computing services for controlled-access data.

The [NIH Security Best Practices for Controlled Access Data Subject to the NIH Genomic Data Sharing \(GDS\) Policy](#) has been updated to include best practices for cloud computing. The Model Data Use Certification has also been updated and is available at http://gds.nih.gov/pdf/Model_DUC.pdf.

8.2.3.3 Sharing Model Organisms

All applications, regardless of amount requested, where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, or state appropriate reasons why such sharing is restricted or not possible.

Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, Arabidopsis, fruit fly, zebrafish, and frog. Research resources to be shared include, but are not limited to, genetically modified organisms, mutant organisms, sperm, embryos, vectors, non-human embryonic stem cells, established cell lines, protocols for genetic and phenotypic screens, mutagenesis protocols, genetic and phenotypic data for all mutant strains.

For additional information on this policy, see the NIH Scientific Data Sharing Model Organism Sharing Policy website.

8.2.4 Inventions and Patents

The Bayh-Dole Act of 1980 (Public Law 96-517; 35 U.S.C. 200-212; Executive Order 12591; 37 C.F.R. 401 et al; updated April 14, 2018.) provides NIH funding recipients incentives to promote the utilization of inventions conceived or reduced to practice (Subject Invention) in the performance of federally supported research and development. Unless waived by NIH or the funding agreement is for educational purposes, e.g. fellowships, training grants or certain types of career development awards, the Bayh-Dole Act applies to all NIH research and development funding granted to for-profit organizations regardless of size and all non-profit entities. (See 2 CFR Part 200 and 37 CFR Part 401.1(b)).

To retain rights and title to Subject Inventions, the NIH funding recipient must comply with the Bayh-Dole statute and implementing regulations that ensure the Invention will be brought to practical application while protecting certain rights of the Federal government. The compliance actions required by the Bayh-Dole Act are summarized below at Exhibit 8.

Failure of the recipient to comply with any of the Bayh-Dole regulations cited at 37 CFR Part 401 or other requirements may result in the loss of patent rights or the suspension, termination or withholding of NIH funding support. See also [Section 8.5.2](#) for additional remedies for noncompliance of the Bayh-Dole Act.

All Bayh-Dole compliance actions are required to be submitted to NIH by using the iEdison data base (See 37 CFR Part 401.16). All issues or questions regarding extramural technology transfer policy and reporting of inventions and their utilization should be referred to the Division of Extramural Inventions and Technology Resources, OPERA/OER at edison@nih.gov.

Exhibit 8. Extramural Invention Reporting Compliance Responsibilities

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. (All Compliance Actions are to be Submitted to NIH through iEdison)	37 CFR Part 401 Reference
Employee Agreement to Disclose All Subject Inventions	Recipient employees working under a federal funding award (other than clerical and nontechnical employees) must sign an agreement with the recipient organization. This agreement requires the Recipient employee to: (1) disclose promptly in writing to personnel identified as responsible for the administration of patent matters each Subject Invention made under NIH funding; (2) assign to the Recipient the entire right, title and interest in and to each Subject Invention made under the funding agreement; (3) execute all papers necessary to file patent applications on Subject Inventions; and, (4) establish the government's right in the Subject Inventions.	Before a Recipient or a consortium employee participates in NIH-funded research and development.	401.14(f)(2)
Consortium Participant Rights in Inventions	All consortium participants, regardless of tier, for experimental, developmental or research work retain all rights and obligations provided to the Consortium Participant in the NIH funding agreement.	At the time of issuance of a consortium agreement, recipient must include in all consortium agreements, regardless of tier, for experimental, development, or research work 37 CFR Part 401 <i>et seq</i> suitably modified to identify the parties and the rights and obligations awarded to the contractor.	401.14(g)(1) 401.14(g)(2) 401.14(g)(3)

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. (All Compliance Actions are to be Submitted to NIH through iEdison)	37 CFR Part 401 Reference
Invention Disclosure	The term "Subject Invention" means any invention of a recipient/consortium participant conceived or first actually reduced to practice in the performance of work under a funding agreement. The recipient must submit to NIH a disclosure for all Subject Inventions. There is no single format for disclosing the invention to NIH. However, the disclosure of the Subject Invention must include: a detailed technical description of the invention conveying a clear understanding of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention; the names of all inventors; title of the Subject Invention; all federal funding agreement numbers; date of disclosure of the Subject Invention from the researcher or inventor to the Recipient; and whether a manuscript describing the invention was submitted, accepted and/or published.	Within 2 months of the inventor's disclosure to the recipient organization.	401.14(a)(2) 401.14(c)(1)
Government Assignment to Recipient of Rights in Invention of Government Employee	Disclosure to NIH that a federal employee is a co-inventor on a Subject Invention.	Within 2 months of receipt of the initial invention report.	401.14(f)(2) 401.10

Invention Compliance Reporting Requirement	Action Required	When Compliance Action Must Be Taken. (All Compliance Actions are to be Submitted to NIH through iEdison)	37 CFR Part 401 Reference
Acceptance of Manuscript following Submission of Initial Invention Disclosure	The recipient needs to promptly notify NIH of the acceptance of any manuscript describing the Subject Invention.	Promptly following the acceptance of a manuscript describing a Subject Invention.	401.14(c)(1)
Election of Title to a Subject Invention	The recipient must notify NIH of its decision to retain title to a Subject Invention and any associated patent rights. Election of title is made before the filing of an Initial Patent Application. Statutory Period is defined as the one-year period before the effective filing date of a claimed invention during which exceptions to prior art exist per 35 U.S.C. 102 (b) as amended by the Leah-Smith American Inventions Act, Public Law 112-29.	Within 2 years of the disclosure of the invention to NIH. In any case where a patent, a printed publication, public use, sale or other availability to the public has initiated the one-year Statutory Period wherein valid patent protection can still be obtained in the United States, the period for election of title is shortened by NIH to a date that is no more than 60 days prior to the end of the statutory period.	401.14(b) 401.14(c)(2) 401.2(n)
Confirmatory License	For each Subject Invention, the recipient must provide a license to NIH confirming the rights the Government has throughout the world in the Subject Invention. When a confirmatory license is filed on the Initial Patent Application the license applies to all subsequent patent applications linked in the patent family.	When the Initial Patent Application is filed.	401.14(f)(1)