

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

AMERICAN ACADEMY OF HIV
MEDICINE, *et al.*,

Plaintiffs,

v.

HEALTH RESOURCES AND SERVICES
ADMINISTRATION, *et al.*,

Defendants.

Case No. 1:26-cv-12638-WGY

PLAINTIFFS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORD

Plaintiffs respectfully move this Court to order Defendants to complete the Administrative Record with documents that Defendants did not include within the filed Administrative Record (ECF No. 53), but which Defendants directly or indirectly considered in issuing the (1) FY 2026 HRSA General Terms and Conditions that apply to all discretionary funding awards issued by Defendant Health Resources and Services Administration after March 11, 2026, and (2) June 2026 Notices of Funding Opportunity pertaining to Part B Supplemental, Part C, Part D, and Part F of the Ryan White HIV/AIDS Program.

Plaintiffs' motion to complete the Administrative Record is supported by the accompanying memorandum of law and the declaration and exhibits attached thereto.

Dated: August 24, 2026

Jeffrey S. Trachtman*
Jason M. Moff*
Hannah Kanter*
Stephen P. Ferguson*
**Herbert Smith Freehills
Kramer (US) LLP**
1177 Avenue of the Americas
New York, NY 10036
Telephone: 212-715-9100
Facsimile: 212-715-8000
jeffrey.trachtman@hsfkramer.com
jason.moff@hsfkramer.com
hannah.kanter@hsfkramer.com
stephen.ferguson@hsfkramer.com

Ryan P. Trumbauer*
**Herbert Smith Freehills
Kramer (US) LLP**
2000 K Street NW, 4th Floor
Washington, DC 20006
Telephone: 202-775-4500
Facsimile: 202-775-4510
ryan.trumbauer@hsfkramer.com

* Admitted *pro hac vice*.

Respectfully submitted,

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan (BBO No. 678517)
Jose I. Abrigo*
Jessica Polansky*
Charlie Ferguson*
**Lambda Legal Defense
and Education Fund, Inc.**
120 Wall Street, 19th Floor
New York, New York 10005
Telephone: 212-809-8585
Facsimile: 855-535-2236
ogonzalez-pagan@lambdalegal.org
jabrigo@lambdalegal.org
jpolansky@lambdalegal.org
cferguson@lambdalegal.org

Kenneth D. Upton, Jr.*
**Lambda Legal Defense
and Education Fund, Inc.**
3656 North Halsted Street
Chicago, Illinois 60613
Telephone: 312-663-4413
Facsimile: 855-535-2236
kupton@lambdalegal.org

Pelecanos*
**Lambda Legal Defense
and Education Fund, Inc.**
800 South Figueroa St., Suite 1260[†]
Los Angeles, California 90017
Telephone: 213-382-7600
Facsimile: 855-535-2236
pelecanos@lambdalegal.org

[†] Mailing address only

Counsel for Plaintiffs

Rule 7.1 Certificate of Compliance

I certify that, on August 23 and 24, 2026, counsel for Plaintiffs provided notice of this motion, seeking to ascertain Defendants' position as to the relief requested herein, to counsel for Defendants. As of the time of filing, Defendants had yet to provide their position on the relief requested herein.

/s/ Omar Gonzalez-Pagan

Omar Gonzalez-Pagan (BBO No. 678517)

**Lambda Legal Defense
and Education Fund, Inc.**

120 Wall Street, 19th Floor
New York, New York 10005

Telephone: 212-809-8585

Facsimile: 855-535-2236

ogonzalez-pagan@lambdalegal.org

CERTIFICATE OF SERVICE

I certify that, on August 24, 2026, electronically with the Clerk of the Court using the CM/ECF system, which will send notice of such filing to the registered participants as identified in the Notice of Electronic Filing (NEF), including the following counsel:

Rayford Farquhar
Chief, Defensive Litigation, Civil Division
U.S. Attorney's Office for the District of Massachusetts
John Joseph Moakley Federal Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
rayford.farquhar@usdoj.gov

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan (BBO No. 678517)
**Lambda Legal Defense
and Education Fund, Inc.**
120 Wall Street, 19th Floor
New York, New York 10005
Telephone: 212-809-8585
Facsimile: 855-535-2236
ogonzalez-pagan@lambdalegal.org

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**MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORD**

TABLE OF CONTENTS

TABLE OF CONTENTS	ii
TABLE OF AUTHORITIES	iii
INTRODUCTION	1
BACKGROUND	2
LEGAL STANDARD	3
ARGUMENT	4
CONCLUSION.....	13
RULE 7.1 CERTIFICATE OF COMPLIANCE	15
CERTIFICATE OF SERVICE	16

TABLE OF AUTHORITIES

CASES	Page(s)
<i>Atieh v. Riordian</i> , 727 F.3d 73 (1st Cir. 2013)	3
<i>Bar MK Ranches v. Yuetter</i> , 944 F.2d 735 (10th Cir. 1993)	3
<i>Citizens to Pres. Overton Park, Inc. v. Volpe</i> , 401 U.S. 402 (1971)	3
<i>Ctr. for Food Safety v. Vilsack</i> , No. 15-cv-01590-HSG-KAW, 2017 WL 1709318 (N.D. Cal. May 3, 2017)	12
<i>Dep't of Com. v. New York</i> , 588 U.S. 752 (2019)	3, 11
<i>Inst. for Fisheries Res. v. Burwell</i> , No. 16-cv-01574-VC, 2017 WL 89003 (N.D. Cal. Jan. 10, 2017)	11
<i>Marcum v. Salazar</i> , 751 F. Supp. 2d 74 (D.D.C. 2010)	4
<i>Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.</i> , 463 U.S. 29 (1983)	13
<i>New York v. McMahon</i> , 826 F. Supp. 3d 184 (D. Mass. 2026)	3, 4, 11, 13
<i>New York v. United States Dep't of Com.</i> , 351 F. Supp. 3d 502 (S.D.N.Y. 2019), <i>aff'd in part, rev'd in part on other grounds, and</i> <i>remanded sub nom. Dep't of Com. v. New York</i> , 588 U.S. 752 (2019)	11
<i>Roe v. Mayorkas</i> , No. 22 Civ. 10808, 2024 WL 5198705 (D. Mass. Oct. 2, 2024)	3, 4, 11
<i>S.C. Coastal Conserv. League v. U.S. Army Corps of Eng'rs</i> , 611 F. Supp. 3d 136 (D.S.C. 2020)	4
<i>Sierra Club v. U.S. Army Corps of Eng'rs</i> , No. 20-cv-00396, 2023 WL 4350730 (D. Me. July 5, 2023)	3, 13
<i>U.S. Lines, Inc. v. Fed. Mar. Comm'n</i> , 584 F.2d 519 (D.C. Cir. 1978)	11
<i>United Farm Workers v. Adm'r, U.S. E.P.A.</i> , No. C 07-3950, 2008 WL 3929140 (N.D. Cal. Aug. 26, 2008)	12

STATUTES

5 U.S.C. § 705.....	2
5 U.S.C. § 706.....	1, 3
5 U.S.C. § 706(2)(A).....	1
5 U.S.C. § 706(2)(B)–(C)	1
20 U.S.C. §§ 1681 et seq.....	9

EXECUTIVE ORDERS

Exec. Order No. 14151, <i>Ending Radical and Wasteful Government DEI Programs and Preferencing</i> , 90 Fed. Reg. 8339 (Jan. 20, 2025)	6
Exec. Order No. 14154, <i>Unleashing American Energy</i> , 90 Fed. Reg. 8353 (Jan. 20, 2025).....	6
Exec. Order No. 14159, <i>Protecting the American People Against Invasion</i> , 90 Fed. Reg. 8843 (Jan. 20, 2025)	6
Exec. Order No. 14162, <i>Putting America First in International Environmental Agreements</i> , 90 Fed. Reg. 8455 (Jan. 20, 2025)	6
Exec. Order No. 14168, <i>Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government</i> , 90 Fed. Reg. 8615 (Jan. 20, 2025)	6, 8, 9
Exec. Order No. 14169, <i>Reevaluating and Realigning United States Foreign Aid</i> , 90 Fed. Reg. 8619 (Jan. 20, 2025)	6
Exec. Order No. 14182, <i>Enforcing the Hyde Amendment</i> , 90 Fed. Reg. 8751 (Jan. 24, 2025).....	6
Exec. Order. No. 14332, <i>Improving Oversight of Government Grantmaking</i> , 90 Fed. Reg. 38929 (Aug. 7, 2025).....	6

OTHER AUTHORITIES

Admin. Conference of the United States, <i>Handbook on Compiling Administrative Records for Informal Rulemaking</i> (2022), https://www.acus.gov/sites/default/files/documents/ACUS_Handbook_on_Compiling_Administrative_Records.pdf	12
ASFR Memorandum, <i>Clarification on Departmental Review of Grants and Contracts</i> (February 20, 2026)	7
Health & Human Resources Administration, <i>Advancing HRSA’s Mission Through Focused, Accountable Action</i> , https://www.hrsa.gov/about/priorities [https://perma.cc/5TS2-8LE2]	6

Health Resources & Services Administration, <i>Part B: Grants to States and Territories</i> , HRSA Ryan White HIV/AIDS Program, https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-grants-states-territories	10
Health Resources & Services Administration, <i>Part C: Early Intervention Services (EIS) and Capacity Development Grants</i> , https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-c-early-intervention	10
Health Resources & Services Administration, <i>Part F: Special Projects of National Significance (SPNS) Program</i> , HRSA Ryan White HIV/AIDS Program, https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-f-spns	11
Health Resources & Services Administration, <i>Who We Are</i> , HRSA Ryan White HIV/AIDS Program, https://ryanwhite.hrsa.gov/	10
HHS (@HHSGov), X.com (Feb. 20, 2025), https://x.com/HHSGov/status/1892731580218474861	10
Letter from Thomas J. Engels, Adm’r, Health Res. & Servs. Admin., to Ryan White HIV/AIDS Program Awardees and Stakeholders (Apr. 7, 2026), https://tinyurl.com/4neauwpd [https://perma.cc/K3TZ-HWEF].....	10
Office of the Secretary, <i>Defining Sex: Guidance for Fed. Agencies, External Partners, and the Public Implementing EO 14168, “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Fed. Gov’t,”</i> U.S. Dept. of Health and Human Servs. (Feb. 19, 2025)	9
U.S. Dep’t of Health & Humans Servs., <i>HHS Grants Policy Statement</i> , https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-oct-2025.pdf	9
U.S. Dep’t of Health and Human Services, <i>Protecting the Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex (LGTBQ+) People</i> , https://www.hhs.gov/ocr/lgbtqi/index.html	11
U.S. Dep’t of Justice, <i>Guidance to Federal Agencies on Compiling the Administrative Record</i> (Jan. 1999), https://www.spd.usace.army.mil/Portals/13/docs/regulatory/qmsref/eis/DOJ%20Guidance.pdf	12

INTRODUCTION

This case arises from Defendants’ decision to impose new conditions on Ryan White HIV/AIDS Program funding. Those conditions seek to prohibit grant recipients—including the individual Provider Plaintiffs and members of Associational Plaintiffs—from acknowledging the identities of their transgender patients and from using Ryan White funds to provide gender-affirming medical care to transgender patients living with HIV (“the Challenged Conditions”). *See* Compl. ¶¶ 164–87, Dkt. 1.

Plaintiffs allege, among other things, that the Challenged Conditions (i) are arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A); (ii) are not in accordance with law, in violation of 5 U.S.C. § 706(2)(A); (iii) exceed Defendants’ statutory authority, in violation of 5 U.S.C. § 706(2)(C); and (iv) are contrary to constitutional rights, in violation of 5 U.S.C. § 706(2)(B). *See* Compl. Counts I-IV, ¶¶ 203–246. To resolve those claims arising under the Administrative Procedure Act (“APA”), this Court must review the “whole record” to determine what drove Defendants’ decision. 5 U.S.C. § 706.

The current Administrative Record is incomplete and, as produced, frustrates meaningful judicial review under the APA. It fails to include not only the Challenged Conditions themselves, but also several documents referenced in the Administrative Record that undoubtedly played a role in Defendants’ decision-making process and some of the Administration’s pronouncements that led directly to the promulgation of the Challenged Conditions. Similarly, the Administrative Record fails to include several public statements of agency and Administration policy made by Defendants that likewise shed light on their decision to impose the Challenged Conditions. Accordingly, Plaintiffs respectfully request that this Court order Defendants to add the missing documents to complete the Administrative Record.

BACKGROUND

On July 20, 2026, this Court collapsed Plaintiffs’ motion for relief under 5 U.S.C. § 705 and a preliminary injunction with trial on the merits. Dkt. 49 at 2 (citing Fed. R. Civ. P. 65(a)). The Court directed the parties to set a filing date for the Administrative Record. *See id.*

On July 30, 2026, the parties filed a Joint Stipulation and Proposed Pre-Trial Schedule. The parties stipulated to bifurcate the APA claims from the non-APA claims, set forth pre-trial dates with regards to the APA claims, and reserve any scheduling with regards to the non-APA claims until after the APA claims were decided. *See* Dkt. 51 at. In addition, Defendants agreed to file the Administrative Record on or before August 14, 2026. *See id.* ¶ 1. And Plaintiffs agreed to file any motion to supplement, modify, or complete the Administrative Record on or before August 24, 2026. *Id.* ¶ 2.

On August 14, 2026, Defendants produced the Administrative Record. *See* Dkt. 53 (HRSA 00001 – HRSA 0083). Defendants certified that the Administrative Record “constitute[s] the non-privileged documents that were considered, either directly or indirectly, in connection with the government actions challenged” in this case. *Id.* at 4.

After reviewing the Administrative Record, Plaintiffs identified a number of materials that should have been included in the Administrative Record. *See* Trumbauer Decl. ¶ 4. These materials fall into three categories. The first category consists of the Challenged Conditions themselves. The second category consists of documents that are referenced, but not included, in the Administrative Record—even though Defendants indisputably had those materials before them and evidently considered them in determining whether to adopt the Challenged Conditions. *See infra* at 5–8. The third category consists of several public statements of agency and Administration policy made by Defendants that shed light on their decision to impose the Challenged Conditions. *See infra* at 8–

10.

Plaintiffs identified the requested documents to Defendants, but as of the time of this filing, Defendants had not provided their positions as to the request to add the requested documents to the Administrative Record. *See* Trumbauer Decl. ¶ 29.

Accordingly, Plaintiffs file this Motion to Complete the Administrative Record.

LEGAL STANDARD

Section 706 of the APA states that courts “shall review the whole record” of agency decision-making. 5 U.S.C. § 706. Judicial review of agency action must therefore be “based on the full administrative record that was before the [agency] at the time [it] made [its] decision.” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971); *see Atieh v. Riordian*, 727 F.3d 73, 76 (1st Cir. 2013) (“The focal point of APA review is the existing administrative record.”). Without the full administrative record, “meaningful judicial review” is impossible. *Dep’t of Com. v. New York*, 588 U.S. 752, 780 (2019) (citation omitted).

An agency may “not unilaterally determine what constitutes’ the administrative record.” *Roe v. Mayorkas*, No. 22 Civ. 10808, 2024 WL 5198705, at *8 (D. Mass. Oct. 2, 2024) (quoting *Bar MK Ranches v. Yuetter*, 944 F.2d 735, 739 (10th Cir. 1993)). Instead, the administrative record “must contain all documents and materials directly or indirectly considered by the agency decision-makers and includes evidence contrary to the agency’s position.” *New York v. McMahon*, 826 F. Supp. 3d 184, 194 (D. Mass. 2026) (internal quotation marks omitted). It also “should include all materials that *might* have influenced the agency’s decision, and *not merely those on which the agency relied in its final decision.*” *Sierra Club v. U.S. Army Corps of Eng’rs*, No. 20-cv-00396, 2023 WL 4350730, at *1 (D. Me. July 5, 2023) (emphasis added).

When an agency does not “include materials that were part of its record, whether by design or accident,” *Marcum v. Salazar*, 751 F. Supp. 2d 74, 78 (D.D.C. 2010), the court may order the agency to correct those deficiencies so that the record “actually reflect[s] the materials that the agency had before it when it made its decision,” *Roe*, 2024 WL 5198705, at *7 n.10. To prevail on a motion to complete, the moving party must present “clear evidence” that the record is incomplete. *Roe*, 2024 WL 5198705, at *2 (quoting *S.C. Coastal Conserv. League v. U.S. Army Corps of Eng’rs*, 611 F. Supp. 3d 136, 142 (D.S.C. 2020)). That is, the moving party must (1) present “reasonable, non-speculative grounds to believe that the materials considered in the decision making process are not included in the record” and (2) “identify the pertinent omitted materials with sufficient specificity[.]” *McMahon*, 826 F. Supp. at 195 (quoting *Roe*, 2024 WL 5198705, at *7). “[N]o showing of bad faith is required.” *Roe*, 2024 WL 5198705, at *2.

ARGUMENT

The Administrative Record in this case should contain *all* materials that were directly or indirectly considered as part of the process of determining whether to include the Challenged Conditions in the FY 2026 HRSA General Terms and Conditions, including its incorporation of HRSA’s priorities and other guidance referenced therein, and the Part B Supplemental, Part C, Part D, and Part F Notices of Funding Opportunity (“NOFOs”). It does not. And Defendants have not agreed to voluntarily complete the record at this point. The Court should thus order completion.

The current Administrative Record is just 83 pages. It consists of (1) an e-mail announcing the issuance of HRSA’s priorities, HRSA 0001–HRSA 0002; (2) a memo describing what content NOFOs must have and how they are approved for issuance, HRSA 0003–HRSA 0025; (3) a document titled “FY 2026 Summary of Changes / Revisions of HRSA General Terms and Conditions,” HRSA 0026; (4) various internal e-mails discussing the Challenged Conditions,

HRSA 0027–HRSA 0033, HRSA 0073–HRSA 0083; and (5) a copy of the approved ADAP NOFO application that contains the Challenged Conditions, HRSA 0034–HRSA 0072.

The current Administrative Record is facially deficient in at least three respects. First, the Administrative Record fails to include the challenged FY 2026 HRSA General Terms and Conditions and NOFOs—the very agency actions that are the subject of this case. *See* Compl. ¶¶ 164–187 (outlining the Challenged Conditions as the FY 2026 HRSA General Terms and Conditions, the Part B Supplemental, Part C, and Part F NOFOs, the forecasted Part D NOFO, and other actions other actions implementing the Executive Order No. 14168 (the “Gender Order”) with regard to the Ryan White Program); *see also* Trumbauer Decl. ¶¶ 5–9.

Second, several documents included in the Administrative Record expressly reference *other* documents that Defendants considered while deciding whether to issue the Challenged Conditions but that were not themselves included in the Record:

1. An e-mail dated September 15, 2025, states that Defendant HRSA “remains firmly committed to protecting and improving the health and well-being of Americans, particularly those who are underserved, medically vulnerable, or live in areas where access to care is limited.” HRSA 0001. The e-mail also states that Defendant HRSA is “committed to supporting programs and initiatives that will focus on the underlying cause of disease, including lifestyle modifications and other modalities that are shown to be effective in improving health outcomes.” *Id.* The e-mail then refers readers to a website link called “Advancing HRSA’s Mission Through Focused, Accountable Action.” HRSA 0002. That website outlines Defendant HRSA’s policy priorities—including its priority to ensure that funding provided under the Ryan White Program is not used “for purposes unrelated to the statute, including for medications that are used

without proper authorization or outside of approved medical guidelines.”¹ The current Administrative Record does not include the website “Advancing HRSA’s Mission Through Focused, Account Action.” *See* Trumbauer Decl. ¶ 10; *see also* Dkt. 19-3.

2. A memorandum dated April 3, 2026, states that “all NOFOs”—including the ones at issue in this case—“must comply with Executive Orders signed by the President.” HRSA 0003. It then lists eight Executive Orders issued by this Administration. HRSA 0003–HRSA 0004.² Yet the Administrative Record does not include any of the Executive Orders. *See* Trumbauer Decl. ¶¶ 11–18; *see also* Dkt. 19-5 (Exec. Order No. 14168); **Exhibits A–G** to Trumbauer Decl.
3. Attachment 1 of the April 3, 2026, memorandum states that “[i]f [a] NOFO has been issued in previous years, [the agency] must include in [a] submission email to ASFR/OB a summary of what changes have been made from the prior year’s version to align with the Administration’s priorities.” HRSA 0006. It continues: “If changes were required, briefly describe any edits made to align with the Administration priorities (*Ex., ‘Removed activities related to DEI and gender in alignment with Administration Priorities’*).” *Id.* Yet the Administrative Record does not include the

¹ *See* Health & Human Resources Administration, *Advancing HRSA’s Mission Through Focused, Accountable Action*, <https://www.hrsa.gov/about/priorities> [<https://perma.cc/5TS2-8LE2>]. A copy of the HRSA priorities was previously filed as Exhibit C to the Abrigo Declaration in relation to Plaintiffs’ motion for preliminary relief. *See* Dkt. 19-3.

² These are: (1) Exec. Order No. 14159, *Protecting the American People Against Invasion*, 90 Fed. Reg. 8843 (Jan. 20, 2025); Exec. Order No. 14169, *Reevaluating and Realigning United States Foreign Aid*, 90 Fed. Reg. 8619 (Jan. 20, 2025); Exec. Order No. 14162, *Putting America First in International Environmental Agreements*, 90 Fed. Reg. 8455 (Jan. 20, 2025); Exec. Order No. 14154, *Unleashing American Energy*, 90 Fed. Reg. 8353 (Jan. 20, 2025); Exec. Order No. 14151, *Ending Radical and Wasteful Government DEI Programs and Preferencing*, 90 Fed. Reg. 8339 (Jan. 20, 2025); Exec. Order No. 14168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8615 (Jan. 20, 2025); Exec. Order No. 14182, *Enforcing the Hyde Amendment*, 90 Fed. Reg. 8751 (Jan. 24, 2025); and Exec. Order No. 14332, *Improving Oversight of Government Grantmaking*, 90 Fed. Reg. 38929 (Aug. 7, 2025). A copy of Executive Order No. 14168 was previously filed as Exhibit E to the Abrigo Declaration in relation to Plaintiffs’ motion for preliminary relief. *See* Dkt. 19-5.

- required summary of changes detailing how any of the current NOFOs—namely, the Part B Supplemental, Part C, Part D, and Part F NOFOs—differ from prior versions.
4. Attachment 3 of the April 3, 2026, memorandum states that Defendant “HHS has established a review process for NOFOs and [Notices of Awards (NOAs)] to help ensure alignment with Agency priorities. For more information about how these reviews work for new and continuing grants”—such as the NOFOs at issue here—“please refer to the ASFR Memorandum, *Clarification on Departmental Review of Grants and Contracts* (February 20, 2026).” HRSA 0013. In addition, Attachment 3 states that agencies “**must include** language that discloses how the agency will review applications, along with any review criteria” and that “senior appointees” will use those “scoring rubrics” when “assess[ing] grant proposals.” *Id.* (emphasis in original). Yet the Administrative Record does not contain the ASFR Memorandum, the referenced new review process for NOFOs and NOAs, or the review criteria for grant applications.
 5. A February 24, 2026, e-mail references an “attached Summary of Key Updates.” HRSA 0028–HRSA 0029. The “Summary of Key Updates” purportedly details “changes” that “apply to all HRSA NOFO Template(s)”—including the template used to create the NOFOs at issue in this case. HRSA 0028. Yet the Administrative Record does not contain the “Summary of Key Updates.”
 6. Several e-mails by Defendants discuss modifications to the “HRSA Standard NOFO template.” HRSA 0028, HRSA 0029, HRSA 0079. Yet the Administrative Record fails to include the “HRSA Standard NOFO template” or any modifications made to it.
 7. An April 27, 2026, e-mail states that multiple “versions of the NOFOs” are “saved on [a] SharePoint.” HRSA 0076. Similarly, a June 25, 2026, e-mail states that HRSA

received feedback on its “FY X09 NOFO.” HRSA 0031. That e-mail also states that Susan Robilotto—Director of the Division of State HIV/AIDS Programs at the HIV/AIDS Bureau—“added [the Challenged Conditions] in question on 9/25/25 with the comment ‘Added per HHS. OGC has approved.’” *Id.*; see HRSA 0082 (referencing a “revised version” of the NOFO). Yet the Administrative Record fails to include any version of FY X09 NOFO, any feedback or commentary related to those versions, and any communications between Defendant HHS and Susan Robilotto.

8. A May 4, 2026, e-mail from an employee at HHS states that the Office of Management & Budget (“OMB”) left comments on “seven additional HRSA NOFOs.” HRSA 0082. The HHS employee asked HRSA to “include a comment in the revised version” of the NOFOs “indicating where OMB can find the link to the gender dysphoria report.” *Id.* Similarly, a May 7, 2026, e-mail from an employee at HHS states that the OMB “will not hold up NOFO clearance” for the NOFOs at issue based on a comment about “the gender dysphoria report.” HRSA 0079. Both statements suggest that Defendants HHS and HRSA considered a version of the challenged NOFOs that referenced, considered, and contained a link to a “gender dysphoria report.” Yet the Administrative Record does not contain those versions of the challenged NOFOs.

Third, the Administrative Record fails to include several policy statements and other public statements made by Defendants demeaning transgender people, “gender ideology,” and gender-affirming medical care that led to their decision to impose the Challenged Conditions:

9. The Administrative Record does not include Defendant HHS’s “Guidance for Federal Agencies, External Partners, and the Public Implementing Executive Order 14168, *Defending Women from Gender Ideology and Restoring Biological Truth to the Federal*

Government.”³ The Guidance explains to “external partners”—like Plaintiffs—that “[t]here are only two sexes, female and male[.]” It also states that “[a] person’s sex is unchangeable and determined by objective biology” and that “[t]he use of hormones or surgical interventions do not change a person’s sex because such actions do not change the type of gamete that the person’s reproductive system has the biological function to produce.” The Guidance is expressly referenced within HRSA’s priorities (*see* Dkt. 19-3), which in turn is expressly incorporated into Challenged Conditions through the FY 2026 HRSA General Terms and Conditions (*see* Dkt. 1-1 at 5).

10. The Administrative Record does not include the HHS Grants Policy Statement (effective October 1, 2025). *See* Compl. ¶¶ 161, 172.⁴ The HHS Grants Policy Statement requires all federal funding recipients—including Ryan White funding recipients—“to certify that they are ‘compliant with Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*,’ and that they will remain so.” *Id.* ¶ 172. The Grants Policy Statement is expressly incorporated into Challenged Conditions through the FY 2026 HRSA General Terms and Conditions (*see* Dkt. 1-1 at 1).

³ Office of the Secretary, *Defining Sex: Guidance for Fed. Agencies, External Partners, and the Public Implementing EO 14168, “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Fed. Gov’t,”* U.S. Dept. of Health and Human Servs. (Feb. 19, 2025) (attached as **Exhibit H** to Trumbauer Decl.).

⁴ *See* U.S. Dep’t of Health & Humans Servs., *HHS Grants Policy Statement*, <https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-oct-2025.pdf> (attached as **Exhibit I** to Trumbauer Decl.).

11. The Administrative Record does not include Defendant Thomas J. Engels's Dear Colleague Letter dated April 7, 2025.⁵ In that letter, Defendant Engels communicates to Ryan White Program awardees and stakeholders—like Plaintiffs—that Defendant HRSA's previous December 2021 Program Letter allowing the use of Ryan White funds to support gender-affirming medical care “co-opted the program's patient-centered mission in favor of radical ideological agendas and policies” and constituted “a vehicle for broader social or medical experimentation.”
12. The Administrative Record does not include Defendant HHS's *own* public statements of agency policy that “[t]he Trump Administration is bringing back common sense and restoring biological truth to the federal government” and that “[t]he prior administration's policy of trying to engineer gender ideology into every aspect of public life is over.”⁶
13. The Administrative Record does not include Defendant HHS's *own* statements of agency policy (included on its public website describing the Ryan White Program) that the promotion of “gender ideology is extremely inaccurate and disconnected from the immutable biological reality that there are two sexes, male and female” and that “gender ideology” harms women “by depriving them of their dignity, safety, well-being, and opportunities.”⁷

⁵ See Letter from Thomas J. Engels, Adm'r, Health Res. & Servs. Admin., to Ryan White HIV/AIDS Program Awardees and Stakeholders (Apr. 7, 2026), <https://tinyurl.com/4neauwpd> [<https://perma.cc/K3TZ-HWEF>] (attached as **Exhibit J** to Trumbauer Decl.).

⁶ HHS (@HHSGov), X.com (Feb. 20, 2025), <https://x.com/HHSGov/status/1892731580218474861> (attached as **Exhibit K** to Trumbauer Decl.).

⁷ See **Exhibits L–P** to Trumbauer Decl. See also Health Resources & Services Administration, *Who We Are*, HRSA Ryan White HIV/AIDS Program, <https://ryanwhite.hrsa.gov/>; Health Resources & Services Administration, *Part B: Grants to States and Territories*, HRSA Ryan White HIV/AIDS Program, <https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-grants-states-territories>; Health Resources & Services Administration, *Part C: Early Intervention Services (EIS) and Capacity Development Grants*, <https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-c-early>

* * *

The aforementioned “specific gaps in the record”—individually and collectively—impede meaningful judicial review under the APA. The Court should thus order that the Administrative Record be completed by requiring inclusion of the aforementioned documents.

First, there can be no question that “the failure to include information relied upon by the agency in the administrative record is inconsistent with the Administrative Procedure Act’s requirement that review take place on the whole record.” *New York v. United States Dep’t of Com.*, 351 F. Supp. 3d 502, 632 (S.D.N.Y. 2019), *aff’d in part, rev’d in part on other grounds, and remanded sub nom. Dep’t of Com. v. New York*, 588 U.S. 752 (2019) (citation modified, citing *U.S. Lines, Inc. v. Fed. Mar. Comm’n*, 584 F.2d 519, 534 n.43 (D.C. Cir. 1978)). As such, the documents and guidance that are expressly referenced within the Administrative Record or the Challenged Conditions themselves should be included in the Administrative Record. *See Roe*, 2024 WL 5198705, at *8 (ordering agency to produce full copies of several documents that were referenced in e-mails produced in the record but not actually included in the record itself); *see McMahon*, 826 F. Supp. 3d at 196 (ordering agency to produce a “final list of terminated positions and offices” under a challenged Reduction in Force because the request was “sufficiently specific and non-speculative”). This applies to document categories 1–10 outlined above.

Defendants might assert that some categories of documents (namely, categories 7 and 8) may be protected by the deliberative process privilege. That assertion is meritless. “[T]he scope of the privilege doesn’t define the scope of the material directly or indirectly considered.” *Inst. for Fisheries Res. v. Burwell*, No. 16-cv-01574-VC, 2017 WL 89003, at *1 (N.D. Cal. Jan. 10, 2017).

intervention; Health Resources & Services Administration, *Part F: Special Projects of National Significance (SPNS) Program*, HRSA Ryan White HIV/AIDS Program, <https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-f-spns>; U.S. Dep’t of Health and Human Services, *Protecting the Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex (LGBTBQ+) People*, <https://www.hhs.gov/ocr/lgbtqi/index.html>.

On the contrary, such “internal agency communications and drafts are part of the administrative record.” *Ctr. for Food Safety v. Vilsack*, No. 15-cv-01590-HSG-KAW, 2017 WL 1709318, at *4 (N.D. Cal. May 3, 2017); *see also United Farm Workers v. Adm’r, U.S. E.P.A.*, No. C 07-3950, 2008 WL 3929140, at *2 (N.D. Cal. Aug. 26, 2008) (explaining that the “‘whole record’ before the [agency] at the time of its decisions . . . includes internal correspondence, memoranda and drafts that were part of the [agency]’s decision making process” (emphasis added)). Indeed, both the U.S. Department of Justice and the Administrative Conference of the United States have explained that an administrative record should typically “include materials that document the agency’s decisionmaking process, such as important drafts and documentation of substantive meetings, regardless of whether they contain protected, privileged, or other sensitive information.” Admin. Conference of the United States, *Handbook on Compiling Administrative Records for Informal Rulemaking* at 17 (2022);⁸ *see also* U.S. Dep’t of Justice, *Guidance to Federal Agencies on Compiling the Administrative Record* (Jan. 1999) (“Generally, include all draft documents that were circulated for comment either outside the agency or outside the author’s immediate office, if changes in these documents reflect significant input into the decision-making process.”).⁹

Second, there can be little doubt that general statements of agency policy pertaining to transgender people and gender-affirming medical care influenced and likely directly led to the promulgation and adoption of the Challenged Conditions. The statements by HRSA and HHS contained within document categories 11–13 noted above, some which pertain specifically to the Ryan White Program, are documents that, at minimum, delineated Defendants’ decision-making as it pertains to transgender people (whose recognition of their very existence Defendants call

⁸ https://www.acus.gov/sites/default/files/documents/ACUS_Handbook_on_Compiling_Administrative_Records.pdf

⁹ <https://www.spd.usace.army.mil/Portals/13/docs/regulatory/qmsref/eis/DOJ%20Guidance.pdf>

“gender ideology”) and even relate to the Ryan White Program at issue here (category 11). And as previously noted, the administrative record “should include all materials that might have influenced the agency’s decision, and not merely those on which the agency relied in its final decision.” *Sierra Club*, 2023 WL 4350730, at *1. Put simply, these are documents that “do exist, are missing from the record, and should have been included,” *McMahon*, 826 F. Supp. 3d at 196, because, at a minimum, they were “directly or indirectly considered by the agency decision-makers,” *id.* at 194 (quotation omitted).

All told, without the documents outlined within this motion, the Court cannot effectively determine whether Defendants “relied on factors which Congress has not intended it to consider,” made a decision that “runs counter to the evidence before” it, or failed to offer a “rational connection between the facts found the choice made.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 42–43 (1983). Accordingly, this Court should direct Defendants to complete the Administrative Record with the aforementioned materials.

CONCLUSION

The Court should grant Plaintiffs’ Motion to Complete the Administrative Record.

Dated: August 24, 2026

Respectfully submitted,

/s/ Omar Gonzalez-Pagan

Omar Gonzalez-Pagan (BBO No. 678517)

Jose I. Abrigo*

Jessica Polansky*

Charlie Ferguson*

**Lambda Legal Defense
and Education Fund, Inc.**

120 Wall Street, 19th Floor

New York, New York 10005

Telephone: 212-809-8585

Facsimile: 855-535-2236

ogonzalez-pagan@lambdalegal.org

jabrigo@lambdalegal.org

Jeffrey S. Trachtman*

Jason M. Moff*

Hannah Kanter*

Stephen P. Ferguson*

Herbert Smith Freehills

Kramer (US) LLP

1177 Avenue of the Americas

New York, NY 10036

Telephone: 212-715-9100

Facsimile: 212-715-8000

jeffrey.trachtman@hsfkramer.com

jason.moff@hsfkramer.com

hannah.kanter@hsfkramer.com
stephen.ferguson@hsfkramer.com

Ryan P. Trumbauer*
**Herbert Smith Freehills
Kramer (US) LLP**
2000 K Street NW, 4th Floor
Washington, DC 20006
Telephone: 202-775-4500
Facsimile: 202-775-4510
ryan.trumbauer@hsfkramer.com

* Admitted *pro hac vice*.

jpolansky@lambdalegal.org
cferguson@lambdalegal.org

Kenneth D. Upton, Jr.*
**Lambda Legal Defense
and Education Fund, Inc.**
3656 North Halsted Street
Chicago, Illinois 60613
Telephone: 312-663-4413
Facsimile: 855-535-2236
kupton@lambdalegal.org

Pelecanos*
**Lambda Legal Defense
and Education Fund, Inc.**
800 South Figueroa St., Suite 1260[†]
Los Angeles, California 90017
Telephone: 213-382-7600
Facsimile: 855-535-2236
pelecanos@lambdalegal.org
[†]Mailing address only

Counsel for Plaintiffs

RULE 7.1 CERTIFICATE OF COMPLIANCE

I certify that, on August 23 and 24, 2026, counsel for Plaintiffs provided notice of this motion, seeking to ascertain Defendants' position as to the relief requested herein, to counsel for Defendants. As of the time of filing, Defendants had yet to provide their position on the relief requested herein.

/s/ Omar Gonzalez-Pagan

Omar Gonzalez-Pagan (BBO No. 678517)

**Lambda Legal Defense
and Education Fund, Inc.**

120 Wall Street, 19th Floor

New York, New York 10005

Telephone: 212-809-8585

Facsimile: 855-535-2236

ogonzalez-pagan@lambdalegal.org

CERTIFICATE OF SERVICE

I certify that, on August 24, 2026, electronically with the Clerk of the Court using the CM/ECF system, which will send notice of such filing to the registered participants as identified in the Notice of Electronic Filing (NEF), including the following counsel:

Rayford Farquhar
Chief, Defensive Litigation, Civil Division
U.S. Attorney's Office for the District of Massachusetts
John Joseph Moakley Federal Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
rayford.farquhar@usdoj.gov

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan (BBO No. 678517)
**Lambda Legal Defense
and Education Fund, Inc.**
120 Wall Street, 19th Floor
New York, New York 10005
Telephone: 212-809-8585
Facsimile: 855-535-2236
ogonzalez-pagan@lambdalegal.org

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

AMERICAN ACADEMY OF HIV
MEDICINE, et al.,

Plaintiffs,

v.

HEALTH RESOURCES AND SERVICES
ADMINISTRATION, et al.,

Defendants.

Case No. 1:26-cv-12638-WGY

DECLARATION OF RYAN P. TRUMBAUER

I, Ryan P. Trumbauer, hereby state and declare as follows:

1. I am an Attorney at Herbert Smith Freehills Kramer (US) LLP and counsel for Plaintiffs in the above-referenced litigation. I am admitted to practice in the State of New York and the District of Columbia and am admitted *pro hac vice* in this matter.

2. I have personal knowledge of the matters stated herein and am competent to testify thereto.

3. I submit this Declaration in support of Plaintiffs' Motion to Complete the Administrative Record.

4. On August 14, 2026, Defendants filed the Administrative Record in this action at Dkt. 53. I reviewed the Administrative Record and, together with other counsel for Plaintiffs, identified materials that Plaintiffs contend should be included in the Administrative Record.

5. Filed as **Dkt. Nos. 1-1** and **19-2** is a true and correct copy of the "FY 2026 HRSA General Terms and Conditions," issued by the Health Resources and Services Administration "HRSA") on March 11, 2026 (hereafter "Updated FY2026 General Terms"), and available at

<https://www.hrsa.gov/sites/default/files/hrsa/grants/manage/fy2026-hrsa-general-terms-andconditions-2026-03-11-update.pdf> [<https://perma.cc/GK9K-2FZ4>].

6. Filed as **Dkt. Nos. 1-2** and **19-9** is a true and correct copy of the Notice of Funding Opportunity, Ryan White HIV/AIDS Program Part B States/Territories Supplemental Grant Program, Opportunity No. HRSA-26-074, issued by HRSA on June 8, 2026.

7. Filed as **Dkt. Nos. 1-3** and **19-10** is a true and correct copy of the Notice of Funding Opportunity: Ryan White HIV/AIDS Program Part C Capacity Development Program, Opportunity No. HRSA-26-061, issued by HRSA on June 5, 2026.

8. Filed as **Dkt. Nos. 1-4** and **19-11** is a true and correct copy of the Notice of Funding Opportunity: Ryan White HIV/AIDS Program Part F Dental Reimbursement Program, Opportunity No. HRSA-26-085, issued by HRSA on June 8, 2026.

9. Filed as **Dkt. No. 47-2** is a true and correct copy of the Notice of Funding Opportunity, Ryan White HIV/AIDS Program Part D Coordinated HIV Services and Access to Research for Women, Infants, Children, and Youth (WICY) Existing Geographic Service Areas, Opportunity No. HRSA-26-067, issued by HRSA on June 11, 2026.

10. Filed as **Dkt. No. 19-3** is a true and correct copy of the Health Resources and Services Administration (“HRSA”) webpage titled “Advancing HRSA’s Mission Through Focused, Accountable Action,” available at <https://www.hrsa.gov/about/priorities>. This is the webpage referenced in the September 15, 2025 email contained at HRSA 0001–0002 of the Administrative Record.

11. Filed as **Dkt. No. 19-5** is a true and correct copy of Executive Order No. 14168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 Fed. Reg. 8615 (Jan. 20, 2025).

12. Attached hereto as **Exhibit A** is a true and correct copy of Executive Order No. 14159, *Protecting the American People Against Invasion*, 90 Fed. Reg. 8843 (Jan. 20, 2025).

13. Attached hereto as **Exhibit B** is a true and correct copy of Executive Order No. 14169, *Reevaluating and Realigning United States Foreign Aid*, 90 Fed. Reg. 8619 (Jan. 20, 2025).

14. Attached hereto as **Exhibit C** is a true and correct copy of Executive Order No. 14162, *Putting America First in International Environmental Agreements*, 90 Fed. Reg. 8455 (Jan. 20, 2025).

15. Attached hereto as **Exhibit D** is a true and correct copy of Executive Order No. 14154, *Unleashing American Energy*, 90 Fed. Reg. 8353 (Jan. 20, 2025).

16. Attached hereto as **Exhibit E** is a true and correct copy of Executive Order No. 14151, *Ending Radical and Wasteful Government DEI Programs and Preferencing*, 90 Fed. Reg. 8339 (Jan. 20, 2025).

17. Attached hereto as **Exhibit F** is a true and correct copy of Executive Order No. 14182, *Enforcing the Hyde Amendment*, 90 Fed. Reg. 8751 (Jan. 24, 2025).

18. Attached hereto as **Exhibit G** is a true and correct copy of Executive Order No. 14332, *Improving Oversight of Federal Grantmaking*, 90 Fed. Reg. 38929 (Aug. 7, 2025).

19. Attached hereto as **Exhibit H** is a true and correct copy of guidance issued by the U.S. Department of Health and Human Services (“HHS”), Office of the Secretary, on February 19, 2025, titled “Defining Sex: Guidance for Federal Agencies, External Partners, and the Public Implementing Executive Order 14168, ‘Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government.’”

20. Attached hereto as **Exhibit I** is a true and correct copy of the HHS Grants Policy Statement, effective October 1, 2025, available at <https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-oct-2025.pdf>.

21. Attached hereto as **Exhibit J** is a true and correct copy of a letter dated April 7, 2026, from Thomas J. Engels, Administrator of HRSA, to Ryan White HIV/AIDS Program awardees and stakeholders. The letter is available at <https://tinyurl.com/4neauwpd> [<https://perma.cc/K3TZ-HWEF>].

22. Attached hereto as **Exhibit K** is a true and correct copy of a February 20, 2025 public statement posted by HHS through its official @HHSGov account on X.com concerning the Administration's implementation of Executive Order 14168 and "gender ideology," and which is publicly available at <https://x.com/HHSGov/status/1892731580218474861>.

23. Attached hereto as **Exhibit L** is a true and correct copy of HRSA's Ryan White HIV/AIDS Program webpage titled "Who We Are," available at <https://ryanwhite.hrsa.gov/>.

24. Attached hereto as **Exhibit M** is a true and correct copy of HRSA's Ryan White HIV/AIDS Program webpage titled "Part B: Grants to States and Territories," available at <https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-grants-states-territories>.

25. Attached hereto as **Exhibit N** is a true and correct copy of HRSA's Ryan White HIV/AIDS Program webpage titled "Part C: Early Intervention Services (EIS) and Capacity Development Grants," available at <https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-c-early-intervention>.

26. Attached hereto as **Exhibit O** is a true and correct copy of HRSA's Ryan White HIV/AIDS Program webpage titled "Part F: Special Projects of National Significance (SPNS) Program," available at <https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-f-spns>.

27. Attached hereto as **Exhibit P** is a true and correct copy of HHS's webpage titled "Protecting the Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex (LGBTQI+) People," available at <https://www.hhs.gov/ocr/lgbtqi/index.html>.

28. Plaintiffs also identified additional internal government materials that are referenced in the Administrative Record but are not themselves contained in the Administrative Record. Because Plaintiffs do not possess copies of those materials, they are not attached to this Declaration. Those materials include:

- a. the summary or summaries identifying changes made from prior-year versions of the challenged Notices of Funding Opportunity ("NOFOs") to align them with Administration priorities, as required by the April 3, 2026 HHS NOFO clearance guidance at HRSA 0006;
- b. the ASFR Memorandum titled "Clarification on Departmental Review of Grants and Contracts," dated February 20, 2026, the referenced new review process for NOFOs and NOAs, or the review criteria for grant applications, each referenced at HRSA 0013;
- c. the "Summary of Key Updates" referenced as an attachment to the February 24–25, 2026 email thread at HRSA 0028–0030;
- d. the HRSA Standard NOFO template and the modifications made to that template referenced at HRSA 0028–0030 and HRSA 0079;
- e. the September 25, 2025 version of the FY 2026 X09 NOFO referenced at HRSA 0031, including the version in which the Challenged Conditions were added with the comment "Added per HHS. OGC has approved," and any nonprivileged feedback or commentary associated with that version;

- f. communications or operative instructions from HHS concerning the addition, approval, or implementation of the Challenged Conditions in the FY 2026 X09 NOFO;
- g. OMB comments, edits, or other materials transmitted to HHS or HRSA concerning the challenged Part B Supplemental, Part C, Part D, and Part F NOFOs during the HHS/OMB clearance process; and
- h. revised versions of the challenged NOFOs submitted through the HHS/OMB clearance process, including versions containing or addressing OMB's comment concerning a link to the "gender dysphoria report."

29. On August 22, 2026, counsel for Plaintiffs indicated to counsel for Defendants on a telephone call that they would be seeking to file a motion to complete to the Administrative Record and that they would be providing a list of the documents sought through such motion via email. On August 23 and 24, 2026, counsel for Plaintiffs provided Defendants via email with a list of materials that Plaintiffs believed were missing from the Administrative Record and requested Defendants' position as to the addition of such documents to the Administrative Record in order to complete the records. As of 5:00pm EST on August 24, Defendants had yet to provide their position on the inclusion of these documents in the Administrative Record.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on August 24, 2026.

/s/ Ryan P. Trumbauer
Ryan P. Trumbauer

EXHIBIT A

Presidential Documents

Executive Order 14159 of January 20, 2025

Protecting the American People Against Invasion

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Immigration and Nationality Act (INA) (8 U.S.C. 1101 *et seq.*) and section 301 of title 3, United States Code, it is hereby ordered:

Section 1. Purpose. Over the last 4 years, the prior administration invited, administered, and oversaw an unprecedented flood of illegal immigration into the United States. Millions of illegal aliens crossed our borders or were permitted to fly directly into the United States on commercial flights and allowed to settle in American communities, in violation of longstanding Federal laws.

Many of these aliens unlawfully within the United States present significant threats to national security and public safety, committing vile and heinous acts against innocent Americans. Others are engaged in hostile activities, including espionage, economic espionage, and preparations for terror-related activities. Many have abused the generosity of the American people, and their presence in the United States has cost taxpayers billions of dollars at the Federal, State, and local levels.

Enforcing our Nation's immigration laws is critically important to the national security and public safety of the United States. The American people deserve a Federal Government that puts their interests first and a Government that understands its sacred obligation to prioritize the safety, security, and financial and economic well-being of Americans.

This order ensures that the Federal Government protects the American people by faithfully executing the immigration laws of the United States.

Sec. 2. Policy. It is the policy of the United States to faithfully execute the immigration laws against all inadmissible and removable aliens, particularly those aliens who threaten the safety or security of the American people. Further, it is the policy of the United States to achieve the total and efficient enforcement of those laws, including through lawful incentives and detention capabilities.

Sec. 3. Faithful Execution of the Immigration Laws. In furtherance of the policies described in section 2 of this order:

(a) Executive Order 13993 of January 20, 2021 (Revision of Civil Immigration Enforcement Policies and Priorities), Executive Order 14010 of February 2, 2021 (Creating a Comprehensive Regional Framework To Address the Causes of Migration, To Manage Migration Throughout North and Central America, and To Provide Safe and Orderly Processing of Asylum Seekers at the United States Border), Executive Order 14011 of February 2, 2021 (Establishment of Interagency Task Force on the Reunification of Families), and Executive Order 14012 of February 2, 2021 (Restoring Faith in Our Legal Immigration Systems and Strengthening Integration and Inclusion Efforts for New Americans) are hereby revoked; and

(b) Executive departments and agencies (agencies) shall take all appropriate action to promptly revoke all memoranda, guidance, or other policies based on the Executive Orders revoked in section 3(a) of this order and shall employ all lawful means to ensure the faithful execution of the immigration laws of the United States against all inadmissible and removable aliens.

Sec. 4. *Civil Enforcement Priorities.* The Secretary of Homeland Security shall take all appropriate action to enable the Director of U.S. Immigration and Customs Enforcement, the Commissioner of U.S. Customs and Border Protection, and the Director of U.S. Citizenship and Immigration Services to set priorities for their agencies that protect the public safety and national security interests of the American people, including by ensuring the successful enforcement of final orders of removal. Further, the Secretary of Homeland Security shall ensure that the primary mission of U.S. Immigration and Customs Enforcement's Homeland Security Investigations division is the enforcement of the provisions of the INA and other Federal laws related to the illegal entry and unlawful presence of aliens in the United States and the enforcement of the purposes of this order.

Sec. 5. *Criminal Enforcement Priorities.* The Attorney General, in coordination with the Secretary of State and the Secretary of Homeland Security, shall take all appropriate action to prioritize the prosecution of criminal offenses related to the unauthorized entry or continued unauthorized presence of aliens in the United States.

Sec. 6. *Federal Homeland Security Task Forces.* (a) The Attorney General and the Secretary of Homeland Security shall take all appropriate action to jointly establish Homeland Security Task Forces (HSTFs) in all States nationwide.

(b) The composition of each HSTF shall be subject to the direction of the Attorney General and the Secretary of Homeland Security, but shall include representation from any other Federal agencies with law enforcement officers, or agencies with the ability to provide logistics, intelligence, and operational support to the HSTFs, and shall also include representation from relevant State and local law enforcement agencies. The heads of all Federal agencies shall take all appropriate action to provide support to the Attorney General and the Secretary of Homeland Security to ensure that the HSTFs fulfill the objectives in subsection (c) of this section, and any other lawful purpose that fulfills the policy objectives of this order.

(c) The objective of each HSTF is to end the presence of criminal cartels, foreign gangs, and transnational criminal organizations throughout the United States, dismantle cross-border human smuggling and trafficking networks, end the scourge of human smuggling and trafficking, with a particular focus on such offenses involving children, and ensure the use of all available law enforcement tools to faithfully execute the immigration laws of the United States.

(d) The Attorney General and the Secretary of Homeland Security shall take all appropriate action to provide an operational command center to coordinate the activities of the HSTFs and provide such support as they may require, and shall also take all appropriate action to provide supervisory direction to their activities as may be required.

Sec. 7. *Identification of Unregistered Illegal Aliens.* The Secretary of Homeland Security, in coordination with the Secretary of State and the Attorney General, shall take all appropriate action to:

(a) Immediately announce and publicize information about the legal obligation of all previously unregistered aliens in the United States to comply with the requirements of part VII of subchapter II of chapter 12 of title 8, United States Code;

(b) Ensure that all previously unregistered aliens in the United States comply with the requirements of part VII of subchapter II of chapter 12 of title 8, United States Code; and

(c) Ensure that failure to comply with the legal obligations of part VII of subchapter II of chapter 12 of title 8, United States Code, is treated as a civil and criminal enforcement priority.

Sec. 8. *Civil Fines and Penalties.* (a) The Secretary of Homeland Security, in coordination with the Secretary of Treasury, shall take all appropriate action to ensure the assessment and collection of all fines and penalties

that the Secretary of Homeland Security is authorized by law to assess and collect from aliens unlawfully present in the United States, including aliens who unlawfully entered or unlawfully attempted to enter the United States, and from those who facilitate such aliens' presence in the United States.

(b) Within 90 days of the date of this order, the Secretary of the Treasury and the Secretary of Homeland Security shall submit a report to the President regarding their progress implementing the requirements of this section and recommending any additional actions that may need to be taken to achieve its objectives.

Sec. 9. *Efficient Removals of Recent Entrants and Other Aliens.* The Secretary of Homeland Security shall take all appropriate action, pursuant to section 235(b)(1)(A)(iii)(I) of the INA (8 U.S.C. 1225(b)(1)(A)(iii)(I)), to apply, in her sole and unreviewable discretion, the provisions of section 235(b)(1)(A)(i) and (ii) of the INA to the aliens designated under section 235(b)(1)(A)(iii)(II). Further, the Secretary of Homeland Security shall promptly take appropriate action to use all other provisions of the immigration laws or any other Federal law, including, but not limited to sections 238 and 240(d) of the INA (8 U.S.C. 1228 and 1229a(d)), to ensure the efficient and expedited removal of aliens from the United States.

Sec. 10. *Detention Facilities.* The Secretary of Homeland Security shall promptly take all appropriate action and allocate all legally available resources or establish contracts to construct, operate, control, or use facilities to detain removable aliens. The Secretary of Homeland Security, further, shall take all appropriate actions to ensure the detention of aliens apprehended for violations of immigration law pending the outcome of their removal proceedings or their removal from the country, to the extent permitted by law.

Sec. 11. *Federal-State Agreements.* To ensure State and local law enforcement agencies across the United States can assist with the protection of the American people, the Secretary of Homeland Security shall, to the maximum extent permitted by law, and with the consent of State or local officials as appropriate, take appropriate action, through agreements under section 287(g) of the INA (8 U.S.C. 1357(g)) or otherwise, to authorize State and local law enforcement officials, as the Secretary of Homeland Security determines are qualified and appropriate, to perform the functions of immigration officers in relation to the investigation, apprehension, or detention of aliens in the United States under the direction and the supervision of the Secretary of Homeland Security. Such authorization shall be in addition to, rather than in place of, Federal performance of these duties. To the extent permitted by law, the Secretary of Homeland Security may structure each agreement under section 287(g) of the INA (8 U.S.C. 1357(g)) in the manner that provides the most effective model for enforcing Federal immigration laws in that jurisdiction.

Sec. 12. *Encouraging Voluntary Compliance with the Law.* The Secretary of Homeland Security shall take all appropriate action, in coordination with the Secretary of State and the Attorney General, and subject to adequate safeguards, assurances, bonds, and any other lawful measure, to adopt policies and procedures to encourage aliens unlawfully in the United States to voluntarily depart as soon as possible, including through enhanced usage of the provisions of section 240B of the INA (8 U.S.C. 1229c), international agreements or assistance, or any other measures that encourage aliens unlawfully in the United States to depart as promptly as possible, including through removals of aliens as provided by section 250 of the INA (8 U.S.C. 1260).

Sec. 13. *Recalcitrant Countries.* The Secretary of State and the Secretary of Homeland Security shall take all appropriate action to:

(a) Cooperate and effectively implement, as appropriate, the sanctions provided by section 243(d) of the INA (8 U.S.C. 1253(d)), with the Secretary of State, to the maximum extent permitted by law, ensuring that diplomatic

efforts and negotiations with foreign states include the foreign states' acceptance of their nationals who are subject to removal from the United States; and

(b) Eliminate all documentary barriers, dilatory tactics, or other restrictions that prevent the prompt repatriation of aliens to any foreign state. Any failure or delay by a foreign state to verify the identity of a national of that state shall be considered in carrying out subsection (a) this section, and shall also be considered regarding the issuance of any other sanctions that may be available to the United States.

Sec. 14. *Visa Bonds.* The Secretary of Treasury shall take all appropriate action, in coordination with the Secretary of State and the Secretary of Homeland Security, to establish a system to facilitate the administration of all bonds that the Secretary of State or the Secretary of Homeland Security may lawfully require to administer the provisions of the INA.

Sec. 15. *Reestablishment of the VOICE Office and Addressing Victims of Crimes Committed by Removable Aliens.* The Secretary of Homeland Security shall direct the Director of U.S. Immigration and Customs Enforcement (ICE) to take all appropriate and lawful action to reestablish within ICE an office to provide proactive, timely, adequate, and professional services to victims of crimes committed by removable aliens, and those victims' family members. The Attorney General shall also ensure that the provisions of 18 U.S.C. 3771 are followed in all Federal prosecutions involving crimes committed by removable aliens.

Sec. 16. *Addressing Actions by the Previous Administration.* The Secretary of State, the Attorney General, and the Secretary of Homeland Security shall promptly take all appropriate action, consistent with law, to rescind the policy decisions of the previous administration that led to the increased or continued presence of illegal aliens in the United States, and align any and all departmental activities with the policies set out by this order and the immigration laws. Such action should include, but is not limited to:

(a) ensuring that the parole authority under section 212(d)(5) of the INA (8 U.S.C. 1182(d)(5)) is exercised on only a case-by-case basis in accordance with the plain language of the statute, and in all circumstances only when an individual alien demonstrates urgent humanitarian reasons or a significant public benefit derived from their particular continued presence in the United States arising from such parole;

(b) ensuring that designations of Temporary Protected Status are consistent with the provisions of section 244 of the INA (8 U.S.C. 1254a), and that such designations are appropriately limited in scope and made for only so long as may be necessary to fulfill the textual requirements of that statute; and

(c) ensuring that employment authorization is provided in a manner consistent with section 274A of the INA (8 U.S.C. 1324a), and that employment authorization is not provided to any unauthorized alien in the United States.

Sec. 17. *Sanctuary Jurisdictions.* The Attorney General and the Secretary of Homeland Security shall, to the maximum extent possible under law, evaluate and undertake any lawful actions to ensure that so-called "sanctuary" jurisdictions, which seek to interfere with the lawful exercise of Federal law enforcement operations, do not receive access to Federal funds. Further, the Attorney General and the Secretary of Homeland Security shall evaluate and undertake any other lawful actions, criminal or civil, that they deem warranted based on any such jurisdiction's practices that interfere with the enforcement of Federal law.

Sec. 18. *Information Sharing.* (a) The Secretary of Homeland Security shall promptly issue guidance to ensure maximum compliance by Department of Homeland Security personnel with the provisions of 8 U.S.C. 1373 and 8 U.S.C. 1644 and ensure that State and local governments are provided with the information necessary to fulfill law enforcement, citizenship, or immigration status verification requirements authorized by law; and

(b) The Attorney General, the Secretary of Health and Human Services, and the Secretary of Homeland Security shall take all appropriate action to stop the trafficking and smuggling of alien children into the United States, including through the sharing of any information necessary to assist in the achievement of that objective.

Sec. 19. *Funding Review.* The Attorney General and the Secretary of Homeland Security shall:

(a) Immediately review and, if appropriate, audit all contracts, grants, or other agreements providing Federal funding to non-governmental organizations supporting or providing services, either directly or indirectly, to removable or illegal aliens, to ensure that such agreements conform to applicable law and are free of waste, fraud, and abuse, and that they do not promote or facilitate violations of our immigration laws;

(b) Pause distribution of all further funds pursuant to such agreements pending the results of the review in subsection (a) of this section;

(c) Terminate all such agreements determined to be in violation of law or to be sources of waste, fraud, or abuse and prohibit any such future agreements;

(d) Coordinate with the Director of the Office of Management and Budget to ensure that no funding for agreements described in subsection (c) of this section is included in any appropriations request for the Department of Justice or the Department of Homeland Security; and

(e) Initiate clawback or recoupment procedures, if appropriate, for any agreements described in subsection (c) of this section.

Sec. 20. *Denial of Public Benefits to Illegal Aliens.* The Director of the Office of Management and Budget shall take all appropriate action to ensure that all agencies identify and stop the provision of any public benefits to any illegal alien not authorized to receive them under the provisions of the INA or other relevant statutory provisions.

Sec. 21. *Hiring More Agents and Officers.* Subject to available appropriations, the Secretary of Homeland Security, through the Commissioner of U.S. Customs and Border Protection and the Director of U.S. Immigration and Customs Enforcement, shall take all appropriate action to significantly increase the number of agents and officers available to perform the duties of immigration officers.

Sec. 22. *Severability.* It is the policy of the United States to enforce this order to the maximum extent possible to advance the interests of the United States. Accordingly:

(a) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of its other provisions to any other persons or circumstances shall not be affected thereby; and

(b) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid because of the failure to follow certain procedures, the relevant executive branch officials shall implement those procedural requirements to conform with existing law and with any applicable court orders.

Sec. 23. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

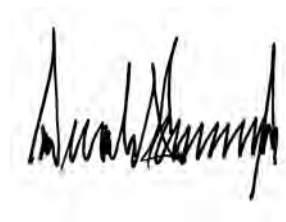
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party

against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", is located in the upper right quadrant of the page. The signature is written in a cursive, stylized script.

THE WHITE HOUSE,
January 20, 2025.

EXHIBIT B

Presidential Documents

Executive Order 14169 of January 20, 2025

Reevaluating and Realigning United States Foreign Aid

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. The United States foreign aid industry and bureaucracy are not aligned with American interests and in many cases antithetical to American values. They serve to destabilize world peace by promoting ideas in foreign countries that are directly inverse to harmonious and stable relations internal to and among countries.

Sec. 2. Policy. It is the policy of United States that no further United States foreign assistance shall be disbursed in a manner that is not fully aligned with the foreign policy of the President of the United States.

Sec. 3. (a) 90-day pause in United States foreign development assistance for assessment of programmatic efficiencies and consistency with United States foreign policy. All department and agency heads with responsibility for United States foreign development assistance programs shall immediately pause new obligations and disbursements of development assistance funds to foreign countries and implementing non-governmental organizations, international organizations, and contractors pending reviews of such programs for programmatic efficiency and consistency with United States foreign policy, to be conducted within 90 days of this order. The Office of Management and Budget (OMB) shall enforce this pause through its apportionment authority.

(b) *Reviews of United States foreign assistance programs.* Reviews of each foreign assistance program shall be ordered by the responsible department and agency heads under guidelines provided by the Secretary of State, in consultation with the Director of OMB.

(c) *Determinations.* The responsible department and agency heads, in consultation with the Director of OMB, will make determinations within 90 days of this order on whether to continue, modify, or cease each foreign assistance program based upon the review recommendations, with the concurrence of the Secretary of State.

(d) *Resumption of paused development assistance funding.* New obligations and disbursements of foreign development assistance funds may resume for a program prior to the end of the 90-day period if a review is conducted, and the Secretary of State or his designee, in consultation with the Director of OMB, decide to continue the program in the same or modified form. Additionally, any other new foreign assistance programs and obligations must be approved by the Secretary of State or his designee, in consultation with the Director of OMB.

(e) *Waiver.* The Secretary of State may waive the pause in Section 3(a) for specific programs.

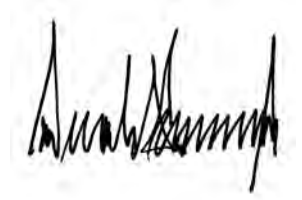
Sec. 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", is located in the upper right quadrant of the page. The signature is stylized with a large, prominent 'D' and 'T'.

THE WHITE HOUSE,
January 20, 2025.

EXHIBIT C

Presidential Documents

Executive Order 14162 of January 20, 2025

Putting America First in International Environmental Agreements

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* The United States must grow its economy and maintain jobs for its citizens while playing a leadership role in global efforts to protect the environment. Over decades, with the help of sensible policies that do not encumber private-sector activity, the United States has simultaneously grown its economy, raised worker wages, increased energy production, reduced air and water pollution, and reduced greenhouse gas emissions. The United States' successful track record of advancing both economic and environmental objectives should be a model for other countries.

In recent years, the United States has purported to join international agreements and initiatives that do not reflect our country's values or our contributions to the pursuit of economic and environmental objectives. Moreover, these agreements steer American taxpayer dollars to countries that do not require, or merit, financial assistance in the interests of the American people.

Sec. 2. *Policy.* It is the policy of my Administration to put the interests of the United States and the American people first in the development and negotiation of any international agreements with the potential to damage or stifle the American economy. These agreements must not unduly or unfairly burden the United States.

Sec. 3. *Implementation.* (a) The United States Ambassador to the United Nations shall immediately submit formal written notification of the United States' withdrawal from the Paris Agreement under the United Nations Framework Convention on Climate Change. The notice shall be submitted to the Secretary-General of the United Nations, the Depositary of the Agreement, attached as Appendix A. The United States will consider its withdrawal from the Agreement and any attendant obligations to be effective immediately upon this provision of notification.

(b) The United States Ambassador to the United Nations shall immediately submit written formal notification to the Secretary-General of the United Nations, or any relevant party, of the United States' withdrawal from any agreement, pact, accord, or similar commitment made under the United Nations Framework Convention on Climate Change.

(c) The United States Ambassador to the United Nations, in collaboration with the Secretary of State and Secretary of the Treasury, shall immediately cease or revoke any purported financial commitment made by the United States under the United Nations Framework Convention on Climate Change.

(d) Immediately upon completion of the tasks listed in subsections (a), (b), and (c), the United States Ambassador to the United Nations, in collaboration with the Secretary of State and Secretary of the Treasury shall certify a report to the Assistant to the President for Economic Policy and Assistant to the President for National Security Affairs that describes in detail any further action required to achieve the policy objectives set forth in section 2 of this order.

(e) The U.S. International Climate Finance Plan is revoked and rescinded immediately. The Director of the Office of Management and Budget shall,

within 10 days of this order, issue guidance for the rescission of all frozen funds.

(f) Within 30 days of this order, the Secretary of State, Secretary of the Treasury, Secretary of Commerce, Secretary of Health and Human Services, Secretary of Energy, Secretary of Agriculture, Administrator of the Environmental Protection Agency, Administrator of the U.S. Agency for International Development, Chief Executive Officer of the International Development Finance Corporation, Chief Executive Officer of the Millennium Challenge Corporation, Director of the U.S. Trade and Development Agency, President of the Export-Import Bank, and head of any other relevant department or agency shall submit a report to the Assistant to the President for Economic Policy and the Assistant to the President for National Security Affairs that details their actions to revoke or rescind policies that were implemented to advance the International Climate Finance Plan.

(g) The Secretary of State, Secretary of Commerce, and the head of any department or agency that plans or coordinates international energy agreements shall henceforth prioritize economic efficiency, the promotion of American prosperity, consumer choice, and fiscal restraint in all foreign engagements that concern energy policy.

Sec. 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented in a manner consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or any other persons.



THE WHITE HOUSE,
January 20, 2025.

APPENDIX A

NOTIFICATION OF WITHDRAWAL ON BEHALF OF
THE UNITED STATES OF AMERICA
NOTIFICATION OF WITHDRAWAL ON BEHALF OF
THE UNITED STATES OF AMERICA

His Excellency António Guterres
Secretary-General of the United Nations

I, Donald J. Trump, President of the United States of America, provide notification of withdrawal from the Paris Agreement, done at Paris, France, on December 12, 2015, on behalf of the United States of America, based on the authorities vested in me by the Constitution of the United States.

Done at Washington, D.C., this 20th day of January, 2025.

EXHIBIT D

Presidential Documents

Executive Order 14154 of January 20, 2025

Unleashing American Energy

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Background.* America is blessed with an abundance of energy and natural resources that have historically powered our Nation's economic prosperity. In recent years, burdensome and ideologically motivated regulations have impeded the development of these resources, limited the generation of reliable and affordable electricity, reduced job creation, and inflicted high energy costs upon our citizens. These high energy costs devastate American consumers by driving up the cost of transportation, heating, utilities, farming, and manufacturing, while weakening our national security.

It is thus in the national interest to unleash America's affordable and reliable energy and natural resources. This will restore American prosperity—including for those men and women who have been forgotten by our economy in recent years. It will also rebuild our Nation's economic and military security, which will deliver peace through strength.

Sec. 2. *Policy.* It is the policy of the United States:

(a) to encourage energy exploration and production on Federal lands and waters, including on the Outer Continental Shelf, in order to meet the needs of our citizens and solidify the United States as a global energy leader long into the future;

(b) to establish our position as the leading producer and processor of non-fuel minerals, including rare earth minerals, which will create jobs and prosperity at home, strengthen supply chains for the United States and its allies, and reduce the global influence of malign and adversarial states;

(c) to protect the United States's economic and national security and military preparedness by ensuring that an abundant supply of reliable energy is readily accessible in every State and territory of the Nation;

(d) to ensure that all regulatory requirements related to energy are grounded in clearly applicable law;

(e) to eliminate the "electric vehicle (EV) mandate" and promote true consumer choice, which is essential for economic growth and innovation, by removing regulatory barriers to motor vehicle access; by ensuring a level regulatory playing field for consumer choice in vehicles; by terminating, where appropriate, state emissions waivers that function to limit sales of gasoline-powered automobiles; and by considering the elimination of unfair subsidies and other ill-conceived government-imposed market distortions that favor EVs over other technologies and effectively mandate their purchase by individuals, private businesses, and government entities alike by rendering other types of vehicles unaffordable;

(f) to safeguard the American people's freedom to choose from a variety of goods and appliances, including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and shower heads, and to promote market competition and innovation within the manufacturing and appliance industries;

(g) to ensure that the global effects of a rule, regulation, or action shall, whenever evaluated, be reported separately from its domestic costs and

benefits, in order to promote sound regulatory decision making and prioritize the interests of the American people;

(h) to guarantee that all executive departments and agencies (agencies) provide opportunity for public comment and rigorous, peer-reviewed scientific analysis; and

(i) to ensure that no Federal funding be employed in a manner contrary to the principles outlined in this section, unless required by law.

Sec. 3. *Immediate Review of All Agency Actions that Potentially Burden the Development of Domestic Energy Resources.* (a) The heads of all agencies shall review all existing regulations, orders, guidance documents, policies, settlements, consent orders, and any other agency actions (collectively, agency actions) to identify those agency actions that impose an undue burden on the identification, development, or use of domestic energy resources—with particular attention to oil, natural gas, coal, hydropower, biofuels, critical mineral, and nuclear energy resources—or that are otherwise inconsistent with the policy set forth in section 2 of this order, including restrictions on consumer choice of vehicles and appliances.

(b) Within 30 days of the date of this order, the head of each agency shall, in consultation with the director of the Office of Management and Budget (OMB) and the National Economic Council (NEC), develop and begin implementing action plans to suspend, revise, or rescind all agency actions identified as unduly burdensome under subsection (a) of this section, as expeditiously as possible and consistent with applicable law. The head of any agency who determines that such agency does not have agency actions described in subsection (a) of this section shall submit to the Director of OMB a written statement to that effect and, absent a determination by the Director of OMB that such agency does have agency actions described in this subsection, shall have no further responsibilities under this section.

(c) Agencies shall promptly notify the Attorney General of any steps taken pursuant to subsection (a) of this section so that the Attorney General may, as appropriate:

(i) provide notice of this Executive Order and any such actions to any court with jurisdiction over pending litigation in which such actions may be relevant; and

(ii) request that such court stay or otherwise delay further litigation, or seek other appropriate relief consistent with this order, pending the completion of the administrative actions described in this order.

(d) Pursuant to the policy outlined in section 2 of this order, the Attorney General shall consider whether pending litigation against illegal, dangerous, or harmful policies should be resolved through stays or other relief.

Sec. 4. *Revocation of and Revisions to Certain Presidential and Regulatory Actions.* (a) The following are revoked and any offices established therein are abolished:

(i) Executive Order 13990 of January 20, 2021 (Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis);

(ii) Executive Order 13992 of January 20, 2021 (Revocation of Certain Executive Orders Concerning Federal Regulation);

(iii) Executive Order 14008 of January 27, 2021 (Tackling the Climate Crisis at Home and Abroad);

(iv) Executive Order 14007 of January 27, 2021 (President's Council of Advisors on Science and Technology);

(v) Executive Order 14013 of February 4, 2021 (Rebuilding and Enhancing Programs to Resettle Refugees and Planning for the Impact of Climate Change on Migration);

(vi) Executive Order 14027 of May 7, 2021 (Establishment of the Climate Change Support Office);

(vii) Executive Order 14030 of May 20, 2021 (Climate-Related Financial Risk);

(viii) Executive Order 14037 of August 5, 2021 (Strengthening American Leadership in Clean Cars and Trucks);

(ix) Executive Order 14057 of December 8, 2021 (Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability);

(x) Executive Order 14072 of April 22, 2022 (Strengthening the Nation's Forests, Communities, and Local Economies);

(xi) Executive Order 14082 of September 12, 2022 (Implementation of the Energy and Infrastructure Provisions of the Inflation Reduction Act of 2022); and

(xii) Executive Order 14096 of April 21, 2023 (Revitalizing Our Nation's Commitment to Environmental Justice for All).

(b) All activities, programs, and operations associated with the American Climate Corps, including actions taken by any agency shall be terminated immediately. Within one day of the date of this order, the Secretary of the Interior shall submit a letter to all parties to the "American Climate Corps Memorandum of Understanding" dated December 2023 to terminate the memorandum, and the head of each party to the memorandum shall agree to the termination in writing.

(c) Any assets, funds, or resources allocated to an entity or program abolished by subsection (a) of this section shall be redirected or disposed of in accordance with applicable law.

(d) The head of any agency that has taken action respecting offices and programs in subsection (a) shall take all necessary steps to ensure that all such actions are terminated or, if necessary, appropriate, or required by law, that such activities are transitioned to other agencies or entities.

(e) Any contract or agreement between the United States and any third party on behalf of the entities or programs abolished in subsection (a) of this section, or in furtherance of them, shall be terminated for convenience, or otherwise, as quickly as permissible under the law.

Sec. 5. *Unleashing Energy Dominance through Efficient Permitting.* (a) Executive Order 11991 of May 24, 1977 (Relating to protection and enhancement of environmental quality) is hereby revoked.

(b) To expedite and simplify the permitting process, within 30 days of the date of this order, the Chairman of the Council on Environmental Quality (CEQ) shall provide guidance on implementing the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, and propose rescinding CEQ's NEPA regulations found at 40 CFR 1500 *et seq.*

(c) Following the provision of the guidance, the Chairman of CEQ shall convene a working group to coordinate the revision of agency-level implementing regulations for consistency. The guidance in subsection (b) and any resulting implementing regulations must expedite permitting approvals and meet deadlines established in the Fiscal Responsibility Act of 2023 (Public Law 118–5). Consistent with applicable law, all agencies must prioritize efficiency and certainty over any other objectives, including those of activist groups, that do not align with the policy goals set forth in section 2 of this order or that could otherwise add delays and ambiguity to the permitting process.

(d) The Secretaries of Defense, Interior, Agriculture, Commerce, Housing and Urban Development, Transportation, Energy, Homeland Security, the Administrator of the Environmental Protection Agency (EPA), the Chairman of CEQ, and the heads of any other relevant agencies shall undertake all available efforts to eliminate all delays within their respective permitting processes, including through, but not limited to, the use of general permitting and permit by rule. For any project an agency head deems essential for the Nation's economy or national security, agencies shall use all possible

authorities, including emergency authorities, to expedite the adjudication of Federal permits. Agencies shall work closely with project sponsors to realize the ultimate construction or development of permitted projects.

(e) The Director of the NEC and the Director of the Office of Legislative Affairs shall jointly prepare recommendations to Congress, which shall:

(i) facilitate the permitting and construction of interstate energy transportation and other critical energy infrastructure, including, but not limited to, pipelines, particularly in regions of the Nation that have lacked such development in recent years; and

(ii) provide greater certainty in the Federal permitting process, including, but not limited to, streamlining the judicial review of the application of NEPA.

Sec. 6. *Prioritizing Accuracy in Environmental Analyses.* (a) In all Federal permitting adjudications or regulatory processes, all agencies shall adhere to only the relevant legislated requirements for environmental considerations and any considerations beyond these requirements are eliminated. In fulfilling all such requirements, agencies shall strictly use the most robust methodologies of assessment at their disposal and shall not use methodologies that are arbitrary or ideologically motivated.

(b) The Interagency Working Group on the Social Cost of Greenhouse Gases (IWG), which was established pursuant to Executive Order 13990, is hereby disbanded, and any guidance, instruction, recommendation, or document issued by the IWG is withdrawn as no longer representative of governmental policy including:

(i) the Presidential Memorandum of January 27, 2021 (Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policy-making);

(ii) the Report of the Greenhouse Gas Monitoring and Measurement Interagency Working Group of November 2023 (National Strategy to Advance an Integrated U.S. Greenhouse Gas Measurement, Monitoring, and Information System);

(iii) the Technical Support Document of February 2021 (Social Cost of Carbon, Methane, and Nitrous Oxide Interim Estimates under Executive Order 13990); and

(iv) estimates of the social cost of greenhouse gases, including the estimates for the social cost of carbon, the social cost of methane, or the social cost of nitrous oxide based, in whole or in part, on the IWG's work or guidance.

(c) The calculation of the "social cost of carbon" is marked by logical deficiencies, a poor basis in empirical science, politicization, and the absence of a foundation in legislation. Its abuse arbitrarily slows regulatory decisions and, by rendering the United States economy internationally uncompetitive, encourages a greater human impact on the environment by affording less efficient foreign energy producers a greater share of the global energy and natural resource market. Consequently, within 60 days of the date of this order, the Administrator of the EPA shall issue guidance to address these harmful and detrimental inadequacies, including consideration of eliminating the "social cost of carbon" calculation from any Federal permitting or regulatory decision.

(d) Prior to the guidance issued pursuant to subsection (c) of this section, agencies shall ensure estimates to assess the value of changes in greenhouse gas emissions resulting from agency actions, including with respect to the consideration of domestic versus international effects and evaluating appropriate discount rates, are, to the extent permitted by law, consistent with the guidance contained in OMB Circular A-4 of September 17, 2003 (Regulatory Analysis).

(e) Furthermore, the head of each agency shall, as appropriate and consistent with applicable law, initiate a process to make such changes to

any rule, regulation, policy or action as may be necessary to ensure consistency with the Regulatory Analysis.

(f) Within 30 days of the date of this order, the Administrator of the EPA, in collaboration with the heads of any other relevant agencies, shall submit joint recommendations to the Director of OMB on the legality and continuing applicability of the Administrator's findings, "Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act," Final Rule, 74 FR 66496 (December 15, 2009).

Sec. 7. *Terminating the Green New Deal.* (a) All agencies shall immediately pause the disbursement of funds appropriated through the Inflation Reduction Act of 2022 (Public Law 117–169) or the Infrastructure Investment and Jobs Act (Public Law 117–58), including but not limited to funds for electric vehicle charging stations made available through the National Electric Vehicle Infrastructure Formula Program and the Charging and Fueling Infrastructure Discretionary Grant Program, and shall review their processes, policies, and programs for issuing grants, loans, contracts, or any other financial disbursements of such appropriated funds for consistency with the law and the policy outlined in section 2 of this order. Within 90 days of the date of this order, all agency heads shall submit a report to the Director of the NEC and Director of OMB that details the findings of this review, including recommendations to enhance their alignment with the policy set forth in section 2. No funds identified in this subsection (a) shall be disbursed by a given agency until the Director of OMB and Assistant to the President for Economic Policy have determined that such disbursements are consistent with any review recommendations they have chosen to adopt.

(b) When procuring goods and services, making decisions about leases, and making other arrangements that result in disbursements of Federal funds, agencies shall prioritize cost-effectiveness, American workers and businesses, and the sensible use of taxpayer money, to the greatest extent. The Director of OMB shall finalize and circulate guidelines to further implement this subsection.

(c) All agencies shall assess whether enforcement discretion of authorities and regulations can be utilized to advance the policy outlined in section 2 of this order. Within 30 days of the date of this order, each agency shall submit a report to the Director of OMB identifying any such instances.

Sec. 8. *Protecting America's National Security.* (a) The Secretary of Energy is directed restart reviews of applications for approvals of liquefied natural gas export projects as expeditiously as possible, consistent with applicable law. In assessing the "Public Interest" to be advanced by any particular application, the Secretary of Energy shall consider the economic and employment impacts to the United States and the impact to the security of allies and partners that would result from granting the application.

(b) With respect to any proposed deepwater port for the export of liquefied natural gas (project) for which a favorable record of decision (ROD) has previously been issued pursuant to the Deepwater Port Act of 1974 (DWPA), 33 U.S.C. 1501 *et seq.*, the Administrator of the Maritime Administration (MARAD) shall, within 30 days of the date of this order and consistent with applicable law, determine whether any refinements to the project proposed subsequent to the ROD are likely to result in adverse environmental consequences that substantially differ from those associated with the originally-evaluated project so as to present a seriously different picture of the foreseeable adverse environmental consequences (seriously different consequences). In making this determination, MARAD shall qualitatively assess any difference in adverse environmental consequences between the project with and without the proposed refinements, including any potential consequences not addressed in the final Environmental Impact Statement (EIS), which shall be considered adequate under NEPA notwithstanding any revisions to NEPA that may have been enacted following the final EIS. MARAD shall submit this determination, together with a detailed justification, to the Secretary of Transportation and to the President.

(c) Pursuant to subsection (b) of this section, if MARAD determines that such refinements are not likely to result in seriously different consequences, it shall include in that determination a description of the refinements to supplement and update the ROD, if necessary and then no later than 30 additional days, he shall issue a DWPA license.

(d) If MARAD determines, with concurrence from the Secretary of Transportation, that such proposed refinements are likely to result in seriously different consequences, it shall, within 60 days after submitting such determination, issue an Environmental Assessment (EA) examining such consequences and, with respect to all other environmental consequences not changed due to project refinements, shall reaffirm the conclusions of the final EIS. Within 30 days after issuing the EA, MARAD shall issue an addendum to the ROD, if necessary, and shall, within 30 additional days, issue a DWPA license consistent with the ROD.

Sec. 9. *Restoring America's Mineral Dominance.* (a) The Secretary of the Interior, Secretary of Agriculture, Administrator of the EPA, Chairman of CEQ, and the heads of any other relevant agencies, as appropriate, shall identify all agency actions that impose undue burdens on the domestic mining and processing of non-fuel minerals and undertake steps to revise or rescind such actions.

(b) The Secretaries of the Interior and Agriculture shall reassess any public lands withdrawals for potential revision.

(c) The Secretary of the Interior shall instruct the Director of the U.S. Geological Survey to consider updating the Survey's list of critical minerals, including for the potential of including uranium.

(d) The Secretary of the Interior shall prioritize efforts to accelerate the ongoing, detailed geologic mapping of the United States, with a focus on locating previously unknown deposits of critical minerals.

(e) The Secretary of Energy shall ensure that critical mineral projects, including the processing of critical minerals, receive consideration for Federal support, contingent on the availability of appropriated funds.

(f) The United States Trade Representative shall assess whether exploitative practices and state-assisted mineral projects abroad are unlawful or unduly burden or restrict United States commerce.

(g) The Secretary of Commerce shall assess the national security implications of the Nation's mineral reliance and the potential for trade action.

(h) The Secretary of Homeland Security shall assess the quantity and inflow of minerals that are likely the product of forced labor into the United States and whether such inflows pose a threat to national security and, within 90 days of the date of this order, shall provide this assessment to the Director of the NEC.

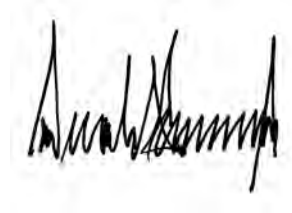
(i) The Secretary of Defense shall consider the needs of the United States in supplying and maintaining the National Defense Stockpile, review the legal authorities and obligations in managing the National Defense Stockpile, and take all appropriate steps to ensure that the National Defense Stockpile will provide a robust supply of critical minerals in event of future shortfall.

(j) Within 60 days of the date of this order, the Secretary of State, Secretary of Commerce, Secretary of Labor, the United States Trade Representative, and the heads of any other relevant agencies, shall submit a report to the Assistant to the President for Economic Policy that includes policy recommendations to enhance the competitiveness of American mining and refining companies in other mineral-wealthy nations.

(k) The Secretary of State shall consider opportunities to advance the mining and processing of minerals within the United States through the Quadrilateral Security Dialogue.

Sec. 10. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
- (ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented in a manner consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", is located on the right side of the page. The signature is stylized with a large, prominent 'D' and 'T'.

THE WHITE HOUSE,
January 20, 2025.

EXHIBIT E

Presidential Documents

Executive Order 14151 of January 20, 2025

Ending Radical and Wasteful Government DEI Programs and Preferencing

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose and Policy. The Biden Administration forced illegal and immoral discrimination programs, going by the name “diversity, equity, and inclusion” (DEI), into virtually all aspects of the Federal Government, in areas ranging from airline safety to the military. This was a concerted effort stemming from President Biden’s first day in office, when he issued Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.”

Pursuant to Executive Order 13985 and follow-on orders, nearly every Federal agency and entity submitted “Equity Action Plans” to detail the ways that they have furthered DEI’s infiltration of the Federal Government. The public release of these plans demonstrated immense public waste and shameful discrimination. That ends today. Americans deserve a government committed to serving every person with equal dignity and respect, and to expending precious taxpayer resources only on making America great.

Sec. 2. Implementation. (a) The Director of the Office of Management and Budget (OMB), assisted by the Attorney General and the Director of the Office of Personnel Management (OPM), shall coordinate the termination of all discriminatory programs, including illegal DEI and “diversity, equity, inclusion, and accessibility” (DEIA) mandates, policies, programs, preferences, and activities in the Federal Government, under whatever name they appear. To carry out this directive, the Director of OPM, with the assistance of the Attorney General as requested, shall review and revise, as appropriate, all existing Federal employment practices, union contracts, and training policies or programs to comply with this order. Federal employment practices, including Federal employee performance reviews, shall reward individual initiative, skills, performance, and hard work and shall not under any circumstances consider DEI or DEIA factors, goals, policies, mandates, or requirements.

(b) Each agency, department, or commission head, in consultation with the Attorney General, the Director of OMB, and the Director of OPM, as appropriate, shall take the following actions within sixty days of this order:

(i) terminate, to the maximum extent allowed by law, all DEI, DEIA, and “environmental justice” offices and positions (including but not limited to “Chief Diversity Officer” positions); all “equity action plans,” “equity” actions, initiatives, or programs, “equity-related” grants or contracts; and all DEI or DEIA performance requirements for employees, contractors, or grantees.

(ii) provide the Director of the OMB with a list of all:

(A) agency or department DEI, DEIA, or “environmental justice” positions, committees, programs, services, activities, budgets, and expenditures in existence on November 4, 2024, and an assessment of whether these positions, committees, programs, services, activities, budgets, and expenditures have been misleadingly relabeled in an attempt to preserve their pre-November 4, 2024 function;

(B) Federal contractors who have provided DEI training or DEI training materials to agency or department employees; and

(C) Federal grantees who received Federal funding to provide or advance DEI, DEIA, or “environmental justice” programs, services, or activities since January 20, 2021.

(iii) direct the deputy agency or department head to:

(A) assess the operational impact (e.g., the number of new DEI hires) and cost of the prior administration’s DEI, DEIA, and “environmental justice” programs and policies; and

(B) recommend actions, such as Congressional notifications under 28 U.S.C. 530D, to align agency or department programs, activities, policies, regulations, guidance, employment practices, enforcement activities, contracts (including set-asides), grants, consent orders, and litigating positions with the policy of equal dignity and respect identified in section 1 of this order. The agency or department head and the Director of OMB shall jointly ensure that the deputy agency or department head has the authority and resources needed to carry out this directive.

(c) To inform and advise the President, so that he may formulate appropriate and effective civil-rights policies for the Executive Branch, the Assistant to the President for Domestic Policy shall convene a monthly meeting attended by the Director of OMB, the Director of OPM, and each deputy agency or department head to:

(i) hear reports on the prevalence and the economic and social costs of DEI, DEIA, and “environmental justice” in agency or department programs, activities, policies, regulations, guidance, employment practices, enforcement activities, contracts (including set-asides), grants, consent orders, and litigating positions;

(ii) discuss any barriers to measures to comply with this order; and

(iii) monitor and track agency and department progress and identify potential areas for additional Presidential or legislative action to advance the policy of equal dignity and respect.

Sec. 3. Severability. If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of its provisions to any other persons or circumstances shall not be affected.

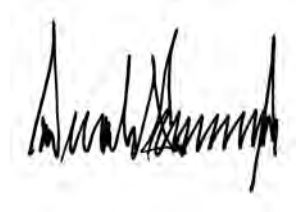
Sec. 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", is located in the upper right quadrant of the page. The signature is stylized with a large, prominent 'D' and 'T'.

THE WHITE HOUSE,
January 20, 2025.

EXHIBIT F

Presidential Documents

Executive Order 14182 of January 24, 2025

Enforcing the Hyde Amendment

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. *Purpose and Policy.* For nearly five decades, the Congress has annually enacted the Hyde Amendment and similar laws that prevent Federal funding of elective abortion, reflecting a longstanding consensus that American taxpayers should not be forced to pay for that practice. However, the previous administration disregarded this established, commonsense policy by embedding forced taxpayer funding of elective abortions in a wide variety of Federal programs.

It is the policy of the United States, consistent with the Hyde Amendment, to end the forced use of Federal taxpayer dollars to fund or promote elective abortion.

Sec. 2. *Revocation of Orders and Actions.* The following Executive Orders are hereby revoked:

(a) Executive Order 14076 of July 8, 2022; and

(b) Executive Order 14079 of August 3, 2022.

Sec. 3. *Implementation.* The Director of the Office of Management and Budget shall promulgate guidance to the heads of executive departments and agencies related to implementation of sections 1 and 2 of this order.

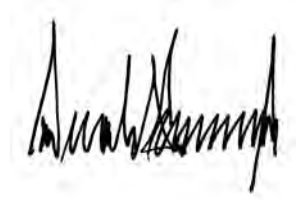
Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", is located in the upper right quadrant of the page. The signature is stylized with a large, prominent 'D' and 'T'.

THE WHITE HOUSE,
January 24, 2025.

EXHIBIT G

Presidential Documents

Executive Order 14332 of August 7, 2025

Improving Oversight of Federal Grantmaking

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to improve the process of Federal grantmaking while ending offensive waste of tax dollars, it is hereby ordered:

Section 1. Purpose. Every tax dollar the Government spends should improve American lives or advance American interests. This often does not happen. Federal grants have funded drag shows in Ecuador, trained doctoral candidates in critical race theory, and developed transgender-sexual-education programs. In 2024, one study claimed that more than one-quarter of new National Science Foundation (NSF) grants went to diversity, equity, and inclusion and other far-left initiatives. These NSF grants included those to educators that promoted Marxism, class warfare propaganda, and other anti-American ideologies in the classroom, masked as rigorous and thoughtful investigation.

The harm imposed by problematic Federal grants does not stop at propagating absurd ideologies. An unsafe lab in Wuhan, China—likely the source of the COVID-19 pandemic—engaged in gain-of-function research funded by the National Institutes of Health. The NSF gave millions to develop AI-powered social media censorship tools—a direct assault on free speech. Taxpayer-funded grants have also gone to non-governmental organizations that provided free services to illegal immigrants, worsening the border crisis and compromising our safety, and to organizations that actively worked against American interests abroad.

Even for projects receiving Federal funds that serve an ostensibly beneficial purpose, the Government has paid insufficient attention to their efficacy. For example, a significant proportion of the results of federally funded scientific research projects cannot be reproduced by external researchers. Even at Harvard and Stanford, once considered among America's most prestigious universities, senior researchers have resigned following accusations of data falsification. A substantial portion of many Federal grants for university-led research goes not to scientific project applicants or groundbreaking research, but to university facilities and administrative costs.

The grant review process itself also undermines the interests of American taxpayers. Writing effective grant applications is notoriously complex, and grant applicants that can afford legal and technical experts are more likely to receive funds—which can then further support these non-mission functions. In addition, there is insufficient interagency coordination and review by relevant subject matter experts to reduce duplication. As a result, the best proposals do not always receive funding, and there is too much unfocused research of marginal social utility.

In short, there is a strong need to strengthen oversight and coordination of, and to streamline, agency grantmaking to address these problems, prevent them from recurring, and ensure greater accountability for use of public funds more broadly. The Government holds tax revenue in trust for the American people, and agencies should treat it accordingly.

Sec. 2. Definitions. For purposes of this order:

(a) The term “agency” has the meaning given to it in section 551 of title 5, United States Code, except that such term includes only agencies that have the statutory authority to award, offer, or manage Federal grants

and does not include the Executive Office of the President or any components thereof.

(b) The term “agency head” means the highest-ranking official or officials of an agency, such as the Secretary, Administrator, Chairman, Director, Commissioners, or Board of Directors, unless otherwise specified in this order.

(c) The term “Director” means the Director of the Office of Management and Budget (OMB).

(d) The term “discretionary award” or “discretionary grant” means a grant that is a “discretionary award” as that term is defined in 2 CFR 200.1. It does not include programs where legislation establishes an entitlement to the funds on the part of the recipient, such as block grants; those awarded based on a statutory formula; or disaster recovery grants.

(e) The term “funding opportunity announcement” means a “notice of funding opportunity” as defined in 2 CFR 200.1, as it pertains to a discretionary award.

(f) The term “grant” means any “grant agreement or grant” as defined in 2 CFR 200.1, “cooperative agreement” as defined in 2 CFR 200.1, or similar award of financial assistance, including foreign assistance awards.

(g) The term “regulation” means an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the procedure or practice requirements of an agency, including, without limitation, regulations, interpretative rules, and statements of policy.

(h) The term “senior appointee” means an individual appointed by the President, a non-career member of the Senior Executive Service, or an employee encumbering a Senior Level, Scientific and Professional, or Grade 15 position in Schedule C of the excepted service.

Sec. 3. Strengthening Accountability for Agency Grantmaking. (a) Each agency head shall promptly designate a senior appointee who shall be responsible for creating a process to review new funding opportunity announcements and to review discretionary grants to ensure that they are consistent with agency priorities and the national interest. For the avoidance of doubt, this process shall not guarantee any particular level of review or consideration to funding applicants except as consistent with applicable law. As consistent with applicable law, this review process shall incorporate, at a minimum:

(i) review and approval of agency funding opportunity announcements by one or more senior appointees or their designees;

(ii) continuation of existing coordination with OMB;

(iii) to the extent appropriate to the subject matter of the announcements, review by designated subject-matter experts as identified by the agency head or the agency head’s designee;

(iv) review of funding opportunity announcements and related forms to ensure that they include only such requirements as are necessary for an adequate evaluation of the application and are written in plain language with a goal of minimizing the need for legal or technical expertise in drafting an application;

(v) interagency coordination to determine whether the subject matter of a particular funding opportunity announcement has already been addressed by another agency announcement and, if so, whether one of the announcements should be modified or withdrawn to promote consistency and eliminate redundancy;

(vi) for scientific research discretionary grants, review by at least one subject matter expert in the field of the application, who may be a member of the grant review panel, the program officer, or an outside expert; and

(vii) pre-issuance review of discretionary awards to ensure that the awards are consistent with applicable law, agency priorities, and the national

interest, which shall involve in-person or virtual discussion of applications by grant review panels or program offices with a senior appointee or that appointee's designee.

(b) Agency heads shall designate one or more senior appointees to review discretionary awards on an annual basis for consistency with agency priorities and substantial progress. Such review shall include an accountability mechanism for officials responsible for selection and granting of the awards.

(c) Until such time as the process specified in subsection (a) of this section is in place, agencies shall not issue any new funding opportunity announcements without prior approval from the senior appointee designated under subsection (a) of this section, except as required by law.

Sec. 4. Considerations for Discretionary Awards. (a) Senior appointees and their designees shall not ministerially ratify or routinely defer to the recommendations of others in reviewing funding opportunity announcements or discretionary awards, but shall instead use their independent judgment.

(b) In reviewing and approving funding opportunity announcements and discretionary awards, as well as in designing the review process described in section 3(a) of this order, senior appointees and their designees shall, as relevant and to the extent consistent with applicable law, apply the following principles, including in any scoring rubrics used to assess grant proposals:

(i) Discretionary awards must, where applicable, demonstrably advance the President's policy priorities.

(ii) Discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate:

(A) racial preferences or other forms of racial discrimination by the grant recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation;

(B) denial by the grant recipient of the sex binary in humans or the notion that sex is a chosen or mutable characteristic;

(C) illegal immigration; or

(D) any other initiatives that compromise public safety or promote anti-American values.

(iii) All else being equal, preference for discretionary awards should be given to institutions with lower indirect cost rates.

(iv) Discretionary grants should be given to a broad range of recipients rather than to a select group of repeat players. Research grants should be awarded to a mix of recipients likely to produce immediately demonstrable results and recipients with the potential for potentially longer-term, breakthrough results, in a manner consistent with the funding opportunity announcement.

(v) Applicants should commit to complying with administration policies, procedures, and guidance respecting Gold Standard Science.

(vi) Discretionary awards should include clear benchmarks for measuring success and progress towards relevant goals and, as relevant for awards pertaining to scientific research, a commitment to achieving Gold Standard Science.

(vii) To the extent institutional affiliation is considered in making discretionary awards, agencies should prioritize an institution's commitment to rigorous, reproducible scholarship over its historical reputation or perceived prestige. As to science grants, agencies should prioritize institutions that have demonstrated success in implementing Gold Standard Science.

(c) Nothing in this order shall be construed to discourage or prevent the use of peer review methods to evaluate proposals for discretionary awards or otherwise inform agency decision making, provided that peer review recommendations remain advisory and are not ministerially ratified,

routinely deferred to, or otherwise treated as de facto binding by senior appointees or their designees. Further, nothing in this order shall be construed to create any rights to any particular level of review or consideration for any funding applicant except as consistent with applicable law.

Sec. 5. *Revisions to the Uniform Guidance.* (a) The Director shall revise the Uniform Guidance and other relevant guidance to streamline application requirements and to further clarify and require all discretionary grants to permit termination for convenience, including when the award no longer advances agency priorities or the national interest, but subject to appropriate exceptions, including agreements entered into in furtherance of international trade agreements or those awarded by the Department of Commerce under title XCIX of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116–283), the CHIPS Act of 2022 (Public Law 117–167), or division F of the Infrastructure Investment and Jobs Act (Public Law 117–58).

(b) The Director shall further revise the Uniform Guidance and other relevant guidance to appropriately limit the use of discretionary grant funds for costs related to facilities and administration.

Sec. 6. *Implementation and Termination Clauses.* (a) Within 30 days of the date of this order, each agency head shall review the agency's standard grant terms and conditions and submit a report to the Director detailing:

(i) whether the agency's standard terms and conditions for discretionary awards permit termination for convenience and include the termination provisions described in 2 CFR 200.340(a), including the provisions that an award may be terminated by the agency "if an award no longer effectuates the program goals or agency priorities" or, in the case of a partial termination by the recipient, if the agency "determines that the remaining portion of the Federal award will not accomplish the purposes for which the Federal award was made";

(ii) whether the agency's standard terms and conditions for discretionary foreign assistance awards permit termination based on the national interest; and

(iii) the approximate number of active discretionary awards at the agency, as well as the approximate percentage of funding obligated under those awards that contains termination provisions allowing for termination under the circumstances described in subsection (i) of this section.

(b) Each agency head shall, to the maximum extent permitted by law and consistent with relevant Executive Orders or other Presidential directives, take steps to revise the terms and conditions of existing discretionary grants to permit immediate termination for convenience, or clarify that such termination is permitted, including if the award no longer advances agency priorities or the national interest. Each agency head shall ensure that such terms are included in all future discretionary grants and likewise shall take steps to revise all applicable regulations binding on or incorporated in discretionary grant terms and conditions to require such terms. Agency heads shall take action to incorporate these new terms and conditions into all future amendments to grant awards.

(c) To the extent practicable and consistent with applicable law, agency heads shall insert in future discretionary grant agreements terms and conditions that:

(i) prohibit recipients from directly drawing down general grant funds for specific projects without the affirmative authorization of the agency; and

(ii) require grantees to provide written explanations or support, with specificity, for requests for each drawdown.

Sec. 7. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of its provisions to any other persons or circumstances shall not be affected thereby.

(e) The costs for publication of this order shall be borne by the Office of Management and Budget.



THE WHITE HOUSE,
August 7, 2025.



February 19, 2025

Defining Sex:

Guidance for Federal Agencies, External Partners, and the Public Implementing Executive Order 14168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*

Background

President Donald Trump issued Executive Order 14168 on January 20, 2025, entitled “Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,” which directs the Department of Health and Human Service (the Department) to promulgate clear guidance to the U.S. Government, external partners, and the public, expanding on the sex-based definitions set forth in the Executive Order.

Defining Sex

There are only two sexes, female and male, because there are only two types of gametes. An individual human is either female or male based on whether the person is of the sex characterized by a reproductive system with the biological function of producing eggs (ova) or sperm.

The sex of a human, female or male, is determined genetically at conception (fertilization), and is observable before birth. Having the biological function to produce eggs or sperm does not require that eggs or sperm are ever produced. Some females or males may not or may no longer produce eggs or sperm due to factors such as age, congenital disorders or other developmental conditions, injury, or medical conditions that cause infertility.

A person’s sex is unchangeable and determined by objective biology. The use of hormones or surgical interventions do not change a person’s sex because such actions do not change the type of gamete that the person’s reproductive system has the biological function to produce. Rare disorders of sexual development do not constitute a third sex because these disorders do not lead to the production of a third gamete. That is, the reproductive system of a person with such a disorder does not produce gametes other than eggs or sperm.

The Department has long recognized that the biological differences between females and males require sex-specific practices in medicine and research to ensure optimal health outcomes and rigorous research, including by considering sex as a biological variable.

Recognizing the immutable and biological nature of sex is essential to ensure the protection of women’s health, safety, private spaces, sports, and opportunities. Restoring biological truth to the Federal government is critical to scientific inquiry, public safety, morale, and trust in government itself. Accordingly, the Department promulgates the following definitions:

Definitions

Sex is a person's immutable biological classification as either male or female.

Female is a person of the sex characterized by a reproductive system with the biological function of producing eggs (ova).

Male is a person of the sex characterized by a reproductive system with the biological function of producing sperm.

Woman is an adult human female.

Girl is a minor human female.

Man is an adult human male.

Boy is a minor human male.

Mother is a female parent.

Father is a male parent.

HHS Grants Policy Statement

DEPARTMENT OF HEALTH & HUMAN SERVICES

Effective date: October 1, 2025

This HHS Grants Policy Statement (GPS) replaces all prior versions.

Contact hhsgrantspolicy@hhs.gov with GPS feedback.



Table of Contents

Version 2.0: Outline of changes from previous Version 1.0	4
Chapter 1: Introduction and General Information	5
1.1: Supersession	5
1.2: Applicability	5
1.3: Requirements	6
1.4: Terms and Conditions	7
1.5: Types of HHS Awards	7
1.6: Award Instruments	7
1.7: Roles and Responsibilities	8
Chapter 2: Pre-Award	9
2.1: Locating Funding Opportunities	9
2.2: Preparing to Apply	10
2.3: HHS Application Process	12
2.4: Applying	19
2.5: Application Receipt and Review	20
2.6: The Notice of Award	22
Chapter 3: Post-Award	25
3.1: Changes to Awards	25
3.2: Financial Management	32
3.3: Procurement Management	42
3.4: Management of Property and Equipment	47
3.5: Oversight and Monitoring	58
3.6: Remedies for Noncompliance	63
3.7: Closeout	65
3.8: Post-Closeout	66
3.9: Appeals	68
Chapter 4: Single Audit	69
4.1: Audit Requirements	69
4.2: Types of Audits	69
4.3: Audit Options	69
4.4: Recipient Responsibilities	70



4.5: Audit Findings and Resolution	70
4.6: Report Submission	71
4.7: HHS Office of Inspector General.....	71
4.8: Additional Information	72
Appendix A: Agencies Overview	73
Appendix B: Acronyms and Glossary.....	76
B.1: Acronyms	76
B.2: Glossary.....	77
Appendix C: Post-Award Considerations by Type of Program, Activity, or Recipient.....	88
C.1: Services Provided by Affiliated Organizations	88
C.2: Data Sharing for Research and Demonstration Projects Considerations	88
C.3: Conference Awards	89
C.4: Construction and Modernization of Facilities Awards.....	90
C.5: Foreign Organizations, International Organizations, and Domestic Recipients with Foreign Components.....	95
C.6: Federal Institutions and Payments to or on Behalf of Federal Employees Under Awards.....	97
C.7: For-Profit Organizations.....	97
C.8: Small Business Innovation Research and Small Business Technology Transfer Programs	99
C.9: Research Awards.....	106
Appendix D: HHS Administrative and National Policy Requirements	110
D.1: HHS Administrative and National Policy Requirements	110
D.2: Uniform Administrative Requirements.....	112
D.3: Financial Assistance General Certifications and Representations	112
D.4: Laws and Policies.....	112
D.5: Supplemental Information.....	123
Appendix E: Financial Assistance General Certifications and Representations	131



Version 2.0: Outline of changes from previous Version 1.0

Version 2.0 of the Health and Human Services (HHS) Grants Policy Statement (GPS), effective October 01, 2025, supersedes previous versions of the HHS GPS.

On October 1, 2025, HHS adopts [2 CFR 200](#) with HHS-specific modifications at [2 CFR 300](#). This version of the HHS GPS removes all references to 45 CFR 75 and updates these references to reflect new requirements in 2 CFR 200 and 300.

Version 2.0 includes the following updates:

- All references to 45 CFR 75 were updated to new regulations at [2 CFR 200](#) and [2 CFR 300](#).
 - Changes to reflect the transition to 2 CFR 200 in this version of the GPS include, but are not limited to:
 - Updated acronyms, terminology, and definitions to align with [2 CFR 200](#).
 - For example, this version updates terminology to change “awarding agency” to “agency,” changes “match” to “cost share,” etc.
 - Updated citations, which include additional detail in some sections, such as those related to cost sharing, personal property, closeout costs, and termination.
 - Included new HHS specific modifications, such as Appendix IX covering Hospital Cost Principals, HHS conflict of interest policies, and special provisions to states and commercial organizations.
 - Updated prior approval requirements to align with those outlined in [2 CFR 200.308](#).
- Other changes not related to 2 CFR 200 include:
 - Chapter 2.5.4.3 includes a Title IX certification requirement and updated non-discrimination language.
 - Chapter C.8.10.3 includes updates to SBIR/STTR data rights language.
 - General updates to Appendix D: Administrative and National Policy Requirements.
- Minor plain language changes to grammar, syntax, and consistency in citations and links.

NOTE: A technical edit to this GPS was published on 12/18/2025. This edit added active links to 2 CFR 300 throughout the document and made a technical correction to language in Section 2.3.4.8. The effective date of this technical edit is October 1st, 2025, consistent with the rest of the GPS.



Chapter 1: Introduction and General Information

The Grants Policy Statement (GPS) is incorporated by reference in the official Notice of Award (NoA) as a standard term and condition.

The GPS provides information on HHS agencies that make awards, the award process, and where to find and apply for awards. The GPS also provides information about the legal and regulatory rules that apply to your award and will be used for enforcement purposes. The GPS will be updated to reflect changes in law and policy.

The latest version of the GPS is on [the HHS Grant Policies and Regulations Webpage](#) and it includes:

- Introduction and General Information
- Pre-Award
- Post-Award
- Single Audit
- Appendices
 - Agencies Overview
 - Acronyms and Glossary
 - Post-Award Considerations by Type of Program, Activity, or Recipient
 - HHS Administrative and National Policy Requirements
 - Financial Assistance General Certifications and Representations

1.1: Supersession

This GPS replaces the HHS Grants Policy Statement dated April 2025. It reflects the current [2 CFR 200](#) and HHS specific provisions at [2 CFR 300](#) regulations, effective on October 1, 2025.

From this date on, HHS plans to update the GPS annually to make sure it reflects changes in statutes, regulations, and policies.

1.2: Applicability

The HHS GPS Version 2.0 applies to awards and award modifications that add funding made on or after October 01, 2025. This includes supplements to award, competing and non-competing continuations. The GPS applies to all HHS discretionary recipients, except for NIH, and the requirements flow down to subrecipients.

The HHS GPS does not apply to awards made by the National Institutes of Health (NIH). For NIH awards, please see the [National Institutes of Health Grants Policy Statement \(NIH GPS\)](#), which is the policy document describing the requirements that serve as the terms and conditions of NIH awards.

Other than Appendix D, HHS Administrative and National Requirements, the HHS GPS does not apply to non-discretionary awards. It does not apply to awards made to individuals. HHS agencies have the



discretion to apply certain parts of the GPS to non-discretionary awards and other policies to your non-discretionary or individual award.

Agencies that administer HHS awards include:

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Assistant Secretary for Planning and Evaluation (ASPE)
- Assistant Secretary for Preparedness and Response (ASPR)
- Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Inspector General (OIG)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

See [Appendix A](#) for more information.

1.3: Requirements

The following impose requirements on your award and are addressed in the GPS:

- The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at [2 CFR 200](#)
- HHS-Specific Modifications to the Uniform Administrative Requirements at [2 CFR 300](#)
- The Notice of Award (NoA)
- The Notice of Funding Opportunity (NOFO), if stated in the NOA

Other regulations or statutes with more requirements might apply to your award. These include:

- Grants for Research Projects [42 CFR 52](#)



- Procedures of the Departmental Grant Appeals Board [45 CFR 16](#)
- Claims Collection [45 CFR 30](#)
- Equal Treatment for Faith-Based Organizations [45 CFR 87](#)
- Restrictions on Lobbying [45 CFR 93](#)
- Metric Conversion Policy for Federal Agencies [15 CFR 273](#)
- Public Health Service Policies on Research Misconduct [42 CFR 93](#)
- Protection of Human Subjects, [45 CFR 46](#)

See [Appendix D](#) for more information.

1.4: Terms and Conditions

HHS states the requirements of an award in the award terms and conditions:

- The GPS is incorporated by reference as a standard term and condition of awards.
- The NoA includes all terms and conditions of a specific award.
- Notice of Funding Opportunities (NOFOs) describe program requirements, which may be included as terms and conditions.

1.5: Types of HHS Awards

Awards fall into two main types:

- Discretionary: HHS chooses who gets the award and how much. Selection of these awards are generally competitive. The amount of an award can be competitive or by a set formula. Types of discretionary awards include research, training, services, construction, and conference support.
- Non-discretionary: A statute determines the recipients and amounts, either directly or by a formula (i.e., each State gets an award of a certain amount). This includes block grants and entitlement programs.

1.6: Award Instruments

Award instruments are legal agreements between an agency and a recipient. The two kinds addressed in the GPS are:

- Grants: The agency is not substantially involved in the project ([31 USC 6302, 6304](#)).
- Cooperative agreements: The agency is substantially involved in the project ([31 USC 6302, 6305](#)).



1.7: Roles and Responsibilities

This section highlights roles and responsibilities. The GPS supplies more details throughout.

1.7.1: Recipient Roles and Responsibilities

Recipients manage performance and funds. Required roles are:

- **Authorized Organizational Representative (AOR):** The AOR has authority to act for the organization and is responsible for meeting award requirements, properly managing the award, and providing oversight. The AOR's signature on a grant application guarantees that the information in the application is correct and the organization is responsible for following all requirements.
- **Principal Investigator or Project Director (PI/PD):** The PI/PD is the individual(s) designated by the recipient to direct the project or program being supported by the award. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity.

1.7.2: Agency Roles and Responsibilities

HHS is responsible to Congress and U.S taxpayers for carrying out its mission in a cost-effective and compliant way. The HHS agencies that administer awards have grants offices and staff designated to conduct this work. The roles and responsibilities of HHS staff (at each agency) include:

- **Grants Management Officer (GMO):** The GMO is the official who handles the non- program parts of an award for the HHS agency. The GMO is the focal point for receiving and acting on requests for prior approval or for changes in the terms and conditions of award. The GMO is the only official authorized to obligate the HHS agency to the expenditure of federal funds or to change the funding, duration, or other terms and conditions of an award.
- **Grants Management Specialist (GMS):** Acts as the main grants administration contact for recipients. Handles administrative activities on behalf of the GMO. The GMS contact information can be found on the NoA.
- **Project Officer or Program Official (PO):** Responsible for the programmatic, scientific, and technical sides of award programs, including oversight and monitoring. The PO contact information can be found on the NoA.
- **Review Administrator (RA):** Provides oversight of the application review process, although not all agencies have this role.



Chapter 2: Pre-Award

This section helps you find funding opportunities, prepare, and apply.

2.1: Locating Funding Opportunities

Agencies announce competitive funding opportunities. All discretionary Notice of Funding Opportunities are listed on [Grants.gov](https://www.grants.gov). There are three other ways to find more information about HHS financial assistance.

2.1.1: Grants.gov, Forecasts, and the Notice of Funding Opportunity (NOFO)

HHS policy requires maximum competition for discretionary grants to the greatest extent possible. As such, HHS agencies promote the widest and earliest possible spread of information through forecasts of upcoming grant opportunities and NOFOs. Agencies post discretionary or competitive NOFOs at [Grants.gov](https://www.grants.gov).

[Grants.gov](https://www.grants.gov) is the direct way to find NOFOs. NOFOs are usually open for at least 60 days. Only rarely are they open for fewer than 30 days.

Because HHS aims for the widest and earliest possible spread of information, HHS agencies post future opportunities on Grants.gov through forecasts. Forecasts may be posted weeks or months before NOFOs. Forecasted NOFOs can be found in the [Grants.gov](https://www.grants.gov) search page by clicking the “forecasted” button. Forecasts include helpful information such as:

- expected number of awards
- estimated award amounts
- description of the program
- estimated NOFO posting date
- estimated application due date
- estimated project start date and period of performance

2.1.1.1: How to Subscribe to HHS Grants Forecast

When you create a Grants.gov account, you can customize the type of email notifications you receive. Log in and then go to [the subscription page](#) to sign up for news updates about system enhancements, notifications about saved searches, new funding opportunities, and more.

2.1.2: Agency Websites

Most agencies have award web pages. See [Appendix A](#).

2.1.3: SAM.gov and Assistance Listings

Assistance listings are public descriptions of federal assistance programs. All assistance listings are included on the System for Award Management (SAM.gov), a site run by the U.S. General Services Administration. Search assistance listings at [SAM.gov](https://www.sam.gov).



2.2: Preparing to Apply

The first step is to read the entire NOFO and the links in it. Each part of the NOFO sets out basic information for that award.

To apply, you must:

- be an eligible entity
- address the NOFO requirements
- submit a complete and compliant application by the deadline(s)

2.2.1: General Eligibility Considerations

In general, HHS awards may be made to domestic public or private, non-profit or for-profit organizations. Foreign or international organizations are eligible for research awards, or if expressly authorized by law.

The NOFO includes specific eligibility criteria and any requirements to prove eligibility. Applicant eligibility criteria for all HHS NOFOs are almost always based on statute or program regulation.

HHS policy requires open competition to the greatest extent possible. Restricting eligibility, as compared to statute or program regulations, is only done with appropriate justification in rare cases.

Agencies review applications for eligibility when they receive them. The AOR signature generally serves as assurance of eligibility, unless additional proof of eligibility is required in the NOFO. If the applicant is not eligible, the application will not be reviewed.

2.2.2: Additional Eligibility Restrictions

2.2.2.1: Concurrent Applications

You cannot apply for funding for the same project or activities from multiple HHS Public Health Service (PHS) agencies at the same time. If you do, your applications will be returned. See [Appendix A](#) for a list of PHS agencies.

2.2.2.2: Suspension, Debarment, and Exclusion

Agencies are required to check [SAM.gov](https://www.sam.gov) for individuals and organizations that are debarred, suspended, declared ineligible, or voluntarily excluded from receiving HHS award funds. HHS will not give awards to or pay these individuals and entities, including as recipients and subrecipients. If such an individual is involved in an award, costs like their salary are not allowed.

Applicants must disclose if any of the following conditions apply to their organization, planned staff or principals (as defined in [2 CFR 180.995](#)), including Principal Investigators (PIs), and other key personnel:

- Are currently excluded or disqualified.
- Were convicted within the previous three years of any offenses listed in [2 CFR 180.800\(a\)](#) or had a civil judgment for one of those offenses during that time.



- Are currently indicted for or otherwise facing criminal or civil charges by a governmental entity (federal, state, or local) for any of the offenses listed in [2 CFR 180.800\(a\)](#).
- Have had any public transactions (federal, state, or local) terminated within the previous three years for cause or default.

Recipients of HHS awards must also make subrecipient organizations and subrecipient participants follow federal Debarment and Suspension regulations ([2 CFR 376](#) and [2 CFR 180](#)). These participants can include:

- Consortia
- Subcontracts
- Consultants
- Collaborators
- Contractors that require the provision of goods or services that will equal or exceed
- \$25,000

These subrecipients must also make sure that anyone they hire with award funds follow the same rules. Before entering into an agreement, these participants should tell the award recipient if he, she, or any principals are excluded or disqualified at that time.

Ultimately, it is the job of the applicant or recipient to make sure none of the subrecipient and principals involved are excluded or disqualified. Award recipients cannot make a transaction with someone who is disqualified unless they get an exception under the disqualifying statute, Executive Order, or regulation from HHS.

For more information, see Suspension and Debarment at [2 CFR 200.214](#), [2 CFR 180](#) and [2 CFR part 376](#).

2.2.2.3: Delinquency on Federal Debt

If an entity or individual owes money to the U.S. with a lien, they cannot get an award. Applicants must state in their applications whether they are delinquent on any federal debts. Agencies may delay awards until federal debts are settled.

Do not include a person in the application if they have unpaid federal debts with a lien. Agencies will disallow costs for these individuals.

See [28 U.S.C. 3201\(e\)](#).

2.2.2.4: Lobbying Prohibition

Applicants must certify they will not use federal funds to pay any person to influence agency staff, Congress members, and officers or employees of Congress about federal awards.

Applicants with total proposed costs of more than \$100,000 must certify that they:

- have not made unallowable lobbying payments.
- will be responsible for reporting on non-federal funds used for lobbying.



- will include these requirements in consortium agreements, subawards, and contracts of more than \$100,000 under their award.

See [2 CFR 93](#), [2 CFR 200.450](#), and the [SF-424](#) for more about lobbying requirements.

2.3: HHS Application Process

2.3.1: Types of Applications

HHS uses these application types:

- New application: A request for funds for new activities. It can be competitive or not.
- Non-competing continuation application: A request for funds for the next budget period(s) within a period of performance. Agencies provide an NoA with new budget details.
- Competing continuation or renewal application: A request to continue a project that is ending with a new period of performance. This is competitive.
- Supplemental application: A request for more funds in the current budget period. This can be for changes in the project scope, expansion of already approved activities, or for unexpected costs.
- Revised application: A previously not funded application updated and submitted again for review.

2.3.2: Letters of Intent

Before a full application, an agency might ask for a pre-application or Letter of Intent (LOI).

- Pre-applications: Used to filter out applicants that are ineligible for funding.
- Letters of Intent: Agencies might want notice that you plan to apply. This is usually optional and doesn't mean you have to apply. It's mostly to gauge interest and help the HHS agency estimate how many applications to expect.

2.3.3: Application Forms

Forms and instructions are on [Grants.gov](https://www.grants.gov). You can find a NOFO's required forms in the application package in Grants.gov. The NOFO is your best source when completing forms. The NOFO agency contact, located on the NOFO, can answer any questions you may have.

2.3.4: Application Budgets

You will need to include a budget as part of your application. Some applications require a detailed budget. The NOFO will describe the budget requirements. For HHS budgets, applicants and recipients need to understand:

- The costs allowable under the program



- The relevant cost principles
- The difference between direct and indirect costs
- When you need an indirect cost rate or research patient care cost rate, and
- Any cost sharing requirements

Project costs include allowable direct costs plus allocable indirect costs, minus applicable credits. See below Cost Principles, Direct Costs and Indirect Costs sections of the GPS.

Cost allowability is subject to the governing statute, program regulations, and award terms and conditions. There are situations when HHS will not reimburse indirect costs.

2.3.4.1: Cost Principles

Developing an application budget depends on understanding what costs are allowable under HHS financial assistance programs.

For more information about how cost principles apply to your organization, see [2 CFR 200.401](#).

This section on cost principles interprets the regulations at [2 CFR 200](#) and is not all-inclusive. Cost principles:

- Establish general standards for the allowability of costs
- Provide guidance on treating costs as direct or indirect
- Provide principles for selected items of cost

The cost principles apply to all recipients.

You can use your own accounting system to implement the cost principles if you meet the standards for financial management systems at [2 CFR 200.302](#).

The federal-wide cost principles are in [2 CFR 200, subpart E](#). The cost principles for:

- Hospitals are at [2 CFR 200 Appendix IX](#)
- For-profit organizations are at [48 CFR 31.2](#)

If specifically identified, use the applicable cost principles for your type of organization. Cases where the cost principles do not apply are listed in [2 CFR 200.401\(a\)](#).

2.3.4.2: Is It Allowed?

As the HHS agency official for the non-program parts of awards, the Grants Management Officer (GMO) makes the final determination on allowability. For all allowability requirements, see [2 CFR 200.403](#).



Following is a summary. A cost is allowable if all the following apply:

- It is necessary and reasonable for award performance,
- It complies with any limitations or exclusions in the cost principles or the federal award about types or amounts of cost items,
- It is consistent with policies and procedures across all recipient activities, regardless of source of funding,
- It is consistent across all activities in identifying direct and indirect costs,
- It follows [generally accepted accounting principles \(GAAP\)](#). See [2 CFR 200.403\(e\)](#) for exceptions,
- It is not used for cost-sharing requirements of another federally financed program, unless specifically allowed by law,
- You maintain required documentation, and
- Administrative closeout costs may be charged until the due date of the final report.

2.3.4.3: Is It Reasonable?

For all reasonableness requirements see [2 CFR 200.404](#). Following is a summary.

Considerations for reasonableness include:

- If the cost is generally recognized as ordinary and necessary.
- The requirements of:
 - Sound business practices
 - Arm's-length bargaining
 - Federal, state, local, tribal, and other laws and regulations
 - Terms and conditions of the federal award
- If the cost aligns with market prices for comparable goods or services in the geographic area.
- The cost does not significantly deviate from your established practices and policies regarding such costs, regardless of source of funding.

2.3.4.4: Allocability

Allocability in grants means costs that can be applied to your award. For all allocability requirements see [2 CFR 200.405](#). Following is a summary.

A cost is allocable if any of the following apply:

- It is spent only for the work under a federal award.



- It benefits both the federal award and other recipient work and can be distributed using reasonable methods.
- It is necessary to your overall operations and can be assigned to the federal award.

2.3.4.5: Direct and Indirect Costs

Costs can be direct or indirect:

- Direct costs: Directly related to the cost of the project or project activities. These costs are based on actual expenses or easily estimated accurately. Examples of direct costs are generally salaries, travel, equipment, and supplies directly for grant activities.
- Indirect costs: Not readily tied directly to the project or project activities. If a cost is indirect, it cannot also be listed as a direct cost for any federal award. Examples may be facilities operation and maintenance costs, depreciation, and administrative expenses. You must have or negotiate an indirect cost rate to reimburse indirect costs.

See [2 CFR 200.413-200.414](#), and [2 CFR 300.414](#).

2.3.4.6: Indirect Cost Rates

As stated above, indirect costs are for common activities that cannot be specifically tied to a particular project. Examples include facilities operation and maintenance costs, depreciation, and administrative expenses. You must treat costs as direct or indirect consistently.

Indirect costs are allowable under most HHS awards and are charged as a rate. There are three ways indirect costs may work:

- (1) Specified rate. The rate may be specified in statute, regulations, or policy. If this is so, the difference between the specified rate and the negotiated rate can satisfy cost sharing requirements. There are two HHS-specific specified rates to consider:
 - Training grants, including career awards, are limited to 8%.
 - Indirect costs to foreign organizations and foreign public entities when the awarded work is performed fully outside of the territorial limits of the U.S. are limited to 8%.
- (2) Negotiated Indirect Cost Rate Agreement (NICRA). You can negotiate a rate with your cognizant federal agency. If the cognizant agency is HHS, a rate is negotiated by [Program Support Center Cost Allocation Services \(CAS\)](#) or the [Division of Financial Advisory Services \(DFAS\)](#) in the NIH Office of Acquisition Management and Policy (responsible for negotiating indirect cost rates for for-profit recipients). Indirect cost proposals must use the applicable cost principles and cognizant agency guidance.
 - See [2 CFR 200 Appendix III](#) for institutions of higher education
 - See [2 CFR 200 Appendix IV](#) for non-profits
 - See [2 CFR 200 Appendix V](#) for state and local government cost allocation plans
 - See [2 CFR 200 Appendix VI](#) for public assistance



- See [2 CFR 200 Appendix VII](#) for states and local governments and Indian Tribe indirect cost proposals
- (3) De minimis rate. If you do not have a NICRA or other specified indirect cost rate, you can use the de minimis rate indefinitely. We are applying the newly revised rate, in [2 CFR 200.414\(f\)](#), of 15% of modified direct costs. Modified direct costs are salaries and wages, fringe benefits, materials and supplies, services, travel, and no more than \$50,000 of each subaward, minus some exclusions. See [2 CFR 200.12](#) for the full definition. See [2 CFR 200.414](#) for more on the de minimis rate.

The de minimis rate is not applicable for some recipients. These recipients include governmental agencies that receive more than \$35 million in direct funding and Indian tribal governments. See [2 CFR part 200 Appendix VII \(D\)\(1\)\(b\)](#).

2.3.4.6.1: Exclusions

Some HHS awards and recipients are not eligible for indirect cost reimbursement. This will be described in the NOFO.

Indirect costs are not paid for grants to federal institutions, [2 CFR 300.219\(b\)\(3\)](#).

2.3.4.7: Pass-through Entities

Pass-through entities must use their subrecipient's federal NICRA. A 15% de minimis rate may be used if there is no federally negotiated agreement. See [2 CFR 200.414](#).

2.3.4.8: Salary Rate Limit (SRL)

Generally, the HHS Appropriations Act includes an SRL. This statutory requirement limits the amount of funds under a grant or other extramural mechanism that can be used to pay individual salaries (including executive salaries) at a rate above the Executive Level II. Recipients may pay salaries at a rate higher than the Executive Level II if the amount beyond the HHS SRL is paid with non-HHS funds. Since the Executive Level II rate and HHS Appropriations Act citation changes each year, HHS refers to the Office of Personnel Management (OPM) posting the most recent information at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/exec/html/EX.aspx>.

The HHS SRL applies to:

- Awards funded by the HHS section of the annual Appropriations Act (most HHS awards)
- Both direct and indirect costs under applicable HHS awards

Effective October 1, 2024, when HHS is the cognizant agency for indirect costs or when HHS is acting as the shared-service provider for another cognizant agency for indirect costs, the HHS component that reviews and negotiates indirect cost rate proposals and cost allocation plans will issue NICRAs that



incorporate the HHS SRL, to comply with the HHS Appropriations Act requirement.

Beginning with HHS awards, including continuation and supplemental awards, made on or after October 1, 2024, HHS recipients that do not have an approved indirect cost rate that complies with the HHS SRL requirement must take and document the following actions:

- Identify any HHS award where HHS funds are used to pay any salary that exceeds the SRL using the HHS award. This includes both direct and indirect costs, both in whole and any portion of a salary that at a full-time equivalent exceeds the SRL.
- Have written policies and procedures that ensure the recipient does not draw down HHS award funds, whether as direct or indirect costs, to pay for salaries above the HHS SRL.

This may occur because the NICRA was issued before October 1, 2024, and it is not yet up for renewal, OR because the NICRA was issued by another cognizant agency for indirect costs that does not have an identical SRL.

A recipient may request a companion rate on the NICRA from HHS that does not incorporate the HHS SRL if:

- HHS is their cognizant agency for indirect costs or HHS is the shared-service provider for their cognizant agency for indirect costs; and
- The recipient is applying for an award from another Federal agency or from a program not subject to the HHS SRL.

2.3.4.9: Cost Sharing

Cost sharing refers to project costs that are not funded by the HHS agency. It is also sometimes called “match.”

Cost sharing can be voluntary or can be required by statute or regulation.

NOFOs include information about:

- Whether there is required or voluntary cost sharing
- The agency's approach to looking at cost sharing during the application review
- Any caps on the agency's portion of total award costs
- Any restrictions on the types of funding that are acceptable as cost-sharing (e.g., in-kind contributions)
- Required documents, like commitment letters See more on cost-sharing requirements at [2 CFR 200.306](#).

2.3.4.9.1: Cost Sharing Waiver for the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands

HHS waives all requirements for local matching funds under \$200,000 for grants to the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands, unless



otherwise directed by any other provision of law.

For local matching funds \$200,000 and greater, HHS agencies may waive the matching requirement for awards to these four areas.

HHS agencies may choose to waive matching funds of any amount for any grants to the Trust Territory of the Pacific Islands.

See 48 U.S.C. 1469a(d) and 48 U.S.C. 1469a(d) note ([Public Law 96-205, title VI, section 601](#)).

2.3.4.10: Program Income and Third-Party Reimbursement

Program income is money a recipient earns that is both:

- Earned during the period of performance
- Earned directly from an activity funded by the award or due to the award

This can include money earned from things like:

- Services performed under the award
- Renting property bought with award funds
- Selling items made with award funds
- Principal and interest on loans made with award funds
- Royalties from patents and copyrights

It does not include:

- Interest earned on advances of Federal funds or things like rebates, credits, discounts, and interest earned on any of them unless stated otherwise in the NOFO or NoA.

The full definition for program income is found at [2 CFR 200.1 “Program Income”](#).

In addition to being encouraged to earn income to defray program costs when appropriate, program income must be used for the original purpose of your award.

NOFOs might ask for estimated program income in the budget. NOFOs explain how to use expected program income.

There are no requirements for what to do with income earned after the end of the award period of performance, unless the NOFO or NoA says otherwise.

See more on the treatment of program income at [2 CFR 200.307](#), [2 CFR 300.218](#), and [2 CFR 300.219](#).

2.3.5: Unique Entity Identifier (UEI) and registering in SAM.gov

Every applicant needs a Unique Entity ID (UEI) from [SAM.gov](#).



- For a new UEI, register on SAM.gov. You'll get an email when it's active. This can take time.
- If you already have a UEI, renew on SAM.gov yearly.
- Keep your SAM registration details current.
- Make sure that your SAM registration is accurate for both contracts and grants.

For more information, see [Get Ready for Grants Management](#) at HHS.gov.

2.3.6: State and Local Review Requirements

Federal rules allow state and local governments and health agencies to review and comment on applications. You will find the requirements in the NOFO. There are two types of reviews:

- Intergovernmental review. [Executive Order 12372](#) and [45 CFR 100](#) allow for intergovernmental review by state and local governments through the State Single Point of Contact (SPOC).
- Public health system reporting. This reporting provides state and local health agencies with information on applications by health care delivery programs. If a state or local health official wants to review a full application, the official contacts the SPOC.

Contact your SPOC to learn more. Find SPOCs at on the [HHS Grants Policies and Regulations webpage](#) under [HHS Intergovernmental Review](#) . Not all states have this process.

2.4: Applying

In almost all cases, you will need to submit applications online. All HHS agencies are required to post their competitive NOFOs on Grants.gov and will also post there how to apply online.

Agencies will not review applications that are from ineligible applicants, incomplete, are not compliant, or are not responsive to program requirements.

Send your application by the NOFO's deadline. If you are late, it will almost always be deemed non-compliant and will not be reviewed.

The AOR's signature on an application certifies that:

- The information in it is truthful, complete, and accurate.
- The applicant will comply with all required certifications and assurances.
- The applicant will comply with terms and conditions when accepting an award; and
- The non-federal entity is aware that any false, fictitious, or fraudulent statements or claims may subject the applicant to criminal, civil, or administrative penalties.

Some agencies might allow paper or email submissions. The NOFO will explain exemption requests. These are rare.



PLEASE NOTE: Applicants must register with Grants.gov. For how to register with Grants.gov, see [Registering an Organization](#) or contact the Grants.gov contact center at 1-800-518-4726 or support@grants.gov. Registering can take up to one month.

2.5: Application Receipt and Review

2.5.1: Initial Eligibility Review

The agency screens applications for eligibility. Unless the NOFO requires specific proof of eligibility, the AOR's application certification is enough.

2.5.2: Use of Application Information

Agencies protect your application information during merit review and in accordance with laws like the [Freedom of Information Act](#) and [Privacy Act of 1974](#). Once awarded, the government can only use or share data as federal law allows. To help safeguard your information:

- Avoid sharing personally identifiable information
- Only add confidential information if necessary

See GPS section [3.4.11.2 Access to Data and Research Data](#).

2.5.3: Merit Review

Merit review is a review by those with expertise in the programmatic subject matter area for the submitted applications.

Applications for discretionary programs, whether received in response to a NOFO, requested from a single source (very rare), or received as an unsolicited request for grant funding, will go through a merit review. (Please note, HHS does not guarantee unsolicited applications will be accepted. Therefore, they may or may not go through a merit review.)

The merit review provides recommendations to the individuals responsible for making award decisions. Merit review is necessary to make sure HHS chooses applications that best meet the needs of the program. These needs must be based on what the NOFO says about what makes a successful application.

Peer review is a form of merit review. Reviewers are peers with expert knowledge about how the program topic. Sometimes, the program statute may tell us which type of reviewers to pick or how a review should happen.

2.5.4: Award Risk and Business Review

Before award, agencies do pre-award risk and business reviews of applications. These can include:

- Cost analysis of the budget
- Assessment of management systems
- Final review of applicant eligibility



- Compliance with public policy requirements

During this review, the agency might request more details or actions from you.

Following review, officials make decisions about making the award, adding special conditions, and funding level.

2.5.4.1: Cost Analysis

HHS agencies careful review of the applicant budget includes:

- a review of the cost breakdowns
- a check to make sure the cost data in the application is correct
- an overall review of the costs for need for and the reasonableness and allowability of proposed costs

The review depth depends on project complexity, applicant prior experience, and other factors.

2.5.4.2: Management System Analysis

Applicants must have systems, policies, and procedures in place to manage award funds and activities. HHS agency staff take a close look at your financial and business management systems. This review includes property management and procurement systems and helps ensure:

- Applicant organizations apply policies and procedures consistently, regardless of funding source; and
- Systems meet the standards and requirements in [2 CFR 200.302](#), Financial Management.

2.5.4.3: Civil Rights Assurance

Domestic recipients, subrecipients, and contractors must file [Form HHS 690](#), Assurance of Compliance once with the HHS Office for Civil Rights (OCR). It is not needed for each application.

The recipient must ensure that subrecipients and contractors have filed the form.

By applying for or accepting federal funds from HHS, recipients certify compliance with all federal antidiscrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

All recipients subject to Title IX requirements must also adhere to the following term:

By accepting this award, including the obligation, expenditure, or drawdown of award funds, recipient certifies as follows:

- Recipient is compliant with [Title IX of the Education Amendments of 1972](#), as amended, [20 U.S.C. §§ 1681 et seq.](#), including the requirements set forth in [Presidential Executive Order 14168 titled Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal](#)



[Government](#), and [Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d et seq.](#), and recipient will remain compliant for the duration of the Agreement.

- The above requirements are conditions of payment that go to the essence of the Agreement and are therefore material terms of the Agreement.
- Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
- Recipient acknowledges that this certification reflects a change in the government's position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
- Recipient acknowledges that a knowing false statement relating to Recipient's compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the [False Claims Act, 31 U.S.C. § 3729](#), and/or criminal liability, including under [18 U.S.C. §§ 287 and 1001](#)

2.5.4.4: Human Subjects and Animal Welfare Assurance

If IRB review and approval is required but still pending at the time of award, agencies will restrict human subjects research until they get and approve the needed proof. Additional information is available on the [Office of Human Research Protections](#) website. This includes a series of [decision charts](#) to help assess whether an activity is human subjects research covered by the regulation and when an exemption may apply.

Before getting an award, if applicants plan to use vertebrate animals, they must send an [Animal Welfare Assurance](#) to HHS' Office of Laboratory Animal Welfare. This confirms that a committee has reviewed the parts of the application related to animals.

2.5.5: Communicating Decisions

Agencies inform applicants about their decisions in various ways:

- Award: If you are getting an award, you will receive a Notice of Award (NoA).
- Denial: If the agency decides not to fund your application, the AOR gets a letter.
- Approved unfunded: Sometimes, despite a good review, there's not enough funds. The agency could keep your application for future funding. The agency will notify the AOR that your application is approved but unfunded.
- Revised application eligibility: If not successful, the NOFO might allow you to adjust and reapply later. However, some agencies cap the number of revisions and retries.

You cannot appeal a denial, or the amount of funds awarded.

2.6: The Notice of Award

The Notice of Award is a legal instrument. See [2 CFR 200.211](#) for the contents of an NoA.



2.6.1: Accepting the Award

Once accepted, the contents of NoAs are binding.

Applicants become recipients when the NoA is signed by the agency's Chief Grants Management Officer (CGMO) or his/her delegate. The recipient accepts an award by drawing down funds.

HHS expects recipients to draw down funds in the first 30 days of the period of performance. If you fail to draw down funds in a timely manner or justify the delay in your acceptance of the award, HHS may take further action to amend or withdraw your award.

2.6.1.1: Declining or Negotiating Awards

During the time between the NoA being signed and the drawing down of funds, if you can no longer accept an award or need to negotiate any award parts, tell the agency. If no agreement is reached, the agency will cancel the award. You cannot challenge the agency's decisions on the terms and conditions.

2.6.2: Periods of Performance

HHS uses the period of performance system for funding awards. Funding is provided in approved yearly increments called budget periods. The total period of performance includes the initial competitive segment, any additional segments authorized by approved continuation applications, and any no-cost extensions.

A competitive segment usually will be no longer than five years, not including no-cost extensions. A single federal award for the entire period of support may be used if the project is only construction or modernization or if the total planned project will be less than 18 months.

The agency will determine the length of the period of performance based on:

- Any statutory, regulatory, or administrative requirements.
- The length of time requested by the applicant.
- Any time limits on the period of performance recommended by merit review.
- The frequency of merit review.
- The funding principles as specified in the NOFO.

The NoA generally approves a period of performance that goes beyond the current budget period, showing the HHS agency's intention to continue providing support. Funding for future budget periods is not guaranteed at the level shown on the current NoA. There is no legal obligation for HHS agencies to provide funding beyond the end date of the current budget period in the NoA.

Recipients must submit a continuation application or annual report to get approval and funding for each new budget period within the approved period of performance. The HHS agency will make its decision to fund the next budget period by issuing a NoA which shows the new budget period and amount of new funding. Funding is based on adequate performance, availability of funding, and program goals and agency priorities.



Budget periods usually last 12 months. However, they may be shorter or longer based on programmatic or administrative needs. The NoA will show the total approved budget for the applicable budget period. This includes direct costs, applicable indirect costs, and any required cost sharing.

2.6.3: Costs In the NoA

The initial NoA and each subsequent NoA provide details of the award, and the amount awarded. After the initial budget period, NoAs may reflect any authorized carryover and amounts previously awarded for the full period of performance. The amount awarded is shown either as total direct and indirect costs or as a categorical (line item) budget breakdown. This is based on the requirements in the NOFO.

Recipients have certain rebudgeting flexibility within the overall amount awarded. However, the total amount awarded is the maximum amount the agency is obligated to pay under that award. Once an award is made, the HHS agency is not required to provide any supplemental or additional funding.



Chapter 3: Post-Award

As a recipient, you will manage HHS awards and activities including:

- Project performance, [2 CFR 200.301](#) and [2 CFR 200.202](#)
- Use of award funds
- Compliance with award terms and conditions
- Issuing and monitoring subawards per [2 CFR 200.332](#) Recipient internal controls and policies must meet [2 CFR 200.303](#).

Agency staff monitor recipients for compliance, performance, and need for technical assistance. Reviews include:

- Recipient reports
- Financial and progress reports
- Audit reports
- Correspondence
- Onsite and remote site visits
- Other information

The Notice of Award supplies HHS contact information and instructions for reporting.

3.1: Changes to Awards

3.1.1: Prior Approvals

At times, you may need to make changes to the program budget or activities. Some changes require prior written approval. To find out if a change needs prior approval:

- Carefully review your NoA.
- Review [2 CFR 200.407](#) for actions needing prior approval.
- Review Appendix E of the GPS for prior approval requirements for certain types of awards.
- Ask your GMS if you are not sure.
- Ask your cognizant agency for indirect costs if you have questions about changes to indirect costs. The cognizant agency is the federal agency that approved your indirect cost proposal.

3.1.1.1: Seeking Prior Approval

Once you know that you need prior approval, you can request it from your GMS. Prior approval requests must include:

- Recipient name



- Principal investigator (PI) or project director (PD) and authorized organizational representative (AOR) name
- PI or PD and AOR telephone numbers and e-mail addresses

You must send your prior approval requests in writing, by mail, prior approval system, or email. It must:

- Be signed by the AOR (if sent in an email, attach the signed letter/memo)
- Include any necessary supporting documentation
- Get to the agency in enough time for approval before making the change

Once received, the agency GMO or his or her designee will review and approve or deny the request:

- If the GMO or GMS decides the change does not actually require prior approval, the agency must promptly inform you.
- If prior approval is required, the GMS will send a decision to the AOR with a copy to the PI or PD within 30 calendar days of receipt.

Only the GMO or GMS, as the GMO's delegate, can issue written approval. Informal answers are not valid.

There is no appeal for denial of a prior approval request.

If costs or actions that require prior approval are detailed in an application, the award's issuance based on that application serves as the prior approval authorization. For indirect cost components, prior approval must come from the relevant agency or as per the associated cost principles.

3.1.1.2: Subrecipient Prior Approvals

The recipient has the authority to give prior approval for changes to sub-award or contract activities or budget. This does not include any action inconsistent with the award purpose or terms and conditions. The agency must approve any actions that will result in a change to project scope. Ask the GMS if you have questions about a proposed change.

3.1.2: Budget and Scope Changes

3.1.2.1: Minor Budget Changes

Within a budget period, you can adjust your budget without prior approval if:

- The change is within or between approved direct cost categories.
- Your award's federal share is below the simplified acquisition threshold, and your NoA doesn't include a prior approval need. Check the current threshold in the [Federal Acquisition Regulation \(FAR\) at 2.101, Definitions](#).

Recipients should ensure that they have appropriately documented budget changes as part of the grant record.



3.1.2.2: Significant Budget Changes

Significant budget changes in line with [2 CFR 200.308\(i\)](#) require prior approval. Budget changes are considered significant when:

- Your award exceeds the simplified acquisition threshold (set by [48 CFR 2.101](#)), and
- The cumulative amount you want to transfer between direct cost categories is expected to be more than 10 percent of the total budget.

If both conditions apply, you need to request prior approval. To calculate the total budget, use the last total budget amount approved by the agency, including cost share.

See [2 CFR 200.308\(i\)](#).

3.1.3: Expanded Authority

If expanded authority is not granted in your NoA, you do not have it. To know if you have any expanded authorities:

- Review your NoA. Expanded authorities may be adopted by reference.
- Review your specific award conditions. These may include expanded authorities or limits on them.

When using expanded authorities as granted in the NoA, make sure you follow award requirements and the cost principles. All changes are subject to monitoring, audit, and related remedies for noncompliance. See the section below.

Expanded authorities may include:

- Waiving the prior approval requirements in [2 CFR 200](#), except for those listed in [2 CFR 200.308\(f\)](#) and
- Three specific waivers in [2 CFR 200.308\(g\)](#), including:
 - Incurring project costs up to 90 calendar days before award. Doing so is at the recipient's risk.
 - Carrying forward unobligated balances to the next budget period unless the funds are currently restricted. You need prior approval to carry forward any unobligated balance to any budget period other than the next budget period.
 - Initiating a one-time extension of the period of performance by up to 12 months unless any of the following are true:
 - The extension requires additional federal funds
 - The extension involves any change in the approved project objectives or scope

Recipients may not use a one-time extension only to use unobligated balances.

Please Note: For awards that support research, unless your agency provides other instructions in the NoA in general or because it is part of a regulation, the three specific waivers above (in [2 CFR](#)



[200.308\(g\)](#)) are automatic and noted in your NoA.

Several expanded authorities have specific deadlines for reports or notification. If a recipient consistently fails to meet them, the agency may stop their ability to use them. Be sure to read your NoA carefully or ask your GMS if you have questions about expanded authorities under your award.

3.1.4: Extensions to Awards

The agency may provide more time and funds after the award. The two types of extensions are:

- No-cost extensions: A time extension without more funds.
- Funded extension: A time extension with added funds.

3.1.4.1: No-Cost Extensions

HHS agency prior approval is required for no-cost extensions, unless provided as an expanded authority. See [2 CFR 200.308](#).

When prior approval is required, the recipient must request the no-cost extension no less than 10 days prior to the end of the budget period in the last year of the period of performance.

In cases where there is expanded authority, the recipient must notify the HHS agency in writing with the supporting reasons and a recommendation for revised period of performance at least 10 calendar days before the end of the period of performance in the original NoA. See [2 CFR 200.308\(g\)\(2\)](#).

Regardless of whether approval is required, no-cost extensions are not meant to just spend unobligated funds. The purpose of a no cost extension is to:

- complete the project
- provide for an orderly shutdown, or
- in some cases, provide a bridge to the next award.

If using expanded authority, and you do not need permission, you must tell the agency.

3.1.4.2: Reminders for All Extensions

- You can't extend a period already lengthened by the agency.
- Award terms and conditions still apply during the extended time.
- No matter the extension length, you must keep sending required reports as set out in your award.
- You must update all necessary certifications and assurances, including those about human subjects and animal welfare, following relevant rules and policies.
- A second extension longer than 12 months should be rare and will need special justification.
- If the agency denies an extension, you cannot appeal it.

3.1.4.3: Supplemental Funding Extension Without Change In Scope



A recipient may request supplemental funding with an extension of time without a change in scope that is under 25% of the total approved budget or \$250,000, whichever is less, for the period of performance. These extensions are not competitive. Approving a request is at the discretion of the agency and depends on availability of funds.

3.1.4.4: Supplemental Funding Extension with Change in Scope

For supplemental funding and an extension of time with a change in scope, you must submit the request at least 30 days before the period of performance ends. The request must include the proposed revised ending date and justify both the extension and any additional funds. These extensions are not competitive. However, the HHS agency will conduct a merit review and will have to internally justify the award.

3.1.5: Transferring Major Work to A Subrecipient

3.1.5.1: Non-Pass-Through Programs

For these awards, you have a substantial project role and cannot just be a conduit for another party.

Before transferring major or substantive work to a subrecipient not in the approved application, you must get prior approval. This does not apply to buying or obtaining regular goods or services.

When asking for prior approval, include:

- What activities or tasks you want to transfer
- Why a third party should do them
- A detailed cost estimate and reasons, including any indirect costs and their reimbursement method
- How you'll choose the subrecipient
- The type of subaward planned
- The types of organizations you'll solicit; If you've already chosen one, name it and explain why

3.1.5.2: Pass-Through Recipient

A pass-through recipient means a non-Federal recipient that provides a subaward to a subrecipient to carry out part of a Federal program. In a pass-through program, the recipient:

- Chooses subrecipients to deliver services
- Coordinates and oversees their activities
- Gives needed administrative support to meet agency requirements

For these programs, you don't need prior approval to give a subaward.



3.1.6: Change In Recipient or Recipient Status

The following section addresses policies for changes in recipient organization, scope, status of key personnel, and organizational status.

3.1.6.1: Change of Recipient Organization

To transfer the legal and management responsibility of an award to another organization, you must get prior approval.

The agency must ensure the award's purpose and scope remain the same and the transfer aligns with federal appropriations laws and the statute or authority for the underlying award.

HHS allows transfer to a new recipient organization if:

- The award to be transferred has been terminated per [2 CFR 200.340](#).
- There is a successor in interest or name change. Please contact your GMS for more information about the difference between these two.
- The agency holds back a non-competing continuation award for reasons other than the project's performance. This can relate to the recipient's award management or not meeting terms and conditions.
- The original recipient agrees to give up the award before the period of performance ends. This can happen if a PI moves to a different organization. The project, with the same PI, can continue up to the current period of performance but not beyond. Costs cannot exceed the approved direct and applicable indirect costs.

Send your request as soon as possible before the end of the approved budget period within the period of performance.

If you want a change in organization, you must get prior approval from the GMS and sometimes, the Office of General Counsel. Contact the GMS if you believe the award needs to go to a new organization, ideally a few months ahead. Early requests enable important discussions, smooth review of the request, and avoid delays.

3.1.6.1.1: Supporting Documentation Needed for Requests

From the original organization:

- The [PHS 3734](#), "Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant," or an equivalent form from the agency.
- For research awards, include a "Final Invention Statement and Certification."
- A final Federal Financial Report within 120 days after the end of HHS support.

From the proposed new organization, the agency will request an application and will provide instructions for completing the application.



3.1.6.1.2: Requirements for Review and Possible Approval

Transfer requests are only considered when:

- All benefits of the original award, including equipment purchased fully or partly with award funds, are transferrable.
- The agency decides there is a continued need.
- There is no change in the project's scope. If there is, it may need a merit review and possibly a different procedure.
- The facilities and resources at the new organization will allow for successful performance.
- For transfers to or between foreign or international organizations, any special approval requirements are met. This might include approval by an advisory council or board.

Even if the requirements above are met, the HHS agency may reject the request or terminate the award.

To implement a recipient change, the HHS agency:

- Sends a revised NoA to the original recipient, updating the budget and end dates.
- Removes any support for future years.
- Deobligates any remaining funds, based on the expenses from the relinquishing statement.
- Issues a NoA to the new recipient, reflecting the balance from the relinquishing statement.

3.1.6.2: Change in Scope

The PI/PD may want to make changes in the methodology, approach, or other aspects of the project that change the scope. The GMS must give prior approval for a proposed change in scope.

A change in scope occurs when the recipient proposes to change the objectives, aims, or purposes identified in the approved application. This might include:

- Shifting the research emphasis from one disease area to another.
- Changing the service area.
- Eliminating a primary care delivery site.
- Making budget changes that cause a project to change substantially.

The HHS agency makes the determination of whether a proposed change is a change in scope.

3.1.6.3: Change in Status of Key Personnel

Key personnel include the PI or PD, and any other key personnel named in the NoA.

Provide written request to the GMS if any key personnel:

- Withdraw from the project entirely.



- Are absent from the project for a period of three months or more.
- Reduce time devoted to the project by 25 percent or more from the approved level.

The agency must approve replacement of key personnel, or any alternate arrangement proposed.

A request for approval to substitute key personnel includes:

- A justification for the change
- The proposed person's biography
- Other sources of support, if applicable
- Any budget changes resulting from the proposed change

If your proposed arrangements are not acceptable to the agency, they may suspend or terminate the award. If unable to make suitable arrangements, you may relinquish the award. To do so, notify the GMS in writing. The GMS will forward closeout instructions.

3.1.6.4: Change in Organizational Status

You must inform the agency ahead of time about specific changes in your organizational status to ensure a smooth transition and maintain compliance with administrative requirements. The following are the situations that require prior notification:

- Successor-in-interest: This happens when the obligations and rights of an award are acquired as a part of the transfer of assets. Common causes include legislation or legal actions such as mergers or shifts in corporate structure.
- Name change: This occurs when an organization changes its name, but it doesn't affect the rights or obligations of the award recipient.
- Merger: This is when two or more entities legally unite. Handling of this scenario depends on its nature:
 - If the merger results in the transfer of awards, use the policies for a successor-in-interest.
 - If the merger doesn't involve award transfers, it's treated as a name change.

If the change would be considered a change of recipient organization as discussed above, then you must obtain prior approval.

For any change in organizational status, ask your GMS. This agency is usually the one that has granted you the most awards. The GMS can clarify whether the change will be treated as a name change or a successor-in-interest and guide you on the necessary steps to follow.

3.2: Financial Management

You must meet the standards and requirements for financial management systems in [2 CFR 200.302](#). You must have adequate internal controls and a way to manage your award consistent with Department of the Treasury requirements. See the Payment section of GPS.



Financial management systems must:

- Provide accurate, current, and complete financial information about federal awards.
- Provide reasonable procedures to ensure that subaward recipients submit timely financial reports.
- Maintain records that:
 - Identify the sources of funds for award-assisted activities.
 - Identify the award's purposes and uses, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income.
 - Include accounting records supported by source documentation, such as canceled checks, paid bills, payrolls, and time and attendance records.
 - Maintain effective control and accountability for all cash, property, and other assets under the award; adequately safeguard them; and ensure that they are used only for authorized purposes.
 - Compare actual expenditures with the approved budget amounts for the award.
 - Include written procedures to implement the requirements of [2 CFR 200.205](#) and [2 CFR 300.305](#).
 - Include written procedures for determining the allowability of costs in accordance with [2 CFR 200 Subpart E](#).

Deficiencies in your financial management system may result in specific award conditions or increased monitoring.

States must expend and account for funds according to state laws and procedures for the state's own funds and ensure compliance with all the requirements above.

3.2.1: Payment

You accept an award and its terms and conditions by drawing down or requesting award funds from the designated HHS payment system or office.

HHS generally makes award payments through the Payment Management System (PMS). HHS grant payments are generally advance payments. You should draw down funds as often as needed.

In accordance with Department of Treasury regulations, you must draw federal cash only for your immediate needs. At time of draw down, you will certify you will not hold cash beyond three working days. You are responsible for knowing when funds are deposited into your bank account so that you can disburse them on time. You may end up with excess Federal cash on hand if you do not disburse or return funds on time. Do not request cash to cover unliquidated encumbrances, obligations, or accrued expenditures until payment is pending.

Refer to the [Payment Management System \(PMS\) website](#) and [PMS User Guide | HHS PSC FMP Payment Management System](#) for further guidance.



3.2.2: Types of Payment

As noted, HHS grant payments are generally advance payments. There are multiple ways to receive payments, including SMARTLINK II/ACH, CASHLINE/ACH, and cash request.

- SMARTLINK II/ACH: directly deposits funds to your bank account after you request them from PMS. You must have Internet access to submit a request for funds to PMS. This method makes funds available the day after the request using the Federal Reserve Bank's Automated Clearinghouse process.
- CASHLINE/ACH: directly deposits funds to your bank account using a telephone to call a "voice-response" computer at PMS. Makes funds available the day after the request with direct deposit using the Federal Reserve Bank's Automated Clearinghouse process.
- Cash request: provides payment if you are not eligible for unrestricted advance of funds. It will say in the NoA if you must use cash requests for payment. Cash requests may be an advance or reimbursement.

You may request funds monthly for advance payments. This request should be based on expected disbursements for following month and the amount of Federal funds already on hand.

A request for reimbursement may be submitted more often than monthly. You should submit requests to the agency at least 2 weeks before the cash is needed. PMS makes payment electronically through the ACH process upon receipt of the approved payment request from the agency.

Refer to the [Payment Management System \(PMS\) website](#) and [PMS User Guide | HHS PSC FMP Payment Management System](#) for further guidance.

3.2.3: Interest Earned on Advances of Award Funds

You must keep advance payments in interest-bearing accounts, except as provided in [2 CFR 200.305\(b\)\(11\)](#). You can keep interest earned up to \$500 per year for administrative expenses. Each year, you must remit any interest earned over \$500 per year to the Payment Management System.

3.2.4: Indirect Costs

3.2.4.1: Indirect Cost Rate Negotiation and Salary Rate Limit (SRL) Policy

Please see [Indirect Cost Rate Negotiation](#) and [SRL Policy in the Application Section](#).

3.2.4.2: New or Amended Indirect Costs

The GMO may permit new or increased indirect costs on an award in alignment with the recipient's negotiated indirect cost rate agreement when:

- A timely cost proposal was not received.
 - This can happen only if funds are available.
 - The amount is limited to the period after the effective date of the rate agreement.
- Rebudgeting changes a direct cost, which impacts an indirect cost.



- The recipient may adjust the budget within the award ceiling and generally does not need prior approval. See Prior Approvals section of the GPS.
- The indirect cost rate changes.
 - Generally, award amounts will not be adjusted based on a negotiated indirect cost different from that used at award.
 - However, if funds are available, a GMO may provide additional funds for indirect costs, only if:
 - An error was made in computing the award. This includes when a higher rate is negotiated after award and the date of the new rate agreement is within a month prior to the budget period start.
 - The agency restores funds previously recaptured as part of an unobligated balance.
 - The recipient is eligible for additional indirect costs associated with additional direct costs awarded, such as a supplemental award.
 - A provisional rate was approved, and an approved indirect cost rate is now in effect.
 - The permanent rate will be used to determine indirect cost reimbursement, however:
 - If the permanent rate is lower than the provisional rate, the award will not be adjusted downward, unless the indirect cost proposal included unallowable costs.
 - The agency is not required to provide new funds to accommodate a higher rate.

3.2.5: Applicable Credits

Applicable credits are funds saved or received that can reduce costs. Common examples include:

- Discounts
- Rebates
- Refunds for losses
- Corrections for overcharges

If you have any of these credits, you need to update the Federal Financial Report (FFR) to ensure that the proper amounts are charged to the award. If there are any extra steps, the agency will let you know.

See [2 CFR 200.406](#).

3.2.6: Allowable Costs and Activities

Allowable costs are either a direct cost or an indirect cost, and:

- Meet the applicable cost principles, including all the following:



- Meet the factors affecting allowability. See [2 CFR 200.403](#);
- Are reasonable. See [2 CFR 200.404](#);
- Are allocable. See [2 CFR 200.405](#); and
- Are allowable under the NOFO, program requirements, and NoA, including specific conditions and overall terms and conditions.
- Are specifically approved in the award, which means either:
 - The cost was included in the original award; or
 - The cost is later approved by the agency. See the Prior Approvals section of GPS.

Contact the GMS before incurring a cost if you have questions about allowability.

Subrecipients and contractors under the award must follow the requirements of their applicable cost principles.

3.2.6.1: Costs that Require Prior Approval

If you specifically describe a cost or activity that requires prior approval in your application budget, that cost is approved by the agency when you receive your award unless otherwise stated in the NoA. You do not need to get additional prior approval for that cost or activity. You must get prior approval from the agency if you do not describe the cost or activity that requires prior approval in your application.

3.2.6.2: Profits and Fees

HHS will not provide profits or fees, except for the Small Innovation in Research (SBIR) and the Small Business Technology Transfer (STTR) Programs.

You can't pay fees to subrecipients or consortium members, even if they are for-profit.

Contractors can make a profit for common goods or services in accordance with normal commercial practice. See [2 CFR 200.331](#).

3.2.7: Expenditure Adjustments

Expenditure adjustments are used to correct accounting or bookkeeping errors. These adjustments move costs between two budget categories, with at least one related to the HHS award. Once the error is found, it must be corrected within 90 days. If after 90 days, you must ask the GMO for approval.

Don't use expenditure adjustments to cover cost overruns or for unallowable costs.

3.2.7.1: Documentation

The adjustment must be supported by documentation that fully explains how the error occurred. Documentation must:

- Explain how the error happened and have an official from your organization certify the correction.



- Show how the adjustment meets the cost principles of allowability, allocability, and reasonableness.
- Support why the adjustment is needed, considering the type of cost, the original charge, and when it was first recorded.

Unless the expenditure adjustment needs GMO approval, you don't need to send the documentation to the GMS. Keep records for monitoring or audits. See [2 CFR 200.337](#).

Send a revised Federal Financial Report (FFR) if the adjustment changes your previous FFR.

Your financial system should catch errors quickly. Regular mistakes suggest you need to improve your accounting or internal controls. Agencies might ask for corrective actions or add terms and conditions to your award.

3.2.8: Rate of Expenditure and Drawdowns

Expenditure and drawdown rates give information about progress, financial management, and internal controls.

3.2.8.1: Expenditures

The GMS monitors spending rates within each budget period and throughout the period of performance.

The funds for each budget period are based on:

- the work planned for that time
- your budget, including any unobligated funds

HHS expects spending rates and types to match the approved plan and budget.

3.2.8.2: Drawdowns

The GMS checks drawdown patterns to see if money is taken out too early or too slowly. This can show:

- problems with your financial management system or internal controls
- risk of not finishing the project on time and within budget

If issues are found, the GMS will ask for more details and help you make corrections, which may include coordinating with the agency PO and GMS.

3.2.9: Cost Allocation

If a cost benefits more than one project or activity, divide the cost based on the benefit to each project.

If it is hard to determine the split because the projects are closely linked, distribute the costs on a reasonable basis with clear and documented explanations.



3.2.10: Treatment of Unobligated Balances

Unobligated balances are funds under an HHS award that you have not obligated. You calculate this by subtracting the cumulative amount of funds obligated from the cumulative amount of funds authorized.

Unliquidated obligations are commitments you have made, but not yet paid. Unliquidated obligations should not be reported as part of an unobligated balance.

If you have unobligated balances in your annual FFR, the agency can:

- Carry Over: Revise the NoA to carry over to a following budget period.
- Offset: Move them to the next budget period but deduct the total from the award amount.
- A Mix: Use a mix of carry over and offset.

During an active budget period, if you have unobligated balances from a previous budget period, you can ask the agency in writing to use them. If approved, the agency will amend the NoA. If approved, funds carried over can be used for costs within scope of the project.

3.2.11: Program Income

Program income is gross income earned by an award recipient, subrecipient, or contractor and directly generated by an award-supported activity or earned because of the award.

Program income includes:

- fees for services
- charges for the use or rental of real property, equipment, or supplies bought with the award
- the sale of products made under an award
- charges for research resources
- license fees and royalties on patents and copyrights

The NoA governs the use of royalties and other income earned from a copyrighted work, patents, patent applications, trademarks, or inventions.

3.2.11.1: Accountability

Accountability refers to whether the agency specifies how the program income is to be used, if the income needs to be reported to the agency, and for what length of time. The following general policies apply:

- Unless otherwise specified in the award terms and conditions, you are not accountable for program income earned after the period of performance ends.
- Program income must be used for the original purpose of the Federal award and may be used only for allowable costs using the applicable cost principles and award terms and conditions.
- Subawards and contracts are subject to the same terms regarding generated income as the



recipient. The following policies apply related to when the program income is earned:

- Received and expended during the period of performance. Recipient is required to use program income as provided in the NoA.
- Received and expended after the period of performance. Required to adjust the final FFR to reflect receipt and use of the income as directed by the GMO.
- Received during the project period but expended after the period of performance. This may happen if you earn the income during the final budget period of the period of performance, please get GMO approval to use income post final budget period and adjust the final FFR accordingly.

3.2.11.2: Alternatives for Use

The NoA will tell you how to use program income. Here are the alternatives:

- Additive: Add it to the project's funds to further allowable objectives. Program income must be used for the purposes and under the conditions of the award.
- Deductive: Deduct it from the project's total costs and reduce federal funds and recipient cost-sharing contributions.
- Combination: Uses the additive alternative for program income up to \$25,000 and the deductive alternative for any amount over \$25,000.
- Cost sharing: Use it as all or part of the non-federal (matching) part of an award. See [2 CFR 200.307\(b\)](#) for more information.

Generally:

- For non-research projects: If not specified in the NoA, use the deductive method.
- For research projects (except for awards to for-profit organizations other than the SBIR and STTR programs): If it is not specified, use the additive method.

3.2.11.3: Reporting of Program Income

Recipients must report the amount of net program income earned and expended on the FFR. This is the gross program income earned minus the costs associated with generating the income.

- Report program income using the additive alternative on line 10n, which will populate line 10o.
- Report program income using the deductive alternative on line 10m, which will populate line 10o.
- Report program income used to satisfy match on line 10j. Do not include it on line 10l.

Reporting requirements are in the NoA for accountable income earned after award support ends.

3.2.12: Cost Sharing

Cost sharing, or matching, is 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
- Non-award funded expenditures made by the recipient

See [2 CFR 200.306](#) for rules on cost sharing.

The following policies apply:

- Cost sharing may be voluntary or required by the NoA.
- Required cost sharing is part of the total approved budget in the NoA. It is part of the award requirements and enforceable.
- Cost sharing must follow the same requirements as the federal portion of the budget. This includes applicable cost principles, prior approval requirements, and other rules for allowability.
- Recipients may apply program income toward cash match only when expressly permitted by the NoA with prior approval.
- All cost sharing contributions must be from allowable sources. See [2 CFR 200.403](#), [2 CFR 200.404](#) and [2 CFR 200.405](#).
- For research awards:
 - Voluntary cost sharing is not expected under research proposals.
 - Voluntary cost sharing cannot be used as a factor during merit review of research applications unless explicitly described in the NOFO review criteria.
 - Only mandatory cost sharing or cost sharing committed in the budget must be included in your research base for computing your indirect cost rate or reflected in allocating indirect costs.

The agency will accept shared costs, including cash and third-party in-kind contributions, when they meet all the following:

- follow [2 CFR 200.306\(e\)](#) for volunteer services
- are verified from the recipient records
- are necessary and reasonable to accomplish project objectives
- are provided for in the approved budget when required
- are not paid by the federal government under another federal award, unless specifically allowed by law. See [2 CFR 200.306\(b\)\(5\)](#).

The following policies apply:

- Sources of cost sharing or matching contributions must follow the applicable cost principles. See [2 CFR 200 Subpart E](#).
- If an agency authorizes the recipient to donate buildings or land for construction or facility



acquisition or long-term use, the value of the donated property for cost sharing is generally the lesser of:

- the value of the remaining life of the property recorded in the recipient's accounting records at the time of donation
- the current fair market value. See [2 CFR 200.306\(d\)](#).
- You must document in your records all costs and contributions used to satisfy a
- cost-sharing requirement. These are subject to audit.
- You may use unrecovered indirect costs to satisfy cost sharing requirements with prior approval. These are the difference between the amount charged to the award and the amount that could have been charged to the award under the recipient's approved negotiated indirect cost rate.
- A third-party in-kind contribution to a fixed-price contract may count towards satisfying a cost sharing requirement only if either:
 - it is an increase in the services or property provided under the contract without added cost to the recipient or subrecipient, or
 - it is a cost savings to the recipient or subrecipient.

If the NOFO specifies that cost sharing is required, it will also say:

- Whether including cost sharing in the application is an eligibility requirement or an evaluation criterion.
- The nature of the requirement. For example, whether it is a fixed percentage.
- Required documentation, like letters of commitment.

3.2.12.1: Valuation of Volunteer Services

Anyone offering skilled or manual work can volunteer for award-related activities. See [2 CFR 200.306\(e\)-\(f\)](#).

To value the services:

- For individuals:
 - Use the usual rates your organization pays or area market rates for similar work.
 - If you do not have a set rate, use the typical local rate for that work.
 - You can also add a fair amount for fringe benefits.
- For employees lent by other companies:
 - Use their regular rate if they are doing their typical job.
 - Use the method for individuals if they are doing something different.



3.2.12.2: Valuation of Donated Buildings and Land

If an agency authorizes you to donate buildings or land for construction or facilities acquisition projects or long-term use, the value of the donated property for cost sharing must be the lesser of the following:

- the value of the remaining life of the property
- the current fair market value See [2 CFR 200.306\(d\), \(h\), and \(i\)](#).

3.2.12.3: Enforcement

If you do not meet the specified level of cost sharing in the NoA, an agency may do any or all the following:

- reduce the award amount
- adjust down award funds during the budget period
- disallow costs post award

3.3: Procurement Management

You may acquire goods or services in support of award activities. The following policies apply when procuring property and services under an award:

- States must follow the same policies and procedures it uses for non-federal funds. Follow the requirements at [2 CFR 200.317](#).
- All other recipients and subrecipients of a state must follow the procurement standards in [2 CFR 200.318](#) through [2 CFR 200.327](#).

To procure goods and services, you must:

- Have written procurement procedures and standards of conduct that reflect applicable state, local, and tribal laws and regulations
- Use a procurement method
- Do a cost or price analysis for all procurements above the simplified acquisition threshold
- Choose responsible contractors
- Follow all requirements in this section of the GPS

The HHS agency has no direct relationship with your contractor.

Recipients other than federal institutions cannot use General Service Administration (GSA) supply sources except states who may acquire hardware and software from the GSA supply sources consistent with the terms and conditions of the GSA schedule.

3.3.1: Fixed Amount Subawards

With prior written approval from the GMO, you may provide subawards based on fixed amounts up to



\$500,000 ([2 CFR 200.333](#)). Fixed amount subawards must meet the requirements for fixed amount awards in [2 CFR 200.201](#).

3.3.2: Requirements for States

States may follow the same policies and procedures for procurements using non-federal funds. States will comply with [2 CFR 200.323](#) and ensure that every purchase order or other contract includes any clauses required by [2 CFR 200.327](#).

States may acquire hardware and software from GSA Federal Supply Schedules consistent with the terms and conditions of the schedules.

State agencies or agencies that are political subdivisions of states must comply with [section 6002 of the Solid Waste Disposal Act as amended by the Resource and Conservation Act](#). The requirements include:

- Procuring only items noted in guidelines of the Environmental Protection Agency (EPA) at [40 CFR 247](#) that contain the highest practical percentage of recovered materials.
- Keeping an acceptable level of competition, where the purchase price of the item is more than \$10,000 or the value of the amount acquired during the previous fiscal year was more than \$10,000.
- Procuring solid waste management services to maximize energy and resource recovery.
- Establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

3.3.3: Requirements for Foreign Entities

The HHS agency may require a review of all proposed procurements exceeding a certain dollar amount or for certain types of services. The HHS agency may also add specific terms and conditions to its awards that address the procurement of such goods and services.

3.3.4: Selecting Responsible Contractors

You must avoid acquiring duplicate or unnecessary services or goods. You should use the most efficient strategy for acquisition. You should use federal excess and surplus property whenever possible to reduce project costs. You must award contracts based on factors like:

- Integrity
- Compliance with public policy
- Past performance
- Financial and technical resources

3.3.5: System for Award Management (SAM) Eligibility

You must check the System for Award Management ([SAM.gov](#)) to make sure you do not make a



subaward or contract to a debarred, suspended, or ineligible organization. SAM needs to be checked:

- By the recipient organization:
 - for all first tier subawards, regardless of the amount
 - for all first-tier procurement contracts of \$25,000 or more
 - for all lower tiers of contracts under covered non-procurement transactions. See [2 CFR 376.220](#).
- By the subaward recipient for all lower tier subaward recipients.

3.3.6: Written Agreements

You must execute a written agreement between your organization and the subrecipient, if applicable. The agreement must not affect your overall responsibility for the project or accountability to the federal government.

The agreement must include all the following:

- the activities to be performed
- time schedule
- the provisions required by [2 CFR 200.327](#) and those found in [2 CFR 200, Appendix II](#)
- policies and requirements that apply to the contractor, including [2 CFR 200.318](#) and other relevant award terms and conditions
- maximum amount of funds to be awarded
- cost principles to be used in determining allowable costs for cost-type contracts

3.3.7: Subrecipient Periods of Performance - Contracts

If the term of the contract and the award budget period are not the same, you may charge the contract costs to the budget period in which the contract is executed even though some of the services will be performed in a later period. These conditions apply:

- You must notify the agency.
- The expected contract performance period must go beyond the current grant budget period.
- You have a legal commitment to settle all contractual and administrative issues. See [2 CFR 200.318\(k\)](#).
- Only costs for services provided during the period of performance are allowable.
- For rental costs for facilities and equipment, charge the applicable amount in each budget period. Contact the GMS before entering leases that will result in direct charges to the award.

All contracts more than the simplified acquisition threshold must include termination provisions in line with [2 CFR 74.48](#) and [45 CFR 92.36\(i\)\(2\)](#). While not required for awards under the



simplified acquisition threshold, recipients should insert a clause stating payment after the end of the current budget period is contingent on continued federal funding.

3.3.7.1: Time and Materials Contracts

Time and materials contracts may only be used if:

- there is no other appropriate contract type
- the contract includes a ceiling price that the contractor exceeds at its own risk
- the direct hours are fixed and include wages, general and administrative expenses, and profit

3.3.8: Procurement Methods

You must use one of the following methods of procurement:

- Micro-purchases
- Small purchase procedures
- Sealed bids
- Competitive proposal
- Noncompetitive proposal

Micro-purchase procurements are the acquisition of supplies or services when the total dollar amount is less than the micro-purchase threshold. Generally, the micro-purchase threshold is \$10,000, but recipients may self-certify a higher threshold, up to \$50,000. If you self-certify a higher micro-purchase thresholds, you have to follow documentation requirements in [2 CFR 200.320\(a\)\(1\)\(iv\)](#).

To the extent possible, you must distribute micro- purchases equitably among qualified suppliers. Micro-purchases do not require soliciting competitive quotations if cost is reasonable.

Small purchase procurements involve simple procurement methods for securing services, supplies, or other property less than the Simplified Acquisition Threshold (\$250,000). Non-federal entities must obtain price or rate quotes from sufficient qualified sources.

Sealed bid procurements require public solicitation for bids, leading to a firm fixed price contract (lump sum or unit price) given to the bidder whose bid is the lowest in price and complies with all material terms and conditions.

Competitive proposals usually involve more than one source sending an offer. A fixed price or cost-reimbursement type contract is awarded. It is generally used when sealed bids are not appropriate. You must adhere to the following requirements when using this procurement method:

- Requests for proposals must be publicized and identify all evaluation factors and their relative importance. Any response to publicized requests for proposals must be considered to the maximum extent practical.
- Proposals must be solicited from an adequate number of qualified sources.



- You must have a written method for technical evaluations of the proposals and for selecting bids.
- Contracts must be awarded to the responsible firm whose proposal is best for the program.

You can also use the competitive proposal procedures for qualifications-based procurement of architectural/engineering (A/E) professional services. Applicant qualifications are evaluated, and the most qualified competitor is selected, subject to negotiation of fair and reasonable compensation.

Non-competitive proposals solicit a proposal from a single source. You may only use this method when the item is only available from a single source or in the event of a public emergency to expedite the acquisition, or when there is inadequate competition for a product, material, or service. You can get approval for non-competitive proposals from the GMO or his/her delegate.

Upon request, you are required to undergo a pre-procurement review and submit procurement documents to the HHS agency or pass-through entity when:

- Your procurement procedures or operations do not comply with the procurement standards required by those regulations.
- The procurement is expected to exceed the Simplified Acquisition Threshold and is to be awarded without competition, or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the Simplified Acquisition Threshold specifies a “brand name” product.
- A proposed award over the Simplified Acquisition Threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.

When prior written approval is required, the non-federal entity must make available sufficient information to enable review. This may include, at discretion, pre-solicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates.

Approval may be deferred pending submission of additional information by the non-federal entity or may be conditioned on the receipt of additional information. Any resulting approval does not constitute a legal endorsement of the business arrangement by the federal government nor does such approval establish the HHS agency as a party to the contract or any of its provisions.

3.3.9: Written Standards of Conduct and Conflict of Interest

Recipients must maintain written standards of conduct covering conflicts of interest. Individuals affiliated with a recipient organization cannot participate in the selection, award, or administration of a contract supported by a federal award if they have a real or apparent conflict of interest with:

- Employees



- Officers
- Agents
- Board members
- Immediate family members, spouses, or partners
- Potential employer

These individuals are prohibited from soliciting gratuities, favors, or anything of monetary value from subrecipients. However, recipients may set standards for situations where financial interest is not substantial or the gift is an unsolicited item of insignificant value. These standards of conduct must be applied for violations of the standards by officers, employees, board members, or agents of the organization.

Recipients that are part of a parent, affiliate, or subsidiary organization that is not a state, local government, or Indian Tribe are required to have an organizational conflict of interest policy.

3.4: Management of Property and Equipment

Real property can only be acquired when authorized by statute and when specifically stated in the NoA.

Generally, recipients may use their own property management policies and procedures for property purchased or constructed as a direct cost using HHS financial assistance funds, provided they comply with the requirements in [2 CFR 200 Subpart D - Property Standards](#). The recipient is responsible for the day-to-day management of [real property](#), [equipment](#) and [supplies](#) acquired or used under an award, whether the title belongs to the recipient or remains with HHS. Recipients must maintain written policies and procedures that address contracting, purchase, and management of all equipment and supplies.

Recipients (and subrecipients, as applicable) must be wise when purchasing property under an award. It is the recipient's responsibility to carefully review each potential property purchase to ensure that it is needed and that the need cannot be met with property already owned by the recipient. If the NoA says the recipient must get permission before buying property, the recipient must make sure they get permission. The recipient must also follow procurement procedures in acquiring property as specified in [2 CFR 200 Subpart D - Property Standards](#).

As mentioned in the prior procurement section, recipients other than federal institutions cannot use General Service Administration (GSA) supply sources except states who may acquire hardware and software from the GSA supply sources consistent with the terms and conditions of the GSA schedule.

3.4.1: Exempt Property

Exempt property means property bought with award funds where the HHS agency has chosen to give the title to the property to the recipient without further obligation, based upon the explicit terms and conditions of the federal award. The HHS agency may exercise this option when statutory authority



exists.

Under a research award to a nonprofit institution of higher education or to a nonprofit organization whose main purpose is conducting scientific research, the HHS agency must use the special authority provided in the [Federal Award and Cooperative Agreement Act \(31 U.S.C. 6306\)](#) to give the title to equipment and supplies to the recipient (except for those obligations in [2 CFR 200.313](#)).

3.4.2: Nonexempt Property

As implemented in [2 CFR 200.312](#), the title to federally owned property belongs to the federal government. Each year, the recipient must submit an inventory listing of federally owned property in its custody to the HHS agency (SF-428-A). Upon completion of the federal award or when the property is no longer needed, the non-federal entity must report the property to the HHS awarding agency for utilization using the SF-428-B (final) or SF-428-C (disposition). The recipient will receive disposal instructions from the HHS agency.

3.4.2.1: Revocable License

In some cases, federally owned property may be made available to a recipient under what is called a “revocable license agreement.” This agreement means the HHS agency allows the recipient to use the property for the period of the award under the following conditions:

- The title to the property belongs to the federal government.
- The HHS agency reserves the right to require the property be returned to HHS should it be determined to be in the best interests of the federal government to do so.
- The use to which the non-federal entity puts the property does not permanently damage it for federal government use.
- The property is controlled and maintained in accordance with the requirements of the NoA.

3.4.3: Equipment

Equipment is tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit purchase cost which equals or exceeds the lesser of the capitalization level established by the recipient for financial statement purposes, or \$10,000. See also the definitions of capital assets, computing devices, general purpose equipment, information technology systems, special purpose equipment, and supplies in [2 CFR 200.1](#).

Please see the general requirements under [2 CFR 200.313](#) and [2 CFR 200.439](#) for how to manage and track equipment. Unless a statute specifically says the recipient should own the title for equipment without further obligation to the HHS agency, the title must be a conditional title. Under this conditional title, the recipient must:

- Use the equipment for the authorized purposes of the project during the period of performance, or until the property is no longer needed for the purposes of the project.



- Put a control system in place to prevent loss, theft, and damage.
- Not restrict the use of the equipment without approval of the HHS agency.
- Subject to disposition instructions provided by the HHS agency, use the equipment in the project it was acquired in as long as needed, whether the project continues to be supported by the federal award.

3.4.4: Important Property Reminders

- You must classify equipment that will be permanently attached or fixed to the land as real property.
- States must use, manage, and dispose of equipment acquired under a federal award by the state in accordance with state laws and procedures.
- Real property constructed or renovated with award support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient, except as expressly authorized in writing by the agency.
- If you default on a mortgage, you must immediately notify the GMS by telephone and in writing. If the mortgage holder intends to foreclose, you must notify the GMS in writing at least 30 days before the foreclosure action is initiated.
- The mortgage agreement must specifically allow, in the case of default, that HHS or its designee may assume the role of mortgagor (borrower) and continue to make payments.

3.4.5: Insurance

You must insure property and equipment acquired or improved under an award. The following policies apply:

- You must provide the same insurance coverage for property under an award as you do for other such property.
- You don't need to insure federally owned property unless required by the award terms and conditions.
- If your organization is a government agency, you may follow your own insurance requirements.
- If title to real property bought with award funds vests with your organization, you must provide the following minimum insurance coverage:
 - Title insurance policy covering the fee interest in the real property for an amount not less than the full appraised value of the property, even if federal support is partial.
 - Physical destruction insurance policy covering the full appraised value of the facility from risk of partial and total physical destruction, even if federal support is partial.
 - You must maintain the insurance policy for the duration of the federal interest in the property.



Within five days of completion or beneficial occupancy, you must submit a written statement signed by the AOR to the GMS. This statement must assure that you have purchased the required insurance policies and will maintain the insurance coverage as required above.

3.4.5.1: Self-Insurance

The agency may waive the requirements above if you are effectively self-insured. If you claim self-insurance, you must provide the agency an assurance that includes:

- A statement that you meet the definition of effectively self-insured. This means that you have sufficient funds to pay for any damage to the facility, including total replacement, or to satisfy any liens placed against the facility.
- The source of the funds, such as the organization's endowment or other special funds set aside for this purpose.

See [2 CFR 200.447](#).

3.4.6: Notice of Federal Interest for Construction, and Acquisition or Modernization of Real Property

A Notice of Federal Interest (NFI) is required for construction, and acquisition or modernization of real property, except for Minor alterations and renovations (A&R). The non-federal entity (or owner, if other than the non-federal entity) must file an NFI prior to initiating construction or modernization, or when an existing facility or land is acquired with federal funds. The non-federal entity must:

- Record the NFI by the owner in the appropriate public records of the jurisdiction where the property is located. Associated fees are allowable costs.
- Provide a copy of the NFI to the HHS agency.
- Accurately indicate that the property was constructed, acquired, or modernized with HHS agency funds and, that during its useful life of the facility, as defined in the NFI, the HHS agency's use and disposition requirements apply.
- Seek review by the HHS agency to make sure it is acceptable.

The federal interest may not be conveyed, transferred, assigned, mortgaged, leased, or otherwise be encumbered or subordinated by a non-federal entity unless approved by the HHS agency.

3.4.7: Property and Equipment Disposition

According to [2 CFR 200.311\(d\)](#) and [2 CFR 200.313\(d\)](#), you must request disposition instructions from the agency when:



- Property under the award is no longer needed for the intended purpose or you will not be using the property for other activities currently or previously supported by an agency.
- Federal statutes, regulations, or agency disposition instructions in the NoA do not say otherwise.



3.4.7.1: Equipment

Unless the NoA or HHS agency instructions say otherwise, you must dispose of the property as follows, in accordance with agency disposition instructions:

- Retain, sell, or dispose of equipment items with a current fair market value of
- \$10,000 or less, with no further responsibility to the government. See [2 CFR 200.313\(e\)\(1\)](#). The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- Retain or sell equipment items with a current fair market value over \$10,000. The following apply:
 - You pay the agency the current fair market value according to the percentage of the federal share in its original cost.
 - If sold, the agency may allow you to deduct the lesser of \$1,000 or ten percent of the proceeds from the federal share.
 - If your organization is a non-profit institution of higher education or non-profit organization with a principal purpose of scientific research, you are exempt from any requirement to account for proceeds from a sale.
- Transfer property title to the federal government or an eligible third party. You are entitled to compensation for its share of the current fair market value.

3.4.7.2: Supplies

Your organization is assigned the title to supplies when you acquire them. If you have more than \$10,000 in supplies after the award is terminated or project is completed, you must retain the supplies for use on other activities, or sell them, and then compensate the federal government for its share. See [2 CFR 200.314](#).

3.4.8: Modernization of Real Property

Modernization includes both major and minor alterations and renovations (A&R) unless otherwise stated. Modernization is not an allowable cost under the following:

- Federal awards to individuals
- Conference awards
- Training awards

You may not perform major A&R using federal funds or required cost sharing unless:

- There is specific statutory authority, and
- The NoA explicitly allows it.



Minor A&R is an allowable cost under all other types of awards with prior approval under the following criteria, unless restricted in the NOFO or NoA:

- The governing statute or program regulations do not exclude it.
- The work is required to use the space more effectively to meet the program needs.
- The building has a useful life consistent with the project and is architecturally and structurally suitable for conversion.
 - If you own the property, it has a useful life consistent with the project.
 - If you lease the property, the terms and length of your lease are consistent with the project.
- Work and costs to get an initial occupancy permit is not an allowable cost. Costs must be for purposes other than human occupancy (e.g., storage).
- If the building is under construction or the A&R will take place in an incomplete structure, the costs are only allowable if:
 - It is cost-effective to perform the A&R while the building is under construction or being completed, and
 - Minor A&R costs are limited to the difference between the cost of completing the interior space for general use and the cost of adapting it for the federal award supported purpose.
- The space involved will be occupied by the project.
- National Environmental Policy Act (NEPA) and the National Historic Preservation Act (NHPA) requirements are followed, as applicable.

The following are not considered minor A&R:

- Costs associated with routine maintenance, painting, and repair of facilities or equipment that are normal business costs and generally charged as indirect.
- Certain 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, unless the non-federal entity's accounting system considers these modernization costs rather than equipment costs.
- Costs of furnishings and movable equipment.

3.4.9: Federal Interest Involving Construction and Modernization of Leased Property

You must make sure any leased property that you propose construction or modernization costs for has a long enough lease for the full value of the federal award supported improvements to benefit the



award activity and support the expected useful life of the facility. You must submit additional documentation to the HHS agency in these cases:

- You must submit lease language to the HHS agency prior to drawing down funds or being reimbursed.
- The property owner must consent to the proposed work, acknowledge federal interest in the property, and file a Notice of Federal Interest (NFI), if required. The lease must include, or be amended to include:
 - Your full use of and access to the leased property during the term of the lease.
 - Your agreement not to sublease, assign, or otherwise transfer the leased property, or use the property for a non-federal award-related purpose(s) without the written approval of the HHS agency (at any time during the term of the lease, whether federal award support has ended).
 - That the lessor will inform the HHS agency of any default by the non-federal entity under the lease.
 - The HHS agency has 60 days from the date of receipt of the lessor's notice of default in which to attempt to eliminate the default, and that the lessor will delay exercising remedies until the end of the 60-day period.
 - The HHS agency intervening to ensure that the default is eliminated by the non-federal entity, or another non-federal entity named by the HHS agency.
 - The lessor accepting payment of money or performance of any other obligation by the HHS agency's designee, for the non-federal entity, as if such payment of money or performance had been made by the non-federal entity.
 - If the non-federal entity defaults, the federal award is terminated, or the non-federal entity vacates the leasehold before the end of the lease term, the HHS agency has the right to designate a replacement for the non-federal entity for the balance of the lease term, subject to approval by the lessor in a separate agreement with HHS, which will not be withheld except for good reason.
 - Documentation of a NFI for the leased property (if required).

3.4.10: Intangible Property

Intangible property is property having no physical existence. These may include:

- trademarks, copyrights, patents, and patent applications
- property, such as loans, notes, and other debt instruments; lease agreements; stock; and other instruments of property ownership

See [2 CFR 200.315](#).

3.4.11: Intellectual Property



HHS expects you and your PIs and PDs to make your award results and accomplishments available to the research community and the public. If the research results in inventions, the [Bayh-Dole Act of 1980](#) and [37 CFR 401](#) apply. If you follow these requirements, you have the right to retain the title to any invention conceived or first actually reduced to practice.

The law and regulation promote:

- commercialization of federally funded inventions
- free competition and enterprise without restricting future research and discovery

The law and regulation require recipients to:

- Make efforts to develop and commercialize the technology to advance to industry
- for development.
- Make unpatented research products or resources available through licensing to vendors or other investigators.
- Share copyright-protected research outcomes in journal articles or other publications.

3.4.11.1: Irrevocable and Royalty-Free License

Except as otherwise provided in the NoA, you may assert copyright in any publications, data, or other copyright-protected work developed under an award. Doing so does not require agency approval.

Rights in data also extend to students, fellows, or trainees under awards with an educational purpose. In this case, authors are free to assert copyright in works.

The federal government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use material resulting from a supported project or program. This applies whether HHS funded all or part of the project. You are responsible for ensuring that any necessary copyrights obtained from your subrecipients also allow the material to be used by the federal government.

HHS may also extend this license to others for federal purposes. For example, to make it available in government-sponsored databases for use by other researchers. The NoA addresses the specific scope of agency rights. See [2 CFR 200.315\(d\)](#), [2 CFR 200.212](#).

3.4.11.2: Access to Data and Research Data

Access to data is addressed in [2 CFR 200.315\(d\)](#).

Specifically for research data, defined at [2 CFR 200.315\(e\)\(3\)](#), a federal agency may use award-related research data in developing an agency action that has the force and effect of law. If so, [2 CFR 200.315\(e\)\(1\)](#) requires recipients to release the research data to the agency to support a FOIA request. See [2 CFR 200.315\(e\)](#). See also the definition of records, which includes research data at [45 CFR 5.3](#).

Excluded are:

- 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 publications in a peer-reviewed journal
- information that is protected under the law such as intellectual property
- personnel, medical files, and similar files, if disclosure would constitute an unwarranted invasion of personal privacy
- information that could be used to identify a particular person in a research study

If the research data are publicly available, HHS directs the requester to the public source. Otherwise, the agency FOIA coordinator handles the request, consulting with the recipient and the PI. HHS may charge a reasonable fee to cover the costs to respond (that may also cover the recipient's cost to respond).

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 government recipient contracts with an educational institution, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to disclosure.

3.4.11.3: Patents and Inventions

Inventions conceived or first actually reduced to practice under awards are governed by the Bayh-Dole Act, [35 USC 200-212](#), and implementing regulations at [37 CFR 401](#).

The regulations at [37 CFR 401](#) apply if both the following are true:

- Inventions result from federally funded research, and
- Your organization or your subrecipient or contractor is a university, non-profit entity, governmental entity, or small or large business.

See [iEdison](#) for more information.

3.4.11.4: Royalties and Licensing Fees from Copyrights, Inventions, and Patents

You may commercially apply intellectual property and require payments for its use.

Unless the NoA says otherwise, you do not have to report program income earned from license fees and royalties. This includes copyright-protected material, patents, patent applications, trademarks, and inventions made under an award.



You may pay royalties to others as an allowable direct cost.

See [2 CFR 200.448](#).

3.4.11.5: Invention Reporting

For information, see [Invention Reports at iEdison](#). See also [37 CFR 401](#). Seek the advice of the GMS about:

- Whether an invention made under a career development award is a subject invention
- The extramural technology transfer policy
- Reporting of inventions

3.4.12: Publications and Acknowledgement of Support

3.4.12.1: Publications

HHS encourages you to publish the results and accomplishments of awards. You can publish your results without prior approval. These policies apply, unless otherwise specifically addressed in your NoA:

- You may assert copyright in scientific and technical articles based on data produced under the award.
- You may transfer copyright to the publisher or others for journal publication or other professional activities.
- All copyrights, including transfers, are subject to a royalty-free, non-exclusive and irrevocable license to the federal government, and any agreement must include that the assignment is subject to the government license.
- You must account for royalties and income earned from a copyrighted work as specified by the agency.
- You must submit one copy of each publication resulting from work under an award with the annual or final progress report and/or where you may be directed in your award.
- If you plan to issue a press release about award-supported activities, you must notify the agency in advance to allow for coordination.

3.4.12.2: Stevens Amendment

HHS will include the following information in your NoA and NOFO. When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents – such as toolkits, resource guides, websites, and presentations – describing the projects or programs funded in whole or in part with HHS funds, the recipient must clearly state:

- the percentage and dollar amount of the total costs of the program or project funded with



federal money; and

- the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

The NoA may provide further instructions and language to use.

3.4.12.3: Acknowledgement of Support

When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents – such as toolkits, resource guides, websites, and presentations (hereafter “statements”) – describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

- the percentage and dollar amount of the total costs of the program or project funded with federal money; and
- the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

- If the HHS Grant or Cooperative Agreement is NOT funded with other non- governmental sources: This [project/publication/program/website, etc.] [is/was] supported by the [full name of the agency] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with 100 percent funded by [agency]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [Name of the Agency]/HHS, or the U.S. Government. For more information, please visit [Award Agency Stevens Amendment website, if available].

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

- This [project/publication/program/website, etc.] [is/was] supported by the [full name of the HHS Agency] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with XX percentage funded by [full name of the HHS Agency]/HHS and \$XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [Agency]/HHS, or the U.S. Government. For more information, please visit [Award Agency’s Stevens Amendment website, if available].

3.5: Oversight and Monitoring

3.5.1: Subrecipient Flow-Down Requirements

The GPS applies to subrecipients and contractors. This includes consortium agreements where the recipient collaborates with other organizations.



The terms and conditions of awards flow down to subawards and subrecipients unless a particular GPS policy or award term and condition specifically says otherwise.

You must have a formal written agreement with each subaward recipient. You must include applicable GPS requirements in your subaward agreements. Agreements must meet programmatic, administrative, financial, and reporting requirements. At a minimum, the subaward agreement must include:

- the PI or PD and subrecipient staff responsible for the program activity, including roles and responsibilities.
- program administration and monitoring procedures.
- policies and process for subrecipient funding, such as allowable costs, expenditure approval, funding caps, payment method and schedule, required documentation.
- travel, salaries, and fringe benefit policies and procedures.
- applicable public policy requirements and applicable assurances and certifications and provisions indicating the intent of the subrecipient to comply, including submission of applicable assurances and certifications.
- conflict of interest requirement.
- provisions regarding property, program income, publications, reporting, record retention, and audit.

3.5.2: Reporting

You must submit financial, performance, and other reports. Not meeting reporting requirements could result in enforcement actions. These actions include those in the Remedies for Noncompliance section of the GPS including [2 CFR 200.339](#) through [200.343](#), and reporting to Responsibility/Qualification in SAM.gov (formerly FAPIIS).

3.5.2.1: Federal Financial Reports

You submit Federal Financial Reports (FFRs) through the Payment Management System (PMS).

How often you need to submit an FFR is in the NoA. This can range from quarterly to annually. Higher risk recipients may report more often.

Updated information on FFRs is at the [Program Support Center for PMS](#).

You may need to revise your FFR in some cases. You must submit a revised FFR to HHS immediately for overcharges. You also must submit revised FFRs as soon as possible for expenditures that you did not report before. You must explain why the revision is necessary and how you will prevent this in the future. For annual FFRs, it is HHS policy that revisions are due no later than 9 months from the end date. For final FFRs, it is HHS policy that revisions are due no later than 6 months after the end date. The agency will tell you how your award will be updated if revised FFRs are accepted.

PLEASE NOTE: The GMS may not accept a revised interim FFR submitted by the recipient that claims



additional expenditures after one year from the end of the reporting period (regardless of when the original report was submitted).

3.5.2.2: Progress Reports

You submit progress reports through [GrantSolutions](#) or [NIH eRA](#).

The reporting schedule and requirements are in the NoA. Schedules can range from quarterly to annually. Higher risk recipients may report more often as part of a special condition of their award.

See [2 CFR 200.329\(c\)\(1\)](#).

3.5.2.3: Other Reporting

Intellectual Property Reporting

If you have a research award, you must report on patents and inventions through iEdison ([iEdison | NIST](#)).

Each competing continuation application and progress report (when used in lieu of a non-competing continuation application) must indicate whether any subject inventions were made during the preceding budget period.

3.5.2.3.1: Invention Reporting

You must report on inventions. The [iEdison website](#) includes information on invention reports. See also [37 CFR 401](#).

You must also submit an annual invention use report for:

- all inventions to which title has been elected; and
- inventions that have been licensed but not patented (research tools).

The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the [Bayh-Dole Act](#).

Contact the GMS for questions, including:

- if inventions under a career development award is a subject invention
- the extramural technology transfer policy
- reporting and use of inventions

3.5.2.3.2: Real Property Reporting

Construction awards must report the status of real property each year for as long as the federal government retains an interest, up to 15 years. If the federal interest lasts beyond 15 years, the agency or pass-through entity may require the recipient to report at various multi-year frequencies.

3.5.2.4: Non-Compliance

3.5.2.4.1: Failure to Submit Reports

When you fail to submit required reports within the time allowed, the agency may take enforcement



actions including those in the Remedies for Noncompliance section of the GPS.

3.5.2.4.2: Overdue Reports

An agency may give a waiver, if permitted by law, or extension if a report is overdue and the reason is beyond your control.

Failure to meet a new date may result in the agency taking enforcement actions.

Submission of a required report does not necessarily fulfill your obligation. Reports must meet content requirements. You must provide the revised report by the indicated due date to avoid enforcement actions.

3.5.2.5: Fraud, Waste, and Abuse

Fraud, waste, or abuse related to HHS awards or use of award funds should be reported to HHS. Fraud, waste, and abuse may be reported:

- By telephone at 1-800- HHS-TIPS (1-800-447-8477) or TTY at 1-800-377-4950
- Fax at 1-800-223-8164. Forms for use are available at the [OIG website](#).
- E-mail at HHSTips@oig.hhs.gov
- USPS mail at U.S. Department of Health and Human Services, Office of Inspector General, Attn: OIG Hotline Operations, P.O. Box 23489, Washington, DC 20026.

If you report, you are not required to give your name, but if you do, your identity is kept confidential.

Fraud, waste, and abuse includes embezzlement, misuse or misappropriation of award funds or property, and false statements or claims. Examples include:

- theft of award funds for personal use
- using funds for non-award-related purposes
- theft of federally owned property or property acquired or leased under an award
- charging inflated building rental fees for a building owned by the recipient
- submitting false financial report
- submitting false financial data in bids submitted to the recipient

The federal government may pursue administrative, civil, or criminal action under a variety of statutes that relate to fraud and false statements or claims. Even if no award is made, you may be subject to penalties if information submitted as part of an application is found to be false, fictitious, or fraudulent. See the statutes referenced in [Appendix D](#) and [Appendix E](#) for statutes related to fraud, waste, and abuse.

3.5.2.6: Paperwork Reduction Act

The Paperwork Reduction Act (PRA), [44 USC 35](#), as implemented by [5 CFR 1320](#), is designed to:



- Reduce, minimize, and control burdens
- Maximize the practical use and public benefit of the information created, collected, disclosed, maintained, used, shared, and disseminated by or for the federal government

OMB clearance is required for agency collection of information. This includes all application or reporting forms, whether paper or electronic. Below is information about how the PRA is implemented.

3.5.2.7: Federally Sponsored Surveys

Recipients may use award funds to collect information through surveys or questionnaires:

- When the collection of information is not a primary objective of the award but is incidental to, or is an integral part of, an award-supported activity.
- When the collection of information is a primary objective of the award, but such information is not intended primarily for use by the federal government, or a party designated by the federal government.

When information is collected, according to either of the two conditions above, you may not represent what the information is being collected for, or in association with, unless:

- You receive agency approval; and
- You follow OMB report clearance procedures, when required. When OMB approval is required, the agency, rather than the recipient, will obtain the necessary clearance.

OMB clearance is required whenever the HHS agency sponsors the use of a reporting form or plans to collect identical kinds of information or data from 10 or more people.

Information collection is considered HHS agency-sponsored when any of the following circumstances exist:

- The agency allows you to state that the information is being collected for, or in association with, the agency.
- You use the report form or collect information that an agency has requested for the planning, operation, or evaluation of its program.
- The award terms and conditions provide agency approval of the study design, questionnaire content, or data collection procedure.
- The award terms and conditions provide for either submission of the data for individual respondents or the preparation and submission of special requested tabulations to the agency.

HHS and OMB approval may also be required if the use of a report form or plan presents a relatively high risk of unwarranted privacy invasion.

Collection of the following types of information is not subject to the clearance requirements at [5 CFR 1320](#):



- health professions data as described in [Section 708 of the Public Health Service \(PHS\) Act](#)
- tests or examinations of individuals for determining knowledge, abilities, or aptitudes, and the collection of information for identification or classification in connection with such tests
- information from patients to be used exclusively for research of or direct treatment of a clinical disorder; for the interpretation of biological analyses of body fluids, tissues, or other specimens; or for identification or classification of such specimens

See [5 CFR 1320](#) for additional clearance requirement exemptions.

3.6: Remedies for Noncompliance

If you do not comply with award terms and conditions, the agency or pass-through entity may take enforcement actions, in accordance with applicable statutes, regulations and policy.

You usually have an opportunity to correct the deficiencies unless there is a serious threat to public health or welfare concerns. The agency may take necessary proactive steps to protect the federal government's interests. Agencies may take any action allowed by law, including those below. See [2 CFR 200.339](#) through [200.343](#).

3.6.1: Implementation of Specific Award Conditions

An agency or pass-through entity may place corrective specific conditions on an award to address issues with your award compliance.

When the agency or pass-through entity imposes specific award conditions, they will notify you of:

- the nature of the conditions
- the reason why
- the type of corrective action needed
- the time allowed for completing corrective actions
- the method for requesting reconsideration of the conditions

Examples of specific award conditions are removing a PI/PD, converting your award from advance payment to reimbursement, and adding reporting requirements.

See [2 CFR 200.208](#).

3.6.2: Disallowed Costs

HHS may disallow all or part of the cost of an activity or action determined not in compliance. This can happen at any time during the award or after closeout.

You must repay disallowed costs with non-federal funds or an offset from future year funds. You may appeal disallowed costs.



3.6.3: Other Remedies

Depending on the nature of the deficiency, an agency also may:

- temporarily withhold payment
- withhold further awards for the project or program

3.6.4: Suspending Award Activities or Termination

Consistent with [2 CFR 200.339](#) and [2 CFR 200.340](#), an agency or pass-through entity may suspend or terminate all or part of your award activities if you fail to materially comply with the award terms and conditions. See [2 CFR 200 Subpart D](#).

The HHS agency generally will suspend, rather than immediately terminate, a federal award. This allows you an opportunity to take appropriate corrective action before making the decision to terminate. The HHS agency may decide to terminate the federal award if you do not take appropriate corrective action during the period of suspension.

Under a suspension, the HHS agency will provide you:

- What project activities, if any, will take place during the period of suspension.
- What costs the HHS agency will reimburse if the enforcement action is ultimately lifted, and the award resumed.
- What corrective actions must occur during the enforcement action.
- The HHS agency's intent to terminate the award if the non-federal entity does not meet the conditions of the enforcement action.

The HHS agency may terminate without first suspending the federal award if the problem is serious enough or if public health or welfare concerns require immediate action. Termination for failure to comply with terms of award may be appealed under the HHS agency and HHS's federal award appeals procedures ([45 CFR Appendix A to part 16](#)).

A federal award also may be terminated, in whole or partially, by the recipient or by the HHS agency with the consent of the recipient. If you decide to terminate a portion of a federal award, the HHS agency may determine that the remaining portion will not accomplish the original purpose. In this case, you will be advised of the possibility of termination of the entire federal award and will be allowed to withdraw your termination request. If you do not withdraw your request for partial termination, the HHS agency may terminate the entire federal award. See [2 CFR 200.340](#).

When an HHS agency terminates a federal award prior to the end of the period of performance due to the non-federal entity's material failure to comply with the federal award terms and conditions, the HHS agency must report the termination to the OMB-designated integrity and performance system accessible through the Responsibility/Qualification System in Sam.gov. This information will be reported after the non-federal entity has exhausted its opportunities to object or challenge the decision or has not within 30 calendar days after being notified of the termination informed the HHS



agency that it intends to appeal the decision to terminate. For full information on reporting termination in FAPIIS, see [2 CFR 200.340\(c\)](#).

Federal awards may also be terminated if an award no longer effectuates the program goals or agency priorities, in line with [2 CFR 200.340\(a\)\(4\)](#).

HHS applies appeal rights in line with [2 CFR 200.342](#). Appeals rights exist for termination actions that are a remedy for non-compliance.

3.6.4.1: Suspension or Debarment

An agency may initiate suspension or debarment proceedings under [2 CFR 180](#) and HHS agency regulations at [2 CFR 376](#). A pass-through entity may recommend that the agency do so for a subaward.

3.7: Closeout

To close an award, you do several steps to include submitting a final report. Ask your GMS and review the closeout provisions HHS now follows at [2 CFR 200.344](#). The agency will resolve any amounts due to them or to you.

Upon the completion date of an award, you have 120 days to liquidate all financial obligations and submit all required reports, including a final FFR, final progress report, tangible and real property reports (if needed), and Final Invention Statement and Certification (if needed). The GMO or their delegate may give an extension upon a written request. Not submitting timely and accurate reports can affect future funding. HHS may close out your award on its own if you fail to provide your reports on time.

HHS may still disallow costs or recover funds based on an audit or review after your award is closed out. After closeout, you still must return any funds due to HHS because of refunds, corrections, indirect cost rate adjustments, or other transactions.

You still need to account for property acquired on your award and follow disposition and record retention requirements after close out.

See [2 CFR Subpart D Property Standards](#) for other disposition requirements. See [2 CFR 200.334 through 200.338](#) for record retention requirements.

3.7.1: Final Federal Financial Report (FFR)

A final FFR is required for all the following:

- terminated awards
- awards transferred to new recipients
- awards at the end of a period of performance

Final FFRs must:

- account for all funds awarded during the period of performance



- have no unliquidated obligations
- say the exact unobligated balance

In some cases, you may need to submit a revised FFR. When a revised final FFR results in additional recipient claims, the agency will consider approval if:

- You show why the revision is needed, explains, and implements internal controls to avoid similar future situations
- The charge is allowable under the award
- There is an unobligated balance for the budget period that can cover the claim
- The funds are still available
- The agency receives the revised FFR within 6 months of its original due date

3.7.2: Final Progress Report

A final progress report is required for all the following:

- terminated awards
- awards at the end of the performance period Submit final progress reports as directed in your NoA.

Use the agency instructions. At a minimum, they include:

- a summary of progress towards achieving the stated aims
- significant results, positive or negative
- publications

If you submit a competing continuation application, the final progress report requirement may be met by the information included in that application.

3.7.3: Final Invention Statement

For research awards, you must submit a Final Invention Statement and Certification (HHS 568). HHS requires this statement even if the award does not result in any inventions. The HHS 568 is at the iEdison Web site at [iEdison | NIST](#).

The HHS 568 lists all inventions conceived or initially reduced to practice under the award. The form must be signed by the PI or PD and AOR. The form covers the period from the original award start date through the award end date. If there were no inventions, the form should indicate “None.”

3.8: Post-Closeout

After award closeout, you still have obligations for record retention, property accountability, and financial accountability. See [2 CFR Subpart D Property Standards](#), [2 CFR 200 Subpart D Record Retention and Access](#), and [2 CFR 200.330](#).



3.8.1: Record Retention and Access

You must keep financial, supporting, and statistical records, and all other records considered pertinent to an award.

The retention periods are three years after sending:

- the final FFR for closed awards
- quarterly or annual reports for awards renewed quarterly or annually

These periods are extended until the conclusion of any litigation matters, claims, or audits and audit findings are fully resolved.

You must allow records access to the:

- HHS Agency
- Inspector General
- Comptroller General
- Pass-through Agency

See:

- Retention requirements for records ([2 CFR 200.334](#))
- Access to records ([2 CFR 200.337](#))
- Restrictions on public access to records ([2 CFR 200.338](#))

3.8.2: Debt Collection

During or after closeout, HHS may find that you received more than the correct amount or that you misspent funds. This may result from disallowed costs, recovery of funds, unobligated balances, or other situations. In these cases, HHS will consider this amount a debt and send you a request for repayment. You have 90 calendar days to repay the amount.

If you do not pay back the funds in 90 calendar days, the HHS agency may reduce your debt by:

- making an administrative offset against payments on other HHS awards.
- withholding advance payments.
- taking other action allowed by law.

HHS must, by law, collect debts due to the federal government. Unless prohibited by law, HHS is also required to charge interest on delinquent debts.

See Collection of Amounts Due ([2 CFR 200.346](#)) for more.

You may appeal a request for repayment. If appealed, HHS suspends the collection pending a final appeal decision. If denied, in whole or in part, HHS will charge interest on the debt starting with the



date of the original request for repayment.

Refer to the HHS Claims Collection ([45 CFR 30](#)) and the Program Support Center's Debt Management Collection System at <https://pms.psc.gov/> for more on collection of debts.

3.9: Appeals

Agencies may have their own appeals procedures. See also the procedures of the Departmental Appeals Board ([45 CFR 16](#)).

Agencies and recipients may use alternative dispute resolution (ADR). ADR can reduce the cost, time, and level of dispute involved in appeals.

For more information on appeals, see the [Departmental Appeals Board website](#).



Chapter 4: Single Audit

An audit is a review to verify if accounting and control systems reasonably assure:

- proper financial operations
- timely, fair, and correct financial reports
- compliance with applicable laws, regulations, and terms and conditions of award
- resources are managed and used economically and efficiently
- desired results and objectives are being achieved effectively
- recipients and subrecipients follow the audit requirements of [2 CFR 200 Subpart F](#).

4.1: Audit Requirements

As of October 1, 2024, you and your subrecipients must have an audit if either spends \$1,000,000 or more in federal awards during its fiscal year (see [2 CFR 200.501](#)). Even if an audit is not required, keep records available for review by federal officials.

You must use an independent auditor who must follow the [Government Auditing Standards](#) and the [audit requirements in 2 CFR 200 Subpart F](#). Audit costs are allowable and often covered by the indirect cost rate.

Pass-through entities are responsible for establishing audit requirements, to ensure compliance by subrecipients.

HHS may request more audits, if necessary.

4.2: Types of Audits

Program Specific Audit: test a single program. Refer to [2 CFR 200.507](#).

- Single Audit: The auditor uses a risk-based approach to identify major programs which the auditor tests and provides an opinion on compliance. See [2 CFR 200 Subpart F](#).
- Financial Related Audit: Specific to for-profit organizations. Must be conducted in accordance with the [Government Auditing Standards](#).

For other types of audits, see [2 CFR 200.501](#).

4.3: Audit Options

If an audit is required, the following options are available:

4.3.1: For Governments, Indian Tribes, Institutions of Higher Education, and Non-Profits

- Only one program: If your organization expends funds in only one program, you may use a program-specific audit as per [2 CFR 200.501\(c\)](#) and [200.501\(d\)](#).



- Multiple programs: If your organization expends \$1,000,000 or more in funds from more than one program, a single audit is required, as per [2 CFR 200.501\(b\)](#).

See full audit requirements in [2 CFR 200.501](#).

4.3.2: For-Profit Organizations

- Only one program: If federal awards are in only one program, then they may opt for a program-specific audit or financial related audit of the award.
- Multiple programs: If federal awards are in more than one program, then they must have a single audit or financial related audit of all awards.

4.3.3: Contractors

Audit requirements for federal awards do not apply to contractors with annual HHS awards less than \$1,000,000. See [2 CFR 200.501](#).

4.3.4: Foreign Entities

Audit requirements and processes for foreign entities will be addressed in your NOFO and NoA.

4.4: Recipient Responsibilities

- Procure or otherwise arrange for the required audit and make sure it is performed properly. See [2 CFR 200.509](#).
- Provide the auditor with access to needed personnel, accounts, books, records, supporting documentation, and other information.
- Prepare financial statements, including the schedule of federal award expenditures. See [2 CFR 200.510](#).
- Make sure the audit is submitted within 30 days after receiving the auditor's report or 9 months after your fiscal year end, whichever is earlier. See [2 CFR 200.512](#).
- Promptly follow up and take corrective action on audit findings. See [2 CFR 200.508](#) for a listing of auditee responsibilities.

4.5: Audit Findings and Resolution

Non-Federal entities and their subrecipients must follow up and take corrective action on all audit findings. This includes preparing:

- a summary schedule of prior audit findings. See [2 CFR 200.511\(b\)](#)
- a corrective action plan. See [2 CFR 200.511\(c\)](#)

4.5.1: Requirements

The summary schedule and the corrective action plan must include:



- reference numbers the auditor assigns to audit findings under [2 CFR 200.516\(c\)](#);
- the fiscal year in which the finding initially happened; and
- findings relating to the financial statements required to be reported under Government Auditing Standards

See [2 CFR 200.511](#).

4.6: Report Submission

Reports for non-profit recipients are submitted to the [Federal Audit Clearinghouse \(FAC\)](#). For-profit and foreign recipients submit reports to the HHS Audit Resolution Division at AuditResolution@HHS.gov.

The HHS assignment system receives single audit reports from the FAC and assigns audit findings to the agencies for resolution.

Both you and your auditors must complete and submit your portions of the reporting package to FAC. They are due within 30 calendar days after receipt of the auditor's report or nine months after the end of the audit period, whichever is earlier. See [2 CFR 200.512](#).

4.6.1: Documentation

Ensure that the basis for valuing services, materials, equipment, buildings, and land can be verified. Make sure your records, including those from your subrecipients, can support the value. If using volunteer services, document their time and attendance as you would for regular employees.

4.6.2: Delinquent Audits

HHS will follow up to obtain audit reports that are delinquent.

If required audits are not completed or do not follow [2 CFR 200](#), audit costs may be disallowed or other sanctions may be taken.

4.7: HHS Office of Inspector General

The HHS Office of Inspector General (OIG) audits programs and their recipients to ensure funds are used correctly and guard against fraud and waste. The OIG:

- can freely access records and information
- can request information and documents through subpoenas
- acts as the National Single Audit Coordinator, giving audit guidance to HHS agencies and recipients

You need to have strong internal controls and guidelines must be in place to ensure proper use of federal funds.



4.8: Additional Information

4.8.1: Cooperative Audit Resolution and Management Decisions

Cooperative audit resolution is a structured approach that brings the appropriate stakeholders together to address audit findings and proposed corrective actions. See [2 CFR 200.513\(c\)\(3\)\(iii\)](#). Non-federal entities must follow this approach to ensuring timely and appropriate resolution of audit findings and recommendations. Recipients usually are allowed 30 days from the date of request to respond to the responsible audit resolution official.

The HHS agency will coordinate with the non-federal entity during the cooperative audit resolution process. The HHS agency will:

- Follow-up on audit findings to ensure the non-federal entity takes appropriate and timely corrective action.
- Issue a management decision, on all assigned reporting packages with audit findings within six months of the date the FAC accepts the reporting package.
- Issue sanctions when the non-federal entity fails to correct conditions identified by audits that are likely to cause improper payments, fraud, waste or abuse.

The HHS agency or pass-through entity responsible for issuing a management decision must do so within 6 months of acceptance of the audit report by the FAC. The management decision provides timely information to the non-federal entity regarding where the HHS agency is in evaluating findings and related corrective actions. The HHS agency management decision will include:

- whether or not the audit finding is sustained.
- the reasons for the decision.
- the expected action the non-federal entity must take to repay disallowed costs, make financial adjustments, or take other action.
- a timetable for follow-up if then non-federal entity has not completed corrective action; and
- a description of the appeal processes available to the non-federal entity.



Appendix A: Agencies Overview

Below is an overview of HHS agencies. Visit [HHS Organization Chart | HHS.gov](https://www.hhs.gov/organization-chart/) for more. GPS refers to “Public Health Service (PHS) agencies.” We have marked them below.

Agency	Overview	Support
Administration for Children and Families (ACF) www.acf.hhs.gov	Promotes economic and social well-being of children, families, and communities.	- childcare for low-income families - foster care and adoption - child abuse and domestic violence prevention
Administration for Community Living (ACL) www.acl.gov	Advocates for older adults, people with disabilities, families, and caregivers to help all people live independently and participate in their communities.	- health, wellness, and nutrition - self-advocacy - connecting people to services - retirement planning - American Indian, Alaska Native, and Native Hawaiian nutrition and older adult support
Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov PHS agency	Improves quality, safety, accessibility, equitability, and affordability of US health care.	- digital healthcare research PSNet (Patient Safety Network) - quality indicators
Administration for Strategic Preparedness and Response (ASPR) www.aspr.hhs.gov	Assists the country in preparing for, responding to, and recovering from public health emergencies and disasters.	- development and stockpiling of medical countermeasures - pandemic preparedness
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP) www.healthit.gov	Administers health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide, standards-based health information exchange to improve health care.	- advance development and use of health IT capabilities - establish expectations for data sharing
Centers for Disease Control and Prevention (CDC) www.cdc.gov PHS Agency	Protects against health and public health, safety, and security threats. Their focus is both foreign and domestic.	- immunization services - monitoring and preventing disease outbreaks - disease prevention strategies - workplace safety



Centers for Medicare & Medicaid Services (CMS) www.cms.gov	Advances health standards and quality, expanding coverage, and improving health outcomes.	• clinical standards and quality • meaningful measures
Food and Drug Administration (FDA) www.fda.gov FDA Grants and Cooperative Agreements Page PHS Agency	Protects public health by ensuring the safety of human and veterinary drugs, biological products, medical devices, cosmetics, and food.	• food safety • animal feed safety • laboratory systems • scientific conferences
Health Resources and Services Administration (HRSA) www.hrsa.gov PHS Agency	Provides access to essential health care services for people who are low-income, uninsured, or live in areas with limited access.	• rural health • maternal and child health • opioid response • health workforce training • telehealth
Indian Health Service (IHS) www.ihs.gov PHS Agency	Ensures comprehensive, culturally appropriate personal and public health services are available to American Indians and Alaska Native people.	• community health • behavioral health • environmental stability • school health
National Institutes of Health (NIH) grants.nih.gov PHS Agency	Seeks knowledge about the nature and behavior of living systems. Applies it to enhance health, lengthen life, and reduce illness and disability.	• biomedical and behavioral research • research training • research infrastructure and communications
Office of the Assistant Secretary (OASH) www.hhs.gov/ash PHS Agency	Seeks to serve the public through responsive public health actions to promote healthy and safe environments and prevent harmful exposures.	• minority health • family planning • adolescent health • women's health • infectious disease and HIV/AIDS policy • research integrity
Office of the Inspector General (OIG) www.oig.hhs.gov	At the forefront of the Nation's efforts to fight waste, fraud and abuse and to improving the efficiency of Medicare, Medicaid and more than 100 other Department of Health & Human Services (HHS) programs.	• Medicare/Medicaid oversight • improved efficiency • fraud, waste, abuse detection



Substance Abuse and Mental Health Services Administration (SAMHSA) www.samhsa.gov PHS Agency	Improves the quality and availability of substance abuse prevention, addiction treatment, and mental health services.	• substance abuse and mental health services.
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For agency staff and recipient roles and responsibilities, see the [Introduction and General Information](#) section.



Appendix B: Acronyms and Glossary

B.1: Acronyms

Please see [acronyms listed in 2 CFR 200.0](#). Although not all the terms are in the GPS, they may be useful to applicants and recipients.



B.2: Glossary

This glossary defines terms commonly used in the HHS GPS. These definitions are for purposes of clarity and do not replace controlling definitions in applicable statutes and regulations.

Acquisition cost	The total cost of an asset, including the cost to get the asset ready for its intended use. For example, acquisition cost for equipment 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. See 2 CFR 200.1 Acquisition cost.
Accrual basis	For reports prepared on an accrual basis, expenditures are the sum of cash disbursements for direct charges for property and services, the amount of indirect expense incurred, the value of third-party in-kind contributions applied, and the net increase or decrease in the amounts owed by the recipient or subrecipient for goods and other property received, services performed by employees, contractors, subrecipients, and other payees, and programs for which no current services or performance are required, such as annuities, insurance claims, or other benefit payments. See 2 CFR 200.1 Expenditures.
Administrative requirements	The general practices that are common to the administration of grants, such as financial accountability, reporting, equipment management, and retention of records.
Advance payment	A payment that a Federal agency or pass-through entity makes by any appropriate payment mechanism and payment method before the recipient or subrecipient disburses the funds for program purposes.
Allocable cost	An allocable cost relates to a specific project or activity based on the relative benefits it provides. It's allocable to a federal award if: • It's specifically for the award • It benefits both the award and other tasks and can be distributed based on those benefits • It's needed for the organization's overall functioning See 2 CFR 200.405 Allocable costs.
Allowable cost	Allowable costs are: • Reasonable for the award's purpose • Allocable • Within the federal cost principles or NoA guidelines • In line with the recipient's consistent policies, covering both federal and non-federal activities • Consistently treated as either a direct or indirect cost • Based on standard accounting principles • Not used in another federal award, unless statute says otherwise See 2 CFR 200.403 Factors affecting allowability of costs



Alteration and renovation (A&R)	Alteration and renovation involve changing the inside or features of a facility or installed equipment to enhance its current use or adapt it for a new purpose. It can include improvements, remodeling, or modernization but is different from construction or major permanent upgrades.
Alternative dispute resolution (ADR)	A method to solve disagreements without going to court. It aims to resolve issues faster, cheaper, and in a less confrontational way, preventing them from becoming bigger problems that need formal legal action.
Applicable credit	Receipts that offset or reduce direct or indirect costs. Typical examples include purchase discounts, rebates, or allowances; recoveries or indemnities on losses; insurance refunds; and adjustments of overpayments or erroneous charges. See 2 CFR 200.406 Applicable credits .
Application	A request for financial support of a project or activity submitted on specified forms and in accordance with agency instructions. See Types of Applications .
Approved budget	The spending plan for a project funded by an award. This budget has both federal funds and, if applicable, non-federal funds like cost-sharing. If both types of funds are in the budget, the recipient must spend them in the same ratio as they appear in the total budget. See 2 CFR 200.1 Budget and 2 CFR 200.308 Revision of budget and program plans .
Assurance	A written statement by an applicant, normally included with the application, that it will follow a particular requirement if there is an award.
Audit resolution	The process of resolving audit findings, including those related to management and systems deficiencies and monetary findings like questioned costs.
Award	The document that provides the agency funds to a recipient to carry out an approved project, based on an approved application. In the GPS, award means both grants and cooperative agreements. See 2 CFR 200.1 Federal award .
Agency	The agency responsible for making, monitoring, and overseeing awards. For changes in award terms or for approval requests, the reference may be to the GMS. This is sometimes referred to as “Federal agency” or “Federal agency.” See 2 CFR 200.1 Federal agency .
Award terms and conditions	The legal requirements set by the agency for the award. These can come from laws, regulations, policies, or the NoA. The NoA might also add specific conditions to ensure the award's goals are met, enable post-award management, save funds, or protect federal interests.
Budget period	The time interval from the start date of a funded portion of an award to the end date of that funded portion during which recipients and subrecipients are authorized to incur financial obligations of the funds awarded. Budget periods are typically 12 months. Funding of individual budget periods sometimes is referred to as “incremental funding.” See 2 CFR 200.1 Budget period .



Carryover	Unobligated (unspent) federal funds from a particular budget period that can be transferred and used in the next, or later, budget period to cover allowable expenses in that subsequent period. Funds that have been committed but not yet spent (obligated but unliquidated) are not considered carryover.
Cash basis	An accounting method in which revenue and expenses are recorded on the books of account when received and paid, respectively, without regard to the period in which they are earned or incurred. It is different than accrual basis.
Change of recipient	Transfer of the legal and administrative responsibility for an award from one legal entity to another before the end of the period of performance.
Closeout	The process by which an agency determines that all applicable administrative actions and all required work of the award have been completed by the recipient and the agency. See 2 CFR 200.344 Closeout .
Cognizant agency for audit	The Federal agency designated to carry out the responsibilities described in 2 CFR 200.513(a) . This agency is not necessarily the same as the cognizant agency for indirect costs. A list of contacts can be found on the Federal Audit Clearinghouse (FAC) website .
Cognizant agency for indirect costs	The Federal agency responsible for reviewing, negotiating and approving cost allocation plans or indirect cost proposals on behalf of all Federal agencies. This agency is not necessarily the same as the cognizant agency for audit. See 2 CFR 200.1 Cognizant agency for indirect costs .
Competition	A process in which applications undergo a merit review and are evaluated against established evaluation criteria in the NOFO. See 2 CFR 200.319 Competition .
Completion date	The date on which all work under an award is completed or the date in the NoA (as amended) on which federal sponsorship ends (i.e., the end of a period of performance).
Consortium agreement	A formal agreement whereby a project is carried out by a 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 project and not merely serve as a conduit of funds to another party or parties. Consortium agreements are considered subawards.
Continuation funding	The second or subsequent budget period within an identified period of performance. See 2 CFR 200.1 Continuation funding .
Contract under an award	A written agreement between a recipient/subrecipient and a third party to acquire commercial goods or services. This may also be called a subcontract. See 2 CFR 200.1 Contract .



Construction	A project to support the initial building or major alteration and renovation like large-scale modernization or permanent improvement of a facility.
Consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. Also includes a firm that provides paid professional advice or services.
Cooperative agreement	A financial assistance support mechanism used when there will be substantial federal programmatic involvement. Substantial involvement means that the agency's program staff will collaborate or participate in project or program activities as specified in the NoA. See 2 CFR 200.1 Cooperative Agreement .
Copyright	Protection provided by statute (Title 17, U.S. Code) to the authors of "original works of authorship," including literary, dramatic, musical, artistic, and certain other intellectual works, including computer programs. This protection applies to both published and unpublished works.
Cost analysis	The systematic review of a budget proposal to detail and assess cost components; ensure costs are necessary, reasonable, and allocable; and confirm alignment with federal guidelines, ensuring no unallowable expenses.
Cost sharing	The portion of project costs not paid by Federal funds or contributions (unless authorized by Federal statute). This term includes matching, which refers to required levels of cost share that must be provided. See 2 CFR 200.1 Cost sharing .
Departmental Appeals Board (DAB)	The DAB is a board within HHS that impartially addresses disputes from HHS assistance programs. It offers a fair hearing process for challenges to certain grants management decisions, with its role and rules outlined in 45 CFR 16 .
Direct costs	Costs directly linked to a specific project, instructional activity, or other institutional activities, which can be accurately and easily allocated to those activities. See 2 CFR 200.413 Direct costs .
Discretionary award	An award in which the Federal agency, in keeping with specific statutory authority that enables the agency to exercise judgment ("discretion"), selects the recipient or the amount of Federal funding awarded through a competitive process or based on merit of proposals. A discretionary award may be selected on a non-competitive basis, as appropriate. See 2 CFR 200.1 Discretionary award .
Entity Identification Number (EIN)	A 12-character code in PMS comprising three parts: the first character indicates if the recipient is an organization or individual; the following 9 characters represent the TIN for organizations or the SSN for individuals; the final 2 characters differentiate between organizational entities with the same or multiple EINs, denoting subsidiaries, branches, or other subdivisions.



Equipment	A tangible item with a lifespan exceeding 1 year and a cost equal to or exceeding \$10,000 per unit, or the recipient's capitalization threshold, whichever is lower. See 2 CFR 200.1 Equipment .
Excess property	Property that, as decided by the head of the agency or its representative, is no longer needed for the agency's functions or responsibilities. See 2 CFR 200.312(b) .
Exempt property	Tangible personal property bought either entirely or partly with federal funds, where the agency has the legal authority to vest title to the recipient without additional obligations to the federal government. See 2 CFR 200.312 Federally owned and exempt property .
Expanded authorities	Permissions granted to recipients by the agency that eliminate the need for prior approval from the agency for certain activities. See 2 CFR 200.308(g) Waiver of prior approvals .
Expenditures	The charges made to the federally sponsored project or program by a recipient or subrecipient. They may be reported on a cash or accrual basis. See 2 CFR 200.1 Expenditures .
Extension	An additional timeframe beyond the original period of performance, granted by the agency or recipient (under expanded authority), to finalize project activities. Extensions can be funded, or no-cost. See Section 3.1.4 Extensions to Awards and 2 CFR 200.309.
Facilities and administrative costs (F&A)	See Indirect costs .
Federal institution	A Cabinet-level department or independent agency within the executive branch of the federal government, or any of its sub-entities.
Federal share	The proportion of the Federal award costs paid using Federal funds. See 2 CFR 200.1 Federal share .
Fee	A sum paid beyond the actual allowable costs to an entity delivering goods or services in line with standard commercial practice, often referred to as "profit."
Financial assistance	The provision of funds, property in place of funds, or other direct aid to a qualified recipient to encourage or further a public purpose authorized by law. See 2 CFR 200.1 Federal financial assistance .
Foreign component	The performance of a major part or component of a project outside the United States by the recipient or by a researcher affiliated with a foreign institution, regardless of whether award funds are used.
Foreign organization	An entity situated in a country outside of the United States and its territories, governed by the laws of that nation, regardless of the nationality of the proposed Principal Investigator/Project Director.



	See 2 CFR 200.1 Foreign organization .
For-profit organization	A legal entity formed for the purpose of generating profit for its shareholders or owners. See 2 CFR 200.1 For-profit organization for a list of general types of organizations that this includes.
Grant	A funding mechanism given to an eligible entity to support a public-purpose project or activity without significant involvement from the agency. Unlike direct benefits for the government, a grant provides financial assistance or other resources to accomplish approved objectives. See 2 CFR 200.1 Grant agreement or grant .
High risk	A recipient with a history of subpar performance, financial instability, or inadequate management, placing them at risk of financial or operational failure.
Human subject	An individual from whom an investigator collects data via intervention, interaction, or acquisition of identifiable private information, including organs, tissues, body fluids, or any related graphic or recorded details. Regulations at 45 CFR 46 govern the use of human subjects.

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 , which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians. See 2 CFR 200.1 Indian Tribe .
Indian tribal government	The governing body overseeing an Indian Tribe, group, or community, including Alaska Native villages per the Alaska Native Claims Settlement Act of 1971 . This body is recognized by the Secretary of the Interior for access to specific programs and services via the Bureau of Indian Affairs and the Indian Health Service.
Indirect costs	Costs incurred 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. For Institutions of Higher Education, the term facilities and administrative cost is often used to refer to indirect costs. See 2 CFR 200.1 Indirect costs , 2 CFR 200.414 , and 2 CFR 300.414 .
Institutional review board (IRB)	A committee that safeguards the rights and well-being of human subjects in research. The IRB can approve, modify, or disapprove research activities under its jurisdiction.



Intangible property	Property without physical existence, such as trademarks, copyrights, data (including data licenses), websites, IP licenses, trade secrets, patents, patent applications, and property such as loans, notes and other debt instruments, lease agreements, stocks and other instruments of property ownership of either tangible or intangible property, such as intellectual property, software, or software subscriptions or licenses. See 2 CFR 200.1 Intangible property .
International Organization	An organization with members from multiple countries, representing their interests, regardless of whether its headquarters or activities are located within or outside of the US.
Invention	A potentially patentable or protectable discovery or invention made by an awardee during work funded by a contract, grant, or cooperative agreement. The term "subject invention" refers to inventions specifically conceived or first reduced to practice as part of the funded work.
Key personnel	The PI/PD and other individuals who contribute to the programmatic development or execution of a project in a substantive, measurable way, whether they receive salaries or compensation under the award.
Local government	Any unit of government within a State, including a county, borough, municipality, city, town, township, parish, local public authority, special district, school district, intrastate district, council of governments, or any other agency or instrumentality of a multi-, regional, or intra-State or local government. See 2 CFR 200.1 Local government .

Matching	See Cost sharing .
Merit review	An objective process of evaluating Federal award applications in accordance with the written standards of the Federal agency. This review is an unbiased evaluation of discretionary applications by experts in the relevant field. Also known as objective review. See 2 CFR 200.205 Federal agency review of merit of proposals .
Micro-purchase threshold	The dollar amount at or below which a recipient or subrecipient may purchase property, or services using micro-purchase procedures. See 2 CFR 200.1 Micro-purchase threshold .
Monitoring	A method of evaluating an award's programmatic and business management performance using data from reports, audits, site visits, and other sources.
Non-discretionary award	An award made by the Federal agency to specific recipients in accordance with statutory, eligibility, and compliance requirements, such that in keeping with specific statutory authority, the Federal agency cannot exercise judgment ("discretion"). A non-discretionary award amount could be specifically determined



	or by formula. See 2 CFR 200.1 Non-discretionary award.
Notice of funding opportunity (NOFO)	A formal announcement of the availability of Federal funding through a financial assistance program from a Federal agency. The notice of funding opportunity provides information on the award, such as who is eligible to apply, the evaluation criteria for selecting a recipient or subrecipient, the required components of an application, and how to submit the application. See 2 CFR 200.1 Notice of funding opportunity.
Objective review	See merit review .
Obligations	The value of commitments made by a recipient during a budget period for orders placed for property and services, contracts and subawards made, and similar transactions that require payment by a recipient or subrecipient under a Federal award that will result in expenditures by a recipient or subrecipient under a Federal award. See 2 CFR 200.1 Financial obligations.
Participant	Generally, an individual participating in or attending program activities under a Federal award, such as trainings or conferences, but who is not responsible for implementation of the Federal award. Individuals committing effort to the development or delivery of program activities under a Federal award (such as consultants, project personnel, or staff members of a recipient or subrecipient) are not participants. See 2 CFR 200.1 Participant.
Patent	A property right awarded by the federal government that grants the right to exclude others from making, using, or selling the invention for a period of years.
Peer review	A form of merit review of applications based on assessment by individuals of equal scientific or technical expertise (peers). This review ensures that applications meet high scientific or technical standards, as determined by experts in the relevant field.
Period of performance	The time interval between the start and end date of a Federal award, which may include one or more budget periods. Identification of the period of performance in the Federal award does not commit the Federal agency to fund the award beyond the currently approved budget period. See 2 CFR 200.1 Period of performance.
Pre-award costs	Costs incurred before the official start date of an award in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work. These costs are only allowable with prior approval of the agency, unless waived by expanded authority. See 2 CFR 200.210 Pre-award costs and 2 CFR 200.458 Pre-award costs.



Principal Investigator/ Program Director	The individual(s) designated by the recipient to direct the project or program being supported by the award. The PI/PD is responsible and accountable to officials of the recipient organization for the proper conduct of the project, program, or activity.
Prior approval	Written approval obtained in advance by an authorized official of a Federal agency of certain costs or programmatic decisions. See 2 CFR 200.1 Prior approval .
Profit	See fee .
Program income	Gross income earned that is directly generated by a supported activity or earned because of the Federal award during the 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. See 2 CFR 200.1 Program income .
Progress report	Regularly submitted reports, typically annually, from the recipient to the agency to evaluate progress and determine funding for the next budget period, excluding the final report.
Real property	Land, including land improvements, structures, and appurtenances, and legal interests in land, including fee interest, licenses, rights of way, and easements. Real property does not include movable machinery and equipment. See 2 CFR 200.1 Real property .
Recipient	The entity that receives a Federal award directly from a Federal agency to carry out an activity under a Federal program. The term recipient does not include subrecipients or individuals that are participants or beneficiaries of the award. See 2 CFR 200.1 Recipient .
Reimbursement	A payment made to a recipient upon its request after it makes cash disbursements.
Renewal award	A Federal award for which the start date is connected with, or closely follows, the end of the expiring Federal award. The start date of a renewal award begins a new and distinct period of performance. See 2 CFR 200.1 Renewal award .
Research	The systematic study directed toward fuller scientific knowledge or understanding of the subject studied. This includes activities involving the training of individuals in research techniques where such activities use the same facilities as other research and development activities and where such activities are not included in the instruction function. See 2 CFR 200.1 Research and Development



Research patient care	Routine and ancillary hospital services given to research participants. The expenses for these services are typically allocated to individual research projects using established research patient care rates or amounts. See 2 CFR 300.308 Research Patient Care.
Research and development	All basic and applied research activities and all development activities performed by a recipient or subrecipient. "Research" is the 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 to produce useful materials, devices, systems, or methods, including designing and developing prototypes and processes. See 2 CFR 200.1 Research and Development
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to contribute to the goals and objectives of the project by carrying out part of an award received by the pass-through entity. It does not include payments to a contractor, beneficiary, or participant. A subaward may be provided through any form of legal agreement consistent with criteria in with 2 CFR 200.331, including an agreement the pass-through entity considers a contract. See 2 CFR 200.1 Subaward.
Subrecipient	An entity that receives a subaward from a pass-through entity under a financial assistance award to carry out part of a Federal award. The term subrecipient does not include a beneficiary or participant. A subrecipient may also be a recipient of other Federal awards directly from a Federal agency. See 2 CFR 200.1 Subrecipient.
Substantive programmatic work	The primary project activities for which award support is provided.
Supply	All tangible personal property other than those described in the equipment definition. A computing device is a supply if the acquisition cost is below the lesser of the capitalization level established by the recipient or subrecipient for financial statement purposes or \$10,000, regardless of the length of its useful life. See 2 CFR 200.1 Supply.
Suspending award activities	A temporary halt on a recipient's ability to use award funds until they take corrective action as directed by the agency or until the agency decides to end the award. This definition of "suspension" is distinct from its use in the context of debarment and suspension procedures. See 2 CFR 200.339(c).
Tangible personal property	Tangible assets including equipment and supplies, excluding intangible property like intellectual property.



Termination	The action a Federal agency takes to discontinue a Federal award, in whole or in part, at any time before the planned end date of the period of performance. Termination does not include discontinuing a Federal award due to a lack of available funds. See 2 CFR 200.1 Termination and 2 CFR 200.340 Termination.
Total costs	The sum of the allowable direct and indirect costs minus any applicable credits. See 2 CFR 200.402 Composition of costs.
Unallowable cost	A cost specified by law or regulation, federal cost principles, or term and condition of award that may not be reimbursed under a grant or cooperative agreement.
Unliquidated financial obligations	Financial obligations incurred by the recipient or subrecipient but not paid (liquidated) for financial reports prepared on a cash basis. For reports prepared on an accrual basis, these are financial obligations incurred by the recipient or subrecipient but for which expenditures have not been recorded. See 2 CFR 200.1 Unliquidated financial obligation.
Unobligated balance	The amount of funds under a Federal award that the recipient or subrecipient has not obligated. The amount is calculated by subtracting the total amount of the recipient's or subrecipient's unliquidated financial obligations and expenditures under the Federal award from the total amount of funds the Federal agency or pass-through entity authorized the recipient or subrecipient to obligate. See 2 CFR 200.1 Unobligated balance.
Vertebrate animal	Any live animal having a backbone or spinal column used or intended for use in research, research training, experimentation, biological testing, or related purposes.
Withholding cash payment	The agency, after following necessary steps, limits a recipient's access to funds until they make the needed corrections. See 2 CFR 200.339(a).



Appendix C: Post-Award Considerations by Type of Program, Activity, or Recipient

C.1: Services Provided by Affiliated Organizations

Universities and other organizations (parent organizations) sometimes create affiliated organizations.

The parent organization often provides considerable support services. These include administration, facilities, equipment, accounting, and other services. The affiliated organization includes the costs of these services in its indirect cost proposal.

In some cases, the agency may reimburse these costs. This happens only when the affiliated organization satisfies any of the following:

- It is charged for, and must legally pay for, the costs.
- It is subject to state or local law that sets out how to spend the federal reimbursement and a state or local official approves the expenditures.
- A formal agreement allows the affiliated organization to keep the related federal reimbursement. The parent organization may direct the expenditure of the funds or allow the affiliated organization to decide.

If these conditions don't apply, the agency cannot reimburse the costs. However, the services may be acceptable for cost-sharing purposes.

C.2: Data Sharing for Research and Demonstration Projects Considerations

C.2.1: Expectations

Sharing data and research tools is important to quickly turn research into useful products and knowledge to improve human health. This includes things like cell lines and software. Sharing information about demonstration projects helps others use and duplicate projects.

HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes and to authorize others to do so. This also means requiring recipients and subrecipients to make such works available through agency-designated public access repositories. (See [2 CFR 200.315\(b\)](#))

HHS encourages researchers to share their findings promptly.

If you enter subawards, including consortium agreements, you will want access to third-party data and/or research tools to ensure HHS can also access data and tools, if desired. Recipients should include a provision in the third-party agreement.

Your agency should provide guidance to you on how to make data available through a variety of ways. Please check the NoA and see [2 CFR 200.315\(f\)](#).

When you share copies or samples of materials developed under the award, you can charge a small fee for shipping and handling these items. Any income earned from this is considered program income.

If you think you can't meet these expectations, talk to the GMS before getting an award.

C.2.2: Timely Release of Research Data and Tools

Investigators should share their final research data and tools either when their main findings are accepted for publication or when they submit findings to the agency.

C.2.3: Protection of Certain Data

HHS knows data sharing can be complicated due to various rules and laws, including the [HIPAA Privacy Rule, Human Research Protections](#), and others. We must always protect the privacy of project participants and their data. HHS will work with you to maximize public access to Federally funded research results and data in a manner that protects data providers' confidentiality, privacy, and security. Please check your NoA and ask your GMS or PO for guidance.

For wider use, data must not include any indicators that could reveal the identity of individual participants. Researchers need to ensure that data from human cells or tissues also can't reveal the identity of the original donors.

Researchers can share materials through their lab or organization or submit them to a repository. They should send unique biological data, like DNA sequences, to the appropriate data banks. When sharing unique resources, investigators must provide details about the nature, quality, or characterization of the materials.

C.3: Conference Awards

If you have questions about conference awards or what's allowed under your award, ask your GMS. Here are definitions and details about costs related to conference awards:

- Conference: Events like meetings, retreats, or seminars that share technical information. They must be necessary and reasonable for the award's success. See 2 CFR 200.432.
- International conference: A meeting open to attendees from at least two countries outside of the U.S. It can be anywhere, even in the U.S. But, if it's outside the U.S., award funds can't cover general support. They can cover specific parts, like a workshop or panel.
- Domestic conference: A meeting in the U.S. mainly for attendees from these two countries. Award funds can support these conferences, whether they're domestic or international.

C.3.1: Funding Requirements

The NoA will include any specific requirements. A change in conference focus is a change in scope and needs prior approval.

C.3.2: Acknowledgment of Support and Disclaimer

All conference materials, like agendas or media promotions, must mention HHS support, whether in whole or in part. Refer to Appendix D for the exact wording of this acknowledgment.

If you're releasing a press statement about activities supported by an HHS award, inform the agency beforehand to coordinate, which may include a review of materials.

C.3.3: Allowable and Unallowable Costs and Activities

Please refer to [2 CFR 200 Subpart E](#), your NOFO/NoA, and the HHS agency.

C.3.3.1: Other Cost Considerations

If you don't have a written travel policy, follow the [Federal Travel Regulation](#). Always adhere to the U.S. foreign travel restrictions in place at the time, which may include restrictions on countries or limits on funds for travel.

When attending a conference:

- Only claim per diem for days you attend and the actual travel time, taking the most direct route.
- Local travel costs can be covered for local attendees only.
- If meals or lodging cost are nominal or free, like within a registration fee, adjust your per diem accordingly.
- Travel costs shouldn't exceed coach fares. Always choose U.S. carriers when possible.

C.3.4: Intellectual Property: Publications, Copyright, and Public Disclosure

If you publish something using HHS funds, you can distribute it for free. If you sell it, the money earned is considered program income and should be reported as directed in your NoA and on the FFR. More details can be found in GPS Chapter 3.2.11 (Program Income).

You can seek copyright for publications from an HHS-supported conference unless your award says otherwise. However, HHS still has rights to the materials, as mentioned in the Irrevocable and the Royalty-Free License GPS section After the Award.

C.4: Construction and Modernization of Facilities Awards

C.4.1: Applicability and Definitions

Note that construction and modernization activities must be allowed by law; that law may provide more specifics about allowable construction and modernization activities. However, as a general matter, this section applies to the following HHS award-supported activities:

- Construction: constructing a new building, structure, or facility that provides new space. It also includes installing fixed equipment in such space. It excludes purchasing land and ancillary improvements like parking lots, roads, or fencing. Constructing shell space is not allowed as a construction activity as it does not provide usable space.
- Modernization: altering, renovating, remodeling, improving, expanding, or repairing an existing building. Also includes completing existing shell space. Activities must make the building suitable for the purposes of a particular program. This can include space used for storage or by people. It can range from updating flooring to replacing everything except for the existing frame and foundations. If the main award purpose is modernizing a biomedical research facility, the award can't also support research.
- Alteration and renovation (A&R) activities: These are modernization activities and can be under research awards where the primary purpose of the award is other than construction or modernization.

Refer to the NoA for additional related requirements.

C.4.2: Allowable and Unallowable Costs and Activities

This section outlines costs and activities generally allowable and unallowable under construction awards. The final decision on whether a cost is allowable is based on the decision of the HHS agency and the program.

These policies apply to the use of federal funds and cost sharing. The lists are not all-inclusive. Consult program guidelines and award terms and conditions for specific costs allowable under a program or award.

C.4.2.1: Allowable Costs and Activities

- Acquisition and installation of fixed equipment
- Architectural and engineering services
- Bid advertising
- Bid guarantees and performance and payment bonds as provided in [2 CFR 200.326](#).
- Contingency funds for unanticipated charges included in the initial cost estimates for construction contracts. Before you receive bids, the budgeted amount can't exceed five percent of expected construction costs. You must reduce it to not more than two percent after you award a construction contract.
- Filing fees for recording the Notice of Federal Interest (NFI)
- Force accounts to provide funding for your own construction and maintenance staff used in carrying out modernization activities. These are allowable if you can document that a force account is less expensive than if you were to competitively bid the work. You must substantiate costs with receipts for the materials and certified labor pay records. Use of a force account requires agency prior approval.
- Compliance with the National Historic Preservation Act. This can include:
 - hiring special consultants to research and document the historic value of proposed performance sites
 - costs to prepare and present required materials to inform the public and others.
- Incentive costs for contractors consistent with contract type as specified in the solicitation of bids or proposals and in the contract. Incentive costs must be reasonable and documented, including that conditions to earn the incentive were met. Incentive-type contracts may also contain a penalty provision. Other types of bonus payments are not allowable.
- Inspection fees.
- Insurance costs of title insurance, physical-destruction insurance, and liability insurance are generally allowable. Physical destruction and liability insurance are usually treated as F&A costs. However, you can treat it as a direct cost if your established policy does so and you consistently do so. You may charge title insurance, if required, to the award in proportion to the amount of agency participation in the property. See Real Property — Insurance.
- Legal fees related to obtaining a legal opinion about title to a site.

- Relocation expenses.
- Sidewalks necessary for use of facility.
- Site clearance costs are allowable if reflected in the bid.
- Site survey and soil investigation costs.
- NEPA analysis costs to evaluate the environmental effects and produce the Environmental Impact Statement (EIS).
- Pre-award costs for architect and consultant fees needed for planning and design are allowable if the project is later approved and funded.
- Project management costs.
- Threat-risk assessment costs for a site-specific or project-specific assessment of security risk by a qualified professional. The threat-risk assessment identifies and quantifies potential threats, both internal and external to the building, its contents, the personnel working in it, and the public. The analysis also includes examination and evaluation of the physical aspects of the proposed facility, along with operational issues.

C.4.2.2: Unallowable Costs and Activities

- Bonus payments other than earned incentive payments to contractors under formal incentive arrangements
- Construction of shell space designed for completion at a future date
- Consultant fees not related to actual construction
- Damage judgment suits
- Equipment purchased through a conditional sales contract
- Indirect/F&A costs
- Fund-raising expenses
- Land acquisition
- Legal services not related to site acquisition
- Movable equipment
- Off-site improvements such as parking lots

C.4.3: Prior-Approval Requirements

You must get agency prior approval for the following types of project or budget changes:

- Any applicable changes as specified in Chapter 3.1 (Prior Approvals).
- Change in the use of the facility. See Appendix C.4.6 (Use of Facility and Disposition).

You must provide enough details in your approval request to explain why you need the change. Once approved, you can make the changes. For smaller changes to construction contracts, you don't need prior

approval. But keep copies of all changes as part of your award records.

C.4.4: Procurement Requirements

Construction activity usually is conducted through one or more contracts. All such procurement must use the methods described in [2 CFR 200.318](#) through [2 CFR 200.327](#) as applicable.

C.4.5: Equal Employment Opportunity, Labor Standards, and Other Contract Requirements

You must provide equal employment opportunity and labor standards requirements for federally assisted construction and modernization to potential bidders/offerors and include them in the resulting contract. See 2 CFR 200.327 (incorporating [2 CFR 200 Appendix II \(C\)](#)) and [41 CFR Subtitle B Chapter 60](#). The Davis-Bacon Act or the Copeland “Anti- Kickback” Act apply only if specifically required by the program’s authorizing statute. The NoA will show if they apply.

C.4.5.1: Equal Employment Opportunity Requirements

Construction contracts (and subcontracts) awarded under HHS awards must follow the requirements of [41 CFR 60-1 \(implementing EO 11246\)](#). Recipients must:

- Include the clause at [41 CFR 60-1.4\(b\)](#) in any construction contract under the award. You must direct the contractor to include this clause in any applicable subcontracts.
- Follow solicitation and contract requirements specified in [41 CFR 60-4](#) for contracts in specified geographical areas (designated by DOL’s Director of the Office of Federal Contract Compliance Programs) that will exceed \$10,000.
- Notify the Office of Federal Contract Compliance Programs regional, area, or field office when you expect to award a construction contract over \$10,000.

Under [41 CFR 60-1.8](#), segregated facilities are not permitted for any contract for construction services that will exceed \$10,000. The recipient must require each prospective contractor to submit a certification that the contractor:

- Maintains all facilities provided to employees in a non-segregated manner.
- Prohibits its employees to perform services at any location, under the contractor’s control, that maintains segregated facilities; and
- Obtains a similar certification before awarding any covered subcontract.

C.4.5.2: Labor Standards Requirements

Under [EO 13202](#), as amended by [EO 13208](#), you must ensure that bid specifications, project agreements, or other controlling documents for construction services contracts:

Ensure that bidders, offerors, contractors, or subcontractors are able and willing to enter or adhere to agreements with one or more labor organizations on the same or other related construction projects. Refrain from discrimination against bidders, offerors, contractors, or subcontractors for initiating, refusing to initiate, or adhering to agreements with one or more labor organizations, on the same or other related construction projects.

Awards, contractors, and subcontractors with construction contracts or subcontracts over \$100,000 financed at least in part with a federal award must follow the Contract Work Hours and Safety Standards Act, [40 USC 3701–3708](#). Among other provisions, the statute covers standards listed below. Consult the statute for proper interpretation and guidance.

- Work hours
- Report of violations and withholding of amounts for unpaid wages and liquidated damages
- Health and safety standards in building trades and construction industry
- Safety programs
- Limitations, variations, tolerances, and exemptions
- Contractor certification or contract clause in acquisition of commercial items not required
- Criminal penalties

C.4.5.3: Other Requirements

C.4.5.3.1: Liquidated Damages

Invitations for bids must supply a date or timeframe to complete the project for each prime contract. You may include a liquidated damages provision in the contract. It allows you to assess damages when the contractor does not complete the construction or modernization by the specified date. Liquidated damages must be real, justified, and approved by the agency before solicitation. Where damages are assessed, any amounts paid belong to the recipient.

C.4.5.3.2: Disposition of Unclaimed Wages

If an employee doesn't claim wages from an HHS-supported construction contract, the recipient might need to pay HHS back. Here's the process:

- Check that the contractor tried to find the employee. This might include forwarding mail or contacting their union.
- If the contractor's search fails but seems incomplete, try to find the employee.
- Open an escrow account in the employee's name. Keep it for two years after the contract ends, or longer if local laws say so. Tell the GMS about this account.
- If you pay wages from the account to the employee or their representative, report to the GMS when you close the account.
- If money is still unclaimed after two years, refund the agency based on the award's contribution to those wages.

C.4.6: Use of Facility and Disposition

Unless a statute or instructions from your agency say otherwise, here's how to manage real property:

- Keep using the property for its intended purpose. Don't sell or encumber the title without approval.
- If you don't need it for the initial purpose, get written approval from the agency to use the facility in a similar federally funded project.

- If you no longer need the property, follow the rules in [2 CFR 200.311\(d\)](#). Your options include:
 - Keep it and pay the agency their fair share based on their contribution and the property's market value.
 - Replace it. If buying new property under the same award, use any sales money to reduce the new property's cost.
 - Sell it and pay the agency based on a formula in [2 CFR 200.311 \(d\)\(2\)](#).
 - Transfer it to the agency or their approved third party. From the sale, you are entitled to your fair share based on your contribution and the property's current market value.

C.5: Foreign Organizations, International Organizations, and Domestic Recipients with Foreign Components

The GPS generally applies to awards made to foreign organizations and international organizations. You can find the definitions of these terms in Appendix B of the GPS. In this section, we refer to them as foreign awards.

The AOR must contact the GMS if their organization can't follow these requirements. This section includes:

- Exceptions and modifications to GPS requirements for foreign awards
- Highlights of other related policies
- Policies that apply to awards with a foreign component

C.5.1: Public Policy Requirements and Objectives

Requirements in Appendix D apply to foreign awards, unless otherwise noted here, the NoA, or in agency policies. Exceptions include:

- Civil rights: The civil rights requirements do not apply to foreign awards.
- Debarment and suspension: These rules and the certification requirement do not apply to:
 - foreign governments and foreign organizations
 - public international organizations
 - entities that are foreign-government-owned or controlled, in whole or in part
 - All other foreign organizations and international organizations are subject to these rules
- Drug-Free workplace: The agency may exempt foreign awards from these
- requirements. To do so, they must find that the requirements are not consistent with U.S. international obligations or the laws and regulations of a foreign government.
- Environmental requirements: A foreign award isn't subject to environmental requirements that would not otherwise apply to it.

C.5.2: Funding and Payment

These policies apply:

- All application budgets, fund requests, and financial reports must be in U.S. dollars.
- If exchange rates change, extra costs might be covered, depending on the agency's available funds.
- You only need prior approval for rate changes if they lead to needing more federal funds or if they will reduce project scope significantly.
- Review local currency gains to determine if you will need additional federal funding before the award ends.
- Adjustments for currency increases may be allowable only when you provide the agency with adequate source documentation from a commonly used source in effect at the time you made the expense.

C.5.3: Allowable and Unallowable Costs

The cost principles that apply to foreign organizations depend on the type of organization. See [Cost Principles](#). There are some exceptions:

- Major A&R are unallowable under foreign awards and domestic awards with foreign components, except where allowed by the governing statute and as indicated in the NoA.
- Minor A&R are generally allowable on awards made to foreign organizations or to a foreign component of a domestic award, unless prohibited by the governing statute or implementing program regulations. You may include and justify minor A&R costs in the detailed application budget. Rebudgeting to accommodate minor A&R requires prior approval.
- F&A Costs under foreign awards, including foreign recipients with a domestic component, are at a fixed rate of eight percent of modified total direct costs. These are direct costs minus tuition and related fees, equipment, and subawards more than \$25,000. See [2 CFR 300.414\(b\)](#). These funds are to support the costs of compliance with federal requirements.
 - [2 CFR 300.414\(c\)](#) allows the World Health Organization and American University, Beirut to use their negotiated indirect cost rates.
- Capital expenses (facilities) are not allowable, except where allowed by the governing statute and as indicated in the NoA. The agency will not support the acquisition cost or provide for depreciation.
- Equipment is an allowable direct cost.
- Research patient care costs are provided only in exceptional circumstances or where allowed by the statute setting up the award program. [See 2 CFR 300.308](#).
- Travel Visas (including short-term) are generally allowable:
 - As a direct cost as part of recruiting costs if the institution has an employee- employer relationship with the individual
 - When identified in specific NOFOs
 - If within the scope of an approved research project

C.5.4: Administrative Requirements

Expanded authorities generally apply to foreign awards. Review the NoA to determine the specific award requirements. See GPS Chapter 3.1 (Prior Approvals and Expanded Authority sections). Requirements for foreign awards also apply to subawards to foreign entities under financial assistance arrangements, rather than acquisition of goods or services.

If you make a subaward to a foreign entity, to comply with audit requirements, you must include oversight methods. These may include reviewing reports, on-site reviews, or alternatives to a single audit, if one will not be available during the period of the subaward.

C.6: Federal Institutions and Payments to or on Behalf of Federal Employees Under Awards

Most policies contained in the GPS apply to awards made to federal institutions. This section includes specific exceptions and modifications of general GPS requirements for federal recipients. It also highlights other related policies.

(See [2 CFR 300.219](#) for the regulatory modifications for federal agency recipients).

C.6.1: Eligibility

Specific eligibility is in each NOFO. An agency may not issue an award to any component of its own organization.

Public Health Service (PHS) organizational segments, other than IHS hospitals, may only receive award support under exceptional circumstances. Such circumstances may include when the work cannot be supported within the mission of the PHS agency and cannot be performed elsewhere.

Regardless of where the work is performed, the federal agency or department is the official applicant. A federal institution must ensure that its own authorizing legislation allows it to receive awards and to be able to comply with the award terms and conditions.

A document that assures both the responsibility and authority to receive an award must be included with each new and competing continuation application. The assurance must be signed by the head of the responsible federal department or independent agency or a designee who reports directly to the department or agency head. This assurance is in addition to those made by the AOR's signature on the face page of the application. The assurance requirement does not apply to Veterans Administration hospitals, Bureau of Prisons' (Department of Justice) hospitals, IHS hospitals, or other PHS organizational segments.

C.7: For-Profit Organizations

C.7.1: General

Terms and conditions for for-profit organizations vary from standard ones. Also, terms and conditions for SBIR and STTR programs vary from those usually applied to for-profit organizations.

C.7.2: Cost Principles

Usual cost principles (2 CFR 200 Subpart E) do not specifically apply to for-profit organizations. As a result, use:

- For for-profit organizations: FAR, [48 CFR 31.2](#)
- For private hospitals: [2 CFR 300 Appendix IX](#)

C.7.3: Allowable and Unallowable Costs

C.7.3.1: Allowable Costs

- Indirect costs
- Travel that does not exceed costs established by the [Federal Travel Regulation](#) (FTR)

C.7.3.2: Unallowable Costs

- Independent research and development costs, as provided in [2 CFR 300.477](#).
- Profits or fees, except for awards under the SBIR and STTR programs and funds paid to a contractor for routine goods or services. See [2 CFR 300.218](#).

Consult the GMS for questions on costs.

C.7.4: Administrative Requirements

For-profit organizations generally are subject to the same administrative requirements as non-profit organizations, including those relating to personal property title and management.

- Equipment: For-profit groups must track equipment. You can't use award-funded equipment to compete unfairly by offering paid services. Any fees charged for using the equipment count as program income and you must report it on the FFR.
- Intellectual property: All for-profit groups, regardless of size, follow the intellectual property rules in [37 CFR 401](#). For-profit organizations have different invention reporting rules than non-profits. For-profit organizations can assign invention rights to others without agency approval, but they must still report each invention. The federal government will keep information about federally supported inventions confidential, as allowed by law.
- Program income: See [Program Income](#).
- Expanded authorities: Standard award terms apply to for-profit organizations. However, some awards will not allow automatic carryover of unobligated fund balances. The NoA specifies the disposition of the reported unobligated balance.
- Audit: Requirements for non-federal audits of for-profit organizations are in [2 CFR 300.218\(d\)](#). See also [2 CFR 200.501\(i\) \(exempting for-profit organizations from the audit requires in 2 CFR 200 Subpart F\)](#). For-profit organizations are subject to requirements for non-federal audits. See [GPS Chapter 4.3.2 \(Audit Requirements\)](#).
- Labor distribution requirements: Salary and wage amounts charged to awards for personal services must:
 - Be based on an adequate labor distribution system that distributes payroll costs in line with generally accepted practices of like organizations
 - Align to industry standards.

- Track time spent on award activities. The time and-effort reporting system used must:
- Be for both professional and other staff
- Reflect daily reporting
- Track time by individual projects and indirect activities
- Record both hours worked, and hours absent
- Enable the AOR to meet the requirement to certify time entries at least every pay period
- The GMS must approve any alternative system.

C.8: Small Business Innovation Research and Small Business Technology Transfer Programs

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs have three phases. Some projects might not be eligible for all three. See [the Small Business Administration's Policy Directive](#) for full detailed SBIR/STTR policies.

C.8.1: SBIR/STTR Phased Awards

C.8.1.1: Phase I

Before providing Phase II support, this phase assesses:

- The technical merit and feasibility of proposed research or R&D
- The quality of the applicant's performance

C.8.1.2: Phase II

This phase advances efforts started in Phase I. These policies apply:

- Funding is based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.
- Usually, only Phase I recipients can apply for Phase II funding.
- You can only submit Phase II applications before a Phase I award if using the Fast-Track application process (see below).
- You must submit standard (not Fast-Track) Phase II applications within the first six receipt dates after the end of your Phase I budget period. This is typically two years.

C.8.1.3: Phase III

The SBIR and STTR programs do not fund Phase III. This phase is for the SBC to work to commercialize the results of the research or R&D done in Phases I and II. In some cases, a federal agency may:

- Use non-SBIR and STTR funds to continue the work
- Contract for items for federal use

C.8.2: SBIR and STTR

C.8.2.1: STTR

The STTR program focuses on teaming a Small Business Concern (SBC) with a non-profit research body for a project that might be turned into a product.

The program requires:

- The SBC collaborates with a single non-profit research institution.
- The SBC must do at least 40% of the research. A domestic non-profit organization does at least 30%. This rule is the same for both Phase I and Phase II.
- Eligible research partners include universities, non-profit hospitals, other non-profits research organizations, and federally funded Research and Development Centers.
- The award goes to the SBC. It disperses funds to the research institution.
- The PI must spend at least 10% of their time on the STTR project.

C.8.2.2: SBIR

The SBIR program requires that SBC employ the PI at least half-time at the time of award and during the project.

C.8.3: Fast-Track Process

The Fast-Track process speeds up decisions and funding for SBIR and STTR Phase II applications. Policies include:

- To be eligible, the project must be scientifically meritorious with a high potential for commercialization.
- Not every agency lets SBCs use Fast-Track. Talk to the agency first before applying.
- If you aren't approved for Fast-Track, your application might go through the regular review.
- With Fast-Track, Phase I and Phase II applications are handled together and usually get one overall score.

For more details, check the SBIR and STTR NOFOs.

C.8.4: Place of Performance and Sources of Materials

All project activities for Phase I and Phase II of SBIR and STTR must be done in the United States. Using a foreign site for research is rare and needs a solid scientific reason. An example includes testing specific patient groups only available abroad. You must attempt to get alternate funding for the part of the work to be done abroad.

If you must buy materials from another country, you must have a good reason and clearly explain it. Approval of such a waiver is rare. The agency reviews each request individually. If you'll need to do this, talk to the GMS before you apply.

GMSs decide waiver requests. The NoA will clearly state if it is approved.

C.8.5: Change In Organization Status & Change of Recipient Institution Actions

The agency makes eligibility decisions at the initial award time.

A later event like a merger or successor-in-interest could alter the organization's status. If the change

makes the organization ineligible for the SBIR or STTR program:

- Any current awards can still proceed unless the small business concern makes a material misstatement that the agency decides poses a risk to national security; or there is a change in ownership, change to entity structure, or other substantial change in circumstances of the small business concern that the Federal agency decides poses a risk to national security.
- After that, the organization will not qualify for new SBIR or STTR awards.

If an SBIR or STTR award needs to be transferred to a different institution or organization, this new entity must also fulfill the eligibility requirements of the SBIR or STTR program.

Contact the agency to discuss options when considering a move to a new organization.

C.8.6: Minimum Level of Effort

Congress requires minimum levels of effort for these programs. SBIR

required levels of effort:

Program and Phase:	SBC level of effort:	Aggregate payments to others may not exceed:
SBIR Phase I	66.67%	33.33%
SBIR Phase II	50%	50%

STTR minimum levels of effort:

Program and Phase:	SBC minimum level of effort:	Single, non-profit research institution minimum LOE:
STTR Phase I	40%	30%
STTR Phase II	40%	30%

Policies include:

- Waivers are not allowed.
- The basis for establishing the percentage of work to be done by each participant is the entire cost (including direct, indirect costs, and fee) related to each party. However, if described and justified under the “Consortium/Contractual Arrangements” section of the application, a different basis might be used.

C.8.7: Multiple Principal Investigator or Program Director Applications and Awards

Team science efforts may use a multiple program director or principal investigator (Multi PI/PD) option. The following policies apply:

- The SBC is always the applicant or recipient organization. Other participants are subcontractors.
- Each PI or PD must commit at least 1.2 calendar months (10% effort) to the project.
- SBIR Phase I and II projects: The contact PI or PD must meet the primary employment

requirement. Other PIs or PDs do not have to meet the requirement.

- STTR Phase I and II projects: The PI listed must have a formal appointment with, or commitment to, the SBC. This must be an official relationship but does not require pay.
- Phase IIB Multi PI/PD competing renewal applications: If previously supported through a single PI/PD award, the new application must state the changes in the project's management that led to the proposed Multi PI/PD model.

C.8.8: Public Policy Requirements

Requirements in Appendix D: Administrative and National Policy Requirements apply, unless otherwise noted here or in agency policies.

- Disclosure of financial conflicts of interest does not apply to Phase I of the SBIR and STTR programs. See [42 CFR 50.602](#).
- Under an SBIR or STTR award, the SBC should purchase only American-made equipment or products when possible.

C.8.9: Allowable Costs and Fees

C.8.9.1: Program Levels (Total Costs)

The [SBA SBIR and STTR Policy Directive](#) provides program levels for SBIR and STTR programs based on statutory guidelines. The directives allow agencies to exceed these levels up to 50% over the guideline when the proposed budget and requested period of support are justified and scientifically appropriate for the proposed research.

In some cases, Phase II SBIR or STTR recipients may apply for Phase IIB competing renewal awards. These are available for projects that require extraordinary time and effort for R&D. Only those SBCs awarded a Phase II may apply for the Phase IIB award.

Applicants must request an appropriate level of funding in the competing application. The agency will not adjust it after submission.

C.8.9.2: Profit or Fee

SBCs can earn a reasonable profit or fee under Phase I and II of the SBIR and STTR programs.

- This profit or fee must be in the application budget.
- The profit or fee isn't considered a cost for determining allowable use, program income accountability, or setting audit thresholds.
- The SBC can use the profit or fee for any purpose, including investment into the awarded project.
- The intent is to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work. Typically, the profit or fee will not surpass seven percent of the total project costs for each phase.
- The profit or fee should be drawn from PMS in proportion to the drawdown of funds for direct and indirect costs.

- The profit or fee is exclusively for the SBC that receives the award. However, in line with regular commercial practices, the SBC can pay a profit or fee to a contractor that provides routine goods or services under the award.

C.8.9.3: Indirect Costs

If the applicant SBC has an effective indirect cost rate with a federal agency, the rate should be used when calculating proposed indirect costs for an application. The rates must be adjusted for independent R&D expenses, which are not allowable under HHS awards.

If that applicant does not have an approved indirect cost rate, one can be proposed in the application. See below for specific requirements for each phase. If awarded at a rate, indirect costs cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate with a federal agency. The agency will not negotiate indirect cost rates for Phase I awards.

If you do not have an effective negotiated indirect cost rate, you may propose estimated indirect costs at a rate not to exceed 40 percent of the total direct costs. You can charge only actual indirect costs to projects.

Phase II

If you do not have an effective negotiated indirect cost rate, you may propose an estimated indirect rate in the application.

If the requested rate is 40 percent of total direct costs or less, you do not need to provide further justification. You can charge only actual indirect costs to projects.

If you choose to negotiate an indirect cost rate greater than 40%, DFAS is the appropriate agency. Upon request, provide DFAS with an indirect cost proposal and supporting financial data for your most recently completed fiscal year. If you do not have financial data for the most recently completed fiscal year, submit a proposal showing estimated rates with supporting documentation.

C.8.10: Administrative Requirements

C.8.10.1: Market Research

HHS will not support market research, including studies of the literature that lead to a new or expanded statement of work.

No SBIR or STTR funds, direct or indirect, can be used to support commercialization.

For SBIR and STTR programs, market research is the systematic gathering, editing, recording, computing, and analyzing of data relating to the sale and distribution of the research subject. It includes research on:

- The size of potential markets and potential sales volume
- Identifying consumers most apt to purchase the products
- The advertising media most likely to stimulate their purchases

Market research does not include activities that include a public survey to determine the research subject's impact on the behavior of individuals.

C.8.10.2: Intellectual Property

The recipient keeps rights to data and software created with award funding. However, the federal government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use the material and to authorize others to do so for Federal purposes.

For SBIR and STTR awards, unlike other commercial awards, such data cannot be released outside the Federal government without the recipient's permission for a period of 20 years from completion of the project.

C.8.10.3: Data Rights

Section 9 of the Small Business Act, as amended ([15 USC 638](#)), allows SBC's under an SBIR or STTR award to retain their data rights for at least 20 years. The SBIR/STTR Policy Directive applies the following data rights:

- The Act allows small business concerns (SBCs) to keep the rights to data they create while working on an SBIR/STTR award. This helps encourage SBCs to participate in Federally funded research and supports them in commercializing their technology. The Federal Government will have access to this data to assess the projects and use the results, but it cannot use the data in ways that would hurt the SBC's rights or economic opportunities. The SBIR/STTR data rights provisions and definitions ensure that the Federal Government effectively protects properly marked SBIR/STTR data during the SBIR/STTR protection period just as well as it protects data developed at private expense.
- Federal agencies that participate in SBIR/STTR awards must make sure that SBC recipients keep appropriate proprietary rights to data generated while working on an award. In general, this means the Federal Government will have rights to that data during the protection period, except for certain types of data that are not subject to such data rights restrictions.
- SBIR/STTR data rights apply to all SBIR/STTR awards, including subcontracts, for all phases of the program (I, II, or III) as defined by the SBA Policy Directive from May 2, 2019. The rights for Phase III awards are the same as those for Phases I and II.
- SBIR/STTR data rights restrict the Federal Government's use and release of properly marked SBIR/STTR data only during the SBIR/STTR protection period. After the protection period, the Federal Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for government purposes. At this time, the Federal Government is relieved of disclosure prohibitions related to such government purposes and assumes no liability for unauthorized use of these data by third parties. The Federal Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.

SBIR/STTR Data Rights - Main Elements:

- An SBC retains title and ownership of all SBIR/STTR data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR data that are not granted to the Government in accordance with the SBA Policy Directive. These rights of the SBC do not expire.
- The Government receives SBIR/STTR data rights during the SBIR/STTR protection period on all appropriately marked SBIR/STTR data. These rights enable the Federal Government to use SBIR/STTR data in limited ways within the Government, such as for project evaluation purposes.

These rights are intended to prohibit use and disclosure of SBIR/STTR data that may undermine the SBC's future commercialization of the associated technology. The Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.

- After the SBIR/STTR protection period has expired, the Federal Government may use, and authorize others to use on its behalf, for government purposes, SBIR/STTR data that was subject to SBIR/STTR data rights during the SBIR/STTR protection period.
- The SBIR/STTR protection period begins with award of an SBIR/STTR funding agreement. It ends twenty years, or longer at the discretion of the participating agency, from the date of award of an SBIR/STTR award (either Phase I, Phase II, or Federally funded SBIR/STTR Phase III) unless the agency and the SBC negotiate for some other protection period for the SBIR/STTR data after the award.
- Any SBIR/STTR data that is delivered must be marked with the appropriate SBIR/STTR data rights legend or notice to receive the protections given to SBIR/STTR data pursuant to SBIR/STTR data rights. The Government is not liable for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR data that is not appropriately marked in line with agency procedures. If SBIR/STTR data is delivered without the required legend or notice, the SBIR/STTR recipient may, within 6 months of such delivery (or a longer period approved by the agency for good cause shown), request to have an omitted SBIR/STTR data legend or notice, as applicable, placed on qualifying data. If SBIR/STTR data is delivered with an incorrect or nonconforming legend or notice, the agency may correct or permit correction at the recipient's expense.

Negotiated Rights:

- An agency must not, in any way, make issuance of an SBIR/STTR award conditional on the SBC negotiating or consenting to negotiate a special license or other agreement regarding SBIR/STTR data. The negotiation of any such specially negotiated license agreements shall be permitted only after award.
- After issuance of an SBIR/STTR award, the SBC may enter into a written agreement with the agency to modify the license rights that would otherwise be granted to the agency during the SBIR/STTR protection period. However, the agreement must be
- entered voluntarily, by mutual agreement of the SBC and agency. The agreement cannot be a condition for additional work under the funding agreement or the exercise of options. The agreement must be entered into only after the SBIR/STTR award, which must include an appropriate SBIR/STTR data rights clause, has been signed. Any such specially negotiated license must be in writing under a separate agreement after the SBIR/STTR funding agreement is signed. A decision by the recipient to relinquish, transfer, or modify in any way its rights in SBIR/STTR data must be made without pressure or coercion by the agency or any other party. Any provision in a competitive non-SBIR or SBIR solicitation that would have the effect of diminishing SBIR/STTR data rights shall have no effect on the provision of SBIR/STTR data rights in a resulting Phase I, Phase II, or Phase III award.
- To ensure that SBIR/STTR recipients receive the applicable data rights, all SBIR and STTR NOFOs and resulting funding agreements must fully implement all the policies, procedures, and requirements set forth in the SBA Policy Directive in appropriate provisions and clauses

incorporated into the SBIR/STTR NOFOs and awards. The SBA Policy Directive provides a sample SBIR/STTR data rights clause containing the key elements that must be reflected in the clause used in Federal Agency solicitations. SBA will report to the Congress any attempt or action by an agency, that it is aware of, to condition an SBIR or STTR award on the negotiation of lesser data rights or to exclude the appropriate data rights clause from the award.

- The STTR program requires that the SBC and the single, non-profit research institution execute an agreement allocating between the parties' intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research.

SBIR and STTR recipients are covered by [35 USC Chapter 18](#) and [37 CFR 401](#) with respect to inventions and patents.

C.8.10.4: Data Sharing

For SBIR Phase II funding over \$500,000 in a year in direct costs, applicants must follow the GPS on data sharing, unless the Small Business Act conflicts. If the data is proprietary or sensitive, the SBC should explain it in the application. Whether or not the award meets the threshold for data sharing under [Intellectual Property](#), HHS won't share data outside the federal government without recipient approval for a period of 20 years from completion of the project.

For more information, please see [NIH's SBIR/STTR information page](#).

C.9: Research Awards

C.9.1: Human Subjects In Research

The regulation for all HHS awards involving human subjects research is [45 CFR 46](#), Basic HHS Policy for Protection of Human Subjects. Subpart A is also known as the Common Rule. These regulations implement Section 491(a) of the Public Health Service (PHS) Act. These regulations apply to both domestic and foreign organizations.

The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is the office with HHS-wide responsibility for research involving human subjects under this policy.

All NOFOs will clearly state:

- The parameters of human subject use
- The information and assurances required from you prior award

There is a single version of the Federal-wide Assurance (FWA) form and Terms of Assurance for domestic and international institutions.

Recipients, whether domestic or international, must safeguard the rights and welfare of human subjects in HHS-conducted or -supported activities ([45 CFR 46.101\(a\)](#) and [45 CFR 46.103\(a\)](#)).

Recipients must ensure that subrecipients follow these requirements, as applicable. Recipients must facilitate the process for obtaining prior approval for subrecipients if not approved in the award.

C.9.1.1: Exemptions

Some human subject research is exempt from the requirements of the HHS regulations.

The categories of research that qualify for exemption are found at [45 CFR 46.104\(d\)\(1\)-\(8\)](#). HHS has final authority to decide if a particular research study supported by HHS is exempt from the HHS regulations. OHRP is the only component of HHS with the delegated authority to interpret and enforce the regulatory requirements in [45 CFR 46.101\(c\)](#) regarding whether a particular activity is regulated by [45 CFR 46](#). Contact OHRP for questions.

C.9.1.2: Policies for Non-Exempt Human Subjects Research

The recipient, including any collaborating organization under a subaward, must:

- Hold or obtain an OHRP-approved FWA ([45 CFR 46.103\(a\)](#)).
- Certify to the agency, within the time frame specified, that the research has been reviewed and approved by an Institutional Review Board (IRB) designated in the FWA ([45 CFR 46.103\(d\)](#)).

The [OHRP website](#) contains a listing of those organizations with OHRP-approved assurances.

The agency must make sure an applicant and any collaborating organizations have the required assurance and certification in place, before:

- Making an award unless there is a specific condition in the NoA restricting expenditures for this purpose.
- You initiate human subjects research, and the agency removes any related NoA specific condition.
- Approving a post-award change in scope that will result in human subjects research. The specific award condition restricting human subjects research must indicate that:
 - You may not draw down funds, obligate or expend federal funds, or claim required cost sharing costs for research involving human subjects at any site engaged in research until you meet all requirements.
 - Failure to comply within the stated time may result in full or partial termination of the award.

The prohibition on expenditures may extend to the whole project if that activity can't be isolated.

C.9.2: Research Involving Animals and Their Welfare

Requirements for using live, vertebrate animals apply to all PHS agencies and other research-related awards. PHS agencies include AHRQ, CDC, FDA, HRSA, IHS, NIH, OASH, and SAMHSA. These requirements apply to recipients, subrecipients, and contractors, whether foreign or domestic.

The requirements:

- Are included in the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#) (PHS Policy).
- Incorporate the [U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training](#).
- Require the recipient to maintain an animal care and use program based on the [Guide for the Care and Use of Laboratory Animals](#).

- Require compliance, as applicable, with the [Animal Welfare Act](#) and other federal statutes and regulations relating to animals.

You must establish appropriate policies and procedures to ensure the humane care and use of animals, and you are ultimately responsible for compliance with the PHS Policy.

You can get information about animal welfare topics from the [Office of Laboratory Animal Welfare](#) (OLAW), Office of Extramural Research, National Institutes of Health.

Before engaging in any HHS award-supported research using animals, applicants must:

- Have a current Animal Welfare Assurance approved by OLAW. The list of organizations with approved assurances is on the OLAW website for both [domestic institutions](#) and [foreign institutions](#).
- Verify, as part of the application or before award, current Institutional Animal Care and Use Committee (IACUC) approval of the animal activities. PHS Policy requires that IACUC approval must have happened within three years of the period of performance start date for new or renewal awards and at least every three years after that.
- Comply with the agency's internal IACUC requirements if a cooperative agreement.

If you do not have a current Animal Welfare Assurance (or made alternative arrangements, like an inter-institutional assurance acceptable to OLAW) or have not provided the required verification by the time an award is to be made, the agency will notify the PO and the applicant. The agency may:

- Delay the award until the recipient and all performance sites are operating in accordance with approved Animal Welfare Assurances and the organization has provided verification of IACUC approval of those sections of the application that involve use of animals.
- Include a specific condition in the NoA restricting expenditures.

The award condition must state that:

- You may not draw down funds, obligate or expend federal funds, or claim required
- cost sharing costs for research involving animals at any site engaged in research until you meet all requirements.
- Failure to comply within the stated time may result in full or partial termination of the award.
- The prohibition on expenditures may extend to the whole project if that activity can't be isolated.

Before approving changes involving animal research after award, the agency needs to confirm that there's a proper Animal Welfare Assurance with OLAW. They also need verification from the IACUC.

C.9.2.1: Reporting

Reporting requirements under the PHS Policy include an annual report to OLAW describing:

- Any updates in your animal care program as mentioned in the Assurance.
- Changes in IACUC membership
- The dates when the IACUC reviewed your program and facilities.

Lastly, the IACUC must quickly report any serious issues or breaches in policies, guidelines, or any suspensions through the official who signed the Assurance.

C.9.2.2: Foreign Applicants

Foreign applicant organizations applying for awards for activities involving animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

This includes providing OLAW with an Animal Welfare Assurance for Foreign Institutions, which includes:

- Institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted
- A commitment to follow the [International Guiding Principles for Biomedical Research Involving Animals.](#)

C.9.2.3: Awards to Individuals

No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS animal welfare policy.

Appendix D: HHS Administrative and National Policy Requirements

D.1: HHS Administrative and National Policy Requirements

The awards process is governed by laws and policies – both federal government-wide and HHS- specific. Below are common general administrative and national policy requirements.

D.1.1: Sources of Laws and Policies

There are four general sources of laws and policies that may apply to awards. This Appendix focuses on federal government-wide and HHS-wide sources.

The first two sources are more fully explained in this Appendix:

- **Federal Government-Wide Sources.** The U.S. Constitution, statutes, regulations, executive orders, and statements of policy.
- **HHS-Wide Sources.** Statutes, regulations, statements of policy, and award terms and conditions.

You will find information about the next two sources in the terms and conditions of award, some of which may be mentioned in the NOFO:

- **Agency-Wide Sources.** Agencies may set policies for their awards through regulations, award terms and conditions, and other means.
- **Program-Wide Sources.** Individual funding programs may have their own specific policies. You may find these in the NOFO or the award terms and conditions. They may be based on the authorizing statute, implementing program regulations, or program guidance.

D.1.2: Locations of Laws and Policies

You can find laws and policies in a variety of places. This Appendix compiles many of the laws and policies that may apply to awards, but it is not intended to be an exhaustive list or to reproduce the full text. Readers are encouraged to review the original sources for more information.

Your award terms and conditions may incorporate specific statutes, regulations, or policies by reference. However, the GPS is a term and condition that applies to every discretionary award.

The following two terms and conditions apply to all HHS awards.

- The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ([2 CFR 200](#)) and HHS Requirements ([2 CFR 300](#)).
- In SAM.gov, you agree to the Financial Assistance General Certifications and Representations. All federal financial assistance awards must adhere to all federal laws, executive orders, regulations, and public policies governing financial assistance. A few of them are specifically mentioned in the Certifications and Representations in SAM.gov. This Appendix addresses those in the tables below. They are marked with “see the Financial Assistance General Certifications and Representations.”

D.1.3: Applicability of Laws and Policies

Many laws and policies apply to all HHS awards. But some apply only to awards with certain types of activities or recipients. For example, some may apply only to construction awards, conference awards, or research awards. Additionally, most apply to subrecipients. Some of the exceptions are noted in the tables below.

D.1.3.1: General Order of Precedence

The general order of precedence determines the order in which laws and policies may apply. The table includes examples of the types of laws and policies at each level; it is not an exhaustive list.

Level of Policy	Examples (Note: This list is not exhaustive.)
1. US Constitution	The foundation of all laws, rules, and policies.
2. Statutes	Program Authorizations and Appropriations Federal Grant and Cooperative Agreement Act of 1977 Federal Funding Accountability and Transparency Act (FFATA) of 2006 Digital Accountability and Transparency Act (DATA) of 2014 Grant Reporting Efficiency and Agreements Transparency (GREAT) Act of 2019
3. Regulations	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards: 2 CFR 200 (government-wide) and 2 CFR 300 (HHS-wide) 42 CFR and 45 CFR series regulations (Program-specific regulations)
4. Policies, Program Guidance, and Award-Specific Requirements	Executive Orders (applies to agencies and recipients to the extent incorporated into agency- and program-specific guidance) OMB Memos (applies to agencies and recipients to the extent incorporated to agency- and program-specific guidance) HHS Grants Policy Statement (GPS) HHS Grants Policy Administration Manual (GPAM) Agency-Specific Grants Policies (apply to agencies) Agency- and program-specific guidance related to one or more award programs such as Notices of Funding Opportunity (NOFO), FAQs, and other program announcements, e.g., agency guidance, manuals, “Dear Colleague” letters. For non-discretionary awards these might include state or Tribal plans, public assistance, or statewide cost allocation plans. Requirements specific to an individual award or class of awards, such as a requirement to perform activities described in the recipient’s application.

D.2: Uniform Administrative Requirements

The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards ([2 CFR 200](#)) apply to all HHS awards, unless specifically exempted by [2 CFR 200.101\(e\) and \(f\)](#).

While all of 2 CFR 200 and 300 apply to grants and cooperative agreements, following are some key requirements:

D.2.1: Subrecipients

The uniform requirements also address subrecipient responsibilities. See [2 CFR 200.101\(b\)-\(c\)](#), [2 CFR 200.331-333](#).

Recipients and subrecipients must follow the award terms and conditions. In general, the primary recipient must:

- Apply terms and conditions to their subawards.
- Evaluate the risk of subawards and use specific conditions, if needed.
- Monitor subaward compliance.
- Verify that the subrecipient meets audit requirements.
- Remedy noncompliance.
- Ensure that their subrecipients have a Unique Entity Identifier and maintain a SAM.gov registration.

D.2.2: Termination

HHS may terminate awards under certain circumstances. See [2 CFR 200.340](#).

D.3: Financial Assistance General Certifications and Representations

When you registered in SAM.gov, your authorized organization representative agreed to the Financial Assistance General Certifications and Representations. These are binding on every award.

You can review these certifications and representations in Appendix I of the SAM.gov Entity Registration Checklist. You can find the checklist on SAM.gov [Get Started with Registration and the Unique Entity ID](#) page.

While the Financial Assistance General Certifications and Representations expressly identify certain requirements, they also require compliance with all applicable laws and policies. Those expressly identified are marked with “See General Certifications and Representations.”

See the [General Certifications and Representations \(Appendix E\)](#).

D.4: Laws and Policies

This section outlines various laws and policies that may apply to HHS awards (including recipients and subrecipients), but it is not intended to be an exhaustive list.

The following laws and policies apply to all recipients and subrecipients, with any exceptions noted within the guidance or notes.

D.4.1: Administrative and Activities

Laws and Policies	Source	Notes
Abortions Related to limitations on use of federal funds for abortions.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title V , Sections 506 and 507	Agreed to in General Certifications and Representations (Appendix E) .
Cybersecurity requirements Related to creating a cybersecurity plan.	M-24-03: Advancing Climate Resilience through Climate-Smart Infrastructure Investments and Implementation Guidance for the Disaster Resiliency Planning Act	See Supplemental Information (Appendix D.5) for more information. NIST Cybersecurity Framework
Debt Collection Related to how the federal government collects debt.	Statute: 31 USC 3701 Regulation: 31 CFR 285	
Health Information Technology Interoperability Related to conditions when implementing, acquiring, or upgrading health IT.	Health Information Technology for Economic and Clinical Health (HITECH) Act is Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009)	See Supplemental Information (Appendix D.5) for more information.
Needle Exchange Related to prohibition on using award funds to give out sterile needles to inject illegal drugs, with some exceptions.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title V , Sections 526	See General Certifications and Representations (Appendix E)
Publications and Acknowledgement of Support Related to recipients acknowledging HHS funding in public documents related to the awarded project.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title V , Section 505	See Supplemental Information (Appendix D.5) for requirements and example.
Reporting Subaward and Executive Compensation Information Related to requirements to report certain information on subawards and executive salaries.	Statute: Federal Funding Accountability and Transparency Act of 2006 (FFATA), 31 USC 6101 note. Regulation: 2 CFR 170	See General Certifications and Representations (Appendix E)
Salary Rate Limitation – Federal Executive Level II. Related to restrictions to not use award funds to pay a salary over the Federal Executive Level II rate for that year.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title II , Section 202	For 2025, the amount is \$225,700. See General Certifications and Representations (Appendix E)
SAM.gov and Universal Entity Identifier (UEI) Related to the requirement to register and maintain registration, including gaining a UEI.	Regulation: 2 CFR 25	See the award term at 2.2 CFR 25, Appendix A . See General Certifications and Representations (Appendix E)

Use of Logos Related to prior approval for using an HHS or agency logo.	Statute: 42 USC 1320b-10 .	See Supplemental Information (Appendix D.5) for more.
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D.4.2: Civil Rights and Other Protections

Laws and Policies	Source	Notes
Civil Rights Assurance of Compliance Related to requirements to certify compliance with civil rights laws.	Required by: Condition of Award; 45 CFR 80.4 ; 84.5 ; 86.4 ; 91.33 ; 92.4	See HHS Form 690, Assurance of Compliance and HHS Grant Policy Statement.
Copeland Anti-Kickback Act Related to requiring contractors to follow 29 CFR 3 under awards that include construction, alteration, and renovation and weekly compliance statements on the wages paid to each employee.	Statutes: 18 USC 874 and 40 USC 3145 Regulation: 48 CFR 22.403-2	Applies to awards with construction or alterations.
Davis-Bacon Wage Protections Related to using contractors that pay prevailing wages and benefits under awards funding construction, alteration, or repair.	Statute: 40 USC 3141, et seq.	Applies to awards with construction or alterations.
Discrimination Based on Age Related to protecting people from discrimination based on age.	Statutes: Age Discrimination Act of 1975, 42 USC 6101, et seq. ; Section 1557 of the Affordable Care Act, 42 USC 18116 Regulations: 45 CFR 91	See General Certifications and Representations (Appendix E)
Discrimination Based on Disabilities Related to protecting people from discrimination based on a disability.	Statutes: Section 504 of the Rehabilitation Act, 29 USC 794 ; (for state and local government recipients; Section 1557 of the Affordable Care Act; 42 USC 18116 Regulations: 45 CFR 84 ; 45 CFR 92	See General Certifications and Representations (Appendix E)
Discrimination Based on Race, Color, and National Origin Related to protecting people from discrimination on the basis of race, color, or national origin.	Statutes: Title VI of the Civil Rights Act, 42 USC 2000d ; Section 1557 of the Affordable Care Act; 42 USC 18116 Regulations: 45 CFR 80 ; 45 CFR 92	See General Certifications and Representations (Appendix E)

Laws and Policies	Source	Notes
Discrimination Based on Religion and Religious Conscience Related to protecting people from discrimination based on their religious beliefs.	Statutes: Church Amendments, 42 USC 300a-7 ; Coates-Snowe Amendment, 42 USC 238n ; and the Weldon Amendment, Further Consolidated Appropriations Act, 2024, Division D, Title V , Section 507(d)(1) Guidance: HHS Office for Civil Rights, Conscience and Religious Freedom for situations where this protection applies.	See General Certifications and Representations (Appendix E)
Discrimination Based on Sex Related to protecting people from discrimination based on sex.	Statutes: Title IX of the Education Amendments of 1972, as amended; 20 USC 1681 et seq.; Section 1557 of the Affordable Care Act, 42 USC 18116 Regulations: 45 CFR 86 ; 45 CFR 92 See other sex discrimination guidance and requirements at HHS Office for Civil Rights, Laws and Regulations Enforced by OCR . See also Sex-Based Harassment .	See General Certifications and Representations (Appendix E) (Title IX)
Drug-Free Workplace Related to maintaining a drug-free workplace and notifying the agency if an employee is convicted of violating a criminal drug law. Failure to follow these requirements may be cause for debarment.	Statute: Drug-Free Workplace Act, 41 USC 8101-8106 Regulation: 2 CFR 182, subpart B	See the award term at 2 CFR 382.400 . See General Certifications and Representations (Appendix E)
Earthquake Hazards Reduction Related to requirements to use earthquake-resistant design when constructing new buildings.	Statute: 42 USC 7701, et seq. Directive: Executive Order 13717	Applies to new construction.
Fair Housing Related to protecting people from discrimination in housing.	Statute: Title VIII of the Civil Rights Act of 1968, 42 USC 3601 , et seq.	See General Certifications and Representations (Appendix E)
Faith-Based Organizations Related to protections for faith-based organizations to apply and receive federal funds without discrimination or interference with their mission. Describes limitations on the use of federal funds.	Statute: 42 USC 2000bb, et seq. Directives: Executive Orders 13279 , 13559 , and 13831 . Regulation: 28 CFR 38, appendix A and 45 CFR 87, appendix A	
Hotel and Motel Fire Safety Related to fire safety activities for hotels and motels used for venues.	Statute: 15 USC 2201, et seq	Applies to awards using hotels or motels as venues.

Laws and Policies	Source	Notes
Limited English Proficiency Related to steps to improve access to persons with limited English proficiency.	Required by: Title VI of the Civil Rights Act, 42 USC 2000d; Section 1557 of the Affordable Care Act, 42 USC 18116 Regulations: 45 CFR 80 ; 45 CFR 92 Guidance: Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons	See also LEP.gov Does not apply to subcontractors.
Military Recruiting and Higher Education Related to limitations on funding institutions of higher education that do not allow Reserve Officer Training Corps (ROTC) on campus and allow military recruiting on campus.	Statute: 10 USC 983	Applies to subrecipients where HHS must approve them. Does not apply to subcontractors.
Pro-Children Act – Non-Smoking Related to prohibiting smoking in indoor facilities where award-funded projects serve children. Not following this law can bring civil monetary penalties.	Statute: Pro-Children Act of 2001, 20 USC 7181 through 7184	
Privacy Act Related to protecting information about a person, unless the person gives permission or under the exceptions at 5 USC 552a(b) .	Statute: 5 USC 552a	
Seat Belts Related to encouragement to adopt and enforce seat belt policies.	Directive: Executive Order 13043	Does not apply to subrecipients or subcontractors.
Texting While Driving Related to limitations on texting while driving when federal funds pay for vehicles or cell phones.	Directive: Executive Order 13513	Does not apply to subcontractors.
Trafficking Victims Protection Related to bans providing funds to organizations involved in human trafficking.	Statute: Trafficking Victims Protection Act (TVPA) of 2000, as amended, 22 USC 7104(g) . Regulation: 2 CFR 175 , Award Term for Trafficking in Persons.	See General Certifications and Representations (Appendix E)
Whistleblower Protections Related to protecting employees from reprisal for disclosing information about violations.	Statute: Protection from Reprisal of Disclosure of Certain Information, 41 USC 4712 .	See General Certifications and Representations (Appendix E)

D.4.3: Environmental

Laws and Policies	Source	Notes
Clean Air and Water Related to the requirement to follow certain environmental laws.	Statute: Clean Air Act of 1970, 42 USC 7401 et seq. Statute: Clean Water Act of 1972, 33 USC 1251 et seq.	See Summary of the Clean Air Act. See Summary of the Clean Water Act.
Climate Resiliency and Energy and Emission Reductions Relating to the purchase or construction of real property and major renovation projects.		Additional Guidance to Advance Climate Resilience and Reduce Energy and Emission See more in Supplemental Information (Appendix D.5)
Earthquake Hazards Reduction Related to using earthquake-resistant design when constructing new buildings.	Statute: 42 USC 7701, et seq. Directive: Executive Order 13717	Applies to new construction.
Flood Insurance Related to requirements for flood insurance in areas with special flood hazards.	Statute: 42 USC 4001, et seq.	Applies to awards that acquire or construct buildings. Does not apply to subrecipient or subcontractors.
National Environmental Policy Act Related to policies to conduct reviews to assess and mitigate environmental impact.	Statute: National Environmental Policy Act of 1969, as amended, 42 USC 4321 et seq. Guidance: HHS General Administration Manual (GAM), Part 30-50 , National Environmental Policy Act Review for the NEPA process.	Applies to construction or major renovation activities. Does not apply to subcontractors. See more in Supplemental Information (Appendix D.5) See General Certifications and Representations (Appendix E)
National Historic Preservation Act (NHPA) Related to requirements to consider the effect of potential awards on historic properties.	Statute: National Historic Preservation Act (NHPA) of 1996, as amended, 54 USC 300101 et seq. Regulation: 36 CFR 800	Applies to awards buying, constructing, or altering real property. See resources and a summary of the process in Supplemental Information (Appendix D.5) .
Resource Conservation and Recovery Relating to requirements to give preference to the purchase of recycled products.	Statute: 42 USC 6962 Regulation: 40 CFR 247 (See list of relevant recycled products at 40 CFR 247, subpart B.)	Applies to state and local institutions of higher education, hospitals, and non-profit organizations.

Safe Drinking Water Act Related to ensuring that public water systems provide safe and reliable drinking water.	Statute: 42 USC 300f, et seq. Regulation: 40 CFR 141	Applies to public water systems.
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Laws and Policies	Source	Notes
Uniform Relocation Assistance Related to real estate activities that may displace people.	Statute: 42 USC 4601 et seq. Regulation: 45 CFR 15 and 49 CFR 24	Does not apply to subcontractors.
Wetland Protection Related to requirements to protect wetlands.	Directives: Executive Orders 11988 and 11990 Regulation: 18 CFR 725	

D.4.4: Lobbying, Advocacy, & Political Activity

Laws and Policies	Source	Notes
Anti-Lobbying, Publicity, and Propaganda Related to restrictions against lobbying, publicity, or propaganda using federal funds. Applicants must certify their compliance.	Statutes: Further Consolidated Appropriations Act, 2024, Division B, Title VII , Section 715, 718, and 731; Consolidated Appropriations Act, 2024, Division E, Title IV , Section 401; Further Consolidated Appropriations Act, 2024, Division D, Title V , Sections 503, 505, and 522 Regulation: 2 CFR 200.450	
Controlled Substances Related to restrictions on activities that promote the legalization of any drug or other substance.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title V , Section 509	See General Certifications and Representations (Appendix E)
Gun Control Related to requirements about not using federal funds to advocate for or promote gun control.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title II , Section 210; Further Consolidated Appropriations Act, 2024, Division D, Title V , Section 503(c)	See General Certifications and Representations (Appendix E)
Hatch Act Related to restrictions on political activity and running for public office.	Statute: 5 USC 1502 (For exceptions see 5 USC 1501) Regulation: 5 CFR 151	Does not apply to subcontractors.
Lobbying Disclosure Act of 1995 Related to requirements to disclose lobbying activities.	Statute: 2 USC 1601 et seq	You can find the Disclosure of Lobbying Activities (SF-LLL) at Grants.gov/Forms . See General Certifications and Representations (Appendix E)

D.4.5: Patents, Inventions, and Data

Laws and Policies	Source	Notes
Federal government rights Related to the federal government's rights to use inventions.	Statute: 35 USC 202-203 Regulation: 37 part 401	Applies to research projects with inventions.
Laws and Policies	Source	Notes
Federal Information Security Management Act (FISMA) Related to policies when recipients collect, store, process or send data on behalf of HHS.	44 USC 3551 et seq.	
Retaining Rights Related to the rights to new inventions developed from funded research.	Statute: Bayh-Dole Act of 1980, 35 USC 200 et seq. and the related EO 12591	Applies to research projects with inventions.

D.4.6: Procurement

Laws and Policies	Source	Notes
American-Manufactured Goods Related to required preferences for certain products and materials made in the US. Waivers may be possible.	Statute: Buy American Act, 41 USC 8301 et seq. Statute: Build America, Buy America Act, Public Law 117-58 , Title IX, Subtitle A Regulations: 2 CFR 184 (BABA) and 48 CFR 25 (Buy American Act) Guidance: M-22-11 and M-24-02	
Fly America Act Related to requirements for travelers to use certified U.S. airlines for award-funded air travel.	Statute: 49 USC 40118 Regulation: 41 CFR 301-10.131 - 143	
Prohibition on certain telecommunications and video surveillance services or equipment Related to restrictions on using federal funds for telecommunications equipment produced by certain companies.	Statute: 41 USC 3901 et seq Regulation: 2 CFR 200.216	
U.S. Flag Vessels Related to using U.S. owned and operated vessels to ship goods and supplies bought with award funds.	Statute: 46 USC 55305 Regulation: 46 CFR part 381.7	

D.4.7: Professional Integrity

Laws and Policies	Source	Notes
Blocking Access to Pornography Related to requirements for computer systems to not allow people to view, download, or exchange pornography. The only exclusion is for law enforcement functions.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title V , Section 520	See General Certifications and Representations (Appendix E)

Laws and Policies	Source	Notes
Civil Actions for False Claims Act Related to the federal government's ability to take civil actions on violations of the false claims act.	Statute: 31 USC 3730	See General Certifications and Representations (Appendix E)
Debarment and Suspension Related to not providing federal funds to excluded parties.	Regulation: 2 CFR 180	Does not apply to subcontractors unless the contract is over \$25,000. See General Certifications and Representations (Appendix E)
False Claims Act Related to liability on persons and companies who defraud government programs	Statutes: 31 USC 3729 , 18 USC 287 , and 18 USC 1001	See General Certifications and Representations (Appendix E)
False or Misleading Information Related to requirements to not use federal funds to share deliberately false or misleading information.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title V , Section 515(b)	See General Certifications and Representations (Appendix E)
Mandatory Disclosure Related to requirements to disclose certain violations of federal criminal law.	Statute: 41 USC 2313 Regulation: 2 CFR 200.113 and 2 CFR 200 Appendix XII	
Program Fraud and Civil Remedies Act Related to administrative hearings for certain false claims actions.	Statute: 31 USC 3801 et seq	See General Certifications and Representations (Appendix E)
Recent Felony Convictions Related to eligibility for awards for corporations with felony criminal convictions in the past 24 months.	Statute: Further Consolidated Appropriations Act, 2024, Division B, Title VII , Section 745	See General Certifications and Representations (Appendix E)
Recipient Integrity and Performance Related to information reported to SAM.gov Responsibility/Qualification.	Regulation: 2 CFR 200.211(c)(1)(iii) and 2 CFR 200 Appendix XII	

Unpaid Federal Tax Liability Related to eligibility corporations with an unpaid tax liability, with some conditions.	Statute: Further Consolidated Appropriations Act, 2024, Division B, Title VII , Section 744	See General Certifications and Representations (Appendix E) Does not apply to subrecipients or subcontractors.
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D.4.8: Research Awards

Laws and Policies	Source	Notes
Animal Welfare Related to requirements when live animals are involved in award-funded programs and	Statutes: 7 USC 2131-2159 and 42 USC 289d Regulation: 9 CFR subchapter A Policy: PHS Policy for the Humane Care and Use of Laboratory Animals	See Supplemental Information (Appendix D.5)

Laws and Policies	Source	Notes
Certificates of Confidentiality Related to protecting subjects from compelled disclosure of identifying information and addressing voluntary disclosure.	Statute: 42 USC 241(d)	
Clinical Investigations of FDA-Regulated Products Related to clinical investigations regulated by FDA.	Statutes: 21 USC 355(i) , 360b(j) , and 360i(g) . Regulations: 21 CFR 50, 54, 56, 21.312, 511, and 812 .	Applies to clinical investigations regulated by FDA.
Cloning Related to ban on cloning human beings.	Directive: Cloning of Human Beings Ban (Presidential memorandum, March 4, 1997)	
Confidentiality: Substance Use Disorder Patient Records Related to requirements for substance use disorder patient confidentiality.	Statute: 42 USC 290dd-2	
Federal Technology Transfer Related to access to federal government laboratories by non-federal organizations	Statute: 15 USC 3701 et seq	
Financial Conflicts of Interest Related to a process to identify and address financial conflicts.	Regulation: 42 CFR 50, Subpart F	Applies to research awards. Does not apply to subcontracts, Phase I of the SBIR/STTR programs, and federal institutions.

HIPAA Related to the Privacy Rule standards that address the use and disclosure of individuals' health information (known as "protected health information") by entities subject to the Privacy Rule.	Statute: Health Insurance Portability and Accountability Act P.L.104-191	Applies to HIPAA covered entities.
Human Embryos Related to policies for the destruction or creation of human embryos.	Statute: Further Consolidated Appropriations Act, 2024, Division D, Title V , Section 508(a)	See General Certifications and Representations (Appendix E)
Human Subjects Protection Related to requirements for research involving human subjects.	Statutes: 42 US. 289 and 42 USC 300v-1(b) Regulation: 45 CFR 46	See Supplemental Information (Appendix D.5)
Recombinant DNA and Human Gene Transfer Related to NIH guidelines for such research.	Guidance: NIH Guidelines	

Laws and Policies	Source	Notes
Research Involving Potential Procurement of Synthetic DNA and RNA Related to scientific research awards that have the potential to procure synthetic nucleic acids or benchtop nucleic acid synthesis equipment.	EO 14110 Section 4.4(b) (referencing The Office of Science and Technology Policy (OSTP) Framework for Nucleic Acid Synthesis Screening)	See Supplemental Information (Appendix D.5)
Research Misconduct Related to Public Health Service Policies on Research Misconduct	Regulation: 42 CFR 93	
Research on Human Fetal Tissue Related to the use of human fetal tissue in research.	Statute: 42 USC 289g-1 and g-2 Regulation: 45 CFR 46.206	

D.4.9: Other

Laws and Policies	Source	Notes
Freedom of Information Act (FOIA) FOIA establishes a 'strong presumption in favor of disclosure of requested information.	Statute: 5 USC 552	
Intergovernmental Personnel Act Provides for the temporary assignment of personnel between the federal government and state and local governments, colleges and universities, Indian tribal governments, federally funded research and development centers, and other eligible organizations	Statute: 5 USC 3371 et seq Regulation: 5 CFR part 334	
Paperwork Reduction Act Minimizes the paperwork burden resulting from the collection of information by or for the federal government	Statute: 44 USC 3501, et seq	
Public Health Security and Bioterrorism Requires the biennial review and republication of the HHS list of select agents and toxins.	Statute: 42 USC 262a	
Standards of Conduct To assure HHS is conducted effectively, objectively, and without improper influence or the appearance of improper influence, sets standards for employees and special Government employees	Regulation: 45 CFR 73	

D.5: Supplemental Information

D.5.1: Administrative and Activities

D.5.1.1: Cybersecurity requirements

You must create a cybersecurity plan if your project involves both of the following conditions:

- You have ongoing access to HHS information or technology systems.
- You handle personal identifiable information (PII) or personal health information (PHI) from HHS.

You must base the plan on the [NIST Cybersecurity Framework](#). Your plan should include the following steps:

Identify:

- List all assets and accounts with access to HHS systems or PII/PHI.

Protect:

- Limit access to only those who need it for award activities.
- Ensure all staff complete annual cybersecurity and privacy training. Free training is available at 405(d): Knowledge on Demand (hhs.gov).
- Use multi-factor authentication for all users accessing HHS systems.
- Regularly backup and test sensitive data.

Detect:

- Install antivirus or anti-malware software on all devices connected to HHS systems.

Respond:

- Create an incident response plan. See [Incident-Response-Plan-Basics_508c.pdf \(cisa.gov\)](#) for guidance.
- Have procedures to report cybersecurity incidents to HHS within 48 hours. A cybersecurity incident is:
 - Any unplanned interruption or reduction of quality, or
 - An event that could actually or potentially jeopardize confidentiality, integrity, or availability of the system and its information.

Recover:

- Investigate and fix security gaps after any incident.

D.5.1.2: Health information technology interoperability

Pursuant to the HITECH Act and HHS policy, if you receive an award, you must agree to the following conditions when implementing, acquiring, or upgrading health IT and the required standards support a related activity. These conditions also apply to all subrecipients.

- For activities by all recipients. Use only health IT that meets the standards and specifications in [45 CFR 170, subpart B](#).
- For activities by eligible clinicians in ambulatory settings or hospitals. Use only health IT certified by the [ONC Health IT Certification Program](#) for activities by eligible clinicians under Sections 4101, 4102, and 4201 of the [HITECH Act](#).

If 45 CFR 170, subpart B standards cannot apply to the activity, we encourage you to:

- Use health IT that meets non-proprietary standards.
- Follow specifications from consensus-based standards development organizations.
- Consider standards identified in the [ONC Interoperability Standards Advisory](#).

D.5.1.3: Use of Logos

Recipients must have prior written approval from the GMO before using an HHS or agency logo. Using a logo without approval may lead to a financial penalty.

D.5.1.4: Publications and Acknowledgement of Support

Recipients must acknowledge HHS funding in public documents related to the awarded project. Acknowledgements must include:

- Name of agency and HHS
- Amount of federal funding
- Percentage of federal funding to total costs
- Disclaimer of HHS endorsement or agreement. Example of statement for public documents:

The [agency], Department of Health and Human Services provided financial support for this [project / publication / website / etc.]. The award provided XX% of total costs and totaled \$XX. The contents are those of the author. They may not reflect the policies of the Department of Health and Human Services or the U.S. government.

Contact the GMO if you need to revise the contents of the acknowledgement statement. Also contact the GMO to coordinate all media releases.

Recipients must include this statement in materials for funded conferences:

“The [Agency] made this conference possible [in part] through [award number]. Views expressed by speakers, moderators, and in writing may not reflect the policies of the Department of Health and Human Services. Mentions of trade names, commercial practices, or organizations do not imply endorsement by the U.S. Government.”

D.1.5.5: National Environmental Protection Act

To comply with NEPA for its award-supported activities, HHS must review the environmental aspects of awards that include construction or major renovation activities before award, unless a specific condition is placed on the award. If, because of a post-award change, an agency determines NEPA applies to an award, the NEPA process must be satisfactorily completed before drawdown of funds for the activity. Consult the agency’s [NEPA contact](#) for specific information on what must be addressed.

D.1.5.6: National Historic Preservation Act (NHPA)

If the recipient takes actions on real property that are not in compliance with historic preservation requirements, the agency may have a basis to take an enforcement action and recoup some or all its funding.

For questions on NHPA, contact [Real Property Policy and Strategy](#), Program Support Center (PSC), Assistant Secretary for Administration (ASA).

The HHS implementation process is detailed in [Chapter 9](#) of the HHS Facilities Program Manual.

The table below summarizes the process used to determine if a proposed activity will have any effects on historic properties. It provides a general outline of the NHPA section 106 process, but not all details.

Therefore, this attachment must be used with, not instead of, the NHPA requirements.

Activity	Guidance
1. Determine if any portion of the project may include activities that affect an historic property. Such activities typically include acquisition, construction, or alteration of real property. Note: The applicant is primarily responsible for this determination. If the agency has concerns about the applicant's determination, they will address them with the applicant and consult the State Historic Preservation Office (SHPO) or Tribal Historic Preservation Office (THPO), as applicable.	If the answer is "yes," then continue with the process. If the answer is "no," then the process may stop.
2. Identify the appropriate SHPO or THPO with jurisdiction in the area where the project will be performed.	Find an SHPO. Find a THPO.
3. In consultation with the SHPO or THPO, identify whether any National Register historic properties (or those eligible for inclusion) are within the project's Area of Potential Effect (APE). The APE can include areas outside of the project's boundaries. For example, constructing a building may not affect an historic resource on the property itself, but may affect the view or setting of a nearby historic resource.	If the answer is "yes," then continue with the process. If the answer is "no," and the SHPO or THPO agrees, then the process may stop.
4. Determine if the undertaking will result in any adverse effects on an historic property.	If the answer is "yes," then continue with the process. If the answer is "no," and the SHPO or THPO agrees, then the process may stop.
5: Consult with SHPO or THPO and other appropriate parties to develop measures that mitigate adverse effects on historic properties. The consultation may result in a Memorandum of Agreement (MOA), signed by each party, which outlines each party's responsibilities for implementing the mitigation measures.	If the parties sign an MOA, the agency must ensure that the undertaking is carried out in accordance with the MOA. If the parties cannot agree and do not execute an MOA, then proceed to Activity 6.
6. Any party terminating consultation shall notify the other parties in writing. 36 CFR 800.7 outlines the procedures to follow, depending on which party terminates the consultation.	If there is a failure to reach resolution, the agency head may decide to approve proceeding with the undertaking after following the applicable requirements of 36 CFR 800.

D.5.2: Research Awards

D.5.2.1: Human Subjects in Research

The regulations for the protection of human subjects in [45 CFR 46](#), Basic HHS Policy for Protection of Human Subjects (Subpart A of which is also known as the Common Rule) implement Section 491(a) of the Public Health Service (PHS) Act. The regulation applies to all HHS awards involving human subjects research.

The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is the office with HHS-wide responsibility for research involving human subjects under this policy. Foreign applicant organizations applying for awards for research involving human subjects are required to comply with [45 CFR 46](#). There is a single version of the Federal- wide Assurance (FWA) form and Terms of Assurance for domestic (U.S.) and international (non- U.S.) institutions.

All NOFOs must clearly state the parameters of human subject use, and indicate the necessary information and assurances required from the applicant prior to the issuance of award.

Recipients, whether domestic or international, must safeguard the rights and welfare of human subjects in HHS-conducted or -supported activities ([45 CFR 46.101\(a\)](#) and [45 CFR 46.103\(a\)](#)).

As a matter of grants policy, recipients must ensure that subrecipients follow these requirements, as applicable. Recipients must facilitate the process for obtaining prior approval for subrecipients if not approved in the award.

Some human subject research is exempt from the requirements of the HHS regulations. The categories of research that qualify for exemption are found at [45 CFR 46.104\(d\)\(1\)-\(8\)](#). OHRP guidance recommends that investigators not be given the authority to make an independent determination that human subjects research is exempt. HHS retains final authority as to whether a particular research study supported by HHS is exempt from the HHS regulations.

Contact OHRP for any related questions.

OHRP is the only component of HHS with the delegated authority to interpret and enforce the regulatory requirements in [45 CFR 46.101\(c\)](#) as to whether a particular activity is regulated by [45 CFR 46](#).

Before engaging in HHS award-supported non-exempt human subjects research, the recipient, including any collaborating organization under a subaward, must:

- Hold or obtain an OHRP-approved FWA ([45 CFR 46.103\(a\)](#)); and
- Certify to the agency, within the time frame specified, that the research has been reviewed and approved by an Institutional Review Board (IRB) designated in the FWA ([45 CFR 46.103\(d\)](#))

The [OHRP web site](#) contains a listing of those organizations with OHRP-approved assurances.

The agency must make sure that an applicant and any collaborating organizations have the required assurance and certification in place, before:

- Making an award, unless a specific condition is included in the NoA restricting expenditures for this purpose.
- Non-exempt human subjects research is initiated, if non-exempt research is planned but will not occur until a subsequent phase of the project, by including a specific condition in the NoA that restricts expenditures for this purpose; or

- Approving a post-award change in scope that will result in non-exempt human subjects research.

The award condition must indicate that the recipient may not draw down funds, obligate or expend federal funds, or claim required cost sharing costs for research involving human subjects at any site engaged in non-exempt research until all requirements for are met. The prohibition on expenditures may extend to the whole project if that activity is not severable. The recipient must be advised that failure to comply within the stated time may result in full or partial termination of the award.

D.5.2.2: Research Involving Animals and Their Welfare

Pursuant to [42 U.S.C. 289d \(Section 495 of the Public Health Service Act\)](#), requirements related to the use of live, vertebrate animals apply to all PHS agencies and to other research-related awards. PHS agencies include AHRQ, CDC, FDA, HRSA, IHS, NIH, and SAMHSA. These requirements apply to recipients, subrecipients, and contractors, whether foreign or domestic.

The requirements:

- Are included in the [Public Health Service Policy on Humane Care and Use of Laboratory Animals](#) (PHS Policy),
- Incorporate the [U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training](#),
- Require the recipient to maintain an animal care and use program based on the [Guide for the Care and Use of Laboratory Animals](#); and
- Require compliance, as applicable, with the [Animal Welfare Act](#) and other federal statutes and regulations relating to animals.

Recipients must establish appropriate policies and procedures to ensure the humane care and use of animals and are ultimately responsible for compliance with the PHS Policy. Information about animal welfare topics is available from the [Office of Laboratory Animal Welfare](#) (OLAW), Office of Extramural Research, National Institutes of Health.

Before engaging in any HHS award-supported research using animals, applicants must:

- Have a current Animal Welfare Assurance approved by OLAW (the list of organizations with approved assurances is available at the OLAW website for both [domestic institutions](#) and [foreign institutions](#);
- Provide, as part of the application or just-in-time, verification of current Institutional Animal Care and Use Committee (IACUC) approval of the animal activities. (PHS Policy requires that IACUC approval must have occurred within three years of the period of performance start date for new or renewal awards and at least every three years after that); and
- Comply with the agency's internal IACUC requirements if a cooperative agreement.

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.

Foreign applicant organizations applying for awards for activities involving animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. This includes providing OLAW with an Animal Welfare Assurance for Foreign Institutions, which 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](#).

No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy.

If the applicant does not have a current Animal Welfare Assurance (or made alternative arrangements, e.g., an inter-institutional assurance acceptable to OLAW) or has not provided the required verification by the time an award will be made, the agency will notify the PO and the applicant and the agency may:

- Delay the award until the recipient and all performance sites are operating in accordance with approved Animal Welfare Assurances and the organization has provided verification of IACUC approval of those sections of the application that involve use of animals; or
- Include a specific condition in the NoA restricting expenditures.

The award condition must prohibit drawdown or expenditure of funds under the award (whether federal funds or any required cost sharing) until the requirements have been met. The prohibition on expenditures may extend to the whole project if that activity is not severable. The recipient must be advised that failure to comply within the stated time may result in full or partial termination of the award.

An agency may not approve a post-award change that will result in research involving animals unless the agency determines that an appropriate Animal Welfare Assurance has been negotiated with OLAW and the required IACUC verification has been received.

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 IACUCs.

D.5.2.3: Research Involving Potential Procurement of Synthetic DNA and RNA

Pursuant to [EO 14110](#) Section 4.4(b), beginning April 26, 2025, all scientific research awards that have the potential to procure synthetic nucleic acids or benchtop nucleic acid synthesis equipment need to have a condition that requires recipients to adhere to and use HHS funds to procure these materials from sources adhering to [the Office of Science and Technology Policy \(OSTP\) Framework for Nucleic Acid Synthesis Screening](#). This includes, but is not limited to, research with the potential to procure synthetic DNA and RNA, as well as whole organism genomes (e.g., viruses, bacteria) containing any synthetic nucleic acid 200 nucleotides or greater, and benchtop equipment capable of synthesizing nucleic acids. Please see [the OSTP Framework for Nucleic Acid Synthesis Screening](#) for additional guidance and definitions of terms. The requirement to use the framework applies to all work performed under the

award.

Appendix E: Financial Assistance General Certifications and Representations

In almost all instances, applicants must have a SAM.gov registration. Agreement to a list of general certifications and representations is required for registration.

Please go to the following page to see updated Certifications and Representations:

<https://www.hhs.gov/sites/default/files/financial-assistance-general-certification-representations.pdf>



5600 Fishers Lane
Rockville, MD 20857



April 7, 2025

Dear Ryan White HIV/AIDS Program Awardees and Stakeholders,

Since its inception over three decades ago, the Ryan White HIV/AIDS Program (RWHAP) has been a cornerstone of hope and a lifeline for Americans living with HIV and AIDS. The largest federal initiative of its kind, RWHAP has provided critical care and support to low-income, uninsured, and under-insured Americans with HIV and AIDS. During his first term, President Donald J. Trump championed the ambitious Ending the HIV Epidemic initiative, a transformative plan to reduce new HIV infections by 75 percent by 2025 and 90 percent by 2030. Now in President Trump's second term, the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) stands recommitted and ready to achieve this bold agenda. With your support and collaboration, HAB will leverage the RWHAP to fulfill this Administration's pledge to all Americans, particularly those living with HIV/AIDS—to Make America Healthy Again.

Program integrity and responsible fiscal stewardship are critical elements of the indispensable services RWHAP provides. But under the previous administration, certain interpretations of RWHAP's allowable uses, as outlined in prior communications, co-opted the program's patient-centered mission in favor of radical ideological agendas and policies.¹ Congress envisioned RWHAP as a lifeline for those battling HIV and AIDS, not as a vehicle for broader social or medical experimentation. More to the point, this politicized commandeering risks diverting resources away from HIV/AIDS patients, whose lives depend on RWHAP's core medical services.

Accordingly, HAB reaffirms that RWHAP funds shall be marshaled exclusively toward evidence-based interventions proven to combat HIV, sustain viral suppression, and improve the quality of life for those living with the disease. This includes outpatient medical care, antiretroviral therapies, and essential support services such as case management, housing assistance, and substance use disorder treatment—each a vital thread in the fabric of HIV/AIDS care, each demonstrably aligned with the program's statutory intent.²

We clarify and remind RWHAP awardees that funds are not authorized for procedures or interventions beyond the scope of outpatient care, as expressly delineated in Policy Clarification Notice #16-02.³ The prohibition on surgeries and inpatient care, irrespective of setting or anesthesia, remains absolute, ensuring that resources remain laser-focused on the HIV-specific

¹ Health Resources and Services Administration, Gender Affirming Care and the Ryan White HIV/AIDS Program (2021), <https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/hiv-care/gender-affirming-care-rwhap.pdf>.

² See generally 42 U.S.C. §§ 300ff-11-140.

³ Eligible Individuals & Allowable Uses of Funds Clarification Notice. Available at: https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf.

Ryan White HIV/AIDS Program Awardees and Stakeholders
Page 2

needs of eligible individuals. Where disparities persist, particularly among underserved populations, our response shall be targeted, evidence-driven enhancements to HIV care delivery, not a broadening of scope that risks undermining this progress.

The Trump Administration, in its renewed commitment to Make America Healthy Again, calls upon RWHAP recipients and subrecipients to join us in this realignment. We will provide training and technical assistance through the AIDS Education and Training Centers to ensure culturally competent, patient-centered care that maximizes antiretroviral adherence and viral suppression—goals that unite us in the fight to end the HIV epidemic. Together, we can honor the congressional vision that birthed RWHAP, delivering on its promise to those it was designed to serve, without deviation or distraction.

Sincerely,

A handwritten signature in black ink, reading "Thomas J. Engels". The signature is fluid and cursive, with the first name "Thomas" and last name "Engels" clearly legible.

Thomas J. Engels
Administrator



HHS
@HHSGov



The Trump administration is bringing back common sense and restoring biological truth to the federal government. The prior administration's policy of trying to engineer gender ideology into every aspect of public life is over.



From [womenshealth.gov](https://www.womenshealth.gov)

7:22 PM · Feb 20, 2025 · **45.3K** Views



Who We Are

The **HIV/AIDS Bureau** provides a comprehensive system of HIV primary medical care, medications, and essential support service for low-income people with HIV.

Through the Ryan White HIV/AIDS Program:

- We fund cities, counties, states, and local community-based organizations to provide HIV care, treatment, and essential services to more than 600,000 people—over half of the people diagnosed with HIV in the United States.
- 91.4% of clients receiving HIV medical care were virally suppressed in 2024, which means they can live longer and healthier lives and cannot sexually transmit HIV.

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[Home](#) » [About the Program](#) » [Program Parts and Initiatives](#) » Part B: Grants to States and Territories

Part B: Grants to States and Territories

The Ryan White HIV/AIDS Program (RWHAP) Part B provides grants to [states and territories](#). This funding helps them improve HIV medical and support services. The improvements focus on making these services better, easier to access, and more organized.

What grants are available under Part B?

The Ryan White HIV/AIDS Program (RWHAP) Part B grants include:

- Base grant - This covers core medical services and support services
- Supplemental grant - This grant gives additional money to states and territories that can show they need more help
- [AIDS Drug Assistance Program \(ADAP\)](#) - This grant helps low-income people with HIV get the medications they need. There are three kinds of ADAP:
 - Regular ADAP grants: this provides money for medications
 - Supplemental ADAP grants: some states receive extra money if they have a greater need
 - Emergency relief funds: some states receive money to help people waiting for ADAP medicine
- Minority AIDS Initiative grants - These grants focus on educating and helping minority communities to access ADAP and other medication assistance programs
- Emerging Communities grants - These grants provide additional money to states that have a growing number of people with AIDS (also known as “emerging communities.”). These are communities that have between 500 and 999 AIDS cases in the past five years

Who are Part B grant recipients?

Part B grant funding goes to the chief elected official (CEO) of a state or territory. The CEO then chooses an agency, like the department of health, to manage the grant.

View the list of [FY 2025 Part B grant awards](#).

Who is eligible for Part B grants?

RWHAP Part B grants are available to all states and territories in the United States. This includes:

- The Commonwealth of Puerto Rico
- Northern Mariana Islands
- American Samoa
- Guam
- U.S. Virgin Islands
- Federated States of Micronesia
- Republic of the Marshall Islands
- Republic of Palau

RWHAP Part B is also available to states or territories with emerging communities.

How do you decide base grants?

The amount of funding each state or territory gets in a base grant depends on how many people are living with HIV. We use a formula and data from the most recent calendar year. This decides Part B and ADAP base grants.

[Learn more about ADAP base and supplemental grants, and emergency relief funding.](#)

What services do Part B grant recipients fund and provide?

Part B grant recipients fund medications, core medical services, and support services. Each state or territory decides which services to offer based on their jurisdiction's needs assessment and available funding.

All Part B recipients and subrecipients must help eligible clients find health care coverage.

Core medical services

- Outpatient and ambulatory health services
- AIDS Drug Assistance Program
- AIDS pharmaceutical assistance
- Oral health care
- Early intervention services
- Health insurance premium and cost-sharing assistance
- Home health care
- Medical nutrition therapy
- Hospice services
- Home and community-based health services
- Mental health services
- Outpatient substance abuse care
- Medical case management, including treatment-adherence services

Support services

- Outreach
- Medical transportation
- Linguistic services
- Respite care for caregivers of people with HIV/AIDS
- Referrals for health care and other support services
- Non-medical case management
- Residential substance abuse treatment services

What percent of funding goes to core medical services and support services?

Part B grant recipients must spend:

- At least 75% on core medical services
- No more than 25% on support services

Part B grant recipients can get a waiver for the 75% core medical services if:

- There are no waiting lists for ADAP
- Core medical services are available to people identified and eligible in an applicant's service area

Date Last Reviewed: February 2026

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[Home](#) » [About the Program](#) » [Program Parts and Initiatives](#) »

Part C: Early Intervention Services (EIS) and Capacity Development Grants

Part C: Early Intervention Services (EIS) and Capacity Development Grants

The Ryan White HIV/AIDS Program (RWHAP) Part C provides grants to community-based organizations. These grants include:

- [EIS Grants](#)
- [Capacity Development Grants](#)

What services do EIS grants fund?

Part C EIS grants fund primary health care and support services in outpatient settings for people with HIV.

Who can apply for an EIS grant?

- [Federally Qualified Health Centers](#)
- Family planning grantees (other than states)
- Comprehensive Hemophilia Diagnostic and Treatment Centers
- Rural health clinics
- Health facilities operated or contracted by the Indian Health Service
- Community-based organizations, clinics, hospitals, and other facilities that provide early intervention services to people with HIV

- Nonprofit private entities that provide complete primary care to groups of people at risk of HIV, including faith-based and community-based organizations

View the list of [FY25 Part C EIS grant awards](#).

What services do capacity development grants fund?

Part C Capacity Development grants help organizations strengthen their infrastructure. This helps grant recipients improve their ability to develop, enhance, or expand access to high-quality HIV primary health care services for people with HIV in low-income or rural communities.

Who can apply for a capacity development grant?

- Public or private nonprofits that provide (or plan to provide) HIV primary care
- Current RWHAP grant recipients
- Faith-based organizations
- Community-based organizations
- Tribes and tribal organizations

View the list of [FY25 Part C Capacity Development grant awards](#).

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[Home](#) » [About the Program](#) » [Program Parts and Initiatives](#) »

Part F: Special Projects of National Significance (SPNS) Program

Part F: Special Projects of National Significance (SPNS) Program

The Ryan White HIV/AIDS Program (RWHAP) Part F Special Projects of National Significance (SPNS) Program supports the development of innovative models of HIV care and treatment to quickly respond to emerging needs of RWHAP clients. Through its demonstration, implementation, and IT projects, SPNS uses implementation science to evaluate the design, implementation, utilization, cost, and health-related outcomes of treatment strategies while promoting the dissemination and replication of successful interventions. This unique program advances knowledge and skills in the delivery of health care, support services and data integration to support underserved populations. Through these special projects, RWHAP SPNS recipients implement a variety of interventions, which contribute to the advancement of public health knowledge and the goal of ending the HIV epidemic in the United States.

[View the FY25 Part F Special Projects of National Significance Program grant awards.](#)

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U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

[OCR Home](#)



PROTECTING THE RIGHTS OF LESBIAN, GAY, BISEXUAL, TRANSGENDER, QUEER, AND INTERSEX (LGBTQI+) PEOPLE

Welcome

We are glad you found us. The Department of Health and Human Services' Office for Civil Rights (OCR) understands that many people, family members, friends, and health care providers are facing fear and concerns about efforts by some state and local governments to prevent people from accessing health care and human services on the basis of their sexual orientation or gender identity.

Understanding Your Rights

Civil rights are personal rights guaranteed and protected by the U.S. Constitution and federal laws. Civil rights include protection from unlawful discrimination.

OCR is the law enforcement agency within HHS that is responsible for guaranteeing that people are free from discrimination based on race, color, national origin (including primary language), disability, age, religion, and sex (including pregnancy, sexual orientation, and gender identity) by certain health care and human services. OCR also enforces a range of civil rights and health information privacy laws. For more information about these laws, see our [Civil Rights page](#) and our [HIPAA page](#).

“The Supreme Court has made clear that people have a right not to be discriminated against on the basis of sex and receive equal treatment under the law, no matter their gender identity or sexual orientation. Fear of discrimination can lead individuals to forgo care, which can have serious negative health consequences. It is the position of the Department of Health and Human Services that everyone – including LGBTQ people - should be able to access health care, free from discrimination or interference, period.” -- HHS Secretary Xavier Becerra.

Discrimination on the Basis of Sexual Orientation and Gender Identity

OCR is responsible for enforcing Section 1557 of the Affordable Care Act (Section 1557), which prohibits discrimination against individuals on the basis of race, color, national origin, sex, age, and disability in covered health programs or activities.

Section 1557’s prohibitions of discrimination on the basis of sex to includes: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. The update was made in light of the U.S. Supreme Court’s decision in *Bostock v. Clayton County* and subsequent court decisions.

OCR recognizes that discrimination in health care impacts health outcomes. Research shows that one quarter of LGBTQ people who faced discrimination postponed or avoided receiving needed medical care for fear of further discrimination. OCR's mission is to protect people from all forms of discrimination. OCR will follow Supreme Court precedent and federal law, and ensure that the law's protections extend to those individuals who are discriminated against based on sexual orientation and gender identity.

On June 15, 2020, the U.S. Supreme Court held that Title VII of the Civil Rights Act of 1964 (Title VII)'s prohibition on employment discrimination based on sex encompasses discrimination based on sexual orientation and gender identity. *Bostock v. Clayton County, GA*, 140 S. Ct. 1731 (2020). The *Bostock* majority concluded that the plain meaning of "because of sex" in Title VII necessarily included discrimination because of sexual orientation and gender identity. *Id.* at 1753-54. Consistent with the Supreme Court's decision in *Bostock* and Title IX, beginning today OCR will interpret Section 1557's prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity. This interpretation will guide OCR in processing complaints and conducting investigations, but does not itself determine the outcome in any particular case or set of facts.

In enforcing Section 1557 as stated above, OCR will comply with the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.*, and all other legal requirements.

Additionally, OCR will comply with all applicable court orders that have been issued in litigation involving the Section 1557 regulations, including *Franciscan Alliance, Inc. v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019); *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F. Supp. 3d 1 (D.D.C. 2020); *Asapansa-Johnson Walker v. Azar*, No. 20-CV-2834, 2020 WL 6363970 (E.D.N.Y. Oct. 29, 2020); and *Religious Sisters of Mercy v. Azar*, No. 3:16-CV-00386, 2021 WL 191009 (D.N.D. Jan. 19, 2021).

OCR applies the enforcement mechanisms provided for and available under Title IX when enforcing Section 1557's prohibition on sex discrimination. 45 C.F.R. § 92.5(a). Title IX's enforcement procedures can be found at 45 C.F.R. § 86.71 (adopting the procedures at 45 C.F.R. §§ 80.6 through 80.11 and 45 C.F.R. Part 81).

Gender Affirming Care

HHS stands with transgender and gender nonconforming youth and their families—and the significant majority of expert medical associations—in unequivocally stating that gender affirming care for minors, when medically appropriate and necessary, improves their physical and mental health. Attempts to restrict, challenge, or falsely characterize this potentially lifesaving care as abuse is dangerous. Such attempts block parents from making critical health care decisions for their children, create a chilling effect on health care providers who are necessary to provide care for these youth, and ultimately negatively impact the health and well-being of transgender and gender nonconforming youth.

- [View OCR's guidance on gender affirming care, civil rights, and patient privacy.](#) - March 2, 2022
- [Read the Statement by HHS Secretary Xavier Becerra Reaffirming HHS Support and Protection for LGBTQI+ Children and Youth](#) - March 2, 2022
- On October 1, 2022, the District Court for the Northern District of Texas issued a judgment vacating this document. HHS is evaluating its next steps in light of that judgment but is complying with it.
- [Read the Statement by HHS Secretary Xavier Becerra on Missouri's Emergency Regulation Restricting Access to Gender Affirming Care](#) – April 25, 2023

As a law enforcement agency, OCR is investigating and, where appropriate, enforcing Section 1557 of the Affordable Care Act cases involving discrimination on the basis of sexual orientation or gender identity in accordance with all applicable law. This means that if people believe they have been discriminated against in a health program or activity that receives financial assistance from HHS, they can [file a complaint](#).

Parents or caregivers who believe their child has been denied health care, including gender affirming care, on the basis of that child's gender identity, may [file a complaint](#) with OCR.

Health care providers who believe that they are or have been unlawfully restricted from providing health care to a patient on the basis of that patient's gender identity may [file a complaint](#) with OCR.

HIPAA and Marriage: Understanding Spouse, Family Member, Marriage, and Personal Representatives in the Privacy Rule

The HIPAA Privacy Rule contains several provisions that recognize the integral role that family members, such as spouses, often play in a patient's health care. For example, the Privacy Rule allows covered entities to share information about the patient's care with family members in various circumstances. It also generally requires covered entities to treat an individual's personal representative, who may be a spouse, as the individual, for purposes such as exercising the individual's rights under the Privacy Rule, including the right to access the individual's health information. In addition, the Privacy Rule provides protections against the use of genetic information about an individual, which also includes certain information about family members of the individual, for underwriting purposes.

OCR has issued guidance that makes clear the terms marriage, spouse, and family member include, respectively, all lawful marriages, lawfully married spouses, and both the lawful spouses and the dependents of all lawful marriages, and clarifies certain rights of individuals under the Privacy Rule. You may find OCR's guidance on HIPAA and marriage here: <https://www.hhs.gov/sites/default/files/hipaa-and-marriage.pdf>.

Resources for LGBTQI+ People

Below are United States Government resources that may be of interest to LGBTQI+ people and allies. Additional resources will be added as they are issued.

Resources from the Department of Health and Human Services

- [LGBTQI+ Older Adults – Know Your Rights Resource Guide](#): The Biden-Harris Administration has taken important steps to improve Federal protections for LGBTQI+ older adults and reinforce their rights to be free from discrimination in health care. **En español:** [Adultos mayores LGBTQI: conozca sus derechos](#)
- [Access to Healthcare](#): The Affordable Care Act is greatly improving access to health coverage for LGBTQ+ Americans.
- [LGBTQ Youth Resources | Lesbian, Gay, Bisexual, and Transgender Health | CDC](#): Find resources from the CDC, other government agencies, and community organizations for LGBT Youth, their friends, educators, parents, and family members to support positive environments.

- [Read the LGBTQI+ Youth – Like All Americans, They Deserve Evidence-Based Care blog](#) from Miriam E. Deplin-Rittmon, PhD, SAMHSA's Assistant Secretary for Mental Health and Substance Use.
- [Learn about gender-affirming care](#) and how it improves the mental health and overall well-being of gender diverse youth (OASH's Office of Population Affairs).
- [Representation matters!](#) Meet Admiral Rachel L. Levine, MD, Assistant Secretary for Health, where she fights every day to improve the health and well-being of all Americans. She's working to help our nation overcome the COVID-19 pandemic and build a stronger foundation for a healthier future - one in which every American can attain their full health potential. ADM Levine also is the head of the U.S. Public Health Service Commissioned Corps, one of the eight uniformed services.
- [Read the Ryan White HIV/AIDS Program letter](#) about the importance of gender-affirming care to effectively meet the health and medical needs of transgender people with HIV (HRSA's HIV/AIDS Bureau).
- [Find technical assistance and trainings](#) on how to build inclusive and supportive health care spaces for LGBTQI+ individuals and families (HRSA).
- [Create a Safe Environment for LGBTQI+ Youth](#) from StopBullying.gov provides resources on how to build a safe environment for all LGBTQI+ youth. Parents, schools, and communities can all play a role in preventing bullying and helping LGBTQI+ youth feel physically and emotionally safe.
- Find [mental health and behavioral health](#) resources for the LGBTQI+ community.
- The [Indian Health Service \(IHS\)](#) works to ensure that Lesbian, Gay, Bisexual, Transgender, Questioning and Two-Spirit (LGBTQ-2S) American Indian and Alaska Native (AI/AN) individuals and their families receive equal access to health services in the communities where they live.
- Learn about [research opportunities](#) at the National Institutes of Health's Sexual & Gender Minority Research Office (SGMRO), which coordinates sexual and gender minority (SGM)-related research and activities by working directly with the NIH Institutes, Centers, and Offices.

Resources from the White House

- [FACT SHEET: Biden-Harris Administration Advances Equality for Transgender Americans](#) (March 31, 2022)
- [White House Toolkit on Transgender Equality](#) (June 30, 2021)
- [Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation](#) (Jan. 21, 2021)
- [Executive Order 14021 on Guaranteeing an Educational Environment Free From Discrimination on the Basis of Sex, Including Sexual Orientation or Gender Identity](#) (March 11, 2021)
- [Memorandum on Advancing the Human Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Persons Around the World](#) (February 4, 2021)
- [FACT SHEET: U.S. Agencies Are Advancing the Human Rights of LGBTQI+ Persons Around the World](#) (April 28, 2022)

Resources from the Department of Justice

- [LGBTQI+ Working Group](#)
- [Memorandum on Application of Bostock v. Clayton County to Title IX](#) (March 26, 2021)
- [Letter to State Attorneys General: Federal Nondiscrimination Protections for Transgender Youth](#) (March 31, 2022)

Resources from the Department of Education

- [Resources for LGBTQI+ Students](#)
- [Notice of Interpretation](#) - Enforcement of Title IX with Respect to Discrimination Based on Sexual Orientation and Gender Identity in Light of *Bostock v. Clayton County* (June 22, 2021)

Resources from the Interagency Working Group on Youth Programs (IWGYP)

- [Youth.gov](https://youth.gov)

If You Are, or You Know Someone Who is, in Crisis

Call the [National Suicide Prevention Lifeline \(Lifeline\)](https://www.suicidalifeline.org/) at **1-800-273-TALK (8255)**, or text the [Crisis Text Line](https://www.crisistextline.org/) (**text HELLO to 741741**). Both services are free and available 24 hours a day, seven days a week. All calls are confidential. Contact social media outlets directly if you are concerned about a friend's social media updates. **Dial 911 in an emergency.** Learn more on the [Lifeline's website](https://www.suicidalifeline.org/) or the [Crisis Text Line's website](https://www.crisistextline.org/).

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