



U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

HHS Administrative and National Policy Requirements

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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.

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.** Awarding 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.

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 HHS Awards ([45 CFR part 75](#)).
- In SAM.gov you agree to the Financial Assistance General Certifications and Representations. These require you to follow all federal laws, executive orders, regulations, and public policies governing financial assistance awards. A few of them are specifically mentioned. This Appendix addresses those in the tables below. They are marked with “see the Financial Assistance General Certifications and Representations.”

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 to certain types of 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.

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	<p>Program Authorizations and Appropriations</p> <p>Federal Grant and Cooperative Agreement Act of 1977</p> <p>Federal Funding Accountability and Transparency Act (FFATA) of 2006 Digital Accountability and Transparency Act (DATA) of 2014</p> <p>Grant Reporting Efficiency and Agreements Transparency (GREAT) Act of 2019</p>
3. Regulations	<p>Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards: 2 CFR 200 (government-wide) & 45 CFR 75 (HHS)</p> <p>Program-specific regulations</p>
4. Policies, Program Guidance, and Award-Specific Requirements	<p>Executive Orders OMB Memos</p> <p>HHS Grants Policy Statement (GPS)</p> <p>HHS Grants Policy Administration Manual (GPAM) Agency-Specific Grants Policies</p> <p>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.</p> <p>Requirements specific to an individual award or class of awards, such as a requirement to perform activities described in the recipient’s application.</p>

HHS Grants Policy Statement

The GPS applies to all discretionary HHS awards. 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. The awarding agency may list any exceptions to the GPS in the Notice of Award.

Uniform Administrative Requirements

The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards ([45 CFR part 75](#)) apply to all HHS awards, unless specifically exempted by [45 CFR § 75.101\(d\) or \(e\)](#).

While all of 45 CFR part 75 applies to grants and cooperative agreements, following are some key requirements:

Subrecipients

The uniform requirements also address subrecipient responsibilities. See [45 CFR § 75.101\(b\)\(1\)](#), [45 CFR § 75.351-353](#).

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.

Termination

HHS may terminate awards under certain circumstances. See [45 CFR § 75.372](#).

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.”

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.

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.
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 for more information. NIST Cybersecurity Framework
Debt Collection Related to how the federal government collects debt.	Statute: 31 USC 3701 Regulation: 31 CFR part 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 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
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 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 part 170	See General Certifications and Representations
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 2023, the amount is \$212,100. See General Certifications and Representations

SAM.gov and Universal Entity Identifier (UEI) Related to the requirement to register and maintain registration, including gaining a UEI.	Regulation: 2 CFR part 25	See the award term at 2.2 CFR part 25, Appendix A . See General Certifications and Representations
Use of Logos Related to prior approval for using an HHS or awarding agency logo.	Statute: 42 USC 1320b-10 .	See Supplemental Information for more.

Civil Rights and Other Protections

Find more detail on civil rights protections at HHS Office for Civil Rights, [Laws and Regulations Enforced by OCR](#).

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 part 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 part 91	See General Certifications and Representations
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 part 84 ; 45 CFR part 92	See General Certifications and Representations
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 part 80 ; 45 CFR part 92	See General Certifications and Representations

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
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 part 86 ; 45 CFR part 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 (Title IX)
Drug-Free Workplace Related to maintaining a drug-free workplace and notifying the awarding 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 part 182, subpart B	See the award term at 2 CFR 382.400 . See General Certifications and Representations
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
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 part 38, appendix A and 45 CFR part 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 part 80 ; 45 CFR part 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 part 175 , Award Term for Trafficking in Persons.	See General Certifications and Representations
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

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.
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. See General Certifications and Representations
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.
Resource Conservation and Recovery Relating to requirements to give preference to the purchase of recycled products.	Statute: 42 USC 6962 Regulation: 40 CFR part 247 (See list of relevant recycled products at 40 CFR part 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 part 141	Applies to public water systems.

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 part 15 and 49 CFR part 24	Does not apply to subcontractors.
Wetland Protection Related to requirements to protect wetlands.	Directives: Executive Orders 11988 and 11990 Regulation: 18 CFR part 725	

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: 45 CFR 75.450	
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
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
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 part 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

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.

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 200.322 and 48 CFR part 25 Guidance: M-22-11	
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 381.7	

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

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
Debarment and Suspension Related to not providing federal funds to excluded parties.	Regulation: 2 CFR part 180	Does not apply to subcontractors unless the contract is over \$25,000. See General Certifications and Representations
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
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
Mandatory Disclosure Related to requirements to disclose certain violations of federal criminal law.	Statute: 41 USC 2313 Regulation: 45 CFR 75.113 and 45 CFR part 75, 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
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
Recipient Integrity and Performance Related to information reported to SAM.gov Responsibility/Qualification.	Regulation: 45 CFR 75.210(b)(1)(iii) and 45 CFR part 75, appendix I, E.3	
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 Does not apply to subrecipients or subcontractors.

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 .

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 360j(g) . Regulations: 21 CFR parts 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 part 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
Human Subjects Protection Related to requirements for research involving human subjects.	Statutes: 42 US. 289 and 42 USC 300v-1(b) Regulation: 45 CFR part 46	See Supplemental Information .
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.	The Office of Science and Technology Policy (OSTP) Framework for Nucleic Acid Synthesis Screening	See Supplemental Information .
Research Misconduct Related to Public Health Service Policies on Research Misconduct	Regulation: 42 CFR part 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	

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	

Supplemental Information

Administrative and Activities

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.

Health information technology interoperability

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 part 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 part 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](#).

Use of Logos

Recipients must have prior written approval from the GMO before using an HHS or awarding agency logo. Using a logo without approval may lead to a financial penalty.

Publications and Acknowledgement of Support

Recipients must acknowledge HHS funding in public documents related to the awarded project. Acknowledgements must include:

- Name of awarding 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 [awarding 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 [Awarding 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.”

Environmental

Climate Resiliency and Energy and Emission Reductions

Effective December 12, 2024, the following [covered HHS agency programs](#) that fund the purchase or construction of real property and major renovation projects must include reporting requirements in their NOFOs funding projects involving a federal interest in [tangible personal property](#) and [real property](#):

- [SF-428](#) (Tangible Personal Property suite of forms (cover page and Attachments)

- [SF-429](#) (Real Property Status Report suite of forms (cover page and Attachments))

For more guidance, go to the [Additional Guidance to Advance Climate Resilience and Reduce Energy and Emission](#).

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 awarding agency determines NEPA applies to an award, the NEPA process must be satisfactorily completed before drawdown of funds for the activity. Consult the awarding agency's [NEPA contact](#) for specific information on what must be addressed.

National Historic Preservation Act (NHPA)

If the recipient takes actions on real property that are not in compliance with historic preservation requirements, the awarding agency may have a basis to take an enforcement action and recoup some or all its funding.

Please see [EO 13287, "Preserve America"](#).

For questions on NHPA, contact [Real Estate 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 awarding 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 .

Activity	Guidance
<p>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).</p> <p>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.</p>	<p>If the answer is "yes," then continue with the process.</p> <p>If the answer is "no," and the SHPO or THPO agrees, then the process may stop.</p>
<p>4. Determine if the undertaking will result in any adverse effects on an historic property.</p>	<p>If the answer is "yes," then continue with the process.</p> <p>If the answer is "no," and the SHPO or THPO agrees, then the process may stop.</p>
<p>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.</p>	<p>If the parties sign an MOA, the awarding agency must ensure that the undertaking is carried out in accordance with the MOA.</p> <p>If the parties cannot agree and do not execute an MOA, then proceed to Activity 6.</p>
<p>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.</p>	<p>If there is a failure to reach resolution, the awarding agency head may decide to approve proceeding with the undertaking after following the applicable requirements of 36 CFR part 800.</p>

Research Awards

Human Subjects in Research

The regulations for the protection of human subjects in [45 CFR part 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 part 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 part 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 awarding 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 awarding 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 or matching 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.

Research Involving Animals and Their Welfare

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 awarding 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 awarding agency will notify the PO and the applicant and the awarding 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 matching or 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 awarding agency may not approve a post-award change that will result in research involving animals unless the awarding 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.

Research Involving Potential Procurement of Synthetic DNA and RNA

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.