U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

General Terms and Conditions for Research Grants and Cooperative Agreements

Incorporation: The U.S. Department of Health and Human Services (HHS) grant recipients must comply with: all terms and conditions outlined in the Notice of Funding Opportunity (NOFO); their Notice of Award (NOA); grants policy contained in applicable HHS Grants Policy Statements; HHS grant administration regulations (e.g., 45 CFR Part 75, 2 CFR 200 (as applicable)); requirements imposed by program statutes and regulations; applicable Executive Orders; HHS Administrative and National Policy Requirements; HHS policies, directives, and guidance; and requirements or limitations in any applicable appropriations acts. The term grant is used throughout these general terms and conditions of award and includes cooperative agreements.

Note: In the event that any requirement in the NOA, the NOFO, the HHS Grants Policy Statement, 45 CFR Part 75, or applicable statutes/appropriations acts conflict, then statutes and regulations take precedence.

Applicability of 2 CFR 200 Provisions Beginning October 1, 2024

This award is subject to the requirements in 45 CFR Part 75, except as amended by the following provisions of 2 CFR Part 200, which apply to new, continuation, and supplemental awards made on or after October 1, 2024.

- 2 CFR § 200.1. Definitions, "*Modified Total Direct Cost*", "*Equipment*", and "*Supplies*"
- 2 CFR § 200.313(e). Equipment, *Disposition*
- 2 CFR § 200.314(a). Supplies
- 2 CFR § 200.320. Procurement methods
- 2 CFR § 200.333. Fixed amount subawards
- 2 CFR § 200.344. Closeout
- 2 CFR § 200.414(f). Indirect costs, *De Minimis Rate*
- 2 CFR § 200.501. Audit requirements

2 CFR 200 citation	**Replaces 45 CFR 75 citation**
2 CFR § 200.1. Definitions, *"Modified Total Direct Cost"*	45 CFR § 75.2. Definitions, *"Modified Total Direct Cost"*
2 CFR § 200.1. Definitions, *"Equipment"*	45 CFR § 75.2. Definitions, *"Equipment"*
2 CFR § 200.1. Definitions, *"Supplies"*	45 CFR § 75.2. Definitions, *"Supplies"*
2 CFR § 200.313(e). Equipment, *Disposition*	45 CFR § 75.320(e). Equipment, *Disposition*
2 CFR § 200.314(a). Supplies	45 CFR § 75.321(a). Supplies

2 CFR § 200.320. Procurement methods	45 CFR § 75.329. Procurement procedures
2 CFR § 200.333. Fixed amount subawards	45 CFR § 75.353. Fixed amount subawards
2 CFR § 200.344. Closeout	45 CFR § 75.381. Closeout
2 CFR § 200.414(f). Indirect costs, *De Minimis Rate*	45 CFR § 75.414(f). Indirect (F&A) costs, *De Minimis Rate*
2 CFR § 200.501. Audit requirements	45 CFR § 75.501. Audit requirements

FEDERAL REGULATIONS AND POLICIES

2 CFR 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Referenced where indicated and applicable.
https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200?toc=1

45 CFR Part 75 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. https://www.ecfr.gov/cgi-bin/text- idx?node=pt45.1.75&rgn=div5

HHS Administrative and National Policy Requirements
https://www.hhs.gov/sites/default/files/hhs-administrative-national-policy-requirements.pdf

HHS Grants Policy and Regulations. https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html

HHS Grants Policy Statement (effective for new, continuation, and supplemental awards made on or after October 1, 2024)
https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-october-2024.pdf

HHS Grants Policy Statement (January 2007 version applies to awards issued before October 1, 2024)
https://public3.pagefreezer.com/browse/HHS.gov/27-09-2024T06:59/https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf

Federal Funding Accountability and Transparency Act (FFATA). https://sam.gov/fsrs.
Refer to the section below on Reporting Requirements for more details.

Trafficking In Persons: Consistent with 2 CFR 175, awards are subject to the requirements of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. Part 7104(g)).
https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-175

FUNDING RESTRICTIONS AND LIMITATIONS

Human Subjects: Under governing regulations, federal funds administered by the Department of Health and Human Services shall not be expended for research involving human subjects, and individuals shall not be enrolled in such research, without prior approval by the Office for Human Research Protection (OHRP) of an assurance to comply with the requirements of 45 CFR Part 46 to protect human research subjects. Whenever an institution receives funding from an HHS agency to support such research, the awardee institution bears the ultimate responsibility for

protecting human subjects under the award. Compliance for all performance sites must be ensured by the awardee.

All recipients of CDC grants and cooperative agreements and their performance sites engaged in research involving human subjects must obtain 1) a Federal wide Assurance (FWA) of Protection for Human Subjects from OHRP and 2) initial and continuing approval of the research by an appropriately constituted and registered institutional review board (IRB). For instructions on registering IRBs and obtaining FWAs, see the OHRP website at: https://www.hhs.gov/ohrp.

Cost Limitations as Stated in Appropriations Acts. Recipients must follow the fiscal year appropriations law in effect at the time of award and consistent with the specific funds provided under that award. The general provisions for grants, cooperative agreements and loans funded by the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act is available at: https://www.congress.gov/resources/display/content/Appropriations+and+Budget.

Though Recipients are required to comply with all applicable appropriations restrictions, please find below specific ones of note. CDC notes that the cited section for each below provision may change annually.

A. Cap on Salaries (Division H, Title II, General Provisions, Sec. 202): None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.

   Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS award or order; it merely limits the portion of that salary that may be paid with federal funds. The HHS Grants Policy Statement further explains the application of this salary rate limitation.

B. Gun Control Prohibition (Div. H, Title II, Sec. 210): None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.

C. Lobbying Restrictions (Div. H, Title V, Sec. 503):

   - 503(a): No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive- legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government itself.

   - 503(b): No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient,

related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

- 503(c): The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale of marketing, including but not limited to the advocacy or promotion of gun control.

For additional information, see Anti-Lobbying Restrictions for CDC Grantees https://www.cdc.gov/grants/documents/Anti-Lobbying-Restrictions.pdf.

D. Blocking access to pornography (Div. H, Title V, Sec. 520): (a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography; (b) Nothing in subsection (a) shall limit the use of funds necessary for any federal, state, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

E. Needle Exchange (Div. H, Title V, Sec. 526): Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

Prohibition on certain telecommunications and video surveillance services or equipment (2 CFR 200.216): For all new, non-competing continuation, renewal or supplemental awards issued on or after August 13, 2020, recipients and subrecipients are prohibited from obligating or expending grant funds (to include direct and indirect expenditures as well as cost share and program funds) to:

1. Procure or obtain,
2. Extend or renew a contract to procure or obtain; or
3. Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in 2 CFR 200.216, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
    i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

ii. Telecommunications or video surveillance services provided by such entities or using such equipment.
iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

President's Emergency Plan for AIDS Relief (PEPFAR) funding is exempt from the prohibition under 2 CFR 200.216 until September 30, 2028. During the exemption period, PEPFAR recipients are expected to work toward implementation of 2 CFR 200.216. The exemption may only be applied when there is no available alternative eligible source for these services.

Certificate of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document but are issued by application of this term and condition to the award. See additional information on requirements at: https://www.cdc.gov/grants/additional-requirements/ar- 36.html.

Dual Use Research of Concern: In 2024, the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential ("the Policy") was released to address oversight of research on biological agents and toxins that, when enhanced, have the potential to pose risks to public health, agriculture, food security, economic security, or national security. The policy applies to recipients in the United States who receive Federal funding for life sciences research and who conduct or sponsor research involving any of the listed pathogens or toxins listed in the policy. This policy also applies to foreign recipients who receive Federal funding to conduct or sponsor research involving any of the listed pathogens or toxins. Research funded by CDC involving these agents or toxins must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC or creates PEPP. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution. Many institutions task their Institutional Biosecurity or Biosafety Boards or Committees with this responsibility. See additional information on requirements at: https://www.cdc.gov/grants/additional-requirements/ar-33.html.

Cancel Year: 31 U.S.C. Part 1552(a) Procedure for Appropriation Accounts Available for Definite Periods states the following: On September 30th of the 5th fiscal year after the period of availability for obligation of a fixed appropriation account ends, the account shall be closed and any remaining balances (whether obligated or unobligated) in the account shall be canceled and thereafter shall not be available for obligation or expenditure for any purpose.

Awards that Involve Procurement of Synthetic Nucleic Acids for Benchtop Synthesizers: Beginning April 26, 2025, HHS funds may only be used to procure synthetic nucleic acids or benchtop nucleic acid synthesis equipment from sources adhering to the Office of Science and Technology Policy Framework for Nucleic Acid Synthesis Screening. HHS awardees are expected to adhere to the Office of Science and Technology Policy Framework for Nucleic Acid Synthesis Screening for HHS projects.

REPORTING REQUIREMENTS

Annual Federal Financial Report (FFR, SF-425): The Annual Federal Financial Report (FFR) SF-425 is required and must be submitted no later than 90 days after the end of the budget period in the Payment Management System.

Additional guidance on submission of Federal Financial Reports can be found at https://www.cdc.gov/grants/documents/change-in-federal-reporting-fy-2021-recipients.pdf.

If more frequent reporting is required, the Notice of Award terms and conditions will explicitly state the reporting requirement.

Annual Performance Reporting: The Research Performance Progress Report (RPPR) serves as the annual performance report and is due no later than (NLT) 120 days prior to the end of the budget period, or the date identified in the guidance distributed by the GMS/GMO. This report also serves as the continuation application.

The RPPR is completed using the NIH eRA Commons system. Refer to the "NIH and Other PHS Agency RPPR Instruction Guide" at https://grants.nih.gov/grants/rppr/index.htm for detailed instructions on completing the report. There are no forms available for download, however instructions on submitting RPPR information are available in the NIH RPPR Instruction Guide. Recipients can find further information on the RPPR at: https://grants.nih.gov/grants/rppr/index.htm.

Recipients must also submit a final RPPR for closeout purposes.

Data Collection and Sharing Under Award: Consistent with strategies and activities expected and anticipated under this award, Recipient, either directly or indirectly, may be expected to collect or generate data for public health purposes. For purposes of this award, data for public health purposes may be administrative data or data commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation, but does not include preliminary analyses, drafts of scientific papers, plans for future research communications with colleagues, or physical objects, such as laboratory notebooks or laboratory specimens unless otherwise specified in the award.

45 C.F.R. 75.322(d) states that the federal government has the right to: 1) obtain, reproduce, publish, or otherwise use the data produced under a federal award; and 2) authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes. In furtherance of various United States Government-wide initiatives and policies, the federal government seeks to make federally funded publications and data underlying them more readily available, and to make public health data more readily accessible within the federal government and to the public.

Consistent with grant regulations, CDC may legally obtain a copy of any data collected or generated under this award. Where CDC has determined that data collected or generated under this award must be shared with CDC, such direction will be further addressed in your Notice of Funding Opportunity, your Notice of Grant Award, or other specific grant guidance. Acceptance of funds under this award is an acknowledgement of this regulatory provision and its application to this award.

Data Management Plan: CDC requires recipients for projects that involve the collection or generation of data with federal funds to develop, submit, and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award. The DMP should take into consideration sharing data with CDC including: 1) the specific data that will be shared under the award, 2) the process and timing planned for such sharing, 3) and any legal limitations that the Recipient asserts would hinder CDC access to, or use of, the data collected or generated under the award. In addition, the DMP should address broader access to and archiving/long-term preservation of collected or generated data. Additional information on the Data Management and Access requirements can be found at https://www.cdc.gov/grants/additional-requirements/ar- 25.html.

Audit Requirement Domestic Organizations *(including US-based organizations implementing projects with foreign components)*: An organization that expends $1,000,000 or more in a fiscal year in federal awards shall have a single or program-specific audit conducted for that year in accordance with the provisions of 2 CFR 200.501. The audit period is an organization's fiscal year. The audit must be completed along with a data collection form (SF-SAC), and the reporting package shall be submitted within the earlier of 30 days after receipt of the auditor's report(s), or nine (9) months after the end of the audit period. The audit report must be sent to:

Federal Audit Clearing House Internet Data Entry System Electronic Submission:
https://harvester.census.gov/facides/(S(0vkw1zaelyzjibnahocga5i0))/account/login.aspx

AND

Office of Financial Resources, Office of Risk Management and Internal Controls, Audit Resolution Team (ART), ORMIC.Audit.Resolution@cdc.gov.

Audit Requirement Foreign Organizations: A foreign organization that expends $300,000 or more in a fiscal year on its federal awards must have a single or program-specific audit conducted for that year. The audit period is an organization's fiscal year. The auditor shall be a U.S.-based Certified Public Accountant firm, the foreign government's Supreme Audit Institution or equivalent, or an audit firm endorsed by the U.S. Agency for International Development's Office of Inspector General. The audit must be completed in English and in US dollars, and submitted within the earlier of 30 days after receipt of the auditor's report(s), or nine (9) months after the end of the audit period. The audit report must be sent to the Office of Financial Resources, Office of Risk Management and Internal Controls, Audit Resolution Team (ART) at ORMIC.Audit.Resolution@cdc.gov. After receipt of the audit report, CDC will resolve findings by issuing Final Management Determination Letters.

Domestic and Foreign organizations: Audit requirements for Subrecipients to whom 45 CFR 75 Subpart F applies: The recipient must ensure that the subrecipients receiving CDC funds also meet

these requirements. The recipient must also ensure to take appropriate corrective action within six months after receipt of the subrecipient audit report in instances of non- compliance with applicable federal law and regulations (45 CFR 75 Subpart F and HHS Grants Policy Statement). The recipient may consider whether subrecipient audits necessitate adjustment of the recipient's own accounting records. If a subrecipient is not required to have a program-specific audit, the recipient is still required to perform adequate monitoring of subrecipient activities. The recipient shall require each subrecipient to permit the independent auditor access to the subrecipient's records and financial statements. The recipient must include this requirement in all subrecipient contracts.

Federal Funding Accountability and Transparency Act (FFATA)
In accordance with 2 CFR Chapter 1, Part 170 Reporting Sub-Award and Executive Compensation Information, Prime Recipients awarded a federal grant are required to file a FFATA sub-award report by the end of the month following the month in which the prime recipient awards any sub-grant equal to or greater than $30,000. Refer to 2 CFR Chapter 1, Part 170 Reporting Sub-Award and Executive Compensation Information at eCFR :: 2 CFR Part 170 -- Reporting Subaward and Executive Compensation Information and https://sam.gov/fsrs for reporting requirements and guidance.

Unique Entity Identifier (UEI)
The UEI is the official identifier for doing business with the U.S. Government as of April 4, 2022. The UEI is generated and assigned by the System for Award Management at SAM.gov. In accordance with 2 CFR part 25, Appendix A, a recipient must maintain current information in SAM.gov, through at least annual review, until it submits the final required financial report or receives the final payment, whichever is later.

Required Disclosures for Responsibility and Qualification (R/Q) (SAM.gov): Consistent with 45 CFR 75.113, applicants and recipients must disclose in a timely manner, in writing to the CDC, with a copy to the HHS Office of Inspector General (OIG), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Subrecipients must disclose, in a timely manner in writing to the prime recipient (pass through entity) and the HHS OIG, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the assigned GMS/GMO identified in the NOA, and to the HHS OIG by email at grantdisclosures@oig.hhs.gov or by mail to the following address:

U.S. Department of Health and Human Services
Office of the Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW
Cohen Building, Room 527
Washington, DC 20201

Recipients must include this mandatory disclosure requirement in all subawards and contracts under this award.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371. Remedies for noncompliance include suspension or debarment (See 2 CFR parts 180 and 376, and

31 U.S.C. 3321).

CDC is required to report any termination of a federal award prior to the end of the period of performance due to material failure to comply with the terms and conditions of this award in the OMB-designated Responsibilities and Qualifications (R/Q) accessible through SAM (45 CFR 75.372(b)). CDC must also notify the recipient if the federal award is terminated for failure to comply with the federal statutes, regulations, or terms and conditions of the federal award (45 CFR 75.373(b)).

1. *General Reporting Requirement*

   If the total value of currently active grants, cooperative agreements, and procurement contracts from all federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this federal award, the recipient must maintain the currency of information reported to the System for Award Management (SAM) and made available in the designated integrity and performance system (currently the Responsibility/Qualification (R/Q) through SAM.gov) about civil, criminal, or administrative proceedings described in section 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C.2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for federal procurement contracts, will be publicly available.

2. *Proceedings About Which You Must Report*

   Submit the information required about each proceeding that:

   a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the federal government;

   b. Reached its final disposition during the most recent five-year period; and

   c. If one of the following:

      (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

      (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more;

      (3) An administrative proceeding, as defined in paragraph 5 of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of $5,000 or more or reimbursement, restitution, or damages in excess of $100,000; or

      (4) Any other criminal, civil, or administrative proceeding if:

         (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;

         (ii) It had a different disposition arrived at by consent or compromise with an acknowledgement of fault on your part; and

         (iii) The requirement in this award term and condition to disclose information

about the proceeding does not conflict with applicable laws and regulations.

3. *Reporting Procedures*

   Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in section 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under federal procurement contracts that you were awarded.

4. *Reporting Frequency*

   During any period of time when you are subject to this requirement in section 1 of this award term and condition, you must report proceedings information through SAM for the most recent five year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. *Definitions*

   For purposes of this award term and condition:

   a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the federal and State level but only in connection with performance of a federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

   b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.

   c. Total value of currently active grants, cooperative agreements, and procurement contracts includes—

      (1) Only the federal share of the funding under any federal award with a recipient cost share or match;

      (2) The value of all expected funding increments under a federal award and options, even if not yet exercised.

GENERAL REQUIREMENTS

You will administer your project in compliance with the HHS Administrative and National Policy Requirements found at https://www.hhs.gov/sites/default/files/hhs-administrative-national-policy-requirements.pdf.

Termination (45 CFR Part 75.372) applies to this award and states, in part, the following:

(a) This award may be terminated in whole or in part:

(1) By the HHS awarding agency or pass-through entity, if a non-Federal entity fails to comply with the terms and conditions of a Federal award;

(2) By the HHS awarding agency or pass-through entity for cause;

(3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated;

(4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the Federal awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

Travel Cost: In accordance with HHS Grants Policy Statement, travel costs are allowable when the travel will provide a direct benefit to the project or program. To prevent disallowance of cost, the recipient is responsible for ensuring travel costs are clearly stated in their budget narrative and are applied in accordance with their organization's established travel policies and procedures. The recipient's established travel policies and procedures must also meet the requirements of 45 CFR Part 75.474.

Food and Meals: Costs associated with food or meals are allowable when consistent with applicable federal regulations and HHS policies. See https://www.hhs.gov/grants/contracts/contract-policies-regulations/spending-on-food/index.html. In addition, costs must be clearly stated in the budget narrative and be consistent with organization approved policies. Recipients must make a determination of reasonableness and organization approved policies must meet the requirements of 45 CFR Part 75.432.

Prior Approval: All requests, which require prior approval, must bear the signature (or electronic authorization) of the authorized organization representative. The recipient should submit these requests no later than 120 days prior to the budget period's end date to ensure ample time remains to process and carry-out the request. Additionally, any requests involving funding issues must include an itemized budget and a narrative justification of the request.

The following types of requests are examples of actions that require prior approval, unless an expanded authority, or conversely a high-risk condition, is explicitly indicated in the NOA.

- Use of unobligated funds from prior budget period (Carryover)
- Lift funding restriction
- Significant redirection of funds (i.e., cumulative changes of 25% of total award)

- Change in scope
- Implement a new activity or enter into a sub-award that is not specified in the approved budget
- Apply for supplemental funds
- Extensions to period of performance

Templates for prior approval requests can be found at: https://www.cdc.gov/grants/already-have-grant/prior-approval-requests.html.

Recipient Contractual/Consultant Cost Agreements: In accordance with 45 CFR 75.333, all supporting documentation related to the contractual/consultant elements outlined in the Budget Preparation Guidelines must be maintained by the recipient and available upon request. Recipients may submit supporting documentation via email to the assigned Grants Management Specialist (GMS) and Scientific Project Officer/Project Officer (SPO/PO).

Key Personnel: In accordance with 45 CFR Part 75.308, CDC recipients must obtain prior approval from CDC for (1) change in the project director/principal investigator, authorized organizational representative, business official or financial director, or other key persons specified in the NOFO, application or award document; and (2) the disengagement from the project for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

Inventions: Acceptance of grant funds obligates recipients to comply with the standard patent rights clause in 37 CFR Part 401.14. Invention reporting responsibilities also are summarized in the HHS Grants Policy Statement, *Exhibit 9. Extramural Invention Reporting Compliance Responsibilities*. CDC requires invention reporting electronically through iEdison, which is available at https://www.nist.gov/iedison.

In addition to complying with Bayh-Dole-related regulations (37 CFR Part 401), each continuation annual performance report for CDC awards must indicate whether or not any subject inventions were made during the preceding budget period.

Information on submitting the Final Invention Statement is located below in the *Closeout Requirements* section of these terms and conditions.

Acknowledgment of Federal Funding: When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as tool-kits, 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:

1. the percentage and dollar amount of the total costs of the program or project funded with federal money; and,
2. 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 Centers for Disease Control and Prevention 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 CDC/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government.

The HHS Grant or Cooperative Agreement IS partially funded with other non-governmental sources:

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The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement.

Any amendments by the recipient to the acknowledgement statement must be coordinated with the HHS Awarding Agency.

If the recipient plans to issue a press release concerning the outcome of activities supported by HHS financial assistance, it should notify the HHS Awarding Agency in advance to allow for coordination.

Copyright Interests Provision: This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available without any embargo or delay after publication. Also, at the time of submission, Recipient and/or the Recipient's submitting author must post the manuscript through PubMed Central (PMC) without any embargo or delay after publication. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements

concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Disclaimer for Conference/Meeting/Seminar Materials: If a conference/meeting/seminar is funded by a grant, cooperative agreement, sub-grant and/or a contract, the recipient must include the following statement on conference materials, including promotional materials, agenda, and internet sites:

> Funding for this conference was made possible (in part) by the Centers for Disease Control and Prevention. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

Logo Use for Conference and Other Materials: Neither the Department of Health and Human Services (HHS) nor the CDC logo may be displayed if such display would cause confusion as to the funding source or give false appearance of Government endorsement. Use of the HHS name or logo is governed by U.S.C. Part 1320b-10, which prohibits misuse of the HHS name and emblem in written communication. As a general matter, a non-federal entity is not authorized to use the HHS name or logo. Moreover, the HHS Office of the Inspector General has authority to impose civil monetary penalties for violations (42 CFR Part 1003). The appropriate use of the HHS logo is subject to review and approval of the HHS Assistant Secretary for Public Affairs (ASPA), and if granted would be governed by a logo license agreement setting forth the terms and conditions of use.

Additionally, the CDC logo cannot be used by the recipient without the express, written consent of CDC, generally in the form of a logo license agreement setting forth the terms and conditions of use. The Program Official/Project Officer identified in the NOA can assist with facilitating such a request. It is the responsibility of the recipient to request consent for use of the logo in sufficient detail to ensure a complete depiction and disclosure of all uses of the Government logos. In all cases for utilization of Government logos, the recipient must ensure written consent is received.

Equipment and Products: To the greatest extent practical, all equipment and products purchased with CDC funds should be American made. CDC defines equipment as tangible non- expendable personal property (including exempt property) charged directly to an award having a useful life of more than one year AND an acquisition cost of $10,000 or more per unit. However, consistent with recipient policy, a lower threshold may be established. Please provide the information to the Grants Management Officer to establish a lower equipment threshold to reflect your organization's policy.

The recipient may use its own property management standards and procedures, provided it observes provisions in applicable grant regulations found at 45 CFR Part 75.

Federal Information Security Management Act (FISMA): All information systems, electronic or hard copy, that contain federal data must be protected from unauthorized access. This standard also applies to information associated with CDC grants. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the federal Information Security Management Act (FISMA), Title III of the E-Government Act of 2002, PL 107-347.

FISMA applies to CDC recipients only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. Under FISMA, the recipient retains the original data and intellectual property, and is responsible for the security of these data, subject to all applicable laws protecting security, privacy, and research. If/When information collected by a recipient is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information, and any derivative copies as required by FISMA. For the full text of the requirements under Federal Information Security Management Act (FISMA), Title III of the E-Government Act of 2002 Pub. L. No. 107-347, please review the following website: https://www.gpo.gov/fdsys/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf.

Whistleblower Protections: As a recipient of this award you must comply with the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 (Pub. L. 112-239, 41 U.S.C. § 4712) "Enhancement of contractor protection from reprisal for disclosure of certain information," and 48 CFR part 3 subpart 3.9, "Whistleblower Protections for Contractor Employees." For more information see: https://oig.hhs.gov/fraud/whistleblower/.

Public Health Service Policies on Research Misconduct: CDC-funded projects must comply with 42 CFR Part 93, PHS Policies on Research Misconduct, Subpart C, "Responsibilities of Institutions." 42 CFR Part 93, Subpart C specifies recipient responsibilities to have written policies and procedures for addressing allegations of research misconduct, to file and maintain an Assurance of Compliance with the HHS Office of Research Integrity (https://ori.hhs.gov/) and take all reasonable and practical steps to foster research integrity.

Inclusion of Persons Under the Age of 21 in Research: It is CDC's policy that persons under the age of 21 must be included in all human subjects research that is conducted or supported by CDC, unless there are scientific and ethical reasons not to include them. This policy applies to all CDC-conducted or CDC-supported research involving human subjects, including research that is otherwise exempt in accordance with Sections 101(b) and 401(b) of 45 C.F.R. Part 46, HHS Policy for the Protection of Human Subjects. Therefore, proposals for research involving human subjects must include a description of plans for including persons under the age of 21. If persons under the age of 21 will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion. Additional information is available at https://www.cdc.gov/grants/additional-requirements/ar-28.html.

Cybersecurity Requirements: Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS and CDC systems and data, if the following

conditions are met: 1) recipients, subrecipients, or third-party entities have ongoing and consistent access to HHS owned or operated information or operational technology systems and 2) recipients, subrecipients, or third-party entities receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award. Where both conditions exist, recipients must develop cybersecurity plans and procedures modeled after the NIST Cybersecurity framework (https://www.nist.gov/cyberframework) to protect HHS systems and data.

PAYMENT INFORMATION

Fraud Waste or Abuse: The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [1-800-447-8477]) for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Information also may be submitted online at https://tips.oig.hhs.gov/ or by mail to U.S. Department of Health and Human Services, Office of the Inspector General, Attn: OIG HOTLINE OPERATIONS, P.O. Box 23489 Washington DC 20026. Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous. For additional information, see: https://oig.hhs.gov/fraud/report-fraud/.

Automatic Drawdown (Direct/Advance Payments): Payments under CDC awards will be made available through the Department of Health and Human Services (HHS) Payment Management System (PMS), under automatic drawdown, unless specified otherwise in the NOA. Recipients must comply with requirements imposed by the PMS on-line system. Questions concerning award payments or audit inquiries should be directed to the payment management services office.

PMS Website: https://pms.psc.gov/
PMS Phone Support: +1(877)614-5533
PMS Email Support: PMSSupport@psc.gov

Payment Management System Subaccount: Funds awarded in support of approved activities will be obligated in an established subaccount in the PMS. Funds must be used in support of approved activities in the NOFO and the approved application. All award funds must be tracked and reported separately.

Exchange Rate: All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will not generally compensate foreign recipients for currency exchange fluctuations through the issuance of supplemental awards.

Acceptance of the Terms of an Award: By drawing or otherwise obtaining funds from PMS, the recipient acknowledges acceptance of the terms and conditions of the award and is obligated to perform in accordance with the requirements of the award. If the recipient cannot accept the terms, the recipient should notify the Grants Management Officer within thirty (30) days of receipt of the NOA.

Certification Statement: By drawing down funds, the recipient certifies that proper financial management controls and accounting systems, to include personnel policies and procedures, have been established to adequately administer federal awards and funds drawn down.

Recipients must comply with all terms and conditions in the NOFO, outlined in their NOA, grant policy terms and conditions contained in applicable HHS Grant Policy Statements, and requirements imposed by program statutes and regulations and HHS grants administration regulations, as applicable; as well as any regulations or limitations in any applicable appropriations acts.

CLOSEOUT REQUIREMENTS

In accordance with 2 CFR 200.344, recipients must submit all closeout reports identified in this section within 120 days of the period of performance end date. The reporting timeframe is the full period of performance. If the recipient does not submit all reports in accordance with this section and the terms and conditions of the Federal Award, CDC may proceed to close out with the information available within one year of the period of performance end date unless otherwise directed by authorizing statutes. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI). If recipients do not submit all closeout reports identified in this section within one year of the period of performance end date, then CDC must report recipients' material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system (currently Responsibility/Qualification section of SAM.gov). CDC may also pursue other enforcement actions per 45 CFR 75.371.

All manuscripts published as a result of the work supported in part or whole by the grant must be submitted with the progress reports.

The final reports required are the following:

Final Research Performance Progress Report: The Final RPPR is completed using the NIH eRA Commons system. Refer to the "NIH and Other PHS Agency RPPR Instruction Guide" at https://grants.nih.gov/grants/rppr/index.htm for detailed instructions on completing the report. There are no forms available for download, however instructions on submitting the Final RPPR information are available in the NIH RPPR Instruction Guide.

Recipients can find further information on the RPPR at: https://grants.nih.gov/grants/rppr/index.htm.

Final Federal Financial Report (FFR, SF-425): The FFR should only include those funds authorized and expended during the timeframe covered by the report. The Final FFR, SF-425 is required and must be submitted no later than 120 days after the period of performance end date through recipient online accounts in the Payment Management System. The final FFR will consolidate data reporting responsibilities to one entry point within PMS which will assist with the reconciliation of expenditures and disbursements to support the timely close-out of grants.

The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. Remaining unobligated funds will be de-obligated and returned to the U.S. Treasury.

Every recipient should already have a PMS account to allow access to complete the SF-425.

Additional guidance on submission of Federal Financial Reports can be found at https://www.cdc.gov/grants/documents/change-in-federal-reporting-fy-2021-recipients.pdf.

Equipment and Supplies - Tangible Personal Property Report (SF-428): A completed Tangible Personal Property Report SF-428 and Final Report SF-428B addendum must be submitted, along with any Supplemental Sheet SF-428S detailing all major equipment acquired or furnished under this project with a unit acquisition cost of $10,000 or more. Electronic versions of the forms can be downloaded by visiting: https://www.grants.gov/forms/forms-repository/post-award-reporting-forms.

If no equipment was acquired under an award, a negative report is required.

The recipient must identify each item of equipment that it wishes to retain for continued use in accordance with 45 CFR Part 75. The awarding agency may exercise its rights to require the transfer of equipment purchased under the assistance award. CDC will notify the recipient if transfer to title will be required and provide disposition instruction on all major equipment.

Equipment with a unit acquisition cost of less than $10,000 that is no longer to be used in projects or programs currently or previously sponsored by the federal government may be retained, sold, or otherwise disposed of, with no further obligation to the federal government (see 2 CFR 200.313(e)(1)).

Final Invention Statement: A Final Invention Statement must be submitted. Electronic versions of the form can be downloaded by visiting https://grants1.nih.gov/grants/hhs568.pdf.

If no inventions were conceived under an assistance award, a negative report is required. This statement may be included in a cover letter.

CDC STAFF RESPONSIBILITIES

Roles and Responsibilities: Grants Management Specialists/Officers (GMO/GMS) and Program Officials (PO) work together to award and manage CDC grants and cooperative agreements. From the pre-planning stage to closeout of an award, grants management and program staff have specific roles and responsibilities for each phase of the grant cycle.

Scientific Program Official: The SPO is the federal official responsible for the normal scientific and programmatic stewardship of grants and cooperative agreements including:

- Being named as the Scientific Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award;
- Collaborating, as appropriate, with the recipient in all stages of the program, and providing post-award scientific review and administrative guidance;
- Monitoring performance against approved project objectives;
- Making recommendations on requests for changes in scope, objectives, and/or budgets that deviate from the approved peer-reviewed application;

- Assessing the public health impact of the research conducted under this funding opportunity announcement and promoting translation of promising practices, programs, interventions, and other results from the research; and
- Serving as the primary point of contact on official award-related activities, including an annual review of the grantee's performance as part of the request for continuation application.

For Cooperative Agreements, substantial involvement is required from CDC. The SPO is the federal official responsible for the collaboration or participation in carrying out the effort under the award. Substantial involvement may include, but is not limited to:

- Review and approval of one stage of work before work can begin on a subsequent stage;
- Review and approval of substantive programmatic provisions of proposed subawards or contracts (beyond existing federal review of procurement or sole source policies);
- Involvement in the selection of key relevant personnel;
- CDC and recipient collaboration or joint participation; and
- Implementing highly prescriptive requirements prior to award limiting recipient discretion with respect to scope of services, organizational structure, staffing, mode of operation, and other management processes.

Grants Management Officer: The GMO is the only official authorized to obligate federal funds and is responsible for signing the NOA, including revisions to the NOA that change the terms and conditions. The GMO serves as the counterpart to the business officer of the recipient organization. The GMO is the federal official responsible for the business and other non-programmatic aspects of grant awards including:

- Determining the appropriate award instrument, i.e., grant or cooperative agreement;
- Determining if an application meets the requirements of the NOFO;
- Ensuring objective reviews are conducted in an above-the-board manner and according to guidelines set forth in grants policy;
- Ensuring recipient compliance with applicable laws, regulations, and policies;
- Negotiating awards, including budgets;
- Responding to recipient inquiries regarding the business and administrative aspects of an award;
- Providing recipients with guidance on the closeout process and administering the closeout of grants;
- Receiving and processing reports and prior approval requests such as changes in funding, budget redirection, or changes to the terms and conditions of an award; and
- Maintaining the official grant file and program book.

Grants Management Specialist: The GMS is the federal staff member responsible for the day- to-day management of grants and cooperative agreements. The GMS is the primary contact of recipients for business and administrative matters pertinent to grant awards. Many of the functions described in the GMO section are performed by the GMS, on behalf of the GMO.