# SECTION I – AWARD DATA – X XXX AX XXXXXX-XX

Project Title: **[Project Title]**

Dear Authorized Organizational Representative:

The Advanced Research Projects Agency for Health (ARPA-H) hereby issues this award to **[FULL INSTITUTION NAME]** in support of the above-referenced project. This award is pursuant to the authority of 42 USC 290c, 42 USC 241, 31 USC 6305, and 42 CFR 52, and is subject to the requirements of these statutes and regulations, and of other referenced, incorporated, and attached terms and conditions.

By signing this award in Section III and returning it to the designated email address(es), the Recipient acknowledges acceptance of the terms and conditions and is obligated to perform in accordance with the requirements of the award. If the Recipient cannot accept the terms, the Recipient must notify the Grants Officer (GO) immediately upon receipt of this Notice of Award.

If you have any questions about this award, please direct questions to the GO or the agency’s contacts identified in Section III of this award.

Sincerely,

**[GO Name]**

Grants Officer

Advanced Research Projects Agency for Health (ARPA-H)

**SECTION I – AWARD DATA X XXX AX XXXXXX-XX**

1. **CUMULATIVE AWARD CALCULATIONS (U.S. Dollars).**

|  |  |
| --- | --- |
| Budget Item | Costs |
| 1. Salaries and Wages
 | $ |
| 1. Fringe Benefits
 | $ |
| 1. Personnel Costs (Subtotal of A+B)
 | $ |
| 1. Materials and Supply
 | $ |
| 1. Other
 | $ |
| 1. Subaward/Consortium/Contractual Costs
 | $ |

|  |
| --- |
| Totals |
| Total Direct Costs (Sum of 1-4) | $ |
| Total Indirect Costs (from Table below) | $ |
| Total Cost | $ |

|  |
| --- |
| Cost Share Information |
| Federal Share | $ |
| Non-Federal Share | $ |

|  |
| --- |
| Facilities and Administrative Costs |
| Indirect Cost Rate | % |
| Indirect Cost Base | $ |
| Indirect Costs | $ |

NOTE: See Section III for identification of this action’s financial obligation, financial obligations to-date, and award value changes.

1. **Fiscal Information for the Payment Management System (PMS).**

Payment System Identifier: **1XXXXXXXXXA1**

Obligating Document Number: **UXXXXXXXXXA**

PMS Account Type: P (Subaccount)

Fiscal Year: **20XX**

**SECTION II – STANDARD TERMS AND CONDITIONS** **X XXX AX XXXXXX-XX**

1. **AWARD.**
2. This Notice of Award (NOA) is based on the application submitted to and approved by ARPA-H with respect to the project identified herein, is subject to the terms and conditions herein, and incorporates the following either directly or by reference:
* The Grants legislation and program regulation cited in this NOA
* Conditions related to activities and the expenditure of funds in other statutory requirements such as those included in Appropriations Acts
* 2 CFR Part 200
* 2 CFR Part 300
* National policy requirements and all other requirements described in the Department of Health and Human Services (HHS) Grants Policy Statement (GPS) in effect at the time of the award (regardless of whether it’s a new award, a non-competing continuation, a competing continuation renewal, or a supplemental award), including addenda in effect as of the beginning date of the budget period. (The HHS GPS can be found at the following web link: <https://www.hhs.gov/grants-contracts/grants/grants-policies-regulations/index.html>)
1. The Recipient is legally and financially responsible for all aspects of this award, including:
* the performance of the project, program, or activity
* the appropriate expenditure of funds under the award by all parties, including funds provided to subrecipients, in accordance with 2 CFR §§200.331-332 and
* all other obligations of the Recipient as cited in this NOA

In general, the requirements that apply to the Recipient (including public policy requirements) also apply to its subrecipients, contractors, and subcontractors unless an exception is specified.

1. By drawing (or otherwise obtaining) funds from the payment system or office for this award, the Recipient accepts the award’s terms and conditions and agrees to perform in accordance with its requirements. The GO may adjust the award amount based on the total allowable costs incurred, the value of third-party in-kind contributions, or a Congressional rescission occurring after the award is issued.
2. **ORDER OF PRECEDENCE**. The order of precedence to be followed in the event this award includes conflicting (or otherwise inconsistent requirements) is, in order:
* United States Constitution
* Statutes
* Regulations
* Policies, Program Guidance, and Award-Specific Requirements
1. **ROLES AND RESPONSIBILITIES**.
2. Grants Officers (GOs) (or Grants Management Officers (GMOs) as defined at 1.7.2 of the GPS). Grants Officers are the officials who handle the non-program parts of an award for the agency. The GO is the focal point for receiving and acting on requests for prior approval and for making changes in the terms and conditions of an award. The GO is the only official authorized to obligate the agency to the expenditure of federal funds, and to make changes to the funding, duration, or other terms and conditions of an award. GOs are responsible for:

• Ensuring assigned activities conform to Departmental grants policies and regulatory requirements; and

• Providing input to the Chief Grants Management Officer (CGMO) on the HHS grants administration policies and regulations (and issues arising during administrative and financial monitoring activities) that may impact the Recipient’s ability to achieve performance goals.

A GO may have additional roles, including those related to collaboration with program officials and others in the development, implementation, and evaluation of program plans, strategies, regulations, announcements, guidelines, and procedures.

1. Program Official (PO). The PO serves as the primary interface between the GO and Recipient for programmatic, scientific, and technical issues of award programs, including oversight and monitoring. The PO consults with the GO concerning the interpretation of Grants policy guidance and seeks the GO’s review of Recipient-facing documents related to the management of awards. The PO contact information is found within the NOA.
2. Recipient(s) and Subrecipient(s).
3. A Recipient is the prime, non-federal entity (NFE) receiving a financial assistance award. It is responsible for receiving, expending, and accounting for all amounts paid under the funding agreement. The Recipient is authorized to act for the award Applicant and to assume the obligations imposed by the federal laws, regulations, requirements, and conditions that apply to financial assistance awards.
4. A subrecipient is an NFE that receives a subaward from a Recipient to carry out part of the scope of work or objectives of a federal award; this does not include the beneficiary of the federal award. When a Recipient passes dollars to a subrecipient for a federally assisted project, the Recipient is referred to as a pass-through entity.
5. Recipients and subrecipients must follow the award’s terms and conditions. In general, the Recipient must:

• Apply award terms and conditions to their sub-awards

• Evaluate the risk of sub-awards and implement specific conditions, if needed

• Monitor sub-award compliance

• Verify that their subrecipients meet audit requirements

• Remedy all instances of their non-compliance and that of their subrecipients, subcontractors, etc.

The Department’s Uniform Administrative Requirements also address subrecipient responsibilities (see 2 CFR §200.101(b), and §§200.331 to 333).

1. Authorized Recipient Representative (ARR) (or Authorized Organizational Representative as defined at section 1.7.1 of the GPS). The ARR is designated by the Applicant/Recipient and has the authority to act on behalf of the Applicant/Recipient with respect to matters related to the award. In signing a financial assistance application, the ARR guarantees that the information on the application is correct, and the organization is responsible for following all requirements.
2. Principal Investigator (PI)/Program or Project Director (PD).

(1) The PI/PD is designated by the Recipient to direct the project or program being supported by the award. The PI/PD is responsible and accountable to officials of the Recipient organization for the proper conduct of the project, program, or activity. As a member of the Recipient’s team, the PI/PD is also responsible for ensuring compliance with the financial and administrative aspects of the award and works closely with designated officials within the Recipient organization to:

• Create and maintain necessary documentation, including both technical and administrative reports

• Prepare justifications

• Appropriately acknowledge federal support in publications, announcements, news programs, and other media

• Ensure compliance with other federal and organizational requirements

The PI/PD is encouraged to maintain contact with the PO with respect to scientific, technical, and programmatic aspects of the project or program, and with the GO concerning the business and administrative aspects of the award.

(2) The PI/PD is generally an employee of the Recipient. However, because the award is made to the Recipient organization, if the PI/PD is not an employee of that organization, the organization must have a formal written agreement with the PI/PD that specifies an official relationship between the parties (even if the relationship does not involve a salary or other form of remuneration). If the PI/PD is not an employee of the Applicant’s organization, ARPA-H will assess whether the arrangement will result in the Applicant organization being able to fulfill its responsibilities under the award.

1. **ASSIGNMENT OF KEY PERSONNEL**. The Recipient shall not assign personnel who are suspended, debarred, or otherwise excluded or ineligible for federal assistance programs/activities to positions identified for Senior Personnel, Key Personnel, or Significant Contributors.
2. **SYSTEM FOR AWARD MANAGEMENT (SAM.GOV) AND UNIQUE ENTITY IDENTIFIER (UEI) REQUIREMENTS**
3. Requirement for System for Award Management. Unless exempt from this requirement under [2 CFR §25.110](https://www.ecfr.gov/current/title-2/section-25.110), the Recipient must maintain a current and active registration in *SAM.gov*. The Recipient's registration must always be current and active until the Recipient submits all final reports required under this federal award or receives the final payment, whichever is later. The Recipient must review and update its information in *SAM.gov* at least annually from the date of its initial registration or any subsequent updates to ensure it is current, accurate, and complete. If applicable, this includes identifying the Recipient's immediate and highest-level owner and subsidiaries and providing information about the Recipient's predecessors that have received a federal award or contract within the last three years.
4. Requirement for Unique Entity Identifier (UEI). If the Recipient is authorized to make subawards under this federal award, the Recipient:
5. Must notify potential subrecipients that no entity may receive a subaward until the entity has provided its UEI to the Recipient.
6. Must not make a subaward to an entity unless the entity has provided its UEI to the Recipient. Subrecipients are not required to complete full registration in SAM.gov to obtain a UEI.
7. Definitions. For the purposes of this award term:
8. *System for Award Management (SAM)* means the federal repository into which a Recipient must provide the information required for the conduct of business as a recipient. Additional information about registration procedures may be found in SAM.gov (currently at https.www.sam.gov).
9. *Unique Entity Identifier* means the universal identifier assigned at SAM.gov to uniquely identify an entity.
10. *Entity* is defined at 2 CFR §25.400 and includes the following types as defined in 2 CFR §200.1:
* Non-federal entity
* Foreign organization
* Foreign public entity
* For-profit organization; and
* Federal agency
1. *Subaward* has the meaning given in 2 CFR §200.1
2. *Subrecipient* has the meaning given in 2 CFR §200.1.
3. **Unique Entity Identifier (UEI) fOR FIRST TIER SUBRECIPIENTS.** As required by paragraph (b) of 2 CFR Part 25, Appendix A, the Recipient must ensure its first-tier subrecipients have a UEI and use it on all registrations, applications, etc. unless:
4. The entity is a foreign organization or a foreign public entity, and
5. This award or subaward will be performed outside the United States; and
6. The award or sub-award is less than $25K; and
7. The federal agency deems it to be impractical for the entity to comply with the requirements of this part

A Recipient may not make a subaward to a subrecipient that has not obtained a UEI and provided it to the Recipient. Subrecipients are not required to complete full registration at SAM.gov to obtain a UEI.

1. **TIMING OF FUNDING**. For most awards, ARPA-H uses the “period of performance” system of funding. Under this system, projects are programmatically approved for support in their entirety, but are funded in annual increments, called “budget periods.” The total period of performance consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. The agency may fund the project in its entirety at award, or at any time thereafter.
2. **Payment.** (See Section III, paragraph entitled, *Payments*)
3. **FAILURE TO DRAW DOWN FUNDS.** Not Used.
4. **FLY AMERICA ACT**. All entities are required by 49 USC 40118 (commonly referred to as the “*Fly America Act*”) to use U.S. flag air carrier service for all air travel funded by the U.S. government, except as provided in 41 CFR §301–10.136 and §301–10.137, or when one of the exceptions thereunder applies.
5. **HOTEL AND MOTEL FIRE SAFETY (SECTION 2225A OF 15 USC CHAPTER 49)**
6. No federal funds may be used to sponsor or fund (in whole or in part) any meeting, convention, conference, or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that does not meet the requirements of the fire prevention and control guidelines described in section 2225 of 15 USC Chapter 49.
7. Waiver.
8. General. The head of an agency that is sponsoring or funding a particular meeting, convention, conference, or training seminar may waive the prohibition described in paragraph (a) if the head of such agency determines that a waiver of such prohibition is necessary in the public interest for the particular event.
9. Delegation of Authority. The head of an agency may delegate the authority provided under paragraph (b)(1) to waive the prohibition described in paragraph (a) and to determine whether such a waiver is necessary in the public interest to an officer or employee of the agency if such officer or employee is given such authority with respect to all meetings, conventions, conferences, and training seminars sponsored or funded by the Agency.
10. Notice Requirements.
11. Advertisements and Applications.
12. Any advertisement for, or application for, attendance at a meeting, convention, conference, or training seminar sponsored or funded in whole or in part by the federal government shall include a notice regarding the prohibition described in paragraph (a).
13. The requirement described in subparagraph (c)(1)(A) shall not apply in the case of an event for which a head of an agency of the federal government, pursuant to paragraph (b), waives the prohibition described in paragraph (a).
14. Providing Notice to Recipients of Funds.
15. Each executive department, government corporation, and independent establishment providing federal funds to NFEs shall notify Recipients of such funds of the prohibition described in paragraph (a).
16. In subparagraph (c)(2)(A), the terms "executive department", "government corporation", and "independent establishment" have the meanings given such terms in Chapter 1 of Title 5 USC.
17. **Exchange Rate:** The Award Application budget, and all requests for funds and financial reports must be stated in U.S. dollars. Once an award is made, foreign Recipients will generally not be compensated for currency exchange fluctuations.
18. **Audit Requirements:**
19. A non-federal entity (NFE) that expends $1,000,000 or more during the NFE’s fiscal year in federal awards must have a single, or program-specific, audit conducted for that year in accordance with the provisions of 2 CFR 200, subpart F.
20. Subrecipients and Contractors:An auditee may simultaneously be a Recipient, a subrecipient, and a contractor. Federal award funds expended as a Recipient or a subrecipient are subject to audit under this part. The payments received for goods or services provided by a contractor are not federal awards for the purposes of this requirement. 2 CFR §200.331 sets forth considerations in determining whether payments constitute a federal award or a payment for goods or services provided as a contractor.
21. Recipients and subrecipients that are for-profit organizations (including for-profit hospitals) have two options regarding audits:
* A financial-related audit (as defined in the Government Auditing Standards) of a particular award in those cases where the Recipient receives award(s) under only one HHS program; or, if awards are received under multiple HHS programs, a financial-related audit of all HHS awards in accordance with Government Auditing Standards; or
* An audit that meets the requirements contained in 2 CFR 200, subpart F
1. The reporting package must contain the following:
2. Financial statements and schedule of expenditures of federal awards discussed in §200.510(a) and (b) respectively.
3. Summary schedule of prior audit findings discussed in §200.511(b).
4. Auditor’s report(s) discussed in §200.515.
5. Corrective action plan discussed in §200.511(c).

The auditee must electronically submit the data collection form described in paragraph (b) to §200.512 and the reporting package to the Federal Audit Clearinghouse (FAC).

1. Research and Development (R&D): All awards issued by or on behalf of ARPA-H meet the definition of “*Research and Development*” at 2 CFR §200.1. As such, NFEs subject to audit should identify ARPA-H awards as part of the R&D cluster on the “*Schedule of Expenditures of Federal Awards (SEFA)*”. ARPA-H recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (e.g., the award is classified as R&D for federal audit requirement purposes but non-research for indirect cost rate purposes), unless the NFE being audited is charging indirect costs at a rate other than the rate(s) specified in the award.
2. **RESERVED.**
3. **Equipment and Products**:
4. To the greatest extent practical, all equipment and products purchased with HHS funds should be American made. 2 CFR §200.1, *Definitions*, defines “*equipment*” as “***tangible personal property (including Information Technology systems) having a useful life of more than one year and a per-unit acquisition cost that equals or exceeds the lesser of the capitalization level established by the Recipient or subrecipient for financial statement purposes, or $10,000*.**” However, consistent with the Recipient’s policy, a lower cost threshold may be established. Please provide information to the GO to establish a lower equipment cost threshold to reflect the Recipient's policy.
5. The Recipient may use its own property management standards and procedures, provided it observes provisions in applicable grant regulations found at 2 CFR 200.
6. **Prohibition on a ByteDance-Covered Application:**
7. *Definitions.* As used in this clause—

*“Covered application”* means the social networking service TikTok or any successor application or service developed or provided by ByteDance, Limited or an entity owned by ByteDance, Limited.

*“Information technology*,” as defined in 40 USC 11101(6)—

1. Means any equipment or interconnected system or subsystem of equipment, used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the executive agency, if the equipment is used by the executive agency directly or is used by a Recipient under an award with the executive agency that requires the use—
2. Of that equipment; or
3. Of that equipment to a significant extent in the performance of a service or the furnishing of a product.
4. Includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources; but
5. Does not include any equipment acquired by a federal award Recipient incidental to a federal award.
6. *Prohibition*. Section 102 of Division R of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), the “*No TikTok on Government Devices Act*,” and its implementing guidance under Office of Management and Budget (OMB) Memorandum M-23-13, dated 27 February 2023, *No TikTok on Government Devices Implementation Guidance*, collectively prohibit the presence or use of a covered application on executive agency information technology, including certain equipment used by federal award Recipients. The award Recipient is prohibited from having or using a covered application on any information technology owned or managed by the government, or on any information technology used or provided by the award Recipient under this award, including equipment provided by the award Recipient’s employees; however, this prohibition does not apply if the Chief Grants Management Officer provides written notification to the award Recipient that an exception has been granted in accordance with OMB Memorandum M-23-13.
7. *Sub-awards*. The award Recipient shall insert the substance of this clause, including this paragraph (c), in all sub-awards, including sub-awards and subcontracts for the acquisition of commercial products or commercial services.
8. **Required Disclosures OF RESPONSIBILITY/QUALIFICATIONS WITHIN SAM.GOV.**
9. Consistent with 2 CFR §200.113, *Mandatory disclosures*, Applicants, Recipients, and subrecipients of a federal award must promptly disclose whenever in connection with the federal award (including any activities or subawards thereunder) it has credible evidence of the commission of a violation of federal criminal law involving fraud, conflict of interest, bribery, or gratuity violations found in Title 18 of the United States Code or a violation of the civil False Claims Act (31 USC §§3729-3733). The disclosure must be made in writing to the federal agency, the agency’s Office of Inspector General, and pass-through entity (if applicable). Recipients and subrecipients are also required to report matters related to Recipient integrity and performance in accordance with Appendix XII of this part. Failure to make required disclosures can result in any of the remedies described in 2 CFR §200.339. (See also 2 CFR Part 180, 31 USC 3321, and 41 USC 2313.) Disclosures must be sent in writing to the assigned GO identified in the NOA, and to the HHS OIG at 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
Fax: (202)-205-0604

or by e-mail to: MandatoryGranteeDisclosures@oig.hhs.gov. In either case, include “Mandatory Grant Disclosures” in the subject line.

1. Recipients must include this disclosure requirement in all sub-awards and subcontracts under this award. Failure to make required disclosures can result in the government pursuing any of the remedies described in 2 CFR §200.339, *Remedies for non-compliance*, including suspension or debarment. See:
* 2 CFR Part 180, OMB *Guidelines to Agencies on Government-wide Debarment and Suspension (Non-Procurement) at*, <https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-180>),
* 2 CFR Part 376, *Non-Procurement Debarment and Suspension,* at <https://www.ecfr.gov/current/title-2/subtitle-B/chapter-III/part-376>, and
* 31 USC 3321, *Disbursing authority in the* *executive branch*, at <https://www.govinfo.gov/content/pkg/USCODE-2018-title31/html/USCODE-2018-title31-subtitleIII-chap33-subchapII-sec3321.htm>.
1. When an agency terminates a federal award prior to the end of the period of performance because of the Recipient’s or subrecipient’s material failure to comply with the federal award terms and conditions, the agency must report the termination to the OMB-designated integrity and performance system accessible through SAM.gov (2 CFR §200.340(c)). ARPA-H 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 (2 CFR §200.341(a)).
2. 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 during the period of performance of this federal award, the Recipient must maintain the currency of information reported to the Responsibility/Qualification section of SAM.gov about civil, criminal, or administrative proceedings described in section (a) of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 USC 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.
3. **Fraud Waste, or Abuse**.
4. To report fraud, waste, or abuse to the HHS, contact the Inspector General’s Hotline by any of the following means:

Toll-free number: 800-HHS-TIPS (800-447-8477), 8 a.m. to 5:30 p.m. (Eastern), Mondays through Fridays)

Telefacsimile (Fax): 800-223-8165 (10 pages or fewer, please)

Tele-Typewriter (TTY): 800-377-4950

OIG website: <https://oig.hhs.gov/fraud/hotline>

Mail: HHS TIPS Hotline (Note: Please do not send original documents.)

P.O. Box 23489

Washington DC 20026

1. Reporting individuals are not required to give their name(s) and, if they do, their identities are kept confidential. For more information, please reference the HHS GPS, and the following website:

<https://www.hhs.gov/answers/hhs-administrative/how-can-i-report-fraud-waste-and-abuse-about-an-hhs-program/index.html>.

1. **Civil Rights:** The Recipientwill comply with and administer this project in compliance with federal civil rights laws.
2. **ACKNOWLEDGEMENT OF FEDERAL FUNDING**
3. Each publication, press release, or other document about research supported by an ARPA-H award must include acknowledgment of the ARPA-H award support, and the following disclaimer (the Recipient is to complete the Project Title, Award Number, percentage of total costs, and total dollars in its disclaimer):

“*Research reported in this publication was supported by the Advanced Research Projects Agency for Health (ARPA-H) under* ***[Award Recipient must identify Project Title here]****, and Award Number* ***[Award Recipient must identify Award Number here]****. The ARPA-H award provided* ***XX****% of total costs and total $****XX [Award Recipient must identify percentage of total award costs and total award dollars]****.*

*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. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Advanced Research Projects Agency for Health*.”

The Recipient must contact the GO when the contents of the acknowledgement statement need to be revised. Also, the Recipient must contact the GO to coordinate all media releases.

1. Recipients must include this statement in materials for funded conferences (and must identify the award number where indicated):

*“The ARPA-H made this conference possible (in part) through* ***[Award Recipient must identify award number here]****. 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.”*

1. Prior to issuing a press release concerning the outcome of this research, Recipients must notify the ARPA-H Division of Communications (DOC) at media@arpa-h.gov at least 30 days in advance of the press release to allow for coordination.
2. **USE OF LOGOS.** Recipients must have prior written approval from ARPA-H before using an HHS- or awarding agency logo. Using a logo without approval may lead to a Recipient incurring a financial penalty. The Recipient must contact the GO for guidance regarding logos.
3. **Federal Information Security Management Act (FISMA).**
4. 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 HHS awards. 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.
5. FISMA applies to HHS Recipients only when they collect, store, process, transmit or use information on behalf of the HHS or any of its component organizations. In all other cases, FISMA is not applicable to Recipients of grants or 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. When information collected by a Recipient is provided to the HHS, responsibility for the protection of the HHS copy of the information is transferred to the 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 PL No. 107-347, please review the following website: <https://www.gpo.gov/fdsys/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf>.
6. **Trafficking in persons** (2 CFR Part 175, Appendix A)
7. Provisions applicable to a Recipient that is a private entity.
8. Under this award, the Recipient, its employees, subrecipients under this award, and subrecipients' employees may not engage in—
9. Severe forms of trafficking in persons;
10. The procurement of a commercial sex act during the period that this award or any subaward is in effect; or
11. The use of forced labor in the performance of this award or sub-award; or
12. Acts that directly support or advance trafficking in persons, including the following acts;
13. Destroying, concealing, removing, confiscating, or otherwise denying an employee access to that employee’s identity- or immigration documents;
14. Failing to provide return transportation, or pay for return transportation costs, for an employee from a country outside the United States to the country from which the employee was recruited upon the end of employment if requested by the employee, unless:
15. Exempted from this requirement to provide or pay for such return transportation by the federal department or agency providing or entering into the grant or cooperative agreement; or
16. The employee is a victim of human trafficking seeking victim services or legal redress in the country of employment or is a witness in a human trafficking enforcement action;
17. Soliciting a person for the purpose of employment, or offering employment, by means of materially false or fraudulent pretenses, representations, or promises regarding that employment;
18. Charging recruited employees a placement or recruitment fee; or
19. Providing or arranging housing that fails to meet the host country’s housing and safety standards.
20. The federal agency may unilaterally terminate this award or take any remedial actions authorized by 22 USC §7104b(c), without penalty, if any private entity under this award:
21. Is determined to have violated a prohibition in paragraph (a)(1) of this appendix; or
22. Has an employee that is determined to have violated a prohibition in paragraph (a)(1) of this appendix through conduct that is either—
23. Associated with the performance under this award; or
24. Imputed to the Recipient or the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR Part 180, “*OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Non-procurement),*” as implemented by our agency at 2 CFR §200.214, *Suspension and Debarment*.
25. Provision applicable to a Recipient other than a private entity.
26. The federal agency may unilaterally terminate this award or take any remedial actions authorized by 22 USC 7104b(c), without penalty, if a subrecipient that is a private entity under this award—
27. Is determined to have violated a prohibition in paragraph (a)(1) of this appendix; or
28. Has an employee that is determined to have violated a prohibition in paragraph (a)(1) of this appendix through conduct that is either—
29. Associated with performance under this award; or
30. Imputed to the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR Part 180, “*OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Non-procurement),*” as implemented by our agency at 2 CFR §200.214, *Suspension and Debarment*.
31. Provisions applicable to any Recipient.
32. The Recipient must inform the federal agency and the Inspector General of the federal agency immediately of any information you receive from any source alleging a violation of a prohibition in paragraph (a)(1) of this appendix.
33. The federal agency’s right to unilaterally terminate this award as described in paragraphs (a)(2) or (b)(1) of this appendix:
34. Implements the requirements of 22 USC 78, and
35. Is in addition to all other remedies for non-compliance that are available to the federal agency under this award.
36. The Recipient must include the requirements of paragraph (a)(1) of this award term in any sub-award it makes to a private entity.
37. If applicable, the Recipient must also comply with the compliance plan and certification requirements in 2 CFR §175.105(b).
38. Definitions. For purposes of this award term:

“*Employee*” means either:

1. An individual employed by the Recipient or a subrecipient who is engaged in the performance of the project or program under this award; or
2. Another person engaged in the performance of the project or program under this award and not compensated by the Recipient including, but not limited to, a volunteer or individual whose services are contributed by a third party as an in-kind contribution toward cost sharing requirements.

“*Private entity*” means any entity, including for-profit organizations, non-profit organizations, institutions of higher education, and hospitals. The term does not include foreign public entities, First Nation (native American) Tribes, local governments, or states as defined in 2 CFR § 200.1.

The terms “*severe forms of trafficking in persons*,” “*commercial sex act*,” and “*sex trafficking*,” “*Abuse or threatened abuse of law or legal process*,“ “*coercion,*” “debt bondage,” and “*involuntary servitude*” have the meanings given at section 103 of the TVPA, as amended (22 USC 7102).

1. **Text Messaging While Driving by Government Contractors, and Recipients and Subrecipients**.
2. The Recipient and its subrecipients and subcontractors are encouraged to adopt and enforce policies that ban text messaging while driving company-owned or -rented vehicles, government-owned vehicles, or while driving privately-owned vehicles when on official government business or when performing any work for or on behalf of the government. (EO 13513, *Federal Leadership on Reducing Text Messaging while Driving*, at <https://obamawhitehouse.archives.gov/the-press-office/executive-order-federal-leadership-reducing-text-messaging-while-driving>).
3. The Recipient and its subrecipients and subcontractors are also encouraged to consider new rules and programs, and to reevaluate existing programs to prohibit text messaging while driving, and to conduct education, awareness, and other outreach initiatives about the safety risks associated with texting while driving. These initiatives should also encourage voluntary compliance with the text messaging policy while off duty.
4. **PROHIBITION AGAINST AWARDS TO NON-DOMESTIC ENTITIES SUBJECT TO OFAC ECONOMIC SANCTIONS.** At no time shall an award or sub-award be made to a non-domestic entity organized under the laws of a covered foreign country or region subject to economic sanctions administered by the Department of Treasury, Office of Foreign Assets Control (OFAC) (e.g., Iran, China, Russia, Cuba, North Korea).
5. **INVENTION REPORTING.** Recipient responsibilities for invention reporting, including Annual and Final Invention Statements, are specified in 37 CFR part 401 and summarized in the HHS GPS under Patents and Inventions, Invention Reporting. Information about and procedures for electronic filing are available at the Interagency Edison website and service center, [*http://www.iedison.gov*](https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.iedison.gov%2F&data=05%7C02%7Celie.stowe%40arpa-h.gov%7Caa89d28ce0de48355afd08dcd9a8858f%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C638624566748317210%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=nCUc0iH4Nj1MSMPDHmKcX4iLA%2F8qu8Hd%2BvYrRePoayU%3D&reserved=0).”

# SECTION III – ARPA-H SPECIFIC TERMS AND CONDITIONS

# X XXX AX XXXXXX-XX

By signing and returning this document, which is based on the Recipient’s application (or submission), dated **YYYY MMM DD**, the Recipient acknowledges acceptance of the terms and conditions of this award and is obligated to perform in accordance with their requirements.

|  |  |
| --- | --- |
| **For the Recipient Organization** | **For the United States of America, Advanced Research Projects Agency for Health (ARPA-H)** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature of Authorized Organizational Representative |  | Signature of US Government Official |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Title of Authorized Organizational Representative |  | Title of US Government Official |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date |  | Date |

* + - * 1. **DISTRIBUTION REQUIRED**. The signed NOA document must be submitted by the Recipient to the following e-mail address(es):

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@arpa-h.gov**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@arpa-h.gov**

* + - * 1. **ARPA-H PERSONNEL CONTACT INFORMATION**

Grants Officer (GO) Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail Address: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@arpa-h.gov**

Program Manager (PM) Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail Address**:** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@arpa-h.gov**

Program Officer (PO) Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail Address: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@arpa-h.gov**

SETA Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail Address: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@arpa-h.gov**

Budget and Financial Manager (BFM) Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail Address: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@arpa-h.gov**

* + - * 1. **RECIPIENT’S SENIOR/KEY PERSONNEL/OTHER SIGNIFICANT CONTRIBUTORS.** Senior/Key Personnel/Other Significant Contributor (OSC) positions are critical to the performance of this award, and for which substitutions/replacements must meet the requirements set forth in the solicitation or this NOA. In addition, an eRA Commons ID must be entered in the “*Credential, e.g. agency login*” field for all Research & Related (R&R) Senior/Key Personnel and OSCs listed on the *R&R Senior/Key Person Profile Form*. Senior/Key Personnel/OSC positions and the personnel assigned to fill them are:

Principal Investigator/Program Director: **[Name]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

E-mail address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[Position/Person]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_: [Name]\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

E-mail address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* + - * 1. **AWARD AND FUNDING SUMMARY**

This action’s increase or decrease to award value: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total award value after this action: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This action’s increase or decrease to financial obligations: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total financial obligations after this action: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| **Award and Funding Summary** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Budget Period | Milestones | Budget Period Value | Duration of Funding | Actual Funding |
| 1 (Base) |  |  |  |  |
| 2 (Option 1) |  |  |  |  |
| 3 (Option 2) |  |  |  |  |
| 4 (Option 3) |  |  |  |  |
| 5 (Option 4) |  |  |  |  |

Base Year: Appropriation Data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Option 1: Appropriation Data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Option 2: Appropriation Data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Option 3: Appropriation Data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Option 4: Appropriation Data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* + - * 1. **Recommended future year total cost support.**

Any funding of a non-competitive continuation is based on the availability of funds, satisfactory progress by the Recipient, and a determination by the agency that continued funding of the award is in the best interest of the government.

BACS 20xx 20xx 20xx 20xx 20xx

XXXXXXX $XXX,XXX $XXX,XXX $XXX,XXX $XXX,XXX $XXX,XXX

* + - * 1. ALLOWABLE PRE-AWARD COSTS. Allowable pre-award costs, if any, are identified here:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NTE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NTE \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* + - * 1. **AWARD VALUE**. This Cooperative Agreement is not subject to any adjustment in total value based on the Recipient’s, subrecipient’s, or subcontractor’s cost experience in performing under this award.
				2. **Salary Cap.** None of the federal funds under this award shall be used to pay the salary of an individual, through a Grant, Cooperative Agreement, or other extramural mechanism, at a rate exceeding the rate identified by the Office of Personnel Management for Executive Level II positions. Nor may the proposed, and later negotiated, salaries escalate to more than that Executive Level II rate for the purpose of invoicing for salary support.

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with federal funds.

* + - * 1. **PAYMENTS**.
1. The Payment Management System (PMS) is a centralized payment- and cash management system, operated by the HHS Program Support Center (PSC) Payment Management Services. Award payments may be made by one of several payment methods as specified in the NOA and as described in the GPS. Payments will generally be made from the PMS in accordance with Department of the Treasury and OMB requirements (as implemented by 2 CFR §200.305, *Federal Payment*).
2. The Payment Office telephone number, e-mail address, URL, and geographic location are:

Telephone Number: 877-614-5533

Email Address: pmssupport@psc.hhs.gov

URL: <https://dpm-portal.psc.gov>

Geographic Location: District of Columbia

1. Regardless of the method(s) of transmittal, payment(s) to the Recipient will be made following completion of the requirements set forth in the Payable Milestones terms of this award, and only after receipt of PM approval.
2. Operational guidance for Recipients can be found here:

<https://pms.psc.gov/training/grant-recipient-training.html>.

* + - * 1. **SUBSTANTIAL FEDERAL INVOLVEMENT**. This award is a Cooperative Agreement, which is a form of financial assistance that allows for substantial involvement between ARPA-H and the Recipient during the period of performance. In addition to the usual monitoring and technical assistance provided to the Recipient by the government (e.g., assistance from an assigned federal project manager, monthly conference calls, periodic site visits, on-going review of plans and progress, relevant meetings, provision of training and technical assistance), the government’s substantial programmatic involvement may include:

• Evaluating progress reports

* Providing post-award technical assistance
* Ensuring compliance with public policy requirements or terms and conditions of award
* Conducting enforcement activities
* Closer monitoring based on designation of an organization as high risk
* Reviewing and evaluating performance after project completion.

Substantial involvement may include collaboration or participation by the awarding agency program staff in activities specified in the award and, as appropriate, decision-making at specified milestones related to performance (e.g., requiring awarding agency approval before undertaking the next phase of a project).

* + - * 1. **PRIOR APPROVAL AND EXPANDED AUTHORITIES**.
1. All requests requiring prior approval must bear the signature (or electronic authorization) of the ARR and PI/PD. All requests must be submitted to the GO no later than 30 days before the proposed change. Any requests involving funding issues must include an itemized budget and a narrative justification of the request.
	1. The following requests require prior approval:

• Change of Recipient organization

• Removal of funding restrictions

• Change in the scope of the award

* Travel

• Change in status of the PI/PD, or personnel named in the NOA as assigned to Key Positions (Key Personnel) and

• Deviation from award Terms and Conditions

Note: This list is not exhaustive. For questions regarding prior approvals, contact the GO.

* 1. This Cooperative Agreement allows the Recipient to exercise expanded authorities, defined in the GPS, and 2 CFR §200.308(g), *Waiver of certain prior approvals*, as follows:

• Pre-award costs. Incur project costs 90 calendar days before the federal award date. Expenses incurred more than 90 calendar days before the award date require prior approval of the agency. All costs incurred before the award date are at the Recipient's own risk (*for example,* the agency is not required to reimburse such costs if the Recipient does not receive the award or if the award is less than anticipated and inadequate to cover such costs). Pre-award costs must be charged to the initial budget period of the award unless otherwise specified by the agency. See also [§ 200.458](https://www.ecfr.gov/current/title-2/section-200.458)

* Unobligated Balances. Carryover of unobligated balances from one budget period to subsequent budget periods and

• One-time extensions. Initiate a one-time extension of the period of performance by up to 12 months unless one or more of the conditions outlined in [paragraphs (g)(2)(i)](https://www.ecfr.gov/current/title-2/section-200.308#p-200.308(g)(2)(i)) through [(iii)](https://www.ecfr.gov/current/title-2/section-200.308#p-200.308(g)(2)(iii)) of this section apply. Prior approval is not required if a Recipient is authorized in the terms and conditions of the federal award to initiate a one-time extension. However, the recipient must notify the federal agency in writing with the supporting justification and a revised period of performance at least 10 calendar days before the conclusion of the period of performance. A one-time extension may not be exercised for the sole purpose of using unobligated balances. This paragraph does not preclude the federal agency from approving further no-cost extensions to the federal award. One-time extensions require prior approval from the federal agency when:

(i) The terms and conditions of the federal award prohibit the extension;

(ii) The extension requires additional federal funds; or

1. The extension involves any change in the approved scope of the project.
2. **military recruiting and higher educations (10 USC 49, §983)**

Note: This award term applies when subrecipients are approved by ARPA-H.

1. Denial of Funds for Preventing ROTC Access to Campus. No funds described in subsection (d)(1) may be provided by contract or by grant to an institution of higher education (including any sub-element of such institution) if the Secretary of Defense determines that that institution (or any sub-element of that institution) has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—
2. the Secretary of a military department from maintaining, establishing, or operating a unit of the Senior Reserve Officer Training Corps (in accordance with section 654-1 of this title and other applicable federal laws) at that institution (or any sub-element of that institution); or
3. a student at that institution (or any sub-element of that institution) from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.
4. Denial of Funds for Preventing Military Recruiting on Campus. No funds described in subsection (d)(1) may be provided by contract or by grant to an institution of higher education (including any sub-element of such institution) if the Secretary of Defense determines that that institution (or any sub-element of that institution) has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—
5. the Secretary of a military department or the Secretary of Homeland Security from gaining access to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of military recruiting in a manner that is at least equal in quality and scope to the access to campuses and to students that is provided to any other employer; or
6. access by military recruiters for purposes of military recruiting to the following information pertaining to students (who are 17 years of age or older) enrolled at that institution (or any sub-element of that institution):
7. Names, addresses, electronic mail addresses (which shall be the electronic mail addresses provided by the institution, if available), and telephone listings.
8. Date and place of birth, levels of education, academic majors, degrees received, and the most recent educational institution enrolled in by the student.
9. Exceptions. The limitation established in subsection (a) or (b) shall not apply to an institution of higher education (or any sub-element of that institution) if the Secretary of Defense determines that—
10. the institution (and each sub-element of that institution) has ceased the policy or practice described in that subsection; or
11. the institution of higher education involved has a longstanding policy of pacifism based on historical religious affiliation.
12. **SELECT AGENTS**.
13. Domestic Recipients that conduct research involving select agents or toxins (see Sections 3 and 4 of 42 CFR Part 73 and 9 CFR Part 121 and Section 3 of 7 CFR Part 331) must maintain a registration with the Centers for Disease Control (CDC) (or the United States Department of Agriculture (USDA), depending on the agent) before using ARPA-H funds. No funds can be used for research involving select agents or toxins if the registration certificate maintained by CDC or USDA is suspended or revoked.
14. Foreign Organizations and International Organizations that conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must provide information satisfactory to ARPA-H that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all select agent work sponsored by ARPA-H funds before using these funds for any work directly involving select agents.
15. Recipients must be willing to address the following key elements appropriate for their institutions:
* safety
* security
* training
* procedures for ensuring that only approved/appropriate individuals have access to the select agents, and
* any applicable laws, regulations, and policies equivalent to 42 CFR Part 73

If this work will not, in fact, involve select agents (e.g. excluded strains), and you provide documentation satisfactory to ARPA-H that your work does not, nor will it in the future (i.e. throughout the life of the award) involve select agents, no further action will be necessary.

1. **HUMAN SUBJECTS RESEARCH (HSR)** (Supplemental Information to the GPS)
2. Any institution or entity engaged in ARPA-H funded research involving human subjects must
	* 1. Obtain a Federal-wide Assurance (FWA) of Protection for Human Subjects from the Office for Human Research Protection (OHRP) (see <https://www.hhs.gov/ohrp/regulations-and-policy/index.html>).
		2. Obtain initial and continuing approval (if required) of the research by an appropriately constituted and registered Institutional Review Board (IRB), and
		3. Submit the full IRB approved package (including protocol, IRB approval letter, any required training certificates, etc.

For instructions on registering IRBs, obtaining FWAs, and completing Human Subjects Education requirements, see the OHRP website at: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/index.html>.

1. In the event the Recipient does not have one or more of the requirements set forth in paragraph (a) herein at the time of award, federal funds are restricted from being used in research involving human subjects and may not be used for any other purpose without ARPA-H approval.
2. Recipients with restricted awards shall submit evidence of the required FWA and IRB approval package to the Program Official and the GO. When the requisite documentation has been reviewed and approved by the government, ARPA-H will lift the restriction via written notification. (See <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html>)
3. **CERTIFICATES OF CONFIDENTIALITY (CoCs)** (Supplemental Information for HSR)

Information on CoCs is available on the HHS website at: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/certificates-of-confidentiality/index.html>. Requests for CoCs should be submitted to the GO; subject to ARPA-H review and approval, a certificate may be issued pursuant to Section 301(d) of 42 USC 241.

1. **ANIMAL WELFARE** (Supplemental Information to the GPS)
2. Any institution or entity engaged in ARPA-H funded research involving animals must first:
3. Obtain an Animal Welfare Assurance (Assurance) from the Office of Laboratory Animal Welfare (OLAW) (see <https://olaw.nih.gov/guidance/obtaining-an-assurance.htm>), and
4. Obtain initial and continuing approval of the research from the Institutional Animal Care and Use Committee (IACUC), prior to utilizing federal funds for animal research.
5. In the event the Recipient does not have both the Assurance and approval from the IACUC at the time of award, federal funds are restricted from being used in research involving live vertebrate animals and may not be used for any other purpose without ARPA-H approval.
6. Recipients with restricted awards shall submit evidence of a valid Assurance and verification of IACUC approval to the Program Official and the GO. When proof of both the Assurance and IACUC approval have been reviewed and approved by the Government, ARPA-H will lift the restriction via written notification.
7. Information about preparing and submitting Animal Welfare Assurances (Assurance) and copies of the Public Health Service (PHS) policy and other relevant materials are available from OLAW at <https://olaw.nih.gov/home.htm>.
8. **TITLE IX COMPLIANCE**

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

* Recipient is compliant with Title IX of the Education Amendments of 1972, as amended, 20 USC §§ 1681 et seq., including the requirements set forth in Presidential Executive Order 14168 titled *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, and Title VI of the Civil Rights Act of 1964, 42 USC §§ 2000d et seq., and Recipient will remain compliant for the duration of the Agreement.
* The above requirements are conditions of payment that go the essence of the Agreement and are therefore material terms of the Agreement.
* Payments under the Agreement are predicated on compliance with the above requirements, and therefore Recipient is not eligible for funding under the Agreement or to retain any funding under the Agreement absent compliance with the above requirements.
* Recipient acknowledges that this certification reflects a change in the government’s position regarding the materiality of the foregoing requirements and therefore any prior payment of similar claims does not reflect the materiality of the foregoing requirements to this Agreement.
* Recipient acknowledges that a knowing false statement relating to Recipient’s compliance with the above requirements and/or eligibility for the Agreement may subject Recipient to liability under the False Claims Act, 31 USC § 3729, and/or criminal liability, including under 18 USC §§ 287 and 1001.
1. **BIOSECURITY**. HHS awardees must adhere to current federal regulations, guidance, and/or policies on biosafety and biosecurity. Representative policy may include, but is not limited to, framework(s) and guidance arising from EO 14292. The Recipient institutions will be required to monitor emerging policies and to update their biosafety and biosecurity protocols to adhere to emerging federal regulations, guidance, and/or policies.
2. **Applicable Regulatory Provisions.** Prior to October 1, 2025, this award is subject to 45 CFR 75 except for eight flexibilities from 2 CFR 200 adopted by HHS on October 1, 2024. After October 1, 2025, this award will be subject to any applicable provisions of 2 CFR 200 and 2 CFR 300.
3. **Termination.** Prior to October 1, 2025, this award is subject to the termination provisions at 45 CFR 75.372. Starting on October 1, 2025, this award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the Recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, Recipient satisfactory performance, compliance with the Terms and Conditions of the award, and a decision by the agency that the award continues to effectuate program goals or agency priorities.
4. **Non-Discrimination.**

The Recipient hereby agrees that it will comply with:

* Title VI of the Civil Rights Act of1964, as amended (codified at 42 USC 2000d et seq.), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 80).
* Section 504 of the Rehabilitation Act of 1973, as amended (codified at 29 USC 794), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 84).
* Title IX of the Education Amendments of 1972, as amended (codified at 20 USC § 1681 et seq.), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 86).
* The Age Discrimination Act of 1975, as amended (codified at 42 USC § 6101 et seq.), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 91); and
* Section 1557 of the Patient Protection and Affordable Care Act, as amended (codified at 42 USC § 18116), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 92).

## **REPORTING REQUIREMENTS – DATA/TECHNICAL/PROGRESS**

1. **Data Management SHARING Plan**. For projects that involve the collection or generation of data, ARPA-H requires Recipients that receive federal funds to develop, submit, and comply with a Data Management Sharing Plan for each collection (or generation) of public health data undertaken as part of the award and, to the extent consistent with law and appropriate, provide access to and archiving/long-term preservation of collected or generated data. Upon PO or GO request, the Recipient shall submit its Data Management Sharing Plan to the PO and GO for review and approval.
2. **HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM.** ARPA-H award Recipients must submit data on participant enrollment in clinical trials in their progress reports. The PHS “*Human Subjects and Clinical Trials Information Form*” is used to collect information on:
* Human Subject Research
* clinical research and/or clinical trials
* clinical study population characteristics
* protection and monitoring plans, and protocol synopsis

and consolidates this information regarding human subjects, their inclusion enrollment, and clinical trial information. Investigators planning to conduct research involving human subjects should design their studies in such a way that their progress reports do not identify individual-level participant data on sex/gender, race, ethnicity, and age at enrollment. Additional information about this form can be found at: <https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm>.

1. **M**onthly Status ReportS and Technical PROGRESS MeetingS. On a monthly basis, the Recipient must participate in a meeting with the Program Official and/or PM. At least 24 hours prior to this meeting, the Recipient must submit its technical and financial progress information in both PowerPoint and Excel formats via e-mail to the GO, the ISC/SETA, and BFM (see the “*ARPA-H Program Personnel Contact Information*” in Section III). Templates will be provided by ARPA-H.
2. **Six-Month Progress Meetings.** Every six months, all project personnel identified by the ARPA-H Program Official must participate in an in-person progress meeting with ARPA-H to report on the project’s progress; this meeting is in lieu of the monthly technical progress meeting and will have its location communicated by and coordinated with the Program Official far enough in advance to allow for sufficient travel planning. The Recipient’s budget representatives must be present to meet with the BFM and/or GO to discuss financial status and address any concerns the parties may have; the financial status portion of the meeting may be conducted virtually.
3. Annual Performance Report (RPPR)**.** See: <https://grants.nih.gov/grants/rppr/index.htm>) serves as the Recipient’s annual performance report and is due annually within 90 calendar days after the budget reporting period to the GO and PO. The Recipient’s RPPR must comply with the guidance in 2 CFR 200.329(c)(1). RPPRs are not available in eRA Commons for APRA-H and must be in the format provided under Section III, *Technical, Milestones, and Deliverables*.
4. **Final Performance Report (Final RPPR).** In accordance with 2 CFR §200.344, Recipients must submit a final RPPR for closeout purposes within 120 days after the performance period ends to the GO and PO (see 2 CFR 200.344). RPPRs are not available in eRA Commons for APRA-H and must be in the format provided under Section III of the Technical, Milestones, and Deliverables. Except for the submittal time, the Final RPPR must comply with the guidance in 2 CFR 200.329(c)(1).

## **REPORTING REQUIREMENTS – FINANCIAL**

1. Monthly Financial Review:
2. On a monthly basis, the Recipient must submit its financial report (to include cumulative costs) for the reporting period to the GO and the Program Official. Costs must be broken down by major cost categories (e.g., salaries & benefits, equipment, subrecipient cost, travel, materials and supply, and indirect costs). The report is due no later than 30 days after the end of each reporting period and must identify the:
* federal award number
* project title
* PI/PD name(s)
* budget dates, and
* reporting period dates.
1. All payments are considered provisional and subject to adjustment within the total costs awarded upon review of any financial reports submitted by the Recipient.
2. Federal Financial Report (FFR) (SF425). At a minimum, Recipients must submit the annual FFR to the GO and the Program Official no later than 90 days after each 12-month budget period (or incremental period) and submit the Final FFR no later than 120 days after the end of the period of performance. The FFR may be downloaded from:

<https://apply07.grants.gov/apply/forms/sample/SF425-V1.0.pdf>.

1. **Reporting INDIRECT Costs by Category**.Concurrent with submittal of the Final RPPR, the Recipient must provide the GO with a report of the award’s indirect costs (broken out by fixed capital costs, administrative overhead, and labor costs) in accordance with [42 USC 290c(g)(1)(a)](https://www.law.cornell.edu/uscode/text/42/290c). If the value of the award is $1,000,000 or greater, this data may be acquired from the financial audit performed in accordance with 45 CFR part 75, subpart F.
2. **FUNDS EXPIRATION**. All federal agencies are required by 31 USC §1552(a) to close fixed-year appropriation accounts and cancel remaining balances by September 30th of the fifth fiscal year after the year of availability, unless otherwise authorized by Congress. For ARPA-H to meet its obligation to close these accounts and cancel remaining balances as required, the Recipient must report fixed-year disbursements on its Federal Financial Report (FFR)(SF425) no later than August 31st of the fifth fiscal year after the fixed-year appropriation’s first year of availability.

## **RESTRICTIONS AND ADDITIONAL SPECIAL AWARD CONDITIONS**

1. **ADDITIONAL AWARD CONDITIONS**
2. **RESTRICTIONS**

## **ACRONYMS, REPORTS, TECHNICAL REQUIREMENTS, MILESTONES, AND DELIVERABLES**

* + - * 1. ACRONYMS
				2. RPPR
				3. TECHNICAL REQUIREMENTS AND OBJECTIVES
				4. MILESTONES
				5. DELIVERABLES

### **ACRONYMS**

|  |  |
| --- | --- |
| ACH | Automated Clearing House |
| ARR | Authorized Recipient Representative |
| ARPA-H  | Advanced Research Projects Agency for Health |
| BACS | Budget Account Classification Structure |
| BFM | (ARPA-H) Business Financial Manager |
| CAA | Consolidated Appropriations Act |
| CDC | Centers for Disease Control |
| CFR | Code of Federal Regulations |
| CoC | Certificate of Confidentiality |
| EO | Executive Order |
| eRA | Electronic Research Administration |
| FAC | Federal Audit Clearinghouse |
| FAPIIS | Federal Awardee Performance and Integrity Information System |
| FAQ | Frequently Asked Questions |
| FFR | Federal Financial Report (SF425) |
| FWA | Federal-Wide Assurance |
| GO | Grants Officer |
| GPS | Grants Policy Statement |
| HHS | (Department of) Health and Human Services |
| IRB | Institutional Review Board |
| ISC | Internal Support Contractor |
| NFE | Non-Federal Entity |
| NOA | Notice of Award |
| NOFO | Notice of Funding Opportunity |
| OHRP | Office of Human Research Protections |
| OIG | Office of Inspector General |
| OLAW | Office of Laboratory Animal Welfare |
| OMB | Office of Management and Budget |
| OSC | Other Significant Contributors |
| PD | Project Director |
| PHS | Public Health Service |
| PI | Principal Investigator |
| PL | Public Law |
| PM | Program Manager |
| PMS | Payment Management Services/System |
| PO | Program Official |
| PSC | Program Support Center |
| R&D | Research and Development |
| ROTC | Reserve Officer Training Corps |
| RPPR | Research Performance Progress Report |
| SAM | System for Award Management |
| SETA | Systems Engineering and Technical Assistance Contractor Support |
| SF | Standard Form |
| UEI | Uniform Entity Identifier |
| USC | United States Code |
| USDA | United States Department of Agriculture |