**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 U.S.C. 290c, 42 U.S.C. 241, 31 U.S.C. 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 the 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)

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 Supplies | $ |
| 1. Other | $ |
| 1. Subaward/Consortium/Contractual Costs | $ |
| Totals | |
| Total Direct Costs (Sum of 1-4) | $ |
| Total F&A Costs (from Table below) | $ |
| Total Cost | $ |
| Cost Share Information | |
| Federal Share | $ |
| Non-Federal Share | $ |

|  |  |
| --- | --- |
| Facilities and Administrative Costs | |
| F&A Cost Rate | % |
| F&A Cost Base | $ |
| F&A Costs | $ |

NOTE: See Section 3 for identification of this action’s obligation, 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**

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 the terms and conditions herein, and incorporates either directly or by reference all of the following:

* 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.
* 45 CFR part 75.
* National policy requirements and all other requirements described in the 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 GPS can be found at the following web link:

<https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>).

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 45 CFR §75.351 through 45 CFR-§75.352, *Subrecipient monitoring and management*; 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 its terms and conditions and agrees to perform in accordance with its requirements. The GO may adjust the award amount based on 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:
3. United States Constitution
4. Statutes:

• Program Authorizations and Appropriations

• Federal Grant and Cooperative Agreement Act of 1977

• Federal Funding Accountability and Transparency Act (FFATA) of 2006

• Digital Accountability and Transparency Act (DATA) of 2014

• Grant Reporting Efficiency and Agreements Transparency (GREAT) Act of 2019

1. Regulations:

• 2 CFR part 200

* 45 CFR part 75

• Program-specific regulations

(d) Policies, Program Guidance, and Award-Specific Requirements.

• Executive Orders

• Office of Management and Budget (OMB) Memoranda

• Department of Health and Human Services (HHS) GPS

• ARPA-H-Specific Policies

• Agency- and program-specific guidance related to one or more award programs such as Notices of Funding Opportunity (NOFOs), Frequently Asked Questions (FAQs), and other program announcements (e.g., agency guidance, manuals, “Dear Colleague” letters, etc.).

• Requirements specific to an individual award or class of awards, such as a requirement to perform activities described in the Recipient’s application.

1. **ROLES AND RESPONSIBILITIES**.
2. Grants Officer. Grants Officers (GOs) are designated by agencies to conduct pre-award, post-award, and close-out activities to ensure the integrity of financial assistance programs from business-, financial-, and administrative perspectives. GOs are responsible for:

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

• Providing input to the Chief Grants Management Officer on the HHS grants administration 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 issues. 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. POs have pre-award, post award, and close-out responsibilities including:

• Setting program goals and objectives;

• Providing advice on the scientific, technical, and programmatic suitability of applications for funding; and

• Providing technical expertise during the administration of awards.

1. Recipient(s) and Subrecipient(s). 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 45 CFR §75.101(b)(1) and 45 CFR §§75.351-353).

(d) Authorized Organizational Representative (AOR). The Authorized Organizational Representative is the designated representative of the Applicant/Recipient and has the authority to act on behalf of the Applicant/Recipient with respect to matters related to the award and administration of grants and cooperative agreements. In signing a grant/cooperative agreement application, the AOR agrees that the Recipient will assume the obligations imposed by federal statutes and regulations (and other terms and conditions of the award, including any assurances) if a grant/cooperative agreement is awarded. These responsibilities include accountability both for the appropriate use of funds awarded and the performance of the award-supported project (or activities specified in the approved application). Although the Department requires that the Recipient designate such an individual, it does not specify the organizational location or full set of responsibilities for this individual.

(e) Principal Investigator (PI)/Program or Project Director (PD).

(1) The PI/PD is the individual designated by the Recipient who is responsible for the scientific, technical, or programmatic aspects of the award and for day-to-day management of the project or program. 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.

(2) The PI/PD is a member of the Recipient’s team and responsible for ensuring compliance with the financial and administrative aspects of the award. This individual 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; and

• 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.

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. **Unique Entity Identifier fOR SUBRECIPIENTS (UEI).** As required by 2 CFR part 25, Appendix A, the Recipient must ensure their subrecipients have a UEI as established in 2 CFR part 25, Appendix A, and use it on all registrations, applications, etc.
3. **TIMING OF FUNDING**. For most awards, ARPA-H uses the “project period” system of funding. Under this system, projects are programmatically approved for support in their entirety, but are funded in annual increments, called budget periods. The total project period consists of the initial competitive segment, any additional competitive segments authorized by approval of a competing continuation application, and any non-competing extensions. If the total planned period of support is less than 18 months, the agency may fund the project period in its entirety at award.
4. **Payment.**
5. 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 advance payment methods (including SMARTLINK II/ACH, cash request, or cash request on a reimbursement basis) as specified in the NOA and as described in the GPS.
6. Payments will generally be made as advance payments from the PMS in accordance with Department of the Treasury and OMB requirements (as implemented by 2 CFR §200.305 and 45 CFR §75.305). These requirements are intended to minimize the time elapsing between the transfer of funds from the government and disbursement by a Recipient. Therefore, although the award may be financed by advance payments, the intent is that Recipients draw funds on an as-needed basis but no more than 3 business days before the funds are needed.
7. All federal funds deposited by the PMS into a Recipient’s bank account as unrestricted advance payments should be fully disbursed (checks written, signed, and issued to the payees) by the close of business the workday after receipt of the funds. The potential for excessive federal cash on hand exists each time a Recipient does not disburse funds in this manner. The Recipient is responsible for determining when funds have been deposited into its bank account for each drawdown, ensuring they are fully disbursed by the close of business the workday after they are received, and immediately returning undisbursed federal funds to the PMS.
8. ARPA-H may use reimbursement as the method of payment if cash management requirements are not met. Advances made by Recipients to subrecipients and subcontractors must conform to substantially the same standards of timing and amount that govern advances to the Recipient.
9. Operational guidance for Recipients can be found here:

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

1. **FAILURE TO DRAW DOWN FUNDS.**

(a) When the Recipient has shown no attempt to receive funds either by drawing down funds or requesting reimbursement within 90 days after the start of the budget period, the awarding agency will determine the cause of the delay and contact the Recipient as necessary. The awarding agency will then determine appropriate next steps (including immediate corrective action or termination).

(b) If, within 120 days after the start of the budget period, the Recipient has still not adequately justified the lack of drawn down funds (or requested reimbursement), the awarding agency will initiate formal corrective action (or termination) unless prohibited by statute or program regulations.

1. **FLY AMERICA ACT**. All entities are required by 49 U.S.C. 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.
2. **HOTEL AND MOTEL FIRE SAFETY (SECTION 2225A OF 15 U.S.C. CHAPTER 49)**
3. No federal funds may be used to sponsor or fund in whole or in part a 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 U.S.C. Chapter 49.

(b) Waiver.

(1) 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 subsection (a) if the head of such agency determines that a waiver of such prohibition is necessary in the public interest in the case of such particular event.

(2) Delegation of Authority. The head of an agency of the federal government may delegate the authority provided under paragraph (1) to waive the prohibition described in subsection (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.

(c) Notice Requirements.

(1) Advertisements and Applications.

(A) 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 subsection (a).

(B) The requirement described in subparagraph (A) shall not apply in the case of an event for which a head of an agency of the federal government, pursuant to subsection (b), waives the prohibition described in subsection (a).

(2) Providing Notice to Recipients of Funds.

(A) Each executive department, government corporation, and independent establishment providing federal funds to NFEs shall notify Recipients of such funds of the prohibition described in subsection (a).

(B) In subparagraph (A), the terms "executive department", "government corporation", and "independent establishment" have the meanings given such terms in chapter 1 of title 5.

1. **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.
2. **Audit Requirements:**
3. A non-federal entity (NFE) that expends $750,000 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 45 CFR part 75.
4. 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 as a contractor are not federal awards for the purposes of this requirement. Section 75.351 of 45 CFR sets forth the considerations in determining whether payments constitute a federal award or a payment for goods or services provided as a contractor.
5. Recipients and subrecipients that are commercial 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 45 CFR part 75, subpart F.

1. The reporting package must contain the following:

* Financial statements and schedule of expenditures of federal awards.
* Independent auditor’s report, including an opinion on the financial statements and the schedule of expenditures of federal awards, a report on compliance and internal control over financial reporting, and a report on compliance with requirements applicable to each major program and on internal control over such compliance requirements.
* A schedule of findings and questioned costs.
* If applicable, a summary of prior audit findings and a corrective action plan.

The data collection form (SF-SAC) and a copy of the Single Audit reporting package must be submitted electronically to the Federal Audit Clearinghouse (FAC) at: <https://facweb.census.gov/uploadpdf.aspx>.

1. Research and Development (R&D): All awards issued by or on behalf of ARPA-H meet the definition of “*Research and Development*” at 45 CFR subpart 75.2. 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. **Equipment and Products**:
3. To the greatest extent practical, all equipment and products purchased with HHS funds should be American made. 45 CFR subpart 75.2, *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 which equals or exceeds the lesser of the capitalization level established by the non-federal entity (NFE) for financial statement purposes, or $5,000*.” However, consistent with Recipient 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 organization's policy.
4. 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.
5. **Prohibition on a ByteDance-Covered Application:**
6. *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 U.S.C. 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

(ii) Of that equipment to a significant extent in the performance of a service or the furnishing of a product;

1. 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
2. Does not include any equipment acquired by a federal award Recipient incidental to a federal award.
3. *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 February 27, 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 Grants Management Officer provides written notification to the award Recipient that an exception has been granted in accordance with OMB Memorandum M-23-13.
4. *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.
5. **Required Disclosures OF RESPONSIBILITY/QUALIFICATIONS WITHIN SAM.GOV.**
6. Consistent with 45 CFR §75.113, Award Applicants and Recipients must disclose in a timely manner, in writing to ARPA-H, 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 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 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

(Include “Mandatory Grant Disclosures” in the subject line); or e-mail: [MandatoryGranteeDisclosures@oig.hhs.gov](mailto:MandatoryGranteeDisclosures@oig.hhs.gov)

1. Recipients must include this mandatory disclosure requirement in all sub-awards and subcontracts under this award. Failure to make required disclosures can result in any of the remedies described in 45 CFR §75.371, *Remedies for non-compliance* (at <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFRb1309e6966399c7/section-75.371>), 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 U.S.C. 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>.)
2. When an HHS awarding agency terminates a federal award prior to the end of the period of performance due to the NFE's material failure to comply with the federal award terms and conditions, the HHS awarding agency must report the termination to the OMB-designated integrity and performance system accessible through SAM.gov (formerly FAPIIS) (45 CFR §75.372(b)). 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 (45 CFR §75.373(b)).
3. 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 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.
4. **Fraud Waste, or Abuse**.
5. To report fraud, waste, or abuse to the HHS, contact the Inspector General’s Hotline by any of the following means:

Toll-free number:

1-800-HHS-TIPS [1-800-447-8477], 8:00 a.m. to 5:30 p.m. (Eastern), Mondays through Fridays)

Telefacsimile (Fax): 1-800-223-8165 (10 pages or fewer, please)

Tele-Typewriter (TTY): 1-800-377-4950

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 Grants Policy Statement, 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 administer this project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, or age, and that comply with applicable conscience protections. The Recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws require taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by the HHS. See

<https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and

<https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

• For guidance on meeting the Recipient’s legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see:

<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html>

and <https://www.lep.gov/>.

• For information on the Recipient’s specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see:

<https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html>

• HHS funded health and education programs must be administered in an environment free of sexual harassment, see

<https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.

• For guidance on administering projects in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see

<https://www.hhs.gov/conscience/conscience-protections/index.html>

and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

1. **ACKNOWLEDGEMENT OF FEDERAL FUNDING**
2. 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](mailto:media@arpa-h.gov) at least 30 days in advance 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>.

1. **Trafficking in persons**.
2. Provisions applicable to a Recipient that is a private entity.
3. You as the Recipient, your employees, subrecipients under this award, and subrecipients' employees may not—
4. Engage in severe forms of trafficking in persons during the period of time that the award is in effect;
5. Procure a commercial sex act during the period of time that the award is in effect; or
6. Use forced labor in the performance of the award or sub-awards under the award.
7. We as the federal awarding agency may unilaterally terminate this award, without penalty, if you or a subrecipient that is a private entity —
8. Is determined to have violated a prohibition in paragraph (a)(1) of this award term; or
9. Has an employee who is determined by the agency official authorized to terminate the award to have violated a prohibition in paragraph (a)(1) of this award term through conduct that is either—
10. Associated with performance under this award; or
11. Imputed to you 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 45 CFR §75.213, *Suspension and Debarment*.
12. Provision applicable to a recipient other than a private entity. We, as the federal awarding agency, may unilaterally terminate this award, without penalty, if a subrecipient that is a private entity—
13. Is determined to have violated an applicable prohibition in paragraph (a)(1) of this award term; or
14. Has an employee who is determined by the agency official authorized to terminate the award to have violated an applicable prohibition in paragraph (a)(1) of this award term through conduct that is either—
15. Associated with performance under this award; or
16. 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 45 CFR §75.213, *Suspension and Debarment*.
17. Provisions applicable to any recipient.
18. You must inform us immediately of any information you receive from any source alleging a violation of a prohibition in paragraph (a)(1) of this award term.
19. Our right to terminate unilaterally that is described in paragraph (a)(2) or (b) of this section:
20. Implements section 106(g) of the *Trafficking Victims Protection Act of 2000 (TVPA)*, as amended (22 U.S.C. 7104(g)), and
21. Is in addition to all other remedies for non-compliance that are available to us under this award.
22. You must include the requirements of paragraph (a)(1) of this award term in any sub-award you make to a private entity.
23. Definitions. For purposes of this award term:
24. “*Employee*” means either:
25. An individual employed by you or a subrecipient who is engaged in the performance of the project or program under this award; or
26. Another person engaged in the performance of the project or program under this award and not compensated by you 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 or matching requirements.
27. “*Forced labor*” means labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.
28. “*Private entity*:”
29. Means any entity other than a State, local government, Indian tribe, or foreign public entity, as those terms are defined in 2 CFR 175.25.
30. Includes:
31. A non-profit organization, including any non-profit institution of higher education, hospital, or tribal organization other than one included in the definition of Indian tribe at 2 CFR 175.25(b).
32. A for-profit organization.
33. “*Severe forms of trafficking in persons*,” “*commercial sex act*,” and “*coercion*” have the meanings given at section 103 of the TVPA, as amended (22 U.S.C. 7102).
34. **Text Messaging While Driving by Government Contractors, Subcontractors, and Recipients and Subrecipients**.
35. 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>).
36. 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.

**SECTION III – ARPA-H SPECIFIC TERMS AND CONDITIONS**

By signing and returning this document, which is based on the Recipient’s application (or submission), dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_@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

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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

[position] \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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

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

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

Total 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 awarding agency that continued funding of the award is in the best interest of the government.

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* + - * 1. **PAYMENT OFFICE POC INFORMATION**. The Payment Office telephone number, e-mail address, URL, and geographic location are:

Telephone Number: 1-877-614-5533

E-Mail Address pmssupport@psc.hhs.gov

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

Geographic Location: District of Columbia

* + - * 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:

• Establishing the Recipient’s organizational structure and operational framework for this project.

• Recommending changes in Recipient effort or replacement of personnel assigned to key positions on this project (which may include the PI/PD).

• Assisting the Recipient to establish, review, and update priorities for activities conducted under this Cooperative Agreement.

• Identifying other organizations with which the Recipient may be asked to develop cooperative and collaborative relationships and partnerships.

• Collaborating on the development of measures, methods, and materials to be tested or used.

• Collaborating to disseminate project findings and lessons learned during the period of performance.

* + - * 1. **PRIOR APPROVAL AND EXPANDED AUTHORITIES**.

(a) All requests requiring prior approval must bear the signature (or electronic authorization) of the Recipient’s AOR 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;

• 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

Does [ ]

Does not [ ]

allow the Recipient to exercise expanded authorities. Expanded Authorities are defined at Exhibit 6 of the GPS, and include:

• Carryover of unobligated balances from one budget period to the next;

• Cost-related prior approvals for direct-cost items;

• No-cost extensions;

• Pre-award costs; and

• Transfer of performance of a substantive programmatic work to a third-party by sub-award or a contract under the Cooperative Agreement.

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 on the basis of 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 in excess of the rate identified by the Office of Personnel Management for Executive Level II positions. Nor may the proposed, and later negotiated, salaries escalate in excess of that Executive Level II rate for the purposes 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. **military recruiting and higher educations (10 U.S.C. 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**.

(a) Domestic recipients who 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.

1. Foreign Organizations and International Organizations who conduct research involving select agents (see 42 CFR Part 73 for the select agent list; and 7 CFR Part 331 and 9 CFR Part 121 for the relevant animal and plant pathogens) must provide information satisfactory to 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.
2. 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 now, 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 (Supplemental Information)**

(a)Under governing regulations, federal funds administered by the HHS shall not be expended for research involving human subjects, and individuals shall not be enrolled in such research without prior approval from the Office for Human Research Protection (OHRP) of an assurance that the Recipient will comply with the requirements of 45 CFR Part 46 to protect human research subjects. Whenever a Recipient receives funding from an HHS agency to support such research, the Recipient bears the ultimate responsibility for protecting human subjects under the award. Compliance for all performance sites must be ensured by the Recipient.

(b) All Recipients of ARPA-H cooperative agreements, and any related performance sites that are engaged in research involving human subjects, must:

(1) Obtain a federal-wide Assurance (FWA) of Protection for Human Subjects from the OHRP.

(2) Obtain initial and continuing approval of the research by an appropriately constituted and registered Institutional Review Board (IRB), and

(3) Submit documentation that all senior/key personnel involved in human subject research have received training in the protection of human subjects.

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

1. **CERTIFICATES OF CONFIDENTIALITY (CoCs) (Supplemental Information)**

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, and, subject to ARPA-H review and approval, a certificate may be issued pursuant to Section 301(d) of 42 U.S.C. 241.

1. **ANIMAL WELFARE (SUPPLEMENTAL INFORMATION)**

Information about preparing and submitting Animal Welfare Assurances and copies of the Public Health Service (PHS) policy and other relevant materials are available from OLAW at: <https://olaw.nih.gov/home.htm>.

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

1. **Data Management SHARING Plan**. For projects that involve the collection or generation of data, ARPA-H requires Recipients who 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 its 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 the human subjects, their inclusion enrollment, and clinical trial information into one place. 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 PO 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 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 required by the ARPA-H PO will participate in a progress meeting with ARPA-H to report on the project’s progress; this meeting will be in lieu of the monthly technical progress meeting. The location of this meeting will be communicated by and coordinated with the PO far enough in advance to allow for sufficient travel planning. If the meeting will be held in-person, project personnel are expected to attend unless there are extenuating circumstances. 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)**.** The Research Performance Progress 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. The Recipient’s RPPR must comply with the guidance in [45 CFR Part 75.342(b)(1)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFR235b0b854924ea0/section-75.342). (There is no RPPR form available for download. Data is submitted by the Recipient online through eRA at the following link:

<https://public.era.nih.gov/commonsplus/public/login.era?TARGET=https%3A%2F%2Fpublic.era.nih.gov%3A443%2Fcommons>.

1. **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 at the following web link:

<https://public.era.nih.gov/commonsplus/public/login.era?TARGET=https%3A%2F%2Fpublic.era.nih.gov%3A443%2Fcommons>. Except for the submittal time, the Final RPPR must comply with the guidance in [45 CFR Part 75.342(b)(1)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFR235b0b854924ea0/section-75.342).

**REPORTING REQUIREMENTS – FINANCIAL**

1. Monthly Financial Review:
2. On a monthly basis, the Recipient must submit a financial report (including costs reconciling the drawdowns) for the reporting period and cumulative costs). Costs must be broken down by major cost categories (e.g., salaries & benefits, equipment, subrecipient cost, travel, materials and supplies, and indirect cost). The report will be due within 30 days after the end of the reporting period. The report must also include the federal award number, project title, PI/PD name, budget dates, and reporting period dates.
3. All payments are considered provisional and are subject to adjustment within the total costs awarded if an adjustment is deemed necessary upon review of any financial reports submitted by the Recipient.
4. Federal Financial Report (FFR)(SF425). At a minimum, Recipients must submit the annual FFR via PMS by no later than 90 days after each 12-month budget period (or incremental period) and the Final FFR no later than 120 days after the end of the project period. The form may be accessed at: <https://apply07.grants.gov/apply/forms/sample/SF425-V1.0.pdf>. Additional guidance on submission of Federal Financial Reports can be found at <https://pms.psc.gov/grant-recipients/ffr-updates.html>.
5. **Reporting FACILITIES AND ADMINISTRATIVE (F&A) Costs by Category**.Concurrent with submittal of the Final RPPR, the Recipient must provide the Grants Officer with a report of the award’s indirect Facilities and Administrative (F&A) 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 $750,000 or greater, this data may be acquired from the financial audit performed in accordance with 45 CFR part 75, subpart F.
6. **FUNDS EXPIRATION**. All federal agencies are required by 31 U.S.C. §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 disbursements on its Federal Financial Report (FFR)(SF425) no later than August 31st of the fifth fiscal year after the year of availability.

**RESTRICTIONS AND ADDITIONAL SPECIAL AWARD CONDITIONS**

As applicable

1. ADDITIONAL AWARD CONDITIONS
2. RESTRICTIONS

**TECHNICAL, MILESTONES, AND DELIVERABLES**

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

ACRONYMS

ACH Automated Clearing House

AOR Authorized Organizational Representative

ARPA-H Advanced Research Projects Agency for Health

AWA Animal Welfare Assurance

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

F&A Facilities and 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

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

SF Standard Form

UEI Uniform Entity Identifier

U.S.C United States Code

USDA United States Department of Agriculture