SCALABLE SOLUTIONS OFFICE

OFFICE-WIDE INNOVATIVE SOLUTIONS OPENING FOR

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

ARPA-H-SOL-24-105

March 14, 2024

Amendment 1: September 25, 2024

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1.0 Innovative Solutions Opening Solicitation Overview Information

FEDERAL AGENCY NAME:	Advanced Research Projects Agency for Health (ARPA-H)
SOLICITATION TITLE:	ARPA-H SCALABLE SOLUTIONS OFFICE INNOVATIVE SOLUTIONS OPENING (ISO)
SOLICITATION NUMBER:	ARPA-H-SOL-24-105
ASSISTANCE LISTING NUMBER:	93.384
ISO CONTACT:	E-mail: ARPA-H SSO ISO@arpa-h.gov ATTN: ARPA-H-SOL-24-105
SOLUTION SUMMARY SUBMISSION SITE:	https://solutions.arpa-h.gov
PROPOSAL SUBMISSION SITE:	https://solutions.arpa-h.gov/Submit-Proposal/
QUESTIONS:	https://solutions.arpa-h.gov/Ask-A-Question/
DATES: (All times listed herein are Eastern Time)	
DRAFT Release Date:	*28 February 2024*
Release Date:	*14 March 2024*
Amendment 01 Release Date:	*25 September 2024*
Questions & Answers (Q&A) due date:	Questions may be asked at any time while this solicitation is open.
Closing Date:	The solicitation will remain open until March 3, 2029.
ANTICIPATED AWARD:	Multiple awards are anticipated.
TYPES OF INSTRUMENTS THAT MAY BE AWARDED:	Other Transactions (OTs) and Cooperative Agreements
PROPOSERS/ELIGIBLE ENTITIES:	Universities, Non-Profit Organizations, Small Businesses, and Other than Small Businesses
COST SHARING:	Cost sharing may be encouraged or requested.

2.0 DESCRIPTION OF THE SOLICITATION:

2.1 INTRODUCTION

This ISO seeks solution summaries and proposals for projects that fall within the general scope of the ARPA-H Scalable Solutions mission office. SSO expands what is technically possible by developing approaches that will leverage an interdisciplinary approach and collaborative networks to address challenges of geography, distribution, manufacturing, data and information, thereby improving health care access and affordability. In the United States, many communities and remote areas lack access to timely and quality health care, which leads to disparities in health outcomes for those populations. Bottlenecks during the manufacturing processes of products and health technologies also lead to delays and limited availability, preventing effective distribution of health care solutions to areas of need, especially in emergencies.

ARPA-H SSO seeks solutions to improve the scalability and affordability of health care solutions, bridge gaps in underserved areas, and extend remote access to expertise by developing location-specific interventions, telemedicine solutions, and mobile health clinics. Solutions should focus on rapid innovation and the use of partnerships, as well as flexible distribution networks and streamlined manufacturing processes. The following SSO interest areas categorize the ground-breaking solutions we seek to support:

Scalable Technologies and Interventions:

- Approaches to improve affordability and equitable access to health care that are adaptable to various geographic, demographic, economic contexts and can be rapidly deployed at scale (e.g., drug-repurposing*, telemedicine, point-of-care diagnostics, and modular health care infrastructure).
- Tailored solutions for the pediatric population that provide parity in access to treatments and other health care interventions with the adult population and adapt to the pediatric patient's changing physiology and developmental status over the course of years.
- Transformational approaches to reduce or eliminate health disparities, including tools and models for product design and care delivery that scale novel approaches in human factors and human-centered design to respond to full diversity of patients.
- Tools to enable the scaling of provider and institutional capabilities (e.g., school nurses and schools, walk-in clinics, homesteading care) to address unmet health care access needs and expand availability of critical services.
- Foundational capabilities to accelerate diagnoses and reduce the cost of treatments for rare diseases wherever patients are, without the need for specialized facilities or healthcare expertise.

* Solution summaries and proposals that focus on testing drugs for effectiveness for other disease states or use cases, are unlikely to be funded unless including additional R&D, or providing gains in cost reduction, accessibility, and/or equity.

Collaborative Distribution Networks:

- Methods for standardization, automation, and democratization of complex procedures
  including, but not limited to, histopathology, rare disease diagnosis and treatment, and surgical interventions to ensure access and delivery to populations diverse in demographics, geographies, and resources at scale.
- Approaches to enhance delivery of effective healthcare solutions in rural or low resource settings, including but not limited to "last mile delivery", at-home monitoring, imaging, drug delivery, telehealth augmentation, and support for remote medical procedures with limited need for specialized training.
- Technologies to enable the deployment of critical healthcare resources rapidly, equitably, and securely at scale to the point of need in permissive and non-permissive (i.e., damaged infrastructure, cyber-denied) environments during a public health crisis or natural disaster.
- Solutions to scale education and training of critical healthcare resources for health care providers and patients to ensure information integrity to prevent negative impacts to resource use/uptake.
- Innovative information technology, data and analytic products and technologies to enable ordering, inventory management, situational awareness, allocation planning and demand forecasting of critical healthcare resources during a public health crisis or natural disaster.

Biomanufacturing Innovations*:

- Innovative manufacturing technologies and approaches that reduce cost, shorten the timeline for production, advance domestic competitiveness and reduce supply chain risk of biologics, cellular and gene therapies, pharmaceuticals, medical devices and personal protective equipment.
- New approaches to support predictable, programable biological production of conventional and novel materials reliability at scale in a cost-effective sustainable manner.
- Novel solutions to reduce the reliance on specialized handling and cold chain management of pharmaceuticals and biologics.
- Scalable innovations to advance and strengthen biomanufacturing supply chain and resolve bottlenecks including:
    - Advances in production of active pharmaceutical ingredients, process consumables, and other critical materials (i.e., enzymes, cell lines, etc);
    - Novel biomanufacturing-related data products, technologies or models to integrate into supply chain situational awareness systems;
    - Alternative materials and new manufacturing capabilities for personal protective equipment; and
    - Improvement of capabilities sustainably re-shore manufacturing and utilize a broad array of readily accessible and cost-efficient feedstocks as part of strengthening the local and national industry base.

- Analytics and novel sensor systems to precisely manage bioproduction, real-time release assays, and predictive capabilities to inform tuning of biological chassis for efficient and effective scale-up of manufacturing to industrial scale.

*ARPA-H is not interested in approaches that merely increase capacity reservation.

Other high-quality submissions that propose revolutionary technologies that meet the goals of SSO will be considered even if they do not address the topics listed above.

Proposals are expected to use innovative approaches to enable revolutionary advances in medicine and healthcare, and the science and technology underlying these areas. While approaches that are disease agnostic are encouraged, ARPA-H welcomes proposals that bring radically new insights to address specific diseases including, but not limited to, cancer, diabetes, neurological diseases, pediatric and maternal/fetal health, infectious diseases, and cardiovascular disease.

Specifically excluded are proposals that represent an evolutionary or incremental advance in the current state of the art or technology that has reached the clinical trial stage. An example of this type of proposal might include the request to fund clinical trials of an otherwise developed product. Additionally, proposals directed towards policy changes, traditional education and training, or center coordination, formation, or development, and construction of physical infrastructure are outside the scope of the ARPA-H mission.

2.2 ACQUISITION STRATEGY

ARPA-H is an R&D government agency tasked with accelerating better health outcomes for everyone by supporting the development of high-impact solutions to society's most challenging health problems. ARPA-H primarily follows a program-model structure where Program Managers (PMs) bring a well-defined problem to the agency. That problem is technically challenged and vetted before it becomes an ARPA-H program and is subsequently solicited to the public for solutions.

While the model has proven to be successful, R&D communities such as ARPA-H recognize the need for a mechanism to receive novel ideas that may fit into a program of record. As such, this ISO affords the public the ability to submit novel ideas that fit within SSO interest areas and advance high-potential, high-impact

biomedical and health research that cannot be readily accomplished through traditional research or commercial activities, ensuring ARPA-H will tackle the hardest health challenges and the highest-impact projects and programs.

ARPA-H is moving from an agency-wide Broad Agency Announcement (BAA), specifically the Open-Office BAA (75N99223S0001), to individual Office-wide solicitations. The SSO Office-wide ISO is just one of several Office solicitations. This ISO targets areas of interest, requests submission of solution summaries and/or proposals, and contains instructions informing industry how to properly submit a responsive solution summary and/or proposal. Further, ARPA-H will leverage its broad acquisition authorities to create a fair and efficient process to solicit, evaluate, and select revolutionary ideas to achieve better health outcomes for all Americans. This ISO will award Other Transactions and Cooperative Agreements; therefore, the Federal Acquisition Regulation (FAR) is not applicable to this solicitation nor subsequent awards. Rather, this solicitation and subsequent awards will be made in accordance with 42 U.S.C. § 290c(g)(1)(D) for the award of Other Transactions and 2 CFR 200, 45 CFR 75, and HHS Grants Policy Statement for the award of Cooperative Agreements.

This ISO is targeting universities, non-profit organizations, small businesses and other-than small businesses, hospitals, community health centers and non-federal research centers capable of performing research and/or development of SSO interest areas.

This ISO requires a potential Proposer to first submit a solution summary prior to submission of a full proposal for ARPA-H to review the idea for novelty and applicability to SSO.

2.3 SOLICITATION PROCEDURES

This ISO will be solicited through ARPA-H ISO external facing (public) website, SAM.gov and Grants.gov. See Section 4 for solution summary and proposal preparation and submission information.

2.4 AWARD INFORMATION

Multiple awards are anticipated under this ISO; however, the number of awards selected will depend on the quality of the proposals received and the availability of funds.

The government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this ISO. If warranted, portions of resulting awards may be segregated into options. If the government desires to

award only portions of a proposal, negotiations will commence upon selection notification. The government reserves the right to fund proposals in phases with options for continued work, as applicable.

The government reserves the right to request any documentation deemed necessary to support the negotiation and award process. The government also reserves the right to remove a proposal from award consideration should the parties fail to reach an agreement on award terms and conditions, cost, and/or if the Proposer fails to provide requested additional information in a timely manner.

In all cases, the government Agreements Officer (AO) shall have sole discretion to select the award type, regardless of the type proposed. This ISO has two (2) attachment bundles that will contain both proposal submission templates and Model Agreements (Other Transaction and Cooperative Agreement) with basic terms and conditions. The Proposer may submit red-line edits to the basic terms and conditions of the selected instrument; however, the government AO shall have sole discretion regarding acceptance of any red-line edits.

> NOTE: Other Transactions allow for greater flexibility in negotiation of terms and conditions than Cooperative Agreements or FAR-based contracts.

ARPA-H will require a Performer to undergo pre-publication reviews if it is determined that the research resulting from the proposed effort will present a high likelihood of disclosing sensitive information, such as Personally Identifiable Information (PII), Protected Health Information (PHI), financial records, proprietary data, or information marked Sensitive but Unclassified (SBU) or Controlled Unclassified Information (CUI), etc. Any award resulting from such a determination will include a requirement for receipt of ARPA-H permission before publication of any information regarding or results from the effort.

3.0 ELIGIBILITY INFORMATION

3.1 ELIGIBLE Proposers

All responsible sources capable of satisfying the government's needs may submit a solution summary and proposal to this ISO.

3.2 PROHIBITION OF PERFORMER PARTICIPATION FROM FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS (FFRDCS) AND GOVERNMENT ENTITIES

ARPA-H is primarily interested in responses to this solicitation from commercial

performers, academia, non-profit organizations, etc. In certain circumstances, FFRDCs and government entities will have unique capabilities that are not available to proposing teams through any other resource. Accordingly, the following principles will apply to this solicitation.

(a) FFRDCs and government entities, including federal government employees, are not permitted to respond to this solicitation as a prime or subperformer on a proposed Performer team.

(b) If an FFRDC or government entity has a unique research idea that is within the technology scope of this solicitation that it would like considered for funding, submit research description to this e-mail address: ARPA-H SSO ISO@arpa-h.gov.

(c) If an FFRDC or government entity, including a federal government employee, is interested in working directly with the government team supporting the research described by this solicitation, that party should contact the ARPA-H SSO ISO@arpa-h.gov.

(d) If a potential prime Performer believes that an FFRDC has a unique capability without which its solution is unachievable, the potential prime Performer should be aware that it will have to provide documentation as part of its proposal submittal showing that it has exhausted all other options for ARPA-H to consider the inclusion of the FFRDC in the proposed solution.

3.3 CURRENT PROFESSIONAL SUPPORT

Those individuals/entities currently providing contracted support services[1] to ARPA-H have an organizational conflict of interest (OCI) that cannot be mitigated, and thus are ineligible for award.

3.4 NON-U.S. ORGANIZATIONS

ARPA-H will prioritize awards to entities (organization and/or individuals) that will conduct funded work in the United States. However, non-U.S. entities may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. In accordance with these laws and regulations, in no case will awards be made to entities organized under the laws of a covered foreign country [as defined in section 119C of the National

[1] Support services are defined as contracted support providing technical, professional, financial expertise, and/or administrative assistance and may have access to internal and privileged information.

Security Act of 1947 (50 U.S.C. Ch 44 § 3059)]; a foreign entity of concern meeting any of the criteria in section 10638(3) of the CHIPS and Science Act of 2022; [an individual that is party to a malign foreign talent recruitment program, as defined in Section 10638(4) of the CHIPS and Science Act of 2022; or entities suspended or debarred from business with the government.

3.5 AWARD LIMITATIONS

While there is statutory language that may suggest ARPA-H is limited in the number of awards it may make to one entity, there are circumstances in which ARPA-H may make more than three awards to an organization entity. ARPA-H encourages organizations to submit their research ideas notwithstanding this perceived limitation. Any proposal received will be fairly considered for award and, if it is of interest to ARPA-H, may be selected for an award.

4.0 SOLUTION SUMMARY AND PROPOSAL PREPARATION AND SUBMISSION INFORMATION

4.1 SOLUTION SUMMARY PREPARATION

Submission of a solution summary is a mechanism for potential Proposers to get feedback prior to investing resources for a full proposal submission. The solution summary is a method to allow a proposer to present their solution in an efficient format to ensure that a proposer does not expend substantial resources submitting a full proposal for a solution that does not fit ARPA-H's mission. Submission of a solution summary is mandatory prior to submission of a full proposal.

4.2 SOLUTION SUMMARY SUBMISSIONS

All solution summary submissions must be written in English and must comply with the content and formatting requirements in Appendix A. Proposers are strongly encouraged to use the template(s) provided. Information not explicitly requested in this ISO or Appendix A may not be reviewed.

Solution summary submissions must be submitted to: https://solutions.arpa-h.gov

4.3 PROPOSAL PREPARATION INFORMATION

System for Award Management (SAM) Registration and Universal Identifier Requirements.

All proposers must be registered in SAM and have a valid Unique Entity ID (UEI) number for their proposal to be found conforming. Proposers must maintain an active registration in SAM.gov with current information at all times during which a proposal is under consideration or have a current award with ARPA-H.

Information on SAM.gov registration is available at SAM.gov.

NOTE: New registrations take an average of 7-10 business days to process in .

SAM.gov registration requires the following information:

- UEI number
- Tax Identification Number (TIN)
- Commercial and Government Entity Code (CAGE) Code. If the Proposer does not already have a CAGE code, one will be assigned during SAM registration.
- Electronic Funds Transfer information (e.g., the Proposer's bank account number, routing number, and bank telephone or fax number).

4.4 PROPOSAL SUBMISSION INFORMATION

A proposal submission must be submitted in English and must comply with the content and formatting requirements in the applicable *Bundle of Attachments*. Proposers should use the template(s) provided in the *Bundle of Attachments*. Information not explicitly requested in the *Bundle of Attachments* may not be evaluated. There is a Bundle of Attachments for Other Transactions and a Bundle of Attachments for Cooperative Agreements:

Other Transactions

1. Tech and Management Volume (20 pages)
2. Task Description Document (no page limit)
3. Cost Proposal (no page limit)
4. Cost Proposal Spreadsheet (fill in applicable tabs)
5. Administration & National Policy (no page limit)

Cooperative Agreements

1. Tech and Management Volume (20 pages)
2. Research Description Document (no page limit)
3. Cost Proposal (no page limit)
4. Cost Proposal Spreadsheet (fill in applicable tabs)
5. Administration & National Policy (no page limit)

The instructions and submission requirements are different for each award type. Please carefully read the attachments to ensure all required information is submitted.

Proposal submissions should be submitted to https://solutions.arpa-h.gov/Submit-Proposal/.

4.5 SOLUTION SUMMARY AND PROPOSAL SUBMISSION DEADLINES

A solution summary must be submitted prior to proposal submission. If encouraged, ARPA-H will request the Proposer submit a full proposal within 45 days from receiving ARPA-H solution summary feedback, unless an alternative timeline is provided.

4.6 PROPRIETARY INFORMATION

Proposers are responsible for clearly identifying proprietary information. Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as "*Proprietary*."

> NOTE: "*Confidential*" is a classification marking used to control the dissemination of U.S. government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

ARPA-H is responsible for handling submissions to the extent permitted under applicable federal law, including the Freedom of Information Act (FOIA).

5.0 SOLUTION SUMMARY REVIEW AND EVALUATION OF PROPOSALS

5.1 SOLUTION SUMMARY REVIEW PROCESS

ARPA-H will review eligible solution summaries and provide written feedback in accordance with the instruction stated in Section 4. At a minimum, feedback will encourage or discourage submission of a full proposal. Feedback will be sent to the administrative and technical points of contact noted on the solution summary cover page. ARPA-H strives to provide solution summary feedback within 30 business days of receipt of the solution summary.

> NOTE: Regardless of whether the Proposer is encouraged to submit a proposal in response to the ISO, it is eligible to do so. Solution summaries must be submitted in accordance with the requirements of Section 4.2; solution summary feedback must be received prior to submission of a proposal.

5.2 EVALUATION CRITERIA FOR AWARD

Proposals will be evaluated using the following evaluation criteria, listed in descending order of importance. Please note that although required to be submitted with the proposal, the Task Description Document for Other Transactions and the Research Description Document for Cooperative Agreements will not be evaluated as part of the proposal evaluation process.

1 CRITERION 1: OVERALL SCIENTIFIC AND TECHNICAL MERIT

The proposed technical approach is innovative, feasible, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible.

2 CRITERION 2: POTENTIAL CONTRIBUTION AND RELEVANCE TO THE ARPA-H MISSION

Potential future R&D, commercial, and/or clinical applications of the project proposed, including whether such applications may have the potential to address areas of currently unmet need within biomedicine and improve health outcomes. Degree to which the proposed project has the potential to transform biomedicine. Potential for the project to take an interdisciplinary approach. In addition, the evaluation may take into consideration the extent to which the proposed intellectual property (IP) rights structure and software components will potentially impact the ability to commercialize the technology and adhere to open-source solutions and/or standards.

3 CRITERION 3: PROPOSER'S CAPABILITIES AND/OR RELATED EXPERIENCE

The proposed technical team has the expertise and experience to accomplish the proposed tasks. The proposer's prior experience in similar efforts clearly demonstrates an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule. Similar efforts completed/ongoing by the proposer in this area are fully described, including identification of other government or commercial activities where they have led or participated.

4. CRITERION 4: Budget Risk Analysis

A budget risk analysis will be performed to assess costs proposed. This is separate from the price reasonableness/value analysis that will be performed prior to award. This analysis may consider the overall

affordability of the proposed project in context of the ARPA-H mission. The analysis may also address discrepancies between the work proposed and the proposed cost for the project (e.g., costs that evince a lack of understanding of necessary resources) and innovative budget approaches that maximize project success.

NOTE: Proposers are encouraged to propose the best technical solution. For example, proposers are discouraged from proposing low-risk ideas with minimum uncertainty or to staff the proposed effort with junior personnel to be more appealing from a budget perspective. ARPA-H seeks novel solutions that are reflective of the level of effort and risk proposed.

5.3 REVIEW AND SELECTION PROCESS

It is the policy of ARPA-H to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed above and to select the source (or sources) whose proposal is determined to be the most technically advantageous to ARPA-H's mission objectives. ARPA-H will conduct a scientific and technical review of each conforming proposal. All proposal evaluations will be based solely on the evaluation criteria in Section 5.2.

NOTE: Proposals will not be evaluated against each other during the scientific technical review process, but rather evaluated on their own individual merit to determine how well the proposal meets the criteria stated in this ISO.

For the purposes of this proposal evaluation process, a selectable proposal is defined as follows:

- SELECTABLE: A selectable proposal is a proposal that is a conforming proposal that has been evaluated by the government against the evaluation criteria listed in this ISO, and the positive aspects of the overall proposal outweigh its negative aspects.

For the purposes of this proposal evaluation process, a non-selectable proposal is defined as follows:

- NON-SELECTABLE: A proposal is considered non-selectable when the proposal has been evaluated by the government against the evaluation criteria listed in this ISO, and the positive aspects of the overall proposal do not outweigh its negative aspects.

CONFORMING PROPOSALS: Conforming proposals contain all requirements and fall within the scope detailed in this ISO. The same proposal, with only minor modifications, may not be submitted to multiple ISOs. Proposals that are more appropriate for a different mission office ISO than the ISO submitted may be referred to more appropriate ISOs. Proposals that fail to include required information may be deemed non-conforming and may be removed from consideration. Non-conforming submissions may be rejected without further review. A proposal may be deemed non-conforming under this ISO if the proposal fails to meet any of the following solicitation requirements:

- The proposed concept is applicable to the SSO interest areas.
- The proposers meet the eligibility requirements.
- The proposal met the submission requirements.
- The proposal met the content and formatting requirements in the attached bundle of attachments.
- The proposer's concept has not already received funding or been selected for award negotiations for another funding opportunity (whether from ARPA-H or another government agency)

Non-conforming proposals may be removed from consideration. Proposers will be notified of non-conforming determinations via email correspondence.

Please note that ARPA-H reserves the right, at its discretion, to reject as non-conforming proposals that it determines are duplicative of previously submitted solution summaries and proposals under this or other ARPA-H solicitations.

ARPA-H's intent is to review proposals as soon as possible after they arrive and strives to respond to proposers within sixty (60) days after receipt of proposal.

5.4 NOTICES

The following notices will be provided as applicable:

- Request for clarifying details (if applicable)
  - ❖ May occur at any time during the evaluation process.
  - ❖ Will not include requests for proposal changes and changes will not be permitted.
- Notice of non-selection
  - ❖ The Proposer will be advised their proposal submission has not been selected.
- Notice of selection
  - ❖ The selection notice will notify the proposer that the government has selected their proposal for negotiation of potential award. This notification may indicate that only a part

of the effort has been selected for negotiation, and may request a revised proposal for only those selected portions, if not apparent through the delineation of proposed tasks

Notices will be sent via email to the Technical and Administrative point of contacts identified in the proposal.

5.5 HANDLING OF COMPETITION SENSITIVE INFORMATION

It is the intent of ARPA-H to protect all proposals as competitive sensitive information and to disclose their contents only for the purpose of evaluation, and only to screened personnel for authorized reasons, to the extent permitted under applicable laws, including FOIA. Restrictive notices notwithstanding, submissions may be handled by ARPA-H support contractors during the evaluation process for administrative purposes and/or to assist with technical evaluation.

ARPA-H support contractors are expressly prohibited from performing ARPA-H-sponsored technical research and are bound by appropriate non-disclosure agreements. Input on technical aspects of a proposal may be solicited by ARPA-H from non-government consultants/experts who are strictly bound by appropriate non-disclosure requirements. No submissions will be returned.

6.0 AWARD ADMINISTRATION INFORMATION

6.1 ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

CONTROLLED UNCLASSIFIED INFORMATION (CUI) ON NON-FEDERAL INFORMATION SYSTEMS

Information on Controlled Unclassified Information (CUI) identification, marking, protection, and control is incorporated herein and can be found at 32 CFR § 2002.

INTELLECTUAL PROPERTY

The Proposer must provide a good faith representation that it either owns or possesses the appropriate licensing rights to all intellectual property (IP) that will be utilized for the proposed effort. ARPA-H strongly encourages IP rights to be aligned with open-source regimes. Further, it is desired that all software (including source code), software documentation, and data generated and/or developed under the proposed project be provided as a deliverable to the government. IP delivered to the government should align with the project or program goals and should be aligned with the level of government funding

provided to generate and/or develop the IP.

NOTE: IP rights assertions will be reviewed under evaluation Criterion 2 as stated in Section 5.2.2.

SOFTWARE COMPONENT STANDARDS

The health- and healthcare data eco-system is complex and multi-dimensional with a variety of standards for data models, data transmission protocols, data routing methods, etc. that are similar to and extend the International Standards Organization (ISO) Open Systems Interconnection Model (OSI)[2]. ARPA-H programs are likely to involve research that touches on multiple layers of the OSI model, from low-level radio frequency (RF) based protocols for transmission of data from implantable devices (potentially OSI layers 1-5), to secure and fault tolerant networking protocols for medical devices (potentially OSI layers 3-6), to the exchange of health information including Electronic Health Records, lab results, and medical images related to a patient between healthcare facilities and health data brokers, including (but not limited to) Health Information Exchanges (HIE) and Trusted Exchange Framework and Common Agreement (TEFCA) Qualified Health Information Networks using protocols such as HL7 FHIR (Fast Healthcare Interoperability Resources, OSI Layer 7). This diversity requires careful consideration of the most appropriate standards to be used for the specific technologies in development and the layer at which they operate.

ARPA-H is committed to advancing interoperability in today's health ecosystem through the adoption of open, consensus-driven standards and laying the foundation for emerging technologies to interoperate in the health ecosystem of the future through the evolution of these standards across all layers of the health data information technology (IT) eco-system. With that in mind, we anticipate that the Performer will develop software and data communication components that fall into three categories:

(1) components that can leverage today's existing standards without impeding the R&D,
(2) components where extensions to existing standards will be necessary to unlock new capabilities in an interoperable way, and
(3) components in areas where consensus-based standards

[2] ISO/IEC 7498 https://www.iso.org/standard/20269.html

do not yet exist or where use of standards would seriously limit the ability to efficiently conduct R&D.

Whenever such an existing standard is available that meets the scientific, technical, and research needs of the proposed effort, proposers must use the existing standard instead of creating their own. In cases where an existing standard provides only partial functionality, proposers should expand upon the existing standard, ideally in a way that does not prohibit or interfere with backward compatibility, and create sufficient documentation for the Office of the National Coordinator for Health Information Technology (ONC), and the U.S. Department of Health and Human Services (HHS) agencies or standards organizations, to evaluate extensions for potential inclusion in the standard (including open Application Programming Interfaces (APIs) and open data formats).

In the case of information relating to health- and healthcare data at higher layers of the OSI model, all health IT components should adhere to or (as needed) expand upon applicable national standards adopted by HHS, including the ONC (e.g., Fast Healthcare Interoperability Resources (FHIR) and United States Core Data for Interoperability (USCDI)).[3]

Technical solutions that contain software elements, commercial-friendly open-source licenses (e.g., MIT, BSD, or Apache 2.0) are preferred. If an open, consensus-based standard does not yet exist, the Proposer should identify the aspects that lack an open standard, describe a plan to develop a general-purpose open data model and to prototype new open APIs. A strong proposal will explain how the Performer will enhance data interoperability (including semantic interoperability) and expand the availability of open, consensus-based standards and data models.

A proposal must include a technical plan to align with applicable standards based on the OSI layer at which they are operating including (but not limited to) HHS-adopted health IT standards (45 CFR Part 170 Subpart B). For the full description of standards adopted in CFR Part 170, Subpart B, please review the complete text of the regulations; a strong technical solution will also outline integration with the Trusted Exchange Framework and Common Agreement (TEFCA). Adhering to international standard ISO/IEEE 11073 will enable broad support for current and future devices, especially those developed internationally. At other layers of the

[3] https://www.healthit.gov/sites/default/files/page/202207/Standards_And_Implementation_Specifications_Adopted_Under_Section_3004.pdf

OSI model, and for software components operating outside the network stack (e.g., health databases, Picture Archiving and Communication Systems (PACS), etc.) other standards will be relevant, and strong technical solutions will seek to utilize or expand upon appropriate open, consensus-based standards[4].

If a technical solution requires an extension of existing standards or development of technologies outside of the standards, the Proposer must schedule a meeting with ARPA-H representatives prior to proposal submission to discuss the deviation to the standards.

GENOMIC DATA SHARING POLICY

If applicable, a resulting award will include the requirement to comply with NIH's Genomic Data Sharing (GDS) Policy (NOT-OD-14-124). Information about the GDS policy can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-157.html.

HUMAN SUBJECTS RESEARCH

A proposal for funding that will involve engagement in human subjects research (HSR)(as defined in 45 CFR § 46) must provide documentation of one or more current *Assurance(s) of Compliance* with federal regulations for human subjects' protection, including at least a Department of Health and Human Services (HHS), Office of Human Research Protection Federal Wide Assurance. All HSR must be reviewed and approved by an Institutional Review Board (IRB), as applicable under 45 CFR § 46 and/or 21 CFR § 56. The entity's HSR protocol must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. Recipients of ARPA-H funding must comply with all applicable laws, regulations, and policies for ARPA-H funded work. This includes, but is not limited to, laws, regulations, and policies regarding the conduct of HSR, such as the U.S. federal regulations protecting human subjects in research (e.g., 45 CFR § 46, 21 CFR § 50, § 56, § 312, § 812) and any other equivalent requirements of the applicable jurisdiction.

The informed consent document utilized in HSR funded by ARPA-H must comply with all applicable laws, regulations, and policies, including but

[4] Examples of such open, consensus-based standards include but are not limited to, the Digital Imaging and Communications in Medicine (DICOM) standard for medical image storage, the Global Alliance for Genomics and Health standards for storage of genomic data such as the Variant Call Format (VCF).

not limited to U.S. federal regulations protecting human subjects in research (45 CFR § 46, and, as applicable, 21 CFR § 50). The protocol package submitted to the IRB must contain evidence of completion of appropriate HSR training by all investigators and key personnel who will be involved in the design or conduct of the ARPA-H funded HSR. Funding cannot be used toward HSR until ALL approvals are granted.

ANIMAL SUBJECTS RESEARCH (ASR)

Award recipients performing research, experimentation, or testing involving the use of animals shall comply with the laws, regulations, and policies on animal acquisition, transport, care, handling, and use as outlined in:

- 9 CFR parts 1-4, U.S. Department of Agriculture rules that implement the Animal Welfare Act of 1966, as amended, (7 U.S.C. § 2131-2159); and

- the Public Health Service Policy on Humane Care and Use of Laboratory Animals, which incorporates the "*U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*," and "*Guide for the Care and Use of Laboratory Animals*" (8th Edition)."

The Proposer must complete and submit the Vertebrate Animal Section worksheet for all proposed research anticipating Animal Subject Research (ASR).

All ASR must undergo review and approval by the local Institutional Animal Care Use Committee (IACUC) prior to incurring any costs related to the animal use research.

ORGANIZATIONAL CONFLICTS OF INTEREST (OCI)

The Proposer, through submission of a proposal, is required to identify and disclose all facts relevant to a potential OCI involving the Proposer, its organization, and/or any proposed team member (proposed subawardee). Along with the disclosure, the Proposer shall submit a mitigation plan, which is a description of the action the Proposer has taken to avoid, neutralize, or mitigate the stated OCI. The government may require the Proposer to provide additional information to assist the government in evaluating the OCI mitigation plan.

If the government determines the Proposer failed to fully disclose an OCI;

or failed to provide the affirmation of ARPA-H support; or failed to reasonably provide additional information requested by the government to assist in evaluating the proposer's OCI mitigation plan, the government may reject the proposal and withdraw it from consideration for award.

AGENCY SUPPLEMENTAL OCI POLICY

ARPA-H restricts Performers from concurrently providing professional support services, including Advisory and Assistance Services or similar contracted support services, in addition to performing as an R&D technical Performer. Therefore, the Proposer must affirm whether it or any proposed team member (proposed subawardee, etc.) is providing professional support services to any ARPA-H office(s) under: (1) a current award or subaward; or (2) a past award or subaward that ended within one calendar year prior to the proposal's submission date.

If any professional support services are or were provided to any ARPA-H office(s), the proposal must include:

- The name of the ARPA-H office receiving the support,
- The prime contract number, and
- Identification of proposed team member (proposed subawardee) providing the support.

RESEARCH SECURITY DISCLOSURES

In accordance with NSPM-33, research organizations should identify and mitigate conflicts of commitment (COCs) and conflicts of interest (COIs) to receive federal funding. A research organization proposing to this ISO must provide additional documentation as requested for Senior/Key Personnel for ARPA-H to determine the existence of any risk. The format for this submission can be found in the Bundle of Attachments, *Administration and National Security*.

ELECTRONIC INVOICING AND PAYMENTS

The Performer will be required to register in, and submit invoices for payment through, the Payment Management Services (PMS) https://pms.psc.gov.

GOVERNMENT-FURNISHED PROPERTY/EQUIPMENT/INFORMATION

Government-furnished property/equipment/information may be provided to the Performer, depending on the award vehicle negotiated and applicable law(s) and/or regulation(s).

QUESTIONS & ANSWERS

All questions regarding this ISO should be submitted to https://solutions.arpa-h.gov/Ask-A-Question/. ARPA-H will post Q&As to the ARPA-H ISO Website on an on-going basis. ARPA-H will attempt to answer questions in a timely manner. ARPA-H highly encourages parties to review the Q&As prior to submitting a question.

APPENDIX A: SOLUTION SUMMARY TEMPLATE

SEE THE ISO ATTACHMENT.

APPENDIX B: ACRONYMS

AO	Agreements Officer
API	Application Programming Interface
ARPA-H	Advanced Research Projects Agency for Health
ASR	Animal Subjects Research
BAA	Broad Agency Announcement
BOE	Basis of Estimate
BSD	Berkley Software Distribution
CAGE	Commercial and Government Entity
CFR	Code of Federal Regulations
CH	Chapter
CHIPS	Creating Helpful Incentives to Produce Semiconductors"
COC	Conflict of Commitment
CP	Commercialization Plan
CUI	Controlled Unclassified Information
EHR	Electronic Health Record
FAR	Federal Acquisition Regulation (FAR)
FHIR	Fast Healthcare Interoperability Resources
FFRDC	Federally Funded Research and Development Centers
FOIA	Freedom of Information Act
GDS	Genomic Data Sharing
GO	Grants Officer
HBCU	Historically Black Colleges and Universities
HCP	Health Care Provider
HHS	Health and Human Services
HIE	Health Information Exchanges
HSR	Human Subjects Research
IACUC	Institutional Animal Care Use Committee
IP	Intellectual Property
IPDM	IP Development and Management (IPDM),
IPSF	Intellectual Property Success Framework (IPSF),
IEEE	Institute of Electrical and Electronics Engineers
ISO	Innovative Solutions Opening
ISO	International Standards Organization
IT	Information Technology
MI	Minority Institution
MIT	Massachusetts Institute of Technology
MOU	Memorandum of Understanding
NDA	Non-Disclosure Agreement
NSPM	National Security Presidential Memorandum
OCI	Organizational Conflict of Interest
ONC	Office of the National Coordinator for Health Information Technology
OSI	Open Systems Interconnection
OT	Other Transaction
PACS	Picture Archiving and Communication Systems
PHI	Protected Health Information
PII	Personally Identifiable Information

PM	Program Manager
PMS	Payment Management Services
Q&As	Questions and Answers
R&D	Research and Development
RF	Radio Frequency
SAM	System for Award Management
SBU	Sensitive but Unclassified
SSO	Scalable Solutions Office
TA	Technical Area
TEFCA	Trusted Exchange Framework and Common Agreement
TIN	Tax Identification Number
UEI	Unique Entity ID
U.S.	United States
U.S.C	United States Code
USCDI	United States Core Data for Interoperability