ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

SCALABLE SOLUTIONS OFFICE

MISSION OFFICE INNOVATIVE SOLUTIONS OPENING (ISO)

ARPA-H-SOL-24-105

Amendment 02: June 06, 2025

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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 Mission Office Innovative Solutions Opening (ISO)
SOLICITATION NUMBER:	ARPA-H-SOL-24-105
SOLUTION SUMMARY SUBMISSIONS (ARPA-H SOLUTION SUBMISSION PORTAL):	https://solutions.arpa-h.gov/Submit-Solution/
PROPOSAL SUBMISSIONS (ARPA-H SOLUTION SUBMISSION PORTAL):	https://solutions.arpa-h.gov/Submit-Proposal/
ISO QUESTIONS (ARPA-H SOLUTION SUBMISSION PORTAL):	https://solutions.arpa-h.gov/Ask-A-Question/
DATES/TIMES:	All times listed herein are Eastern Time
RELEASE AND AMENDMENT DATES:	Release: March 14, 2024 Amendment 01: September 25, 2024 Amendment 02: June 06, 2025
QUESTIONS & ANSWERS (Q&A) DUE DATE:	Questions may be asked while this solicitation is open
CLOSING DATE:	The solicitation will remain open until March 5, 2029
ANTICIPATED AWARD:	Multiple awards are anticipated
TYPES OF INSTRUMENTS THAT MAY BE AWARDED:	Other Transactions (OTs)
PROPOSERS/ELIGIBLE ENTITIES:	Academia, Non-Profit Organizations, and For-Profit Entities
RESOURCE SHARING:	Resource 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 Office (SSO). The SSO seeks to improve health care access and affordability through revolutionary technical innovations that address the challenges of geography, distribution, manufacturing, and data- and information management. Many communities and remote areas in the United States 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.

Funded SSO health innovation projects will improve the readiness of technologies and medical capabilities to be rapidly, broadly, and affordably adopted by patients, providers, and payers throughout the healthcare ecosystem and improve the patient experience. Manufacturing and supply chain focused SSO projects will lower the bar to entry for new developers, accelerate the rate of development, reduce development and product costs, and improve reliability and agility in manufacturing and product distribution.

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:

- Health Technologies and Interventions:

    - Approaches to improve affordability and access to health care that are adaptable to various geographic, demographic, economic contexts and can be rapidly and broadly deployed (e.g., drug-repurposing, point-of-care diagnostics, and modular health care infrastructure).
    - Tailored solutions that provide the pediatric population parity with the adult population with respect to access to treatments and other health care interventions, and that 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 leap-ahead technologies that scale novel approaches in human factors, and human-centered design to respond to full diversity of patients in varied geographic settings. Tools to enable expansion of capacities, capabilities, and reach of

individual and institutional healthcare providers (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 of rare diseases and reduce the cost and increase the availability rare disease treatments wherever patients are, without the need for specialized facilities or healthcare expertise.
- Novel materials and technologies to not only return autonomy to limited mobility and/or home bound patients.

NOTE: Solution summaries and proposals that focus on testing drugs for effectiveness for other disease states or use cases are unlikely to be funded unless they include additional research and development (R&D) or provide gains in cost reduction and accessibility.

➢ Advanced Technologies for Medical Product and Capability Distribution:

- Methods for standardization, automation, and broad distribution of complex procedures including, but not limited to, histopathology, rare disease diagnosis and treatment, and surgical interventions to ensure access and delivery to all populations.
- Technical approaches to enhance delivery of effective healthcare solutions, to include dentistry, in rural or low resource settings, including but not limited to "last mile delivery", at-home monitoring and diagnosis, 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 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.
- 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
  - Approaches that reduce costs; improve access; expedite production timelines; and strengthen domestic competitiveness for biologics, pharmaceuticals, medical devices and personal

protective equipment (PPE). These innovations aim to mitigate supply chain risks through:

- Novel solutions to minimize the reliance on cold chain management and specialized handling of pharmaceuticals and biologics.
- Scalable solutions to strengthen biomanufacturing supply chains, resolve bottlenecks, and enable domestic production, such as:
  - ❖ Improved production of active pharmaceutical ingredients, process consumables, and other critical materials (e.g., enzymes, cell lines, etc.).
  - ❖ Data-driven models to optimize bioprocessing, enhance process control, and bolster supply chain visibility.
  - ❖ Development of alternative materials and innovative methods for PPE manufacturing.
  - ❖ Improvement of capabilities to sustainably re-shore manufacturing and utilize readily accessible, cost-efficient feedstocks to strengthen the local and national industry bases.

- Predictable, programable biological production
  - Advanced analytical technologies designed to improve product knowledge, accelerate release, and/or significantly improve analytical figures of merit.
  - Novel sensor systems, process analytical technologies, and associated process models to precisely manage bioproduction management, including:
    - Process control and monitoring systems.
    - Real-time release assays for rapid product validation.
    - Predictive capabilities to inform process development and enable efficient and effective scale-up of manufacturing to industrial scale.

NOTE: ARPA-H is not interested in approaches that merely increase production capacity reservation. Other high-quality submissions that propose revolutionary technologies that meet the goals of the 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 technologies 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. Proposals may include innovative care models, business solutions and/or partnerships but must also contain substantial technical innovations.

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 a federal R&D agency tasked with accelerating better health outcomes for all Americans by supporting the development of high-impact solutions to society's most challenging health problems. ARPA-H primarily follows a program-model structure under which Program Managers bring a well-defined problem to the agency. That problem is technically challenged and vetted before it becomes an ARPA-H program that solicits the public for solutions.

While the program 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 not fit into a program of record. As such, through the issuance of this ISO, ARPA-H affords the public the ability to submit novel ideas that fit within the ISO's interest areas and that will advance high-potential and 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.

This SSO Mission Office ISO is one of several mission office solicitations that target areas of interest; each contains instructions informing industry how to properly submit a Solution Summary and/or proposal. ARPA-H leverages its broad acquisition authorities to create a fair and efficient process through which it solicits, evaluates, and selects revolutionary ideas to achieve better health outcomes for all Americans. This ISO will award Other Transactions (OTs); therefore, the Federal Acquisition Regulation (FAR) is not applicable to this solicitation nor its subsequent awards. Rather, this solicitation is issued under the authority of (and awards will be made in accordance with) 42 U.S.C. § 290c(g)(1)(D).

This ISO is targeting academia, non-profit organizations, for-profit entities, hospitals, community health centers, and non-federal research centers capable of performing research and/or development within the ISO interest areas.

This ISO requires each Proposer to submit a Solution Summary and receive written feedback from ARPA-H before submitting a proposal; ARPA-H will review each idea for its novelty and applicability to SSO. ARPA-H will not reimburse Proposers for Solution Summary- or proposal submission-related costs.

2.3 SOLICITATION PROCEDURES

ARPA-H will solicit Solution Summaries and proposals in response to this ISO through ARPA-H's public website, SAM.gov, and other forums as appropriate. (See Section 4.0, *Solution Summary and Proposal Preparation and Submission Information*, which discusses submission of a Solution Summary and a proposal.)

2.4 AWARD INFORMATION

ARPA-H will only accept new submissions under this ISO; Proposers may not seek renewal or supplementation of any existing awards through this ISO. The government reserves the right to select all, some, one, or none of the proposals received in response to this ISO for negotiations. If necessary, portions of awards may be divided into options. Should the government opt to award specific segments of a proposal, negotiations will begin following the selection notification. The government retains the right to fund proposals in phases, incorporating options for further work as appropriate.

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 eliminate 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 timely provide requested information.

This ISO has an attachment bundle that contains templates for proposal submission. The model OT Agreement with basic terms and conditions and other resources and documents can be found at https://arpa-h.gov/explore-funding/submission-resources-and-FAQs. The Proposer may submit red-line edits to the basic terms and conditions of the OT Agreement; however, the government Agreements Officer (AO) has sole discretion regarding the acceptance of those edits. The government AO also has sole discretion to determine the award payment structure, regardless of that proposed.

ARPA-H will require Performers to undergo pre-publication reviews if it is determined that the research resulting from the award will present a high

likelihood of disclosing sensitive information such as Personally Identifiable Information (PII), Protected Health Information, financial records, proprietary data, or information marked or considered Controlled Unclassified Information (CUI) per the guidance found at the National Archives (CUI Registry). Any award subject to such a determination will include the requirement to receive ARPA-H permission before the publication of any information regarding (or results from) the award. Performers must submit public release requests to media@arpa-h.gov and should allow ARPA-H twenty-one (21) calendar days to process these requests.

3.0 ELIGIBILITY INFORMATION

3.1 ELIGIBLE PROPOSERS

All responsible sources capable of satisfying the government's needs may submit Solution Summaries and proposals in response to this ISO. Proposers must first receive Solution Summary feedback before submitting a proposal; proposals submitted without an initial Solution Summary will not be reviewed by the government.

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 for-profit entities, academia, and non-profit organizations, hospitals, community health centers, and non-federal research centers. In certain circumstances, FFRDCs and government entities will have unique capabilities that are otherwise not available to proposing teams. Accordingly, the following will apply to this solicitation.

(a) FFRDCs and government entities, including federal government employees, are not permitted to respond to this solicitation as team members (including as sub-performers).

(b) If an FFRDC or government entity has a unique research idea that is within the scope of this solicitation and that it would like to have considered for funding, it must submit the research description to ARPA-H's Solution Submission Portal.

(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 ARPA-H via ARPA-H's Solution Submission Portal.

(d) If a Proposer believes that an FFRDC has a unique capability without

which its solution is unachievable, the Proposer must provide documentation and/or justification as part of its proposal showing that it has exhausted all other resource options before ARPA-H will consider the inclusion of the FFRDC in the proposed solution. Additional information can be found in the Administrative & National Policy Requirements Document of this ISO.

3.3 CURRENT PROFESSIONAL SUPPORT

Individuals/entities currently providing contracted support services[1] to ARPA-H have an organizational conflict of interest (OCI) that cannot be mitigated and 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 U.S. 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 award(s) be made to:

- 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 (MFTRP), as defined in Section 10638(4) of the CHIPS and Science Act of 2022; or
- entities suspended or debarred from doing business with the government.

Non-domestic entities organized under the laws of a "covered" foreign country (as defined in 50 U.S.C. § 3059) are ineligible to participate as either a prime or a sub-awardee in this selection.

4.0 SOLUTION SUMMARY AND PROPOSAL PREPARATION AND SUBMISSION INFORMATION

4.1 SOLUTION SUMMARY PREPARATION

Submission of a Solution Summary is a mechanism for a potential Proposer to receive written feedback from ARPA-H before investing resources for proposal submission. The Solution Summary allows a Proposer to present its solution in an efficient format to ensure it does not expend substantial resources developing a

[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.

proposal for a solution that does not fit ARPA-H's mission. Submission of a Solution Summary and the receipt of ARPA-H written feedback is mandatory before submitting a proposal.

4.2 SOLUTION SUMMARY SUBMISSIONS

All Solution Summaries must be written in English and comply with the content and formatting requirements of Appendix A of this ISO. Proposers are strongly encouraged to use the templates provided in this ISO. Information not explicitly requested in this ISO may not be reviewed. Solution Summary submissions must be submitted through ARPA-H's Solution Submission Portal.

4.3 SAM.GOV INFORMATION

At the time of proposal submission, the Proposer must be registered in the System for Award Management (SAM.gov) and have a valid Unique Entity Identifier (UEI). Proposers must also have an active, accurate registration in SAM.gov at the time of award and through its expiration. (SAM.gov requires certain information to register and obtain a UEI (e.g., Taxpayer Identification Number, Electronic Funds Transfer info, etc.); go to SAM.gov and click the "Get Started" button on the home screen to begin the registration process. New registrations take an average of 7-10 business days to process.)

4.4 PROPOSAL SUBMISSION INFORMATION

After receiving written feedback from ARPA-H for a Solution Summary, the Proposer may prepare a proposal for submission. Each proposal submission must be written in English and comply with the content and formatting requirements in the *Bundle of Attachments* of this ISO. Proposers should use the templates provided in the *Bundle of Attachments*. (Information not explicitly requested in the *Bundle of Attachments* may not be evaluated.) The Bundle of Attachments includes:

1. Technical & Management Proposal (20 pages)
2. Task Description Document (no page limit)
3. Cost Proposal (no page limit)
4. Cost Proposal Workbook (fill in applicable spreadsheets)
5. Administration & National Policy Requirements Document (no page limit)

Carefully read the attachments to ensure all required information is submitted. Proposals must be submitted through ARPA-H's Solution Submission Portal.

4.5 SOLUTION SUMMARY AND PROPOSAL SUBMISSION DEADLINES

The deadline for Solution Summary submissions is March 5, 2029. If the Proposer is encouraged to do so, ARPA-H will request it submit a proposal within forty-five

(45) calendar days from receiving ARPA-H Solution Summary feedback, unless ARPA-H provides an alternative timeline.

> NOTE: A Proposer must submit a Solution Summary and receive written Solution Summary feedback prior to submitting a proposal.

4.6 PROPRIETARY INFORMATION

Proposers are responsible for clear identification of 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 Solution Summaries and provide written feedback in accordance with Section 4.0, *Solution Summary and Proposal Preparation and Submission Information*, of this ISO. At a minimum, the feedback will encourage or discourage the submission of a proposal. Feedback will be sent to the Technical and Administrative points of contact indicated by the Proposer on ARPA-H's Solution Submission Portal. ARPA-H strives to provide Solution Summary feedback within thirty (30) business days of receipt of the Solution Summary.

> NOTE: Regardless of whether the Proposer is encouraged to submit a proposal in response to this ISO, it is eligible to do so after having received its Solution Summary feedback. Solution Summaries must be submitted in accordance with the requirements of Section 4.2, *Solution Summary Submissions*.

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 OTs 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 an outcome that achieves the goal can be expected from the 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 are proposed, including whether such applications may have the potential to address areas of currently unmet need within biomedicine and improve health outcomes. The proposed project has the potential to transform biomedicine, develop high-impact solutions, and take a multidisciplinary approach. 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. If applicable, the proposal addresses commercialization and transition strategies.

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 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 it has led or participated.

4. CRITERION 4: COST/PRICE/BUDGET ASSESSMENT

   The proposed cost/price/budget appropriately aligns with the proposed technical solution and reflects an understanding of the resources, schedule, risks, and effort necessary for the project. The proposal also provides sufficient information and/or documentation for ARPA-H to conduct an efficient evaluation of cost/price/budget.

   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, fair, transparent, and comprehensive evaluations of proposals based on the evaluation criteria listed herein and to select the source (or sources) with the proposal(s) determined to be the most 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, *Evaluation Criteria for Award*. ARPA-H intends to review proposals as soon as possible after their receipt, and strives to respond to each Proposer within sixty (60) calendar days after receipt of their proposal(s).

> NOTE: ARPA-H will not evaluate proposals against each other during the scientific technical review process; rather, ARPA-H will evaluate each proposal based on its own merit to determine how well it meets ISO criteria.

CONFORMING PROPOSALS: A conforming proposal contains all required information and falls within the scope detailed in this ISO. Proposers may not submit the same proposal with only minor modifications to multiple ISOs. Proposals that are more appropriate for a different mission office ISO than the one for which it was submitted may be referred by ARPA-H to more appropriate ISOs.

NON-CONFORMING PROPOSALS: A proposal may be deemed non-conforming under this ISO if it fails to include the required information or meet any of the following solicitation requirements:

- The proposed concept is applicable to the ISO interest areas.
- The Proposer meets the eligibility requirements.
- The proposal meets the submission requirements.
- The proposal meets 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).

ARPA-H may eliminate non-conforming proposals without further review or

consideration. ARPA-H may not consider non-conforming proposals for negotiations or award. ARPA-H reserves the right to reject proposals as non-conforming when it determines they are duplicative of previously submitted Solution Summaries or proposals under this or other ARPA-H solicitations. Proposers will be notified of non-conforming determinations via email correspondence.

5.4 NOTICES

The following notices will be provided as applicable:

- Request for clarifying details (if applicable)
  - ❖ May occur any time during the proposal evaluation process.
  - ❖ Will not include requests for proposal changes; changes to proposals will not be permitted at this stage.
- Notice of non-selection
  - ❖ The Proposer will be advised that its proposal submission has not been selected.
- Notice of selection
  - ❖ The selection notice will notify the Proposer that the government has selected its proposal for negotiation of a 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 points of contact identified in the proposal on ARPA-H's Solution Submission Portal.

5.5 HANDLING OF SELECTION SENSITIVE INFORMATION

It is the intent of ARPA-H to protect all proposals as selection sensitive information and to disclose their contents only for the purpose of evaluation, and only to appropriate 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 (NDAs). Input on technical aspects of a proposal may be solicited by ARPA-H from non-government consultants/experts who are strictly bound by appropriate NDA requirements.

6.0 AWARD ADMINISTRATION INFORMATION

6.1 ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS

CUI ON NON-FEDERAL INFORMATION SYSTEMS

Information on CUI identification, marking, protection, and control 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 rules. 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, *Potential Contribution and Relevance to the ARPA-H Mission*.

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's Open Systems Interconnection (OSI)[2] Model. ARPA-H programs are likely to involve research that touches on multiple layers of the OSI model, from low-level radio frequency 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 and Trusted Exchange Framework and Common Agreement (TEFCA) Qualified Health Information Networks using protocols such as HL7 Fast

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

Healthcare Interoperability Resources (FHIR), 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:

- components that can leverage today's existing standards without impeding the R&D,
- components where extensions to existing standards will be necessary to unlock new capabilities in an interoperable way, and
- components in areas where consensus-based standards 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., FHIR and United States Core Data for Interoperability).[3]

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

Technical solutions that contain software elements with commercial-friendly open-source licenses (e.g., Massachusetts Institute of Technology, Berkley Software Distribution, 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, review the complete text of the regulations; a strong technical solution will also outline integration with the TEFCA. Adhering to International Standards Organization/Institute of Electrical and Electronics Engineers standard 11073 will enable broad support for current and future devices, especially those developed internationally. At other layers of the OSI model, and for software components operating outside the network stack (e.g., health databases, Picture Archiving and Communication Systems, 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 (GDS) POLICY

If applicable, an award resulting from this ISO will include the requirement to comply with the National Institutes of Health's 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.

[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).

HUMAN SUBJECTS RESEARCH (HSR)

A proposal for funding that will involve engagement in 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 an 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 HSR-performing 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; and 21 CFR § 50, § 56, § 312, and § 812) and any other equivalent requirements of the applicable jurisdiction(s).

The informed consent document utilized in HSR funded by ARPA-H must comply with all applicable laws, regulations, and policies including (but 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 must 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: Eighth Edition, Copyright 2011, NAS*."

The Proposer must complete and submit the Vertebrate Animal Section worksheet for all proposed research anticipating ASR. All ASR must undergo review and approval by the local Institutional Animal Care Use Committee (IACUC) before incurring any costs related to the animal use research.

ORGANIZATIONAL CONFLICTS OF INTEREST (OCI)

Through submission of a proposal, the Proposer 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 sub-awardee). Along with the OCI disclosure, the Proposer must submit an OCI 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.

The government may reject the proposal and withdraw it from consideration for award if it determines the Proposer failed to:

- fully disclose an OCI; or
- provide the affirmation of ARPA-H support; or
- provide information requested by the government to assist in evaluating the Proposer's OCI mitigation plan.

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 sub-awardee, 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 sub-

awardee) providing the support.

RESEARCH SECURITY DISCLOSURES

Conforming proposals selected for negotiation of a potential award will undergo a Research Security Review (RSR). The RSR involves a review of the Proposer's disclosures made as part of the Administrative & National Policy Requirements document, and a validation and comparison of those disclosures utilizing publicly available information and commercially available information tools. Section 10631 of the CHIPS and Science Act of 2022 prohibits federal research agencies, such as ARPA-H, from providing R&D awards in response to any proposal in which a covered individual is participating in a Malign Foreign Talent Recruitment Program (MFTRP). It also requires federal agencies to require recipient institutions to prohibit covered individuals participating in MFTRPs from working on projects supported by federal R&D awards.

In accordance with National Security Policy Memorandum 33, to receive federal funding, research organizations should identify and mitigate conflicts of commitment (COCs) and conflicts of interest (COIs). COCs and COIs involving foreign countries of concern (FCOCs), including the People's Republic of China, the Russian Federation, the Islamic Republic of Iran, and the Democratic People's Republic of Korea (also known as North Korea), will require risk mitigation plans. A research organization proposing in response to this ISO must provide research security disclosures as described in the Administrative & National Policy Requirements document and the Office of Science and Technology Policy-identified Common Forms. The Common Forms are required for all senior or key personnel.

After a proposal is selected for negotiations of a potential award, ARPA-H will conduct an RSR of each Proposer and its senior or key personnel. The RSR is not part of the ARPA-H scientific merit review process. The RSR reviews include assessments of potential risks associated with covered individuals' disclosed or undisclosed participation in MFTRPs, funding received from FCOCs, collaboration with FCOC entities (including researchers and research institutions that have been identified on various entity lists), foreign ownership control or influence with regard to FCOCs identified in proposals, and the pursuit of foreign patents stemming from U.S. government funded research prior to obtaining U.S. patent protections.

If ARPA-H determines the Proposer failed to provide all requisite research

security disclosures or failed to reasonably provide information requested by ARPA-H to assist in evaluating the Proposer's disclosures and/or research security mitigations, ARPA-H may eliminate the proposal from award consideration. ARPA-H may also eliminate the proposal from award consideration if ARPA-H determines the Proposer did not or cannot properly mitigate research security-related risks.

ELECTRONIC INVOICING AND PAYMENTS

The Performer will be required to register in and submit invoices for payment through the Payment Management Services.

GOVERNMENT-FURNISHED PROPERTY/EQUIPMENT/INFORMATION

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

QUESTIONS & ANSWERS (Q&AS)

All questions regarding this ISO should be submitted through the ARPA-H's Solution Submission Portal. A profile is required to submit questions. ARPA-H will attempt to answer questions in a timely manner. ARPA-H posts Q&As to its website on an on-going basis and recommends parties review the Q&As before 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
CFR	Code of Federal Regulations
CHIPS	Creating Helpful Incentives to Produce Semiconductors
COC	Conflict of Commitment
COI	Conflict of Interest
CUI	Controlled Unclassified Information
FAR	Federal Acquisition Regulation (FAR)
FCOC	Foreign Country of Concern
FHIR	Fast Healthcare Interoperability Resources
FFRDC	Federally Funded Research and Development Center
FOIA	Freedom of Information Act
GDS	Genomic Data Sharing
HHS	Health and Human Services
HSR	Human Subjects Research
IP	Intellectual Property
IRB	Institutional Review Board
ISO	Innovative Solutions Opening
IT	Information Technology
MFTRP	Malign Foreign Talent Recruitment Program
NDA	Non-Disclosure Agreement
OCI	Organizational Conflict of Interest
ONC	Office of the National Coordinator for Health Information Technology
OSI	Open Systems Interconnection
OT	Other Transaction
PII	Personally Identifiable Information
Q&As	Questions and Answers
R&D	Research and Development
RSR	Research Security Review
SAM	System for Award Management
SSO	Scalable Solutions Office
TEFCA	Trusted Exchange Framework and Common Agreement
UEI	Unique Entity Identifier
U.S.	United States
U.S.C	United States Code

APPENDIX C: HYPERLINKS

ISO Section	Reference and Hyperlink
2.2	42 U.S.C. § 290c(g)(1)(D) https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section290c&num=0&edition=prelim
2.3	ARPA-H's public website https://arpa-h.gov/explore-funding/open-funding-opportunities SAM.gov https://sam.gov/content/home
2.4	National Archives (CUI Registry) https://www.archives.gov/cui/registry/category-list
3.2	ARPA-H's Solution Submission Portal https://solutions.arpa-h.gov/Ask-A-Question/
3.4	CHIPS and Science Act of 2022 https://www.govinfo.gov/content/pkg/PLAW-117publ167/pdf/PLAW-117publ167.pdf 50 U.S.C. § 3059 https://uscode.house.gov/view.xhtml?req=(title:50%20section:3059%20edition:prelim)
4.2	ARPA-H's Solution Submission Portal https://solutions.arpa-h.gov/Ask-A-Question/
4.3	SAM.gov https://sam.gov/content/home
4.4	ARPA-H's Solution Submission Portal https://solutions.arpa-h.gov/Ask-A-Question/
6.1	Controlled Unclassified Information on Non-Federal Information Systems 32 CFR § 2002 https://www.ecfr.gov/current/title-32/subtitle-B/chapter-XX/part-2002

Human Subjects Research (HSR)

45 CFR § 46
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

Office of Human Research Protection Federal Wide Assurance
https://www.hhs.gov/ohrp/index.html

45 CFR § 46
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

21 CFR § 56
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56

45 CFR § 46
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

§ 56
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56

§ 312
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312

§ 812
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812

45 CFR § 46
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

21 CFR § 50
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50

Animal Subjects Research

Department of Agriculture rules that implement the Animal Welfare Act of 1966
https://www.nal.usda.gov/animal-health-and-welfare/animal-welfare-act

7 U.S.C. § 2131-2159
https://www.govinfo.gov/content/pkg/USCODE-2015-title7/html/USCODE-2015-title7-chap54.htm

Public Health Service Policy on Humane Care and Use of Laboratory Animals
https://olaw.nih.gov/policies-laws/phs-policy.htm

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
https://olaw.nih.gov/policies-laws/gov-principles.htm

Guide for the Care and Use of Laboratory Animals: Eighth Edition, Copyright 2011, NAS
https://olaw.nih.gov/policies-laws/guide-care-use-lab-animals

worksheet
https://olaw.nih.gov/sites/default/files/VASchecklist.pdf

Research Security Disclosures

National Security Policy Memorandum 33
https://www.nsf.gov/bfa/dias/policy/nspm-33-implementation-guidance

Electronic Invoicing and Payments

Payment Management Services
https://pms.psc.gov/

Questions & Answers (Q&As)

ARPA-H's Solution Submission Portal
https://solutions.arpa-h.gov/Ask-A-Question/

website
https://arpa-h.gov/explore-funding/submission-resources-and-FAQs