INNOVATIVE SOLUTIONS OPENING FOR

TECHNOLOGY INTEGRATOR AND ACCELERATOR

TIGAR

SCALABLE SOLUTIONS OFFICE

ARPA-H-SOL-26-144

APRIL 22, 2026

Amendment 3: This amendment removes track changes and comments from Appendix B and Appendix C4. Please see new Appendices uploaded to ISO attachments on SAM.gov.

TABLE OF CONTENTS

1. WEBINAR 4
2. INTRODUCTION TO TIGAR 4
3. ELIGIBILITY INFORMATION 5
   3.1 ELIGIBLE PROPOSERS 5
      3.1.1 PROHIBITION ON PARTICIPATION BY FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS (FFRDCS) AND GOVERNMENT ENTITIES 5
      3.1.2 CURRENT PROFESSIONAL SUPPORT TO ARPA-H 5
      3.1.3 FOREIGN ENTITIES 6
   3.2 SYSTEM FOR AWARD MANAGEMENT (SAM.GOV) 6
4. SUBMISSION PROCESS 7
   4.1 OVERVIEW 7
   4.2 SOLUTION VIDEO SUBMISSIONS 7
   4.3 FULL PROPOSAL SUBMISSIONS 8
   4.4 SUBMISSION INFORMATION 8
   4.5 PROPRIETARY INFORMATION 9
5. SUBMISSION REVIEW AND EVALATION PROCESS 9
   5.1 SOLUTION VIDEO REVIEW 9
   5.2 FULL PROPOSAL EVALUATION 10
   5.3 EVALUATION CRITERIA 10
6. POLICY REQUIREMENTS AND MISCELLANEOUS OTHER INFORMATION 13
   6.1 CONTROLLED UNCLASSIFIED INFORMATION (CUI) ON NON-FEDERAL INFORMATION SYSTEMS 13
   6.2 INTELLECTUAL PROPERTY 13
   6.3 SOFTWARE COMPONENT STANDARDS 14
   6.4 GENOMIC DATA SHARING (GDS) POLICY 16
   6.5 ORGANIZATIONAL CONFLICTS OF INTEREST(OCI) 16
   6.6 ORGANIZATIONAL AGENCY SUPPLEMENTAL OCI POLICY 17
   6.7 RESEARCH SECURITY DISCLOSURES 17
   6.8 ELECTRONIC INVOICING AND PAYMENTS 18

6.9 PROCUREMENT OF SYNTHETIC NUCLEIC ACIDS OR BENCHTOP SYNTHESIZERS 19
6.10 DANGEROUS GAIN-OF-FUNCTION RESEARCH 19
6.11 HUMAN SUBJECTS RESEARCH 19
6.12 VERTEBRATE ANIMAL SUBJECTS RESEARCH 20
ADDITIONAL LINKS 21

APPENDIX A: Program and Technical Description

APPENDIX B.0: Solution Video Format and Instructions

APPENDIX B.1: Template for Supplemental Slides

APPENDIX C.0: Full Proposal Format and Instructions

APPENDIX C.1: Technical and Management Proposal

APPENDIX C.2: Cost Proposal

APPENDIX C.3: Cost Proposal Workbook

APPENDIX C.4: Admin National Policy Requirements Document

Additional resources:
TIGAR Exploratory Topic Video: https://www.youtube.com/watch?v=cZs1DQPftGw

APPENDIX D: Draft OT Agreement (available at https://arpah.gov/explore-funding/submission-resources-and-FAQs)

INNOVATIVE SOLUTIONS OPENING (ISO) SUMMARY INFORMATION

FEDERAL AGENCY: Advanced Research Projects Agency for Health (ARPA-H)

EFFORT TITLE: Technology InteGrator and AcceleratoR (TIGAR)

ANNOUNCEMENT TYPE: Innovative Solutions Opening (ISO)

ISO NUMBER: ARPA-H-SOL-26-144

ISO CONTACT: TIGAR@arpa-h.gov

ANTICIPATED AWARD(S):

Multiple Other Transaction (OTs) Agreements

For this solicitation, ARPA-H will only accept prime/subcontractor teaming arrangements and will not accept multi-party teaming arrangements.

DATES: (All times listed are Eastern Time)

Posting Date: April 22nd, 2026
Webinar: May 20th, 2026
Webinar Registration deadline: May 18th, 2026 at 11:59 PM ET
Intake Group 1:

- Solution Video due date: June 8th, 2026, 5:00 PM ET
- Full Proposal due date: August 5th, 2026, 5:00 PM ET

Intake Group 2:

- Solution Video due date: December 8th, 2026, 5:00 PM ET
- Full Proposal due date: February 5th, 2027, 5:00 PM ET

ISO closing date: February 5th, 2027, 11:59 PM ET

WHERE TO SUBMIT:

Questions:	https://solutions.arpa-h.gov/Ask-A-Question/
Solution Videos:	https://solutions.arpa-h.gov/Submit-Solution/
Full Proposals:	https://solutions.arpa-h.gov/Submit-Proposal/

Registration is required to submit documents via the ARPA-H Solution Submission Portal. Plan to register well in advance of the Solution Video submission deadline; late submissions resulting solely from delays with registration will not be considered.

RESOURCE SHARING: Resource sharing is encouraged.

1. WEBINAR

ARPA-H will host a virtual webinar in support of the TIGAR Exploratory Topic as described in Special Notice ARPA-H-SN-26-142.

2. INTRODUCTION TO TIGAR

Exploratory Topics are fast-paced efforts that pursue topics strategically aligned with ARPA-H Mission Offices. They provide foundational proofs-of-concept to be used in future research.

TIGAR Exploratory Topic will forge entirely new paths to stabilizing regenerative tissues and organs by seeding the development of enabling technologies that can unlock temperature-flexible storage in increasingly larger and more complex biological systems. Solutions may involve any combination of new materials, artificial intelligence/machine learning, high-throughput screening methods, biological interventions, devices, processing methods, analytical technology, and packaging approaches that can overcome current roadblocks and yield a leap in the ability to store and distribute complex biologics, without introducing high cost or complexity. Strategies that reduce reliance on strictly controlled temperature zones and can ensure safe storage in a range of environmental conditions are preferred. While long-term temperature-flexible storage is ideal, any advance that removes logistical hurdles or establishes shelf-life stability at easy to maintain temperatures (preferably non-cryogenic) will be considered. Innovations at the cellular level without a strategy for deployment in thick tissues will not be considered.

TIGAR will have two intake groups for the submission of well-scoped, early-stage, high-risk/high-impact biopreservation concepts. To demonstrate concept feasibility, each approach should be structured as an 18-month period of performance (from kickoff to completion), comprising two 9-month phases with a down-select decision at the end of Phase 1. Milestones and metrics for moving to Phase 2 are described in Section 3.3 of Appendix A Program and Technical Description. Proposers must demonstrate progress towards functional preservation of either entire structures (organoids, organs, or organ sub-units) or one (1) cubic centimeter volumes of tissue for ≥30 days, at practical temperatures, attainable with conventional equipment (i.e., -80˚C, -20˚C, 4˚C, 20 ˚C-25˚C room temperature (RT)) by the end of the performance period. Measurable progress should include demonstrating advances on a clearly identified technical hurdle, as well as demonstrating preservation of cell viability, function, and critical quality attributes specific to the proposed tissue system. The total ARPA-H funding requested must not exceed $2 million USD over the 18-month period of performance. Preferred demonstration tissue systems are those that are currently challenging to biobank or stockpile, such as organoids, donated tissues, whole organs, organ sub-structures,

vascularized allografts, and engineered tissues. Systems selected for demonstration may be vascularized or non-vascularized. See Appendix A Program and Technical Description for complete details.

3. ELIGIBILITY INFORMATION

3.1 ELIGIBLE PROPOSERS

Except as noted herein, all sources that can satisfy the government's needs and that are neither debarred nor suspended from doing business with the government may respond to this ISO. Universities, non-profit organizations, small businesses and other commercial entities are encouraged to respond. Any submission received will be fairly considered against the terms and conditions of the solicitation and may be selected for award.

3.1.1 PROHIBITION ON PARTICIPATION BY FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS (FFRDCS) AND GOVERNMENT ENTITIES

(a) ARPA-H is primarily interested in responses to this solicitation from commercial entities, academia, and non-profit organizations, not from federal or state governments. As such, Federally Funded Research and Development Centers (FFRDCs) and government entities (which include government employees) will not be considered as either the prime or a sub-performer.

(b) However, an FFRDC or government entity may have unique capabilities that are not otherwise available. Accordingly, when a potential prime performer believes an FFRDC has a unique capability without which its solution is unachievable, it may provide documentation demonstrating it has exhausted all other options as part of its submission(s). ARPA-H will determine whether inclusion of the FFRDC is necessary for the Solution.

(c) If an FFRDC or government entity is interested in working directly with the ARPA-H team supporting the research described by this ISO, contact TIGAR@arpa-h.gov for guidance.

3.1.2 CURRENT PROFESSIONAL SUPPORT TO ARPA-H

Support services involve contracted labor providing technical, professional, and/or financial expertise, and/or administrative assistance.

Individuals and entities providing support services to ARPA-H are ineligible for an award stemming from this ISO.

3.1.3 FOREIGN ENTITIES

While ARPA-H prioritizes awards to entities (organizations and/or individuals) that conduct funded work in the United States, foreign entities may participate to the extent that they comply with non-disclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. In no case will award be made to:

- An entity of concern meeting any of the criteria in Section 10638(3) of the CHIPS and Science Act of 2022;
- An individual who is a party to a malign foreign talent recruitment program (MFTRP) as defined in Section 10638(4) of the CHIPS and Science Act of 2022;
- Non-domestic entities organized under the laws of a "covered" foreign country (as defined in 50 U.S.C. § 3059); or
- Entities suspended or debarred from doing business with the government.

3.2 SYSTEM FOR AWARD MANAGEMENT (SAM.GOV)

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 the period of performance. SAM.gov is a U.S. government–wide registration system administered outside of ARPA-H. ARPA-H cannot create, modify, or expedite SAM registrations on behalf of proposers. SAM.gov requires certain information to register and obtain a UEI (e.g., Taxpayer Identification Number, Electronic Funds Transfer information). To begin the registration process, go to SAM.gov and click the "Get Started" button on the home screen.

While new registrations may be completed in as little as 7–10 business days, processing times can be longer depending on the completeness and accuracy of the information provided and any required validations. Proposers are solely responsible for initiating and maintaining their SAM.gov registration sufficiently in advance of ISO submission and award timelines. Failure to obtain or maintain an active SAM.gov registration may delay or preclude award.

4. SUBMISSION PROCESS

4.1 OVERVIEW

The following are the required steps for the submission process:

- ✓ **Step 1: Submit Solution Video.** Proposers are encouraged or discouraged to move to Step 2.
- ✓ **Step 2: Submit Full Proposal.** Proposers may submit full proposals, regardless of whether encouraged or discouraged in Step 1.

NOTE: There are two (2) intake groups for submissions. Accordingly, for each intake group, there are two (2) associated deadlines for the Solution Video and Full Proposal as listed in the ISO Summary Information Section on page 3.

NOTE: ARPA-H will not reimburse entities for costs incurred in responding to this ISO.

4.2 SOLUTION VIDEO SUBMISSIONS

Solution Video submissions are **required** and due by the date listed in the ISO Summary Information Section on page 3. Solution Video submissions are a package of materials containing:

- **Solution Video**: a 7 minute pre-recorded video (e.g., narrated PowerPoint presentation or equivalent) defining the scope of the problem and state-of-the-art, proposed solution, team capabilities, and solution impact. See **Appendix B.0** Solution Video Format and Instructions for complete details.
- **Solution Video Captions file:** a captions file of the Solution Video as a standard caption format (e.g., .vtt, .srt).
- **Supplemental Slides:** a PowerPoint slide deck consisting of supporting concept information including an overview of the proposing team's organization, risk and mitigation strategies, proposed timeline and milestones, and cost summary. See **Appendix B.1** Template for Supplemental Slides for complete details.

To submit a Solution Video through the ARPA-H Solutions Portal, first create an account or sign in to an existing account, then follow the steps below:

1. Select the drop-down arrow next to 'Start a Submission'
2. Select '→ Solution Summary'
3. Select 'Start Submission'
4. Enter information as it applies to your TIGAR submission and select 'Continue' to proceed to the following pages:

a. Solution Summary Information
b. Budget Information
c. Organization & Key Personnel
d. File Uploads

   Note: To upload a Solution Video, you must first acknowledge the Video Upload Consent, Privacy, and Use by selecting 'Accept'.

   i. Upload your Solution Video by selecting 'Choose File' in the Video Submission field.
   ii. Upload a single captions file for your video submission by selecting 'Choose File' in the Video Captions field, or
   iii. Upload a single transcript file for your video submission by selecting 'Choose File' in the Video Transcript field
   iv. Upload your Supplemental Slides by selecting 'Choose File' in the Optional Uploads section.

   Note: The Supplemental Slides are required as part of the complete TIGAR Solution Video submission package. You must upload the Supplemental Slides in the Optional Uploads section.

5. Review the submitted content for accuracy and complete your submission by selecting 'Submit'.

4.3 FULL PROPOSAL SUBMISSIONS

Full Proposal submissions are due by the date listed in the ISO Summary Information Section on page 3. Proposers must be able to articulate a clear and testable biopreservation concept that includes a logical experimental design and justification to support the proposed concept. Proposers are also expected to identify potential technical challenges and present comprehensive risk mitigation approaches. Full Proposals are a package of materials containing:

- Technical & Management Proposal. See Appendix C.1 Full Proposal Format and Instructions for complete details.
- Cost Proposal. See Appendix C.2 Cost Proposal Model for complete details.
- Cost Proposal Workbook. See Appendix C.3 Cost Proposal Workbook for complete details.
- Administrative & National Policy Document. See Appendix C.4 Administrative National Policy Document for complete details.

4.4 SUBMISSION INFORMATION

Non-conforming submissions that do not follow ISO instructions, or concepts that are explicitly stated in the ISO as out of scope, may be rejected without further review at any stage of the process.

All materials must be in English. Written materials should be written with a *sans serif* font type NO smaller than 11-point and with a readability similar to that of Calibri, Arial, or Avenir Next Pro Light. Smaller *sans serif* fonts may be used for figures, tables, and charts, if applicable. Template text in blue font is provided for guidance only and should be deleted by the proposer before submitting a Solution Video package.

All submissions must be consistent with the instructions and requirements of Appendix B.0 Solution Video Format and Instructions, Appendix B.1 Template for Supplemental Slides, Appendix C.0 Full Proposal Format and Instructions, Appendix C.1 Technical and Management Proposal, Appendix C.2 Cost Proposal, Appendix C.3 Cost Proposal Workbook, and Appendix C.4 Administrative National Policy Document. File names must not include spaces or symbols. Proposers are responsible for submitting all materials via the ARPA-H Solution Submission Portal and ensuring receipt by the date and time specified in the ISO. No other method of submission is permitted. Registration is required to submit via the ARPA-H Solution Submission Portal and registration may take several business days to process. Plan to register well in advance of the Solution Video submission deadline as late submissions resulting from delays with registration may not be accepted or considered.

4.5 PROPRIETARY INFORMATION

The originator of a submission is responsible for identifying all proprietary information therein. Submissions containing proprietary information must clearly mark the cover page, and each page that contains such information, with a label such as "Proprietary".

NOTE: "Confidential" is a classification marking used to control the dissemination of information related to National Security and should not be used to identify proprietary business information. ARPA-H handles submissions in accordance with applicable federal law, including the Freedom of Information Act (FOIA).

5. SUBMISSION REVIEW AND EVALATION PROCESS

5.1 SOLUTION VIDEO REVIEW

ARPA-H will conduct a scientific and technical review of each conforming Solution Video and will generally respond within 30 business days of receipt. Solution Videos will be reviewed based on evaluation criteria stated in this ISO (see Section 5.4 for full details) to provide proposers with feedback on whether ARPA-H is interested in the proposed concept. At a minimum, the response will indicate whether a proposer is encouraged or discouraged from submitting a Full

Proposal. Although potential proposers may submit a Full Proposal regardless of the feedback provided in response to a Solution Video submission, ARPA-H Solution Video feedback is provided to ensure that potential proposers are making an informed decision on the investment of time and resources toward a Full Proposal. Feedback will be provided to the administrative and technical points of contact noted on the Solution Video cover page.

NOTE: A Solution Video submission with a proposed budget in excess of $2M USD will **not** be reviewed.

5.2 FULL PROPOSAL EVALUATION

ARPA-H will conduct a scientific and technical evaluation of each conforming Full Proposal and will generally respond within 30 business days of receipt. Full Proposals will be evaluated on how well the submission meets the criteria stated in this ISO (see Section 5.4 for full details). At a minimum, proposers will be provided with notification of the Government's decision on whether the proposal was selected for negotiation of an award. Notification of the Government's decision will be provided to the primary technical point of contact included in the solutions tool.

5.3 EVALUATION CRITERIA

Full Proposals will be evaluated using the following evaluation criteria, listed in descending order of importance.

5.3.1 Criterion 1: Overall Scientific and Technical Merit

The proposed technical approach is highly innovative and technically sound with a well-defined path to completion. 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 is plausible. The proposal identifies major technical risks, expected for ARPA-H projects, and planned mitigation efforts are clearly defined and feasible. 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.

5.3.2 Criterion 2: Proposer's Capabilities and/or Related Experience

(a) 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, and 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.

(b) In terms of capability, the government will assess the bio-sketches provided for the performer team members including the Principal Investigator, Project Manager, Regulatory Expert, Product Development Lead (PDL), Commercialization Experts, and any other key personnel on the project team as requested by ARPA-H.

5.3.3 Criterion 3: Contribution to the ARPA-H Mission and Relevance to the User Experience

Proposals will be evaluated on the potential future research and development, commercial, and/or clinical applications of the project proposed, including whether such applications have the potential to address areas of currently unmet need within biomedicine and improve health outcomes, and the degree to which the proposed project has the potential to transform biomedicine. The interdisciplinarity of the approach will also be considered. Further, whether the proposed solution contemplates the end user and reflects an understanding of the direct needs and benefits for stakeholders, whether they are patients, providers, health systems or payers, will be considered. For example, how would this solution fit inside the clinical workflow? Or, how will this be accessible to users in all geographies, and at an affordable cost?

5.3.4 Criterion 4: Assessment of Proposed Cost/Price

(a) All proposals will be evaluated to determine the reasonableness or value of the estimated price/cost proposed to accomplish the technical approach. Analysis may be performed to ensure proposed costs are realistic for the proposed scientific and technical approach and capabilities/related experience, accurately reflect the technical goals and objectives of the solicitation, are consistent with the proposer's technical approach, and reflect a sufficient understanding of the costs and effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed sub-awardees should be substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs including the basis for the estimates.)

(b) It is expected the effort will leverage all available relevant prior research to obtain the maximum benefit from the available funding. For efforts with

a likelihood of commercial application, appropriate resource sharing may be a positive factor in the evaluation. Proposers are encouraged to incorporate creative approaches to resource sharing, resource contributions, and/or return-on-investment (ROI) mechanisms that align with program objectives and anticipated project outcomes. Examples may include, but are not limited to, cash or in-kind performer contributions, shared-use infrastructure, data or IP access arrangements, or post-performance value-sharing models (e.g., revenue participation, discounted buy-back rights, or royalty considerations).

(c) Inclusion of such mechanisms is not required and may be evaluated in the context of overall technical merit, reasonableness, value, and potential public benefit. Agreement Officers (AO) retain discretion to negotiate, adjust, or omit such provisions based on the unique nature, risk profile, and expected impact of the proposed effort. Proposers are encouraged to describe how their approach contributes to maximizing taxpayer value and sustaining long-term innovation outcomes.

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.

5.4 HANDLING SELECTION SENSITIVE INFORMATION

It is the intent of ARPA-H to protect all submissions as selection sensitive information and to disclose their contents only for the purpose of evaluation, and only to screened personnel for authorized reasons, in accordance with applicable federal laws and regulations, 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.

When large language models (LLMs) are used (to extract data elements, summarize text, and generate text), all data will be transmitted exclusively through secure API calls, with external tool calls such as web searches disabled. Vendor contracts and technical controls enforce strict security measures: data

sent for inference is never used to train public models, and all access, retention, and logging are tightly restricted and fully auditable.

5.5 EVALUATION AND AWARD DISCLAIMERS

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this ISO. In the event the Government desires to award only portions of a proposal, negotiations will commence upon selection notification. The Government reserves the right to fund proposals with phases or options for continued work, as applicable.

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

In all cases, the government AO will have sole discretion to negotiate all terms and conditions with proposers. ARPA-H will apply publication or other restrictions, as necessary, if it is determined the research resulting from the proposed effort will present a high likelihood of disclosing sensitive information including Personally Identifiable Information (PII), Protected Health Information (PHI), financial records, proprietary data, any information marked Sensitive but Unclassified (SBU), etc. Any award resulting from such a determination will include a requirement for ARPA-H concurrence before publishing any information or results on the effort.

6. POLICY REQUIREMENTS AND MISCELLANEOUS OTHER INFORMATION

6.1 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.

6.2 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 TIGAR Exploratory Topic goals and should be aligned with the level of government funding provided to generate and/or develop the IP.

6.3 SOFTWARE COMPONENT STANDARDS

6.3.1 The health and healthcare data eco-system is complex and multidimensional 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)[1] 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 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.

6.3.2 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

[1] https://www.iso.org/standard/20269.html

- 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.

6.3.3 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).

6.3.4 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).[2]

6.3.5 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 and describe a plan to develop a general-purpose open data model and 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.

6.3.6 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

---

2 https://www.healthit.gov/sites/default/files/page/202207/Standards_And_Implementation_Specifications_Adopted_Under_Section_3004.pdf

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[3].

6.3.7 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.

6.4 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.

6.5 ORGANIZATIONAL CONFLICTS OF INTEREST(OCI)

Through submission of a Full 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

[3] 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).

- provide the affirmation of ARPA-H support; or
- reasonably provide additional information requested by the government to assist in evaluating the proposer's OCI mitigation plan.

6.6 ORGANIZATIONAL 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 Full Proposal must include:

- The name of the ARPA-H office receiving the support
- The prime contract number and
- Identification of any and all proposed team member(s) (including any proposed sub-awardee) providing the support.

Compliance to report an OCI is required. If ARPA-H identifies an OCI that is not reported, it may result in rejection of a Full Proposal as non-conforming.

6.7 RESEARCH SECURITY DISCLOSURES

6.7.1 Conforming Full 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.

6.7.2 In accordance with NSPM-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.

6.7.3 After a Full Proposal is selected for negotiation of a potential award, ARPAH 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.

6.7.4 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.

6.8 ELECTRONIC INVOICING AND PAYMENTS

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

Invoices must include a justification (limited to 1,000 characters) such as the following, due to the requirement for government approval in the Defend the Spend (DTS) System:

The payment is justified for the TIGAR program to [include the purpose of the project] for Milestones (s) [x.x] that were accepted by the Program Manager on [date].

6.9 PROCUREMENT OF SYNTHETIC NUCLEIC ACIDS OR BENCHTOP SYNTHESIZERS

HHS funds may only be used to procure synthetic nucleic acids or benchtop nucleic acid synthesis equipment from sources adhering to the Office of Science and Technology Policy Framework for Nucleic Acid Synthesis Screening.

6.10 DANGEROUS GAIN-OF-FUNCTION RESEARCH

HHS Funds may not be used to conduct any dangerous gain-of-function research, per the definition in Section 8 of Executive Order (E.O.) 14292 on Improving the Safety and Security of Biological Research. Further, per Section 3 of E.O. 14292, no HHS Funds may be used to fund life science research with foreign entities in countries of concern (e.g., China) pursuant to 42 U.S.C. 6627(c), or in other countries where there is not adequate oversight to ensure that the countries are compliant with United States oversight standards and policies.

6.11 HUMAN SUBJECTS RESEARCH

6.11.1 A Full 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.

6.11.2 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.

6.12 VERTEBRATE ANIMAL SUBJECTS RESEARCH

6.12.1 All entities submitting a Full Proposal for funding that will involve engagement in vertebrate animal subjects research (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" (8th Edition)."

6.12.2 Proposers must provide documentation of a current Animal Welfare Assurance (AWA) on file with the Office of Laboratory Animal Welfare (OLAW). The proposer must complete and submit the Vertebrate Animal Section worksheet for all proposed research anticipating Animal Subject Research (ASR). All Animal Use Research 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. For all proposed research anticipating animal use, proposals should briefly describe plans for IACUC review and approval as described in the Appendix E Administrative & National Policy Document.

ADDITIONAL LINKS

42 U.S.C. § 290c(g)(1)(D)
https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section290c&num=0&edition=prelim

ARPA-H's public website
https://arpa-h.gov/explore-funding/open-funding-opportunities

SAM.gov
https://sam.gov/content/home

National Archives (CUI Registry)
https://www.archives.gov/cui/registry/category-list

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

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)

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

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

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/