



MASTER ANNOUNCEMENT INSTRUCTIONS

FOR

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

ARPA-H-MAI-24-01

October 20, 2023

## TABLE OF CONTENTS

|    |  |    |
|----|--|----|
| 1. | MASTER APPLICATION INSTRUCTIONS OVERVIEW INFORMATION ..... | 3  |
| 2. | ELIGIBILITY INFORMATION .....                              | 6  |
| 3. | APPLICATION AND SUBMISSION INFORMATION .....               | 8  |
| 4. | EVALUATION OF PROPOSALS .....                              | 9  |
| 5. | AWARD ADMINISTRATION INFORMATION .....                     | 12 |
| 6. | COMMUNICATIONS .....                                       | 15 |
|    | APPENDIX A: RSO INTEREST AREAS.....                        | 16 |
|    | APPENDIX B: ASSOCIATE CONTRACTOR AGREEMENT .....           | 17 |

## 1. MASTER ANNOUNCEMENT INSTRUCTIONS OVERVIEW INFORMATION

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

**FUNDING OPPORTUNITY TITLE:** To be solicited under Module Announcements

**ANNOUNCEMENT TYPE:** Initial Announcement

**FUNDING OPPORTUNITY NUMBER:** ARPA-H-MAI-24-01

**ASSISTANCE LISTING NUMBER:** 93.384 Research and Development that accelerates better health outcomes for all Americans.

**DATES:** (All times listed herein are Eastern Time)

- *Master Announcement Instructions DRAFT Release Date:* September 13, 2023
- *Master Announcement Instructions DRAFT 2 Release Date:* September 29, 2023
- *Master Announcement Instructions Release Date:* October 20, 2023
- *Master Announcement Instructions Questions & Answers (Q&A) due date:* MAI FAQs may be submitted up until 6-months prior to the MAI Closing Date.
- *Master Announcement Instructions Closing Date:* The MAI will remain open for 12-month after date of release.

**CONCISE DESCRIPTION OF THE FUNDING OPPORTUNITY:** The MAI aims to create standard tiered proposal submission requirements, so the amount of work required to write a proposal is commensurate with the size of the proposed effort. It also aims to reduce the up-front work required to submit cost information to reduce the barrier to entry for non-traditional performers. Module announcements that link to this MAI will provide more specific instructions about how the proposal requirements vary across tiers of effort.

Mission Alignment: Funding modules will solicit proposals for specific projects that fall within scope of the ARPA-H mission Resilient Systems Office (RSO). ARPA-H RSO's focus area aims to create capabilities, develop mechanisms, and accelerate system integrations that enhance stability in the face of disruptive events. Resilient systems need to sustain themselves between crises – from the molecular to the societal – to better achieve outcomes that advance American health resilience at the population level. From software systems to manufacturing pipelines, biophysical systems to microbiomes, and patient communities to provider networks, reliability is key to maintaining high-quality care between and throughout crises such as pandemics, social disruption, cyberattacks, and financial disruptions. Proposals are expected to use innovative approaches to enable revolutionary advances in science, technology, or systems. ARPA-H will also foster innovations that are entirely novel proofs of concept or contribute directly to advance the goals of government-wide initiatives such as the Cancer Moonshot<sup>SM</sup>; Advancing the American Bioeconomy; Clinical Trial Readiness; the National Strategy on Hunger, Nutrition, and Health; the National Action Plan for Combatting Anti-Microbial Resistance; or Unity Agenda priorities on addressing mental health and curbing the opioid epidemic. Specifically excluded are proposals that represent an evolutionary or incremental advance in the state of the art. Additionally, proposals directed towards policy changes, traditional education and training, or center coordination and construction of physical infrastructure are outside the scope of the ARPA-H mission. This announcement targets revolutionary innovative solutions in support of the ARPA-H Resilient Systems areas of interest found in [Appendix A](#).

ARPA-H may also consider soliciting modules outside of these interest areas if the proposal involves the development of a novel capability to improve health outcomes or prolong well-being, especially if it would help either a substantial number of people or a population that currently lacks effective

treatment options.

**ANTICIPATED INDIVIDUAL AWARD:** Multiple awards are anticipated.

**TYPES OF INSTRUMENTS THAT MAY BE AWARDED:** Other Transactions (OT) and Cooperative Agreements

**ANY COST SHARING REQUIREMENTS:** Cost sharing may be requested in certain situations for Other Transactions awarded under the authority of 42 U.S.C. § 290c(g)(1)(D).

**TECHNICAL POINT OF CONTACT:** Identified at the time of MAI Module Announcement.

#### **AGENCY CONTACT**

The MAI Coordinator for this effort can be reached at:

Unclassified Email: [MAIQuestions@arpa-h.gov](mailto:MAIQuestions@arpa-h.gov)

ATTN: ARPA-H-MAI-24-01

### **1.1 ACQUISITION STRATEGY**

Multiple Module Announcements may be solicited under the MAI at any time while the MAI remains open, currently anticipated to be 12-months from the date of release. Module Announcements will be broken into categories based on the estimated value of a potential award or technical area (TA). The following represent the Module categories anticipated under the MAI:

BIT Module is  $\leq$  \$2,000,000

BYTE Module is  $>$  \$2,000,000  $\leq$  \$4,499,999

KILO Module is  $>$  \$5,000,000  $\leq$  \$10,000,000

MEGA Module is  $>$  10,000,000  $\leq$  \$25,000,000

GIG Module  $>$  \$25,000,000  $\leq$  \$50,000,000

TERA Module  $>$  \$50,000,000

When a Module Announcement is solicited, the Module category will be listed to inform the proposer of the Government's anticipated value per award or TA. For example, a KILO Module Announcement solicited to the public is anticipated to be  $>$  \$5,000,000 and  $\leq$  \$10,000,000; therefore, the total value for each award or TA is estimated to be greater than \$5,000,000 but equal to or less than \$10,000,000. If the Government determines to define Module categories by TA, the Module will be solicited as a Combined Module noting the respective categories anticipated.

ARPA-H expects that proposals for larger efforts will include more thorough technical descriptions, more ambitious milestones, and more details regarding metrics. Larger efforts should also create more mature or comprehensive capabilities that are more thoroughly tested and evaluated. Smaller efforts may be more exploratory or focus on a subset of the overall TA. As such, Module categories will also apply page restrictions commensurate to the level of effort anticipated. If the Module allows for combined TA submissions, the Module will provide additional guidance on page restrictions and the anticipated dollar value for the combination of two or several TAs.

Based on the establishment of Module categories, Module Announcements will be broken up into a two-stage submission process. Stage one (1) will require submission of technical proposals with an applicable basis of estimate (BOE). If a technical proposal is selected for potential award, Stage two (2) will require submission of a full cost/price proposal commensurate to the Module category along with additional required documentation (i.e., Agreement Certifications).

**NOTE:** Module category dollar thresholds are only an estimate to guide the acquisition process; the category should not constrain the proposal of novel ideas. Proposers are encouraged to propose the best technical solution for each Module Announcement and provide a BOE that reflects the proposed effort. Conversely, proposers are discouraged from proposing low-risk ideas with minimum uncertainty and to staff the proposed effort with junior personnel to be more competitive or meet the Module category dollar threshold.

Each Module Announcement will have two separate bundles of attachments. Bundles will be for Other Transaction (OT) submissions and the other for Cooperative Agreement submissions. Each bundle will have proposal templates (content and formatting requirements) and required documents for the category of announcement. Bundle documents should be used in the construction of proposal responses.

If the Government determines abstract submissions would benefit the acquisition strategy, the Government may solicit abstract submissions independently or in conjunction with a Module Announcement.

## **1.2 MAI AUTHORITY**

Multiple Module Announcements may be solicited under the MAI at any time while the MAI remains open, currently anticipated to be 12-months after date of release. Module Announcements may result in multiple awards of OTs or Cooperative Agreements. In all cases, the Government Agreement Officer (AO) shall have sole discretion to select the award Agreement type, regardless of Agreement type proposed. Each Module Announcement will have two attachment bundles that will contain a Model Agreement (OT and Cooperative Agreement) with basic terms and conditions. Proposers may submit red-line edits to the basic terms and conditions of the resulting instrument; however, the Government AO shall have sole discretion to negotiate any red-line edits that deviate from the basic terms and conditions. Further, a resulting OT Agreement will not require cost-sharing; however, ARPA-H reserves the right to negotiate cost-sharing as appropriate to the situation.

## **1.3 MODULE ANNOUNCEMENT PROCEDURES**

Opportunities to perform will be announced via Module Announcements issued under this MAI, ARPA-H-MAI-24-01. These announcements will be solicited through [SAM.gov](https://sam.gov) and/or [Grants.gov](https://grants.gov) and therefore open to the public. The goal of each Module Announcement is to solicit revolutionary innovative solutions that will help meet the ARPA-H RSO areas of interest.

Each Module Announcement will 1) describe the technical requirements and 2) provide proposal content and submission instructions in addition to those outlined in this MAI, including the due date for proposal submissions.

**NOTE:** The MAI Model Agreements shall only be submitted in response to a Module Announcement. See Section 3 for application and submission information.

## **1.4 MODULE ANNOUNCEMENT AWARD INFORMATION**

Multiple awards are anticipated under Module Announcement(s) issued under ARPA-H-MAI-24-01; however, the number of awards selected will depend on the quality of the proposals received and the availability of funds.

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to a Module Announcement issued under this MAI. If warranted, portions of resulting awards may be segregated into pre-priced options. In the event that the Government desires to award only portions of a proposal, negotiations will commence upon selection notification. The Government reserves the right to fund proposals in phases with options for continued work, as applicable.

The Government reserves the right to request any 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, cost, and/or 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 instrument terms and conditions with selectees. ARPA-H will apply publication or other restrictions, as necessary, if it is determined that 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, and any information marked Sensitive but Unclassified (SBU), Controlled Unclassified Information (CUI), etc. Any award resulting from such a determination will include a requirement for ARPA-H permission before publishing any information or results on the effort.

## **2. ELIGIBILITY INFORMATION**

### **2.1 ELIGIBLE APPLICANTS**

All responsible sources capable of satisfying the Government's needs may submit a proposal to a Module Announcement. Specifically, universities, non-profit organizations, small businesses and other than small businesses are eligible and encouraged to propose to Module Announcements.

#### **2.1.1 FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS (FFRDCs) AND GOVERNMENT ENTITIES**

##### **2.1.1.1 FFRDCs**

FFRDCs are subject to applicable direct competition limitations and cannot propose to Module announcements in any capacity. If an FFRDC would like to assist ARPA-H with a Module Announcement, the FFRDC should contact the technical point of contact on the applicable Module Announcement.

##### **GOVERNMENT ENTITIES**

Government Entities (e.g., Government/National laboratories, military educational institutions, etc.) cannot propose to Module announcements in any capacity. If a Government Entity would like to assist ARPA-H with a Module Announcement, the Government Entity should contact the technical point of contact on the applicable Module Announcement.

### **2.1.1 NON-U.S. ORGANIZATIONS**

Pursuant to 42 U.S.C. 290c(n)(1), ARPA-H will prioritize awards to entities (organization and/or individuals) that will conduct funded work in the United States. However, non-U.S. entities may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. Non-US entities are encouraged to collaborate with domestic U.S. entities. In no case will awards be made to entities organized under the laws of a covered foreign country (as defined in section 119C of the National Security Act of 1947 ([50 U.S.C. § 3059](#))) or entities suspended or debarred from business with the Government

## **2.2 ORGANIZATIONAL CONFLICTS OF INTEREST (OCI)**

Proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and any proposed team member (proposed subawardee). Although the FAR does not apply to OTs and, Cooperative Agreements, ARPA-H requires OCIs be addressed in the same manner prescribed in FAR subpart 9.5. Regardless of whether the proposer has identified potential OCIs under this section, the proposer is responsible for providing a disclosure with its proposal. The disclosure must include the proposers, and as applicable, proposed team members' OCI mitigation plans. The OCI mitigation plan(s) must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4. The disclosure and mitigation plan(s) do not count toward the page limit.

### **Agency Supplemental OCI Policy**

In addition, ARPA-H restricts performers from concurrently providing professional support services, including, Advisory and Assistance Services or similar support services, and being a technical performer. Therefore, as part of the FAR 9.5 disclosure requirement above, a proposer must affirm whether the proposer or any proposed team member (proposed subawardee, etc.) is providing professional support services to any ARPA-H office(s) under: (a) a current award or subaward; or (b) a past award or subaward that ended within one calendar year prior to the proposal's submission date.

If any professional support services are being 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;
- Identification of proposed team member (proposed subawardee) providing the support; and

- An OCI mitigation plan in accordance with FAR 9.5.

## **GOVERNMENT PROCEDURES**

The Government will evaluate OCI mitigation plans to avoid, neutralize, or mitigate potential OCI issues before award and to determine whether it is in the Government's interest to grant a waiver. The Government will only evaluate OCI mitigation plans for proposals selected for potential award under the Module Announcement evaluation criteria and funding availability.

The Government may require proposers to provide additional information to assist the Government in evaluating the OCI mitigation plan.

If the Government determines a proposer failed to fully disclose an OCI; or failed to provide the affirmation of ARPA-H support as described above; or failed to reasonably provide additional information requested by the Government to assist in evaluating the proposer's OCI mitigation plan, the Government may reject the proposal and withdraw it from consideration for award.

## **3. APPLICATION AND SUBMISSION INFORMATION**

### **3.1 PROPOSAL PREPARATION INSTRUCTIONS**

Volume 1 Proposals must consist of the following documents in Stage 1 submissions:

TECHNICAL & MANAGEMENT  
BASIS OF ESTIMATE (BOE)  
TASK DESCRIPTION DOCUMENT OR RESEARCH DESCRIPTION DOCUMENT  
ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS

**Only** upon notification of selection for potential award will the proposer be required to submit a Stage 2 volume 2 submission with the following documents:

PRICE/COST PROPOSAL  
AGREEMENT CERTIFICATION  
MODEL AGREEMENT

**REMINDER:** Each Module Announcement will have two (2) bundles of attachments; one for OT's and the other for Cooperative Agreements.

### **3.2 PROPOSAL SUBMISSION INFORMATION**

All submissions, including proposals, must be written in English with font type NOT smaller than 12-point font. Smaller font may be used for figures, tables, and charts.

Responses to all Module Announcements shall be submitted to the [electronic Contract Proposal Submission](#) (eCPS)<sup>1</sup>, ensuring receipt by the date and time specified in the Module Announcement. Further detailed instructions will be provided within each Module

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<sup>1</sup> electronic Contract Proposal Submission (eCPS) is a component of an integrated, secure system for electronic submission, capture, tracking and review of contract proposals. Be advised eCPS requires user registration to submit a proposal response (<https://ecps.nih.gov/>).



Announcement.

When planning a response to a Module Announcements, proposers should consider the submission time zone and that some parts of the submission process may take from one business day to one month to complete (e.g., registering for a SAM Unique Entity ID (UEI) number or Tax Identification Number (TIN); see Section 5.2.1 for information on obtaining a UEI and TIN).

### **3.3 SUBMISSION DEADLINES**

Proposal packages must include Volume 1: Technical and Management, BOE, TDD or RDD, and Administrative and National Policy Requirements, and must be submitted per the instructions outlined in the Module Announcement and received by ARPA-H no later than the due date and time listed in the Module Announcement to which the proposal is submitted. Proposals and proposal modifications, unless requested by the Government AO received after the due date set forth in the Module Announcement will be considered late and may not be evaluated.

**3.3.1 PROPOSAL SELECTION VOLUME 2 SUBMISSION DEADLINE:** ONLY upon notification of technical proposal selection for potential award will a proposer submit a Volume 2 Price/Cost Proposal and, as applicable, proprietary subawardee price/cost proposals. Additional instruction will be provided independently to each proposer selected for a Volume 2 submission.

### **3.4 PROPRIETARY INFORMATION**

Regarding proprietary markings, proposers are responsible for clearly identifying proprietary information. Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as “Proprietary.” **NOTE:** “Confidential” is a classification marking used to control the dissemination of U.S. Government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

### **3.5 SECURITY INFORMATION**

See Section 5.2.2 for Sensitive but Unclassified (SBU) and Controlled Unclassified Information (CUI) compliance requirements. Further security requirements will be stated in Module Announcements.

## **4. EVALUATION OF PROPOSALS**

### **4.1 EVALUATION STAGES**

1. Stage one (1) evaluation: Volume 1 proposals will be evaluated against evaluation criteria 1-3 noted below.
2. Stage two (2) evaluation: If stage one (1) results in proposal selection for potential award, the proposer will be required to submit Volume 2, which will be evaluated against evaluation criteria 4 as distinguished below.

### **4.2 EVALUATION CRITERIA FOR AWARD**

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

**1. OVERALL SCIENTIFIC AND TECHNICAL MERIT**

The proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible. In addition, the evaluation will take into consideration the extent to which the proposed intellectual property (IP) rights structure will potentially impact the Government's ability to transition the technology.

**2. PROPOSER'S CAPABILITIES AND/OR RELATED EXPERIENCE**

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

**3. POTENTIAL CONTRIBUTION TO RELEVANCE TO THE ARPA-H MISSION**

Potential future R&D, commercial, and/or clinical applications of the project proposed, including whether such applications may have the potential to address areas of currently unmet need within biomedicine and improve health outcomes. Degree to which the proposed project has the potential to transform biomedicine. Potential for the project to take an interdisciplinary approach.

**4. PRICE AND VALUE ANALYSIS/COST REALISM/REASONABLENESS**

Price and value analysis will be performed on each proposal to assess the reasonableness and value the overall proposed price provides the Government for the technical solution selected.

When price and value analysis are inconclusive, cost realism analysis may be performed to ensure proposed costs are realistic for the technical and management approach, accurately reflect the technical goals and objectives of the solicitation, the proposed costs are consistent with the proposer's Scope of Work and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed subawardees 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 and the basis for the estimates).

It is expected that 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 direct cost sharing may be a positive factor in the evaluation. As noted in Section 1.1, ARPA-H recognizes that undue emphasis on cost may motivate proposers to offer low-risk ideas with minimum uncertainty and to staff the

effort with junior personnel to be in a more competitive posture. ARPA-H discourages such cost strategies.

#### 4.3 REVIEW AND SELECTION PROCESS

It is the policy of ARPA-H to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed above and to select the source (or sources) whose offer meets the Government's technical, policy, and programmatic goals.

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 4.2

Relative to the evaluation criteria, the Government will evaluate each conforming proposal in its entirety, documenting the strengths and weaknesses. Based on the identified strengths and weaknesses, ARPA-H will determine whether a proposal will be selected for award. Proposals will not be evaluated against each other during the scientific review process, but rather evaluated on their own individual merit to determine how well the proposal meets the criteria stated in this MAI.

An award will be made to a proposer(s) whose proposal is determined to be selectable by the Government, consistent with instructions and evaluation criteria specified in the MAI herein and based on availability of funding. Given the limited funding available for each Module Announcement, not all proposals considered selectable may receive an award and funding.

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

**SELECTABLE:** A selectable proposal is a proposal that has been evaluated by the Government against the evaluation criteria listed in the MAI, and the positive aspects of the overall proposal outweigh its negative aspects. Additionally, there are no accumulated weaknesses that would require extensive negotiations and/or a resubmitted proposal.

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

**NON-SELECTABLE:** A proposal is considered non-selectable when the proposal has been evaluated by the Government against the evaluation criteria listed in the MAI, and the positive aspects of the overall proposal do not outweigh its negative aspects. Additionally, there are accumulated weaknesses that would require extensive negotiations and/or a resubmitted proposal.

**CONFORMING PROPOSALS:** Conforming proposals contain all requirements detailed in this MAI and the Module Announcements to which the proposal is submitted. Proposals that fail to include required information may be deemed non-conforming and may be removed from consideration. Non-conforming submissions may be rejected without further review. A proposal will be deemed non-conforming if the proposal fails to meet one or more of the following requirements:

- The proposed concept is applicable to the technical area(s) described in the Module Announcement to which they are applying.
- The proposers meet the eligibility requirements of the MAI.
- The proposal met the submission requirements of the MAI.

- The proposal met the content and formatting requirements in the attached templates to this MAI.
- The proposal provided sufficient information to assess the validity/feasibility of its claims.
- The proposer has not already received funding or a positive funding decision for the proposed concept (whether from ARPA-H or another Government agency).

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

ARPA-H's intent is to review proposals as soon as possible after they arrive.

#### **4.3 HANDLING OF COMPETITIVE SENSITIVE INFORMATION**

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

All ARPA-H support contractors are expressly prohibited from performing ARPA-H sponsored technical research and are bound by appropriate nondisclosure agreements. Input on technical aspects of the proposals 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.

### **5. AWARD ADMINISTRATION INFORMATION**

#### **5.1 NOTICES**

The following notices will be provided as applicable:

- Request for clarifying details (if applicable)
  - May occur at any time during the evaluation process
  - Will not include requests for proposal changes and changes will not be permitted
- Request for additional information (if needed)
  - Proposers will be advised of any deficiencies and/or major weaknesses in their proposals and given an opportunity to respond, to include offering proposal amendments
- Notice of non-selection
  - Proposer will be advised their proposal submission has not been selected to advance to Stage 2
- Notice of selection
  - Stage 1 selection notice; Volume 2 submission requirements. This notification may indicate that all or part of the technical effort has been selected for Stage 2; Volume 2 proposals should only address those selected tasks

- Stage 2 selection notice: selection notice will notify the proposer that the Government has selected their proposal for negotiation of potential award. This notification may indicate that only a part of the effort has been selected for negotiation, and may request a revised proposal for only those selected portions, if not apparent through the delineation of proposed tasks

The above listed notifications will be sent via email to the Technical and Administrative point of contacts identified on the proposal coversheet.

## **5.2 ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS**

### **5.2.1 SYSTEM FOR AWARD MANAGEMENT (SAM) REGISTRATION AND UNIVERSAL IDENTIFIER REQUIREMENTS**

All proposers must be registered in SAM and have a valid Unique Entity ID (UEI) number in order to propose to a Module Announcement. You must maintain an active registration in [SAM.gov](https://sam.gov) with current information at all times during which you have an active Federal award or idea under consideration by ARPA-H. Information on [SAM.gov](https://sam.gov) registration is available at [SAM.gov](https://sam.gov).

**NOTE:** New registrations can take an average of 7-10 business days to process in [SAM.gov](https://sam.gov). Registration requires the following information:

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

### **5.2.2 CONTROLLED UNCLASSIFIED INFORMATION (CUI) OR CONTROLLED TECHNICAL INFORMATION (CTI) ON NON-DOD INFORMATION SYSTEMS**

Further information on Controlled Unclassified Information identification, marking, protecting and control is incorporated herein and can be found at 32 CFR 2002.

### **5.2.3 INTELLECTUAL PROPERTY**

Proposers must provide a good faith representation that the proposer either owns or possesses the appropriate licensing rights to all intellectual property that will be utilized for the proposed effort. Each Module Announcement will state goals and/or requirements associated with intellectual property right assertions.

### **5.2.4 HUMAN SUBJECTS RESEARCH**

All entities submitting a proposal for funding that will involve engagement in human subjects research (as defined in [45 CFR § 46](https://www.fda.gov/oc/ohrt/45-cfr-46)) must provide documentation of one or more current Assurance 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](https://www.hhs.gov/ohrt/). All human subjects research must be

reviewed and approved by an Institutional Review Board (IRB), as applicable under [45 CFR § 46](#) and/or 21 CFR § 56. The entities human subjects research 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 the ARPA-H funded work. This includes, but is not limited to, laws, regulations, and policies regarding the conduct of human subjects research, such as the U.S. federal regulations protecting human subjects in research (e.g., 45 CFR § 46, 21 CFR § 50, § 56, § 312, § 812) and any other equivalent requirements of the applicable jurisdiction.

The informed consent document utilized in human subjects research 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 human subjects research training by all investigators and key personnel who will be involved in the design or conduct of the ARPA-H funded human subjects research. Funding cannot be used toward human subjects research until ALL approvals are granted.

#### **5.2.5 ANIMAL SUBJECTS RESEARCH**

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

Proposers must complete and submit the Vertebrate Animal Section [worksheet](#) for all proposed research anticipating Animal Subject Research.

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.

#### **5.2.6 ELECTRONIC INVOICING AND PAYMENTS**

Performers will be required register in and to submit invoices for payment directly to [Invoice Processing Platform](#) unless an exception applies.

#### **5.2.7 GOVERNMENT-FURNISHED PROPERTY/EQUIPMENT**

Government-furnished property/equipment may be provided to selected performers. Module Announcement(s) will contain information and instructions.

#### **5.2.8 ASSOCIATE CONTRACTOR AGREEMENT (ACA)**

An Associate Contractor Agreement (ACA) is an agreement between non-Federal entities

or Federal contractors (hereinafter Contractor) working in furtherance of an ARPA-H agreement that requires the parties to share information, data, technical knowledge, expertise, or resources. An Associate Contractor is defined as a party to an ACA. ARPA-H is not a party to an ACA.

Each Module Announcements may have the same or similar ACA language included in each resulting award. See [Appendix B](#) for a full description of the ACA.

## **6. COMMUNICATIONS**

ARPA-H intends to use electronic mail for all correspondence regarding solicitation ARPA-H-MAI-24-01. Administrative questions regarding this MAI should be emailed to the MAI Coordinator. ARPA-H will post a Q&A document to [SAM.gov](#) regarding all administrative questions submitted to this MAI on an as needed basis. All questions must be in English and must include the name, email address, and telephone number of a point of contact.

Module Announcement: A Q&A document will be provided in accordance with the instructions in each Module Announcement. All questions must be in English and must include the name, email address, and telephone number of a point of contact.

ARPA-H will attempt to answer questions in a timely manner; however, questions submitted within 10 days of the proposal due date listed in the Module Announcement may not be answered.

## APPENDIX A: RSO INTEREST AREAS

Interest areas include, but are not limited to:

- Novel methods to engineer resilient tissues, microbiomes, and biophysical systems to combat disease or maintain health.
- Approaches that enable health infrastructure to rapidly integrate commercial-off-the-shelf solutions, create decision support tools, and adapt supply chains, manufacturing, logistics, and strategies to leverage workforce during public health emergencies.
- Novel ways to protect, secure, integrate, analyze, communicate, and present health data, including but not limited to advances in privacy, cyber security, artificial intelligence with enhanced patient safety properties, low-code or no-code technologies, semantic approaches, and rapid integration techniques.
- Strategies and technologies to leverage homes, community centers, pharmacies, and other accessible locations as distributed clinical trial sites to diversify participation in clinical trials and integrate end-user feedback to rapidly iterate prototype designs.
- Approaches to build trust in the healthcare system and distribute high-quality health guidance in an understandable manner that improves patient outcomes.
- Novel real-time measurement tools to track health outcomes, evaluate post-market performance of new interventions, and enable convergence on the most effective strategies to improve the quality of care, especially for underserved communities.
- Development of novel approaches to address ELSI challenges governance frameworks for health information, consent, data reuse, biosecurity, and potential unintended consequences.



## APPENDIX B: ASSOCIATE CONTRACTOR AGREEMENT (ACA)

An Associate Contractor Agreement (ACA) is an agreement between non-Federal entities or Federal contractors (hereinafter Contractor) working in furtherance of an ARPA-H agreement that requires the parties to share information, data, technical knowledge, expertise, or resources. An Associate Contractor is defined as a party to an ACA. ARPA-H is not a party to an ACA.

Each Module Announcements may have the same or similar ACA language included in each resulting award.

Submission of a conforming proposal or receipt of an award under an ARPA-H solicitation is not conditioned on Associate Contractors or their subcontractors selling, furnishing, or relinquishing proprietary information or confidential data (e.g., intellectual property).

- (a) It is recognized that success of the research effort depends in part upon the open exchange of information between the various Associate Contractors involved in the effort. This is intended to ensure that there will be appropriate coordination and integration of work by the Associate Contractors to achieve complete compatibility and to prevent unnecessary duplication of effort. By executing this Agreement, the Contractor assumes the responsibilities of an Associate Contractor. For this ACA, the term Contractor includes subsidiaries, affiliates, and organizations under the control of the Contractor (e.g., subcontractors).
- (b) Work under this Agreement may involve access to proprietary information or confidential data from an Associate Contractor. Associate Contractor and their subcontractor are not required to sell, furnish, or relinquish proprietary information or confidential data developed at private expense unless mutually agreed. To the extent that such data is received by the Contractor from any Associate Contractor for the performance of this contract, the Contractor hereby agrees that any proprietary information or confidential data received shall remain the property of the Associate Contractor and shall be used solely for the purpose of the research effort. Only that information received from another contractor, in writing, and is clearly identified as proprietary or confidential shall be protected in accordance with this provision. A Contractor's obligation to retain such information in confidence will be satisfied if the Contractor utilizes the same controls to avoid disclosure, publication, or dissemination of its own proprietary information. The receiving Contractor agrees to hold such information in confidence as provided herein so long as such information is of a proprietary/confidential or limited rights nature.
- (c) The Contractor hereby agrees to closely cooperate as an Associate Contractor with the other Associate Contractors on this research effort. This involves as a minimum:
  - (1) maintenance of a close liaison and working relationship;
  - (2) maintenance of a free and open information network with all Government-identified associate Contractors;
  - (3) delineation of detailed interface responsibilities;
  - (4) entering into a written agreement with the other Associate Contractors setting forth the substance and procedures relating to the foregoing, and promptly providing the Agreements Officer with a copy of same; and,

- (5) receipt of proprietary information from the Associate Contractor and transmittal of Contractor proprietary information to the Associate Contractors subject to any applicable proprietary information exchange agreements between associate contractors when, in either case, those actions are necessary for the performance of either.
- (d) In the event that the Contractor and the Associate Contractor are unable to agree upon any such interface matter of substance, or if the technical data identified is not provided as scheduled, the Contractor shall promptly notify the ARPA-H Program Manager. The Government will determine the appropriate corrective action and will issue written guidance to the affected Contractor.
- (e) The Contractor agrees to insert in all subcontracts hereunder which require access to proprietary information belonging to the Associate Contractor, a clause which shall conform substantially to this language, including this paragraph (e).
- (f) Associate Contractors for this research effort include:

Contractor

Technical Area