INNOVATIVE SOLUTIONS OPENING

FOR

BRAIN REPAIR OF ANY INJURED NEURAL STRUCTURE

BRAINS

HEALTH SCIENCE FUTURES

ARPA-H-SOL-26-148

JUNE 8, 2026

Amendment 01: June 23, 2026

Table of Contents

INNOVATIVE SOLUTIONS OPENING (ISO) SUMMARY INFORMATION 4
1. INTRODUCTION TO BRAINS 4
1.1 BACKGROUND 4
1.2 EXPLORATORY TOPIC OVERVIEW 5
2. THE EXPLORATORY TOPIC 6
3. ELIGIBILITY INFORMATION 9
3.1 ELIGIBLE PROPOSERS 9
3.1.1 PROHIBITION OF PERFORMER PARTICIPATION FROM FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS (FFRDCs) AND OTHER GOVERNMENT ENTITIES. 9
3.1.2 CURRENT PROFESSIONAL SUPPORT 10
3.1.3 NON-U.S. ENTITIES 10
3.2 SYSTEM FOR AWARD MANAGEMENT (SAM) 10
4 SUBMISSION PROCESS 10
4.1 SUBMISSION PROCESS OVERVIEW 10
4.2 SOLUTION SUMMARY SUBMISSIONS 11
4.3 FULL PROPOSAL SUBMISSIONS 11
4.4 SUBMISSION INFORMATION 11
4.5 PROPRIETARY INFORMATION 12
5 SUBMISSION REVIEW AND EVALUATION PROCESSES 12
5.1 CONFORMING SUBMISSIONS 12
5.2 SOLUTION SUMMARY REVIEW PROCESS 12
5.3 PROPOSAL REVIEW PROCESS 13
5.4 EVALUATION CRITERIA FOR PROPOSALS 13
5.4.1 CRITERIA 1: OVERALL SCIENTIFIC AND TECHNICAL MERIT 13
5.4.2 CRITERIA 2: PROPOSER'S CAPABILITIES AND/OR RELATED EXPERIENCE 13
5.4.3 CRITERIA 3: POTENTIAL CONTRIBUTION TO RELEVANCE TO THE ARPA-H MISSION AND USER EXPERIENCE 13
5.4.4 CRITERIA 4: ASSESSMENT OF PROPOSED COST/PRICE 13
5.5 HANDLING COMPETITION SENSITIVE INFORMATION 14
5.6 EVALUTION AND AWARD DISCLAIMERS 14

6 POLICY REQUIREMENTS AND MISCELLANEOUS OTHER INFORMATION 14
6.1 CONTROLLED UNCLASSIFIED INFORMATION (CUI) ON NON-FEDERAL INFORMATION SYSTEMS 14
6.2 ORGANIZATIONAL CONFLICTS OF INTEREST (OCI) 15
6.2.1 AGENCY SUPPLEMENTAL OCI POLICY 15
6.2.2 RESEARCH SECURITY DISCLOSURES 15
6.3 INTELLECTUAL PROPERTY 16
6.4 ANIMAL SUBJECTS RESEARCH 16
6.5 ELECTRONIC INVOICING AND PAYMENTS 17
6.6 PROCUREMENT OF SYNTHETIC NUCLEIC ACIDS OR BENCHTOP SYNTHESIZERS 17
6.7 DANGEROUS GAIN OF FUNCTION RESEARCH 17

APPENDIX A: Solution Summary Content and Instructions

APPENDIX B: Full Proposal Content and Instructions

INNOVATIVE SOLUTIONS OPENING (ISO) SUMMARY INFORMATION

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

EXPLORATORY TOPIC TITLE: Brain Repair of Any Injured Neural Structure (BRAINS)

ANNOUNCEMENT TYPE: Innovative Solutions Opening (ISO)

ISO SOLICITATION NUMBER: ARPA-H-SOL-26-148

ISO CONTACT: BRAINS@ARPA-H.gov

ANTICIPATED AWARDS: Other Transactions

DATES: (All times listed are Eastern Time)

Posting Date: June 8th, 2026
Virtual Only Proposers' Day (PD): June 9th, 2026, 12:00 PM
Virtual Only Proposers' Day Video Link: https://arpa-h.gov/explore-funding/initiatives-and-sprints/BRAINS
Questions & Answers (Q&A) due date: June 22nd, 2026, 5:00 PM
Questions & Answers (Q&A) session: June 24th, 2026, 3:30 - 5:30 PM
Sidebar session: June 25th, 2026, 3:30 - 5:30 PM

Intake Group 1:
Solution Summaries Due: July 9th, 2026, 5:00 PM
Full Proposals Due: August 6th, 2026, 5:00 PM

Intake Group 2:
Solution Summaries Due: January 7th, 2027, 5:00 PM
Full Proposals Due: February 6th, 2027, 5:00 PM

WHERE TO SUBMIT:

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

1. INTRODUCTION TO BRAINS

1.1 BACKGROUND

Many forms of degenerative disease or damage (e.g. strokes, ataxias, tumors, congenital conditions, injury, aging, neurodegeneration etc.) can afflict specific brain structures, leaving tens of millions of Americans permanently disabled, with no effective way to recover lost abilities or independence.

Today, no procedure or therapy exists to replace damaged or degenerated brain tissue to restore lost function. Treatments are limited to physical, psychological, and occupational

therapies, which provide only partial compensation of function for a fraction of patients. In the U.S. alone, brain damage from stroke, neurodegeneration, injury, cancer, congenital conditions, and aging leaves tens of millions disabled, with direct and indirect costs exceeding $1 trillion per year.

Attempts to grow new tissue ex vivo have focused primarily on organoid technologies and cell-based therapies, but these approaches are fundamentally unsuited for functional restoration because they lack essential cell types, proper cell ratios, vasculature, normal cytoarchitecture, physiology, and connectivity - thus failing to mimic the complexity needed for normal function and behavior.

Overcoming these challenges would enable true functional restoration, dramatically improving outcomes for patients and families.

1.2 EXPLORATORY TOPIC OVERVIEW

BRAINS will take the first technological steps toward regrowing in situ normal region-specific brain tissue from transplanted precursor tissue. The goal of this Exploratory Topic is to demonstrate the feasibility of replacing damaged tissue in any part of the brain.

BRAINS is complementary to the Functional Repair of Neocortical Tissue (FRONT) Program, which focuses exclusively on neocortical tissue. BRAINS will target brain regions including but not limited to the hippocampus, amygdala, thalamus, hypothalamus, striatum, cingulate cortex, substantia nigra, brainstem, and cerebellum. Specifically excluded regions are the neocortex and spinal cord. The technologies required for success will likely differ for each brain area: generating precursor tissues will require different cell or developmental differentiation protocols, different assembly and extracellular components, and different surgical implementation tools and strategies. Proposals submitted to address damage or disease to the neocortex or spinal cord will not be reviewed. The brain regions of interest are collectively responsible for movement, balance, mood, autonomic body functions, memory formation, and other functions, thus addressing a wide range of disabilities caused by any form of brain damage (aging, congenital diseases, strokes, injuries, tumors, infections, etc.).

Recent advances in bioengineering, omics, cell mapping, and Artificial Intelligence/Machine Learning (AI/ML) guided methods enable the creation and validation of precursor tissues that match their natural counterparts. Breakthroughs in neuroscience, imaging, advanced surgical tools, robotics, and brain stimulation make graft transplantation, integration, and functional restoration feasible capabilities that were not possible five years ago.

BRAINS aims to advance technology for generating precursor tissue products that can restore function to damaged regions of the brain. Cell and state-of-the-art organoid-based approaches will not be considered. Applicants are encouraged to consider approaches that closely mimic natural precursor tissue and natural development, however alternative approaches may be considered if there is a compelling case that functional tissue can be produced, integrated with the brain, and function normally.

With BRAINS, ARPA-H aims to catalyze rapid progress that would not otherwise occur. By the end of this 18-month Exploratory Topic, BRAINS will deliver validated methods for generating

region-specific precursor brain tissue and demonstrate proof-of-concept of surgical engraftment in preclinical models, paving the way for future clinical trials aimed at restoring lost abilities and independence to patients in need.

2. THE EXPLORATORY TOPIC

BRAINS is an Exploratory Topic with two (2) intake groups, each will take 18 months from kickoff to completion and will consist of two (2) 9-month phases with a down select at the end of Phase 1. Criteria for moving to Phase 2 are the metrics as described in Tables 2, 3, and 4 for Phase 1.

2.1 Technical Areas (TAs) and Milestones

Using natural brain development as a blueprint, BRAINS will seed efforts for two (2) technical areas, which are essential for later steps in functionally replacing damaged brain tissue. In TA1 teams will design developmental mimicking or tissue engineering methods capable of generating precursor tissue for a part of the brain other than neocortex. In TA2 teams will provide proof-of-concept for surgical engraftment into adult brains of non-human fetal precursor tissues for their selected brain area. Teams must propose to address all milestones and metrics of either one TA or both.

TA1: Defining and generating precursor tissue for any brain region, including identification of all cellular and extracellular components via omics and histology, and protocols for generating human iPSC-derived precursor cells.

TA1 Milestones:

1. Detail specifications of target tissue via characterizing natural precursor tissue (all cell types, density, spatial organization, non-cellular components).
2. Establish protocols for generating all the relevant precursor cell types.
3. Elaborate a detailed tissue generation method.
4. Generate prototype precursor tissue with demonstrated metrics of equivalence to natural precursor tissue.

TA2: Optimizing surgical engraftment of precursor tissue into adult brains, with proof-of-concept in animal models, measuring survival, vascularization, tissue structure, connectivity, and functional integration. In choosing the type of damage or lesion, consideration should be given to how useful it will be for future functional assessment of the tissue graft in demonstrating reacquisition of lost function (without proposing to demonstrate function in this initial effort.

TA2 Milestones:

1. Establish method for surgically transplanting donor tissue demonstrated using a fetal, non-human donor into a conspecific host.
2. Demonstrate grafted donor tissue vascularization within 48 hours of transplantation and survival for minimally 21 days.
3. Demonstrate grafted donor tissue matures in situ, forming appropriate internal structure and connections to appropriate targets.

Table 1. BRAINS Phase Structure

Technical Areas	Phase I: 9 months			Phase II: 9 months		
TA1: Generate precursor tissue	Q1	Q2	Q3	Q4	Q1	Q2
Characterize natural tissue						
Establish precursor cell production protocols						
Elaborate a detailed tissue generation method						
Prototype precursor tissue produced						
TA2: Engraftment POC with native fetal tissue						
Develop surgical method						
Demonstrate graft survival and vascularization						
Demonstrate graft structure and connectivity						

2.2 Metrics and Deliverables

Table 2. TA1 Milestones and Metrics

Milestone	Metrics
Natural Tissue Characterization	1. Using published and/or newly generated datasets, identification of all cellular and major extracellular components in each early-stage brain region by omics analysis of natural tissue, with histological validation to determine presence of components, cell ratios, densities, and structural organization.
Pre-cursor Cell Protocols	1. Generate from human induced Pluripotent Stem Cells (iPSCs) all precursor cell types for the targeted brain regions (neuronal, glial, vascular, and other specialized cells). 2. For developmental mimetic approaches, validate that structures can be comprised of the same cellular and major extracellular components as their natural counterparts.
Elaborated Tissue Generation Method	3. Develop a clear and detailed strategy to generate human precursor tissue that mimics all aspects of its native equivalent: cell types, ratios, densities, cell-cell contacts, and extracellular structural and guidance cues. Strategies might employ an engineering approach whereby components are assembled, or employ the growth of developmental mimetics from iPSCs, or combinations of both. Strategies must include a detailed plan for demonstrating that the new tissue, by virtue of its normal function, is responsible for a reacquired behavior.
Prototype Precursor Tissue	1. For developmental mimetic approaches, validate that the cell types and ratios, major extracellular components, and tissue structure are >80% similar to their natural counterparts. 2. For engineered approaches, the tissue prototype should contain the 10-20 most relevant extracellular components per tissue substructure (e.g. layers or nuclei or other) to make a natural biogel for each to enable initial normal growth and differentiation. The tissue substructures should have cell types and ratios >80% similar to their natural counterparts.

Table 3. TA2 Milestones and Metrics	
Milestone	**Metrics**
Surgical Method	1. In a pre-clinical animal model, develop a clear and detailed strategy, including risks and mitigations, for surgical transplantation and support of engraftment of donor fetal animal tissue into adult animals; demonstrate initial proof-of-concept of surgical engraftment. 2. Tissue removal/lesioning in the host at the engraftment site shows measurable (statistically significant) functional impairment useful for a future function reacquisition test.
Survival & Vascularization	1. Rapid and robust vascularization of the grafted tissue (within 48 hours) demonstrated by >80% cell survival.
Structure & Connectivity	1. Tissue structure parameters (e.g. cell ratios, positions) within +/-20% of age-matched native tissue (2-weeks post-transplant and when tissue should be more mature). 2. Neural projections and connectivity of the grafted tissue with relevant host brain areas, as well as intra-graft connectivity within 30% of age-matched native tissue.

Table 4. Deliverables by Phase	
Phase I	1. Detailed plan and cell protocols for making precursor tissue, meeting all metrics described in Table 2 2. Surgical method with initial proof-of-concept, meeting all metrics described in Table 3.
Phase II	1. Validated precursor tissue. 2. Validated surgical delivery with donor tissue (survival, vascularization, appropriate connections).

2.3 Terms, Exclusions, and Regulations

ARPA-H intends to negotiate multiple Other Transaction (OT) Agreements with proposers whose proposals are most advantageous to the Government.

It is important to note that specifically excluded are proposals that: 1) offer incremental improvements to the existing state-of-the-art, 2) make use of human embryos or human fetal tissue, and 3) do not address the objectives of the Exploratory Topic. Furthermore, all proposals must comply with all relevant HHS regulations on research and pre-clinical studies using human stem cells:

https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research

https://osp.od.nih.gov/wp-content/uploads/QA_Chimera_Policy_updated_1_Feb_2017.pdf

For this Exploratory Topic, ARPA-H anticipates Phase I awards of $500,000 per team per TA, with the possibility of an additional $500,000 per team per TA for Phase II. Proposers are encouraged to structure their budgets to reflect this guidance.

2.4 Reporting

Performance reporting will be required throughout the Exploratory Topic, and will include:

- Monthly technical status reports for discussion with the ARPA-H Program Manager and team.
- Minimally, monthly check-ins (virtually) of at least 1 hour to discuss project results, science, challenges and solutions, and other project-related topics.
- ARPA-H may request performer data and arrange visits to their facilities as deemed necessary throughout the work timeline to validate technical progress.
- Attendance at meetings must include the performer Principal Investigator (PI), and in addition ARPA-H may request members of the performer teams to attend as it deems necessary.

3. ELIGIBILITY INFORMATION

3.1 ELIGIBLE PROPOSERS

All responsible sources capable of satisfying the Government's needs may submit a proposal to this ISO. Specifically, universities, non-profit organizations, small businesses and other than small businesses are eligible and encouraged to propose to this ISO. Early career investigators are preferred.

While there is statutory language that may suggest ARPA-H is limited in the number of awards it may make to one entity, there are circumstances in which ARPA-H may make more than three (3) awards to a particular person or entity. ARPA-H encourages entities to submit their research ideas notwithstanding this perceived limitation. Any proposal received will be fairly considered for award and, if it is of interest to ARPA-H, will be selected for an award.

3.1.1 PROHIBITION OF PERFORMER PARTICIPATION FROM FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS (FFRDCs) AND OTHER GOVERNMENT ENTITIES

ARPA-H is primarily interested in responses to this solicitation from commercial performers, academia, non-profit organizations, etc. In certain circumstances, FFRDCs and Government Entities may have unique capabilities that are not available to proposing teams through any other resource. Accordingly, the following principles will apply to this solicitation.

- FFRDCs and Government entities, including federal Government employees, **are not** permitted to respond to this solicitation as a prime or sub-performer on a proposed performer team.

- If an FFRDC or Government entity has a unique research idea that is within the technology scope of this solicitation that they would like considered for funding; OR, 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, contact BRAINS@arpa-h.gov.

- If a potential prime performer believes an FFRDC has a unique capability without which their solution is unachievable, they may provide documentation as part of their Solution Summary submission demonstrating they have exhausted all other

options. ARPA-H will consider the documentation to determine if inclusion of the FFRDC is necessary for the Solution.

3.1.2 CURRENT PROFESSIONAL SUPPORT

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

3.1.3 NON-U.S. ENTITIES

ARPA-H will prioritize awards to entities (organization and/or individuals) that will conduct funded work in the United States. Non-U.S. entities may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. In accordance with these laws and regulations, in no case will awards be made to entities organized under the laws of a covered foreign country [as defined in section 119C of the National Security Act of 1947 (50 U.S.C. Ch 44 § 3059)]; a foreign entity of concern meeting any of the criteria in section 10638(3) of the CHIPS and Science Act of 2022; an individual that is party to a malign foreign talent recruitment program, as defined in Section 10638(4) of the CHIPS and Science Act of 2022; or entities suspended or debarred from business with the government.

3.2 SYSTEM FOR AWARD MANAGEMENT (SAM)

All proposers must have an active registration in SAM.gov for their proposal to be found conforming. Proposers must maintain an active registration in SAM.gov with current information at all times during which a proposal is under consideration or a current award from ARPA-H is held. Information on SAM.gov registration is available at SAM.gov.

NOTE: New registrations as well as renewals may take more than 14 business days to process in SAM.gov. SAM.gov is independent of ARPA-H and thus ARPA-H representatives have no influence over processing timeframes.

Information related to updates to this ISO can be found on the SAM.gov listing along with ancillary material to support proposal submission. ARPA-H cannot provide technical support for software issues encountered while using these materials. If you believe there is an error in the content of these materials, please email BRAINS@arpa-h.gov.

4 SUBMISSION PROCESS

4.1 SUBMISSION PROCESS OVERVIEW

Submissions for BRAINS are as follows:

- ✓ **Step 1:** Submit Solution Summary during one of the two intake groups (Proposers are encouraged / discouraged to move to Step 2). If unsuccessful with the first submission, resubmissions in the second intake are permitted.
- ✓ **Step 2:** Submit Full Proposal(s)

4.2 SOLUTION SUMMARY SUBMISSIONS

Solution summaries shall not exceed three (3) pages, excluding the cover page, Rough Order of Magnitude (ROM), team qualifications, and references. ***The Government will not review pages beyond three (3) pages.***

Based on the evaluation of solution summaries, selected teams will be encouraged or discouraged to submit full proposals

Solution Summary submissions are required and are due by the date listed in the ISO Summary Information Section. See Appendix A for the required Solution Summary format.

4.3 FULL PROPOSAL SUBMISSIONS

All proposals submitted in response to this ISO must comply with the content and formatting requirements in the applicable Bundle of Attachments templates. Proposers should use the templates provided in the Bundle of Attachments. The Bundle of Attachments includes the following five (5) templates:

1. Tech and Management (10 pages)
2. Task Description Document (TDD) (no page limit)
3. Cost Proposal (no page limit)
4. Cost Proposal Spreadsheet (fill in applicable tabs)
5. Administration & National Policy (no page limit)

Documents requested to be submitted with the templates should be included as attachments to the applicable template (e.g., HSR/ASR documents included as attachments to the Administration & National Policy template, cost back-up as attachments to the Cost Proposal template, etc.). Each template includes instructions for completion.

Full proposal submissions are due by the date listed in the ISO Summary Information Section. See Appendix B for the required Full Proposal format.

4.4 SUBMISSION INFORMATION

Non-conforming submissions that do not follow ISO instructions may be rejected without further review at any stage of the process.

All submissions in response to this solicitation must be written in English and must be consistent with the content and formatting requirements of Appendix A (Solution Summary Format and Instructions), and Appendix B (Full Proposal Format and Instructions).

Proposers are responsible for submitting all written submissions 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 summary submission deadline as late submissions resulting from delays with registration may not be accepted or considered.

4.5 PROPRIETARY INFORMATION

Proposers are responsible for identifying proprietary information in any submissions. 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 in accordance with applicable federal law, including the Freedom of Information Act (FOIA).

5 SUBMISSION REVIEW AND EVALUATION PROCESSES

5.1 CONFORMING SUBMISSIONS

Conforming submissions contain all requirements detailed in this ISO. Submissions that fail to include required information may be deemed non-conforming and may be removed from further consideration and/or rejected without further review. A submission may be deemed non-conforming under this ISO if it fails to meet one or more of the following solicitation requirements:

- The proposed concept is applicable to the BRAINS Exploratory Topic.
- The proposers meet the eligibility requirements.
- The submission meets the submission requirements.
- The submission meets the content and formatting requirements in the attached instructions.
- 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).

Proposers will be notified of non-conforming determinations via email correspondence.

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

Prior to submission deadlines, errors in submitted materials may be corrected via resubmission to the Submission Portal, provided an email is sent to BRAINS@arpa-h.gov documenting this action and its intent. After the submission deadline, the most recently received conforming proposal version will be reviewed.

5.2 SOLUTION SUMMARY REVIEW PROCESS

ARPA-H will review and respond to all proposers submitting solution summaries. Solution summaries will be reviewed to provide potential proposers with feedback on whether ARPA-H is interested in the proposed solution/concept. At a minimum the response will indicate whether a proposer is encouraged or discouraged from submitting a proposal. ARPA-H solution summary feedback is provided to ensure that potential proposers are making an

informed decision on the investment of time and resources to submit a full proposal. Feedback will be provided to the administrative and technical points of contacts noted on the solution summary cover page.

5.3 PROPOSAL REVIEW PROCESS

ARPA-H will conduct a scientific and technical review of each conforming full proposal, evaluating proposals on how well the submission meets the criteria stated in this ISO. 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.

5.4 EVALUATION CRITERIA FOR PROPOSALS

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

5.4.1 CRITERIA 1: OVERALL SCIENTIFIC AND TECHNICAL MERIT

The proposed technical approach is innovative, feasible, and complete.

5.4.2 CRITERIA 2: PROPOSER'S CAPABILITIES AND/OR RELATED EXPERIENCE

The proposed technical team has the expertise and experience to accomplish the proposed tasks.

In terms of capability, the Government shall assess the Volume III bio-sketches provided for the performer team members including the Principal Investigator and any other key personnel on the project team as requested by ARPA-H.

5.4.3 CRITERIA 3: POTENTIAL CONTRIBUTION TO RELEVANCE TO THE ARPA-H MISSION AND USER EXPERIENCE

Proposals will be evaluated on the potential future Research & Development, 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; the degree to which the proposed project has the potential to transform biomedicine; and/or the potential for the project to take an interdisciplinary approach.

5.4.4 CRITERIA 4: ASSESSMENT OF PROPOSED COST/PRICE

All proposals will be evaluated to determine the reasonableness or value of the estimated price/cost proposed to accomplish the work in the Statement of Work (SOW). 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).

It is expected the effort will leverage all available relevant prior research to obtain the maximum benefit from the available funding.

Proposers are encouraged to propose the best technical solution. ARPA-H seeks novel

solutions that are reflective of the level of effort and risk proposed.

For this Exploratory Topic, ARPA-H anticipates Phase I awards of $500,000 per team per TA, with the possibility of an additional $500,000 per team per TA for Phase II. Proposers are encouraged to structure their budgets to reflect this guidance.

5.5 HANDLING COMPETITION SENSITIVE INFORMATION

It is the intent of ARPA-H to protect all proposals as competitive sensitive information and to disclose their contents only for the purpose of evaluation, and only to screened personnel for authorized reasons, 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.

5.6 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 Agreements Officer (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 ORGANIZATIONAL CONFLICTS OF INTEREST (OCI)

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

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

6.2.1 AGENCY SUPPLEMENTAL OCI POLICY

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

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

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

6.2.2 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 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. The format for this submission can be found in the Administration and National Security Document Template (Appendix B).

After a proposal is selected for negotiations 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.

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.

6.3 INTELLECTUAL PROPERTY

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

6.4 ANIMAL SUBJECTS RESEARCH

All entities submitting a proposal for funding that will involve engagement in 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:

- 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)."

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.]

6.5 ELECTRONIC INVOICING AND PAYMENTS

Performers will be required to register in, and submit invoices for payment through, the Payment Management Services (PMS) 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 BRAINS program to [include the purpose of the project] for Milestones (s) (or TDD tasks/references) [xx] that were accepted by the Program Manager on [date]. https://pms.psc.gov.

6.6 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.

6.7 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.

APPENDIX A: SOLUTION SUMMARY FORMAT AND INSTRUCTIONS

A. General Instructions

All Solution Summaries must use a font type not smaller than 11-point font. Smaller font may be used for figures, tables, and charts (but should be legible). Margins may be no less than 0.5" inch in width. Solution Summaries are limited to three (3) pages, exclusive of a cover page, rough order of magnitude budget, team qualifications, and references. No tables of content shall be provided. The Government may not review pages beyond (3) total; and any Solution Summary submitted that exceeds (3) pages will only be reviewed at ARPA-H's discretion. Solution Summaries should be submitted in a PDF format to ARPA-H Solution Submission Portal. Attachments and embedded links shall not be included. The Solution Summary should address why the proposed idea is relevant to the ARPA-H mission and the proposed BRAINS Exploratory Topic. Your Solution Summary should address the technical merit of the proposed approach and team organization, capabilities, and qualifications for this proposed idea. Proposers should frame their responses using at least the first 3 of the 10 ARPA-H Heilmeier Questions (HQs):

1. What health problem are you trying to solve? Articulate your objectives using absolutely no jargon.

2. How is it done today, and what are the limits of current practice?

3. What is new in your approach, and why do you think it will be successful?

And include the following items:

- ✓ Team qualifications
- ✓ R&D timeline—what you can accomplish in the agreed upon project timelines?
- ✓ Rough Order of Magnitude (ROM)

B. Cover Page

The cover page should follow the format below. The cover page does not count towards the page limit.

Innovative Solutions Opening	ARPA-H-SOL-26-148
Solution Summary Title	
Submitter Organization	
Unique Entity Identifier of prime proposer/awardee (UEI), if known	

Type of Organization and website URL if applicable	**Choose all that apply:** Large Business, Other Small Business, Other Educational, or Other Nonprofit
Technical Point of Contact (POC)	Name: Mailing Address: Telephone: Email:
Administrative POC	Name: Mailing Address: Telephone: Email:
Total Estimated Budget	Total: $
Place(s) of Performance	
Other Team Members (sub-performers, including consultants) if any	Technical POC Name: Organization: Organization Type:

C. Proposed Work

Clearly identify the problem(s) to be solved and the outcome(s) sought with the proposed technology concept. Explain the concept's potential to be disruptive compared to existing or emerging technologies, including anything with pre-existing funding and how the proposed approach will go far beyond current commercial capabilities.

Describe the final deliverable(s) for the project, one or two key interim milestones, and the overall technical approach used to achieve project objectives. Describe the background, theory, simulation, modeling, experimental data, or other sound engineering and scientific practices or principles that support the proposed approach. Identify adoption challenges to be overcome for the proposed technology to be successful. Describe key technical risks.

D. Team Organization and Capabilities

Indicate the roles and responsibilities of the organizations and key personnel that comprise the Performer Team. Provide the name, position, and institution of each key team member; and describe in 1-2 sentences the skills and experience they bring to the team.

E. Rough Order of Magnitude (ROM)

Please include a ROM to support the proposed project budget as well as the total project cost including cost sharing, if applicable. The ROM should also include a breakdown of the work by fully burdened labor (inclusive of fringe), subcontracts, materials, equipment, travel, other direct costs, indirect costs, profit, cost sharing, and any other relevant costs. Also, estimate the total number of labor hours anticipated per phase in the labor hours row. All subcontracts should total together in the subcontracts line. The below table may be used for this breakdown:

Categories	**Phase I Amount**	**Phase II Amount**		**Total**
Direct Labor (including fringe)				
Labor Hours				
Subcontracts				
Materials				
Equipment				
Travel				
Other Direct Costs				
Indirect Costs				
Profit/Fee				
Total				
Cost Sharing (if applicable/appropriate)				

Proposers must ensure the ROM encompasses all applicable costs and should modify the above to best reflect the proposer's expected costs. The ROM does not count toward the page limit.

NOTE: Delete all formatting and content instructions prior to submission.

APPENDIX B: FULL PROPOSAL FORMAT AND INSTRUCTIONS

Full proposals must follow the guidance in Appendix B. Conforming full proposals should consist of three volumes as follows:

1) Volume I, Technical and Management Proposal

2) Volume II, Cost Proposal

3) Volume III, Administrative and Policy Requirements Submission

Summary of Full Proposal Requirements, including page limits. The following must be used by the prime organization and all sub-awardees at any tier.

Volume I, Technical and Management Proposal

Volume Element	Page Limit
Cover Page	1
A. Executive Summary	10
B. Solution Fit with BRAINS	
C. Technical Plan	
D. Management Plan	
E. Capabilities	
F. Task Description Document (TDD)	N/A, use provided template/format
G. Schedule and Milestones	N/A use provided template/format
H. Data Management and Sharing Plan (DMSP)	N/A (estimated 2 pages)
I. References	N/A

Volume II, Cost Proposal including Cost Narrative

Volume Element	Page Limit
Cover Page	1

A. Cost Proposal Spreadsheet(s), including for subcontractors at any tier	N/A, use provided template/format
B. Cost and Pricing Data Support including a Cost Narrative	N/A

Volume III, Administrative and Policy Requirement Submission

Volume Element	Page Limit
Cover Page	1
1. Team Member Identification	N/A, use provided template/format
2. Federally Funded Research and Development Center (FFRDC) Participation	
3. OCI Affirmations and Disclosure	
4. Research Security Disclosure	
5. Novelty of Proposed Work	
6. Intellectual Property (IP)	
7. Patents	
8. Human Subjects Research	
9. Animal Subjects Research	
10. Representations Regarding Unpaid Delinquent Tax Liability or a Felony Conviction Under any Federal Law	
11. Cybersecurity	
12. Biosecurity	

The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1-inch on all sides, font size should be no less than 11 point (Arial or non-serif font), and page numbers should be included at the bottom of each page.

Documents must be clearly labeled with the ISO number, proposer organization, and proposal title/proposal short title (in the header of each page). Use the following Title Format: "Volume I_XYZ Institution", "Volume II_XYZ Institution", "Volume II Supporting Documents", etc.

I. Volume I, Technical and Management Proposal

The maximum page count for Volume I is ten (10) pages, with exclusions as noted in the table above. The cover page and sections G-J below are not included in the page count. However, for all sections, ARPA-H encourages conciseness to the maximum extent practicable. No other supporting materials may be submitted for review. Note that while the Government's evaluation of Volume I against criteria 1-5 is limited to the sections included in the page count limitations, it will be reviewing all sections. The other documents may be used to cross-check the proposal and will also inform feedback for proposers whose full proposals are determined most advantageous and selected for award negotiations.

Volume I should include the following components:

Cover Page

Innovative Solutions Summary	ARPA-H-SOL-26-148
Full Proposal Title	
Prime Awardee/entity submitting the proposal	
Unique Entity Identifier of prime proposer/awardee (UEI)	
Type of Organization and website URL if applicable	**Choose all that apply:** LARGE BUSINESS, OTHER SMALL BUSINESS, OTHER EDUCATIONAL, OR OTHER NONPROFIT (including non-educational government entities) (NOTE: The Small Business Administration's (SBA) size standards determine whether or not a business qualifies as small.). Size standards may be found here: https://www.ecfr.gov/current/title-13/chapter-I/part-121#121.201
Date of Submission	
Technical Point of Contact (POC)	Include salutation Last Name: First Name

	Mailing Address: Telephone: Email:
Administrative POC	Include salutation Last Name: First Name: Mailing Address: Telephone: Email:
Other Team Members (sub-performers, including consultants) if applicable.	Technical POC Name: Organization: Organization Type:
Total funds requested from ARPA-H, and the amount of cost share (if any)	Total: $
Place(s) of Performance	

A. Executive Summary: Provide a synopsis of the proposed project including answers to the following questions:

1. What is the proposed work attempting to accomplish or solve?
2. How is it done today? What are the limitations of present approaches?
    - *What is the competitive landscape?*
3. What are the key technical challenges in your approach, and how do you plan to overcome these?
4. What is new about your approach? Why do you think you can be successful at this time?
    - *Who will benefit from your solution?*
    - *What health outcomes are you accelerating?*
5. Who cares? If you succeed, what difference will it make?
6. What are the risks? Identify any risks that may prevent you from reaching your objectives as well as any risks the Exploratory Topic itself may present.

Please also describe plans to mitigate these risks at a high level.

7. How much will your project cost?
8. What are your milestones to check for success consistent with BRAINS metrics?

B. Solution Fit with BRAINS: Clearly describe what the team is trying to achieve and the difference it will make (qualitatively and quantitatively) if successful relative to BRAINS's vision and metrics. Provide an overview of the current and previous research and development (R&D) efforts related to the proposed research and identify any challenges associated with such efforts including any scientific or technical barriers encountered during such efforts or challenges in securing sources of funding as applicable. Describe the innovative aspects of the project in the context of existing capabilities and approaches clearly delineating the uniqueness and benefits of this project in the context of the state of the art, alternative approaches, and other projects from the past and present. Describe how the proposed project is revolutionary and how it significantly rises above the current state-of-the-art. Describe the deliverables associated with the proposed project as well as how the project will integrate into existing clinical workflows and successfully improve patient care.

C. Technical Plan: Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) at intermediate stages of the Exploratory Topic to demonstrate progress, a plan for achieving the milestones, and a simple process flow diagram of the final system concept. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the Exploratory goal. Discuss mitigation of technical risk.

D. Management Plan: Provide a summary of the expertise of the team including any subcontractors and key personnel who will be doing the work. A PI for the project must be identified, along with a description of the team's organization, including the breakdown by TA. All teams are required to identify a lead to serve as the primary POC to communicate with the ARPA-H PM team and OT/Contracts equivalent for each award instrument (e.g., Agreements Officer), coordinate the effort across the team, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables. Provide a clear description of the team's organization including an organization chart that includes as applicable: the programmatic relationship of team members; the unique capabilities of team members; the task responsibilities of team members and the teaming strategy among the team members; and key personnel with the amount of effort to be expended by each person during each year. Provide a detailed plan for coordination including explicit guidelines for interaction among collaborators/subcontractors of the proposed effort. Include risk management approaches. Describe any formal teaming agreements required to execute this Exploratory Topic.

E. Capabilities: Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Describe any specialized facilities to be used as part of the project, the extent of access to these facilities, and any biological containment, biosafety, and

certification requirements. Discuss any work in closely related research areas and previous accomplishments.

F. Task Description Document (TDD): The TDD should provide a detailed task breakdown, citing specific tasks for each TA and their connection to the milestones and Exploratory Topic metrics. Each Phase of the Exploratory Topic should be separately defined. The TDD must not include proprietary information. Please note the technical proposal must stand on its own as the TDD cannot be used to supplement the 10 pages of the technical proposal.

For each task/subtask, provide:

- A detailed description of the approach to be taken to accomplish each defined task/subtask.
- Identification of the primary organization responsible for task execution (prime awardee, sub-performer(s), by name).
- A measurable milestone, i.e., a deliverable, demonstration, or other event/activity that marks task completion. Include completion dates for all milestones. Include quantitative metrics.
- A definition of all deliverables (e.g., data, reports, software) to be provided to the Government in support of the proposed tasks/subtasks.

It is recommended that the TDD be developed so that each TA and phase of the Exploratory Topic is separately defined.

G. Schedule and Milestones: Using the provided format, provide a detailed schedule showing tasks (task name, duration, work breakdown structure element as applicable, and performing organization), milestones, and the interrelationships among tasks. The task structure must be consistent with that in the TDD Measurable milestones should be clearly articulated and defined in time relative to the start of the project.

H. Data Management and Sharing Plan (DMSP) (recommend NTE 2 pages) The DMSP shall include all information included in the 6-Element plan format recommended by the National Institutes of Health (to view the 6-Element suggested format visit https://grants.nih.gov/grants/forms/data-management-and-sharing-plan-format-page). Note this plan will not be specifically evaluated against Criteria 1-5, but will likely be used to inform feedback for proposals who are selected for award negotiations.

I. References: Add a list with the cited literature.

II. Volume II, Cost Proposal

There is no maximum page count for Volume II. The Cost Proposal shall be comprised of the editable Excel Cost Proposal spreadsheet and associated supporting materials ideally provided in a single attachment (e.g., Adobe pdf) led by a Cover page as follows.

Cover Page

Innovative Solutions Summary	ARPA-H-SOL-26-148
Full Proposal Title	
Prime Awardee/entity submitting the proposal	
Unique Entity Identifier of prime proposer/awardee (UEI)	
Type of Organization and website URL if applicable	**Choose all that apply:** LARGE BUSINESS, OTHER SMALL BUSINESS, OTHER EDUCATIONAL, OR OTHER NONPROFIT (including non-educational government entities) (NOTE: The Small Business Administration's (SBA) size standards determine whether or not a business qualifies as small.). Size standards may be found here: https://www.ecfr.gov/current/title-13/chapter-I/part-121#121.201
Technical Point of Contact (POC)	Include salutation Last Name: First Name Mailing Address: Telephone: Email:
Administrative POC	Include salutation Last Name: First Name: Mailing Address:

	Telephone: Email:
Other Team Members (sub-performers, including consultants) if applicable and type of organization for each	Technical POC Name: Organization: Organization Type:
Total proposed cost separated by base and option(s) (if any)	
Name, address and telephone number of the proposer's cognizant auditor (as applicable)	
Date proposal was submitted	
Commercial and Government Entity (CAGE) Code	
Proposal validity period (Minimum of 120 days)	

A. Cost Proposal Spreadsheet: ARPA-H Standard Excel Cost Proposal Spreadsheet (See Attachment 2). All tabs and tables in the cost proposal spreadsheet should be developed in an editable format with calculation formulas intact to allow traceability of the cost proposal. The cost proposal spreadsheet must be used by the prime organization and all subcontractors at any tier.

While the prime proposer is ultimately responsible for submission of all required documents, sub-performer cost proposal spreadsheets may be submitted directly to the Government by the proposed subcontractor via email to BRAINS@ARPA-H.gov. Sub-performer proposals should include Interdivisional Work Transfer Agreements or similar arrangements between the awardee and divisions within the same organization as the awardee.

B. Cost and Pricing Data Support: In addition to using the cost proposal spreadsheet, the cost proposal must include documentation to support the proposed price/budget. Supporting documentation must be in sufficient detail to substantiate the summary cost estimates and should include a description of the method used to estimate costs (e.g., vendor quotes). For indirect costs provide the most current indirect cost agreement (e.g., Colleges and Universities Rate Agreement, Forward Pricing Agreement, Provisional Billing Rates, etc.).

Cost and pricing support may also facilitate a value analysis by the Government through information other than detailed cost and pricing data. Proposers are encouraged to

include information related to value-added resources or conditions that are not immediately obvious in the Cost Proposal Spreadsheet or the traditional forms of cost and pricing support information like vendor quotes (e.g., intended intellectual property terms and conditions with perceived future value).

Salary Cap: None of the federal funds awarded under this program shall be used to pay the salary of an individual at a rate in excess of the rate identified by the Office of Personnel Management for Executive Level II positions. Nor may the proposed and later negotiated salaries escalate in excess of the Executive Level II rate for the purposes of invoicing for salary support.

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an award; it merely limits the portion of that salary that may be paid with federal funds.

Volume III, Administrative and Policy Requirements Submission

ADMINISTRATIVE & NATIONAL POLICY REQUIREMENTS DOCUMENT

This Administrative & National Policy Requirements Document must be completed in full and included as part of the proposal submission. Other than the instructions in blue font, do not delete any portion of this document.

All pages must be formatted for printing on 8-1/2 by 11-inch paper with 1-inch margins and sans-serif font size not smaller than 11 points. Sans-serif font sizes of 8 or 10 point may be used for figures, tables, and charts. There is no page limit for this document.

The Administrative & National Policy Requirements Document must be in .pdf, .doc, or .docx formats. Submissions must be in English.

CONTENTS

COVER PAGE 1
1. TEAM MEMBER IDENTIFICATION 2
SENIOR/KEY PERSONNEL (I.E., COVERED PERSONNEL) 2
2. FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTER (FFRDC) PARTICIPATION 2
3. ORGANIZATIONAL CONFLICT OF INTEREST (OCI) AFFIRMATIONS AND DISCLOSURE 3
4. RESEARCH SECURITY DISCLOSURE 4
5. NOVELTY OF PROPOSED WORK 5
6. INTELLECTUAL PROPERTY (IP) 5
7. PATENTS 9
8. HUMAN SUBJECTS RESEARCH (HSR) 9
9. ANIMAL SUBJECTS RESEARCH (ASR) 10
10. REPRESENTATIONS REGARDING UNPAID DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW 10
11. CYBERSECURITY 10
12. BIOSECURITY 11

<PRIME ORGANIZATION LOGO (OPTIONAL)>

COVER PAGE

Proposal Title	
Proposer Organization	
Technical Point of Contact (TPOC)	Name: Address: Telephone: Email:
Administrative POC (APOC)	Name: Address: Telephone: Email:
Date of Proposal Submission	(MM/DD/YYYY)
Proposal Validity Period (minimum 120 days)	_____ Days

1. TEAM MEMBER IDENTIFICATION

List the organizations/institutions that comprise your team. Organization/Institution roles include prime awardees, sub-awardees, team members, contractors, and vendors that will be supplying components, information, data, or material that is critical to your proposal. Add rows as needed.

Organization /Institution Name	Status	Organization/Institution Role
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	
	☐ U.S. ☐ non-U.S.	

SENIOR/KEY PERSONNEL (I.E., COVERED PERSONNEL)

Complete the following table for each Senior/Key Person[1]. Add rows, as needed.

Senior/Key Personnel Names	Organization/Institution	Confirmation Common Forms Are Attached
		Biographical Sketch Attached: ☐ Yes ☐ No Current & Pending Support Attached: ☐ Yes ☐ No
		Biographical Sketch Attached: ☐ Yes ☐ No Current & Pending Support Attached: ☐ Yes ☐ No
		Biographical Sketch Attached: ☐ Yes ☐ No Current & Pending Support Attached: ☐ Yes ☐ No

2. FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTER (FFRDC) PARTICIPATION

Is any member of your proposed team an FFRDC?

[1] In addition to the Principal Investigator or Program/Project Director, Senior/Key Personnel includes individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, regardless of whether they receive salaries or compensation under the award. These include individuals whose absence from the project would significantly impact the approved scope of the project; in other words, were the individual to leave the program, the change would be so substantial that ARPA-H would need to be notified. It is typical that each awardee has at least one Principal Investigator or Program/Project Director, including one from each sub-awardee or teaming partner that is expected to perform critical work for the proposed effort.

☐ No ☐ Yes

If yes, provide justification for inclusion of the FFRDC and separate documentation that indicates that no other source will meet the needs that the FFRDC will meet.

3. ORGANIZATIONAL CONFLICT OF INTEREST (OCI) AFFIRMATIONS AND DISCLOSURE

In accordance with the National Security Presidential Memorandum (NSPM)-33 and the associated White House Office of Science and Technology Policy Implementation Guidance, senior/key personnel are required to disclose potential conflicts of interest (COIs) and conflicts of commitment (COCs). Those disclosures are captured by senior/key personnel completing the Biographical Common Form, the Current and Pending (other) Support Common Form, and the Collaborators and Other Affiliations document as attachments to this template. These forms can be found at: https://www.nsf.gov/bfa/dias/policy/nstc_disclosure.jsp.

Additional information about potential collaborations can be found at: https://www.nsf.gov/funding/senior-personnel-documents#collaborators-and-other-affiliations-2b3.

a. Are any of the proposed team members or organizations (whether prime, sub-awardee, or consultant) providing support in the form of an Internal Support Contractor (ISC)/Systems Engineering Technical Assistance (SETA) Agreement, Partnership Intermediary Agreement (PIA), or similar support to ARPA-H?

☐ No ☐ Yes

b. Has any proposed team member or organization (whether prime or sub-awardee or consultant) provided ISC/SETA support or similar support to ARPA-H within one calendar year of this proposal submission?

☐ No ☐ Yes

If the answer to 3.a. or 3.b. is yes, provide a separate document with the following information for each such team member:

- The name of the ARPA-H office receiving the support
- The prime contract number
- Name and type of support (e.g., prime, sub-awardee, consultant)
- An OCI mitigation plan

c. Are there other potential Organizational Conflicts of Interest involving a proposed team member *or* organization (whether prime, sub-awardee, or consultant)?

☐ No ☐ Yes

If yes, for each team member for which an OCI or a potential OCI exists, provide a separate document with the following information:

- Identification (name), and
- An OCI mitigation plan

4. RESEARCH SECURITY DISCLOSURE

ARPA-H's research security program (RSP) involves research security reviews (RSRs) to determine whether Proposers are covered individuals or have behaviors that: (a) may be contrary to federal policy; (b) undermine the integrity of ARPA-H-funded research; or (c) bring risk to the agency's research programs. The RSP aims to mitigate the risk of unwanted knowledge and technology transfers to foreign countries of concern (FCOCs)[2]

In addition to the senior/key personnel disclosures, answer the following:

a. Has every PI and senior/key person certified (in writing or by digital signature) that they are (or are not) party to a malign foreign talent recruitment program (FTRP)? In accordance with 42 USC §19232, individuals are prohibited from being a party in a malign FTRP (as defined in 42 USC §19232).

☐ No ☐ Yes

b. Are any members of the proposal team participating in, or previously participated in, any FTRPs?

☐ No ☐ Yes

If yes, please list the name(s) of the team member(s), the year(s) of their participation, the FCOC(s) in which the program(s) is/are based, and the terms of the FTRP.

c. Are any of the proposed team organizations/entities or partners (e.g., the prime proposer, sub-awardees) owned wholly or in part by foreign individuals, entities, or governments?

☐ No ☐ Yes

If yes, provide the name(s) of the foreign-owned entities, and the name(s) of the owner(s) (e.g., individual(s), partner(s), or government(s), etc.) and identify the percentage(s) owned.

d. Is any of the proposed research projected to be executed within an FCOC?

☐ No ☐ Yes

If yes, please identify each FCOC, each entity executing research in an FCOC, and a narrative discussing the criticality of executing research to your proposal.

e. Do any of the proposing entities (e.g., prime, sub-awardee, or consultant) intend

[2] Public Law 117-167, The CHIPS and Science Act, Section 10612, Aug 9. 2022; the People's Republic of China, the Russian Federation, the Islamic Republic of Iran, the Democratic People's Republic of North Korea, and any other country so designated by the Department of State.

to rely on technology, information, data sets, or equipment (including known supply chain) that will be provided by or transmit data to or through an FCOC?

☐ No ☐ Yes

If yes, identify each entity that intends to do so, and provide a narrative discussing the criticality to your proposal.

By submitting this document to ARPA-H, you are certifying that the information provided in this section is current, accurate, and complete. This includes (but is not limited to) information related to current-, pending-, and other support (both foreign and domestic) as defined in 42 U.S.C. § 6605.

By submitting this document to ARPA-H, you are also certifying that at the time of submission, no member of the proposed team is a party in a malign foreign talent recruitment program.

By submitting this document to ARPA-H, you acknowledge that misrepresentations and/or omissions may be subject to prosecution and liability pursuant to, but not limited to, 18 U.S.C. §§ 287, 1001, 1031 and 31 U.S.C. §§ 3729-3733, and 3802.

5. Novelty of Proposed Work

Has the proposed work been submitted to any other government solicitation?

☐ No ☐ Yes

If yes, provide the following information (and change the font color to black):

- Solicitation number _____
- Agency/Office _____
- Has the proposed work already received funding or a positive funding decision?

  ☐ No ☐ Yes ☐ Decision pending

6. Intellectual Property (IP)

6.1 Proposer information regarding IP and data restrictions promotes transparency, impacts ARPA-H's proposal evaluation efforts, and allows ARPA-H to evaluate how this information will affect the project/program and the government's rights in deliverables. Complete and accurate information also reduces the chances of delays and conflicts affecting negotiations and eventual project performance.

6.2 For the primary proposer or any teaming partner or sub-awardee, identify background IP or otherwise restricted data (e.g., data subject to confidentiality agreement) that would be relevant to/incorporated into the proposed work and any deliverables in the table below. Furthermore, identify what rights the

government can expect to have in that data or IP.

- Background IP consists of trade secrets, patents, data, or non-provisional patent applications owned or controlled by the proposer team that exist prior to the date of any future agreement with ARPA-H or are conceived and otherwise created outside the scope of any future agreement with ARPA-H.

6.3 Use the following rights categories in completing the "Associated Rights" column of the table.

- *Unlimited Rights*: The government's right to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

- *Government Purpose Rights*: The government's right to use, modify, reproduce, perform, display, release, or disclose, in whole or in part and in any manner, for government purposes only, and to have or permit others to do so for government purposes only. Government purposes are activities in which the U.S. government is a party, including cooperative agreements with international or multi-national organizations, or sales or transfers by the U.S. government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose for commercial purposes or authorize others to do so.

- *Limited Rights*: The government's right to use, modify, reproduce, release, perform, display, or disclose, in whole or in part, within the government. The government may not, without the written permission of the Performer, release or disclose outside the government, use for manufacture, or authorize use by another party. The government may release or disclose to a covered government support contractor in performance of a covered government support contract.

- *Specially Negotiated/Other Rights*: Rights proposed by the Performer that differ from the standard categories described above. Open Source/End User License Agreements/Data Use Agreements might fall under this category. Include a description of the license proposed.

6.4 The table below includes an example to assist Proposers complete it. Add rows to the table if needed. In general, Proposers can assume the following in completing this table.

a. ARPA-H does not, unless specified in the solicitation, intend to own IP. Rather, ARPA-H's expectation is that it will receive licenses to IP sufficient to meet the needs of the project or program.

b. ARPA-H generally expects to receive license rights commensurate with its contribution to the IP's/data's development. Where ARPA-H has funded some or all of the IP/data, the agency would typically expect at least Government Purpose Rights. This may vary based on the needs of the program or in recognition of a proposer's heavy prior/internal investment. Where IP/data has been created entirely at private expense, Limited Rights or Specially Negotiated/Other Rights would be appropriate, though Government Purpose Rights are also common. Proposed resource share may be a factor in the rights proposed. The "Basis for Assertion" would typically have to do with the source of the IP, how it was funded, and when the IP/data was created.

Background IP and Data Assertions

General description of background IP or restricted data (e.g., inventions, proprietary information or data subject to confidentiality agreements, computer software, etc.). For inventions, please provide the application/patent number if available.	Expected role of this IP or data in performance of the work	Basis for Assertion	Associated Rights (see rights categories above)	Name of person/entity asserting the restriction and their role in the requirement (i.e., primary proposer, teaming partner, or sub-awardee)
ARPA-H Example Background IP ("Image-recognition software" or "wireless biosensor technology")	*ARPA-H Example Used as a core software module in the prototype system or Embedded into the device as the primary sensing component*	*ARPA-H Example Developed exclusively at private expense or developed under agreement number ABC.*	*ARPA-H Example Limited or Government Purpose Rights*	*ARPA-H Example ("Company Name (Prime)" or "Company Name (Sub-Awardee)")*

7. PATENTS

7.1 For patents identified above, provide documentation demonstrating ownership or possession of appropriate licensing rights for the proposed work. If a patent application has been filed for an invention, but it includes proprietary information and is not publicly available, provide the following information:

- The patent number
- The inventor name(s)
- The assignee names (if any)
- The filing date
- The filing date of any related provisional application and
- A summary of the patent title, with either:
  - (1) a representation of invention ownership; or
  - (2) proof of possession of appropriate licensing rights in the invention (i.e., an agreement from the owner of the patent-granting license to the proposer).

7.2 If any IP listed was developed in whole or in part with government funding from any Agency, specify under what agreements that IP was developed.

7.3 Background IP of ap partners and sub-awardees should be included if restrictions on that IP have implications for the success of the award or the rights the Government can expect to receive.

8. HUMAN SUBJECTS RESEARCH (HSR)

Does the proposed work involve Human Subjects Research?

☐ No ☐ Yes

If yes, provide separate documentation showing evidence of, or a plan for, review by an Institutional Review Board (IRB) and include evidence of a Federal-wide Assurance for the Protection of Human Subjects. Complete the following table to identify each organization, team member, and sub-awardee performing HSR. Add rows as needed.

Organization Performing HSR	Institution Site	Federal-Wide Assurance Number	Approved IRB Protocol (Y/N)

9. ANIMAL SUBJECTS RESEARCH (ASR)

Does the proposed work involve Animal Subjects Research?

☐ No ☐ Yes

If yes, provide:

- separate documentation that gives a brief description of the plan for Institutional Animal Care and Use Committee (IACUC) review and approval
- the Vertebrate Animal Section (VAS) worksheet, found at: https://olaw.nih.gov/sites/default/files/VASchecklist.pdf
- evidence of each applicable organization's Animal Welfare Assurance

Complete the following table to identify each organization, team member, and sub-awardee performing ASR. Add rows as needed.

Organization Performing ASR	Institution Site	Approved IACUC Protocol (Y/N)	Completed VAS (Y/N)	Animal Welfare Assurance Number

10. REPRESENTATIONS REGARDING UNPAID DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW

The Proposer represents that it –

a. Is ☐ Is not ☐
a corporation that has any unpaid federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

b. Is ☐ Is not ☐
a corporation that was convicted of a felony criminal violation under a federal law within the preceding 24 months.

11. CYBERSECURITY

a. Does your organization implement a cybersecurity program leveraging industry and/or government standards to secure and defend your systems, networks, and/or data?

☐ No ☐ Yes

If yes, provide a brief description of the program, including the specific standard(s) that guide the program, the abilities of the organization to respond to a cybersecurity incident, and how the organization assesses the security posture of its systems and/or networks.

b. Does your organization have experience with managing and securing Controlled Unclassified Information (CUI)?

☐ No ☐ Yes

Describe how the proposing institution and sub-awardee/subcontractor organizations manage CUI, including details of access control for research designated as CUI, information systems security protocols, storage, communicating unclassified fundamental research with foreign nationals, and risk mitigation strategies for unclassified research that may ultimately become CUI as the research proceeds.

12. BIOSECURITY

a. Dangerous Gain-of-Function Research: Does the proposal involve 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*[3]?

☐ No ☐ Yes

b. Synthetic Nucleic Acids or Benchtop Nucleic Acid Synthesis Equipment: Does the proposed work include the potential to procure synthetic nucleic acids or benchtop nucleic acid synthesis equipment?

- This includes, but is not limited to, procuring synthetic DNA and RNA, as well as whole organism genomes (e.g., viruses, bacteria) containing any synthetic nucleic acid 200 nucleotides or greater, and benchtop equipment capable of synthesizing nucleic acids.

☐ No ☐ Yes

If yes, refer to the OSTP Framework for Nucleic Acid Synthesis Screening for guidance, attestation requirements, and definitions of terms. The requirement to use the framework applies to all work performed under the award.

[3] https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/