INNOVATIVE SOLUTIONS OPENING

FOR

UNIFYING IMAGING WITH QUANTUM ENTANGLEMENT

UNIQUE

HEALTH SCIENCE FUTURES

ARPA-H-SOL-26-162

SEPTEMBER 16, 2026

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INNOVATIVE SOLUTIONS OPENING (ISO) SUMMARY INFORMATION

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

PROGRAM TITLE: UNifying Imaging with QUantum Entanglement (UNIQUE)

ANNOUNCEMENT TYPE: Innovative Solutions Opening (ISO)

ISO SOLICITATION NUMBER: ARPA-H-SOL-26-162

ISO CONTACT: UNIQUE@ARPA-H.gov

ANTICIPATED AWARDS: Other Transactions

DATES: (All times listed are Eastern Time)

Posting Date: September 16th, 2026
In Person and Virtual Proposers' Day (PD): October 15th, 2026, 8:30 AM
Proposers' Day Video Link: https://arpa-h.gov/explore-funding/programs/unique
Questions & Answers (Q&A) due date: October 10th, 2026, 1:00 PM
Lightning Talk / Sidebar session: October 15th, 2026, 3:00 - 5:00 PM
Solution Summaries Due: October 30th, 2026, 11:59 PM
Full Proposals Due: December 15th, 2026, 11:59 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/

PROPOSERS' DAY

ARPA-H will host a Proposers' Day in support of the UNIQUE program as described in Special Notice ARPA-H-SN-26-126. The purpose is to provide potential proposers with information on the UNIQUE program, promote additional discussions, and encourage teaming and networking.

Interested proposers are not required to attend, and materials formally presented during Proposers' Day will be posted to the ARPA-H Program Webpage (https://arpa-h.gov/explore-funding/programs/unique) and on SAM.gov.

ARPA-H will not reimburse potential proposers for participation at Proposers' Day (or time and effort related to developing submissions in response to this ISO).

1. INTRODUCTION TO UNIQUE

1.1 BACKGROUND

Every major revolution in medical imaging has been driven by a new way to measure biology. X-ray and computed tomography (CT) revealed internal anatomy; magnetic resonance imaging (MRI) revealed soft-tissue structure and physiology; positron emission tomography (PET) revealed molecular activity. Each new imaging contrast exposed previously inaccessible biological information and changed how disease is detected, understood, and treated.

Despite these advances, important dimensions of biology remain beyond the reach of today's imaging technologies. Current modalities provide powerful but incomplete views of anatomy, physiology, and molecular activity. Even when combined, they cannot fully characterize the dynamic tissue microenvironment, including subtle changes in microstructure, oxygenation, metabolism, redox state, molecular organization, and other processes that may precede structural disease. As a result, many devastating conditions, including chronic traumatic encephalopathy (CTE), neurodegenerative disorders, pancreatic cancer, and other chronic diseases, are often detected only after substantial, and sometimes irreversible biological damage has occurred. Medicine remains fundamentally constrained by what it can measure.

Recent advances in quantum science suggest a new opportunity to expand the measurable biology of disease. Studies have shown that 511 keV photon pairs generated during positron annihilation can retain measurable quantum correlations. These quantum-derived observables, including photon correlation signatures, correlation loss or decoherence, and positronium-sensitive interactions, may encode biological information distinct from conventional imaging contrast. If measurable and interpretable in biomedical settings, these observables could provide a new window into tissue composition, microstructure, molecular organization, oxygenation, metabolism, and other features of the disease microenvironment.

However, major barriers remain. Scattering, environmental interactions, and detector noise can reduce or obscure measurable quantum correlations; current detector architectures are not optimized for high-rate, high-resolution quantum coincidence imaging; and existing reconstruction methods cannot yet translate multidimensional quantum observables into biologically meaningful images in real time. Such challenges have kept quantum biomedical imaging largely at the proof-of-concept stage.

UNIQUE asks whether quantum observables can open a new frontier in biomedical measurement, revealing disease biology that remains invisible to today's imaging technologies.

1.2 PROGRAM OVERVIEW

UNIQUE will explore a fundamentally new imaging contrast for biomedicine, with quantum-derived observables. Rather than treating quantum correlations, decoherence, and positronium-sensitive interactions as artifacts or secondary physical effects, UNIQUE will establish whether they can serve as biologically meaningful signals that complement today's anatomical, functional, and molecular imaging.

UNIQUE's goal is not to replace existing imaging technologies, but to expand what medicine can measure. The effort will test whether entangled or otherwise quantum-correlated 511 keV photon pairs can support a unified imaging framework that integrates anatomical, functional, molecular, and quantum-derived information, including ghost-imaging-inspired approaches that infer biological information from photon-pair correlations. UNIQUE envisions this integrated quantum-derived biological signal space as a complementary imaging dimension that extends conventional anatomical, functional, and molecular characterization.

UNIQUE is organized around two integrated technical areas (TAs). TA1 will focus on the physical systems needed to generate and measure quantum observables in clinically relevant biomedical settings. This includes advances in quantum-correlated photon production and collection, engineered source materials and nanomaterials, quantum-aware detectors, other materials and methods to determine whether decoherence and correlation loss can become sources of biological contrast.

TA2 will develop a computational foundation for quantum-derived imaging, including physics-informed artificial intelligence, quantum-aware reconstruction, multimodal data fusion, uncertainty quantification, and real-time interpretation of multidimensional quantum observables.

Together, these TAs will demonstrate whether quantum observables can be reproducibly measured, reconstructed, and linked to meaningful biological states. If successful, UNIQUE would establish the feasibility of a new imaging paradigm that integrates anatomical, functional, molecular, and quantum derived information, laying the foundation for the next revolution of biomedical imaging.

2. THE PROGRAM

The UNIQUE Program will support research that combines quantum-enabled 511 keV photon-pair imaging technologies with computational methods capable of reconstructing and interpreting multidimensional anatomical, functional, molecular, and quantum-derived information. UNIQUE is an 18-month, 2-phase program that consists of two TAs. In Phase 1 (9-months), performers will establish feasibility of quantum-derived imaging signals in TA1 and develop foundational AI-driven reconstruction and fusion framework for TA2. During Phase 2 (9-months), performers will demonstrate integrated multidimensional quantum-derived imaging for TA1 and demonstrate unified multidimensional reconstruction and biological interpretation in TA2 work. Continuation into Phase II will be determined by the ARPA-H program manager and based on progress toward achieving the goals and metrics of Phase I below.

2.1 Technical Areas (TAs) and Milestones

UNIQUE will seed efforts for two (2) technical areas. Proposers must submit a comprehensive proposal addressing both TA1 and TA2.

TA1: Imaging Core

The goal of TA1 is to establish the feasibility of generating and measuring quantum-derived imaging contrast using entangled 511 keV photons, positronium-sensitive interactions, and decoherence-aware imaging architectures in controlled phantom and benchtop systems. A

competitive submission should specify the mechanism(s) for producing entangled 511 keV photon pairs and the rationale for achieving the entanglement yield and usable flux in the Program Metrics [see Table 1] while balancing flux against imaging dose. It should describe how quantum correlations will be measured and verified across scattering media, and detail the phantoms, materials, detectors, timing, and filtering being employed to deliver the required signal-to-background and localization performance. Proposers should identify the candidate quantum-derived observables and biologically meaningful phantom states (e.g., pyruvate/lactate-linked microenvironments) used to demonstrate reproducible contrast separation, define the data products delivered to TA2, and articulate primary risks with mitigations.

TA1 Milestones:

1. Establish feasibility for ghost image reconstruction from correlated signal–idler measurements in controlled phantoms
2. Demonstrate reproducible quantum-derived contrast with repeatability variation
3. Demonstrate ≥3 metabolic phantom states (e.g., pyruvate/lactate-linked) or other states with statistically significant signal separation modeling neurodegenerative or tumor microenvironment states

TA2: Quantum AI Interpretation and Fusion

The goal of TA2 is to develop AI-driven reconstruction and fusion methods capable of integrating anatomical, functional, molecular, and quantum-derived observables into unified multidimensional imaging representations. A competitive submission should explain what is genuinely quantum-aware about its reconstruction methodology and why it suits correlated, sparse, or low-count data. It should describe how diagnostic features are extracted from quantum-derived signals (e.g., entanglement witnesses, decoherence signatures, positronium states) and fused with anatomical, functional, and molecular information into a single interpretable representation. Proposers should outline a plan for AI-based differentiation of distinct phantom microenvironments and a preliminary quantum-derived contrast atlas (e.g., quantum decorrelation tomography – QDT, or quantum derived index - QDI) that outperforms conventional observables, consistent with the Program Metrics [see Table 2]. Proposers should specify how outputs are validated against ground truth, how uncertainty and interpretability are addressed given limited data, define the TA1 interface for co-optimization, and detail risks and risk mitigation strategies.

TA2 Milestones:

1. Generate fused UNIQUE outputs integrating anatomical, functional, molecular, and quantum-derived information
2. Establish preliminary QDT/QDI atlas across multiple phantom microenvironment states and improved phantom-state differentiation versus conventional attenuation/scatter observables alone

Independent Verification and Validation (IV&V)

UNIQUE performers addressing the TAs described above will interact throughout the program with an independent verification and validation (IV&V) team, established by ARPA-H that will help test and validate progress. The IV&V team may consist of subject matter experts from Government, Federally Funded Research and Development Centers (FFRDCs), academia and/or other relevant domains. Over the course of the program, the IV&V team will provide

benchmark phantoms with relevance to the performers concept of operations to allow performers to demonstrate the reproducibility and performance of the developed systems.

To avoid potential conflicts of interest, UNIQUE performers will not be allowed to compete for the IV&V work. ARPA-H is not soliciting proposals for IV&V under this ISO.

2.2 Metrics and Deliverables

To evaluate the effectiveness of a proposed solution in achieving the program's goal, the following metrics will serve as the basis for determination of satisfactory progress to warrant continued funding. Although the metrics are specified below, proposers should note that the Government has identified these goals with the intention of outlining the scope of effort while affording maximum flexibility, creativity, and innovation of proposed solutions to the goals. Proposals must cite the quantitative and qualitative success criteria that the effort will achieve at each phase's milestone, as well as the measurement of intermediary metrics. If the metrics are not meaningful for a particular case, proposing teams are expected to provide their own metrics and describe the quantitative improvement that those metrics represent over the state-of-the-art. Power analysis calculations may be needed to support the proposed metrics.

The expected metrics are listed in Table 1and Table 2.

Table 1

TA1 Milestones and Metrics	
	Metrics
Phase 1 (9 mos.)	• Demonstrate measurable non-classical entanglement correlations with entanglement witness: $R > 1.6$ • Achieve coincidence timing resolution: <300 ps; stretch <150 ps • Achieve generated entangled 511 keV photon-pair flux: $>10^5$–10^6 pairs/s in benchtop/source geometry • Demonstrate usable filtered coincidence rate: $>10^3$–10^4 events/s with signal-to-random ratio >3:1 • Demonstrate measurable decoherence and positronium-sensitive variation across ≥3 controlled phantom microenvironment states • Demonstrate preliminary ghost imaging feasibility using correlated signal-idler reconstruction in controlled phantom geometry
Phase 2 (9 mos.)	• Demonstrate preserved entanglement through scattering media in phantom with entanglement witness $R \approx 2.0$–2.3 in selected angular regimes • Achieve usable filtered coincidence rate: $>10^4$–10^5 events/s; stretch toward $>10^6$ events/s • Demonstrate signal-to-random or signal-to-background ratio: >5:1, stretch >10:1 after timing/energy/angular filtering • Demonstrate ghost image reconstruction from correlated signal–idler measurements in controlled phantoms • Demonstrate reproducible quantum-derived contrast with repeatability variation <10% • Demonstrate ≥3 metabolic phantom (e.g., pyruvate/lactate-linked) states or other states with statistically significant signal separation modeling neurodegenerative or tumor microenvironment states

Table 2

TA2 Milestones and Metrics	
	Metrics
Phase 1 (9 mos.)	• Develop simulation-to-reconstruction pipeline integrating timing, angle, scatter, and positronium observables • Generate physics-informed synthetic and experimental datasets containing $>10^5$ correlated events • Generate prototype voxel-level QDT/QDI maps from phantom and synthetic datasets • Demonstrate statistically distinguishable clustering of ≥3 phantom states using quantum-derived features • Establish uncertainty-aware reconstruction framework with reproducible outputs across repeated phantom studies
Phase 2 (9 mos.)	• Generate fused outputs integrating anatomical, functional, molecular, and quantum-derived information • Build preliminary QDT/QDI atlas across multiple phantom microenvironment states • Demonstrate improved phantom-state differentiation versus conventional attenuation/scatter observables alone • Generate scalable dataset with $>10^6$ correlated events • Demonstrate effective 3D localization/reconstruction resolution: target ≤2–3 mm, stretch sub-mm in simplified benchtop geometry • Demonstrate AI-based differentiation of biologically distinct phantom microenvironments (e.g. pyruvate/lactate-linked metabolic states) using quantum-derived observables

The metrics and timelines as outlined in the above tables may increase in difficulty and complexity over the course of UNIQUE. Monthly technical and financial status reports will be required and discussed with the ARPA-H Program Manager at monthly meetings. ARPA-H may request performer data as deemed necessary throughout the program to validate progress toward achieving the program's goals.

At the time of submission, proposers **must**:

- Propose to meet all milestones and metrics for all TAs in accordance with the timelines outlined in the Phases.

2.3 TEAM REQUIREMENTS

Proposals are expected to involve teams with the expertise needed to collectively achieve the goals of the proposed TA(s). Communications, networking, and team formation are the sole responsibility of the proposer. Proposers must submit a single, integrated proposal led by a Principal Investigator, under a single lead proposer that addresses all program phases as applicable. Teaming (that considers access across geographies) is highly encouraged to accomplish the transformational goals set forth in the UNIQUE program.

Proposers may only submit one proposal as the lead proposer. The Government's expectation is that all key members of the performer team will be onboard within 60 days of the award.

2.4 REPORTING

- **Monthly Status Reports (MSRs)** – Status reports outlining technical and financial updates will be required at monthly meetings with the PM and team.
    - Minimally, monthly check-ins (virtually) to discuss project results, science, challenges and solutions, and other project-related topics.
    - 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.
- **Principal Investigator (PI) Review Meetings** – On a six-month basis, UNIQUE will organize, in-person, PI Review Meetings (site to be determined) where all performers will present progress and updates on their technology and will have the opportunity to meet representatives of key stakeholder organizations. The meetings will provide opportunities for participants to share knowledge, learn, network and grow collaborations. Teams should budget for participation at these meetings.
- **Site Visits** – ARPA-H may request performer data and arrange visits to their facilities as deemed necessary throughout the work timeline to validate technical progress

2.5 AWARD STRATEGY

The ISO constitutes a merit-based solicitation, and the number of awards made will depend on the quality of the proposals received and the availability of funds. Proposals are expected to use innovative approaches that include novel technology, enabling revolutionary advances in medicine and healthcare.

The Government may select for negotiation all, some, one, or none of the proposals received in response to this ISO and to make awards without negotiations with proposers. The Government also may conduct negotiations if it is later determined to be necessary. Additionally, ARPA-H may accept proposals in their entirety or to select only portions of proposals for negotiation and award. The Government may fund proposals in phases, including as optional phases, as applicable. ARPA-H may make multiple awards, a single award, or no awards. Multiple awards are anticipated.

Proposals identified for negotiation are expected to result in Other Transactions (OTs). The Government may request additional necessary documentation, tailored to the individual proposals, during negotiations. The Government may remove proposals from award consideration should the parties fail to reach agreement on award terms, conditions, and/or cost/price within a reasonable time, and/or if the proposer fails to timely provide requested additional information. The Agreements Officer has sole discretion to negotiate all terms and conditions with selectees.

For-profit organizations, as determined in SAM.gov, that do not qualify as small businesses under the NAICS 541714 SBA size standard of 1000 employees are required to contribute a meaningful cost share to participate in the UNIQUE program. Cost shares may be provided in cash or in-kind (e.g., equipment, facilities, or technical labor) and must directly support the execution of proposed milestones. The level of cost share should reflect the scale, maturity, and resources of the proposing organization and must be explicitly detailed in the proposal's budget justification. This requirement is intended to ensure sustained performer commitment

and to increase the likelihood of rapid, cost-effective transition of UNIQUE technologies. Other organizations are not required to provide cost share but may do so voluntarily.

2.6 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, 3) do not address the objectives of the Program, and 4)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

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 UNIQUE@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 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 UNIQUE@arpa-h.gov.

4 SUBMISSION PROCESS

4.1 SUBMISSION PROCESS OVERVIEW

Submissions for UNIQUE are as follows:

1. **Proposers' Day (Optional).** ARPA-H organized event to allow interested proposers to meet and self-organize into comprehensive teams capable of meeting all UNIQUE technical and non-technical requirements.

2. **Solution Summary.** Required overview of the effort to be proposed summarizing the goals of the proposed work, the research plan, and the team.
3. **Review of Solution Summaries.** Based on the evaluation of Solution Summaries, selected teams will be encouraged or discouraged to submit full proposals.
4. **Full Proposal.** Required document package comprising a detailed description of the proposed effort, expected outcomes, performing team, timeline, budget, and any supporting materials.
5. **Review of Full Proposals.**
6. **Feedback and Awards.**

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. Although a proposal may be submitted regardless of the feedback provided, potential proposers are advised to give the government's decision significant weight when making decisions regarding whether it is worth the investment of time and resources in the development of a proposal.

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 Appendices. Proposers should use the templates provided in the Appendices. The Appendices includes the following five (5) templates:

1. Tech and Management (12 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 Solutions site 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 Solutions site.

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). Protection of proprietary information is discussed below.

4.6 FUNDING RESTRICTION

Pre-award costs will not be reimbursed unless a pre-award agreement is negotiated prior to award.

4.7 QUESTION AND ANSWER (Q&A)

All questions regarding this ISO must be submitted to UNIQUE@arpa-h.gov. ARPA-H will post Q&As to the ARPA-H UNIQUE Website and SAM.gov on an on-going basis and may not respond directly to email inquiries. All questions must be in English and must include the name, email address, and telephone number of a point of contact, and must be submitted by the Q&A deadline posted with other key dates. Proposers submitting questions to individual Government team members (e.g., Program Manager) should not expect a response.

ARPA-H will attempt to answer questions in a timely manner; however, questions submitted after the due date may not be answered. Further, duplicative questions may be combined and rephrased to streamline responses.

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 UNIQUE Program.
- 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 UNIQUE@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 contact 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 highly innovative, feasible, and with a well-defined path to completion. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that an outcome that achieves the goal is plausible. The proposal identifies major technical risks, expected for ARPA-H projects, and planned mitigation efforts are clearly defined and feasible. In addition, the evaluation may take into consideration the extent to which the proposed intellectual property (IP) rights structure and software components will potentially impact the ability to commercialize the technology and adhere to open-source solutions and/or standards.

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

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

In terms of capability, the Government will 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.

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 competition 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 H on SAM.gov). Additional information can be found at https://arpa-h.gov/explore-funding/submission-resources-and-FAQs/research-security-review.

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

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

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 Program goals and should be aligned with the level of government funding provided to generate and/or develop the IP.

6.4 VERTEBRATE 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.]

Funding cannot be used toward ASR until approval is granted by the government.

6.5 HUMAN SUBJECTS RESEARCH

Human subject research (HSR) is not anticipated within this program. If a proposal includes HSR, the following language applies.

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

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

6.6 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 UNIQUE 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.

6.7 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.

6.8 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. The policy for applicable research may be found in the United States Government Policy for Stopping High-Risk Life Sciences Research.

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 UNIQUE Program. 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-26-162
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)

The ROM does not count towards the page limit. 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 table below 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	N/A, use provided template/format
A. Executive Summary	12
B. Solution Fit with UNIQUE	
C. Technical Plan	
D. Management Plan	
E. Capabilities	
F. References	N/A
G. Task Description Document (TDD)	N/A, use provided template/format Appendix C
H. Milestone Payment Schedule	N/A use provided template/format Appendix D
I. Data Management and Sharing Plan (DMSP)	N/A (estimated 2 pages)
J. Draft Other Transactions Agreement	N/A use provided template/format Appendix E

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 Appendix F
B. Cost and Pricing Data Support including a Cost Narrative	N/A, use provided template/format Appendix G

Volume III, Administrative and Policy Requirement Submission

Volume Element	Page Limit
Cover Page	1
1. Team Member Identification	N/A, use provided template/format Appendix H
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	
13. Security Attestation Form	N/A, use provided template Appendix I

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 twelve (12) 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 1-4 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-26-162
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?

- *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 Program 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 UNIQUE metrics?

B. Solution Fit with UNIQUE: Clearly describe what the team is trying to achieve and the difference it will make (qualitatively and quantitatively) if successful relative to UNIQUE'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 Program 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 Program 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 Program.

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. References: Add a list with the cited literature.

G. 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 Program metrics. Each Phase of the Program 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 12 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 Program is separately defined.

H. Milestone Payment Schedule (MPS): Using the provided format 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.

I. 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 1-4, but will likely be used to inform feedback for proposals who are selected for award negotiations.

J. Draft Other Transactions Agreement: Appendix E - Draft Other Transaction Agreement is available on SAM.gov and has been included to provide potential proposers an initial draft of the ARPA-H agreement for this effort. The proposer may include a copy of the draft agreement with any redlines/comments/proposed edits as a part of the proposal package. If no redline/comments/edits are proposed, the proposer must provide a written statement that there are no proposed changes. The redlined copy of the agreement or the statement of no proposed changes does not count towards any page limitations for the proposal.

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-26-162
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 Appendix F on SAM.gov. 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 UNIQUE@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. Details and model format can be found in Appendix G on SAM.Gov. 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

Appendix H: Admin & National Policy Requirements Document and Appendix I: Security Attestation Form are available on SAM.gov