INNOVATIVE SOLUTIONS OPENING

FOR

EMERGING

HEALTH

INNOVATORS

EHI

HEALTH SCIENCE FUTURES

ARPA-H-SOL-25-118

January 6, 2025
Amended March 18, 2025

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1. INNOVATIVE SOLUTIONS OPENING SUMMARY INFORMATION

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

PROGRAM TITLE: Emerging Health Innovators (EHI) Initiative

ANNOUNCEMENT TYPE: Solicitation

ISO SOLICITATION NUMBER: ARPA-H-SOL-25-118

DATES: (All times listed are Eastern Time)

- **Proposers' Day:** January 8, 2025, 11:00 AM - 4:00 PM ET
- **Questions & Answers (Q&A) due date:** Jan 27, 2025, 2:00 PM ET

- **ISO Closing Date (Solution Summaries Due):** February 5, 2025, 2:00 PM ET
- **Encourage / Discourage Letter Release:** March 18th, 2025
- **Pitch Deck Submission Due Date:** April 21st, 2025
- **Pitch Presentation:** May 12–16th, 2025
- **Tentative Performer Selection Date:** June 2025
- **Tentative Award Start Date:** August 2025

ANTICIPATED AWARDS: Multiple Other Transaction (OT) Agreements and Cooperative Agreements (CAs)

AWARD AMOUNT: Individual awards under EHI will be limited to a maximum of $350,000 per year for 2 years, with an optional third year.

AGENCY CONTACT: All inquiries should be sent to EHI@ARPA-H.gov

1.1 ISO PURPOSE

ARPA-H seeks proposals from all eligible entities (see Section 3.3 *Eligibility Information*) to accomplish the EHI Program goals as described in this solicitation package. Ultimately, ARPA-H intends to negotiate multiple OT Agreements and Cooperative Agreements with proposers whose proposals are most advantageous to the Government.

1.2 ISO QUESTIONS AND ANSWERS

All questions regarding this ISO must be submitted to EHI@ARPA-H.gov. ARPA-H will post Q&As to the ARPA-H ISO Website on an ongoing basis and may not respond directly to email inquiries. All questions must be in English and must include the name, email address, telephone number of a point of contact, and should 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.

1.3 PROPOSERS' DAY

ARPA-H will host a virtual Proposers' Day in support of the EHI Initiative as described in Special Notice ARPA-H-SN-25-119. Proposers' Day provides potential proposers with information on the EHI Initiative, promote additional discussions, and encourage team networking.

Interested proposers are not required to attend, and materials formally presented during Proposers' Day by ARPA-H will be posted to SAM.gov.

ARPA-H will not reimburse potential proposers for participation at Proposers' Day (or time and effort related to submission of solution summaries, pitch decks, presentations or full proposals).

1.4 DEFINITIONS

Several important terms used within this solicitation are defined below:

- Proposer – A "proposer" is the *organization* responding to this ISO. Proposers must have a unique entity identifier (UEI) and be registered in SAM to submit a response to this ISO.
- Project Lead – The "project lead" is the *individual* representative from the proposer's organization who leads the project's progress and success.
- Selectee – After a proposer is selected for negotiation of a potential award, they are considered a "selectee."
- Performer – After a selectee's agreement has been awarded, they are considered a "performer."
- Track – "Track" indicates one of two submission pathways within the EHI Initiative. A proposer must respond to one track only.
- Topic – "Topic" is a subset of the track. Each topic is specific to one track. A proposer must respond to only one topic in the chosen track.

2. THE INITIATIVE

2.1 EHI OVERVIEW

Initiative Overview: The EHI Initiative will ensure ARPA-H identifies and engages community innovators and early career investigators. To achieve this goal, ARPA-H is soliciting proposals from these researchers and innovators and their organizations to develop cutting-edge biomedical, health, and community-engaged research and innovation.

Two distinct tracks exist within the EHI Initiative, as detailed below. A proposer must submit a proposal to only one track and only one topic within that chosen track.

Track 1- Technology-Driven Innovation:

This track engages researchers conducting biomedical and health research to develop innovative health technologies. The project lead should be a researcher, not an administrator, at an institute for research or higher education, who has been appointed to their first research-based position within the last ten years and intends to remain at the proposer institution for the three-year award period, as defined in Section 3.3.1.

Track 2 - Community-Centered Innovation:

This track engages community innovators that apply or utilize community-engaged research methods to develop innovative technologies, tools, and/or platforms that can have significant impact on the health of communities across the U.S. The project lead should be a team member at a community-based organization (CBO), as defined in Section 3.3.2.

2.2 INITIATIVE STRUCTURE, TIMELINE AND TOPICS

The EHI Initiative seeks proposals for research activity consisting of a 24-month base period. Proposals should also include a 12-month optional period, referred to as the "Director's Award." This optional period will be reserved for a limited number of performers who demonstrate exceptional EHI project performance over the 24-month base period.

To accomplish its goals, the EHI Initiative contains two tracks, which each focus on supporting a different type of innovator and topic area.

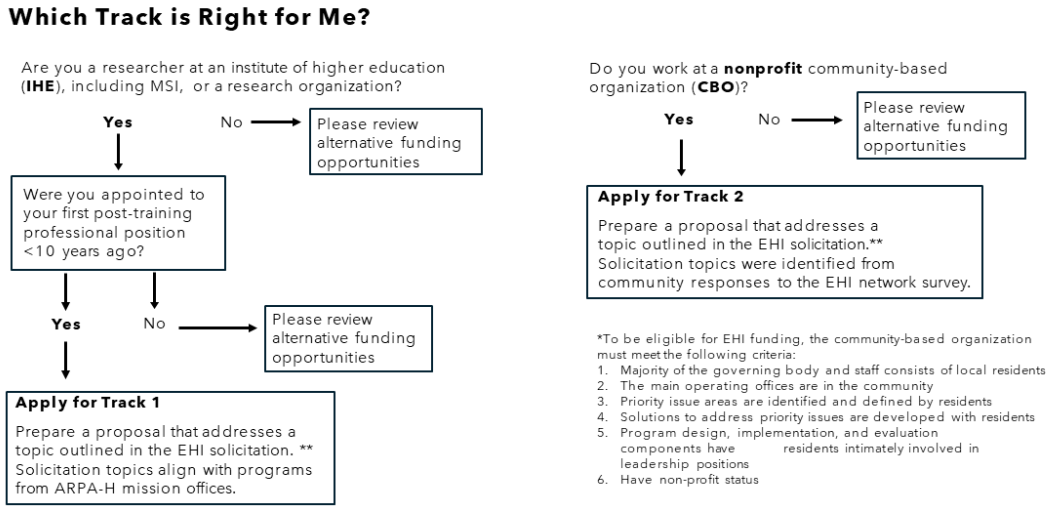
At the time of submission, proposers **must**:

1. Step 1: Select One Track
   Determine the appropriate track based on the eligibility requirements in Section 3.3.

2. Step 2: Respond to One Topic within the Selected Track
   Evaluate the topics listed for each track, and submit a solution summary to one topic.

Refer to **Figure 1** for additional assistance in selecting the most appropriate track for a proposing entity.

Figure 1. Track Selection Guide



2.3 TRACKS AND TOPICS

2.3.1 Track 1: Technology-Driven Innovation

Topic 1: **LS-SAFE - The Lymphatic System's Role in Infectious Disease Makes Us SAFE via Surveillance, Activation, Fluid Return and Elimination**

Background:

The human body comprises 11 systems crucial for maintaining health: the circulatory, respiratory, integumentary, endocrine, gastrointestinal, urinary, musculoskeletal, nervous, reproductive, immune, and lymphatic systems. Yet, the lymphatic system (LS) is currently the only one that lacks early diagnostic and therapeutic options that are safe, effective, and tolerable. This paradox is significant, considering the LS connects the circulatory and immune systems. ARPA-H's Lymphatic Imaging, Genomics, and pHenotyping Technologies and Groundbreaking Lymphatic Interventions and Drug Exploration programs were launched to address this gap, accelerating lymphatic research to align its importance with other body systems.

Situated at the intersection of the circulatory and immune systems, the LS and its lymphatic endothelial cells (LECs) hold crucial insights for understanding biological, molecular, and anatomical foundations, as well as pathophysiological mechanisms. Addressing foundational gaps is vital, as the LS regulates immune function.

LS-SAFE, as an EHI Track 1 topic, aims to complement ARPA-H's lymphatic portfolio by encouraging early investigators from diverse fields to explore knowledge gaps at the intersection of the immune, circulatory, and lymphatic systems. We challenge Track 1 proposers to address the following topic area that may lead to transformative diagnostic and therapeutic technologies focused on this unsung hero: the LS.

During any type of infection, the LS is crucial for mounting the body's immune responses to protect against harm.[1] It surveys and detects pathogens, and activated immune cells return to the bloodstream via lymph fluid to fight infection. The LS also helps eliminate harmful pathogens, cellular waste, and toxins, promoting recovery and healing. Recent findings demonstrate that LECs have an emerging role in acquiring and presenting antigens to migrating immune cells, promoting tolerance, memory, or activation depending on the context.[2,3]

In diseases like HIV, the virus specifically targets lymphoid tissues, leading to immune system dysfunction and lymphatic tissue damage.[4] Lymphatic filariasis, the leading cause of lymphedema worldwide, directly impairs lymphatic function and leads to severe swelling and tissue fibrosis. The larvae of these filarial worms migrate directly into lymphatic vasculature where they mature and spread over the course of months.[5] Other pathogens, such as Mycobacterium tuberculosis and Leishmaniasis, reside in the LS for extended periods, evading immune detection.[6,7]

Proposers responding to this topic will study the mechanisms by which infectious agents penetrate, manipulate, and utilize the human LS to effectively spread and evade traditional immune responses. Once specific pathways and molecular targets involved in the dysregulation of the LS and immune system during pathogen infection are identified, performers should develop treatments that address slow-growing or dormant stages of these infections through these pathways and mechanisms. Researchers may focus on a variety of novel therapeutic interventions to prevent pathogens from exploiting lymphatic pathways to evade immune response.

At submission, proposers are expected to fulfill the following:

- Identify 1-2 specific infection indications that will be studied. Proposals should describe how the selected indication is currently understood to leverage lymphatic-immune signaling to evade detection and spread. Potential indications to be selected from the following:
    - Lymphatic filariasis
    - HIV
    - Chikungunya virus
    - Mycobacterium
    - Leishmaniasis
    - Hepatitis
    - SARS-CoV-2/Long COVID
    - Cytomegalovirus (CMV)
    - Zika Virus
    - Epstein-Barr Virus (EBV)
- Demonstrate capacity for high throughput mechanism exploration
- Outline relevant in-vitro, in-vivo, and/or in-situ models that will be implemented

Topic 2: **MATCH- Advanced Machine Learning AlgoriThm for Compatible Human Leukocyte Antigen**

The principles of Human Leukocyte Antigen (HLA) matching for hematopoietic cell and organ transplant have remained mostly unchanged for decades. The standard method heavily relies on immunosuppressive agents and conventional donor-matching approaches that do not utilize the most current data from novel allogeneic transplant strategies nor deep sequencing and structural understanding of HLA phenotypes. Currently, histocompatibility assessment mainly focuses on HLA-A, HLA-B, and HLA-heterodimer (HLA-DR) loci with the assumption that all mismatches equally contribute to transplant outcomes. Graft vs. Host Disease (GvHD) remains a prevalent hurdle for all transplant patients (this includes hematopoietic stem cell and solid organ transplantation), as the disease state depends on the degree of HLA mismatching between donor and recipient. On average, a person has a 25% chance of having the same HLA type as their sibling, but many transplant recipients do not have a matched family donor and are forced to undergo allogeneic transplantation from an unrelated donor with similar HLA. Eight thousand allogenic stem cell transplants occur annually in the U.S.; the majority (43%) of transplants use an unrelated matched donor, exceeding the number of related matched donors (22%).[8] Allogeneic transplants critically increase the risk of GvHD and the dependence on immunosuppressive drugs. Existing technological tools that incorporate machine learning (ML) from large transplant databases and computational HLA modeling could predict outcomes and HLA matching recommendations at an individual level.

To address this topic, proposers should leverage efforts across different donor/transplantation consortiums, database management, and ML components of artificial intelligence (AI) to develop a computational model that can provide clinical decision support for matching transplantation recipients with an allogeneic donor, lowering the risk of GvHD.

The proposer selected for this topic will be expected to deliver a computational model which could include an app, with the potential to increase transplant recipient options while

remaining current with gene editing technology in relation to allogeneic transplant data and strategies. For example, customizable app features like deletion or replacement of HLA alleles would allow the app to remain relevant as transplant immunology and human gene editing continue to advance the field. Additional considerations and expectations for proposers are listed below:

- Proposers are encouraged to propose forward-thinking technology capable of expanding the matching donor pool for allogeneic sources using ML data training. Emerging resources, like a recently published research article on ML capabilities for predicting stem cell transplant efficacy in pediatric patients, may contribute to this effort.[9] Other metadata (e.g., donor age, recipient age, platelet recovery, or conditioning reagent dosage) may be taken into consideration for predicting immunological risk. Proposers should also improve or develop computational HLA immunogenicity algorithms to assist in predicting GvHD development.
- Proposers may consider features such as HLA structural properties or epitope determinants to further assess HLA phenotype compatibility.
- For validation of the donor-matching model or app capabilities, performers will be expected to complete in vitro functional immuno-assays, such as mixed-lymphocyte reaction, comparing conventional HLA mismatch guidelines to potential matches suggested by the app to confirm histocompatibility and immunological risk. This model or app could provide a decision support system to predict GvHD occurrence and immune rejection in all transplants – changing the paradigm focus to HLA compatibility instead of the long-term use of immunosuppressive drugs.
- Finally, this model or app would assist in the advancement of personalized medicine by allowing clinical decisions at the patient level, improving quality of life.

References

1. Tewalt, E. F., Cohen, J. N., Rouhani, S. J. & Engelhard, V. H. Lymphatic endothelial cells - key players in regulation of tolerance and immunity. *Front. Immunol.* **3**, 305 (2012).
2. Vokali, E. *et al.* Lymphatic endothelial cells prime naïve CD8+ T cells into memory cells under steady-state conditions. *Nat. Commun.* **11**, 538 (2020).
3. Tamburini, B. *et al.* Vaccine-induced antigen archiving enhances local memory CD8+ T cell responses following an unrelated viral infection. *Res. Sq.* rs.3.rs-3307809 (2023) doi:10.21203/rs.3.rs-3307809/v1.
4. Scholz, E. M. B. & Kashuba, A. D. M. The Lymph Node Reservoir: Physiology, HIV Infection, and Antiretroviral Therapy. *Clin. Pharmacol. Ther.* **109**, 918–927 (2021).
5. Medeiros, Z. M. *et al.* Lymphatic Filariasis: A Systematic Review on Morbidity and Its Repercussions in Countries in the Americas. *Int. J. Environ. Res. Public. Health* **19**, 316 (2021).
6. Ganchua, S. K. C., White, A. G., Klein, E. C. & Flynn, J. L. Lymph nodes-The neglected battlefield in tuberculosis. *PLoS Pathog.* **16**, e1008632 (2020).
7. Mann, S. *et al.* A Review of Leishmaniasis: Current Knowledge and Future Directions. *Curr. Trop. Med. Rep.* **8**, 121 (2021).
8. Salhotra, A., Yuan, S. & Ali, H. Fifty years of BMT: risk stratification, donor matching, and stem cell collection for transplantation. *Front. Oncol.* **13**, 1196564 (2023).

9. Chadaga, K., Prabhu, S., Sampathila, N. & Chadaga, R. A machine learning and explainable artificial intelligence approach for predicting the efficacy of hematopoietic stem cell transplant in pediatric patients. *Healthc. Anal.* **3**, 100170 (2023).

2.3.2 Track 2: Community Centered Innovation

Topic 1: **Disrupting asthma: Empowering community-based organizations to leverage technology and deliver personalized and effective asthma management for children**

Asthma is a chronic respiratory condition that affects approximately 25 million people in US including 4.6 million children under the age of 18[1]. It is one of the most common chronic diseases in children[2]. Effective management of childhood asthma requires a comprehensive approach, including proper diagnosis, education, and regular monitoring of symptoms and lung function[3].

The current problems with asthma management in children include the reliance on subjective patient reports for symptom tracking. Additionally, studies have shown that inadequate adherence to medication regimens is a significant barrier to effective asthma control in children as well as the inadequate use of inhalers[4]. Furthermore, limited access to healthcare services in underserved communities exacerbates these issues.

ARPA-H seeks novel technology solutions to asthma management for children that allow for accessible, easy-to-use, non-invasive, portable and cost-effective solutions. These solutions will provide greater access to be used at home or at community health centers and improving asthma management outcomes in children.

Community-based organizations will lead the development and can partner/collaborate with an academic/research institution of a proposed technology or platforms solution. Potential solutions may include, but are not limited to:

- Developing a new flow sensing device for those with asthma that accurately measure lung function, provides real-time feedback, is non-invasive, is portable, easy-to-use, is safe and secure with patient health information.
- Developing an innovative platform to manage asthma (symptoms, medicine, etc.) in children. This platform could use AI to offer features that are user-friendly, seamless translation, educational content for caregivers and children, provide real-time feedback on inhaler technique to ensure proper use, and be safe and secure with personal health information.
- Developing a wearable device to measure personal health environmental variables such as ambient temperature, humidity, air quality, volatile organic compounds (VOCs), aerosols and vital signs such as respiration rate, heart rate, O2. The data can be used by CBOs and/or medical providers to understand health issues and improve outcomes.

Requirements should be directed by the community-based organization. These technologies should not aim to replace health providers or CBOs but to enhance their valuable work.

References

1. CDC National Center for Health Statistics, National Health Interview Survey (NHIS). National Surveillance of Asthma: United States, 2001–202. https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm
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Topic 2: **Community care for personal wellbeing: Empowering community-based organizations to leverage technology to deliver personalized environmental monitoring and recommendations**

Indirect health variables refer to the non-biomedical factors that influence an individual's health, such as housing stability, education level, employment status, food security, and access to healthcare. Addressing these variables at the community level is critical to improving health outcomes among vulnerable populations[1].

In addition, environmental conditions such as air quality, weather and heat exposure are part of daily life and can impact health[2]. Accurate measurement of temperature, air quality, and these other environmental variables is important and not available at the personal level.

ARPA-H seeks novel technology solutions to community care for personal well-being that allow for accessible, easy-to-use, non-invasive, portable and cost-effective solutions. These solutions will provide greater access to be used at home and/or at community health centers and improving health outcomes.

CBOs will lead the development and can partner/collaborate with an academic/research institution of a proposed technology or platforms solution. Potential solutions may include, but are not limited to:

- Developing a wearable device to measure personal health environmental variables such as ambient temperature, humidity, air quality, VOCs, aerosols and vital signs such a body temperature, respiration rate, heart rate, O2. The data can be used by CBOs and/or medical providers to understand health issues and improve outcomes.
- Developing a state-of-the-art virtual assistant that engages the specific CBO's community in their own language to provide personalized service recommendation, scheduling services, and offer additional resources at city or county level. An open-source AI model would keep maintenance costs low and permanent access for the CBOs. Retrieval-Augmented Generation (RAG) support systems or other support

systems are encouraged to minimize hallucinations and improve accuracy and reliability.

Requirements for the technologies should be directed by the CBO. These technologies should not aim to replace CBOs but to enhance and assist in their valuable work. Personal health and environmental information must be safe and secure.

References

1. Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. Retrieved Nov 2024 from https://odphp.health.gov/healthypeople/objectives-and-data/social-determinants-health
2. Morello-Frosch, R., Pastor, M., Sadd, J., & Shonkoff, S. B. (n.d.). The climate gap: Inequalities in how climate change hurts Americans & how to close the gap. https://dornsife.usc.edu/assets/sites/242/docs/ClimateGapReport_full_report_web.pdf

3. GENERAL REQUIREMENTS

3.1 PROPOSERS

Proposers may only submit one proposal as the prime proposer. See Section 3.3 for information on what constitutes a proposer. The Government's expectation is that all key members of the performer team will be onboard within 60 days of the award.

Track 1

The proposal must demonstrate the expertise needed to collectively achieve the goals of the proposed topic. Communications, networking, and team formation are the sole responsibility of the proposer. Proposals must be led by one early-career investigator, as defined in Section 3.3.1. Proposers can propose a statement of work that they will accomplish independently or through a collaborative team effort with contractors and/or subawardees.

Track 2

The proposal must demonstrate the expertise needed to collectively achieve the goals of the proposed topic. Communications, networking, and team formation are the responsibility of the proposer alone. Proposals must be led by one community innovator employed at the proposing community-based organization– as defined in Section 3.3.2. Proposers can propose a statement of work that they will accomplish independently or through a collaborative team effort with contractors and/or subawardees.

3.2 TENTATIVE EHI PROGRAM MEETINGS AND ATTENDANCE

This information is provided for time and resource planning purposes.

- **Monthly Status Reports (MSR) with PM/EHI Team** – Each project lead will be required to meet virtually with the PM/EHI team at least monthly (estimated at 1 hour each meeting)

to review progress, metrics, milestones, and deliverables, as determined in the final award. Status reports outlining technical and financial updates will be required at monthly meetings with the program manager (PM).

- **EHI's Initiative Kick-off** – EHI will host an in-person kick-off event in the Washington D.C. area where performers will come together. The project lead and one additional attendee should attend.

- **Annual In-Person Meeting** – Budget should include attendance of the in-person EHI annual meeting for the project lead and one additional attendee. All EHI performers will provide updates on their projects to ARPA-H and other EHI performers. They will have the opportunity to visit other agencies and potential partners.

3.3 ELIGIBILITY INFORMATION

All responsible sources capable of satisfying the Government's needs and meeting the eligibility criteria listed below may submit a proposal to this ISO.

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 awards to a particular person or organization. ARPA-H encourages organizations to submit their research ideas notwithstanding this perceived limitation. Any conforming proposal received will be fairly considered for award and, if it is of interest to ARPA-H, will be selected for an award.

3.3.1 Track 1 Eligibility

Proposal submissions must be led by early-career investigators – such as medical fellows, research scientists, and tenure-track assistance/associate professors – less than 10 years from first appointment at an academic or research institution across the U.S. Post-doctoral fellows/trainees and clinical trainees are ineligible. Investigators who expect to leave their current institution within the next 3 years should not submit a solution summary or proposal, as this would preclude completion of the award period.

Proposals from non-U.S. entities **will not be accepted**. All project leads **must** be employed at a U.S. institution, which includes those in U.S. states and territories.

NOTE: Early career investigators with past or current ARPA-H funding as either a prime or subawardee are not eligible to apply for the EHI Initiative.

3.3.2 Track 2 Eligibility

Proposal submissions must be led by community innovators – such as community healthcare workers, medical professionals, nurses, and social workers – employed at a CBO.

All proposers submitting a response to Track 2 must self-certify that they meet the following criteria, see Track 2 Appendix:

- Nonprofit organization (organization completes the tax form 990)

- The organization's governing body and/or staff consists of local residents, as evidenced by the board of directors
- The main operating offices are in the community
- Priority issue areas are identified and/or defined by residents
- Solutions to address priority issues are developed with residents
- Program design, implementation, and evaluation components have residents involved in leadership positions
- Organization provides social or health services

Proposals from non-U.S. entities **will not be accepted**. All project leads **must** be employed at a U.S. institution, which includes those in U.S. states and territories.

NOTE: Proposal submissions from non-eligible proposers may be deemed non-conforming and may be rejected without further review.

3.3.3 Federally Funded Research and Development Centers (FFRDCs) and Other Government Entities

ARPA-H is primarily interested in responses to this solicitation from eligible proposers as described above. In certain circumstances, FFRDCs and Government entities will 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 EHI@arpa-h.gov.
- If a potential prime proposers 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.

3.3.4 Non-U.S. Entities

Proposals from non-U.S. entities **will not be accepted**. All project leads **must** be employed at a U.S. institution, which includes those in U.S. states and territories.

3.4 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 proposal consideration or holding and active ARPA-H award. 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 is independent of ARPA-H and thus ARPA-H representatives have no influence over processing timeframes.

4. EHI SUBMISSION AND EVALUATION PROCESS

4.1 SUBMISSION PROCESS OVERVIEW

An overview of the anticipated review and evaluation process and requirements is depicted in Figure 2. Proposals to EHI will be reviewed in two steps that consist of the following:

- ✓ **Step 1:** Solution Summary Submission. This two-page solution summary provides the proposed project overview and impact on the field. Please refer to the appendix that corresponds with your chosen track for additional information (Track 1 Appendix, Track 2 Appendix).
- ✓ After reviewing the solution summary, proposers will be encouraged / discouraged to move to Step 2. Proposers will receive written notification of the recommendation. All parties, whether encouraged or discouraged, are eligible to move to Step 2.
- ✓ **Step 2:** Pitch the full proposal. The oral presentation takes the place of a full written proposal: it will be prepared using the track specific appendix template. During the virtual one-hour pitch presentation, proposers will expand upon and discuss their concept with ARPA-H personnel. Please refer to the appendix for the corresponding track for additional information.
- ✓ Proposers selected to negotiate an award following step 2 may be required to submit additional documentation before an agreement can be finalized.

Solution Summary Q1 2025	Pitch Presentation Q2 2025	Agreement Negotiation Q3 2025	Phase One Months 1-24	Phase Two Months 25-36
Two-page technical summary "Encourage" or "discourage" pitch participation feedback	Sixty-minute presentation Evaluation on ✓Technical Merit ✓Impact ✓Cost Analysis	Additional documentation may be required from selectee Selectee transitions to performer	R&D period in collaboration with EHI team In-person and virtual meetings with EHI team, relevant program managers, and other EHI performers	*OPTIONAL* Top performers will be recommended for "Directors" award, which includes an additional twelve months of funding

Figure 2 Tentative Evaluation Process and Requirements

4.2 SOLUTION SUMMARY SUBMISSIONS

Solution summary submissions are required for proposers to progress to Step 2. Proposers cannot pitch without first submitting a solution summary. See Step 1 in the appendix that corresponds with your chosen track for the required solution summary format.

4.3 PITCH PRESENTATION SUBMISSIONS

Based on the solution summary, ARPA-H will encourage/discourage proposers of conforming solution summaries to submit a pitch deck for virtual oral presentations. See Step 2 in the appendix that corresponds with your chosen track for the required EHI Pitch Presentation format.

4.4 SUBMISSION INFORMATION

All solution summaries and pitch presentations submitted in response to this solicitation must be written and presented in English and must be consistent with the content and formatting requirements provided in the corresponding appendices.

Proposers are responsible for submitting their solution summary and pitch presentation via the ARPA-H Solution Submission Portal and ensuring receipt by the date and time specified in the ISO or as communicated through feedback letters. 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 will not be accepted or considered.

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

4.5 SOLUTION SUMMARY AND PITCH PRESENTATION

Solution summaries are due on the closing date of this solicitation, as established in Section 1. After reviewing the solution summary, ARPA-H will provide written feedback encouraging or discouraging a proposer to submit a pitch. Solution summary submission precedes pitch presentation. Proposers that do not submit a solution summary will not be allowed to present a pitch.

Please refer to the corresponding track appendix (Track 1 Appendix, Track 2 Appendix) for template information for the solution summary and pitch presentation required format.

4.6 PROPRIETARY INFORMATION

Proposers are responsible for clearly identifying proprietary information. Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as “Proprietary.”

NOTE: “Confidential” is a classification marking used to control the dissemination of U.S. Government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

5. SOLUTION SUMMARY REVIEW AND PROPOSAL EVALUATION

5.1 CONFORMING SOLUTION SUMMARY AND PITCH PRESENTATION

Conforming submissions contain all requirements detailed in this ISO. Solution summaries and pitch presentations that fail to include required information may be deemed non-conforming and may be removed from further consideration. Non-conforming submissions may be rejected without further review. A solution summary or pitch presentation can be deemed non-conforming under this ISO if it fails to meet one or more of the following solicitation requirements:

- The proposed solution is applicable to the EHI Initiative.
- The proposers meet the eligibility requirements.
- The solution summary/pitch deck meets the submission requirements.
- The solution summary/pitch deck 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).

Non-conforming solution summary and pitch deck submissions may be removed from consideration. Proposers will be notified of non-conforming determinations via email correspondence.

5.2 STEP 1: SOLUTION SUMMARY REVIEW PROCESS

ARPA-H will review and respond to all proposers submitting solution summaries indicating whether a proposer is encouraged/discouraged to submit a pitch deck for oral presentation (Step 2). Conforming solution summaries will be reviewed and encouraged/discouraged to pitch based on ARPA-H's interest in the solution summary. Feedback will be provided to the administrative and technical points of contacts noted on the solution summary cover page.

5.3 STEP 2: PITCH PRESENTATION EVALUATION PROCESS

ARPA-H will evaluate and respond to all conforming proposers who complete a virtual oral presentation.

5.4 REVIEW, EVALUATION, AND SELECTION PROCESS FOR AWARD

It is the policy of ARPA-H to ensure impartial and comprehensive evaluations based on the evaluation criteria listed below and to select the proposals whose solutions are most advantageous to the Government.

ARPA-H will evaluate each conforming pitch presentation. All pitch presentation evaluations will be based solely on the evaluation criteria. A selection for award negotiation will be made to proposers whose pitch presentation is determined to be most advantageous by the Government.

NOTE: Pitch presentations will not be evaluated against each other during the scientific review process, but rather evaluated on their own individual merit to determine how well the submission meets the criteria stated in this ISO.

5.4.1 Review and Evaluation Timelines

ARPA-H intends to review solution summaries and evaluate pitch presentations as soon as possible after the closing of the submission deadlines and pitch presentations.

5.4.2 Evaluation Criteria for Step 2 and Award

Pitch presentations will be evaluated using the following criteria listed in descending order of importance.

Track 1

Criteria 1: Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and clearly defines feasible planned mitigation efforts. In addition, the evaluation may take into consideration the extent to which the proposed (IP rights structure and software components will potentially impact the ability to commercialize the technology and adhere to open-source solutions and/or standards.

Criteria 2: Potential Contribution and Relevance to the ARPA-H Mission

The potential contributions of the proposed effort support ARPA-H's mission to accelerate better health outcomes for all will be evaluated. The proposed effort's demonstrated potential to invigorate exceptionally innovative and impactful health and biomedical research more broadly in the nation should be evident. The proposed intellectual property restrictions (if any) will not significantly impact the Government's ability to transition the technology.

Criteria 3: 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). Analysis may be performed to ensure proposed costs are realistic for the proposed scientific and technical approach and capabilities/related experience, accurately reflect the technical goals and objectives of the solicitation, the proposed costs are consistent with the proposer's SOW and reflect a sufficient understanding of the costs and effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed subawardees should be substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs 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. For efforts with a likelihood of commercial application,

appropriate resource sharing may be a positive factor in the evaluation.

Track 2

Criteria 1: Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and clearly defines feasible planned mitigation efforts. In addition, the evaluation may take into consideration the extent to which the proposed IP rights structure and software components will potentially impact the ability to commercialize the technology and adhere to open-source solutions and/or standards.

Criteria 2: Potential Community Impact and Contribution to the ARPA-H Mission

The proposed effort's potential impact on the served community and the effort's ability to support ARPA-H's mission to accelerate better health outcomes for all will be evaluated. The proposed efforts demonstrated potential to invigorate exceptionally engaged, community-driven, innovative, and impactful health research should be evident. In addition, the proposed effort should offer significant advantages over existing approaches, methodologies, or interventions currently used in practice.

Criteria 3: 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). Analysis may be performed to ensure proposed costs are realistic for the proposed scientific and technical approach and capabilities/related experience, accurately reflect the technical goals and objectives of the solicitation, the proposed costs are consistent with the proposer's SOW and reflect a sufficient understanding of the costs and effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed subawardees should be substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs 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. For efforts with a likelihood of commercial application, appropriate resource sharing may be a positive factor in the evaluation.

Handling of Competition Sensitive Information

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

All ARPA-H support contractors are expressly prohibited from performing ARPA-H sponsored technical research and are bound by appropriate nondisclosure agreements. Input on technical aspects of the solution summaries and proposals may be solicited by ARPA-H from non-Government consultants/experts who are strictly bound by appropriate non-disclosure requirements. No submissions will be returned.

5.5 EVALUATION AND AWARD DISCLAIMERS

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this ISO. If warranted, portions of resulting awards may be segregated into pre-priced options. 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 in phases with options for continued work, as applicable.

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

In all cases, the Government will have sole discretion to negotiate all instrument terms and conditions with selectees. ARPA-H will apply publication or other restrictions, as necessary, if it is determined 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. At a minimum, all awards will include a requirement for performer teams to submit information for review to ARPA-H before publishing.

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. The disclosure and mitigation plan(s) do not count toward the page limit.

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

In addition, ARPA-H restricts performers from concurrently providing professional support services, or similar support services and being a technical performer. Therefore, as part of the FAR 9.5 disclosure requirement above, a proposer must affirm whether the proposer or any proposed team member (proposed subawardee, etc.) is providing professional support services to any ARPA-H office(s) under: (a) a current award or subaward; or (b) a past award or subaward that ended within one (1) calendar year prior to the proposal's submission date.

Proposers shall follow the instructions in and complete the relevant track-specific appendix to address the requirements of this ISO Section.

Note: An OCI based on a proposer currently providing professional support services as described above, cannot be mitigated.

6.2.2 RESEARCH SECURITY DISCLOSURES

In accordance with NSPM-33, research organizations should identify and mitigate conflicts of commitment (COCs) and conflicts of interest (COIs) to receive federal funding. A research organization proposing to this ISO must provide additional documentation as requested for Senior/Key Personnel for ARPA-H to determine the existence of any risk. The format for this submission can be found in the Administration and National Security Document Templates (Attachment 4 & Attachment 5).

6.3 INTELLECTUAL PROPERTY (IP)

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.

NOTE: IP rights assertions will be reviewed under Criteria 1 for both tracks.

6.4 HUMAN SUBJECTS RESEARCH

All entities submitting a proposal for funding that will involve engagement in human subjects research (as defined in 45 CFR § 46) must provide documentation of one or more current Assurance of Compliance with federal regulations for human subjects protection including at least a Department of Health and Human Services (HHS) Office of Human Research Protection

Federal Wide Assurance. All human subjects research must be reviewed and approved by an Institutional Review Board (IRB), as applicable under 45 CFR § 46 and/or 21 CFR § 56. The entities human subjects research protocol must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. Recipients of ARPA-H funding must comply with all applicable laws, regulations, and policies for the ARPA-H funded work. This includes but is not limited to laws, regulations, and policies regarding the conduct of human subjects research, such as the U.S. federal regulations protecting human subjects in research (e.g., 45 CFR § 46, 21 CFR § 50, § 56, § 312, § 812) and any other equivalent requirements of the applicable jurisdiction.

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

6.5 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) must comply with the laws, regulations, and policies on animal acquisition, transport, care, handling, and use as outlined in: (i) 9 CFR parts 1-4, U.S. Department of Agriculture rules that implement the Animal Welfare Act of 1966, as amended, (7 U.S.C. § 2131-2159); (ii) the Public Health Service Policy on Humane Care and Use of Laboratory Animals, which incorporates the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," and "Guide for the Care and Use of Laboratory Animals" (8th Edition)."

Proposers must provide documentation of a current Animal Welfare Assurance (AWA) on file with the Office of Laboratory Animal Welfare (OLAW).

Proposers must complete and submit the Vertebrate Animal Section (VAS) for all proposed research anticipating animal subjects research. A guide for completing the VAS can be found at https://olaw.nih.gov/sites/default/files/VAChecklist.pdf worksheet for all proposed research anticipating Animal Subject Research.

All animal use research must undergo review and approval by the local Institutional Animal Care Use Committee (IACUC) prior to incurring any costs related to the animal use research. For all proposed research anticipating animal use, proposals should briefly describe plans for IACUC review and approval.

6.6 ELECTRONIC INVOICING AND PAYMENTS

Performers will be required to submit invoices in a designated electronic payment system, as described in the award document.

6.7 GOVERNMENT-FURNISHED PROPERTY/EQUIPMENT/INFORMATION

Government-furnished property (GFP)/equipment (GFE)/information (GFI) may be provided to selected performers. Any instances of GFP/GFE/GFI will be specifically negotiated.

APPENDIX | TRACK 1

Step 1: Solution summary format and instructions

A. General Instructions

This template must be used for all solution summary submissions to **Track 1** of this ISO. The body text for solution summaries must be 11-point font or larger. Smaller font may be used for figures, tables, and charts but must be legible. Margins may be no less than 0.5" inch in width. Solution summaries are limited to two pages; the cover page, project lead, team organization and capabilities, and Rough Order of Magnitude (ROM) **do not** count toward the two-page limit. A table of contents must not be provided.

The solution summary should address why the proposed idea is relevant to the ARPA-H mission and responsive to the topic selected in **Track 1.** The solution summary should demonstrate the proposed work's technical merit and impact and will be reviewed accordingly. The Government may not review pages beyond two total; any solution summary submitted that exceeds two pages will only be reviewed at ARPA-H's discretion. Solution summaries should be submitted in a PDF format to the ARPA-H Solution Submission Portal. Attachments and embedded links should not be included.

B. Cover Page

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

Solicitation #	ARPA-H-SOL-25-118
Solution Summary Title	
Track Selection (must select only one)	Track 1
Topic Selection (must select one topic within the Track)	
Proposer Organization	
Type of Organization and website URL if applicable	**Choose all that apply:** Historically Black Colleges and Universities (HBCU), Minority Serving Institution (MSI), Other Educational, Community-based organization (CBO), Federally Qualified Health Center (FQHC) or Other Nonprofit
Technical Point of Contact (POC)/ Project Lead	Name: Mailing Address: Telephone: Email:
Project Lead Appointment Date (Tenure-Track Start Date, Non-tenure track start date, Medical Fellowship Start Date)	
Administrative POC	Name: Mailing Address: Telephone:
Other Team Members (subperformers, including consultants) if any	Technical POC Name: Organization: Organization Type:

C. Self-Certification of Early Career Investigator Eligibility

I certify that I meet the following criteria for eligibility for this ISO:

- ☐ I was appointed to my first research- or clinic-based position within the last 10 years
- ☐ I have not received ARPA-H funds as a prime performer
- ☐ I intend to stay at the proposer institution for the next 3 years

NOTE: In Step 2, proposers will provide a letter that confirms the project lead's eligibility (appointment year and position, as well as institutional support to retain investigator for at least the 3-year award period).

D. Solution summary content

1. Summary:

Provide a 1-2 sentence summary of your effort:

a. What you are trying to do and why does it matter? Please minimize jargon.

2. Introduction/Background:

Describe the problem space you are trying to explore. (Two paragraphs)

a. What is the problem you are trying to solve and why is it important?
b. What is/are the current state(s) of the art and what are the limitations to current approaches?

3. Impact:

Describe the impact your project will have within the field, community, and wider audience. (Two paragraphs)

a. If you succeed, what difference do you think it will make?
b. How will the project impact this field of work?

4. Methods/Approach:

Identify and describe the scientific phenomena and/or engineering capability under consideration. Outline your research plan and summarize the methodologies you will be employing. Please incorporate the answers to the following questions within your description. (Up to remainder of 2 pages)

a. What methodologies will you be employing?
b. What is new about your approach?
c. What are the advantages of your proposed methodologies over existing ones?

E. Project Lead, team organization and capabilities

Indicate the roles and responsibilities of the project lead and the support provided by their respective organizations. Identify and describe in 1-2 sentences the skills and experience of any key personnel on the proposed performer team. Briefly summarize the project lead's history and professional development (current and future) within the proposing institution.

F. Rough Order of Magnitude (ROM)

Please include provide an estimate of your costs to include labor (your fully burdened labor), any subperformer costs, materials, equipment and travel costs you will need in order to complete the work. All subperformers should total together in the subperformers line. The below table may be used for this breakdown:

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

Categories	Year 1	Year 2	Year 3 (Optional)	Total
Labor Cost				
Subperformers				
Materials				
Equipment				
Travel				
Total				

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.

G. References

References should be included on an independent sheet that does not contribute to the two-page limit.

Step 2: Pitch Presentation and Supplementary Information Instructions

A. General Instructions

All EHI pitch submissions must use the pitch deck slides provided on SAM.gov. See Attachment 1. Go to the ARPA-H Solution Submission Portal and follow the directions to create a username and password and navigate to pitch submission. Submit your pitch presentation slide deck.

Be advised of the following important information:

- It is recommended that all proposers review and follow all pitch presentation slide deck instructions provided.
- Submissions will not be considered complete until all required files have been uploaded.
- Your pitch presentation submission will be set-up for you on pitch day. No revisions post **submission will be allowed.**

B. Pitch Presentation Format and Logistics

All EHI Step 2 pitch oral presentations will be virtual. Two people from each team will be allowed to attend the presentation. All pitch presentations will be 60 minutes total, constituting 40 minutes for the presentation and 20 minutes of questions and answers (Q&A). Proposers must include a statement of work (SOW), technical milestones and costs. Pictures, figures and diagrams are encouraged in place of text where relevant.

C. Statement of Work

An SOW must be included in the presentation. The SOW provides a comprehensive list of specific tasks for the selected topic and their connection to the milestones and program metrics. Each year of the initiative should be separately defined, including the optional third year. The SOW must not include proprietary information.

For each task/subtask, applicants must provide the following:

- A brief description of the approach to accomplish the task/subtask.
- Identification of the primary person responsible for task execution.
- A quantitative milestone (i.e., a deliverable, demonstration, or other event/activity) and its metrics that mark task completion and success
- A definition of all deliverables (e.g., data, reports, software) to be provided to the Government in support of the proposed task/subtask.

D. Team Member Identification and Biosketches

Proposers must provide a list of all team members including the prime, subawardee(s), and consultant(s), as applicable. Identify specifically whether any subawardees or consultants are a non-U.S. organization or individual. Use the format below for this list. In addition, all team

members must submit a concise Biosketch (max 3 pages) briefly summarizing experience relevant to the proposed project.

Note: Consultants (e.g., 1099s) are considered subawardees and must be listed.

List Format: List all team members, including contractors.

PRIME			
Individual Name:	**Organization:**	Non-U.S. Organization: ☐ Yes Non-U.S. Individual: ☐ Yes	☐ No ☐ No
SUBAWARDEES/CONSULTANTS			
Individual Name:	**Organization:**	Non-U.S. Organization: ☐ Yes Non-U.S. Individual: ☐ Yes	☐ No ☐ No
Individual Name:	**Organization:**	Non-U.S. Organization: ☐ Yes Non-U.S. Individual: ☐ Yes	☐ No ☐ No

Biosketch Format: Provide the following information for each team member. Each Biosketch should be 3 pages or less.

Team Member Name	
Role on Project	
Current Position	
Title	
Time in Position	
Time at Institution	
Educational History	*Graduate and post-graduate education only*
Personal Statement	(e.g., what inspired this solution, what will be your contribution to the project)
Relevant Publications	*List only those publications that support your intended contribution to this project*
Professional Involvement	*Previous positions, appointments, and honors related to the proposed project*

E. Cost Proposal

There is no maximum page count for the Cost Proposal. 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.

Cost Proposal Spreadsheet: ARPA-H Standard Excel Cost Proposal Spreadsheet (See Attachment 3). 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 subperformers at any tier.

The prime proposer is responsible for submission of all required documents, including sub-performer cost proposal spreadsheets, and can email them directly to the Government at EHI@ARPA-H.gov. Subperformer proposals should include Interdivisional Work Transfer Agreements or similar arrangements between the awardee and divisions within the same organization as the awardee.

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, 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 found at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/. 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.

F. Letter of Support

Project leads should include letters of support from the proposer institution, confirming their "early career" status, as defined in the ISO Eligibility Section 3.3.

G. For **Other Transactions**, please submit **Attachment 4**. For **cooperative agreements**, please submit **Attachment 5**.

APPENDIX | TRACK 2

Step 1: Solution Summary format and instructions

A. General Instructions

This template must be used for all solution summary submissions to **Track 2** of this ISO. The body text for solution summaries must be 11-point font or larger. Smaller font may be used for figures, tables, and charts but must be legible. Margins may be no less than 0.5" inch in width. Solution summaries are limited to two pages; the cover page, project lead, team organization and capabilities, and Rough Order of Magnitude (ROM) **do not** count toward the two-page limit. A table of contents must not be provided.

The solution summary should address why the proposed idea is relevant to the ARPA-H mission and responsive to the topic selected in **Track 2.** The solution summary should demonstrate the proposed work's technical merit and community impact will be reviewed accordingly. The Government may not review pages beyond two total; any solution summary submitted that exceeds two pages will only be reviewed at ARPA-H's discretion. Solution summaries should be submitted in a PDF format to the ARPA-H Solution Submission Portal. Attachments and embedded links should not be included.

B. Cover Page

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

Solicitation #	ARPA-H-SOL-25-118
Solution Summary Title	
Track Selection (must select only one)	Track 2
Topic Selection (must select one topic within the Track)	
Submitter Organization	
Type of Organization and website URL if applicable	**Choose all that apply:** Community-based organization, FQHC or Other Nonprofit
Technical Point of Contact (POC)/ Project Lead	Name: Mailing Address: Telephone: Email:
Administrative POC	Name: Mailing Address: Telephone: Email:
Other Team Members (subperformers, including consultants) if any	Technical POC Name: Organization: Organization Type:

C. Community-Based Organization Self Certification

All proposers submitting a response to Track 2 must self-certify that they meet the following criteria.

- ☐ Nonprofit organization (organization completes the tax form 990)
- ☐ Governing body and/or staff consists of local residents (please include a list of your board of directors)
- ☐ The main operating offices are in the community
- ☐ Priority issue areas are identified and/or defined by residents
- ☐ Solutions to address priority issues are developed with residents
- ☐ Program design, implementation, and evaluation components have residents involved in leadership positions
- ☐ Organization provides social or health services

D. Solution summary content

1. Summary:
   Provide a 1-2 sentence summary of your effort:

   a. What you are trying to do and why does it matter? Please minimize jargon.

2. Introduction/Background:
   Please describe the specific area or issue you are looking to work on. (Two paragraphs)

   a. What is the problem you are trying to solve and why is it important?
   b. What is/are the current state(s) of the art and what are the limitations to current approaches?

3. Impact:
   Describe the impact your project will have within the community that you serve. (Two paragraphs)

   a. If you succeed, what difference will it make in the community you serve?
   b. How will the project impact your field?

4. Methods/Approach:
   Identify and describe the scientific phenomena and/or engineering capability under consideration. Outline your research plan and summarize the methodologies you will be employing. Please incorporate the answers to the following questions within your description. (Up to remainder of two pages)

   a. What methodologies will you be employing?
   b. What is new about your approach?
   c. What are the advantages of your proposed methodologies over existing ones?

E. Project Lead, team organization and capabilities

Indicate the roles and responsibilities of the project lead and the support provided by their respective organizations. Identify and describe in 1-2 sentences the skills and experience of key personnel on the proposed performer team. Briefly summarize the project lead's history and professional development (current and future) within the proposing institution.

F. Rough Order of Magnitude (ROM)

Please include provide an estimate of your costs to include labor (your fully burdened labor), any subperformer costs, materials, equipment and travel costs you will need in order to complete the work. All sub-performers should total together in the subperformers line. The below table may be used for this breakdown:

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

Categories	**Year 1**	**Year 2**	**Year 3 (Optional)**	**Total**
Labor Cost				
Subperformers				
Materials				
Equipment				
Travel				
Total				

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.

G. References

References should be included on an independent sheet that does not contribute to the two-page limit.

Step 2: Pitch Presentation and Supplementary Information Instructions

A. General Instructions

All EHI pitch submissions must use the pitch deck slides provided on SAM.gov. See Attachment 2. Go to the ARPA-H Solution Submission Portal and follow the directions to create a username and password and navigate to pitch submission. Submit your pitch presentation slide deck.

Be advised of the following important information:

- It is recommended that all proposers review and follow all pitch presentation slide deck instructions provided.
- Submissions will not be considered complete until all required files have been uploaded.
- Your pitch presentation submission will be set-up for you on pitch day. **No revisions post submission will be allowed.**

B. Pitch Presentation Format and Logistics

All EHI Step 2 pitch presentations will be virtual. Two people from each team will be allowed to attend the presentation. All pitch presentations will be 60 minutes total, constituting 40 minutes for the presentation and 20 minutes of questions and answers (Q&A). Proposers must include a statement of work (SOW), technical milestones and costs. Pictures, figures and diagrams are encouraged in place of text where relevant.

C. Statement of Work

A SOW should be included in the presentation. The SOW provides a comprehensive list of specific tasks for the selected topic and their connection to the milestones and program metrics. Each year of the initiative should be separately defined. The SOW must not include proprietary information.

For each task/subtask, applicants must provide the following:

- A brief description of the approach to accomplish the task/subtask.
- Identification of the primary person responsible for task execution.
- A quantitative milestone (i.e., a deliverable, demonstration, or other event/activity) and its metrics that mark task completion and success
- A definition of all deliverables (e.g., data, reports, software) to be provided to the Government in support of the proposed task/subtask.

D. Team Member Identification and Biosketches

Proposers must provide a list of all team members including the prime, subawardee(s), and consultant(s), as applicable. Identify specifically whether any subawardees or consultant are a non-US organization or individual. Use the format below for this list. In addition, all team members must submit a concise Biosketch (max 3 pages) briefly summarizing experience relevant to the proposed project.

Note: Consultants (e.g., 1099s) are considered subawardee and must be listed.

List Format: List all team members, including contractors.

PRIME			
Individual Name:	**Organization:**	Non-U.S. Organization: ☐ Yes	☐ No
		Non-U.S. Individual: ☐ Yes	☐ No
SUBAWARDEES/CONSULTANTS			
Individual Name:	**Organization:**	Non-U.S. Organization: ☐ Yes	☐ No
		Non-U.S. Individual: ☐ Yes	☐ No
Individual Name:	**Organization:**	Non-U.S. Organization: ☐ Yes	☐ No
		Non-U.S. Individual: ☐ Yes	☐ No

Biosketch Format: Provide the following information for each team member. Each Biosketch should be 3 pages or less.

Team Member Name	
Role on Project	
Current Position	
Title	
Time in Position	
Time at Institution	
Relevant Credentials	(e.g. certifications, fellowships)
Personal Statement	(e.g., what inspired this solution, what will be your contribution to the project)
Professional Involvement	*Previous positions, appointments, and honors related to the proposed project*
Other Contributions	*Include relevant involvement in the community or otherwise*

E. Cost Proposal

There is no maximum page count for the Cost Proposal. 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.
Cost Proposal Spreadsheet: ARPA-H Standard Excel Cost Proposal Spreadsheet (See Attachment 3). 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 sub-performers at any tier.

The prime proposer is responsible for submission of all required documents, including subperformer cost proposal spreadsheets, and can email them directly to the Government at EHI@ARPA-H.gov. Subperformer proposals should include Interdivisional Work Transfer Agreements or similar arrangements between the awardee and divisions within the same organization as the awardee.

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, 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.

H. For **other transactions**, please submit **Attachment 4**. For **cooperative agreements**, please submit **Attachment 5**.

6.8

APPENDIX | ACRONYMS

Acronym	Definition
AI	Artificial Intelligence
AWA	Animal Welfare Assurance
CA	Cooperative Agreements
EHI	Emerging Health Innovators
FAR	Federal Acquisition Regulation
GFE	Government-Furnished Equipment
GFP	Government-Furnished Property
GFI	Government-Furnished Information
GvHD	Graft Versus Host Disease
HLA	Human Leukocyte Antigen
HLA-DR	HLA-Heterodimer
IP	Intellectual Property
ISO	Innovative Solutions Opening
LECs	Lymphatic Endothelial Cells
LS	Lymphatic System
ML	Machine Learning
OCI	Organizational Conflicts of Interest
OLAW	Office of Laboratory Animal Welfare
OT	Other Transactions
PHI	Protected Health Information
PII	Personally Identifiable Information
PM	Program Manager
SBU	Sensitive But Unclassified
VAS	Vertebrate Animal Section