



INNOVATIVE SOLUTIONS OPENING

FOR

**Hearing Enhancement through ARtificially Intelligent  
NeurotechnoloGy**

**HEARING**

HEALTH SCIENCE FUTURES (HSF) OFFICE

ARPA-H-SOL-26-154

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## **INNOVATIVE SOLUTIONS OPENING (ISO) SUMMARY INFORMATION**

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

**PROGRAM TITLE:** Hearing Enhancement through ARtificially Intelligent NeurotechnoloGy (HEARING)

**ANNOUNCEMENT TYPE:** Innovative Solutions Opening (ISO)

**ISO SOLICITATION NUMBER:** ARPA-H-SOL-26-154

**ISO CONTACT:** [HEARING@arpa-h.gov](mailto:HEARING@arpa-h.gov)

**ANTICIPATED AWARDS:** Multiple Other Transaction (OTs) Agreements

**COST SHARING:** Encouraged (Optional)

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

**Proposers' Day:** Monday, June 8, 2026

**Questions & Answers (Q&A) due date:** Monday, June 15<sup>th</sup>, 2026, 5:00 PM ET

**Solution Summaries due date:** Monday, June 29, 2026, 2:00 PM ET

**Full Proposals due date:** Friday, August 14<sup>th</sup>, 2026, 2:00 PM ET

### **WHERE TO SUBMIT:**

**Proposers' Day Registration:** <https://solutions.arpa-h.gov/events>

**Solution Summaries:** <https://solutions.arpa-h.gov/Submit-Solution/>

**Proposals:** <https://solutions.arpa-h.gov/proposal>

**Questions:** <https://solutions.arpa-h.gov/Ask-A-Question/>

### **PROPOSERS' DAY**

ARPA-H will host a Proposers' Day in support of the HEARING Program as described in Special Notice ARPA-H-SN-26-154. The purpose is to provide potential proposers with information on the HEARING 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 Website. However, proposers are encouraged to attend to facilitate teaming discussions with other attendees. ARPA-H will not host additional events in-person or virtually for the HEARING program.

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

## **1. INTRODUCTION TO HEARING**

### **1.1 BACKGROUND**

Age-related hearing loss is the second most common health problem in older adults. Yet, the current solutions are inadequate for many people, and there has not been a major innovation in hearing improvement in over 40 years. Today, the primary treatments for hearing loss continue to be hearing aids and cochlear implants, which succeed at amplifying sounds in the environment, but are not selective for the listener's intent or attention in real time.

Most hearing loss, especially age-related hearing loss, is caused by degeneration of the delicate structures in the cochlea and inner ear that are responsible for converting sound waves into electrochemical signals for the brain. As these sensory cells and neural pathways deteriorate, simply making sounds louder is often not enough; the damaged pathway cannot faithfully transmit detailed sound information to the brain. Current technologies primarily work by amplifying or encoding sound at the ear and then pushing these signals up the compromised auditory pathway. While this approach can provide benefit for some, it often fails to restore natural, effortless hearing, especially in noisy environments or for those with more extensive neural degeneration. This limitation underscores the need for solutions that bypass or compensate for the damaged pathway and work directly with the brain's own auditory centers to restore meaningful hearing.

To safely access the brain's auditory centers, there is a critical need for a new class of minimally invasive, brain-connected hearing devices that can capture real-time brain signals reflecting listener intent and use these signals to guide algorithms that both interpret and help to reconstruct sound. Such devices would shift hearing care from ear-only devices to technologies that work directly with the brain's own processing, enabling a step change beyond incremental improvements in acoustic signal processing.

The HEARING platform will be the first ever, minimally invasive brain-connected hearing system that can adjust sound based on the listener's focus, reduce background noise in real time, and fill in missing sound information to restore close to normal hearing for people with mild to severe hearing loss.

### **1.2 PROGRAM OVERVIEW**

#### **1.2.1 VISION AND CHALLENGE**

The HEARING program aims to develop a new kind of hearing-assistive platform that directly engages the brain's hearing centers to improve how people hear in complex, real-world environments. Many people with hearing loss still struggle to understand speech in noisy places, even when using today's best hearing aids or implants, because current devices only repair missing pieces of sound when the ear or auditory nerve is damaged or react to sound in the environment, rather than what the listener is trying to focus on. This limits everyday communication and contributes to social isolation, depression, and cognitive decline, particularly for older adults, veterans, and workers from high-noise occupations. HEARING is designed to solve this problem by shifting hearing restoration from current care at the ear alone to a neurological condition by focusing on the auditory cortex, where the brain separates speech from noise to makes sense of what we hear.

To do this, HEARING will build a closed-loop, brain-connected system that can record (read out), neuromodulate, and stimulate (write in) information in key auditory cortical regions. The program is organized into three (3) Technical Areas (TAs) (**Figure 1**):

- **TA1 Intracortical Device(s):** Creation of minimally invasive devices that can interface with key auditory regions through recording and stimulation, without requiring surgical access through the skull, and are suitable for chronic use.
- **TA2 Dynamic Sound Modulator:** Development of an external, hearing-aid-like hub that wirelessly powers and bi-directionally communicates with the brain interface, adjusting sound in real time based on algorithmic control informed by neural signals.
- **TA3 Auditory Read & Write Algorithms:** Design and deployment of algorithms within a processing unit that decode what the listener is trying to hear to determine how to deliver or supplement sound so that speech becomes clearer, more complete and understanding speech is less strenuous. This will be accomplished either by enhancing the TA2 device with code to control audio input gain or by transmitting restorative code to stimulate the brain through the TA1 device.

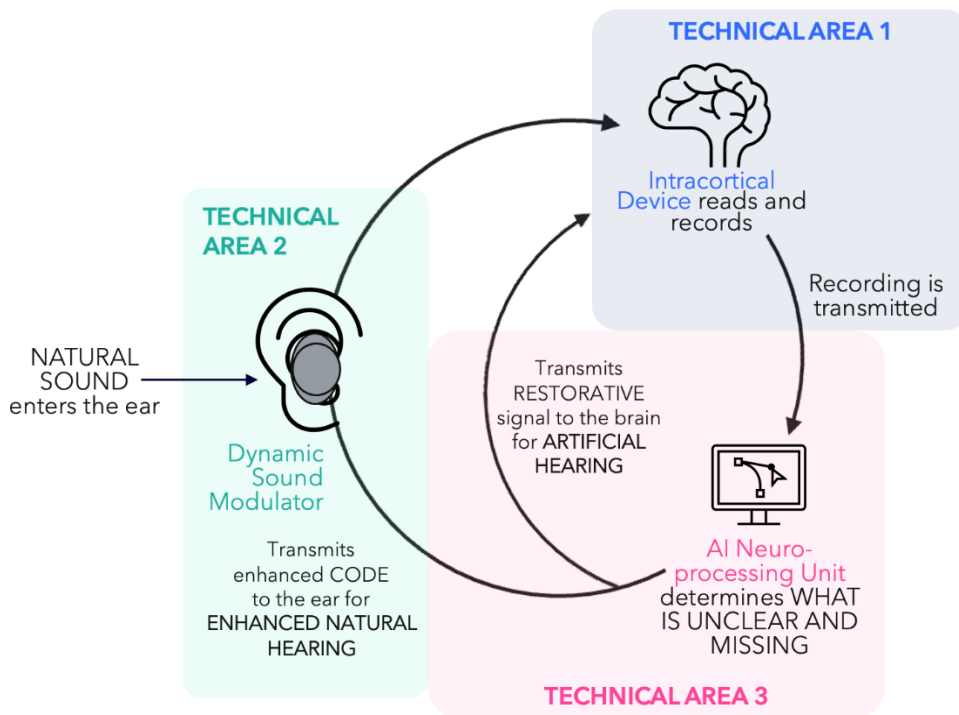


Figure 1. Mechanisms for the HEARING Platform

Together, these components are intended to adjust sound based on the listener's focus, reduce background noise in real time, and fill in missing sound information to restore hearing close to normal for people with mild to severe hearing loss.

This integrated approach is newly feasible because advances in minimally invasive brain interfaces, flexible electronics, low-power wireless communication and power transfer, real-time decoding of brain activity, and our understanding of auditory processing have matured to the point where they can be combined into practical systems rather than isolated laboratory demonstrations.

### 1.2.2 GOALS AND DEFINITION OF SUCCESS

Success for HEARING means delivering an integrated prototype that:

- In mild, moderate, and severe hearing loss patients, measurably improve speech understanding and listening comfort in realistic noisy environments.
- Restore hearing ability approaching the performance of age-matched listeners with normal hearing.
- Is positioned on a pathway for clinical translation, including alignment with regulatory, safety, usability, and manufacturability requirements.

### 1.2.3 DESIRED IMPACT

By funding HEARING, ARPA-H seeks to catalyze a shift from devices that simply make sounds louder to therapies that actively partner with the brain. The envisioned systems will reduce the effort required to follow conversations, provide benefit even when the ear or auditory nerve is severely damaged, and lay the foundation for a new class of cortical hearing therapies that improve communication, mood, and cognitive health for large populations affected by hearing loss. ARPA-H is uniquely positioned to convene multidisciplinary teams, set aggressive system-level milestones, and provide commercialization and regulatory support needed to transform a collection of promising but disconnected research efforts into a practical therapeutic option.

To meet this desired impact, proposers should adhere to the following key tenets:

- More effective than currently available therapies for speech-in-noise and related functional outcomes.
- Minimally invasive so that the relevant populations have broad access and are willing to adopt the technology.
- Sufficiently safe and durable to be used chronically, potentially for the lifetime of the patient.

By shifting the paradigm of hearing loss from an ear-only problem to one that explicitly engages the brain, HEARING will enable future technologies to address broader auditory processing conditions such as tinnitus and hyperacusis and ultimately support a more holistic approach to auditory health.

### 1.2.4 PERFORMER EXPECTATIONS

There is currently no solution that restores hearing in a fully personalized way that explicitly incorporates the brain's auditory processing centers. HEARING emphasizes engagement with end users, clinicians, and regulatory experts from the outset. To ensure the perspectives necessary to achieve program milestones and deliverables:

- Performers are required to include representative end user, clinical, and regulatory expertise as part of their teams.
- Performers must form interdisciplinary teams capable of delivering innovative, integrated solutions spanning all three (3) TAs.

The end of program deliverable is a fully integrated platform with a bidirectional brain computer interface (BCI) system that can restore a patient's hearing with bilateral mild,

moderate, and severe hearing loss demonstrated in a first-in-human (FIH) trial (see [Section 2.2](#)). The results of the FIH study should provide statistically significant and clinically meaningful improvement in one's speech-in-noise perception and reduced cognitive burden compared to baseline state-of-the-art hearing aids.

### 1.2.5 OUT-OF-SCOPE EFFORTS

The following are considered out of scope and may be deemed non-responsive to the HEARING program:

- Proposals that do not address all TAs and all program phases, or that offer only incremental advances in the state of the art for BCIs, wireless power and data transmission, or decoder/encoder algorithms.
- **Proposals that deliver the final TA1 devices for intracortical interfacing via surgical access through the cranium at the end of Phase 2 and Phase 3 (e.g., craniotomy, craniectomy, small burr holes or millimeter-scale access).**
- Solutions that are designed with batteries implanted subdurally or deeper into the brain on the final TA1 device.
- Solutions that require form factors that would be cumbersome, limit normal daily living and locomotion, or that only function in highly controlled environments. **For example, hats, helmets, headbands, and similar wearables are considered noncompliant. In contrast, form factors such as glasses, hearing aid- or external processor for cochlear implant-like devices, and armbands are considered compliant.**
- Solutions that are not supported by sufficient preliminary evidence to justify the innovation claims and feasibility within the program timeframe.

Proposers are encouraged to carefully read the detailed description of the program's requirements below in [Section 2](#) before responding to this solicitation.

## 2. THE PROGRAM

### 2.1 TECHNICAL AREAS

The HEARING program takes a new approach to hearing restoration by focusing on how sound is processed in the auditory cortex, rather than at the ear.

HEARING will build a closed-loop system that:

1. Reads activity from the auditory cortex,
2. Uses it to control sound entering the ear in real time, and
3. Writes back missing information through targeted stimulation.

To develop such a platform, HEARING will occur over three-phases in a multi-disciplinary approach. Performer efforts will be organized around three (3) tightly integrated TAs whose outputs must be combined into a single, functioning platform:

- **TA1-Intracortical Device(s):** TA1 will deliver minimally invasive neural interfaces to key auditory cortical regions, enabling HEARING technologies to be accessible to patients at scale. Approaches may leverage any technology that allows final device delivery to target the auditory cortex without requiring surgical access through the

skull (e.g., no craniotomy or craniectomy). Neural interfaces are not limited to electronic, biohybrid, ultrasound, or other specific modalities, but proposed technologies must be sufficiently mature at the time of award to meet program schedules and milestones. TA1 devices must support wireless bidirectional communication with TA2 devices. ARPA-H will assess record and stimulation, and safety in vivo performance capabilities as key end of phase deliverables.

- **TA2-Dynamic Sound Modulator:** TA2 will deliver an external wearable device that functions similarly to a hearing aid and serves as the hub between TA1 hardware and TA3 software. This device must: (1) Operate within a 16-hour total power budget under read-only conditions, (2) deliver power and support bi-directional wireless communication with TA1 devices, (3) be developed in a form factor that is not a burden to the daily living activities of the patient, and (4) interface with external devices (e.g., smartphones, clinical programming tools) to support optimization and adjustment of hearing performance. TA2 devices will be evaluated, in conjunction with TA1 devices, for sustained operational performance and safety in vivo as end-of-phase deliverables.
- **TA3 Auditory Read & Write Algorithms:** TA3 will deliver the first auditory BCI algorithms capable of both reading from and writing to the auditory cortex while controlling audio signals amplified through the ear (TA2). Algorithms are expected to: (1) Personalize to individual users by leveraging sensory-neural profiles to determine how auditory information should be controlled in the TA2 device, (2) drive neuromodulation at key auditory regions and/or write in missing frequencies via TA1 devices at the auditory cortex, and (3) balance trade-offs among latency, decision-window length, decoding accuracy, model personalization time, and re-calibration frequency.
  - Performers that collect data from neurosurgical populations (e.g., intracranial recording) and/or individuals with hearing loss (e.g., EEG or functional magnetic resonance imaging (fMRI)) are required to obtain Institutional Review Board (IRB) protocol approval following the time of award and justify data harmonization plans that align collected data to TA1 devices. TA3 is expected to drive both software behavior and clinical decision-making in assessing and demonstrating functional hearing recovery at the end of each phase.
  - Software for real-time decoding/encoding is not required to be processed on the TA2 device (e.g., cloud computing via smart phone). However, the required metrics for latency still must be addressed and justified.

All proposals must address all three (3) TAs (TA1-3) across the program. TA1 and TA2 technologies may be combined into a single hardware platform if that better fits the proposed solution, provided all functional requirements can be met. Given the integration challenges inherent in HEARING, the program is best suited for teams that can address the full system to avoid development of orphaned technologies that are not compatible with a complete platform. Interim technologies in development do not need to be wireless or delivered minimally invasively, except to meet end-of-phase requirements (see [Section 2.2](#)).

Where appropriate, proposers are encouraged to identify components (e.g., interfaces, data formats, benchmarking tools, or non-core software utilities) that could be made available to other performers under open or permissive licenses to facilitate interoperability and broader

impact, while preserving commercially valuable intellectual property (IP). Proposers are encouraged to outline plans for responsible data sharing and interoperability (e.g., contribution to common data standards or shared reference datasets) consistent with privacy, regulatory, and contractual requirements.

### TA1 Intracortical Device(s)

This sub-section outlines the broad scope of the TA1 objectives. Development of the TA1 device will require coordinated integration with TA2 wireless power and communication specifications and with TA3 requirements for precise targeting of specific auditory cortical regions to restore one's hearing. A successful proposal should consider each of the following, and include strategies and information to achieve each goal:

- Delivery approach and target auditory regions:
  - Describe the minimally invasive delivery approach (e.g., endovascular, sub-galeal, transnasal, etc.) for the intracortical device(s) in relevant animal models and human use including pre-operative planning, intra-procedural guidance, and post-procedural verification to ensure accurate placement and coverage of cortical regions.
  - Specify target locations within the auditory cortex (e.g., Heschl's gyrus, superior temporal gyrus, planar temporale, etc.) and justify their relevance to hearing restoration, including the level of spatial and temporal resolution to the approach.
- Device design, operation parameters, and interfaces:
  - Specify device form factor(s), size, and configuration and how this supports minimally invasive delivery and fit within anatomical constraints.
  - Read-out (recording) capabilities and data outputs:
    - Describe how the device will sense or record activity from target regions of the auditory cortex, as appropriate to the chosen modality.
    - Summarize key performance characteristics and explain how noise and artifacts will be managed.
    - Define types of data collected under TA1 to support algorithm development, personalization and drift correction in TA3.
    - Validate newly developed technology against state-of-the-art methods (e.g., intracortical electrodes, scalp EEG, electrocorticography (ECoG) or comparable). Proposers must define quantitative metrics and validation methods to demonstrate reliability and fidelity of the new recording technology (e.g., correlation). Proposers must justify their chosen metrics and thresholds, and provide a rationale for how their approach establishes equivalence or improvement over existing methods (see [Section 2.3](#))
      - For technologies that will not leverage electrophysiological outputs, teams must identify and justify state of the art technologies for validation of recording/stimulation output.
  - Write-in (stimulation) capabilities:
    - Describe how stimulation and/or modulation will be delivered to targeted regions of the auditory cortex.
    - Define and justify quantitative metrics for stimulation accuracy and specificity, (e.g., behavioral response rates or comparable) to verify that stimulation reliably evokes intended auditory percepts and behaviors in

animal models. Validation should include comparison to state-of-the-art methods (see [Section 2.3](#)).

- Power budget, communication, and latency:
  - Describe the overall power budget and communication strategy for the TA1 device(s), including mechanism for power supplied from TA2, how data will be exchanged reliably, and plan for thermal management (see [Section 2.3](#)) and timing requirements to support real-time operation with TA2 and TA3.
- Biocompatibility, safety, and stability for chronic implantation:
  - Outline a plan to validate the performance of the TA1 device(s) *in vivo* including in small and/or large animal models as relevant.
  - Describe how you will ensure longevity (see [Section 2.3](#)) safety and stability of the implant, including material biocompatibility, monitoring and mitigation of tissue/device changes over time, and built-in safety features within the device and clinical procedures in case of device malfunction.
- Manufacturing and scaling for FIH trials:
  - Summarize how fabrication and assembly plans for the intracortical device(s) from prototype through pilot scale, will be developed. Include identification of potential facilities/partners and describe how standardization and reproducibility for FIH studies will be ensured during the program.
- End of Phase Demonstrations:
  - Proposals should include detailed strategies for demonstrating system capabilities in small and large animals, and humans (see [Section 2.3](#)).
- Integration and Management:
  - Identify the integration lead responsible for TA1 sub-component integration and coordination with TA2 and TA3.
  - Discuss anticipated obstacles that could require a revision in the scope of work or milestones and propose alternative approaches.
  - A detailed schedule or timeline for each milestone, deliverable, and the overall goal (see [Section 2.3](#)).

TA1 program metrics and timeline are outlined in Tables 1, 2 and 4 of [Section 2.3](#), and will increase in difficulty and complexity over the course of the HEARING program. Proposers must align technical requirements with program metrics and timeline for full consideration. Proposers are encouraged to include additional metrics and key milestones as relevant to their respective solution.

### TA2 Dynamic Sound Modulator

This sub-section outlines the broad scope of the TA2 objectives. TA2 serves as the central hub between TA1 and TA3 and is critical to the success of HEARING. A successful proposal should consider each of the following, and include strategies and information to achieve each goal:

- Overall device role, form factor, and usability:
  - Describe how the TA2 device functions as the primary interface between the user, TA1 device(s), and TA3 algorithms, including operation in real-world environments and support functional hearing restoration metrics (see [Section 2.3](#)).
  - Specify the intended form factor(s) and justify why these are compatible with long-term daily use for the relevant hearing-loss populations, not limited to details such as size and weight.

- Outline user interface capabilities and strategies for engaging end-user feedback.
- Audio pathway and closed-loop performance:
  - Describe how environmental sounds (i.e. speech, wind, traffic, music, etc.) will be captured, processed, and delivered to the ear, highlighting the main components and processing steps of this audio pathway.
  - Explain the key performance goals for this pathway and how it will support closed-loop interaction with TA1 and TA3.
- Power, Communication, and TA1 Coupling:
  - Provide an overall power budget for TA2, including different operating modes, and how the final system will achieve  $\geq 16$  hours of continuous operation under read-only conditions, as well as the expected operating time under read-and-stimulate conditions.
  - Describe the power source, capacity, charging method, and include strategies for safe and reliable daily use for at least one year (see [Section 2.3](#)).
  - Specify wireless communication modalities between TA2 and TA1, and between TA3 and external devices, including expected data rates, robustness to interference, security, and data formats or protocols that support interoperability and firmware updates.
  - Explain how TA2 will deliver power wirelessly to TA1 devices, including the basic mechanism, expected efficiency, and alignment tolerances.
- Compute Architecture and External Interfaces:
  - Describe the architecture that will be required for signal processing, including which elements of TA3 decoding/encoding will operate on the TA2 device and/or off-device, and justify how closed-loop timing requirements and power constraints will be satisfied.
  - Detail capabilities and validation plan for external device interfacing such as setup and personalization for users and clinicians, and which parameters will be adjusted versus locked.
- Safety, Security and Reliability for Real-World Robustness:
  - Identify key safety and security considerations and features for various scenarios, including scenarios such as hardware malfunction, loss of communication between TA1 and/or TA3, potential hacking or cybersecurity breaches. Describe how the system will fail safely in each scenario.
  - Plan to manage thermal fluctuations and ensure comfortable and safe temperature during use (see [Section 2.3](#)).
  - Highlight strategies for reliability and durability during daily life usage and methods to validate robustness.
- Manufacturing and scaling for FIH Trials:
  - Summarize fabrication and assembly plans for the wearable device from, prototype through pilot scale, will be developed. Include identification of potential facilities/partners and describe how standardization and reproducibility will be ensured for FIH studies.
- End of Phase Demonstrations:
  - Proposals should include detailed strategies for demonstrating devices in small and large animals, and humans (see [Section 2.3](#)).
- Clinical protocols:

- Describe the proposed clinical protocols and end-user usability evaluations for device application during Phase 3 FIH Trials (see [Section 2.3](#)).
- Integration and Management:
  - Identify the integration lead responsible for TA2 sub-component integration and coordination with TA1 and TA3.
  - Discuss anticipated obstacles that could require a revision in the scope of work or milestones and propose alternative approaches.
  - A detailed schedule or timeline for each milestone, deliverable, and the overall goal (see [Section 2.3](#)).

TA2 metrics and timeline are outlined in Tables 1, 2 and 4 of [Section 2.3](#), and will increase in difficulty and complexity over the course of the HEARING program. Proposers must align TA2 proposal elements with the program metrics and schedule for full consideration. Proposers are encouraged to include additional metrics and key milestones as relevant to their respective solution.

### TA3 Auditory Read & Write Algorithms

This sub-section outlines the broad scope of the TA3 objectives. TA3 responsibilities include the development of real-time decoder/encoder software of auditory signals, clinical expertise in neurology and audiology, and will facilitate patient engagement. TA3 will require integration with TA1 and TA2 hardware requirements relevant to controlling the physiology of auditory processing in Phase 3. A successful proposal should consider each of the following, and include strategies and information to achieve each goal:

- Overall device role and system context:
  - Describe how TA3 will function as the “controller” for the HEARING system, linking signals received from TA1 and TA2 for closed-loop action to restore one’s hearing.
  - Explain how TA3’s algorithms and clinical workflows will support program metrics for functional hearing restoration across all phases (see [Section 2.3](#)).
- Data strategy and model development:
  - Describe and justify the types, sources, and size of data that will be used to develop and train TA3 algorithms, including plans for Institutional Review Board (IRB) protocol approval to conduct human research where applicable.
  - Provide a data collection and quality-control plan adequate to train and validate models.
  - Explain how data from different sources and TA1 hardware configurations will be aligned and harmonized to support model development, comparison across users and sites, and longitudinal analysis, as relevant.
  - Outline approaches for building, training, validating, and updating models over time. Include a plan to achieve personalization including personalization training time of  $\leq 30$  minutes, and strategy to meet proposer set goals for model drift and recalibration by the end of Phase 3 (see [Section 2.3](#)).
  - Describe how TA3 will manage data security, privacy, consent, and how common data formats/standards or shared tools will be implemented, as appropriate.
- Algorithmic strategies for read and write:
  - Auditory reading algorithm capability:
    - Describe how TA3 will interpret signals from target regions of the auditory cortex and/or related neural or physiological signals to estimate

- user intent, listening state, or other relevant features of auditory perception.
      - Specify key performance goals and how these will be measured and reported.
    - Auditory intent algorithm capability:
      - Describe how TA3 will control TA2 device auditory processing and delivery to the ear to improve speech-in-noise perception and listener intent.
      - Define initial safety and efficacy criteria for modulating auditory input.
    - Auditory writing algorithm capability:
      - Describe how TA3 will control TA1 delivery of targeted stimulation or modulation that restores or enhances auditory perception at target cortical regions.
      - Explain how stimulation and encoding strategies will be personalized to an individual's sensory-neural profile, including how targets, patterns, and intensities will be selected and adapted.
      - Define initial safety and efficacy criteria for stimulation paradigms and how these will be refined through clinical testing.
  - Closed-loop control:
    - Describe the closed-loop control architecture and framework that links TA1 and TA2 devices with algorithmic processing and output, including information used as feedback.
    - Explain how TA3 will balance key trade-offs such as latency, decision-window lengths, decoding accuracy, stimulation timing, and performance specifications that align with real-world use.
    - Describe safety mechanisms in the software strategy and how they will integrate with TA1 and TA2 safety features.
    - Outline plans for software verification and validation before use in Phase 3 studies.
  - Clinical protocols, evaluation, and outcome measures:
    - Describe the proposed clinical and behavioral testing protocols that will be used to evaluate TA3 performance during Phases 1-3 for audibility, lab-assessments for speech-in-noise (SIN) perception, and real-world world assessments for SIN perception (see [Section 2.3](#)).
      - Example gold-standard assessments include but are not limited to: audiogram, real ear measurements, Quick speech-in-noise (QuickSIN), words in noise (WIN), and coordinate response measure (CRM). Proposers must identify which tests will be used for assessing functional hearing assessments of auditory perception and justify any adaptations that will be made to meet the requirements of the HEARING Program.
    - Explain how TA3 will work with clinical teams for surgical protocols, rehabilitation, and technology training to interpret study protocols over the course of the program. In addition, explain how technology training will be provided to both clinicians and patients to ensure effective use and understanding of the technology developed in the program.
  - End of Phase Demonstrations:
    - Proposals should include detailed strategies for demonstrating software capabilities in human populations, as relevant to each phase (see [Section 2.3](#)).

- Integration and management:
  - Identify the TA3 lead responsible for coordinating algorithm development, data collection, and clinical activities, and for integration with TA1 and TA2 teams.
  - Describe strategies for iterative integration and testing with TA1 and TA2, and key milestones for system-level demonstrations.
  - Discuss anticipated technical, clinical, and regulatory risks and propose mitigation strategies.
  - Provide a schedule or timeline for TA3 milestones and deliverables and explain how these align with overall HEARING program metrics and Phase 1-3 deliverables (see [Section 2.3](#)).

TA3 metrics and timeline are outlined in Tables 1, 3 and 4 of [Section 2.3](#), and will increase in difficulty and complexity over the course of the HEARING program. Proposers must align TA3 proposal elements with the program metrics and schedule for full consideration. Proposers are encouraged to include additional metrics and key milestones as relevant to their respective solution.

### **Regulatory Requirements**

The HEARING program is intended to end with a completed FIH trial for mild, moderate, and severe hearing loss populations demonstrating the benefit of developed technologies. Regulatory milestones will be considered key deliverables to inform the government's decision to continue work into subsequent Phases after Phase 1, for all technologies developed as relevant. Proposals should lay out clear and concise regulatory plans for engagement with the U.S. Food and Drug Administration (FDA), not limited to details including proposed product classification, regulatory pathway, timeline to meet key regulatory milestones within each phase, security measures, locked prototype(s), and meeting frequency. The HEARING program is open to the integration of technologies and sub-components that have been previously approved for clinical use by the FDA.

## **2.2 PROGRAM STRUCTURE**

The HEARING program is structured as a 4.5-year effort consisting of three (3) phases, as shown in **Figure 2**. HEARING Phase 1 (18 months) includes realistic and measurable goals for performers to ensure the success of the program, including checkpoints at the transition between phases (see [Section 2.3](#)). To progress to HEARING Phase 3 (FIH studies), performers must obtain relevant IND/IDE approvals or equivalent documentation from the U.S. Food and Drug Administration (FDA).



possible, performers conducting pre-clinical studies to meet regulatory requirements are encouraged to leverage the same or similar animal populations.

Where appropriate and with all necessary regulatory approvals and IRB-protocol approvals in place, TA1 and TA2 performers may also conduct limited human feasibility studies during Phase 2 to further de-risk their technologies prior to FIH trials. TA3 performers may continue to collect only the data necessary to advance algorithm development and are expected to begin formal validation of their algorithms, including implementation of data harmonization plans with TA1 and TA2 devices.

Throughout Phase 2, TAs 1-3 will begin systematic integration of their systems and test them according to their proposed strategies. Before the end of Phase 2, it is expected that performers will initiate clinical trial patient recruitment and obtain informed consent in preparation for Phase 3.

**2.2.3 PHASE 3: CLINICAL, 12 MONTHS**

Performers will fully integrate TAs 1-3 to conduct FIH studies in a total of six (6) patients with mild, moderate, and severe hearing loss. Performing teams will work together to harmonize TA1 and TA2 outputs with TA3 read/write algorithms and to ensure the safe delivery and operation of cortical devices. Success will be measured based on the ability to restore hearing in alignment with the Phase 3 metrics, including user satisfaction (see [Section 2.3](#)).

**2.3 METRICS**

To evaluate the effectiveness of a proposed solution in achieving the stated program objectives, the following program metrics will serve as the basis for determination of satisfactory progress to warrant program continuation. Although the program metrics are specified below, proposers should note that the Government has identified these goals with the intention of bounding the scope of effort while affording maximum flexibility, creativity, and innovation or proposed solutions to the goals. Proposals should cite the quantitative and qualitative success criteria that the effort will achieve at each phase’s program 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.

**Metrics and Deliverables**

**Table 1. Overall Program Metrics and Deliverables**

Overall Program Metrics and Deliverables	
<b>HEARING Restorative System</b>	Development of (1) <b>≥1 device(s) capable of being delivered to the auditory cortex</b> through minimally invasive procedures with recording and stimulation functionalities; and (2) <b>≥1 wearable, dynamic sound modulator</b> with wireless power and data transmission to enable closed-loop system functionality.
<b>Neuroprocessing Algorithm</b>	Integrate a neuroprocessing algorithm capable of <b>personalization to new patients in ≤30 minutes</b> , interpreting neural signals from the auditory cortex to

	dynamically control the sound modulator in real time and deliver signals for precise stimulation for hearing restoration.
<b>First-in-human (FIH) studies of HEARING device in hearing loss populations</b>	Demonstrate closed-loop system efficacy in restoring hearing function across the outcomes below in <b>≥6 patients with mild, moderate, and severe hearing loss</b> , compared to unaided hearing and patients' current hearing assistive device.
<b>Speech-in-quiet</b>	Demonstrate restored audibility, validated by <b>≥2 gold-standard assessments</b> (e.g., audiogram, real-ear measurements, or comparable).
<b>Speech-in-noise</b>	Demonstrate significant improvement in <b>≥2 measurable speech-in-noise outcomes</b> (e.g., SNR, intelligibility, or equivalent) using <b>≥4 relevant assessments</b> (e.g., QuickSIN, WIN, HINT, CRM, or comparable).
<b>Real-world user-feedback</b>	Demonstrate significant improvement in patients' ability to hear speech in real-world environments, validated by <b>≥2 assessments</b> (e.g., rHHI, APHAB, SSQ, or comparable).

**Definitions:** QuickSIN: quick speech in noise; WIN: words in noise; HINT: hearing in noise test; CRM: coordinate response measure; rHHI: revised hearing handicap inventory; APHAB: abbreviated profile of hearing aid benefit; SSQ: speech, spatial and qualities of hearing scale; SNR: signal-to-noise ratio

**Table 2. TA1 & TA2 Phase 1-2 Metrics and Deliverables**

The expected metrics of HEARING TA1 & 2 Phases 1-2 are listed below.

<b>TA1 &amp; 2 Phase 1 Metrics and Deliverables</b>	
<b>Prototype Development</b>	Produce <b>≥1</b> prototypes for (1) External processing and communication device, (2) brain computer interface(s).
<b>Proof-of-concept Demonstration</b>	Demonstrate capabilities below <i>in vivo</i> using six small or large animal models.
<b>Auditory Behavioral Task</b>	Design and implement a behavioral task in animal models to demonstrate hardware capabilities to record and interpret auditory signals and evoke percepts <i>via</i> stimulation. Proposers must also establish and justify quantitative metrics that will verify the accuracy and specificity of the evoked percepts, ensuring that these percepts reliably result in the intended behavior (see <a href="#">Section 2.1</a> TA1 for additional details).
<b>Spatial Resolution</b>	Ability to record and stimulate with effective spatial resolution of $\leq 1 \text{ mm}^3$ per addressable volume at the level of neural tissue.
<b>Sampling Rate</b>	Proposer set target for sampling rate to record relevant neural signals that will inform TA2 and TA3 technologies. Performer must meet <b>≥75% target</b> by the end of Phase 1.
<b>Accuracy</b>	Validate newly developed technology for the HEARING program against state-of-the-art methods for recording and stimulation capabilities (e.g., scalp EEG, ECoG, or

	comparable). Define quantitative metrics and thresholds that will provide evidence for the demonstration of equivalence or improvement over the state-of-the-art (see <a href="#">Section 2.1</a> TA1 for additional details).
<b>Powering</b>	Demonstrate continuous operation for recording only, on a single charge for <b>≥8 hours</b> on a single charge.
<b>Latency</b>	The system must demonstrate <b>≤10 ms</b> unidirectional latency for both recording (neural event to signal availability) and stimulation (command issuance to stimulus delivery), measured under standard operating conditions.
<b>Longevity</b>	Maintain device performance and stability for <b>≥3 months</b> .
<b>Delivery procedure</b>	Demonstrate <b>≥1 surgical delivery procedures</b> to implant a mock-prototype device to a target cortical region in small or large animals and assess relevant safety metrics as proposed. <i>Note: Only the form-factor of the prototype(s) and other relevant components need to be demonstrated, a fully integrated device is not required.</i>
<b>Regulatory Engagement</b>	Submit evidence of US FDA partner engagement, including relevant contacts/offices, and revised regulatory plans and milestones.
<b>TA1 &amp; 2 Phase 2 Program Metrics and Deliverables</b>	
<b>Regulatory Approval</b>	IND/IDE approved device(s) for (1) in ear listening device, (2) external to ear wireless powering and data transmission wearable, and (3) minimally invasive brain computer interface(s).
<b>Functional Performance for Closed-Loop Capabilities in Large Animal Models</b>	Using six large animal models (e.g., sheep, bovine, non-human primate models, etc.), demonstrate closed loop capabilities of the technology developed in the program below.
<b>Auditory Behavioral Task</b>	Design and implement a behavioral task in animal models to demonstrate closed-loop capabilities to record and interpret auditory signals and evoke percepts <i>via</i> stimulation. Proposers must also establish and justify quantitative metrics that will verify the accuracy and specificity of the evoked percepts, ensuring that these percepts reliably result in the intended behavior.
<b>Sampling Rate</b>	Performer must meet <b>≥95% target</b> rate by end of Phase 2.
<b>Powering</b>	Demonstrate continuous operation for record only, on a single charge for <b>≥16 hours</b> .  Closed-loop continuous operation for read and write should be demonstrated for <b>≥4 hours</b> on a single charge.
<b>Latency</b>	The closed-loop system should operate <b>≤50 ms</b> from signal recording to response.

<b>Longevity</b>	Maintain performance and safety for <b>≥6 months</b> .
<b>Delivery procedure</b>	Demonstrate <b>delivery protocol(s)</b> to implant fully integrated TA1 and TA2 device(s) to target cortical regions.
<b>Safety</b>	Proposer set metrics and validation to demonstrate safety, must include thermal safety <b>≤1°C</b> rise in tissue being recorded or stimulated.

**Table 3. TA3 Phase 1-2 Metrics and Deliverables**

The expected metrics for HEARING TA3 Phases 1-2 are below.

<b>TA 3 Phase 1 Metrics and Deliverables</b>	
<b>Software proof-of-concept performance using human data</b>	Performers will demonstrate software capabilities below using human data for read and write, as relevant. At minimum, data should be collected based on intracranial recordings (e.g., neurosurgery patient populations).
<b>Personalization training time</b>	Data collection to personalizing algorithms to new users should require <b>≤1.5 hours</b> of training data.
<b>Model drift</b>	Proposer set target and metrics to monitor drift and re-calibration frequency. By the end of Phase 1, performers should achieve <b>≥90% of target</b> .
<b>Neuroprocessing algorithm functionality in neurosurgical patient population</b>	Assess algorithm functionality to improve hearing function across the outcomes below in <b>≥6 neurosurgical patients</b> or comparable, compared to unaided baseline.
<b>Speech-in-quiet</b>	Demonstrate patient audibility using <b>≥2 gold-assessments</b> (e.g., audiogram, real-ear measurements, or equivalent).
<b>Speech-in-noise</b>	Demonstrate improvement in <b>≥2 measurable speech-in-noise outcomes</b> (e.g., SNR, intelligibility, or comparable) using <b>≥2 relevant assessments</b> .
<b>TA3 Phase 2 Metrics and Deliverables</b>	
<b>Software validation performance using human data</b>	Performers will validate software capabilities below using human data for read and write, as relevant.
<b>Personalization training time</b>	Data collection to personalizing algorithms to new users should require <b>≤1 hour</b> of training data.
<b>Model drift</b>	Proposer set target and metrics to monitor drift and re-calibration frequency. By the end of Phase 2, performers should achieve <b>≥75% of target</b> .
<b>Closed-loop neuroprocessing algorithm capabilities in neurosurgical patient population</b>	Verify closed-loop system efficacy to improve hearing function across the outcomes below in <b>≥6 neurosurgical patients</b> or comparable, compared to unaided baseline.
<b>Speech-in-quiet</b>	Demonstrate patient audibility using <b>≥2 gold-standard assessments</b> (e.g., audiogram, real-ear measurements, or

	comparable).
<b>Speech-in-noise</b>	Demonstrate improvement in <b>≥2 measurable speech-in-noise outcomes</b> (e.g., SNR, intelligibility, or comparable) using <b>≥2 relevant assessments</b> .

**Table 4. TA 1-3 Phase 3 Metrics and Deliverables**

The expected metrics for HEARING TAs 1-3 Phase 3 are below.

<b>TA1-3 Phase 3 Metrics and Deliverables</b>	
<b>First-in-human (FIH) studies of HEARING device in hearing loss populations.</b>	Demonstrate closed-loop system efficacy to restore hearing function across the outcomes below in <b>≥6</b> patients with mild, moderate, and severe hearing loss, compared to unaided and standard hearing aids.
<b>Speech-in-quiet</b>	Demonstrate restored audibility, validated by <b>≥2 gold-standard assessments</b> (e.g., audiogram, real-ear measurements, or comparable).
<b>Speech-in-noise</b>	Demonstrate significant improvement in improvement in <b>≥2 measurable speech-in-noise outcomes</b> (e.g., SNR, intelligibility, or comparable) using <b>≥4 relevant assessments</b>
<b>Real-world user-feedback</b>	Demonstrate significant improvement in patients' ability to hear speech in real-world environments, validated by <b>≥2 relevant assessments</b> (e.g., rHHI, APHAB, SSQ, or comparable).
<b>Hardware performance in FIH studies</b>	Demonstrate the hardware capabilities below during the FIH studies.
<b>Power</b>	Proposer set target in <b>hours</b> for continuous closed-loop operation of record and stimulate.
<b>Longevity</b>	Maintain device performance and stability for <b>≥1 year</b> .
<b>Delivery procedure</b>	Deliver device(s) in <b>single procedure</b> to target auditory cortical regions (e.g., Heschl's gyrus, superior temporal gyrus, planar temporale, etc.)
<b>Software performance in FIH studies</b>	Demonstrate the software capabilities below during the FIH studies.
<b>Personalization training time</b>	Data collection to personalizing algorithms to new users should require <b>≤30 minutes</b> of training data.
<b>Model drift</b>	Proposer set target and metrics to monitor drift and re-calibration frequency. By the end of Phase 3, performers should achieve <b>≥100% of target</b> .

## 2.4 GENERAL REQUIREMENTS

### Project System Integration Lead

Due to the complexity and performance objectives of the HEARING platform, proposals must identify a lead program integrator with a proven track record of managing and integrating

disparate technologies. Starting as early as Phase 1, system integration should be a consideration throughout the program.

### **Clinical Expertise**

The goal of the HEARING platform is to generalize enough to enable personalization for new patients and prove more beneficial than the current state of the art. Hearing loss varies patient-to-patient, requiring a comprehensive clinical understanding of the different severities and types. Proposals must identify the relevant expertise that will enable solutions that address the different varieties of hearing loss, patient engagement, clinical perspectives towards design and implementation, and relevant auditory assessments.

### **Proposing Teams**

Proposals are expected to involve teams with **the expertise needed to collectively achieve** the goals across all TAs. Specific content, communications, networking, and team formation are the sole responsibility of the proposer. Proposers must submit a single- integrated proposal led by a Principal Investigator (PI), under a single prime awardee that addresses all program phases and TAs. Proposers may submit a maximum of (1) proposal as the prime proposer, and two (2) proposals as a sub proposer. Multiple awards are within scope of the HEARING program, but funding will not be duplicitous for the same subset of work.

Proposers are encouraged to attend the ARPA-H [Proposers' Day](#) to facilitate the formation of proposer teams and enable sharing of information among interested proposers.

### **Monthly Status Reports (MSRs) and Performer Meetings**

Monthly technical and financial status reports will be required and discussed with the ARPA-H Program Manager Team at monthly meetings. ARPA-H may request performer data as deemed necessary throughout the program to validate progress toward achieving the program goals. ARPA-H will host two HEARING program meetings per program year to disseminate learnings, technological advances, and clinical practices amongst all awardees.

### **Cost Sharing (Optional)**

Stakeholders who may support resource sharing in the future are encouraged to communicate what technical milestones must be met to unlock matching resources in kind. Appropriate cost sharing mechanisms may include matching funds, direct labor offset (e.g., hours and/or fully burdened rates), and in-kind contributions (e.g., equipment, materials). Cost share may be contributed by nonfederal or Federal sources; however, only contributions that are directly relevant to the goals and objectives of the HEARING program should be proposed.

## **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.

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 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 [HEARING@arpa-h.gov](mailto:HEARING@arpa-h.gov).
- If a potential prime performer believes an FFRDC has a unique capability without which their solution is unachievable, they may provide documentation as part of their Solution Summary submission demonstrating they have exhausted all other options. ARPA-H will consider the documentation to determine if inclusion of the FFRDC is necessary for the Solution.

### **3.1.2 CURRENT PROFESSIONAL SUPPORT**

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

### **3.1.3 NON-U.S. ENTITIES**

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

## **3.2 SYSTEM FOR AWARD MANAGEMENT (SAM)**

All proposers must have an active registration in [SAM.gov](https://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.

## **4 SUBMISSION PROCESS**

### **4.1 SUBMISSION PROCESS OVERVIEW**

Submissions for HEARING are as follows:

- ✓ **Step 1:** Submit Solution Summary (Proposers are encouraged / discouraged to move to Step 2).
- ✓ **Step 2:** Submit Full Proposals (Proposers may submit full proposals, only if a solution summary has been submitted in Step 1).

### **4.2 SOLUTION SUMMARY SUBMISSIONS**

Solution Summary submissions are required and are due by the date listed in the ISO Summary Information Section on page 4. See Appendix A for the required Solution Summary format.

### **4.3 FULL PROPOSAL SUBMISSIONS**

Full proposal submissions are due by the date listed in the ISO Summary Information Section on page 5. See Appendix B for the required Full Proposal format.

Appendix F: Administrative & National Policy Requirements Document Template OTs is required to be submitted.

### **4.4 SUBMISSION INFORMATION**

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

Proposers are responsible for submitting all written submissions via the ARPA-H Solution Submission Portal and ensuring receipt by the date and time specified in the ISO. No other method of submission is permitted.

Registration is required to submit via the ARPA-H Solution Submission Portal and registration may take several business days to process. Plan to register well in advance of the solution summary submission deadline as late submissions resulting from delays with registration may not be accepted or considered.

### **4.5 PROPRIETARY INFORMATION**

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

**NOTE:** "Confidential" is a classification marking used to control the dissemination of U.S.

Government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

ARPA-H is responsible for handling submissions in accordance with applicable federal law, including the Freedom of Information Act (FOIA).

## **5 SUBMISSION REVIEW AND EVALUATION PROCESSES**

### **5.1 CONFORMING SUBMISSIONS**

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 does not meet one or more of the following solicitation requirements:

- The proposed concept responds to the metrics of the HEARING 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 (see [Section 4.4](#)).
- 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).

ARPA-H may eliminate non-conforming proposals without further review or consideration. ARPA-H also reserves the right to reject proposals as nonconforming when it determines a previous submission was scientifically meritorious but was not reviewed due to lack of relevance to the ISO or not selected for award due to programmatic fit. Proposers will be notified of non-conforming determinations via email correspondence.

### **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. Although potential proposers may submit a proposal regardless of the feedback provided in response to a solution summary, 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 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 technical and administrative points of contact included in the solutions tool.

## **5.4 EVALUATION CRITERIA FOR PROPOSALS**

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

### **5.4.1 CRITERIA 1: OVERALL SCIENTIFIC AND TECHNICAL MERIT**

The proposed technical approach is innovative, feasible, complete, and supported by preliminary evidence. 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 can be expected as a result of the award. The proposal identifies major technical risks 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 prior experience in similar efforts clearly demonstrates an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule; the proposed team has the expertise to manage the cost and schedule and; similar efforts completed/ongoing by the proposer in this area are fully described, including identification of other Government entities (see [Section 3.1.1](#)).

In terms of capability, the Government shall assess the Appendix C bio-sketches provided for the performer team members including the Principal Investigator, Project Manager, ~~the Discovery Duo team (Early Investigator and Patient/Parent/Caregiver Ambassador); Regulatory expert (PDL), Commercialization Experts~~, and any other key personnel on the project team as requested by ARPA-H (see [Section 2](#)).

### **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. Further, the proposed solution contemplates the end user and reflects an understanding of the direct needs and benefits for stakeholders, whether they are patients, providers, health systems or payers. For example, how would this solution fit inside the clinical workflow? Or how will this be accessible to users in all geographies, and at an affordable cost?

### **5.4.4 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). 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 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. For efforts with a likelihood of commercial application, appropriate resource sharing may be a positive factor in the evaluation.

NOTE: Proposers are encouraged to propose the best technical solution. For example, proposers are discouraged from proposing low-risk ideas with minimum uncertainty or to staff the proposed effort with junior personnel to be more appealing from a budget perspective. ARPA-H seeks novel solutions that are reflective of the level of effort and risk proposed.

## **5.5 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-FERERAL 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 Government may reject the proposal and withdraw it from consideration for award if it determines the proposer failed to:

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

#### **6.2.1 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.

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

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

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

### **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 HUMAN SUBJECTS RESEARCH**

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.]

## **6.5 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) 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 as described in the Appendix F - Administrative & National Policy Document.

## **6.6 ELECTRONIC INVOICING AND PAYMENTS**

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

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

The payment is justified for the [fill in program name] program to [include the purpose of the project] for Milestones (s) (or TDD tasks/references) [x.x] that were accepted by the Program Manager on [date].

## **6.7 SOFTWARE COMPONENT STANDARDS**

The health- and healthcare data eco-system is complex and multi-dimensional with a variety of standards for data models, data transmission protocols, data routing methods, etc. that are similar to and extend the International Standards Organization (ISO) Open Systems Interconnection Model (OSI). ARPA-H programs are likely to involve research that touches on multiple layers of the OSI model, from low-level radio frequency (RF) based protocols for transmission of data from implantable devices (potentially OSI layers 1-5), to secure and fault tolerant networking protocols for medical devices (potentially OSI layers 3-6), to the exchange of health information including Electronic Health Records, lab results, and medical images related to a patient between healthcare facilities and health data brokers, including (but not limited to) Health Information Exchanges (HIE) and Trusted Exchange Framework and Common Agreement (TEFCA) Qualified Health Information Networks using protocols such as HL7 FHIR (Fast Healthcare Interoperability Resources, OSI Layer 7). This diversity requires careful consideration of the most appropriate standards to be used for the specific technologies in development and the layer at which they operate.

ARPA-H is committed to advancing interoperability in today's health ecosystem through the adoption of open, consensus-driven standards and laying the foundation for emerging technologies to interoperate in the health ecosystem of the future through the evolution of these standards across all layers of the health data information technology (IT) eco-system. With that in mind, we anticipate that the Performer will develop software and data communication components that fall into three categories:

- (1) components that can leverage today's existing standards without impeding the R&D,
- (2) components where extensions to existing standards will be necessary to unlock new capabilities in an interoperable way, and
- (3) components in areas where consensus-based standards do not yet exist or where use of standards would seriously limit the ability to efficiently conduct R&D.

Whenever such an existing standard is available that meets the scientific, technical, and research needs of the proposed effort, proposers must use the existing standard instead of creating their own. In cases where an existing standard provides only partial functionality, proposers should expand upon the existing standard, ideally in a way that does not prohibit or interfere with backward compatibility, and create sufficient documentation for the Office of the National Coordinator for Health Information Technology (ONC), and the U.S. Department of Health and Human Services (HHS) agencies or standards organizations, to evaluate extensions for potential inclusion in the standard (including open Application Programming Interfaces (APIs) and open data formats).

In the case of information relating to health- and healthcare data at higher layers of the OSI model, all health IT components should adhere to or (as needed) expand upon applicable

national standards adopted by HHS, including the ONC (e.g., Fast Healthcare Interoperability Resources (FHIR) and United States Core Data for Interoperability (USCDI)).

Technical solutions that contain software elements, commercial-friendly open-source licenses (e.g., MIT, BSD, or Apache 2.0) are preferred. If an open, consensus-based standard does not yet exist, the Proposer should identify the aspects that lack an open standard, describe a plan to develop a general-purpose open data model and to prototype new open APIs. A strong proposal will explain how the Performer will enhance data interoperability (including semantic interoperability) and expand the availability of open, consensus-based standards and data models.

A proposal must include a technical plan to align with applicable standards based on the OSI layer at which they are operating including (but not limited to) HHS-adopted health IT standards (45 CFR Part 170 Subpart B). For the full description of standards adopted in CFR Part 170, Subpart B, please review the complete text of the regulations; a strong technical solution will also outline integration with the Trusted Exchange Framework and Common Agreement (TEFCA). Adhering to international standard ISO/IEEE 11073 will enable broad support for current and future devices, especially those developed internationally. At other layers of the OSI model, and for software components operating outside the network stack (e.g., health databases, Picture Archiving and Communication Systems (PACS), etc.) other standards will be relevant, and strong technical solutions will seek to utilize or expand upon appropriate open, consensus-based standards.

If a technical solution requires an extension of existing standards or development of technologies outside of the standards, the Proposer must schedule a meeting with ARPA-H representatives prior to proposal submission to discuss the deviation to the standards.

## **6.8 GENOMIC DATA SHARING**

A resulting award will include the requirement to comply with NIH's Genomic Data Sharing (GDS) Policy (NOT-OD-14-124). Information about the GDS policy can be found at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-157.html>.

## **6.9 PROCUREMENT OF SYNTHETIC NUCLEIC ACIDS OR BENCHTOP SYNTHESIZERS**

Beginning April 26, 2025, 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. HHS awardees are expected to adhere to the Office of Science and Technology Policy Framework for Nucleic Acid Synthesis Screening for HHS projects.]

## **6.10 DANGEROUS GAIN-OF-FUNCTION RESEARCH**

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

## 6.11 SAMPLE OT

Appendix G has been included to provide potential proposers a sample of the ARPA-H agreement for this effort. The proposer must include a copy of their agreement with any redlines/comments/proposed edits to ARPA-H as a part of the proposal package. The OT agreement does not count towards any page limitations for the proposal.

## 6.12 ADDITIONAL LINKS

42 U.S.C. § 290c(g)(1)(D)

<https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section290c&num=0&edition=prelim>

ARPA-H's public website

<https://arpa-h.gov/explore-funding/open-funding-opportunities>

SAM.gov

<https://sam.gov/workspace/contract/opp/e6b40defee104f668b388e85583e8126/view>

National Archives (CUI Registry)

<https://www.archives.gov/cui/registry/category-list>

ARPA-H's Solution Submission Portal

<https://solutions.arpa-h.gov/Ask-A-Question/>

CHIPS and Science Act of 2022

<https://www.govinfo.gov/content/pkg/PLAW-117publ167/pdf/PLAW-117publ167.pdf>

50 U.S.C. § 3059

[https://uscode.house.gov/view.xhtml?req=\(title:50%20section:3059%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:50%20section:3059%20edition:prelim))

Controlled Unclassified Information on Non-Federal Information Systems

32 CFR § 2002

<https://www.ecfr.gov/current/title-32/subtitle-B/chapter-XX/part-2002>

Human Subjects Research (HSR)

45 CFR § 46

<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46>

Office of Human Research Protection Federal Wide Assurance

<https://www.hhs.gov/ohrp/index.html>

21 CFR § 56

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

21 CFR § 50

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50>

Animal Subjects Research

Department of Agriculture rules that implement the Animal Welfare Act of 1966

<https://www.nal.usda.gov/animal-health-and-welfare/animal-welfare-act>

7 U.S.C. § 2131-2159

<https://www.govinfo.gov/content/pkg/USCODE-2015-title7/html/USCODE-2015-title7-chap54.htm>

Public Health Service Policy on Humane Care and Use of Laboratory Animals

<https://olaw.nih.gov/policies-laws/phs-policy.htm>

U.S. Government Principles for the Utilization and Care of Vertebrate Animals  
Used in Testing, Research, and Training

<https://olaw.nih.gov/policies-laws/gov-principles.htm>

Guide for the Care and Use of Laboratory Animals: Eighth Edition, Copyright  
2011, NAS

<https://olaw.nih.gov/policies-laws/guide-care-use-lab-animals>

Vertebrate Animals Section Checklist

<https://olaw.nih.gov/sites/default/files/VASchecklist.pdf>

Research Security Disclosures

National Security Policy Memorandum 33

<https://www.nsf.gov/bfa/dias/policy/nspm-33-implementation-guidance>

Electronic Invoicing and Payments

Payment Management Services

<https://pms.psc.gov/>