Innovative Solutions Opening

For

MAKING OBSTETRIC CARE SMART

MOCS

Scalable Solutions Office

ARPA-H-SOL-26-143

AMENDMENT 01

12/16/2025

AMENDMENT 01, SUMMARY OF CHANGES

1. Page 4, under INNOVATIVE SOLUTIONS OPENING (ISO) SUMMARY INFORMATION **Dates** from:

Dates:
- **Teaming Page Opens:** 11/13/2025
- **Proposer's Day:** 12/11/2025 (full day)
- **Mandatory Pre-Proposal Discussions:** 12/15/2025 – 12/19/2025; 30-45 min slots between 9 AM-5 PM ET
- **Proposal Due Date:** 1/21/2026, 12 PM ET

to:

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- **Teaming Page Opens:** 11/13/2025
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- **Frequently Asked Questions:** All questions must be submitted via the portal no later than 01/14/26**.**
- **Proposal Due Date:** 1/21/2026, 12 PM ET

TABLE OF CONTENTS

ATTACHMENTS AND APPENDICES

APPENDIX A: Pre-Proposal Discussion Template and Instructions

APPENDIX B: Full Proposal Format and Instructions

ATTACHMENT 1: Cost Proposal Narrative

ATTACHMENT 2: Cost Proposal Spreadsheet

ATTACHMENT 3: Administrative and National Policy Requirements Document

1. INNOVATIVE SOLUTIONS OPENING (ISO) SUMMARY INFORMATION

Federal Agency Name: Advanced Research Projects Agency for Health (ARPA-H)

Program Title: Making Obstetric Care Smart (MOCS)

Announcement Type: Innovative Solutions Opening (ISO)

ISO Solicitation Number: ARPA-H-SOL-26-143

Anticipated Awards: Multiple Other Transaction (OTs) Agreements

Cost Sharing: Cost sharing is not required but is highly encouraged

Program Website: arpa-h.gov/explore-funding/programs/mocs

Teaming Page: solutions.arpa-h.gov/teaming

Agency Contact: All inquiries should be sent through solutions.arpa-h.gov/ask-a-question

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- **Proposal Due Date:** 1/21/2026, 12 PM ET

Proposers' Day & Teaming:

ARPA-H will host a Proposers' Day (see ARPA-H-SN-26-141) in support of the MOCS program. The purpose is to provide potential proposers with information on the MOCS program, promote additional discussions, and encourage teaming and networking to help facilitate the formation of proposer teams and enable sharing of information among interested proposers.

This program is a complex acquisition, and because of the different expertise required for varying phases and aspects of the program, and the need for teams that can perform dynamically, the formation of teams will be vital for successful proposals. Due to the criticality of teaming to address the complexities of the MOCS program, potential proposers are highly encouraged to view and utilize the teaming page as early as possible, and to attend the Proposers' Day teaming engagements.

1.1. INTRODUCTION

Making Obstetric Care Smart (MOCS) aims to launch a new era of data-driven maternity care—transforming labor and delivery decision making from guesswork into one of objective insight and individually tailored care. These innovations will equip both clinicians and families with the clarity and confidence needed for safer births.

MOCS will focus on two Technical Areas (TAs) of critical need:

- First, a new risk assessment tool will provide care teams and patients with information regarding the risk of a difficult delivery due to fetal hypoxia (TA 1). The results will be available within 15 minutes and are designed to be reliable and easy for families and care teams to interpret. This data will enable informed decision-making about the safest place for delivery and help clinical staff plan for the right team to be present. Importantly, this test will be performed when the delivery is still some time away, so changes to a plan can be accomplished safely.
- Second, the development of novel intrapartum fetal monitoring system, powered by multiplexed sensors and machine learning, to provide information that is easy to understand for the patient and clinically actionable for the care team (TA 2). This monitor will be wireless allowing for maternal ambulation in the delivery room, it will be comfortable, and it will be reliable at predicting fetal pH. Using the same data, the monitor will be able to predict the cause and suggest the best intervention to treat the fetal hypoxia.

This ISO solicits for performer teams that can pioneer these breakthroughs in maternal and fetal care during labor and delivery as well as translate them into routine clinical practice.

1.2. BACKGROUND

Maternal and fetal outcomes in the United States (U.S.) are worsening, even as innovation in healthcare progresses rapidly elsewhere. Currently, women choose where to deliver without data to predict their risk for intrapartum fetal hypoxia. During delivery, fetal monitoring is highly subjective, leaving care teams and patients to decide on the correct path forward with limited information. According to the American College of Obstetricians and Gynecologists (ACOG), the intrapartum fetal heart rate monitor was introduced in the 1970s and is still the standard of care, despite evidence showing it increases cesarean deliveries (CDs) without decreasing cerebral palsy or perinatal mortality. Currently when a baby is suspected to be hypoxic, care teams, often chaotically, perform all interventions simultaneously because the etiology is not known.

While varying technologies have been promising in the research space, a lack of stakeholder engagement and robust commercialization pathways have prohibited innovation from reaching the bedside. Minimal industry investment, a history of past failures in the area, and the inherent high-risk and difficult nature of non-invasively assessing the fetus have all contributed to a deeply entrenched status quo. The result is that the United States spends the most on maternal care, but has the worst outcomes compared to other high-income countries.

MOCS has been designed to address these barriers by increasing our understanding of fetal status, providing the patient and care teams with the information they need to make labor safer, and by engaging stakeholders throughout the process. The ambiguity in our current system that causes litigation, unnecessary cesarean sections and unnecessary NICU (neonatal intensive care unit) admissions, and provider burnout will be replaced by tools that provide trustworthy, clinically actionable data to keep mothers and babies safe. This will redefine the standard for maternal and fetal well-being, making every birth more informed, more

equitable, and more precise. Only necessary cesarean sections will be done, in a timely fashion, so that the baby is healthy, making the United States the safest place to have a baby.

1.3. PROGRAM OVERVIEW

MOCS seeks proposers who will create new technologies to transform the birthing journey and redefine the future of labor and delivery across the country. In this vision the patient will have access to rapid, advanced testing that assesses the risk and presence of fetal hypoxia. This will allow the patient and provider to determine an appropriate delivery site and or staffing at that delivery site (nurse ratio, in-house versus home call), ensuring that every family, regardless of geography, benefits from the safest possible environment. Accurate and reliable intrapartum fetal monitoring will allow clinicians to deliver healthy babies vaginally and to only do truly necessary cesarian deliveries at the right time. Increased knowledge about the baby's risk for fetal hypoxia and the current oxygenation status will allow clinicians to tailor interventions during labor, bringing precision care to what has long been one of the most subjective and variable aspects of medicine. Lastly, if hypoxia is suspected, the most effective intervention will be suggested based on the suspected etiology. Through the combination of these two TAs, selected proposers will usher in a new era of data-driven maternity care, and the United States will be the safest and best place in the world to deliver children.

Innovations will be considered in two technical focus areas:

1) Development of a point of care test to stratify risk for fetal hypoxia.
2) The creation of a novel intrapartum fetal monitor than can objectively assess the fetus and suggest the next best step for treatment of hypoxia.

Performer Expectations:
Many technologies have failed to satisfy the complex network of stakeholders in this area, hence MOCS places a heavy emphasis on engagement with end users, regulatory, and legal experts (see Sections 2.2.1, 2.2.4). To ensure all necessary perspectives to achieve program goals are included in every stage of development, performers are required to have representative personnel as part of the team (see Section 2.2.6). Additionally, performers will partner with three disparate delivery sites to obtain continual feedback regarding their product and will ultimately submit their product to hospital systems identified by ARPA-H for an assessment of usability and scalability (see Section 2.2.5). The program will conclude with one product from each technical area completing phase 1 clinical trials.

2. THE MOCS PROGRAM

2.1. PROGRAM STRUCTURE

The MOCS program is soliciting proposals to realize this vision. It is defined by two TAs:

TA1: Development of a Point of Care Test for Stratification by Risk for Intrapartum Fetal Hypoxia.
The objective of TA1 is the development of a point of care test to stratify patients by risk for intrapartum fetal hypoxia to be done in triage upon the decision to admit to labor and delivery for all patients, allowing patients and care teams to make informed decisions

regarding if their chosen delivery site is safe (or not) and to inform staffing decisions at that site. The point of care test will give patients and the care team a categorical and numerical result that predicts the risk for fetal hypoxia. Through engaging frequently with diverse delivery sites, performers will create products that are integral to patient care. Changes in management may include a change in planned delivery site (birthing center versus hospital) and/or a change in staffing (nurse ratio, providers on home call versus in house). While the test must be point of care and performed independent of a provider, the technology is not prescribed and MOCS welcomes creative submissions.

TA2: Development of a Novel Intrapartum Fetal Monitor for Objective Assessment of the Fetus with Suggested Next Best Step for Treatment of Hypoxia.
The objective of TA 2 is the development of an intrapartum fetal monitor that accurately reflects fetal status and has predictive capabilities. It's important to note that this TA involves replacing the current standard of care for all patients, as opposed to existing innovation, which is designed to augment the current system and to be used as needed.

The new technology must be accurate, sensitive, and specific for identifying fetal hypoxia, but it must also be highly desirable to stakeholders due to comfort, ease of use, and clarity in the output for the patient and the care team. There are three components for TA2:

- Development of a novel, wireless, and non-invasive fetal monitor to assess fetal oxygenation status.
- Development of a computational algorithm to interpret the novel signals and produce a real-time, objective, data-driven, assessment of fetal oxygenation status during labor. The data insights are provided in simple, clinically actionable alerts to the care team and patient when hypoxia is detected.
- Development of a computational algorithm to interpret signal data during a hypoxic event to determine the cause of the hypoxia and to suggest a next best step in treatment of the hypoxia.

2.2. PROGRAM TIMELINE, GOALS, AND METRICS

Timeline:
MOCS is a 48-month, three-phase program, which is divided into the following phases:

- Phase 1 (Base): Prototyping, 12 months.
- Phase 2 (Option 1): Refinement, 12 months.
- Phase 3 (Option 2): Translation, 24 months.

Multiple awards are anticipated, and it is expected that not all performers will be selected to move forward into each phase. Continued performance of awardees through all phases of the program will be at the sole discretion of the Government, and may be based on several factors, including technical progress measured against the metrics and milestones defined in the ISO, and availability of funding.

Descriptions of the phases, which are aligned with critical program milestones, are described in the following sections, and associated metrics are shown for each TA.

Goals:

The goal of this program is to create products that end users and the ecosystem are delighted with, as opposed to products that are sufficient. This view should inform the importance of the stakeholder and end-user engagement.

Metrics:
The program metrics will serve as the basis for determining satisfactory progress and continued funding (see Table 1, Table 2, and Table 3). While the program metrics are specified below, proposers should note that these metrics are intended as guidelines for achieving the program's goals. Proposers have flexibility in how they meet these metrics and are encouraged to demonstrate creativity and innovation in their proposed solutions. Proposals involving development or testing in animal models will not be considered.

Successful adoption of innovations in labor and delivery will be driven by end-users. Given this, ARPA-H will engage with multiple hospital partners geographically distributed across the U.S. that will perform Independent Verification & Validation (IV&V) solely focused on usability and scalability (see Section 2.2.5). The results of IV&V will be a critical factor in informing selection for progression to subsequent phases within the program.

2.2.1. CLINICAL COLLABORATION REQUIREMENTS

Although promising technologies have been developed in the past, they have failed to reach the bedside due to the complex matrix of end-users and stakeholders. Even small changes in product design can have significant implications for clinical use, affecting everything from patient comfort to integration into current workflows to malpractice considerations. Additionally, ethical, social, and legal implications must be carefully considered. Given that collaboration with end-users and stakeholders is crucial for successful implementation and adoption, MOCS has built in several requirements (see Section 2.2.4) to de-risk this element including:

- **Performer engagement with End-Users**
  - Proposers must partner with a minimum of three delivery sites. The names of these delivery sites must be submitted with proposals and associated Memoranda of Understanding (MOUs) must be submitted prior to award.
  - Delivery sites should include an urban delivery hospital, a rural delivery hospital, and a birthing center, with one of these sites being an academic institution. Ideally, these delivery sites will differ in practice setting, patient population, and payer mix.
  - A list of end-user participant roles should be included in the proposal. These participants may include, but are not limited to, patients, nurses, delivering providers, hospital administrators, electronic medical record representatives, and malpractice attorneys to meet all required metrics (see Tables 1-3).
  - At the discretion of the proposer, additional end-users and/or delivery sites may be included.
  - Documentation of engagement must be submitted on a quarterly basis. Engagement may be conducted virtually or in person. Each encounter must include an update on the product and a solicitation of feedback from participants.
  - Potential clinical collaborators will be invited to submit teaming profiles and to attend Proposer's Day to facilitate connections. Proposers are not limited to working with these collaborators and may engage with other clinical sites.

- Contracting with clinical collaborators will be negotiated with the proposer and will not involve ARPA-H.

- **Ecosystem Engagement Events:**
  - ARPA-H will host a two-day Ecosystem Engagement Event during Phase 2 with in-person attendance required. This event will be designed to foster buy-in from investors and healthcare organizations and to provide performers with an opportunity to showcase their achievements.
  - Day 1 will focus on funding partners, offering performers the opportunity to pitch to potential commercialization partners.
  - Day 2 will focus on hospital system leadership, featuring discussions on product use, cost, and efficacy.
  - Ecosystem attendees may include patients, nurses, physicians, midwives, hospital representatives, payers, malpractice attorneys, patient advocacy groups, industry, venture capital, private equity, and professional organizations.
  - Performers will present their products in lightning talks. Following the presentations, there will be dedicated time for feedback solicitation and networking.

2.2.2. TA 1 REQUIREMENTS

The objective of TA1 is to develop a point-of-care test that stratifies patients by their risk for intrapartum fetal hypoxia. This test will be administered in labor and delivery triage upon decision to admit the patient for delivery and is intended for all patients between 36 and 42 weeks gestation. The results will be used to inform decisions regarding the location and staffing of the delivery. Please note that it is understood acute causes of hypoxia cannot be predicted; therefore, test accuracy will not reach 100%.

Proposed solutions should consider and reflect the specifications below:

- Testing of biomarker should be simple and reliable with easy to interpret with both binary (yes / no) and quantitative results (numerical with low, medium, and high thresholds).
- A positive result indicates the patient has uteroplacental insufficiency and has a high risk of the following complications: undergo a CD for suspected fetal hypoxia at cervical dilation of less than 6 cm, have an umbilical artery pH of <7.05 at delivery, an unanticipated NICU admission, or a 5-minute Apgar score of 5 or less. If proposers disagree with the definition of a positive result, they should submit their proposed metric and reasoning for consideration.
  - Accuracy is defined as the test's ability to predict patients who will have stated complications.
  - Sensitivity is defined as probability that a patient with a positive test will have stated complications.
  - Specificity is defined as the probability that a patient with a negative test will not have any of the stated complications.
- The test should be able to be performed independently by a registered nurse or birthing assistant who conveys the results to the delivery provider.
- The test should be accurate in patients with a Body Mass Index (BMI) up to 50 and in gestations between 36 and 42 weeks.

- Biomarkers may include, but are not limited to biological, metabolic, or imaging technologies. Artificial Intelligence/Machine Learning (AI/ ML) may be part of the solution, but AI/ML as the sole innovation will not be encouraged.
    - Ultrasound specific: solution should use a device that would be designated for this purpose as opposed to requiring use of an existing bedside ultrasound.
    - Biological or metabolic: testing must be able to be done in any care setting, including outside of a hospital, and compliant with relevant regulatory requirements. Source may be urine, blood, saliva, vaginal secretions, or other.
    - Optical sensors: must be able to meet program requirements across all skin tones.
- Proposed solutions should reflect the milestones, metrics and deliverables in **Table 1** and FDA regulatory requirements to complete FDA submission in Phase 3.

Phase 1 (12 Months): Prototyping
Phase 1 will be used to explore biomarkers that may be useful in determining risk of fetal hypoxia. During this stage, proposers will test technologies in the laboratory using biological and metabolic samples, as well as in a small cohort of patients, following all applicable institutional ethics and biosafety protocols. The goal is to identify relevant biomarkers, assess their correlation with fetal hypoxia risk, and develop algorithms for risk stratification. This phase will also include an assessment of clinical user needs for the test, legal considerations for protected populations, and determination of regulatory pathways. A pre-submission to the FDA will occur during this phase. By the end of the phase, the feasibility of all test methods will be demonstrated, and a proposed workflow will be developed based on stakeholder feedback.

Phase 2 (12 Months): Refinement
Phase 2 will concentrate on refining the tests developed in Phase 1 to better meet end-user expectations. This will include integrating the test into a standard clinical workflow and usability testing through IV&V. Proof of concept testing developed in Phase 1 will be repeated in an expanded patient population to ensure the device functions as intended and thresholds for biomarkers are appropriately set. Design controls will be implemented to prepare the prototype for clinical data collection in Phase 3. Feedback from the FDA pre-submission will be incorporated and preparation for the clinical study will begin, including draft protocols, determining the need for an Investigational Device Exemption (IDE) submission, and initiating any necessary institutional ethics approval processes.

Phase 3 (24 Months): Translation
Phase 3 will focus on further refinement of the test based on the usability study, collection of human data for Phase 1 Clinical Trials, and FDA submission. Guided by the regulatory strategy developed in Phase 1, this phase will likely include the preparation and submission of an IDE for the planned clinical study. Study protocols will be developed in accordance with the design controls established in Phase 2. Any remaining tasks for clinical trial start will be completed including: identification and contracting of clinical trial sites, ethics review board approval, onboarding and training of study personnel, and commencement of the data collection. By the end of the phase, data collection will be complete for the Phase 1 clinical trial, device verification and validation tests will be complete, and all relevant documentation will be prepared for FDA submission.

Table 1: TA1 Milestones, Metrics & Deliverables by Program Phases

Milestone Title	Phase 1: Prototyping (12 months, Q1 - Q4)	Phase 2: Refinement (12 months, Q5 - Q8)	Phase 3: Translation (24 months, Q9 – Q16)
Tasks	**Metrics & Deliverables:** • Identify biomarker(s) for risk for hypoxia. • Develop testing method. • Identify Target Product Profile (TPP), user needs, and workflow	**Metrics & Deliverables:** • Identify thresholds for biomarker results and clinical utility. • IV&V.	**Metrics & Deliverables:** • Submit to FDA • Complete Phase 1 Clinical Trial.
	Analytical & Clinical Validity		
Accuracy:	• >=80%	• >=83%	• >=85%
Sensitivity:	• >=70%	• >=76%	• >=80%
Specificity:	• >=50%	• >=55%	• >=60%
Precision & Repeatability in Intended use and Population	Meet FDA regulatory standards for consistency at the 95% confidence interval: • Gestational age 39-40 weeks • Patient BMI 20-40	Meet FDA regulatory standards for consistency at the 95% confidence interval: • Gestational age 37-41 weeks • Patient BMI 20-45	Meet FDA regulatory standards for consistency at the 95% confidence interval: • Gestational age 36-42 weeks • Patient BMI 20-50
Biomarker Clinical Association	• Normal and abnormal values in pregnancy must be established for gestational ages 36 – 42 weeks.	• Develop use cases and thresholds. • Results must be both binary and quantitative.	• Testing of biomarker must be simple and reliable with easy to interpret binary and quantitative results.
	Operational Characteristics		
Time to result (from sample collection to result)	• <60 minutes	• <20 minutes	• <15 minutes
Time to perform test (Time with patient to collect sample / image)	• <15 minutes	• <10 minutes	• <5 minutes
Form Factor (as applicable)	• Portable to patient bedside (peripheries can be separate of sensors) • Processing and output result offline of device	• Handheld by one operator with all needed components in one chassis • Output viewable on the device and in the patient EMR	• Unobtrusive to patient and operator with all needed components in one chassis • Output viewable on the device and in the patient EMR
	End-User Engagement		
Topics Addressed:	• TPP, user needs, workflow, and use cases. • End-user preference for result output. • Exploration of liability concerns.	• End of phase prototype demonstration. • Solicitation of user feedback.	• Demonstration of final product & training materials. • Solicitation of feedback.

End-User Engagement	Quarterly engagement to continuously evaluate product iterations. Deliverable is documentation of such including information shared and feedback obtained.		
		IV&V Metrics*	
Comfortable Easy Actionable Trustworthy Desirable	---	95% of end-users agree or strongly agree with structured questions regarding product's usability.	---
	Phase-End Performance Evaluations based on Above Metrics & Milestones.		
---	• Performance Evaluations	• Performance Evaluations	---

* IV&V Details in Section 2.2.5

2.2.3. TA 2 REQUIREMENTS

The objective of TA2 is the development of a continuous, wireless, and non-invasive tool that assesses fetal oxygenation status during labor with simple, clinically actionable alerts to care team and patient if hypoxia is detected. Additionally, through interpretation of the sensor data, etiology and most effective intervention to treat acute fetal hypoxia will be suggested. This technology will replace the current standard of care for all patients.

Proposed solutions should consider and reflect the specifications below:

- Umbilical artery pH and its correlation with neonatal outcomes should be used as the reference for ground truth regarding fetal status. If proposers disagree, they must submit their proposed metric and reasoning.
- Sensors:
  - Must include fetal heart rate, tocometer, and two additional non-invasive fetal sensors. If placed vaginally, the sensor must work with intact membranes.
  - Data from sensors should be integrated into an output that is continuous and can be read as numerical and categorically.
  - Output should be simple, continuous, easy to interpret, and clinically actionable.
  - The system should interpret all sensor data and provide suspected etiology and next best intervention during a hypoxic event.
  - Encouraged: Ability to sense maternal vital signs such as blood pressure, heart rate, oxygen saturation, and temperature. Sensors for this purpose will not be included in the overall sensor count.
- Usability:
  - Device should be wireless and allow for maternal movement with minimum range of 30 feet.
  - Monitor should be able to be independently placed by a nurse or birthing assistant.
  - Monitor should be comfortable to wear for up to 48 hours.
  - Device should operate a minimum of 48 hours; however, the battery may be changed up to every 12 hours if applicable.
  - Encouraged: inclusion of comfort measures such as ability to labor in water or to provide heat / massage.
- Technical Requirements:
  - Compliant with HIPAA and FDA device requirements (or pathway to approval).

    - End-to-end data encryption, secure storage, and role-based access control compliant with relevant standards organizations cybersecurity requirements.
    - Should integrate that data into the different EHRs for interoperability without relying on nurses to input data.
- Proposed solutions should reflect the milestones, metrics and deliverables in ***Table 2*** and FDA regulatory requirements to complete FDA submission in Phase 3.

Phase 1 (12 months): Prototyping
Phase 1 will focus on developing the sensor technology as well as demonstrating proof of concept for the prototype. End users will be engaged to inform user needs and develop design requirements for the device. Legal and regulatory experts will be consulted to address clinical user needs, legal considerations for protected populations, and regulatory pathways. The prototype will be tested in a small cohort of patients according to Institutional Review Board (IRB) approved protocols. A pre-submission to the FDA will be completed during this phase. By the end of Phase 1, the feasibility of the multimodal sensing device and corresponding algorithms will be demonstrated. Additionally, a workflow for further refinement will be proposed for further refinement according to the gathered stakeholder data.

Phase 2 (12 months): Refinement
Phase 2 will focus on refining the prototype developed in Phase 1 to better meet end-user expectations and ensure output thresholds are appropriately set. This will include integration into standard clinical workflows and usability testing through IV&V. Proof of concept testing developed in Phase 1 will be repeated to ensure refined device functions as expected in the expanded patient population. Design controls will be implemented to ensure the prototype is prepared for Phase 3 validation and data collection. Feedback from the FDA pre-submission will be incorporated and preparation for the clinical study will begin, including drafting protocols, determining the need for an IDE submission, and initiating any applicable institutional and regulatory ethics approval processes.

Phase 3 (24 months): Translation
Phase 3 will focus on further refinement of the device based on the usability study, FDA submission, and collection of human data for Phase 1 Clinical Trials. Based on the regulatory strategy determined in Phase 1, this phase will likely include the preparation and submission of an IDE for the planned clinical study. Study protocols will be developed according to the design controls from Phase 2. All remaining tasks to initiate the clinical trial will be completed including: identification and contracting of clinical trial sites, ethics review board approvals, onboarding and training of study personnel, and commencement of the data collection. By the end of the phase, data collection will be complete for the Phase 1 clinical trial, device verification and validation tests will be finalized, and all relevant documentation will be prepared for FDA submission.

Table 2: TA2 Milestones, Metrics & Deliverables by Program Phases

Milestone Title	**Phase 1: Prototyping (12 months, Q1 - Q4) Metrics & Deliverables:**	**Phase 2: Refinement (12 months, Q5 - Q8) Metrics & Deliverables:**	**Phase 3: Translation (24 months, Q9 – Q16) Metrics & Deliverables:**
Tasks	Integration & Prototype	Prototype Refinement &	• Submit to FDA

	Development • Develop prototype to integrate input from 2 novel fetal sensors with fetal heart rate and tocometry into clinically useful output. • Engage with end-users to identify target product profile.	Preparation for FDA Submission. • Suggest etiology and effective intervention in hypoxic episodes. • Engage with end-users to refine product.	• Phase 1 Clinical Trials.
	Analytical & Clinical Validity for Detection of Hypoxia		
Accuracy: Sensitivity Specificity	• >=85% • >=80% • >=93%	• >=93% • >=90% • >=98%	• >=98% • >=95% • >=99.5%
Clinical Utility	• Develop output that is both categorical & numerical	• Refine output and thresholds based on clinical data and end-user feedback.	• Refine output and thresholds based on clinical data and end-user feedback.
Placement of Device	• Placed correctly 6/10 times in less than 5 minutes • Signal loss requiring adjustment less than every 30 minutes	• Placed correctly 8/10 times in less than 5 minutes • Signal loss requiring adjustment less than every hour	• Placed correctly 9/10 times in less than 5 minutes • Signal loss requiring adjustment at most every 2 hours
Precision & Repeatability	Meet FDA regulatory standards for consistency at the 95% confidence interval: • Gestational age 32-40 weeks. • Patient BMI 16-30 • All skin tones.	Meet FDA regulatory standards for consistency at the 95% confidence interval: • Gestational age 28-42 weeks. • Patient BMI 16-50	Meet FDA regulatory standards for consistency at the 95% confidence interval: • Gestational age 22-42 weeks • Patient BMI 20-70
	Analytical & Clinical Validity for Etiology of Hypoxia and Next Best Step in Management		
Percent Resolution in Suspected Hypoxia:	---	• >=60%	• >=85%
Clinical Utility:	• Suggests cause from submitted list of causes of acute hypoxia and provides associated interventions **	• Uses output from new sensor and analytics to suggest etiology and next best step in management. • Integrate output into prototype function & display	• Refine accuracy, sensitivity, and specificity.
	Product Specifications		
Device Use Threshold:	• >=12 hours	• >=24 hours	• >=48 hours
Wireless Range	• >=5 feet	• >=20 feet	• >=30 feet
Liability Concerns	• Engage with malpractice attorney regarding TPP	• Review product & specifications, and proposed FDA classification with malpractice attorney and elicit feedback.	• Adjust specifications to balance clinical need with malpractice implications.

Form Factor	• Portable to patient (peripheries can be separate of sensors) • Processing and output result provided offline of device	• Sensors integrated into one chassis that may or may not include peripheries and is portable to bedside • Output viewable on the device and in centralized monitoring location	• Sensor chassis unobtrusive to patient and operator • Output visible on device, in-room patient monitor, and in centralized monitoring location
Timing	• <= 30 min of baseline data may be acquired • <= 5 min to display output	• <= 15 min of baseline data may be acquired • <= 1 min to display output	• <= 10 min of baseline data may be acquired • <= 1 s to display output
Alarm	• Triggered appropriately in processing	• Triggered appropriately in processing • Audible and visible at bedside and in centralized monitoring location	• Triggered appropriately in processing • Audible and visible at bedside and in centralized monitoring location
		EMR Integration	
Interface with electronic medical record (EMR)	• Establish list of three EMRs to integrate with and submit plan for evaluation • Establish what thresholds will trigger different alarms to care team members	• Establish what data will be transferred and how often • Data must be sufficient so that no additional translation from care team is necessary	• Pursue contracts and formal relationships to assure swift clinical adoption due to seamless integration.
Data Synchronization	• Create plan for routine synchronization	• Create back up plan in case of network outage	• Review plans with malpractice attorney
		End-User Engagement	
Topics Addressed:	• TPP. • End-user preference for result output. • Exploration of liability concerns. • Specific difficult scenarios with current monitoring.	• End of phase prototype demonstration • Discussion of communication preference for etiology and best intervention • Solicitation of feedback.	• Demonstration of final product & training materials. • Solicitation of feedback.
End-User Engagement	Quarterly engagement to continuously evaluate product iterations. Deliverable is documentation of such including information shared and feedback obtained.		
		IV&V Metrics*	
Comfortable Easy Actionable Trustworthy Desirable	---	95% of end-users agree or strongly agree with structured questions regarding product's usability.	---
	Performance Evaluations based on Above Metrics & Milestones.		
---	• Performance Evaluations	• Performance Evaluations	---

* IV&V Details in Section 2.2.5

** Only one intervention may be CD, and this is excluded from ability to resolve hypoxia calculation.

2.2.4. COMMERCIALIZATION METRICS

Proposers for both TAs must meet additional commercialization metrics as below:

Table 3: Commercialization Metrics

	Phase 1: Prototyping	Phase 2: Refinement	Phase 3: Translation
Product Development & Business Model	• Product roadmap (technical goals and individual components, prototyping and testing) • Plan for manufacturability	• Reimbursement consultant to support performers in creation of reimbursement strategies	• Established partnerships to ensure commercialization
End User / Market	• Conduct market segmentation and define target clinical users • Interview 10+ stakeholders to understand standard of care and product differentiation • Summarize findings & strategic recommendations with integration into product development	• Identify early adopters for pilot studies and implementation • Define use cases and early adopter hospital profiles • Plan for health economics and outcomes research studies to support reimbursement decisions	• Launch pilot studies with selected hospitals and/clinics • Collect voice of customer for product refinement • Clinical key opinion leader engagement, plan for inclusion in treatment guidelines
Regulatory	• Determine regulatory classification • Submit FDA pre-submission.	• Begin design controls under QMS • Initiate pilot study planning	• Submission of IDE • Complete phase 1 clinical trials.
Exit Strategy	• List 5 potential strategic partners or acquirers	• Begin informal discussions with potential exits partners • Assess strategic alignment	• Formalize exit path and prepare data room or similar documentation (startup formation, licensing model)
Deliverables	• Voice of consumer analysis and integration into design • Regulatory strategy timeline and milestones • List 5 potential strategic partners or acquirers	• List of potential early adopter institutions • Pilot study protocol outline, including objectives, endpoints, site selection criteria, and projected timeline	• Consumer and opinion leader insights and feedback incorporated into product plan • Clinical study protocol initiated • Comprehensive data room or similar documents to support licensing discussions
End-of-phase Demonstrations	• Demonstration of prototype meeting TA metrics	• Field study of prototype in clinical settings with emphasis on TA Clinical Utility and IV&V metrics	• Advancement of prototype in clinical practice focusing on FDA requirements
Scalability	• Engage with hospital leadership to understand cost limitations at different	• Demonstrate capabilities to hospitals along with planned price point to	• Continued market research on acceptability of planned one-time purchase and subscription fees

sites	elicit feedback ● IV&V: Average 4/5 on scalability questions

2.2.5. INDEPENDENT VERIFICATION AND VALIDATION

IV&V is not being solicited for in this ISO.

ARPA-H will engage with multiple community hospital systems that care for a mix of Medicaid and private payers, high and low risk patients, and rural and urban delivery centers.

IV&V will be conducted once during Phase 2 for both TAs, utilizing hospital systems selected by the government. This process is distinct from the end-user engagement and clinical partners required of performer teams. Performers will provide their products and training materials to the designated hospital systems, which will then conduct usability and scalability studies. These metrics will be included in the phase-end performance evaluation for Phase 2. IV&V partners must not be associated with any performer and may not operate their own innovation or venture capital hubs.

An example of the populations to be surveyed and suggested sample sizes are included here. This is based on FDA guidance on applying on Human Factors and Usability Engineering to Medical Devices of 15-20 participants per unique user group and may be tuned according to the needs of the program. Populations recommended: Pregnant women (with at least 5 of whom have a BMI above 40; total n=20), labor nurses (n=20), delivery providers (n=20), and nurses, physicians and hospital leaders (n=10).

Questions will be answered on a Likert scale ranging from 1-5 with strongly disagree to strongly agree and those marked with an Asterix are fill in the blank. No data or specimens will be collected. IV&V partners and performers will be responsible for providing suitable simulations or mock data as indicated.

TA1 IV&V:

Question	Pregnant women	Nurse	Delivery Provider	Leadership
1. Performing the test was comfortable.	X			
2. Performing the test was easy.		X		
3. Collecting the test took < 10 minutes.		X		
4. Reading the results was easy.		X	X	X
5. The numerical result was simple and easy to understand.	X	X	X	X
6. The binary (yes / no) result was simple and easy to understand.	X	X	X	X
7. Clinical information was actionable.		X	X	X
8. I would trust these results to change my plan.	X	X	X	X
9. Overall, I would want to use this test / would want it used in my care.	X	X	X	X
10. What did you think of the test overall? *	X	X	X	X
11. Did you have any trouble using it? If so, what kind of trouble did you have? *		X	X	
12. Was anything confusing? Please tell me about	X	X	X	X

	this. *				
13.	Is there anything you would change? *	X	X	X	X
14.	Do you have any final thoughts you would like to share? *	X	X	X	X

*Fill in blank

TA2 IV&V:

Question		Pregnant women	Nurse	Delivery Provider	Leadership
1.	The monitor was easy to place and start using.	X	X	X	
2.	The monitor was comfortable.	X			
3.	The results of the monitoring were easy to read.	X	X	X	X
4.	The results were clinically actionable.		X	X	
5.	I would trust these results to tell me if the baby was getting enough oxygen.	X	X	X	X
6.	The next best step in management was helpful.		X	X	
7.	I trusted the next best step in management.		X	X	
8.	I believe that this product will significantly improve the current standard of care.	X	X	X	X
9.	This device would vastly improve my experiences on labor and delivery (L&D) (patient) and make me more likely to continue to practice on L&D (care team).	X	X	X	
10.	Etiology of hypoxia was easy to understand and seemed clinically reasonable.		X	X	
11.	Overall, I would want to use this test / would want it used in my care.	X	X	X	X
12.	What did you think of the device overall?*	X	X	X	X
13.	Did you have any trouble using it? If so, what kind of trouble did you have?*	X	X	X	X
14.	Was anything confusing? Please tell me about this.*	X	X	X	X
15.	Is there anything you would change?*	X	X	X	X
16.	Do you have any final thoughts you would like to share?*	X	X	X	X

*Fill in blank

Scalability (TA1 and TA2):

Question		Delivery Provider	Leadership
1.	The implementation cost is reasonable for the technology	X	X
2.	The subscription cost is reasonable for the technology	X	X
3.	Given the cost, I believe my hospital would purchase and implement this technology.	X	X
4.	It would be easy to advocate for purchasing this technology.	X	X
5.	I would push my hardest to have this approved for purchase by my hospital leadership / board.	X	X

2.2.6. GENERAL REQUIREMENTS

No collaboration between performers will be required, and proposers may submit a proposal to either single TA or both Tas combined. Proposing teams with multiple team members must be configured as multi-party teams, and not prime/sub teams.

Proposal Submission:

- Performers must submit a full proposal, see Appendix B for template.
- Intellectual Property (IP) ownership must be clearly established and agreements submitted.
- Teams must include: a full-time program manager, a full-time clinical research coordinator, an ACOG certified OBGYN who actively practices high volume obstetrics and cares for Medicaid patients (0.2 FTE suggested) and a clinical bioethicist (0.2 FTE suggested).
- Proposers responding to TA 2 must include a malpractice attorney who specializes in obstetrics.
- Performers must submit plans for performance of human subjects research.
- Performers must submit names of clinical partners for end-user engagement to include a rural labor and delivery, an urban academic labor and delivery, and a freestanding birthing center. Prior to contracting, MOUs must be submitted.

Program Performance:

- Performers will be required to provide monthly technical and financial status reports at least 48 hours prior to scheduled performance review meetings.
- Performers must attend monthly performance review meetings – which can be virtual – of at least 45 min to discuss results, technical challenges and solutions, and all other project-related topics. Attendance of these meetings must include the performer's Principal Investigator (PI), project manager, and all relevant technical personnel as necessary for in-depth, meaningful discussion of technical progress.
- At its own discretion, ARPA-H may request additional meetings and or data and reports for review.
- Performers are expected to accommodate ARPA-H program team visits to their facilities.

Phase-end Evaluations:

- ARPA-H may conduct phase-end evaluations towards the end of each phase, for both Tas, to review performer progress and make decisions on continued performance to subsequent phases. These decisions may be based on a variety of factors, including progress against stated program metrics and availability of funding.

In person meetings, attendance required:

- Phase 1:
    - Kick off in Washington, DC. Minimum of two people per performer present.
    - Site visit: Individual meeting with performer team at their site.
- Phase 2:
    - Ecosystem Engagement Event.
    - ACOG Annual Clinical Meeting.
    - Site visit: Individual meeting with performer team at their site.

- Phase 3:
    - Site visit: Individual meeting with performer team at their site, yearly.

3. ELIGIBILITY INFORMATION

3.1. ELIGIBLE PROPOSERS

All responsible sources capable of satisfying the Government's needs may submit a proposal to this ISO. Proposers are required to meet with the ARPA-H MOCS program team for a pre-proposal discussion prior to submitting a proposal.

If the performer is an academic institution, they may be required to apply with an industry partner, or sufficiently address commercialization capabilities of their institution, in order to facilitate adoption and rollout of the device.

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 the team through solutions.arpa-h.gov/ask-a-question.

- If a potential performer believes an FFRDC has a unique capability without which their solution is unachievable, they may provide documentation as part of their 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 proposed 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 U.S. However, non-U.S. entities may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. In accordance with these laws and regulations, in no case will awards be made to entities organized under the laws of a covered foreign country [as defined in section 119C of the National Security Act of 1947 (50 U.S.C. Ch 44 § 3059)]; a foreign entity of concern meeting any of the criteria in section 10638(3) of the CHIPS and Science Act of 2022; [an individual that is party to a malign foreign talent recruitment program, as defined in Section 10638(4) of the CHIPS and Science Act of 2022; or entities suspended or debarred from business with the government.

3.2. SYSTEM FOR AWARD MANAGEMENT (SAM)

All proposers must have an active registration in SAM.gov for their proposal to be found conforming. Proposers must have an active registration in SAM.GOV at the time of proposal submission and at the time an award is made. Performers must also have an active registration in SAM.gov with current information during the time in which 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.

3.3. PROPOSER TEAM STRUCTURE

The multi-party teaming arrangement is anticipated to be utilized in a team wherein a group of organizations and/or performers work together to accomplish a common goal, with members sharing resources, knowledge, and expertise. While one team member is usually elected to serve as the lead member or authorized agent for administrative purposes, such as executing documents or receiving payment on behalf of the team, each member must be bound to the team membership agreement and must be a party to the resultant OT award with ARPA-H. In this type of team structure, each member must perform substantive technical work as part of the team.

Unlike a prime/sub arrangement where the prime performer is the leader of the team throughout the duration of the project, the multi-party teaming structure allows different members of the team to take the lead role at different stages of the program life cycle based on expertise and experience, as needed. Additionally, the team structure allows for changes in team membership whenever necessary. The multi-party team arrangement allows for dynamic changes as needed throughout the course of performance, allows for open communication between the government and all performers on a team, and ensures that all team members are responsible for performance and invested in the success of the program.

A multi-party team is formed by having all team members sign a teaming agreement (also referred to as "articles of collaboration"), a contract which binds signing members together as a team and which identifies team members, roles, responsibilities, etc. The government is not a party to this teaming agreement and is not involved in the negotiation of the terms amongst the team members. This is a private arrangement amongst the team members with no

government-dictated terms. Most teaming arrangements allow for members to leave the team during performance or for new members to join when needed but those options are at the discretion of the team members. Team members have a wide range of options regarding how they establish and internally handle the teaming arrangement and the teaming agreement.

A multi-party team does NOT need to be established as a separate legal entity as the teaming agreement serves to bind all members to the team. The team must choose one member to act as the agent and/or lead member to handle administration duties on behalf of the team. For example, although the government contract is between the multi-party team and the government, the lead member will sign the contract as the representative for the team. Additionally, the lead member is usually the direct payee, receiving funds from the government and distributing payment to team members.

A multi-party team structure has many advantages over a typical prime/sub-performer team. Because the team has chosen to work together in a collaborative manner, the multi-party team approach is usually advantageous to all members and oftentimes, teams forge relationships and alliances that continue beyond the program. This type of team structure also gives the government privity of contract with all team members, allowing the government insight and visibility into all levels of technical and management actions, providing for direct communication between all team members and the government, ensuring that all team members are responsible for successful performance, and enabling seamless leadership changes of the effort and/or addition of new team members (e.g. product sponsors), if necessary, as the program project evolves.

At a minimum, a proposing team must:

1. Not be a prime/sub-performer team. While a multi-party team may still choose to subcontract with commercial vendors and consultants not performing essential components of the program project, entities that are performing substantive work should be members of the team, not sub-contractors.
2. Identify a team member to perform administrative functions and act as an agent or lead member for the team. The agent does not need to be the lead performing organization, but the agent should perform substantive technical work on the program project beyond program management and administrative functions.
3. Execute, prior to award, a teaming agreement that details the team structure, roles, and responsibilities and which binds the team members to the agreement. All members of the team will be party to the OT agreement with the government. Whatever the team structure, the lead performing organization must be able to change during performance or between phases, if necessary. The teaming agreement must account for the full scope of the MOCS program. The government is not a party to and will not approve the teaming agreement, however ARPA-H will require evidence that the teaming agreement has been fully executed by all team members in order to make an award to the team.

ARPA-H recognizes that this approach may be unfamiliar or new to many performers. ARPA-H strongly encourages performers who are interested in a deeper explanation of this approach and how it can be fully utilized by teams to attend the MOCS Proposers' Day and ask any questions they may have.

4. SUBMISSION PROCESS

4.1. SUBMISSION PROCESS OVERVIEW

Submissions for MOCS are as follows:

- ✓ **Step 1 (Optional, Encouraged):** Submit teaming profile on webpage.
- ✓ **Step 2:** Mandatory Pre-Proposal Discussion with MOCS team (Proposers will be given verbal feedback that they may incorporate in Step 3).
- ✓ **Step 3:** Submit Full Proposals (Proposers may submit full proposals, regardless of whether they participated in Step 1).

4.2. TEAMING PROFILE

It is anticipated that creation of a quality proposal to meet all criteria will require combining technologies and/or companies, which can be time consuming and challenging. It is recommended that proposers submit a teaming profile in order to engage with potential collaborators as soon as possible to form the best teams possible. Teaming profiles can be submitted at solutions.arpa-h.gov/teaming.

4.3. MANDATORY PRE-PROPOSAL DISCUSSION

Pre-Proposal Discussions are required in order to submit a proposal. At least one team member from each proposing team must participate in a discussion in order to submit. See Appendix A for the suggested slide deck format. No written feedback will be provided. Discussions are intended to facilitate communication with the MOCS team and ensure alignment with program needs. Verbal feedback will be provided during the discussion to ensure proposers are making an informed decision on devoting time and resources to a full proposal.

ARPA-H will not be using information obtained during the discussion in the award selection process and it will not be subject to review criteria. Any feedback provided during the discussion may be incorporated into the full proposal at the proposer's discretion.

Discussions may be scheduled by submitting a request through the ARPA-H questions portal (solutions.arpa-h.gov/ask-a-question). Please select the MOCS discussion option to request a booking link.

4.4. PROPOSAL SUBMISSIONS

Full proposal submissions are due by the date listed in the ISO Summary Information (Section 1). See Appendix B for the required Proposal format. The government may, at its discretion, reach out during the evaluation process to request clarifications via a virtual discussion.

4.5. SUBMISSION INFORMATION

Proposals submitted in response to this solicitation must be written in English and must be consistent with the content and formatting requirements of Appendix B (Full Proposal Format and Instructions).

Appendix A (Pre-Proposal Discussion Template and Instructions) provides suggested format and content for the Pre-Proposal Discussion slide deck to be displayed during the discussion.

Proposers are responsible for submitting proposals 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.

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."

"Confidential" is a governmental classification and should not be used to identify proprietary business information.

ARPA-H is responsible for handling submissions to the extent permitted under applicable federal law, including the Freedom of Information Act (FOIA).

5. SUBMISSION REVIEW AND EVALUATION PROCESSES

5.1. CONFORMING PROPOSAL SUBMISSIONS

Proposals that fail to include required information or documentation may be deemed non-conforming and may be removed from further consideration and/or rejected without further review. Proposers will be notified of non-conforming determinations via email correspondence.

Please note that ARPA-H reserves the right, at its discretion, to reject proposals as non-conforming if they are determined to be duplicative of previously submitted materials.

5.2. PROPOSAL REVIEW PROCESS

ARPA-H will conduct a scientific and technical review of each conforming full proposal, evaluating proposals on how well the submission meets the criteria stated in this ISO. At a minimum, proposers will be provided with notification of the government's decision on whether the proposal was selected for negotiation of an award. Notification of the government's decision will be provided to the primary technical point of contact included in the solutions tool.

5.3. EVALUATION CRITERIA FOR PROPOSALS

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

5.3.1. CRITERIA 1: OVERALL SCIENTIFIC AND TECHNICAL MERIT

The proposed technical approach is innovative, feasible, and complete. The proposal meets or exceeds the requirements outlined in Section 2 of this ISO. 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 IP rights structure and software components will potentially impact the ability to commercialize the technology and adhere to open-source solutions and/or standards.

5.3.2. 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 will assess the bio-sketches provided for the performer team members including the PI, Project Manager, and any other key personnel on the project team the performer desired to include or as requested by ARPA-H.

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

Proposals will be evaluated on the potential impact on clinical practice and on research and development including whether the proposal has the potential to improve health outcomes, to transform clinical medicine, and to create new opportunities for basic research in the maternal care space. Diverse user needs will be considered including patient, care teams, health systems, insurance payers, malpractice attorneys as well as diverse practice conditions. Questions such as "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?" will be heavily considered.

5.3.4. CRITERIA 4: ASSESSMENT OF PROPOSED COST/PRICE

All proposals will be evaluated to determine the reasonableness or value of the estimated budget proposed to accomplish the work in Task Description Document (TDD). Analysis may be performed to ensure proposed costs are realistic for the technical and management approach, accurately reflect the technical goals and objectives of the solicitation, and the proposed costs are consistent with the proposer's TDD and reflect a sufficient understanding of the costs and effort needed to successfully accomplish the proposed technical approach. The costs for all 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. As consideration of commercial applications is required, appropriate cost sharing may be part of 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.

5.4. HANDLING SELECTION SENSITIVE INFORMATION

It is the intent of ARPA-H to protect all proposals as selection sensitive information and to disclose their contents only for the purpose of evaluation, and only to screened personnel for authorized reasons, to the extent permitted under applicable laws, including the Freedom of Information Act (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.

5.5. 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. 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 or without 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. 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 is required to disclose all facts relevant to a potential OCI involving the Proposer, its organization, and/or any proposed team member. The Proposer shall submit a mitigation plan, which is a description of the action the proposer has taken to avoid, neutralize, or mitigate the stated OCI. The government may require the Proposer to provide additional information to assist the government in evaluating the OCI mitigation plan.

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

6.2.1. AGENCY SUPPLEMENTAL OCI POLICY

ARPA-H restricts performers from concurrently providing professional support services, including Advisory and Assistance Services or similar contracted support services, in addition to performing as a research and development (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 providing the support.

6.2.2. RESEARCH SECURITY DISCLOSURES

In accordance with National Security Presidential Memorandum-33 (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 Policy Requirements Document (Attachment #3).

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. As TA2 will likely require combining multiple technologies, all IP agreements may be submitted with the proposal, but must be submitted prior to contract award to mitigate the risk that disagreements over IP could delay commercialization.

NOTE: IP rights assertions will be evaluated under Section 5.4.1 Criterion 1.

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. ELECTRONIC INVOICING AND PAYMENTS

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

6.6. 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 EHRs, 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.