

**Scaling Health Applications Research for Everyone (SHARE)
Broad Agency Announcement (BAA)**

**The Advanced Research Projects Agency for Health (ARPA-H)
Scaling Health Applications Research for Everyone (SHARE)
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SP4701-23-B-0002



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A. OVERVIEW INFORMATION

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

Document Type: Combined BAA / Synopsis

Solicitation Number: SP4701-23-B-0002

Classification Code: A -- Research & Development

Set Asides: N/A

North American Industry Classification System (NAICS) Codes: 541714 *Research and Development in Biotechnology (except Nanobiotechnology)*

Product Service Code (PSC): AN12, *Health R&D Services; Health care services; Applied Research*

Announcement Type: Initial Announcement

Part: U.S. Government Procurements

Subpart: Services

Contracting Office Address:

DLA Contracting Services Office – Philadelphia (DCSO-P)

Attn: Mark Sullivan, Bldg. 6, Station 6D412

700 Robbins Street

Philadelphia, PA 19111-5092

Dates:

- **Posting Date:** August 04, 2023
- **Optional Abstract or Proposals Due Date and Time:** September 07, 2023 @ 12:00pm Est.

Concise Description of the Funding Opportunity: ARPA-H seeks to adapt Department of Defense (DoD) and other related Government entities health innovations more broadly to all Americans. For example, pediatric and geriatric populations would benefit from many underlying innovations but cannot use them “out of the box.” These branch projects developed for this BAA would identify and address the unique technical challenges inherent in translating this work to include dosage, form factor, and manufacturing capacity. Proposals should demonstrate prior success and detail the specific technical work required to tailor these solutions.

Anticipated Individual Awards: Multiple awards are anticipated.

Potential Award Instruments: Firm Fixed Price or Cost Reimbursement (cost-plus-fixed fee, cost no fee, cost-plus-award-fee) type contracts, or a combination of firm fixed price and cost reimbursement line items.

Point of Contacts (POC) Contracting: Contracting Officer, Mark Sullivan, Email:

Mark.Sullivan@dla.mil, Phone: 215-922-8346, **Contract Specialist, Michelle Harrison,** Email:

Michelle.Harrison@dla.mil, Phone: 267-432-2731

Submission of Abstracts/Proposals: Please submit all abstracts and proposals to both DCSO-P, R&D Mailbox RandD.DCSO@dla.mil and ARPA-H Mailbox DIGIHEALS@ARPA-H.GOV. Please also send to the Contracting POCs listed above.

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B. FULL TEXT OF ANNOUNCEMENT

B.1 Funding Opportunity Description

This publication constitutes a combined synopsis and Broad Agency Announcement (BAA) for the acquisition of research and development in accordance with Federal Acquisition Regulation (FAR) 35.016. ARPA-H posts this funding opportunity within the framework of a BAA because of its widely recognized use in funding basic and applied research as well as the ability to negotiate multiple contract types in accordance with the FAR. Any resultant award negotiations will follow all pertinent laws and regulations. No other solicitation will be issued. Only the information provided in this notice is available. Requests for other forms of solicitations shall be disregarded.

The Government reserves the right to award all, some, or none of the proposals submitted. The BAA will open for an initial round of abstract and proposal submissions on August 4, 2023, and close on September 7, 2023 @ 12:00pm est. Future openings for abstract and proposal submissions will be determined at a later date and an amendment to this BAA will be posted on SAM.gov specifying the dates and areas of interest. During the open period, offerors may submit optional abstracts or proposals up until the closing date and time listed above.

The mission of ARPA-H is to accelerate better health outcomes for all Americans by advancing innovative research that addresses society's most challenging health problems. Awardees will develop groundbreaking new ways to tackle health-related challenges through high potential, high-impact biomedical and health research. For this BAA, ARPA-H seeks proposals that will transform health innovations into healthcare solutions that can be adapted to health systems (e.g., medical devices or health records systems) or scaled to larger application areas.

ARPA-H specifically excludes:

- 1) Proposals that represent an evolutionary or incremental advance in the current state of the art (e.g., it is NOT sufficient to merely apply the same technology to new populations; instead contractors should highlight the unique extensions required to transition technology to a new population / health system or expand the scale of the application);
- 2) Proposals that fail to address the objectives of the program;
- 3) Proposals directed towards policy changes, traditional education and training, or center coordination and construction of physical infrastructure, which are outside the scope of the ARPA-H mission (note that infrastructure required to perform the proposed research will be considered on a case-by-case basis and must be essential to the goals of the research effort);
- 4) Basic research proposals where the link to improved health outcomes or improvements in the reliability of health systems is unclear.

C. SHARE PROGRAM

C.1 Program Overview

ARPA-H's mission is to accelerate better health outcomes for all Americans. This solicitation, "Scaling

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Health Applications Research for Everyone (SHARE),” seeks to capitalize on and expand existing government R&D investments. Those innovations are often, but not limited to, those developed by the Department of Defense (DoD). Inside DoD, the Defense Research Projects Agency (DARPA) is an exemplar model for this type of innovation.

SHARE extends health innovations—or innovations from other domains that could be adapted to health—to accelerate better health outcomes more broadly. In the DoD context, these innovations are developed to support a specific population: the warfighter. Under SHARE, these technologies would be adapted to other populations, such as pediatric and geriatric. Proposals to the SHARE program may align with the four ARPA-H thrust areas (Health Science Futures, Proactive Health, Scalable Solutions, or Resilient Health Systems), and contractors may leverage services provided by the ARPA-H Project Accelerator Transition Innovation Office (PATIO), including:

- Building trust with target communities
- Increasing accessibility so these solutions would be available to as many Americans as possible
- Decreasing cost so Americans can afford these solutions
- Testing of minimum viable products (MVPs)
- Clinical trial support, to include readiness and ensuring diverse and representative populations
- Regulatory support
- Entrepreneurship education

C.2 Program Objectives

The purpose of this program is to increase the probability of adapting and scaling high-risk and potentially disruptive new technologies and solutions across the full spectrum of health-related applications. Projects will focus on adapting, scaling, and transition challenges associated with the underlying technology. These can be related to technology integration, manufacturing, and proving efficacy, building capacity, and adapting the technology to the health sector. The specific objectives of the program are to develop proven demonstrations of efficacy in civilian populations or civilian health infrastructure, receive regulatory approvals, eliminate barriers to manufacturing or distribution, secure key partnerships with commercial entities, user-groups, and other stakeholders, and to attract outside investment.

Building on the groundbreaking successes achieved by DARPA, DIU, and other government entities, this program aims to translate these achievements into transformative civilian healthcare solutions. Applicants **MUST** demonstrate three things:

1. **Technical Feasibility.** Prior success within a DoD/USG context, substantiated by advancements like verified progress towards FDA approval, independent verification and validation, or successful operational prototypes.
2. **An “ARPA-H/ard” Pivot & Target Population and/or Health Application.** An R&D plan for a compelling, innovative prototype that adapts existing technology to the unique physiological and psychosocial considerations of pediatric and geriatric populations, other identifiable beneficiary, or health-related system.

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3. Clear Mission Alignment. Alignment with the ARPA-H mission and one or more ARPA-H Focus Areas (Health Science Futures, Scalable Solutions, Proactive Health, Resilient Health Systems)

C.3 Scope of Work

The successful contractor(s) will:

- Leverage the critical groundwork laid by any DoD/USG like DARPA project while clearly articulating the specific R&D effort required to adapt these innovations to civilian healthcare settings.
- Conduct an in-depth feasibility study that appreciates the unique clinical, physiological, and social considerations of broad populations or health systems.
- Develop a prototype or pilot program through rigorous R&D that transforms existing DoD or other USG funded technology to the specific needs of these new demographics or health infrastructure.
- Develop a plan to commercialize or scale the prototype or technology, incorporating successful strategies for transitioning technologies from demonstration to market-readiness.
- Establish a collaborative framework with relevant stakeholders, ensuring a comprehensive approach to adaptation and implementation.
- Conduct ongoing evaluation and quality improvement activities to ensure the technology meets the needs of the target populations and maintains high standards of care.

C.5 Program Deliverables

Specific deliverables will be determined at contract award. Example deliverables include:

- R&D Plan and Scale-Up Strategy Report
- Feasibility study report for different or broader populations
- Prototype development or pilot program plan
- Stakeholder engagement strategy
- Ongoing evaluation and quality improvement plan

C.6 Areas of Interest (See Attachment B)

The Areas of Interest for this BAA are listed in Attachment B. ARPA-H may amend Attachment B as needed to add, modify, or remove Areas of Interest. Amendments modifying Attachment B will be posted to the government-wide Contract Opportunities portal at <https://www.SAM.gov>.

D. GENERAL REQUIREMENTS

D.1 Proposing Teams

It is expected proposals will involve teams with the expertise needed to achieve the goals of the areas of interest stated above. Specific content, communications, networking, and team formation are the sole

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responsibility of the contractor. Contractors must submit a single, integrated proposal led by a Principal Investigator (PI), under a single prime awardee² that addresses all program Phases, as applicable. Contractors may only submit one proposal as the prime contractor.

D.2 General Award Information

Multiple awards are anticipated. The resources made available under this BAA, and number of awards made will depend on the quality of the proposals received and the availability of funds. ARPA-H with the assistance of the DLA Contracting Services Office – Philadelphia (DCSO-P) reserves the right to make multiple awards, a single award, or no awards.

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this BAA and to make awards without negotiations with contractors. The Government also reserves the right to conduct negotiations if it is later determined to be necessary. Additionally, ARPA-H reserves the right to accept proposals in their entirety or to select only portions of proposals for negotiation and award. The Government reserves the right to fund proposals in phases, including as optional phases, as applicable.

Proposals identified for negotiation are expected to result in a Firm Fixed Price or Cost Reimbursement contract type. Selection of contract type will be based upon consideration of the nature of the work proposed, the required degree of interaction between parties, and other factors. The Government may request additional necessary documentation, tailored to the individual proposals once it makes the award instrument determination. The Government reserves the right to remove proposals from award consideration should the parties fail to reach agreement on award terms, conditions, and/or cost/price within a reasonable time, and/or if the contractor fails to timely provide requested additional information.

D.3 Contract Type

ARPA-H intends to award FFP or cost-reimbursement (FAR Subpart 16.3) contracts under this BAA. ARPA-H will consider proposals based on cost (cost-plus-fixed-fee, cost (no fee), cost-plus-award-fee, cost-plus-fixed-fee completion, or cost-sharing), or fixed-price, including FFP or FFP Level of Effort (LOE) (FAR Subpart 16.2) contracts, but reserves the right to award other contract types when ARPA-H in its sole discretion deems such award to be in the best interests of the Government. Submittals based on contract types other than those listed above, may be rejected and may not be reviewed or evaluated at the government's discretion.

D.4 Eligibility Information

All responsible sources capable of satisfying the Government's needs may submit a proposal. However, to be eligible for award, all prospective offerors must meet certain minimum standards pertaining to financial resources, adequacy of accounting systems, ability to comply with performance schedules, prior record of past performance, integrity, organization structure, experience, operational controls, technical skills facilities and equipment. For additional information and guidance concerning qualifications and standards for responsibility of prospective contractors, please refer to Part 9 of the

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Federal Acquisition Regulation (FAR).

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

FFRDCs

FFRDCs are subject to applicable direct competition limitations and cannot propose to this BAA in any capacity unless they meet the following conditions. (1) FFRDCs must clearly demonstrate that the proposed work is not otherwise available from the private sector. (2) FFRDCs must provide a letter, on official letterhead from their sponsoring organization, that (a) cites the specific authority establishing their eligibility to propose to Government BAAs and compete with industry, and (b) certifies the FFRDC's compliance with the associated FFRDC sponsor agreement's terms and conditions. These conditions are a requirement for FFRDCs proposing to be awardees or subcontractors.

Government Entities

Government Entities (e.g., Government/National laboratories, military educational institutions, etc.) are subject to applicable direct competition limitations. Government Entities must clearly demonstrate that the work is not otherwise available from the private sector and provide written documentation citing the specific statutory authority and contractual authority, if relevant, establishing their ability to propose to Government BAAs and compete with industry. This information is required for Government Entities proposing to be awardees or subcontractors.

Other Applicants

ARPA-H will prioritize awards in accordance with Public Law No. 117-328 (Section 499A(n) of the PHSA). Without limiting the foregoing ARPA-H will prioritize awards to domestic entities (organization and/or individuals) that will conduct funded work in the US. However, non-US entities may participate to the extent such participants comply with nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. Non-US entities are encouraged to collaborate with domestic US entities. 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. § 3059)) or entities suspended or debarred from business with the Government.

D.5 Debriefs

No debrief after review of abstracts will be provided as no award can result from an abstract.

D.6 Organizational Conflicts of Interest (OCI)

Contractors are required to identify and disclose all facts relevant to potential OCIs involving the contractor's organization and any proposed team member (proposed subcontractor) as prescribed in FAR subpart 9.5. Regardless of whether the contractor has identified potential OCIs under this section, the contractor is responsible for providing a disclosure with its proposal. The disclosure must include the contractors, and as applicable, proposed team members' OCI mitigation plans. The OCI mitigation plan(s) must include a description of the actions the contractor has taken, or intends to take, to prevent the existence of conflicting roles that might bias the contractor's judgment and to prevent the contractor from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the

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disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4. The disclosure and mitigation plan(s) do not count toward the page limit (see sections E.3 and E.4).

Agency Supplemental OCI Policy

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

If any professional support services are being 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;
- Identification of proposed team member (proposed subcontractor) providing the support; and
- An OCI mitigation plan in accordance with FAR 9.5.

Government Procedures

The Government will evaluate OCI mitigation plans to avoid, neutralize, or mitigate potential OCI issues before award and to determine whether it is in the Government's interest to grant a waiver. The Government will only evaluate OCI mitigation plans for proposals determined selectable under the BAA evaluation criteria and funding availability.

The Government may require contractors to provide additional information to assist the Government in evaluating the OCI mitigation plan.

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

D.7 Subcontracting Plans

For proposed contract awards exceeding \$750,000.00 large businesses and non-profits (including educational institutions) shall provide a Small Business Subcontracting Plan that contains all elements required by the most recent versions of FAR 19.704, FAR 52.219-9 and DFARS 252.219-7003. The Plan must be submitted as an attachment to the Proposal Adequacy Checklist and will not be included in the page count. If a company has a Master or Individual Subcontracting Plan, as described in FAR 19.701 or a Comprehensive Subcontracting Plan described in DFARS 219.702, a copy of the Plan shall also be submitted as an attachment to the Proposal Adequacy Checklist in attachment A.

Plans will be reviewed for adequacy, ensuring that the required information, goals, and assurances are

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included. If an apparent successful offeror fails to negotiate a Plan acceptable to the contracting officer within the time limit prescribed by the contracting officer, the offeror will be ineligible for award. Offerors shall propose a plan that ensures small businesses (inclusive of SDBs, WOSBs, HUBZone, VOSBs and SDVOSBs) will have the maximum practicable opportunity to participate in contract performance consistent with efficient performance.

As a baseline, Offerors shall, to the best extent possible, propose realistic goals to ensure small business participation in accordance with the current or most recent fiscal year subcontracting goals found on the DoD Office of Small Business Program website at: <https://business.defense.gov/About/Goals-and-Performance/>. Please refer to the website for most accurate list of goals. If proposed goals are below the statutory requirements, then the offeror shall include in the Plan a viable written explanation as to why small businesses are unable to be utilized and what attempts were taken to ensure that small business were given the opportunity to participate in the effort to the maximum extent practicable.

a. Subcontracting Resources -

Subcontracting can be a good way to participate in the contracting process. The following is a list of potential resources that may assist in locating potential subcontracting partners/opportunities/resources:

*Companies Participating in DoD Subcontracting Program Report -

<https://business.defense.gov/Acquisition/Subcontracting/Subcontracting-For-Small-Business/>

*DoD OSBP Prime Contractors and Subcontractors with Subcontracting Plans -

<https://business.defense.gov/Acquisition/Subcontracting/Subcontracting-For-Small-Business/>

*DefenseLink ≥ \$7.0 M Award Notices - <https://www.defense.gov/News/Contracts/>

*SBA Dynamic Small Business Search - https://web.sba.gov/pro-net/search/dsp_dsbs.cfm

*Electronic Subcontracting Reporting System (eSRS) - <https://www.esrs.gov/>

*DLA SBIR/STTR Search – Website or Brochure -

<https://www.dla.mil/Portals/104/Documents/SmallBusiness/Small%20Business%20-%20SBIP%20-%20January%202020.pdf?ver=2019-12-27-081121-487>

*DoD Procurement Technical Assistance Centers (PTAC) - <https://www.aptac-us.org/>

*U.S. Small Business Administration (SBA) Subcontracting Opportunities Directory - <https://www.sba.gov/document/support-directory-federal-government-prime-contractors-subcontracting-plans>

*U.S. Small Business Administration Subcontracting Network (SubNet) -

https://eweb1.sba.gov/subnet/client/dsp_Landing.cfm

In accordance with FAR 5.206 Notices of Subcontracting Opportunities, the following entities may transmit a notice to the GPE to seek competition for subcontracts, to increase participation by qualified HUBZONE small business, small, small disadvantaged, women-owned small business, veteran-owned small business, and service-disabled veteran-owned small business concerns, and to meet established subcontracting plan goals:

- (1) A contractor awarded a contract exceeding the simplified acquisition threshold that is likely to result in the award of any subcontracts.
- (2) A subcontractor or supplier, at any tier, under a contract exceeding the simplified acquisition threshold, that has a subcontracting opportunity exceeding \$15,000.

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The notices must describe:

- The business opportunity
- Any prequalification requirements; and
- Where to obtain technical data needed to respond to the requirement

In addition, another place prime contractors may post solicitations or sources sought notices for small business is the U.S. SBA SUB-Net: https://eweb.sba.gov/gls/dsp_sbabanner.cfm. The SUB- Net database provides a listing of subcontracting solicitations and opportunities posted by large prime contractors and other non-federal organizations.

E. APPLICATION INSTRUCTIONS AND SUBMISSION INFORMATION

E.1 Markings for Abstracts and Proposals

Contractors 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.” Research and Development is considered CUI. In accordance with the Department of Defense (DoD) phased CUI Program, any form of communication or documentation containing CUI must carry the appropriate markings, i.e., header and footer identifying the document as “CUI” and a completed CUI Designation Indicator.

CUI

Source Selection Information – See FAR 2.101 and 3.104

Proposals shall include all proprietary claims to results, prototypes, or systems supporting or necessary for the use of the research, results, or prototypes. If there are no proprietary claims, then the proposal must include a statement to that effect. Do not put proprietary data or markings in the Statement of Work (SOW). Proposals containing data that is not to be disclosed to the public for any purpose or used by the Government except for review purposes shall include the following sentences in accordance with FAR 52.215- 1e(1) and (2) on the cover page) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of-or in connection with-the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

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In accordance with FAR 3.104-4, your company is required to mark all material that may be Source Selection Information as described at paragraph (10) of the “Source Selection Information” definition in FAR 2.101, to include the cover page and each page that may contain source selection information, with the legend “Source Selection Information – See FAR 2.101 and 3.104”. Although the information in paragraphs (1) through (9) of the definition in 2.101 is considered to be Source Selection Information whether or not marked, all reasonable efforts must be made to mark such material with the same legend. If you are unsure if particular information is Source Selection Information as defined in FAR 2.101, consult the Contracting Officer POC listed in the BAA. In addition, your company is required to mark all material that may be procurement sensitive, or defense covered information with the legend “Controlled Unclassified Information” (CUI). If the information is also source selection information both markings must be present.

Note: Source Selection markings are required for all documents submitted in response to this BAA, which includes Abstracts and Technical/Price Proposals (when applicable).

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.

This announcement and any references to external websites herein constitute the total solicitation. If contractors cannot access the referenced material posted in the announcement found at <https://www.sam.gov/>, please contact the contracting officer listed in Section A of the BAA.

E.2 Content and Form of Application Submission

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

All submissions must be written in English with type not smaller than 12-point font. Smaller font may be used for figures, tables, and charts. Documents submitted must be clearly labeled with the ARPA-H BAA number, contractor organization, and proposal title/proposal short title.

Proposal prices and all other terms and conditions must remain valid for 180 days from the submission date of the proposal. Information in the technical proposal that is deemed by the Respondent to be proprietary must be clearly marked as proprietary information.

This announcement and any references to external websites herein constitute the total solicitation. If contractors cannot access the referenced material posted in the announcement found at <https://www.sam.gov/>, please contact the contracting officer listed in Section A of the BAA.

E.3 Abstract Format

Contractors are not required to but are welcome to submit an abstract in advance of a full proposal submission to minimize effort and reduce the potential expense of preparing an out-of-scope proposal. While not required, abstracts are intended for contractors to receive a recommendation from ARPA-H

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to submit or not submit a full proposal. Based on evaluation of the abstract, ARPA-H may recommend contractors not submit a full proposal. The cover sheet should be clearly marked “ABSTRACT,” and the total length should not exceed 3 pages in length. The maximum page count excludes the cover page and the Rough Order of Magnitude. The Government will not review pages beyond 3; and any abstract submitted that exceeds 3 pages will only be reviewed at ARPA-H’s discretion. Official transmittal letter is not required.

E.3.1 Cover Page

The cover page should follow the same format as the full proposal format, as detailed below in Volume I, Technical and Management Proposal. The cover page does not count towards the abstract 3-page limit.

E.3.2 Concept Summary

Describe the proposed concept with minimal jargon and explain how it addresses the topic area(s) of the BAA.

E.3.3 Innovation and Impact

Clearly identify the health outcome(s) sought and/or the problem(s) to be solved with the proposed technology concept. Describe how the proposed effort represents an innovative and potentially revolutionary solution to the technical challenges posed by the BAA. Explain the concept’s potential to be disruptive compared to existing or emerging technologies. Describe how the concept will have a positive impact on at least one of ARPA-H’s mission areas.

To the extent possible, provide quantitative metrics in a table that compares the proposed technology concept to current and emerging technologies and includes:

- State of the art / emerging technology “baseline”
- Target for proposed technology in its final, commercializable form
- Target for proposed technology at the end of the proposed ARPA-H project

E.3.4 Proposed Work

Describe the final deliverable(s) for the project, one or two key interim milestones, and the overall technical approach used to achieve project objectives. Discuss alternative approaches considered, if any, and why the proposed approach is most appropriate for the project objectives. Describe the background, theory, simulation, modeling, experimental data, or other sound engineering and scientific practices or principles that support the proposed approach. Provide specific examples of supporting data and/or appropriate citations to the scientific and technical literature. Identify commercialization challenges to be overcome for the proposed technology to be successful in the health market.

Describe why the proposed effort is a significant technical challenge and the key technical risks to the project. At a minimum, the abstract should address:

- Does the approach require one or more entirely new technical developments to succeed?
- How will technical risk be mitigated?

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E.3.5 Team Organization and Capabilities

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

E.3.6 Rough Order of Magnitude (ROM)

Please include a ROM estimate of timeline and federal funds requested, as well as the total project cost. The ROM should also include a breakdown of the work by direct labor, labor rates, subcontracts, materials, equipment, other direct costs (e.g., travel), indirect costs, profit, and any other relevant costs. The below table may be used for this breakdown:

Cost Category	Amount
Direct Labor	
Indirect Costs	
Subcontractors	
Materials	
Equipment	
Travel	
Other Direct Costs	
Indirect Costs	
Profit	
Total	

However, contractors should ensure the ROM encompasses all applicable costs and should modify the above to best reflect the contractor's expected costs. The ROM does not count toward the page limit.

E.4 Full Proposal Format

Proposals must be in the format given below. The typical proposal should express a consolidated effort in support of one or more related technical concepts or ideas. Disjointed or unrelated efforts should not be included in a single proposal. Proposals shall consist of two volumes: 1) Volume I, Technical and Management Proposal (composed of 3 parts), and 2) Volume II, Cost Proposal. The Cover Page shall be no more than 1 page in length. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8- 1/2 by 11- inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the ARPA-H BAA number, contractor organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for

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review. The maximum page count for Volume 1 is 30 pages; excluding the Statement of Work (SOW). However, for all sections, ARPA-H encourages conciseness to the maximum extent practicable. Volume I should include the following components:

E.4.1 Volume I, Technical and Management Proposal

Technical Proposals shall consist of three parts:

Section I – Administration

Section II – Summary of Proposal

Section II – Detailed Proposal Information

Section I: Administrative

Cover Page

1. BAA number;
2. Technical area;
3. Proposal title;
4. Prime Awardee/entity submitting proposal;
5. Type of organization, selected among the following categories: LARGE BUSINESS, SMALL DISADVANTAGED BUSINESS, OTHER SMALL BUSINESS”, Historically Black Colleges and Universities (HBCUs), Minority Institution (MI), OTHER EDUCATIONAL, OR OTHER NONPROFIT (including non-educational government entities) (NOTE: The Small Business Administration’s (SBA) size standards determine whether or not a business qualifies as small.). Size standards may be found here: <https://www.ecfr.gov/current/title-13/chapter-I/part-121#121.201>
6. Date of submission;
7. Other team members (if applicable) and type of organization for each;
8. Proposal title;
9. Technical point of contact (POC) to include: salutation, last name, first name, street address, city, state, zip code, telephone, email;
10. Administrative POC to include: salutation, last name, first name, street address, city, state, zip code, telephone, email; and
11. Total dollar amount of proposal

Section II: Summary of Proposal

Proposal Content

- A. Technical rationale, technical approach, and constructive plan for accomplishment of technical goals in support of innovative claims and deliverable creation. (In the full proposal, this section should be supplemented by a more detailed plan in Section III of the Technical and Management Proposal.)
- B. Innovative claims for the proposed research. This section is the centerpiece of the proposal and should succinctly describe the uniqueness and benefits of the proposed

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approach relative to the current state-of-art alternate approaches.

- C. Deliverables associated with the proposed research and the plans and capability to accomplish technology transition and commercialization. Include in this section all proprietary claims to the results, prototypes, intellectual property, or systems supporting and/or necessary for the use of the research, results, and/or prototype. If there are no proprietary claims, this should be stated. See the section entitled intellectual property for more information.
- D. General discussion of other research in this area. Contractors must disclose current and previous research and development (R&D) efforts related to the proposed research and identify any challenges associated with such efforts, including any scientific or technical barriers encountered in the course of such efforts or challenges in securing sources of funding, as applicable.
- E. A clearly defined organization chart for the program team. Please also include information describing (1) the programmatic relationship of team member; (2) the unique capabilities of team members; (3) the task of responsibilities of team members; (4) the teaming strategy among the team members; and (5) the key personnel along with the amount of effort to be expended by each person during each year.

Section III: Detailed Proposal Information

A. Executive Summary:

Provide a synopsis of the proposed project, including answers to the following questions:

- What is the proposed work attempting to accomplish or do?
- How is the proposed work leading to improved health outcomes or improvements in the reliability of health systems?
- How is it done today, and what are the limitations?
- What is innovative in your approach?
- What are the key technical challenges in your approach, and how do you plan to overcome these?
- Who or what will be affected, and what will be the impact if the work is successful?
- How much will it cost, and how long will it take?

B. Goals and Impact:

Clearly describe what the team is trying to achieve and the difference it will make (qualitatively and quantitatively) if successful. Describe the innovative aspects of the project in the context of existing capabilities and approaches, clearly delineating the uniqueness and benefits of this project in the context of the state of the art, alternative approaches, and other projects from the past and present. Describe how the proposed project is revolutionary and how it significantly rises above the current state-of-the-art. Describe the deliverables associated with the proposed project and any plans to commercialize the technology, transition it to a customer, or further the

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work.

C. Technical Plan:

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

D. Technical Factors

D.1 Overall Scientific and Technical Merit

Contractors must explain the proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided must be complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible.

D.2 Past Performance, Contractor's Capabilities and/or Related Experience

Contractors must show that the technical team has the expertise and experience to accomplish the proposed tasks. The contractor'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. Similar efforts completed/ongoing by the contractor in this area are fully described including identification of other Government entities.

D.3 Potential Contribution and Relevance to the ARPA-H Mission

Contractors must show potential future R&D, 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. Degree to which the proposed project has the potential to transform biomedicine. Potential for the project to take an interdisciplinary approach. In addition, the evaluation will take into consideration the extent to which the proposed intellectual property (IP) rights structure will potentially impact the Government's ability to transition the technology.

E. Management Plan:

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Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. A PI for the project must be identified, along with a description of the team's organization, including the breakdown by Technical Area. All teams are strongly encouraged to identify a Project Manager/Integrator to serve as the primary POC to communicate with the ARPA-H PM, IV&V team, and Contracting Officer Representative, coordinate the effort across co-performer, vendor, and subcontractor teams, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables.

Provide a clear description of the team's organization including an organization chart that includes, as applicable: the programmatic relationship of team members; the unique capabilities of team members; the task responsibilities of team members, the teaming strategy among the team members; and key personnel with the amount of effort to be expended by each person during each year. Provide a detailed plan for coordination, including explicit guidelines for interaction among collaborators/subcontractors of the proposed effort. Include risk management approaches. Describe any formal teaming agreements required to execute this program.

F. Metrics:

Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Describe any specialized facilities to be used as part of the project, the extent of access to these facilities, and any biological containment, biosafety, and certification requirements. Discuss any work in closely related research areas and previous accomplishments.

G. Statement of Work (SOW) NOT INCLUDED IN PAGE COUNT:

The SOW should provide a detailed task breakdown, citing specific tasks for each TA, and their connection to the milestones and program metrics. Each Phase of the program should be separately defined. The SOW must not include proprietary information.

For each task/subtask, provide:

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

It is recommended the SOW be developed so that each TA and Phase of the program is separately defined.

H. Schedule and Milestones:

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Provide a detailed schedule showing tasks (task name, duration, work breakdown structure element as applicable, performing organization), milestones, and the interrelationships among tasks. The task structure must be consistent with that in the SOW. Measurable milestones should be clearly articulated and defined in time relative to the start of the project.

I. Technology Transfer Plan:

Provide information regarding the types of partners (e.g., government, private industry) that will be pursued and submit a timeline with incremental milestones toward successful engagement. The plan should include a description of how ARPA-H will be included in the development of potential technology transfer relationships. If the Technology Transfer Plan includes the formation of a start-up company, a business development strategy must also be provided.

E.4.2 Volume II, Cost/Price Proposal

Note: It is expected that the effort will leverage all available relevant prior research to obtain the maximum benefit from the available funding. ARPA-H recognizes that undue emphasis on cost may motivate contractors to offer low-risk ideas with minimum uncertainty and to staff the effort with junior personnel to be in a more competitive posture. ARPA-H discourages such cost strategies.

No page limits apply to the Cost Proposal. The cost proposal shall include total project cost by month. The offeror shall also give a detailed breakdown of the total project costs by each task listed in the technical proposal. If subcontracts are contemplated, the offeror must estimate the total amount of effort to be subcontracted and specify the “burden” or “pass through rate” that will be applied to those subcontracts. Offerors are required to submit certification of current cost or pricing data in accordance with FAR 15.406-2 (Certificate of Current Cost or Pricing Data). The total cost of each major cost element and the make-up of those costs shall be presented in the offeror's proposal. A statement related to the latest DCAA audit and whether the offeror's accounting system has been approved by the DCAA shall be included in the Cost Proposal. State if there are currently negotiated DCAA rates or forward pricing rate agreements and factors being used in the proposal. Include a detailed breakdown of costs by cost category by offeror's calendar or fiscal year:

- Direct Labor - Individual labor categories or person with associated labor hours and unburdened direct labor rates.
- Indirect Costs - Fringe benefit, Overhead, G&A, Cost of Money, etc. (must show base amount and rate)
- Travel - Number of trips, destinations, durations, purpose, etc.
- Subcontracts - A cost proposal is required to be submitted by any proposed subcontractor and “burden” or “pass through rate” shall be clearly stated.
- Materials - Specifically itemized with estimated (or actual) costs.
- Lease Items - Fair market value of lease items and the method used for making such evaluations.

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Sufficient information shall be provided in supporting documents to evaluate the reasonableness and realism of these proposed costs. Additionally, a completed Cost Proposal Adequacy Checklist (Attachment A) shall be included with each proposal submission.

Cost Proposal Format

To ensure all cost proposals receive proper consideration, DLA requires all offerors to follow the same format. Cost proposals that do not conform to the format may not be evaluated or be eligible for award. Cost proposals shall be in the following format: (1) 8.5" x 11"-page size; (2) a header on each page to identify page content and page number; and (3) type font 12-point Times New Roman with 1-inch margins around the page. No page limits apply to cost proposals. The cost proposal must reflect an understanding of the research, perception of risks, and ability to organize and perform the task(s) stated in the technical proposal. Respondents shall submit the following information:

- Part 1 - Overview
- Part 2 - Cost or Pricing Data (certified when requested by the Contracting Officer)
- Part 3 - Work Breakdown Structure
- Part 4 - Proposal Adequacy Checklist (Attachment A)

Part 1 – Overview

- a. **Cost Proposal Cover Sheet:** respondents shall provide the following information:
- (1) BAA Number
 - (2) NAICS code
 - (3) BAA Area(s) of Interest from Section C.6 above
 - (4) Offeror's Technical Point of Contact, including name, telephone number, e-mail address, and mailing address (no post office box)
 - (5) Offeror's Administrative/Contracting Point of Contact, including name, telephone number, e-mail address, and mailing address (no post office box)
 - (6) Contractor's business type selected among the following categories: Large Business, Small Disadvantaged Business (SDB), Other Small Business, HBCU, MI, Other Educational, or Other Nonprofit.
 - (7) CAGE Code
 - (8) Unique Entity Identification (UEI) number
 - (9) Subcontractors participating in the research and estimated cost (if none state "not applicable")
 - (10) Small businesses participating in the research and estimated cost (if none state "not applicable")
 - (11) Historically Black Colleges and Universities or Minority Institutions participating in the research (if none state "not applicable") Performance Period
 - (12) Contract type selected from one of the cost-reimbursement contract types or FFP types.
 - (13) Research title
 - (14) Brief research description

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(15) Total Estimated Cost

(16) Fixed Fee Amount - the fee shall not exceed 10% of the estimated cost (if proposal is for a cost-plus-fixed-fee contract).

b. Accounting System

Offerors shall provide a description of the accounting system proposed for this research and a copy of accounting system approval from Defense Contract Audit Agency (DCAA) or the Department of Health and Human Services (HHS).

c. Approved Rates

Offerors shall provide a statement regarding current negotiated DCAA or HHS rates, factors, forward pricing agreements, and/or other related cost factors and considerations being used in the cost proposal.

d. Audit or Forward Pricing Agreement

Offerors shall provide a copy of the latest audit or forward pricing agreement from DCAA or HHS.

Part 2 – Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data

Offerors shall submit certified cost or pricing data when requested by the contracting officer to support a determination of cost realism for cost proposals with a total estimated value of \$2,000,000.00 or more in accordance with FAR 15.403-4. If the total estimated value is under \$2,000,000.00, offerors shall submit data other than certified cost or pricing data to support a determination of cost realism in accordance with FAR 15.403-3. Offerors shall submit data in accordance with FAR 52.215-20 Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data.

Offerors shall submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408. Offerors shall submit subcontractors' certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments. If the subcontractor will not submit this information to the offerors, this information must be submitted directly to the contracting officer for cost realism analysis.

Small Business concerns or Nontraditional Defense contractors are exempt from the submission of certified cost or pricing data requirements for contracts valued at less than \$7.5 million. However, these entities are still required to submit other than certified cost or pricing data. The term "nontraditional defense contractor," means an entity that is not currently performing and has not performed any contract or subcontract for DoD that is subject to full coverage under the cost accounting standards or prescribed pursuant to 41 U.S.C. 1502 and the regulations implementing such section, for at least the one-year period preceding the solicitation of sources

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by DoD for the procurement (10 U.S.C. 2302(9)).

Part 3 – Work Breakdown Structure

Respondents shall submit a detailed work breakdown structure including all costs in a table format for all research tasks. Respondent shall include at a minimum, the costs cited herein.

Part 4 – Proposal Adequacy Checklist regarding Cost and Pricing Information

Sufficient information should be provided in supporting documents to evaluate the reasonableness and realism of the proposed costs. A cost proposal adequacy checklist from DFARS 252-215-7009, has been included an Attachment to the BAA for guidance (See Attachment A).

Cost Realism Analysis

DLA will perform a cost realism analysis on cost proposals in accordance with FAR 15.404-1(d), Cost Realism Analysis. Realism determination will be based on an evaluation of the cost proposal to determine whether the estimated cost elements are realistic for the proposed research; reflect a clear understanding of the applicable BAA Strategic Focus Areas and are consistent with the proposal research plan.

a. Labor Mix and Indirect Costs

Offerors are required to provide their proposed labor rates and total cost for each labor category. In addition, offerors are required to provide applicable indirect cost rates, which should include, but may not be limited to, G&A, Fringe, Overhead, and Sub-contractor “burden” or “pass through rate.” Offerors are additionally required to provide labor category descriptions that include minimum education, experience, and certification requirements.

- **Direct Labor:** Individual labor categories or person with associated labor hours and unburdened direct labor rates.
- **Indirect Costs:** Fringe benefit, Overhead, G&A, etc. (must show base amount and rate)
- **Travel:** Estimated number of trips, destinations, durations, etc.
- **Subcontracts:** A cost proposal is required to be submitted for any proposed subcontractor, and “burden” or “pass through rate” shall be clearly stated.
- **Materials:** Specifically itemize and identify as estimated or actual costs.

Cost proposals shall include the following summary tables in addition to the vendor’s other cost proposal information:

Labor Category (identify)	Hours	Unburdened Labor Rate	Overhead	G&A	Burdened Labor Rate

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Totals:					

Indirect Costs (%)	
Indirect Cost Rate	
1. G&A	
2. Overhead	
3. Fringe	
4. Subcontractor Burden Rate	

E.4.4 Other Documents

Contractors should include any other required documents, as applicable, in the cost proposal. This may include OCI disclosures, OCI mitigation plans, intellectual property representations and assertions, etc. We do not anticipate any human subjects or animal subjects research to the current topics of interest.,

E.4.5 Additional Proposal Information

Section 508 of the Rehabilitation Act (29 U.S.C. § 749d)/FAR 39.2

All electronic and information technology acquired or created through this BAA must satisfy the accessibility requirements of Section 508 of the Rehabilitation Act (29 U.S.C. § 749d).

Intellectual Property

All contractors must provide a good faith representation that the contractor either owns or possesses the appropriate licensing rights to all intellectual property that will be utilized under the proposed effort. The information will be requested as part of a full proposal request.

Contractors responding to this BAA should appropriately identify any desired restrictions on the Government's use of any Intellectual Property contemplated under the award instrument in question. This includes both noncommercial items and commercial items. Respondents are encouraged to use a format similar to that shown in the table below. If no restrictions are intended, then the proposal should state "NONE."

Technical Data Computer Software To be Furnished With	Summary of Intended Use in the Conduct of the Research	Basis for Assertion	Asserted Rights Category (e.g., Unlimited, Limited, Restricted, or negotiated, as	Name of Person Asserting Restrictions
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Restrictions			defined in FAR 27.401)	
(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)

System for Award Management (SAM) and Unique Identifier Requirements

Regardless of award type, all contractors must be registered in SAM before submitting an abstract. International entities can register in SAM by following the instructions in this link: https://www.fsd.gov/sys_attachment.do?sys_id=c08b64ab1b4434109ac5ddb6bc4bcbb8.

Questions

Interested entities may submit questions to the Contracting Officer and Specialist listed in Section A. Answers to questions received will be posted to www.SAM.gov.

E.4.6 Required Disclosures of Foreign Affiliations or Relationships to Foreign Countries

Respondents submitting abstracts or proposal shall complete a copy of the required disclosure at Attachment C and include it with the abstract or proposal.

F. APPLICATION REVIEW INFORMATION

F.1 Technical Evaluation Criteria

After an initial compliance review, abstracts will be evaluated based only on evaluation criteria #1. Abstracts that are outside the scope of the BAA will not be evaluated further. In addition, Abstracts that do not meet the required program objectives, submission requirements, or do not contain one or more of the required items listed above may be deemed nonresponsive and will not be evaluated further.

Full proposals will be evaluated using Evaluation Criteria #1-3, listed in descending order of importance.

1. Evaluation Criteria #1: Overall Scientific and Technical Merit

Proposals will be evaluated to ensure the proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible.

2. Evaluation Criteria #2: Past Performance, Contractor's Capabilities and/or Related

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Experience

Technical proposals will be evaluated to ensure the proposed technical team has the expertise and experience to accomplish the proposed tasks. The contractor'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. Similar efforts completed/ongoing by the contractor in this area are fully described including identification of other Government entities.

3. Evaluation Criteria #3: Potential Contribution and Relevance to the ARPA-H Mission

Technical proposals will be evaluated to ensure potential future R&D, 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. Degree to which the proposed project has the potential to transform biomedicine. Potential for the project to take an interdisciplinary approach. In addition, the evaluation will take into consideration the extent to which the proposed intellectual property (IP) rights structure will potentially impact the Government's ability to transition the technology.

F.2 Review of Abstracts and Full Proposals

1. Review Process

It is ARPA-H policy to ensure impartial, equitable, comprehensive abstract/proposal evaluations based on the evaluation criteria listed in Section F.1. and to select the source(s) whose proposed solution meets the Government's technical, policy, and programmatic goals.

ARPA-H will conduct a scientific/technical review of each conforming abstract/proposal. Conforming abstracts/proposals comply with all requirements detailed in this BAA; abstracts/proposals that fail to do so may be deemed non-conforming and may be removed from consideration. Abstracts/proposals will not be evaluated against each other since they are not submitted in accordance with a common work statement. ARPA-H's intent is to review abstracts/proposals as soon as possible after they arrive; however, abstracts/proposals reviews may be delayed (e.g., conducted periodically for administrative reasons).

Award(s) will be made to contractors whose proposals are determined to be the most advantageous to the Government, consistent with instructions and evaluation criteria specified in the BAA, and availability of funding.

2. Handling of Source Selection Information

ARPA-H policy is to treat all submissions as source selection information (see FAR 2.101 and 3.104), and to disclose their contents only for the purpose of evaluation. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All ARPA-H support contractors performing this role are expressly prohibited from performing ARPA-H sponsored technical research and are bound by

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appropriate nondisclosure agreements. Subject to the restrictions set forth in FAR 37.203(d), input on technical aspects of the abstracts/proposals may be solicited by ARPA-H from non-Government consultants/experts who are strictly bound by the appropriate non-disclosure requirements.

Information may also be provided to Courts and the U.S. Government Accountability Office, to the extent that the information is necessary for compliance with federal law or a court order.

3. Federal Awardee Performance and Integrity Information (FAPIS)

Per 41 U.S.C. § 2313, as implemented by FAR 9.103 and 2 CFR § 200.205, prior to making an award above the simplified acquisition threshold, ARPA-H is required to review and consider any information available through the designated integrity and performance system (currently FAPIS). Entities can comment on any information about themselves entered in the database, and ARPA-H will consider any comments, along with other information in FAPIS or other systems, prior to making an award.

F.3 Adjectival Technical Ratings

Proposals will be assigned a rating on each evaluation factor from the adjectival ratings below.

Factor 1 – Overall Scientific and Technical Merit

Acceptable (A): Response demonstrates the proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible. No deficiencies are identified in the response.

Unacceptable (U): Response does not demonstrate the proposed technical approach is innovative, feasible, achievable, and complete. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible. No deficiencies are identified in the response. Response may contain some strengths, but probability of success is low as the offeror's response contains significant weaknesses or deficiencies that are unlikely to be corrected through negotiations or clarifications.

Factor 2 – Past Performance, Contractor's Capabilities and/or Related Experience

Acceptable (A): Response demonstrates the proposed technical team has the expertise and experience to accomplish the proposed tasks. The contractor'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. Similar efforts completed/ongoing by the contractor in this area are fully described including identification of other Government entities. No deficiencies are identified in the response.

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Unacceptable (U): Response does not demonstrate the proposed technical team has the expertise and experience to accomplish the proposed tasks. The contractor'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. Similar efforts completed/ongoing by the contractor in this area are fully described including identification of other Government entities. Response may contain some strengths but identified significant weaknesses and/or deficiencies are determined as having a critical impact on successfully fulfilling the Government's requirement.

Factor 3 – Potential Contribution and Relevance to the ARPA-H Mission

Acceptable (A): Response demonstrates potential future R&D, 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. Response demonstrates degree to which the proposed project has the potential to transform biomedicine. Response demonstrates potential for the project to take an interdisciplinary approach. Response demonstrates the extent to which the proposed intellectual property (IP) rights structure will potentially impact the Government's ability to transition the technology. No deficiencies are identified in the response.

Unacceptable (U): Response does not demonstrate potential future R&D, 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. Response does not demonstrate, the degree to which the proposed project has the potential to transform biomedicine. Response does not demonstrate, potential for the project to take an interdisciplinary approach. Response does not demonstrate, the extent to which the proposed intellectual property (IP) rights structure will potentially impact the Government's ability to transition the technology. Response may contain some strengths, but identification of significant weaknesses and/or deficiencies are determined as having a critical impact on successfully fulfilling the Government's requirement.

Overall Technical Consensus Ratings

Acceptable (A): Response addresses the minimal level of information requested in the BAA. Respondent's response may contain strengths and weaknesses. Weaknesses in the offeror's response, where and if applicable, are not substantial enough to adversely impact respondent's strengths. Weaknesses identified may be corrected through negotiations or clarifications.

Unacceptable (U): Response does not address the minimal level of information requested in the BAA. The offeror's response did not demonstrate an understanding of the BAA and ability to meet applicable program objectives and/or performance parameters. It is unlikely that significant weaknesses and/or deficiencies can be corrected through negotiations or clarifications.

F.4 Cost and Price Evaluation:

A cost realism analysis shall be performed in accordance with FAR 15.404-1(d) Cost realism analysis. Realism will be based on an evaluation of the respondent's cost proposal to determine whether the estimated cost elements are realistic for the work to be performed; reflect a clear understanding of the

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requirements and are consistent with the respondent's technical proposal. In addition, funds availability will be a basis for selection.

The Government will perform, for proposed cost contracts, a cost realism analysis. For proposed fixed price contracts, the government will perform a price realism analysis. To be eligible for award, any and all costs and prices must be both 1) realistic and 2) fair and reasonable. Regardless of a proposal's factorial rating, the government will not make any award to an offeror who proposes 1) unrealistic costs or prices or 2) costs or prices that are not fair and reasonable.

The Government reserves the right to make awards based on all, some, or none of the proposals received. Proposals will not be evaluated against each other since they are not submitted in accordance with a common work statement. Offerors are encouraged to form teams to expand the level of technical expertise in their proposals.

The Government intends to evaluate proposals without communicating with the offeror after the offeror has submitted a proposal. Therefore, offerors are encouraged to submit complete proposals with their best cost and pricing rates. The Government, though, retains the right to communicate with the offeror after receipt of the offeror's proposal to better understand and eventually evaluate the proposal. If these communications lead to material changes to the proposal, the Government may request the offeror submit a revised proposal incorporating those material changes for evaluation. Because proposals are not submitted against a common statement of work and will likely focus on different solutions and approaches to the Area of Interest, the Government may communicate as described above with some offerors and not others.

G. AWARD DECISION

G.1 Basis for Contract Award

ARPA-H may select technical proposals that are most promising for further consideration and may request additional information from the Respondent. In accordance with FAR 35.016(e), ARPA-H will select proposals for award based on technical evaluation, importance to agency programs, and funds availability. Cost realism and reasonableness will be considered to the extent appropriate. ARPA-H anticipates making, but is not obligated to make, multiple awards under this BAA. ARPA-H reserves the right to select for award all, some, or none of the proposals. Proposals for non-innovative concepts, marginal improvements, normal qualification requirements, or commercial items or services are inappropriate under this BAA and will receive no award consideration. ARPA-H plans to award, but is not obligated to award contracts to one or more responsible Respondents whose technical proposals conform to the BAA, reflect a clear understanding of the specified BAA Area of Interest, are in the best interest of ARPA-H, and offer a benefit to ARPA-H, and whose cost/price proposals conform to the BAA, offer fair and reasonable pricing and realistic estimated cost that satisfy the cost realism analysis, and are consistent with the Respondent's technical proposal.

G.2 Basis for Award without Discussion

ARPA-H may evaluate technical proposals and conduct cost realism analysis on cost/price proposals

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and make award without discussions. Proposals should contain the Respondent's best terms. However, ARPA-H reserves the right to conduct discussions and request revisions to proposals if it is determined to be necessary.

G.3 Basis for No Award

ARPA-H reserves the right not to make an award as a result of this BAA if such award is determined to be contrary to the best interest of ARPA-H.

H. AWARD ADMINISTRATION INFORMATION

H.1 Selection Notices and Notifications

1. Abstracts

ARPA-H will respond to each responsive abstract. At that time the contractor will be informed that:

- a. ARPA-H does not recommend the contractor moves forward with a full proposal;
- b. ARPA-H requests that the contractor submit a full proposal;
- c. ARPA-H will not recommend a full proposal at this time but will place the abstract in the "basket" for potential future consideration; or
- d. ARPA-H will contact the contractor for explanation on any unclear elements in the submitted abstract in order to determine whether the abstract will be selected or not.

Timelines for receipt of proposals will be provided to contractors as part of the request.

ARPA-H will review all conforming full proposals using the published evaluation criteria and without regard to any comments resulting from the review of an abstract.

2. Full Proposals

As soon as the evaluation of a full proposal is complete, the contractor will be notified that:

- a. ARPA-H has not selected the proposal; or
- b. ARPA-H has selected the proposal for funding pending award negotiations, in whole or in part. Official notifications will be sent via email to the Technical POC and/or Administrative POC identified on the proposal coversheet.

H.2 Administrative and Policy Requirements

1. Meeting and Travel Requirements

There will be a program kickoff meeting and all key participants are required to attend. Contractors should also anticipate regular program-wide PI Meetings and/or periodic site visits at the PM's discretion.

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2. Award Clauses, Terms and Conditions

Specific terms and conditions will be negotiated for each award instrument.

H.3 Reporting

In addition to the reports noted above in the technical section, the number and types of reports will be specified in the individual award document. As a typical model, ARPA-H expects the reporting to include monthly financial status reports, monthly technical status reports, quarterly reports, and an end-of-phase report. The reports shall be prepared and submitted in accordance with the procedures contained in the award document and mutually agreed on before award.

Reports and briefing material will also be required as appropriate to document progress in accomplishing program metrics. A Final Report that summarizes the project and tasks will be required at the conclusion of the performance period for the award, notwithstanding the fact that the research may be continued under a follow-on vehicle.

H.4 Electronic Systems

1. Payment/Funding Receipt

Contractors will be required register in and to submit invoices for payment directly to the Invoicing Processing Platform (IPP) at <https://www.ipp.gov>, unless an exception applies.

2. i-Edison

The award document for each proposal selected for funding will contain a mandatory requirement for patent reports and notifications to be submitted electronically through i-Edison (<https://public.era.nih.gov/iedison>).

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ATTACHMENT A: PROPOSAL ADEQUACY CHECKLIST

Proposal Adequacy Checklist
DFARS 252.215-7009

	<u>REFERENCES</u>	<u>SUBMISSION ITEM</u>	<u>PROPOSAL PAGE No.</u>	<u>If not provided EXPLAIN (may use continuation pages)</u>
<u>GENERAL INSTRUCTIONS</u>				
1.	FAR 15.408, Table 15-2, Section I Paragraph A	Is there a properly completed first page of the proposal per FAR 15.408 Table 15-2 I.A or as specified in the solicitation?		
2.	FAR 15.408, Table 15-2, Section I Paragraph A (7)	Does the proposal identify the need for Government-furnished material/tooling/test equipment? Include the accountable contract number and contracting officer contact information if known.		
3.	FAR 15.408, Table 15-2, Section I Paragraph A (8)	Does the proposal identify and explain notifications of noncompliance with Cost Accounting Standards Board or Cost Accounting Standards (CAS); any proposal inconsistencies with your disclosed practices or applicable CAS; and inconsistencies with your established estimating and accounting principles and procedures?		
4.	FAR 15.408, Table 15-2, Section I, Paragraph C (1) FAR 2.101, "Cost or pricing data"	Does the proposal disclose any other known activity that could materially impact the costs? This may include, but is not limited to, such factors as— (1) Vendor quotations; (2) Nonrecurring costs; (3) Information on changes in production methods and in production or purchasing volume; (4) Data supporting projections of business prospects and objectives and related operations costs; (5) Unit-cost trends such as those associated with labor efficiency; (6) Make-or-buy decisions; (7) Estimated resources to attain business goals; and (8) Information on management decisions that could have a significant bearing on costs.		
5.	FAR 15.408, Table 15-2, Section I Paragraph B	Is an Index of all certified cost or pricing data and information accompanying or identified in the proposal provided and appropriately referenced?		
6.	FAR 15.403-1(b)	Are there any exceptions to submission of certified cost or pricing data pursuant to FAR 15.403-1(b)? If so, is supporting documentation included in the proposal? (Note questions 18-20.)		
7.	FAR 15.408, Table 15-2, Section I Paragraph C(2)(i)	Does the proposal disclose the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data?		

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8.	FAR 15.408, Table 15-2, Section I Paragraph C(2)(ii)	Does the proposal disclose the nature and amount of any contingencies included in the proposed price?		
9.	FAR 15.408 Table 15-2, Section II, Paragraph A or B	Does the proposal explain the basis of all cost estimating relationships (labor hours or material) proposed on other than a discrete basis?		
10.	FAR 15.408, Table 15-2, Section I Paragraphs D and E	Is there a summary of total cost by element of cost and are the elements of cost cross-referenced to the supporting cost or pricing data? (Breakdowns for each cost element must be consistent with your cost accounting system, including breakdown by year.)		
11.	FAR 15.408, Table 15-2, Section I Paragraphs D and E	If more than one Contract Line-Item Number (CLIN) or subcontract Line-Item Number (sub-CLIN) is proposed as required by the RFP, are there summary total amounts covering all line items for each element of cost and is it cross-referenced to the supporting cost or pricing data?		
12.	FAR 15.408, Table 15-2, Section I Paragraph F	Does the proposal identify any incurred costs for work performed before the submission of the proposal?		
13.	FAR 15.408, Table 15-2, Section I Paragraph G	Is there a Government forward pricing rate agreement (FPRA)? If so, the offeror shall identify the official submittal of such rate and factor data. If not, does the proposal include all rates and factors by year that are utilized in the development of the proposal and the basis for those rates and factors?		
<u>COST ELEMENTS</u>				
MATERIALS AND SERVICES				
14.	FAR 15.408, Table 15-2, Section II Paragraph A	Does the proposal include a consolidated summary of individual material and services, frequently referred to as a Consolidated Bill of Material (CBOM), to include the basis for pricing? The offeror's consolidated summary shall include raw materials, parts, components, assemblies, subcontracts, and services to be produced or performed by others, identifying as a minimum the item, source, quantity, and price.		
SUBCONTRACTS (Purchased materials or services)				
15.	DFARS 215.404-3	Has the offeror identified in the proposal those subcontractor proposals, for which the contracting officer has initiated or may need to request field pricing analysis?		
16.	FAR 15.404-3(c) FAR 52.244-2	Per the thresholds of FAR 15.404-3(c), Subcontract Pricing Considerations, does the proposal include a copy of the applicable subcontractor's certified cost or pricing data?		
17.	FAR 15.408, Table 15-2, Note 1; Section II Paragraph A	Is there a price/cost analysis establishing the reasonableness of each of the proposed subcontracts included with the proposal? If the offeror's price/cost analyses are not provided with the proposal, does the proposal include a matrix identifying dates for receipt of subcontractor proposal, completion of fact finding for purposes of price/cost analysis, and submission of the price/cost analysis?		

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<u>EXCEPTIONS TO CERTIFIED COST OR PRICING DATA</u>				
18.	FAR 52.215-20 FAR 2.101, “commercial item”	Has the offeror submitted an exception to the submission of certified cost or pricing data for commercial items proposed either at the prime or subcontractor level, in accordance with provision 52.215-20? a. Has the offeror specifically identified the type of commercial item claim (FAR 2.101 commercial item definition, paragraphs (1) through (8)), and the basis on which the item meets the definition? b. For modified commercial items (FAR 2.101 commercial item definition paragraph (3)); did the offeror classify the modification(s) as either— i. A modification of a type customarily available in the commercial marketplace (paragraph (3)(i)); or ii. A minor modification (paragraph (3)(ii)) of a type not customarily available in the commercial marketplace made to meet Federal Government requirements not exceeding the thresholds in FAR 15.403-1(c)(3)(iii)(B)? c. For proposed commercial items “of a type”, or “evolved” or modified (FAR 2.101 commercial item definition paragraphs (1) through (3)), did the contractor provide a technical description of the differences between the proposed item and the comparison item(s)?		
19.		[Reserved]		
20.	FAR 15.408, Table 15-2, Section II Paragraph A (1)	Does the proposal support the degree of competition and the basis for establishing the source and reasonableness of price for each subcontract or purchase order priced on a competitive basis exceeding the threshold for certified cost or pricing data?		
INTERORGANIZATIONAL TRANSFERS				
21.	FAR 15.408, Table 15-2, Section II Paragraph A. (2)	For inter-organizational transfers proposed at cost, does the proposal include a complete cost proposal in compliance with Table 15-2?		
22.	FAR 15.408, Table 15-2, Section II Paragraph A (1)	For inter-organizational transfers proposed at price in accordance with FAR 31.205-26(e), does the proposal provide an analysis by the prime that supports the exception from certified cost or pricing data in accordance with FAR 15.403-1?		
DIRECT LABOR				
23.	FAR 15.408, Table 15-2, Section II Paragraph B	Does the proposal include a time phased (i.e., monthly, quarterly) breakdown of labor hours, rates and costs by category or skill level? If labor is the allocation base for indirect costs, the labor cost must be summarized in order that the applicable overhead rate can be applied.		
24.	FAR 15.408, Table 15-2, Section II Paragraph B	For labor Basis of Estimates (BOEs), does the proposal include labor categories, labor hours, and task descriptions, (e.g., Statement of Work reference, applicable CLIN, Work Breakdown Structure, rationale for estimate, applicable history, and time-phasing)?		
25.	FAR subpart 22.10	If covered by the Service Contract Labor Standards statute (41 U.S.C. chapter 67), are the rates in the proposal in compliance with		

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		the minimum rates specified in the statute?		
<u>INDIRECT COSTS</u>				
26.	FAR 15.408, Table 15-2, Section II Paragraph C	Does the proposal indicate the basis of estimate for proposed indirect costs and how they are applied? (Support for the indirect rates could consist of cost breakdowns, trends, and budgetary data.)		
<u>OTHER COSTS</u>				
27.	FAR 15.408, Table 15-2, Section II Paragraph D	Does the proposal include indirect costs and the basis for pricing? If travel is included does the proposal include number of trips, number of people, number of days per trip, locations, and rates (e.g., airfare, per diem, hotel, car rental, etc.)?		
28.	FAR 15.408, Table 15-2, Section II Paragraph E	If royalties exceed \$1,500 does the proposal provide the information/data identified by Table 15-2?		
29.	FAR 15.408, Table 15-2, Section II Paragraph F	When facilities capital cost of money is proposed, does the proposal include submission of Form CASB-CMF or reference to an FPRA/FPRP and show the calculation of the proposed amount?		
<u>FORMATS FOR SUBMISSION OF LINE-ITEM SUMMARIES</u>				
30.	FAR 15.408, Table 15-2, Section III	Are all cost element breakdowns provided using the applicable format prescribed in FAR 15.408, Table 15-2 III? (or alternative format if specified in the request for proposal)		
31.	FAR 15.408, Table 15-2, Section III Paragraph B	If the proposal is for a modification or change order, have cost of work deleted (credits) and cost of work added (debits) been provided in the format described in FAR 15.408, Table 15-2.III.B?		
32.	FAR 15.408, Table 15-2, Section III Paragraph C	For price revisions/redeterminations, does the proposal follow the format in FAR 15.408, Table 15-2.III.C?		
<u>OTHER</u>				
33.	FAR 16.4	If an incentive contract type, does the proposal include offeror proposed target cost, target profit or fee, share ratio, and, when applicable, minimum/maximum fee, ceiling price?		
34.	FAR 16.203-4 and FAR 15.408 Table 15-2, Section II, Paragraphs A, B, C, and D	If Economic Price Adjustments are being proposed, does the proposal show the rationale and application for the economic price adjustment?		
35.	FAR 52.232-28	If the offeror is proposing Performance-Based Payments did the offeror comply with FAR 52.232-28?		
36.	FAR 15.408(n) FAR 52.215-22 FAR 52.215-23	Excessive Pass-through Charges– Identification of Subcontract Effort: If the offeror intends to subcontract more than 70% of the total cost of work to be performed, does the proposal identify: (i) the amount of the offeror’s indirect costs and profit applicable to the work to be performed by the proposed subcontractor(s); and (ii) a description of the added value provided by the offeror as related to		

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	the work to be performed by the proposed subcontractor(s)?	
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Additional Clauses

DFARS 252.2004-7000, Disclosure of Information (OCT 2016)

FAR 52.204-27 Prohibition on a ByteDance Covered Application (Jun 2023)

(a) *Definitions.* As used in this clause—

Covered application means the social networking service TikTok or any successor application or service developed or provided by ByteDance Limited or an entity owned by ByteDance Limited.

Information technology, as defined in 40 U.S.C. 11101(6)—

(1) Means any equipment or interconnected system or subsystem of equipment, used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the executive agency, if the equipment is used by the executive agency directly or is used by a contractor under a contract with the executive agency that requires the use—

(i) Of that equipment; or

(ii) Of that equipment to a significant extent in the performance of a service or the furnishing of a product;

(2) Includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources; but

(3) Does not include any equipment acquired by a Federal contractor incidental to a Federal contract.

(b) *Prohibition.* Section 102 of Division R of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), the No TikTok on Government Devices Act, and its implementing guidance under Office of Management and Budget (OMB) Memorandum M-23-13, dated February 27, 2023, “No TikTok on Government Devices” Implementation Guidance, collectively prohibit the presence or use of a covered application on executive agency information technology, including certain equipment used by Federal contractors. The Contractor is prohibited from having or using a covered application on any information technology owned or managed by the Government, or on any information technology used or provided by the Contractor under this contract, including equipment provided by the Contractor’s employees; however, this prohibition does not apply if the Contracting Officer provides written notification to the Contractor that an exception has been granted in accordance with OMB Memorandum M-23-13.

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(c) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (c), in all subcontracts, including subcontracts for the acquisition of commercial products or commercial services.

(End of clause)

HHSAR 352.231-70 Salary Rate Limitation (DEC 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms “direct salary,” “salary,” and “institutional base salary,” have the same meaning and are collectively referred to as “direct salary,” in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the Office of Personnel Management Web site for Federal Executive Schedule salary levels.

(End of clause)

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ATTACHMENT B: AREAS OF INTEREST

The following is a list of source projects that fit under this program, along with possible branch/fork projects that would constitute an acceptable pivot of sufficient technical complexity. Note: The government reserves the right to add additional areas of interest in the future if it determines it is in the best interest of the government.

Digital Health Security (DIGIHEALS)

- **Buttressing the Security of Digital Health Technology.** Capabilities for finding flaws in and rapid patching of legacy binaries in mission critical systems, including the cases where the original source code version and/or build process is not available. Technologies aimed to create new capabilities for health technologies and software to analyze, modify, and fix legacy software in binary form, capable of producing assured targeted micropatches for known security flaws in existing binaries.
- **Gathering Insights Through Novel Approaches to Data and Analytics.** Development of novel verified programming methodologies for building high assurance parsers, data transformers, and converters for extant electronic data formats; techniques to improve the fitness for purpose of data, artificial intelligence, or machine learning techniques; and novel methodologies for comprehending, simplifying, and reducing data formats to their safe, unambiguous, interoperability-enabling, and verification-friendly subsets (“safe sub-setting”).
- **Rapidly Developing Secure Digital Health Technology.** Developer-accessible capabilities for piece-by-piece evergreen enhancement of software components with new verified code that is both correct-by-construction and compatible-by-construction, i.e., safely composable with the rest of the system.

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ATTACHMENT C: REQUIRED DISCLOSURES OF FOREIGN AFFILIATIONS

**Required Disclosures of Foreign Affiliations or Relationships to Foreign
Countries**

Relevant Definitions

Covered individual - the term "covered individual" means an individual who-
(A) contributes in a substantive, meaningful way to the scientific development or execution of a research and development project proposed to be carried out with a research and development award from a federal research agency; and
(B) is designated as a covered individual by the federal research agency concerned.

Foreign affiliation - the term "foreign affiliation" means a funded or unfunded academic, professional, or institutional appointment or position with a foreign government or government-owned entity, whether full-time, part-time, or voluntary. This includes appointments or positions deemed adjunct, visiting, or honorary with research institutions located in a foreign country of concern.

Foreign country of concern - the term "foreign country of concern" means the People's Republic of China, the Democratic People's Republic of Korea, the Russian Federation, the Islamic Republic of Iran, or any other country determined to be a country of concern by the Secretary of State.

Malign foreign talent recruitment program - the term "malign foreign talent recruitment program" has the meaning given such term in section 19237 of title 42.

Federally funded award - the term "federally funded award" means any contract or task order that is funded with an approved Government funding document

Applicant or awardee Name: _____
Applicant or awardee EIN (UEI if EIN is unavailable): _____

Responses to disclosure questions may contain trade secrets or commercial or financial information that is privileged or confidential and is exempt from public disclosure. Such information shall be used or disclosed only for evaluation purposes or in accordance with an award between the submitter and the Government.

An up-to-date list of countries determined to be countries of concern by the Secretary of State will be accessible at:

<https://www.state.gov/countries-of-particular-concern-special-watch-list-countries-entities-of-particular-concern/#:~:text=The%20most%20recent%20Countries%20of,Arabia%2C%20Tajikista>

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Disclosure Questions

1. Is any owner or covered individual of the applicant or awardee party to any malign foreign talent recruitment program?

☐ Yes ☐ No

If yes, disclose the first and last name of each owner or covered individual, identify their role (i.e., owner or covered individual), and the malign foreign talent recruitment program.

2. Is there a parent company, joint venture, or subsidiary, of the applicant or awardee that is based in or receives funding from, any foreign country of concern?

☐ Yes ☐ No

If yes, disclose the name, full address, applicant or awardee relationships (i.e., parent company, joint venture, or subsidiary) of each entity based in, or funded by, any foreign country of concern:

3. Does the applicant or awardee have any current or pending contractual or financial obligation or other agreement specific to a business arrangement, or joint venture-like arrangement with an enterprise owned by a foreign state or any foreign entity?

☐ Yes ☐ No

If yes, disclose the name of each enterprise or foreign entity, type of obligation, agreement, or arrangement (i.e., contractual, financial, or other), description of obligation, agreement, or arrangement, and the foreign state(s) and/or the country of the foreign entity (or entities).

4. Is the applicant or awardee wholly owned in a foreign country?

☐ Yes ☐ No

If yes, disclose the foreign country.

5. Does the applicant or awardee have any venture capital or institutional investment?

☐ Yes ☐ No

If yes, proceed to question 5a. If no, proceed to question 6.

5a. Does the investing entity have a general partner or any other individual holding a leadership role who has a foreign affiliation with any foreign country of concern?

☐ Yes ☐ No ☐ Unable to determine

If yes or unable to determine, disclose the venture capital or institutional investing entity's name, the percentage of ownership obtained by the investing entity, and the type of investment (i.e., equity, debt, or combination of equity and

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debt).

6. During the previous 5-year period, did the applicant or awardee have any technology licensing or intellectual property sales or transfers, to a foreign country of concern?

☐ Yes ☐ No

If yes, disclose the name, address, and country, of the institution or entity that licensed, purchased, or received the technology or intellectual property.

7. Is there any foreign business entity, offshore entity, or entity outside the United States related to the applicant or awardee?

☐ Yes ☐ No

If yes, disclose the entity name, relationship type (i.e., foreign business entity, offshore entity, entity outside the United States), description of the relationship to the applicant or awardee, and entity address and country.

8. Does the applicant or awardee have an owner, officer, or covered individual that has a foreign affiliation with a research institution located in a foreign country of concern?

☐ Yes ☐ No

If yes, disclose the first and last name of each owner, officer, or covered individual that has a foreign affiliation with a foreign country of concern, identify their role (i.e., owner, officer, or covered individual), and the name of the foreign research institution and the foreign country of concern where it is located: