



Advanced Research Projects Agency for Health
(ARPA-H)

Open-Office Broad Agency Announcement (BAA)

75N99223S0001

March 15, 2023

PART I: OVERVIEW INFORMATION.....	3
PART II: FULL TEXT OF ANNOUNCEMENT	4
I. Funding Opportunity Description	4
II. General Award Information.....	8
III. Eligibility Information	9
A. Eligible Applicants.....	9
B. Organizational Conflicts of Interest	10
C. Address to Request Application Package.....	11
D. Content and Form of Application Submission	11
IV. Application Review Information.....	23
A. Evaluation Criteria for Procurement Contracts, Cooperative Agreements, and Other Transactions	24
B. Review of Abstracts and Full Proposals.....	25
V. Award Administration Information	26
A. Selection Notices and Notifications	26
B. Administrative and National Policy Requirements	27
C. Reporting.....	27
D. Electronic Systems	27
VI. Other Information.....	27
PART III: ATTACHMENTS.....	28
1. Keywords	28
2. Packaging and Delivery of Proposals for Use with the electronic Contract Proposal Submission (eCPS) Website	28
3. SF 424 Research and Related (R&R) Application for Federal Assistance	28
4. The Research and Related Senior/Key Person Profile (Expanded).....	28
5. Research and Related Personal Data.....	28

PART I: OVERVIEW INFORMATION

- Federal Agency Name – Advanced Research Projects Agency for Health (ARPA-H),
- Funding Opportunity Title – ARPA-H Open Broad Agency Announcement
- Announcement Type – Initial Announcement
- Funding Opportunity Number – 75N99223S0001
- Assistance Listing number – 12.910 Research and Technology Development
- Dates
 - o Posting Date: March 15, 2023
 - o Abstract Due Date and Time (indicate Eastern Time): March 14, 2024
- Multiple awards are anticipated
- Types of instruments that may be awarded – Cooperative Agreements, Other Transactions (OTs), and Procurement Contract.
- Agency contact
 - o Points of Contact
 - The BAA Coordinator for this effort can be reached at:
ARPA-H/Office
ATTN: 75N99223S0001
EMAIL: BAAQuestions@ARPA-H.gov

PART II: FULL TEXT OF ANNOUNCEMENT

I. Funding Opportunity Description

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2), FAR 35.016, 2 Code of Federal Regulations (CFR) § 200.203, and in accordance with Public Law No: 117-328. Any resultant award negotiations will follow all pertinent laws and regulations, and any negotiations and/or awards for procurement contracts will use procedures under the FAR.

The mission of ARPA-H is to accelerate better health outcomes for everyone by supporting the development of high-impact solutions to 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. With a scope spanning the molecular to the societal, ARPA-H seeks proposals that aim to rapidly achieve better health outcomes across patient populations, communities, diseases, and health conditions, including in support of the Cancer Moonshot. Proposals are expected to use innovative approaches to enable revolutionary advances in science, technology, or systems.

ARPA-H will also foster innovations that are entirely novel proofs of concept or contribute directly to advance the goals of government-wide initiatives such as the Cancer Moonshot; Advancing the American Bioeconomy; Clinical Trial Readiness; the National Strategy on Hunger, Nutrition, and Health; the National Action Plan for Combatting Anti-Microbial Resistance; or unity agenda priorities on addressing mental health and curbing the opioid epidemic.

Specifically excluded are proposals that represent an evolutionary or incremental advance in the current state of the art. Additionally, proposals directed towards policy changes, traditional education and training, or center coordination and construction of physical infrastructure are outside the scope of the ARPA-H mission.

ARPA-H has identified four initial focus areas that are a priority for investment:

- (1) Health Science Futures;
- (2) Scalable Solutions;
- (3) Proactive Health;
- (4) Resilient Systems;

as well as targeted investments in tools that enable quantitative measurements of health outcomes, promote end-user adoption, facilitate participatory research, and advance relevant Ethical, Legal, and Societal Implications (ELSI) topics. ARPA-H may also consider submissions outside of these thrust areas if the proposal involves the development of a novel capability to improve health outcomes or prolong well-being, especially if it would help either a substantial number of people or a population that currently lacks effective treatment options.

ARPA-H will foster innovations across the spectrum of technology readiness – from foundational science to the introduction of new prototypes into the marketplace. To receive funding, efforts must align with ARPA-H’s mission to accelerate better health outcomes and undertake research that cannot otherwise be pursued within the health funding ecosystem due to the nature of the technical risk.

Health Science Futures:

The Health Science Futures focus area seeks to develop the innovative tools, technologies, and platforms that can be applied to a broad range of diseases. While approaches that are disease agnostic are encouraged, proposals are welcome that bring radically new insights to address diseases that include, but are not limited to cancer, diabetes, Alzheimer’s Disease, infectious diseases, and cardiovascular disease, which may serve to establish generalizable paradigms. Proposers are encouraged to address diseases that affect large populations, rare diseases, or diseases for which treatment options are limited.

Topics of interest include, *but are not limited to:*

- Novel molecular platform approaches to include the modulation of host systems, delivery to targets with spatial and temporal precision, and mitigation of off-target effects to accelerate interventions that dramatically improve health outcomes.
- New approaches to accelerate and routinize mammalian and microbial cellular engineering to enable next generation therapeutic applications, develop multiscale interventions, and automate hypothesis generation and discovery to expand those applications to disease states in which cellular therapies have not traditionally been employed.
- Foundational interventions that target and reverse disease pathogenesis and/or enhance plasticity to address degenerative diseases of the nervous, neuromuscular, skeletal, and other organ systems.
- Foundational advances in genetic, cellular, tissue, and organ replacement therapies that enable personalized medical interventions at scale in a manner that is accessible, cost-effective and designed to impact the communities of greatest need.
- AI-enabled, and empirically validated physiological models that accurately reflect the biological basis of complex diseases, the interface between biological and physical systems, and mimic human response to potential therapeutic or multiscale interventions from the atomic/molecular to systemic/whole human scales.
- Miniaturization of complex hardware to enable broader access and portability such as diagnostic, treatment, imaging, or other devices.

Scalable Solutions:

The Scalable Solutions focus area seeks to improve access and affordability and address health ecosystem challenges that impede effective and timely development and distribution of healthcare and disease response at a scale that reaches every citizen regardless of geography or resources. Anticipated approaches include innovations that overcome challenges in geography,

distribution, manufacturing, data and information, and economies of scale to ensure solutions can reach everyone quickly. Topics of interest include, *but are not limited to*:

- Scalable treatments for the pediatric population that go beyond reducing the size/dose of an adult treatment and may include solutions that adapt to the pediatric patient's changing physiology and developmental status over the course of years.
- Innovative manufacturing technologies that reduce cost, shorten the timeline for production, and eliminate supply chain risk of biologics, cellular therapies, or medical hardware.
- Methods for standardization, automation, and democratization of complex procedures including, but not limited to, histopathology, rare disease diagnosis and treatment, and surgical interventions to ensure access and delivery to populations diverse in demographics, geographies, and resources at scale.
- Methods to enhance delivery of effective healthcare solutions in rural or low resource settings, including but not limited to "last mile" delivery, at-home monitoring, imaging, drug delivery, telehealth augmentation, and support for remote medical procedures with limited need for specialized training.
- Transformational approaches to reduce or eliminate health disparities, including tools and models for product design and care delivery that scale novel approaches in human factors and human-centered design to respond to full diversity of patients.
- Foundational capabilities to accelerate diagnoses and reduce the cost of treatments for rare diseases wherever patients are, without the need for specialized facilities or healthcare expertise.

Proactive Health:

The Proactive Health focus area aims to improve personal health and wellness to reduce the likelihood that people require medical intervention or minimize the time that they remain in acute care through accelerated recovery and regeneration capabilities. Proactive health programs will create new capabilities to identify and characterize disease risk, reduce comorbidities, and promote treatments and behaviors to address challenges to human health, whether those are viral, bacterial, physical, psychological, environmental, or caused by the natural aging process. Interest areas include, *but are not limited to*:

- Novel techniques to reduce the spread of disease or eliminate risk factors, including new vaccine or therapeutic modalities that block pathogen transmission, induce mucosal immunity, or boost or sustain native immunity without triggering auto-immune dysfunction.
- Novel diagnoses, prognostics, treatments, technologies, and interventions to reduce health disparities, especially in the areas of mental health disorders, substance use disorders, maternal morbidity and mortality, and chronic conditions, such as diabetes, obesity, and heart disease.
- Development of novel approaches to continuously measure, analyze, and enhance health-promoting activities to accelerate recovery, enhance immune function, improve mental health, or treat sleep disorders.

- Development of robotics, wearables, and other devices to enhance independence for aging populations and people with cognitive or movement disorders, and to help people age in place.
- Novel approaches to accelerate recovery from injury or stress, including tissue regeneration and healing broadly, as well as methods to regenerate injured brain tissue after trauma or stroke to end paralysis and cognitive loss.
- Non-invasive approaches to characterize brain and other deep tissue and organ health with quantitative and accurate outcomes equivalent to invasive health monitoring, to include innovations in hardware as well as imaging tools and reagents.
- Development of machine-enhanced computational models to predict changes in health status, reduce medical errors, and improve standard of care while ensuring safety, accuracy, and quality assurance across patient populations in clinical settings.

Resilient Systems:

The Resilient Systems focus area aims to create capabilities, develop mechanisms, and accelerate system integrations to enhance stability in the face of disruptive events. Resilient systems need to sustain themselves between crises – from the molecular to the societal – to better achieve outcomes that advance American health resilience at the population level. From software systems to manufacturing pipelines, biophysical systems to microbiomes, and patient communities to provider networks, reliability is key to weather crises such as pandemics, social disruption, climate change, molecular disturbances, and economic instability. Interest areas include, *but are not limited to:*

- Novel methods to engineer resilient tissues, microbiomes, and biophysical systems to combat disease or maintain health.
- Approaches that enable health infrastructure to rapidly integrate commercial-off-the-shelf solutions, create decision support tools, and adapt supply chains, manufacturing, logistics, and strategies to leverage workforce during public health emergencies.
- Novel ways to protect, secure, integrate, analyze, communicate, and present health data, including but not limited to advances in privacy, cyber security, artificial intelligence with enhanced patient safety properties, low-code or no-code technologies, semantic approaches, and rapid integration techniques.
- Strategies and technologies to leverage homes, community centers, pharmacies, and other accessible locations as distributed clinical trial sites to diversify participation in clinical trials and integrate end-user feedback to rapidly iterate prototype designs.
- Approaches to build trust in the healthcare system and distribute high-quality health guidance in an understandable manner that improves patient outcomes.
- Novel real-time measurement tools to track health outcomes, evaluate post-market performance of new interventions, and enable convergence on the most effective strategies to improve the quality of care, especially for underserved communities.

- Development of novel approaches to address ELSI challenges governance frameworks for health information, consent, data reuse, biosecurity, and potential unintended consequences.

II. 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 proposals¹ received and the availability of funds. ARPA-H reserves the right to make multiple awards, a single award, or no awards based on the above stated considerations.

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this solicitation and to make awards without negotiations with proposers. The Government also reserves the right to conduct negotiations if it is later determined to be necessary. If warranted, portions of resulting awards may be segregated into options. Additionally, ARPA-H reserves the right to accept proposals in their entirety or to select only portions of proposals for award. If ARPA-H desires to award only portions of a proposal, negotiations may be opened with that proposer². The Government reserves the right to fund proposals in phases, including as optional phases, as applicable.

The Government may request additional necessary documentation, tailored to the individual proposals, once it makes the award instrument determination. Such additional information may include, but is not limited to, Representations and Certifications (see Section VI.B.2., “Representations and Certifications”). 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 the proposer fails to timely provide requested additional information. Proposals identified for negotiation may result in a procurement contract, cooperative agreement, or OT, depending upon the nature of the work proposed, the required degree of interaction between parties, and other factors.

Proposers looking for innovative, commercial-like contractual arrangements are encouraged to consider requesting OTs.

In all cases, the Government Procuring Contracting Officers (PCO)/Agreements Officers (AO)/Other Transaction Agreements Officers (OTAO) shall have sole discretion to select award instrument type, regardless of instrument type proposed, and to negotiate all instrument terms and conditions with selectees. ARPA-H will apply publication or other restrictions, as necessary, if it determines that the research resulting from the proposed effort will present a high likelihood of disclosing sensitive information including Personally Identifiable Information (PII), Protected Health Information (PHI), financial records, proprietary data, and any information marked Sensitive but Unclassified (SBU), Controlled Unclassified Information (CUI), etc. Any award

¹ In this document, “proposal” refers both to the initial abstract and the subsequent proposal ARPA-H may request from proposers, unless otherwise indicated.

² “Proposer” refers to all respondents to this Broad Agency Announcement, whether submitting an abstract/proposal for a procurement contract, cooperative agreement, or other transaction.

resulting from such a determination will include a requirement for ARPA-H permission before publishing any information or results on the program.

III. Eligibility Information

A. Eligible Applicants

All responsible sources capable of satisfying the Government's needs may submit a proposal that shall be considered by ARPA-H.

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

a) FFRDCs

FFRDCs are subject to applicable direct competition limitations and cannot propose to this solicitation 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 solicitations 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 subawardees.

b) 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 solicitations and compete with industry. This information is required for Government Entities proposing to be awardees or subawardees.

c) Authority and Eligibility

At the present time, ARPA-H does not consider 15 U.S.C. § 3710a Cooperative research and development agreements to be sufficient legal authority to show specific authority establishing their eligibility to propose to Government solicitations and compete with industry. Additional specific authority must be cited to establish eligibility. ARPA-H will consider FFRDC and Government Entity eligibility submissions on a case-by-case basis; however, the burden to prove eligibility for all team members rests solely with the proposer.

2. Other Applicants

ARPA-H will prioritize awards to entities (organization and/or individuals) that will conduct funded work in the United States. However, non-U.S. entities may participate to the extent that

such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. Non-US entities are encouraged to collaborate with domestic U.S. 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.

3. Limitation on Number of Awards

Entities with more than three ongoing concurrent awards with ARPA-H will not be eligible for award. The Director of ARPA-H may waive the award preference, but only if the requirements cannot reasonably be met and the proposing entity has the potential to advance ARPA-H's statutorily defined goals.

B. Organizational Conflicts of Interest

In accordance with FAR 9.5, proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and *any* proposed team member (proposed subcontractor, subawardee, consultant, etc.). Regardless of whether or not the proposer has identified potential OCIs, under this Section, the proposer is responsible for providing a disclosure with each proposal submitted to the solicitation. The disclosure must include the proposer's, and as applicable, proposed team member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4. Furthermore, although the FAR does not apply to OTs, OCIs must be addressed in the same manner prescribed in FAR subpart 9.5. The disclosure and mitigation plan to not count toward the page limit.

Agency Supplemental OCI Policy

In addition, ARPA-H restricts contractors/performers from concurrently providing professional support services, including), Advisory and Assistance Services (A&AS) or similar support services, and being a technical performer. Therefore, as part of the FAR 9.5 disclosure requirement above, a proposer must affirm whether the proposer or *any* proposed team member (proposed subcontractor, subawardee, consultant, etc.) is providing Science Engineering and Technical Assistance (SETA), A&AS, or similar support 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 SETA, A&AS, or similar support is being or was 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, subawardee, consultant, etc.) providing the support; and
- An OCI mitigation plan in accordance with FAR 9.5.

Government Procedures

In accordance with FAR 9.503, 9.504 and 9.506, 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 that are determined selectable under the solicitation evaluation criteria and funding availability.

The Government may require proposers to provide additional information to assist the Government in evaluating the proposer's OCI mitigation plan.

If the Government determines that a proposer 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 proposer's OCI mitigation plan, the Government may reject the proposal and withdraw it from consideration for award.

C. Address to Request Application Package

This announcement, any attachments, and any references to external websites herein constitute the total solicitation. If proposers cannot access the referenced material posted in the announcement found at SAM.gov, please contact the administrative contact listed herein.

D. Content and Form of Application Submission

All submissions, including abstracts and proposals, 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, proposer organization, and proposal title/proposal short title.

1. Abstract Format

Proposers to the BAA must submit an abstract. Based on evaluation of the abstract, ARPA-H may request a full proposal from BAA respondents. The cover sheet should be clearly marked "ABSTRACT," and the total length should not exceed three pages in length. The maximum page count excludes the cover page and the Rough Order of Magnitude (ROM). Any abstract submitted that exceeds three pages will only be reviewed at ARPA-H's discretion. Official transmittal letter is not required.

a) Cover Page

The cover page should follow the same format as the full proposal described in Section III.D.2.(a)(1)(a). The cover page does not count towards the page limit.

b) Concept Summary (Estimated $\frac{1}{4}$ page)

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

c) Innovation and Impact (Estimated $\frac{3}{4}$ page)

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

d) Proposed Work (Estimated 1.5 pages)

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?

e) Team Organization and Capabilities (Estimated $\frac{1}{2}$ page)

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 that he/she brings to the team.

f) Rough Order of Magnitude (ROM)

Please include a ROM estimate of timeline and federal funds requested, as well as the total project cost including cost sharing. 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, cost sharing, and any other relevant costs. The below table may be used for this breakdown:

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

The ROM does not count toward the page limit.

2. Full Proposal Format

Full 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 into 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. Bracketed numbers before each section denote recommended page limits. The Cover Page shall be no more than one page in length. The Summary of Proposal and Detailed Proposal Information, shall be no more than thirty pages in total length, excluding the Statement of Work. There is no page limit for the Statement of Work. However, for all sections, ARPA-H encourages conciseness to the maximum extent practicable.

NOTE: Non-conforming submissions that do not follow the instructions may be rejected without further review.

a) Volume I, Technical and Management Proposal

(1) Section I: Administrative

(a) Cover Page to Include

- (1) BAA number (75N992XXXXXXX);
- (2) Technical area;
- (3) Lead Organization submitting proposal;
- (4) 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: SBA’s 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>

- (5) Proposer’s reference number (if any);
- (6) Other team members (if applicable) and type of organization for each;
- (7) Proposal title;
- (8) Technical point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, email;
- (9) Administrative point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, email;
- (10) Total funds requested from ARPA-H, and the amount of cost share (if any); AND
- (11) Date proposal was submitted.
- (12) Keywords – Please see Attachment No. 1 for a list of keywords. Submitters may choose up to three keywords. The keywords will be used to direct submissions to the most appropriate reviewers.

b) Proposal Content

(1) Section II: Summary of Proposal

- 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 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. For forms to be completed regarding intellectual property, see Section IV.B.3.h of this BAA. There will be no page limit for the listed forms.
- D. General discussion of other research in this area. Proposers must disclose current and previous research and development 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.

(2) Section III: Detailed Proposal Information

- A. Statement of Work (SOW) - Clearly define the technical tasks/subtasks to be performed, their durations, and dependencies among them. The page length for the SOW will be dependent on the amount of the effort. For each task/subtask, provide:
- A general description of the objective (for each defined task/activity);
 - A detailed description of the approach to be taken to accomplish each defined task/activity;
 - Identification of the primary organization responsible for task execution (prime, sub, team member, by name, etc.);
 - The completion criteria for each task/activity - a product, event or milestone that defines its completion.
 - Define all deliverables (reporting, data, reports, software, etc.) to be provided to the Government in support of the proposed research tasks/activities; and
 - Clearly identify any tasks/subtasks (to be performed by either an awardee or subawardee) that will be accomplished on-campus at a university, if applicable.

Other Transaction Requests - All proposers requesting an OT must include in the Statement of Work a detailed list of milestones that relate directly to accomplishment of program technical metrics as defined in the BAA and/or the proposer's proposal. Each milestone must include the following:

- Milestone description,
- Completion criteria,
- Due date, and
- Payment/funding schedule (to include, if cost share is proposed, proposer and Government share amounts).

It is noted that, at a minimum, milestones should relate directly to accomplishment of program technical metrics as defined in the BAA and/or the proposer's proposal. The agreement type (e.g., expenditure, fixed, etc.) will be subject to negotiation by the OTA. Do not include proprietary data in the milestone submission.

Note: It is recommended that the SOW should be developed so that each phase of the program is separately defined.

Do not include any proprietary information in the SOW

- B. Description of the results, products, transferable technology, and expected technology transfer path to supplement information included in the summary of the proposal. This should also address mitigation of life-cycle and sustainment risks associated with transitioning intellectual property for Government applications, if applicable. See also Section IV.B.3.h of this BAA., "Intellectual Property."
- C. Detailed technical approach enhancing and completing the description in the Summary of Proposal.
- D. Comparison with other ongoing research indicating advantages and disadvantages of the proposed effort.

- E. Discussion of proposer’s previous accomplishments and work in closely related research areas.
- F. Description of Security Management architecture and/or approach for the proposed effort. Detail unique additional security requirements information system certification expertise for CUI or classified processing, operations security, program protection planning, test planning, transportation plans, work being performed at different classification levels, and/or utilizing test equipment not approved at appropriate classification level
- G. Description of the facilities that would be used for the proposed effort.
- H. Detail support enhancing the description in the Summary of Proposal, including formal teaming agreements which may be required to execute this program.
- I. Provide description of milestone cost and accomplishments.

c) Volume II, Cost Proposal

(1) All proposers, including FFRDCs, must submit the following:

Cover sheet to include:

1. BAA number (75N992XXXXXXX);
2. Technical area;
3. Lead Organization submitting proposal;
4. Type of organization selected among the following categories: “LARGE BUSINESS”, “SMALL DISADVANTAGED BUSINESS”, “OTHER SMALL BUSINESS”, “HBCU”, “MI”, “OTHER EDUCATIONAL”, OR “OTHER NONPROFIT (including non-educational government entities)” (Note: SBA’s 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>
5. Proposer’s reference number (if any);
6. Other team members (if applicable) and type of organization for each;
7. Proposal title;
8. Technical point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, email;
9. Administrative point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, and email;
10. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, cost sharing contract, other type of procurement contract (specify), cooperative agreement, or OT;
11. Place(s) and period(s) of performance;
12. Total proposed cost separated by base and option(s) (if any);
13. Name, address, and telephone number of the proposer’s cognizant administration office (as applicable);

14. Name, address, and telephone number of the proposer's cognizant auditor (as applicable);
15. Date proposal was prepared;
16. Unique Entity Identification (UEI) number;
17. Taxpayer Identification Number (TIN);
18. Commercial and Government Entity (CAGE) Code;
19. Proposal validity period.

(2) Additional Cost Proposal Information

d) Supporting Cost and Pricing Data

Respondents to the BAA should include supporting cost and pricing information in sufficient detail to substantiate the summary cost estimates and should include a description of the method used to estimate costs and supporting documentation.

e) Cost Breakdown Information and Format

Detailed cost breakdown to include³:

- Total program costs broken down by major cost items (e.g., direct labor, including labor categories; subagreements, materials; other direct costs; overhead charges, etc.) and further broken down by task and phase
- Major program tasks by fiscal year
- An itemization of major subagreements, in the same detail as the total program cost breakdown, and equipment purchases.
- Documentation supporting the reasonableness of the proposed equipment costs (e.g. vendor quotes, past purchase orders/purchase history, detailed estimates from technical personnel, etc.) shall be provided.
- An itemization of any information technology (IT) purchase, as defined by FAR 2.101 – Documentation supporting the reasonableness of the proposed equipment costs (e.g., vendor quotes, past purchase orders/purchase history, detailed estimates from technical personnel, etc.) shall be provided.
- A summary of projected funding requirements by month
- The source, nature, and amount of any industry cost-sharing
- Identification of pricing assumptions of which may require incorporation into the resulting award instrument (e.g., use of Government Furnished Property/Facilities/Information, access to Government Subject Matter experts, etc.)

³ Per FAR 15.403-4, certified cost or pricing data shall be required if the proposer is seeking a procurement contract award per the referenced threshold, unless the proposer requests and is granted an exception from the requirement to submit cost or pricing data. Certified cost or pricing data is not required if the proposer proposes an award instrument other than a procurement contract (e.g., cooperative agreement, or Other Transaction.)

Tables included in the cost proposal in editable (e.g., MS Excel) format with calculation formulas intact. NOTE: If PDF submissions differ from the Excel submission, the PDF will take precedence.

The Government requires that proposers use the provided MS Excel ARPA-H Standard Cost Proposal Spreadsheet in the development of their cost proposals. A customized cost proposal spreadsheet will be provided with requests for full proposals. All tabs and tables in the cost proposal spreadsheet should be developed in an editable format with calculation formulas intact to allow traceability of the cost proposal. This cost proposal spreadsheet should be used by the prime organization and all subcontractors, subawardees, etc. In addition to using the cost proposal spreadsheet, the cost proposal still must include all other items required in this announcement that are not covered by the editable spreadsheet. Subcontractor, subawardee, etc. cost proposal spreadsheets may be submitted directly to the Government by the proposed subcontractor, subawardee, etc. via email to the address in the Part I solicitation overview. Using the provided cost proposal spreadsheet will assist the Government in a rapid analysis of your proposed costs and, if your proposal is selected for a potential award, speed up the negotiation and award execution process.

f) Subcontractor/Subawardee, Etc. Proposals

The awardee is responsible for compiling and providing all subcontractor, subawardee, etc. proposals for the PCO/AO/OTAO as applicable. Subcontractor, subawardee, etc. proposals should include Interdivisional Work Transfer Agreements or similar arrangements between the awardee and divisions within the same organization as the awardee. Where the effort consists of multiple portions which could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.

All proprietary subcontractor, subawardee, etc. proposal documentation, prepared at the same level of detail as that required of the respondent's proposal and which cannot be uploaded with the proposed awardee's proposal, shall be provided to the Government either by the proposer or by the subcontractor, subawardee, etc. when the proposal is submitted. Subcontractor, subawardee, etc. proprietary proposals may be submitted directly to the Government by email to the PCO/AO/OTO. See Section IV.B.5.b. of this BAA for proposal submission information.

g) Other Documents

Proposers should include any other required documents, as applicable, in the cost proposal. This may include OCI disclosures, OCI mitigation plans, small business subcontracting plans, Human Subjects and Animal Subjects Research documentation, intellectual property representations and assertions, etc.

3. Additional Proposal Information

a) Proprietary Markings

Proposers are responsible for clearly identifying proprietary information. Submissions containing proprietary information must have the cover page and each page containing such information clearly marked with a label such as “Proprietary.” NOTE: “Confidential” is a classification marking used to control the dissemination of U.S. Government National Security Information as dictated in Executive Order 13526 and should not be used to identify proprietary business information.

b) Representations and Certifications

In accordance with FAR 4.1102 and 4.1201, proposers requesting a procurement contract must complete electronic annual representations and certifications at <https://www.sam.gov/>.

c) Human Subjects Research (HSR)/Animal Use

Human Subjects

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

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

Animal Subjects Research

Award recipients performing research, experimentation, or testing involving the use of animals shall comply with the laws, regulations, and policies on animal acquisition, transport, care, handling, and use as outlined in: (i) 9 CFR parts 1-4, U.S. Department of Agriculture rules that implement the Animal Welfare Act of 1966, as amended, (7 U.S.C. § 2131-2159); (ii) the Public Health Service Policy on Humane Care and Use of Laboratory Animals⁴, which incorporates the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training,”⁵ and "Guide for the Care and Use of Laboratory Animals" (8th Edition).⁶”

For all proposed research anticipating animal use, proposals should briefly describe plans for Institutional Animal Care and Use Committee (IACUC) review and approval.

d) Small Business Subcontracting Plan

Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. § 637(d)) and FAR 19.702(a)(1), any proposal for a procurement contract may be required to submit a subcontracting plan with their proposal. The plan format is outlined in FAR 19.704.

e) 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)/FAR 39.2.

f) Cooperative Agreement Summary

Proposers requesting cooperative agreements awards must submit a maximum one (1) page summary that may be publicly posted and explains the program or project to the public. The proposer should sign the bottom of the summary confirming the information in the abstract is approved for public release. Proposers are advised to provide both a signed PDF copy, as well as an editable (e.g., Microsoft word) copy. Summaries contained in cooperative agreements proposals that are not selected for award will not be publicly posted. The document will only be requested if a full proposal is requested.

g) Intellectual Property

All proposers must provide a good faith representation that the proposer 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.

(1) For Procurement Contracts

⁴ olaw.nih.gov/sites/default/files/PHSPolicyLabAnimals.pdf

⁵ olaw.nih.gov/policies-laws/gov-principles.htm

⁶ olaw.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf

Proposers responding to this BAA requesting procurement contracts will need to complete the below table. If no restrictions are intended, the proposer should state “NONE.” The table below captures the requested information:

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

(2) For All Non-Procurement Contracts

Proposers responding to this BAA requesting a cooperative agreement or OT shall follow the applicable laws, rules, and regulations governing these various award instruments, but, in all cases, 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 described under Additional Proposal Information Paragraph (g)(1) above. If no restrictions are intended, then the proposal should state “NONE.”

h) System for Award Management (SAM) and Unique Identifier Requirements

All proposers must be registered in SAM unless exempt per FAR 4.1102. FAR 52.204-7, International entities can register in SAM by following the instructions in this link: https://www.fsd.gov/sys_attachment.do?sys_id=c08b64ab1b4434109ac5ddb6bc4bcbb8.

4. Submission Information

Proposers are responsible for submitting abstracts and proposals to the electronic Contract Proposal Submission (eCPS) website at <https://ecps.nih.gov/> and ensuring receipt by the date and time specified. Proposers must use this electronic transmission method. No other method of abstract and proposal submission is permitted. (b) Instructions on how to submit a proposal into eCPS are available at <https://ecps.nih.gov/howtosubmit>. Proposers may also reference Frequently Asked Questions regarding online submissions at <https://ecps.nih.gov/faq>. Proposers may also refer to Attachment No. 2 for submission instructions. Be advised that registration is required to submit an abstract into eCPS and registration may take several business days to process. It is highly recommended that offerors plan to register through eCPS well in advance of the white paper submission deadline, late abstract submissions resulting from delays with eCPS registration will not be accepted or considered.

This BAA is open and in effect for one year from the date of release. Prior to submission of an abstract proposer are strongly encouraged to contact the ARPA-H BAA technical point of contact for the research topic/subtopic of interest. Abstracts must be received electronically by 3:00 PM EST by **March 14, 2024** in order to be considered for further evaluation. Abstracts must be submitted electronically to <https://ecps.nih.gov>.

For abstract and proposal submission dates, see Part I., Overview Information. Submissions received after these dates and times may not be reviewed.

a) Abstract Submission

Refer to Section V.A.1. for ARPA-H response to abstract submissions.

b) Proposal Submission

Refer to Section V.A.2. for how ARPA-H will notify proposers as to whether their proposal has been selected for potential award.

(1) For Proposers Requesting Cooperative Agreements

In addition to the volumes and corresponding attachments requested elsewhere in this solicitation, proposers submitting a requested full proposal must also submit the three forms listed below. The forms do not count toward the page limitations.

Form 1: SF 424 Research and Related (R&R) Application for Federal Assistance, available on the Grants.gov website at <https://www.grants.gov/web/grants/forms/r-r-family.html>. *This form must be completed and submitted.* The form is included as Attachment No. 3.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et seq.), the Department of Health and Human Services is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, or mathematics disciplines. HHS is using the forms below to collect the necessary information to satisfy these requirements. Detailed instructions for each form are available on Grants.gov.

Form 2: The Research and Related Senior/Key Person Profile (Expanded) form, available on the Grants.gov website at <https://www.grants.gov/web/grants/forms/r-r-family.html>, will be used to collect the following information for all senior/key personnel, including Project Director/Principal Investigator and Co-Project Director/Co-Principal Investigator, whether or not the individuals' efforts under the project are funded by HHS. The form includes 3 parts: the main form administrative information, including the Project Role, Degree Type and Degree Year; the biographical sketch; and the current and pending support. The biographical sketch and current and pending support are to be provided as attachments:

- Biographical Sketch: Mandatory for Project Directors (PD) and Principal Investigators (PI), optional, but desired, for all other Senior/Key Personnel. The biographical sketch should include information pertaining to the researchers:

- o Education and Training.
- o Research and Professional Experience.
- o Collaborations and Affiliations (for conflict of interest).
- o Publications and Synergistic Activities.
- Current and Pending Support: Mandatory for all Senior/Key Personnel including the PD/PI. This attachment should include the following information:
 - o A list of all current projects the individual is working on, in addition to any future support the individual has applied to receive, regardless of the source.
 - o Title and objectives of the other research projects.
 - o The percentage per year to be devoted to the other projects.
 - o The total amount of support the individual is receiving in connection to each of the other research projects or will receive if other proposals are awarded.
 - o Name and address of the agencies and/or other parties supporting the other research projects
 - o Period of performance for the other research projects.

Additional senior/key persons can be added by selecting the “Next Person” button at the bottom of the form. Note that, although applications without this information completed may pass Grants.gov edit checks, if ARPA-H receives an application without the required information, ARPA-H may determine that the application is incomplete and may cause your submission to be rejected and eliminated from further review and consideration under the solicitation. ARPA-H reserves the right to request further details from the applicant before making a final determination on funding the effort. The form is included as Attachment No. 4.

Form 3: Research and Related Personal Data, available on the Grants.gov website at <https://www.grants.gov/web/grants/forms/r-r-family.html>. *Each applicant must complete the name field of this form, however, provision of the demographic information is voluntary. Regardless of whether the demographic fields are completed or not, this form must be submitted with at least the applicant’s name completed.* The form is included as Attachment No. 4.

5. Funding Restrictions

Preaward costs will not be reimbursed unless a preaward cost agreement is negotiated prior to award.

6. Questions

Interested entities may submit questions via eCPS.gov. Answers to questions received will be posted to the same website. Given the nature of the BAA, ARPA-H will answer all relevant questions. Answers, if provided, may only be posted at intervals.

IV. Application Review Information

A. Evaluation Criteria for Procurement Contracts, Cooperative Agreements, and Other Transactions

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

Abstracts will be evaluated based only on evaluation criteria #1, #2, and #4, in descending order of importance, however, the ROM will only be reviewed for affordability and not for realism or reasonableness.

Abstracts will undergo an initial review for responsiveness. Abstracts that are outside the scope of the BAA will not be evaluated further. In addition, Abstracts that do not meet the 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.

1. Overall Scientific and Technical Merit

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

2. Proposer's Capabilities and/or Related Experience

The proposed technical team has the expertise and experience to accomplish the proposed tasks. The proposer's prior experience in similar efforts clearly demonstrates an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule. Similar efforts completed/ongoing by the proposer in this area are fully described including identification of other Government entities.

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

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.

4. Cost Realism/Price Reasonableness/Funding Availability/Affordability

Price analysis will be performed on each proposal to ensure the reasonableness of the overall price. In addition, cost realism analysis may be performed to ensure proposed costs are realistic for the technical and management approach, accurately reflect the technical goals and objectives of the solicitation, the proposed costs are consistent with the proposer's Statement of Work and reflect a sufficient understanding of the costs and level of effort needed to successfully

accomplish the proposed technical approach. The costs for the prime proposer and proposed subawardees will be substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs and the basis for the estimates). 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.

It is expected that the effort will leverage all available relevant prior research to obtain the maximum benefit from the available funding. For efforts with a likelihood of commercial application, appropriate direct cost sharing may be a positive factor in the evaluation. ARPA-H recognizes that undue emphasis on cost may motivate proposers 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.

B. 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 V.A. 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 solicitation; 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). ARPA-H reserves the full period of this solicitation plus [time until after final deadline] for review of proposals.

Award(s) will be made to proposers whose abstracts/proposals are determined to be the most advantageous to the Government, consistent with instructions and evaluation criteria specified in the BAA herein, 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 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 (FAPIIS)

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 FAPIIS). Entities can comment on any information about themselves entered in the database, and ARPA-H will consider any comments, along with other information in FAPIIS or other systems, prior to making an award.

V. Award Administration Information

A. Selection Notices and Notifications

1. Abstracts

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

- 1.) ARPA-H has not selected the proposer to move forward with the submitted abstract;
- 2.) ARPA-H requests that the proposer submit a full proposal;
- 3.) ARPA-H will not request a full proposal at this time but will place the abstract in the “basket” for potential future consideration
- 4.) ARPA-H will contact the proposer 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 proposers 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 proposer will be notified that:

- 1.) ARPA-H has not selected the proposal; or
- 2.) 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.

B. Administrative and National Policy Requirements

1. Meeting and Travel Requirements

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

2. Solicitation Provisions and Award Clauses, Terms and Conditions

Solicitation clauses in the FAR and HHSAR relevant to procurement contracts and FAR and HHSAR clauses that may be included in any resultant procurement contracts are incorporated can be found www.acquisition.gov.

3. Cooperative Agreements Terms and Conditions

All cooperative agreements are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement and 45 CFR 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

C. Reporting

The number and types of reports will be specified in the award document but will include at a minimum: 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.

D. Electronic Systems

1. Invoicing Processing Platform (IPP)

Performers will be required register in and to submit invoices for payment directly to <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>).

VI. Other Information

Collaborative efforts/teaming are encouraged. Interested parties should submit a one page profile with their contact information, a brief description of their technical capabilities, and the desired

expertise from other teams, as applicable.

PART III: ATTACHMENTS

1. Keywords
2. Packaging and Delivery of Proposals for Use with the electronic Contract Proposal Submission (eCPS) Website
3. SF 424 Research and Related (R&R) Application for Federal Assistance
4. Research and Related Senior/Key Person Profile (Expanded)
5. Research and Related Personal Data