

Broad Agency Announcement ASSESSING IMMUNE MEMORY (AIM) BIOLOGICAL TECHNOLOGIES OFFICE HR001121S0037 August 20, 2021

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PART I: OVERVIEW INFORMATION

- Federal Agency Name Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- Funding Opportunity Title Assessing Immune Memory
- Announcement Type Initial Announcement
- Funding Opportunity Number HR001121S0037
- North American Industry Classification System (NAICS) 541714
- Catalog of Federal Domestic Assistance Numbers (CFDA) 12.910 Research and Technology Development
- Dates
 - Posting Date: August 20, 2021
 - Proposal Abstract Due Date and Time: September 9, 2021, 4:00 PM ET
 - Full Proposal Due Date and Time: October 26, 2021, 4:00 PM ET
 - o BAA Closing Date: October 26, 2021
 - Proposers Day: https://sam.gov/opp/633df2f92a7d495792fd9b3b65bee03f/view?watch=fal se
- Concise description of the funding opportunity Military service members rely on effective vaccination for the prevention of communicable disease as well as to guard against biothreat exposure. Many current vaccines lack durability (i.e., do not provide effective protection over long periods of time), and there are pathogens and threats that lack prophylactic options altogether. It is currently impossible to predict vaccine durability from early response profiles, largely owing to ignorance of mechanisms underlying immune memory as well as an inability to measure the cellular contributors that invoke long-lasting immune protection. Formation of immune memory is a complex physiological process characterized by a diverse array of cellular interactions and signaling processes. AIM seeks to develop a platform capability to predict immune memory informed by a systems-level view of the host response to vaccination and its mechanisms.
- **Types of instruments that may be awarded** Procurement contract, cooperative agreement, or other transaction.
- Any cost sharing requirements Cost sharing may be required under applicable statutory regulations for other transactions for prototype projects awarded under the authority of 10 U.S.C. § 2371b.
- Agency contact

The BAA Coordinator for this effort may be reached at: <u>AIM@darpa.mil</u> DARPA/BTO ATTN: HR001121S0037 675 North Randolph Street Arlington, VA 22203-2114

PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and 2 C.F.R. § 200.203. Any resultant award negotiations will follow all pertinent law and regulation, and any negotiations and/or awards for procurement contracts will use procedures under FAR 15.4, Contract Pricing, as specified in the BAA.

DARPA is soliciting innovative proposals that will apply systems biology principles to develop a research and evaluation (R&E) tool for practical assessment of immune memory responses to vaccination. A responsive proposal will integrate biomolecular profiling approaches with computational tools and methods to derive actionable and testable mechanisms from multidimensional datasets.

Specifically excluded is research that involves:

- 1. The focused development of new vaccines or vaccine modalities.
- 2. Sole reliance on existing data sets or data mining for mechanistic inference.
- 3. Development of novel vaccine components (i.e., adjuvants, excipients, etc.).
- 4. The development of model systems not currently accepted as preclinical or clinically relevant animal models.
- 5. Advanced development of a product that is out of scope.

Proposals that employ the approaches described in the above list may be deemed non-responsive and may not be considered for review.

1.1. PROGRAM OVERVIEW

Why some vaccines provide lifetime protection and others protect for only a few months remains enigmatic and difficult to predict during vaccine product development. AIM seeks to determine early on if a vaccine candidate will later provide long-lasting immune protection in humans, a current impossibility that would benefit the warfighter and nation immensely. To accomplish this goal, AIM will take a systems-level view of the immune response to vaccination and dissect it with next-generation analytical and computational approaches to determine the host response mechanisms that lead to long-lasting protection. This systems-level understanding will then be implemented as a tool that can predict vaccine duration of protection and the associated mechanisms without waiting years for retrospective determination. Upon successful demonstration of the underlying principles of AIM, the same technology can be explored for use in a prognostic capacity to predict individual levels of immune protection.

Duration of immune protection for new vaccines currently takes a "wait and see" approach. It is a grand challenge in vaccine development to be able to predict how long a vaccine will be protective before it is administered to humans, and more importantly, *why* protection is conveyed or not. Standard methods for measuring immune system response lack the ability to establish host mechanisms that contribute to [good and poor] immune protection and focus on simple markers (e.g., antibody levels, etc.) that do not capture the breadth of immune system responses possible. Rather, antibody levels and select immune cell type markers act as simple proxies that miss critical features of the immune response at a systems level, particularly the ability of the immune system to recognize a pathogen months or years after vaccination - the physiology of immune memory. AIM will uncover new biomolecular correlates using leading edge technologies from both preclinical animal models and human samples. Biomolecular correlates are defined as collections of measured responses from organisms to an immune system challenge, such as vaccination. These correlates will be assembled from quantitative features that are observed at the activity level (such as change in number or location of a given cell type) and the abundance level (such as a change in the total per-cell content of a given gene product). The central hypothesis of the AIM program is that immune memory can be predicted from multiple biomolecular correlates that are present earlier in the systems response to vaccination than the months-long profiles collected currently. Further, those correlates will be used to predict and understand why successful vaccines produce long-lasting protection. This approach will view the contributors to immune memory as an integrated system of cellular and molecular actors, and will determine relationships among them that are unknown, but whose presence has been appreciated in the field for decades. Success with AIM will provide the nation with the following capabilities: 1) upfront assessments of vaccine duration of protection early in development; 2) reduced need for unnecessary re-vaccination of operators upon deployment; 3) progress towards individualized assessments of immune protection for a given pathogen following vaccination. Technologies that can change the way we measure and perceive vaccination-induced immune protection will eliminate the uncertainty and retrospective evaluation process that is the current state of affairs.

Proposals to the AIM program must describe approaches to achieve the following:

- 1. Rational selection and justification of experimental vaccine perturbations (e.g., formulations, doses, schedules, etc.) for comparative analysis, from which response profiles will be collected.
- 2. Systems-level measurements of immune cell responses to vaccine perturbations (e.g., lineage maps, cell activity dynamics, gene expression profiles, cell surface markers, metabolic markers, etc.).
- 3. Rational selection of established preclinical biological models and/or human samples. Proposals must provide justification for the use of these preclinical models and evidence for their human translational validity.
- 4. Computational approaches providing testable mechanisms contributing to, or responsible for, the development of immune memory.
- 5. Integration of computational approaches and biomarker discovery to produce a validated suite of approaches and/or R&E tool capable of predicting immune memory from early host response.

1.2. PROGRAM STRUCTURE AND TECHNICAL APPROACH

The AIM program is divided into two sequential phases over 60 months. Phase 1 (24 months): Assemble an immune memory road map; and Phase 2 Option (36 months): Platform capability development. Proposals must address both Phases for exactly five years (one 24-month Phase 1

base period and one 36-month Phase 2 option), along with the necessary expertise required for meeting the program milestones (see Table 1). Proposals utilizing multiple teams (from the same or different institutions) and/or developing multiple approaches to addressing the phase goals should be assembled as a single research entity, and must propose and report as such. <u>Proposals that fail to address both Phases will be considered non-conforming and may be rejected without further review.</u>

1.2.1. Phase 1: Immune memory road map - identify cell and signaling contributors to generate a "road map" to immune memory.

The goal of Phase 1 is to dissect immune memory formation at the single cell level to define the responses that lead to lasting immune protection following vaccination. Capturing relevant cellular players and signaling events following infection or vaccination is challenging since most measurement techniques evaluate samples of multiple mixed cell types. The events leading to the production of cell subtypes responsible for persistent immunity must be defined in order to predict which vaccines convey protection for years. In order to generate a systems-level understanding of immune memory, AIM is supporting: 1) employing molecular profiling technologies to define vaccine response in animal model(s) that recapitulates key aspects of immune memory (i.e. a bottom-up approach); and/or 2) deep molecular interrogations of human samples (i.e. a top-down approach). Proposers must provide justification for their model selection and experiment design parameters (e.g., sample size, limit of detection, etc.). Approaches resolving multiple cellular features (protein and gene expression, etc.) from multiple, complex tissues are required. It is anticipated that proposers will target tissue types critical for the production and maturation of immune responders profiled over multiple time points and multiple perturbations to capture response dynamics of immune memory formation.

The rational selection of vaccine perturbations is key to program success. Proposers must provide justification for their selection of vaccines and experimental conditions that will be used to establish comparative datasets for multiple levels of "good and poor" immune memory response. Successful demonstrations will satisfy at least a 2.5x difference between good and poor responses, as measured by duration of protection and magnitude of selected features.

During Phase 1, performers will identify critical cellular features and signaling events that will be used to build a roadmap to immune memory. To generate the data necessary for this roadmap, contributors to immune memory will be profiled with sufficient depth and temporal sampling to assemble cell features that correlate with immune memory in the chosen model system(s). At the culmination of Phase 1 efforts, performers will need to validate the predictive accuracy of their road map by establishing biomolecular correlates of immune memory in their model system(s).

The Government will utilize Independent Validation and Verification (IV&V) partners throughout the program to aid in the evaluation of program progress and intermediate program demonstrations. By the end of Phase 1, at month 24, , a demonstration will be completed to determine entry into the Phase 2 option.

1.2.2. Phase 2: Road Map Generalizability and Tool Validation – assemble and validate an R&E tool for predicting vaccine duration of protection.

The first challenge in Phase 2 will be to establish the generalizability of the roadmap from Phase 1 by cross-validating the immune mechanisms described. To address this, animal data will need to be validated for relevance in human samples, and human data will need to demonstrate that the processes are comparable in an animal model(s). It is anticipated that additional experimental data collection will be part of this cross-validation to further establish biomolecular correlates of immune mechanisms that are representative of durability. To be of practical use during vaccine development, the R&E tool must demonstrate that mechanisms established in the chosen preclinical animal model(s) are transferrable to the human system. To evaluate this transferability, a comparison of at least four types of vaccine challenge (such as doses, adjuvant formulations, schedules, etc.) should be used in a suitable animal challenge model to predict duration of protection when compared to existing longitudinal data and determine generalizable mechanisms towards the production of diverse immune cell responders.

Another key challenge in Phase 2 is establishing the most robust and relevant biomolecular correlates representative of immune memory – across different individuals. The specific cell signaling processes that lead to the development of immune memory in one individual may not be exactly the same as in another, but there will be common features at some level that result in similar clinical end points. Deriving these types of relationships from dense, multivariate data is a perennial challenge for advanced computation in biology. It is anticipated that proposers will test the performance of multiple computational methods to determine which yields the most efficient and accurate mechanistic output and why. The proposers will leverage these computational approaches to select the most informative sets of immune memory biomolecular correlates from the dense data networks generated in the program. The computational approaches to be pursued in AIM will: 1) utilize the contextually appropriate data generated in Phase 1 and the first component of Phase 2 as it applies to the formation of immune memory; 2) derive immunological mechanisms that can be validated experimentally; and 3) use lessons learned from the mechanisms to assemble an R&E tool for predicting the duration of protection following vaccination.

By the end of the fourth year, an R&E tool (e.g., suite of biomolecular assays and computational analysis pipeline) should be developed. The final R&E tool will need to be able to reliably detect biomolecular correlates from blood and/or other readily accessible immune tissues sampled during preclinical animal model evaluation of vaccine candidates. Proposers will generate a unified set of practices and targeted biomolecule measurements to accurately capture the often rare and low-abundance cellular features that define correlates of immune protection conferred by vaccines. During this time, the performers should evaluate the R&E tool's predictive accuracy in determining the extent and mechanistic route of immune memory formation following vaccination. To be a valuable preclinical R&E tool for vaccine development, it must be capable of predicting long-term (months-years) immune protection (more than simple antibody abundance) from early post-vaccination measures (i.e., approximately 0-10 days).

DARPA will facilitate the collaboration of performer groups with an IV&V team. The last year of Phase 2 performance (year five; months 49-60) is dedicated to a cooperative transfer of tools

and techniques (i.e., the R&E tool) to the IV&V team for demonstration of capability performance. In consultation with DARPA, the IV&V team and performers will design multiple blinded experiments with vaccine candidates administered to produce a range of immune responses and utilize the mature AIM tool to predict duration of protection prior to pathogen challenge. Finally, the IV&V team will collect data assessing the performance of the R&E tool in determining the degree and mechanism of immune protection from a cohort of previously vaccinated subjects (preclinical animal models or human clinical subjects).

1.3. PROGRAM METRICS

Proposals must follow the program metric structure below:

Table 1 below lists Milestones and Metrics for the AIM program. Progression from Phase 1 to the Phase 2 option is dependent on funding availability and Phase I performance; and progression into final IV&V demonstration (months 49-60) is contingent on successful completion of month 48 metrics, with the **underlined bold** metrics weighted most heavily.

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Phase 1	Phase Deliverable: Road map to immune memory from systems-level					
integration of molecular signatures						
	Milestones & Metrics					
6 Months	Milestone: Establish cell and molecular profiling methods and a					
	biological model of good immune memory.					
	Metrics:					
	• Demonstrate antibody and associated quantitative responses to a					
	"good" vaccine that produces at least 2.5x enhancement over a					
	"poor" vaccine that currently lacks durable protection.					
12 Months	Milestone: Define "good" immune memory in terms of cell and					
	molecular features from >2 immune-associated tissues that correlate					
	with observably long durations of protection as opposed to those that					
	do not.					
	Metrics:					
	• Demonstrate that this profile is consistent across individuals at early					
	(e.g., day 10) and late (e.g., day 120) timepoints following					
	vaccination.					
	• Categorize at least 5 (3 known, and 2 novel) sets of cell-type					
	identifiers (e.g., cell surface markers, gene or protein expression					
	defining cell subpopulations) that contribute to immune memory.					
24 Months	24 Mo Milestone and Criteria: Assemble the roadmap of routes to					
	immune memory.					
	Metrics:					
	• Quantify single cell molecular features in excess of 1000 transcripts					
	and ≥ 15 proteins per cell from immune cell subpopulations captured					
	following vaccination.					
	• Demonstration of no fewer than five immune cell features that					
correlate with immune memory in the chosen model sys						
	Confirmatory analysis by IV&V team.					

 Table 1: Milestones and Metrics

vaccine's ability to provide long-lasting protection and proof-of- ncept for pathogen-specific individual immune assessment <u>Milestones & Metrics</u> ilestone: Demonstrate transferability of immune mechanisms from A1 roadmap to humans etrics: Fest mechanistic generalizability across ≥4 variations of vaccine challenge (e.g., live-attenuated, component, adjuvant formulation, etc.)			
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challenge (e.g., live-attenuated, component, adjuvant formulation,			
dentify at least 3 pathways from unbiased molecular profiles conserved in humans that lead to B cell maturation			
ilestone : Demonstrate research tool's ability to accurately predict ccine duration of protection			
etrics:			
Capability Demo: Predict duration of protection from early (day			
0-10) features of response to vaccine in a preclinical challenge model and demonstrate accuracy of correlates to corresponding samples from a human population (≥70%).			
			Determine contributions of ≥ 3 conserved pathways to immune
			nemory formation
&V Capability Demo:			
Predict performance of vaccine candidates against a pathogen of Department of Defense (DoD) need (Category A-C). The experiment will take a comparative approach with a minimum of four different delivery conditions (such as dose regimens, adjuvants, pathogen components, etc.) and will predict performance in a suitable animal challenge model. Success will be determined as an accurate rank- order of duration of protection when compared to existing ongitudinal data.			
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1.4. GENERAL INFORMATION

1.4.1. Data Management and Sharing:

All raw data, metadata and informatics analyses, and tools specific to each experiment must be curated and made available. All data (raw data, highly-detailed metadata, and key analysis files) from profiling experiments will be uploaded to an appropriate server and be made widely available. Software design and analyses must be systematically documented with coding tools (e.g., Jupyter notebook) for evaluation and reproducibility.

1.4.2. IV&V

The Government is not soliciting IV&V proposals under HR001121S0037. To avoid potential conflicts of interest, performers for HR001121S0037 will not be allowed to compete for the IV&V contract. Throughout the program, the performers will work with a Government-furnished IV&V team. This partnership will be facilitated by the Government. The IV&V team will consist of subject matter experts from the Government, Federally Funded Research and Development Centers (FFRDCs), academia and/or other relevant domains capable of meeting the desired IV&V goals of the program as established by DARPA.

2. Award Information

2.1. GENERAL AWARD INFORMATION

Multiple awards are possible. The amount of resources made available under this BAA will depend on the quality of the proposals received and the availability of funds.

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 discussions with proposers. The Government also reserves the right to conduct discussions if it is later determined to be necessary. If warranted, portions of resulting awards may be segregated into pre-priced options. Additionally, DARPA reserves the right to accept proposals in their entirety or to select only portions of proposals for award. In the event that DARPA desires to award only portions of a proposal, negotiations may be opened with that proposer. The Government reserves the right to fund proposals in phases with options for continued work, as applicable.

The Government reserves the right to request any additional, necessary documentation 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 proposers 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 other transaction, depending upon the nature of the work proposed, the required degree of interaction between parties, whether or not the research is classified as Fundamental Research, and other factors.

Proposers looking for innovative, commercial-like contractual arrangements are encouraged to consider requesting Other Transactions. To understand the flexibility and options associated with Other Transactions, consult <u>http://www.darpa.mil/work-with-us/contract-management#OtherTransactions</u>.

In accordance with 10 U.S.C. § 2371b(f), the Government may award a follow-on production contract or Other Transaction (OT) for any OT awarded under this solicitation if: (1) that participant in the OT, or a recognized successor in interest to the OT, successfully completed the entire prototype project provided for in the OT, as modified; and (2) the OT provides for the award of a follow-on production contract or OT to the participant, or a recognized successor in interest to the OT.

In all cases, the Government contracting officer shall have sole discretion to select award instrument type, regardless of instrument type proposed, and to negotiate all instrument terms and conditions with selectees. DARPA 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 performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Any award resulting from such a determination will include a requirement for DARPA permission before publishing any information or results on the program. For more information on publication restrictions, see the section below on Fundamental Research.

2.2. FUNDAMENTAL RESEARCH

It is DoD policy that the publication of products of fundamental research will remain unrestricted to the maximum extent possible. National Security Decision Directive (NSDD) 189 defines fundamental research as follows:

'Fundamental research' means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

As of the date of publication of this solicitation, the Government expects that program goals as described herein may be met by proposers intending to perform fundamental research and does not anticipate applying publication restrictions of any kind to individual awards for fundamental research that may result from this solicitation. Notwithstanding this statement of expectation, the Government is not prohibited from considering and selecting research proposals that, while perhaps not qualifying as fundamental research under the foregoing definition, still meet the solicitation criteria for submissions. If proposals are selected for award that offer other than a fundamental research solution, the Government will either work with the proposer to modify the proposed statement of work to bring the research back into line with fundamental research or else the proposer will agree to restrictions in order to receive an award.

Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to determine whether the proposed research shall be considered fundamental and to select the award instrument type. Appropriate language will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate. This language can be found at http://www.darpa.mil/work-with-us/additional-baa. For certain research projects, it may be possible that although the research to be performed by a potential awardee is non-fundamental research, its proposed subawardee's effort may be fundamental research. It is also possible that the research performed by a potential awardee is fundamental research while its proposed subawardee's effort may be non-fundamental research. In all cases, it is the potential awardee's responsibility to explain in its proposal which proposed efforts are fundamental research and why the proposed efforts should be considered fundamental research.

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

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

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

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.

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.

Authority and Eligibility

At the present time, DARPA does not consider 15 U.S.C. § 3710a to be sufficient legal authority to show eligibility. While 10 U.S.C.§ 2539b may be the appropriate statutory starting point for some entities, specific supporting regulatory guidance, together with evidence of agency approval, will still be required to fully establish eligibility. DARPA 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.

3.1.2. Non-U.S. Organizations

Non-U.S. organizations and/or individuals 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.

3.2. ORGANIZATIONAL CONFLICTS OF INTEREST

FAR 9.5 Requirements

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

(subawardee, consultant). Under this Section, the proposer is responsible for providing this 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.

Agency Supplemental OCI Policy

In addition, DARPA has a supplemental OCI policy that prohibits contractors/performers from concurrently providing Scientific Engineering Technical Assistance (SETA), 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 (subawardee, consultant) is providing SETA, A&AS, or similar support to any DARPA 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 DARPA office(s), the proposal must include:

- The name of the DARPA office receiving the support;
- The prime contract number;
- Identification of proposed team member (subawardee, consultant) 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 DARPA 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.

3.3. COST SHARING/MATCHING

Cost sharing is not required; however, it will be carefully considered where there is an applicable statutory condition relating to the selected funding instrument. Cost sharing is encouraged where there is a reasonable probability of a potential commercial application related to the proposed research and development effort.

4. Application and Submission Information

4.1. 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 <u>http://www.darpa.mil</u>, contact the administrative contact listed herein.

4.2. CONTACT AND FORM OF APPLICATION SUBMISSION

All submissions, including abstracts and proposals, must be written in English with type no smaller than 12-point font. Smaller font may be used for figures, tables, and charts. 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 DARPA BAA number, proposer organization, and proposal title/proposal short title.

4.2.1. Proposal Abstract Format

Proposers are strongly encouraged to submit an abstract in advance of a proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. The abstract is a concise version of the proposal comprising a maximum of **8** pages including all figures, tables, and charts. The submission letter is not included in the page count. All submissions must be written in English with type no smaller than 12-point font. Smaller font may be used for figures, tables, and charts. The page limitation for abstracts 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 DARPA BAA number, proposer organization, and proposal abstract title/proposal abstract short title.

Abstracts must include the following components:

A. Cover Sheet (does not count towards page limit): Include the administrative and technical points of contact (name, address, phone, fax, email, lead organization). Also include the BAA number, title of the proposed project, primary subcontractors, estimated cost, duration of the project, and the label "ABSTRACT."

B. Goals and Impact: Clearly describe what is being proposed and what difference it will make (qualitatively and quantitatively), including brief answers to the following questions:

- 1. What is the proposed work attempting to accomplish or do?
- 2. How is it done today? And what are the limitations?
- 3. What is innovative in your approach and how does it compare to the current state-of-the-art (SOA)?
- 4. What are the key technical challenges in your approach and how do you plan to overcome these?
- 5. Who will care and what will the impact be if you are successful?
- 6. How much will it cost and how long will it take? Ensure that the cost and schedule are aligned with the phases outlined in Table 1.

C. Technical Plan: Outline and address all technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should

provide appropriate specific milestones at intermediate stages of the project to demonstrate progress, and a brief plan for accomplishment of the milestones.

D. Capabilities: Provide a brief summary of expertise of the team, including subcontractors and key personnel. A principal investigator for the project must be identified. <u>No more than two resumes should be included as part of the abstract, and one resume must be from the PI.</u> Resumes do not count as part of the page limit. Include a description of the team's organization including roles and responsibilities. Describe the organizational experience in this area, existing intellectual property required to complete the project, and any specialized facilities to be used as part of the project. List Government-furnished materials or data assumed to be available. If desired, include a brief bibliography with links to relevant papers, reports, or resumes of key personnel.

E. Cost and Schedule: Cost and schedule for the proposed research, including an estimate of (a) total cost, (b) cost for each task in each phase of the effort by prime and major subcontractors, and (c) any cost share (if applicable).

4.2.2. Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal.** All submissions must be written in English with type no smaller than 12-point font. A smaller font may be used for figures, tables, and charts. 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 DARPA BAA number, proposer 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 (3) 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 review. The maximum page count for Volume I is 35 pages. The submission letter is not included in the page count. Volume I should include the following components:

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

a. Volume I, Technical and Management Proposal

Section I. Administrative

A. Cover Sheet (LABELED "PROPOSAL: VOLUME I"):

- 1. BAA number (HR001121S0037);
- 2. Lead organization submitting proposal (prime contractor);

- 3. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
- 4. Proposer's reference number (if any);
- 5. Other team members (if applicable) and type of business for each;
- 6. Proposal title;
- 7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
- 8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
- 9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, firm-fixed-price, cooperative agreement, other transaction, or other type (specify);
- 10. Place(s) of performance, including all subcontractors and consultants;
- 11. Period of performance;
- 12. Total funds requested from DARPA, total funds requested per phase (as defined in Table 1), and the amount of any cost share (if any);
- 13. Proposal validity period; AND
- 14. Date proposal was submitted.

Information on award instruments is available at <u>http://www.darpa.mil/work-with-us/contract-management</u>.

B. Official Transmittal Letter.

Section II. Detailed Proposal Information

- **A. Executive Summary (1-2 pages):** 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 it done today, and what are the limitations?
 - What is innovative in your approach? How is your approach better than the current state-of-the-art, alternative approaches, and previous efforts? Why do you think your approach will succeed? Summarize scientific rationale supporting 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? Ensure that the cost and schedule are aligned with the phases outlined in Section 1.4 Program Metrics and as outlined in Table 1.
- **B.** Goals and Impact (1-2 pages): 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 work.
- C. Technical Plan (12 -15 pages): Provide a detailed scientific rationale and description of the planned approach and execution plan. The technical plan should demonstrate a deep understanding of the scientific challenges and present a credible (even if risky) plan to achieve the program goals. The technical approach should address all applicable proposal content instructions in Sections 1.1 1.4.
 - **a. Approach:** Describe the scientific and technical approach. Hypotheses should be articulated clearly and include a rigorous test plan with quantitative metrics to yield unambiguous results. Experimental designs and procedures must be described thoroughly, including aspects such as equipment, behavioral paradigms, animal models, approximate numbers of subjects, software, analysis plan, statistical reporting etc. Figures and diagrams that help illustrate the experimental design may be included.
 - **b. Rationale:** Provide a clear rationale for the approach, including a justification for the feasibility of the proposed task. Proposers are highly encouraged to include supporting data when available, even if preliminary. Figures included within the proposal should be accompanied by a brief description of how data was collected, what analysis was performed, what the results mean, and why the result supports the feasibility of the proposed task.
 - c. Schedule: Include a narrative overview of the timeline of the task/objective. Intermediate milestones and final completion criteria should be identified along with the quantitative metrics that will be used to evaluate progress. Include a one-page high-level graphical (Gantt or flow chart style) timeline of the outlined tasks/objectives described in the Scientific Approach and Plan.
 - **d.** Challenges and Risks: Articulate the scientific and technical challenges and risks facing this effort. Include a risk mitigation plan including possible solutions for overcoming potential hurdles or alternative approaches.

- e. **Personnel:** Identify the personnel responsible for each major task (e.g., "led by Jane Smith with support from one graduate student at 50% effort").
- **D.** Management Plan (2-3 pages): Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. Include an organization chart for the entire team which includes, as applicable: (1) the programmatic relationship of team member; (2) the unique capabilities of team members; (3) the task 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. Resumes do not count against the proposal page count. Identify a principal investigator for the project. Proposals must designate a project manager for the entirety of the effort. The project manager will serve alongside the PI as a primary point of contact for scientific and administrative matters, and will ideally hold an advanced degree in a relevant field of study. Provide a detailed plan for coordination including explicit guidelines for interaction among collaborators/subcontractors of the proposed effort. Numbers of dedicated personnel at all hierarchical levels of the effort should reflect the substantial scale anticipated to meet the critical program objectives and contain detailed information about specific expertise.
- **E.** Capabilities (1-3 pages): Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Discuss any work in closely related research areas and previous accomplishments. Include a description of the facilities that would be used for the proposed effort.
- F. Statement of Work (SOW) (3-6 pages): The SOW must be read as a stand-alone document without references to text or figures included in Section B. Each Phase of the program should be defined separately: Phase 1 (Base) and Phase 2 (Option). Dependencies between tasks and/or subtasks should be identified clearly. The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. 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 contractor, subcontractor(s), consultant(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.
- **G.** Schedule and Milestones (1-3 pages): 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.
- H. Transition Plan (0.5-1 pages): Proposals are encouraged to outline a plan for potential clinical translation of the products that are developed in AIM. While AIM is a fundamental research program, it is anticipated that the capabilities, knowledge, and products developed by the end of the program will be suitable for advanced development for medical use and for National Security purposes. It is DARPA's vision that by the end of the program, proposers should have identified partners for advanced development in pursuit of a preclinical R&E tool. Additionally, transition elements should include aspects of commercial ventures, licensing agreements, or other pathways from basic research into health and medical applications.
- I. Summary Slides (Does not count towards page limit; two (2) slides maximum): PowerPoint slide(s) summarizing the proposed effort's vision, goals, impact, scientific/technical approach, and milestone schedule. Download and use the template provided in Attachment 1 posted with the subject BAA. Submit the PowerPoint file in addition to Volume I and II of your proposal.
 - a. Volume II, Cost Management Proposal

Cover Sheet (LABELED "PROPOSAL: VOLUME II"):

- 1. BAA Number (HR001121S0037);
- 2. Technical area;
- 3. Lead Organization Submitting proposal;
- Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
- 5. Proposer's reference number (if any);
- 6. Other team members (if applicable) and type of business for each;
- 7. Proposal title;

- 8. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
- 9. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
- 10. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;
- 11. Place(s) of performance, including all subcontractors and consultants;
- 12. Period of performance;
- 13. Total funds requested from DARPA, total funds requested per phase (as defined in Table 1), and the amount of any cost share (if any);
- 14. Name, address, and telephone number of the proposer's cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
- 15. Name, address, and telephone number of the proposer's cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
- 16. Date proposal was prepared;
- 17. DUNS number (<u>http://www.dnb.com/get-a-duns-number.html</u>);
- 18. Taxpayer ID number (<u>https://www.irs.gov/Individuals/International-</u> <u>Taxpayers/Taxpayer-Identification-Numbers-TIN</u>);
- 19. CAGE code (<u>https://cage.dla.mil/Home/UsageAgree</u>); and
- 20. Proposal validity period.

Note that nonconforming proposals may be rejected without review.

The Government requires that proposers use the provided MS Excel[™] DARPA Standard Cost Proposal Spreadsheet in the development of their cost proposals. A customized cost proposal spreadsheet may be an attachment to this solicitation. If not, the spreadsheet can be found on the DARPA website at <u>http://www.darpa.mil/work-with-us/contract-management</u> (under "Resources" on the right-hand side of the webpage). 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. 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 cost proposal spreadsheets may be submitted directly to the Government by the proposed subcontractor via e-mail to the address in Part I of this solicitation. **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.**

• Please submit any breakdown of expenses in an editable, MS EXCEL cost file.

- Total program, per phase (Phase 1 (Base) and Phase 2 (Option); and per task cost broken down by major cost items to include:
 - Direct labor provide an itemized breakout of all personnel, listed by name or TBD, with labor rate (or salary), labor hours (or percent effort), and labor category. All senior personnel must be identified by name.
 - Materials and Supplies itemized list which includes description of material, quantity, unit price, and total price. If a material factor is used based on historical purchases, provide data to justify the rate.
 - Equipment itemized list which includes description of equipment, unit price, quantity, and total price. Any equipment item with a unit price over \$5,000 must include a vendor quote.
 - Animal Use Costs itemized list of all materials, animal purchases, and per diem costs, associated with proposed animal use; include documentation supporting daily rates.
 - Travel provide an itemized list of travel costs to include purpose of trips, departure and arrival destinations, projected airfare, rental car and per GSA approved diem, number of travelers, number of days); provide screenshots from travel website for proposed airfare and rental car, as applicable; provide screenshot or web link for conference registration fee and note if the fee includes hotel cost. Conference attendance must be justified, explain how it is in the best interest of the project. Plan for two (2) DARPA program review meetings per year.
 - Other Direct Costs (e.g., computer support, clean room fees) Should be itemized with costs or estimated costs. Backup documentation and/or a supporting cost breakdown is required to support proposed costs with a unit price over \$5,000. An explanation of any estimating factors, including their derivation and application, must be provided. Please include a brief description of the proposers' procurement method to be used.
 - Other Direct Costs Consultants: provide executed Consultant Agreement that describes work scope, rate and hours.
 - Indirect costs including, as applicable, fringe benefits, overhead, General and Administrative (G&A) expense, and cost of money (see university vs. company specific requirements below).
 - Indirect costs specific to a University proposer: (1) Fringe Benefit Rate (provide current DHHS or ONR negotiated rate package; if calculated by other than a rate, provide University documentation identifying fringe costs by position or HR documentation if unique to each person); (2) F&A Indirect Overhead Rate (provide current DHHS or ONR negotiated rate package); (3) Tuition Remission (provide current University documentation justifying per student amount); and (4) Health Insurance/Fee (provide current University documentation justifying per student amount, if priced separately from fringe benefits with calculations included in the EXCEL cost file).
 - Indirect costs specific to a Company proposer: (1) Fee/Profit (provide rationale for proposed fee/profit percentage using criteria found in DFARS 215.404-70); and (2) Fringe Benefit/Labor OH/Material OH/G&A

Rates (provide current Forwarding Pricing Rate Proposal (FPRP) or DCMA/DCAA Forward Pricing Rate Recommendation or Agreement (FPRR or FPRA). If these documents are not available, provide company historical data, preferably two years, minimum of one, to include both pool and expense costs used to generate the rates).

- A summary of total program costs by phase and task.
- An itemization of Subcontracts. All subcontractor cost proposal documentation must be prepared at the same level of detail as that required of the prime. Subcontractor proposals should include Interdivisional Work Transfer Agreements (IWTA) or evidence of similar arrangements (an IWTA is an agreement between multiple divisions of the same organization). The prime proposer is responsible for compiling and providing all subcontractor proposals for the Procuring Contracting Officer (PCO). The proposal must show how subcontractor costs are applied to each phase and task. If consultants are to be used, proposer must provide consultant agreement or other document which verifies the proposed loaded daily/hourly rate.
- An itemization of any information technology (IT) purchase (including a letter stating why the proposer cannot provide the requested resources from its own funding), as defined in FAR Part 2.101.
- A summary of projected funding requirements by month for both phases of the project.
- A summary of tasks that have animal or human use funding.
- The source, nature, and amount of any industry cost-sharing. 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.
- 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 Expert/s, etc.).
- Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available).
- Proposers with a Government acceptable accounting system who are proposing a cost-type contract must submit the DCAA document approving the cost accounting system.

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" are not required if the proposer proposes an award instrument other than a procurement contract (e.g., a grant, cooperative agreement, or other transaction.)

Subawardee Proposals

The awardee is responsible for compiling and providing all subawardee proposals for the Procuring Contracting Officer (PCO)/Grants Officer (GO)/Agreements Officer (AO), as

applicable. Subawardee proposals should include Interdivisional Work Transfer Agreements (ITWA) or similar arrangements. Where the effort consists of multiple portions which could reasonable be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.

All proprietary subawardee proposal documentation, prepared at the same level of detail as that required of the awardee's proposal and which cannot be uploaded with the proposed awardee's proposal, shall be provided to the Government either by the awardee or by the subawardee organization when the proposal is submitted. Subawardee proposals submitted to the Government by the proposed subawardee should be submitted via e-mail to the address in Section I.

Other Transaction Requests

All proposers requesting an OT must include a detailed list of milestones. Each milestone must include the following:

- milestone description;
- completion criteria;
- due date; and
- payment/funding schedule (to include, if cost share is proposed, awardee 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. Agreement type, expenditure or fixed-price based, will be subject to negotiation by the Agreements Officer. Do not include proprietary data.

4.2.3. Additional Proposal Information

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" or "Company 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.

Unclassified Submissions

DARPA anticipates that submissions received under this BAA will be unclassified. However, should a proposer wish to submit classified information, an *unclassified* email must be sent to the BAA mailbox requesting submission instructions from the Technical Office Program Security Officer. If a determination is made that the award instrument may result in access to classified information, a Security Classification Guide and/or DD Form 254 will be issued by DARPA and attached as part of the award.

Disclosure of Information and Compliance with Safeguarding Covered Defense Information Controls

The following provisions and clause apply to all solicitations and contracts; however, the definition of "controlled technical information" clearly exempts work considered fundamental research and therefore, even though included in the contract, will not apply if the work is fundamental research.

DFARS 252.204-7000, "Disclosure of Information"

DFARS 252.204-7008, "Compliance with Safeguarding Covered Defense Information Controls" DFARS 252.204-7012, "Safeguarding Covered Defense Information and Cyber Incident Reporting"

The full text of the above solicitation provision and contract clauses can be found at <u>http://www.darpa.mil/work-with-us/additional-baa#NPRPAC</u>.

Compliance with the above requirements includes the mandate for proposers to implement the security requirements specified by National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations" (see

https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-171r2.pdf) and DoDI 8582.01 that are in effect at the time the solicitation is issued.

For awards where the work is considered fundamental research, the contractor will not have to implement the aforementioned requirements and safeguards. However, should the nature of the work change during performance of the award, work not considered fundamental research will be subject to these requirements.

Human Subjects Research (HSR)/Animal Use

Proposers that anticipate involving human subjects or animals in the proposed research must comply with the approval procedures detailed at <u>http://www.darpa.mil/work-with-us/additional-baa</u>, to include providing the information specified therein as required for proposal submission.

Approved Cost Accounting System Documentation

Proposers that do not have a Cost Accounting Standards (CAS) complaint accounting system considered adequate for determining accurate costs that are negotiating a cost- type procurement contract must complete an SF 1408. For more information on CAS compliance, see http://www.dcaa.mil/cas.html. To facilitate this process, proposers should complete the SF 1408 found at http://www.dcaa.mil/cas.html. To facilitate this process, proposers should complete the SF 1408 found at http://www.gsa.gov/portal/forms/download/115778 and submit the completed form with the proposal.

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), each proposer who submits a contract proposal and includes subcontractors might be required to submit a subcontracting plan with their proposal. The plan format is outlined in FAR 19.704.

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.

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.

For Procurement Contracts

Proposers responding to this BAA requesting procurement contracts will need to complete the certifications at DFARS 252.227-7017. See <u>http://www.darpa.mil/work-with-us/additional-baa</u> for further information. 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	Name of Person Asserting Restrictions
(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)

For All Non-Procurement Contracts

Proposers responding to this BAA requesting a Cooperative Agreement, Technology Investment Agreement, or Other Transaction for Prototypes shall follow the applicable rules and regulations governing these various award instruments, but, in all cases, should appropriately identify any potential 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. Proposers are encouraged to use a format similar to that described in the section above. If no restrictions are intended, then the proposer should state "NONE."

System for Award Management (SAM) and Universal Identifier Requirements

All proposers must be registered in SAM unless exempt per FAR 4.1102. FAR 52.204-7, "System for Award Management" and FAR 52.204-13, "System for Award Management Maintenance" are incorporated into this solicitation. See <u>http://www.darpa.mil/work-with-us/additional-baa</u> for further information.

International entities can register in SAM by following the instructions in this link: <u>https://www.fsd.gov/sys_attachment.do?sys_id=c08b64ab1b4434109ac5ddb6bc4bcbb8</u>.

4.2.4. Submission Information

DARPA will acknowledge receipt of all submissions and assign an identifying control number that should be used in all further correspondence regarding the submission. DARPA intends to use electronic mail correspondence regarding HR001121S0037. <u>Submissions may not be submitted by fax or e-mail; any so sent will be disregarded.</u>

Submissions will not be returned. An electronic copy of each submission received will be retained at DARPA and all other non-required copies destroyed. A certification of destruction

may be requested, provided the formal request is received by DARPA within 5 days after notification that a proposal was not selected.

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

Abstracts and Full Proposals sent in response to HR001121S0037 may be submitted via DARPA's BAA Website (<u>https://baa.darpa.mil</u>). Visit the website to complete the two-step registration process. Submitters will need to register for an Extranet account (via the form at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the abstract. Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process be started as early as possible.

All unclassified concepts submitted electronically through DARPA's BAA Website must be uploaded as zip files (.zip or .zipx extension). The final zip file should be no greater than 50 MB in size. Only one zip file will be accepted per submission. Classified submissions and proposals requesting or cooperative agreements should NOT be submitted through DARPA's BAA Website (https://baa.darpa.mil), though proposers will likely still need to visit https://baa.darpa.mil to register their organization (or verify an existing registration) to ensure the BAA office can verify and finalize their submission.

Technical support for BAA Website may be reached at <u>BAAT_Support@darpa.mil</u>, and is typically available during regular business hours, (9:00 AM- 5:00 PM EST Monday – Friday).

Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process is started as early as possible.

For Cooperative Agreements only:

Proposers requesting cooperative agreements must submit proposals through one of the following methods: (1) electronic upload per the instructions at

<u>https://www.grants.gov/applicants/apply-for-grants.html</u> (DARPA-preferred); or (2) hard-copy mailed directly to DARPA. If proposers intend to use Grants.gov as their means of submission, then they must submit their entire proposal through Grants.gov; applications cannot be submitted in part to Grants.gov and in part as a hard-copy. Proposers using Grants.gov do not submit hard-copy proposals in addition to the Grants.gov electronic submission.

Submissions: In addition to the volumes and corresponding attachments requested elsewhere in this solicitation, proposers must also submit the three forms listed below.

Form 1: <u>SF 424 Research and Related (R&R) Application for Federal Assistance</u>, available on the Grants.gov website at <u>https://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf</u>. *This form must be completed and submitted*.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et.seq.), the Department of Defense (DoD) 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. In addition, the National Defense Authorization Act (NDAA) for FY 2019, Section 1286, directs the Secretary of Defense to protect intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security and limit undue influence, including foreign talent programs by countries that desire to exploit United States' technology within the DoD research, science and technology, and innovation enterprise. This requirement is necessary for all research and research-related educational activities. The DoD is using the two forms below to collect the necessary information to satisfy these requirements. Detailed instructions for each form are available on Grants.gov.

Form 2: <u>Research and Related Senior/Key Person Profile (Expanded)</u>, available on the Grants.gov website at

<u>https://apply07.grants.gov/apply/forms/sample/RR_KeyPersonExpanded_2_0-V2.0.pdf</u>. *This form must be completed and submitted*.

The Research and Related Senior/Key Person Profile (Expanded) form 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 the DoD:

- Degree Type and Degree Year.
- Current and Pending Support, including:
 - 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.
 - Title and objectives of the other research projects.
 - The percentage per year to be devoted to the other projects.
 - 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.
 - Name and address of the agencies and/or other parties supporting the other research projects
 - 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 DARPA receives an application without the required information, DARPA 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. DARPA reserves the right to request further details from the applicant before making a final determination on funding the effort.

Form 3: <u>Research and Related Personal Data</u>, available on the Grants.gov website at <u>https://apply07.grants.gov/apply/forms/sample/RR_PersonalData_1_2-V1.2.pdf</u>. *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.*

<u>Grants.gov Submissions:</u> Grants.gov requires proposers to complete a one-time registration process before a proposal can be electronically submitted. First-time registration can take between three business days and four weeks. For more information about registering for Grants.gov, see <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

Proposal abstracts will not be accepted if submitted via Grants.gov.

<u>Hard-copy Submissions</u>: Proposers electing to submit cooperative agreement proposals as hard copies must complete the SF 424 R&R form (Application for Federal Assistance,) available on the Grants.gov website (<u>https://apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf</u>).

Failure to comply with the submission procedures may result in the submission not being evaluated. DARPA will acknowledge receipt of complete submissions via email and assign control numbers that should be used in all further correspondence regarding proposals.

4.3. FUNDING RESTRICTIONS

Pre-award costs will not be reimbursed unless a pre-award cost agreement is negotiated prior to award.

4.4. OTHER SUBMISSION INFORMATION

DARPA will post a consolidated Frequently Asked Questions (FAQ) document. To access the posting go to: <u>http://www.darpa.mil/work-with-us/opportunities</u>. A link to the FAQ will appear under the HR001121S0037 summary. Submit your question(s) via e-mail to <u>AIM@darpa.mil</u>.

5. Application Review Information

5.1. EVALUATION CRITERIA

Proposals will be evaluated using the following criteria, listed in descending order of importance: 5.1.1 Overall Scientific and Technical Merit; 5.1.2 Potential Contribution and Relevance to the DARPA Mission; and 5.1.3 Cost Realism.

5.1.1. 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. The timeline for achieving major milestones is aggressive, but rationally supported with a clear description of the requirements and risks. The proposer's prior experience in similar efforts must clearly demonstrate 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.

5.1.2. Potential Contribution and Relevance to the DARPA Mission

The potential contributions of the proposed effort are relevant to the national technology base. Specifically, DARPA's mission is to make pivotal early technology investments that create or prevent strategic surprise for U.S. National Security.

5.1.3. Cost Realism

The proposed costs are realistic for the technical and management approach and 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 are 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).

It is expected that the effort will leverage all available relevant prior research in order 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. DARPA 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 in order to be in a more competitive posture. DARPA discourages such cost strategies.

5.2. REVIEW OF PROPOSALS

Review Process

It is the policy of DARPA to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed in Section V.A. and to select the source (or sources) whose offer meets the Government's technical, policy, and programmatic goals.

DARPA will conduct a scientific/technical review of each conforming proposal. Conforming proposals comply with all requirements detailed in this solicitation; proposals that fail to do so may be deemed non-conforming and may be removed from consideration. Proposals will not be evaluated against each other since they are not submitted in accordance with a common work statement. DARPA's intent is to review proposals as soon as possible after they arrive; however, proposals may be reviewed periodically for administrative reasons.

Award(s) will be made to proposers whose 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.

Handling of Source Selection Information

DARPA 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 DARPA support contractors performing this role are expressly prohibited from performing DARPA-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 proposals may be solicited by DARPA from non-Government consultants/experts who are strictly bound by the appropriate non-disclosure requirements.

Federal Awardee Performance and Integrity Information (FAPIIS)

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

6. Award Administration Information

6.1. SELECTION NOTICES

6.1.1. Proposal Abstracts

DARPA will respond to abstracts with a statement as to whether DARPA is interested in the idea. If DARPA does not recommend the proposer submit a full proposal, DARPA will provide feedback to the proposer regarding the rationale for this decision. Regardless of DARPA's response to an abstract, proposers may submit a full proposal. DARPA will review all conforming full proposals using the published evaluation criteria and without regard to any comments resulting from the review of an abstract.

6.1.2. Full Proposals

As soon as the evaluation of a proposal is complete, the proposer will be notified that (1) the proposal has been selected for funding pending award negotiations, in whole or in part,;or (2) the proposal has not been selected. These official notifications will be sent via e-mail to the Technical POC and Administrative POC identified on the proposal coversheet.

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

There will be a program kickoff meeting in the Arlington, VA vicinity and all key participants are required to attend. Proposers should also anticipate regular program-wide PI meetings and periodic site visits at the Program Manager's discretion to the Arlington, VA vicinity. Proposers shall include within the content of their proposal details and costs of any travel or meetings they deem to be necessary throughout the course of the effort, to include periodic status reviews by the Government.

6.2.1. Solicitation Provisions and Award Clauses, Terms and Conditions

Solicitation clauses in the FAR and DFARS relevant to procurement contracts and FAR and DFARS clauses that may be included in any resultant procurement contracts are incorporated herein and can be found at <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

6.2.2. Controlled Unclassified Information (CUI) and Controlled Technical Information (CTI) on Non-DoD Information Systems

Further information on Controlled Unclassified Information on Non-DoD Information Systems is incorporated herein can be found at <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

6.2.3. 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 <u>https://www.sam.gov/</u>. In addition, all proposers are required to submit for all award instrument types supplementary DARPA-specific representations and certifications at the time of proposal submission. See <u>http://www.darpa.mil/work-with-us/reps-certs</u> for further information on required representation and certification depending on your requested award instrument.

6.2.4. Terms and Conditions

For terms and conditions specific to grants and/or cooperative agreements, see the DoD General Research Terms and Conditions (latest version) at <u>http://www.onr.navy.mil/Contracts-Grants/submit-proposal/grants-proposal/grants-terms-conditions</u> and the supplemental DARPA-specific terms and conditions at <u>http://www.darpa.mil/work-with-us/contract-management#GrantsCooperativeAgreements</u>.

6.3. **REPORTING**

The number and types of reports will be specified in the award document, but will include as a minimum monthly financial status reports, 6-week technical status reports, and quarterly technical status reports. 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.

6.4. ELECTRONIC SYSTEMS

6.4.1. Wide Area Work Flow (WAWF)

Performers will be required to submit invoices for payment directly to <u>https://wawf.eb.mil</u>, unless an exception applies. Performers must register in WAWF prior to any award under this BAA.

6.4.2. 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 (<u>http://public.era.nih.gov/iedison</u>).

7. Agency Contacts

Administrative, technical or contractual questions should be sent via e-mail to the mailbox listed below.

Points of Contact The BAA Coordinator for this effort may be reached at: <u>AIM@darpa.mil</u> DARPA/BTO ATTN: HR001121S0037 675 North Randolph Street Arlington, VA 22203-2114

For information concerning agency level protests see <u>http://www.darpa.mil/work-with-us/additional-baa#NPRPAC</u>.

8. Other Information

DARPA will host a Virtual Proposers Day via webinar format in support of the AIM program on August 27, 2021. The purpose is to provide potential proposers with information on the AIM program, promote additional discussion on this topic, and address questions.

Interested proposers are not required to attend to respond to the AIM BAA, and relevant information and materials discussed at Proposers Day will be made available to all potential proposers in the form of a FAQ posted on the DARPA Opportunities Page.

DARPA will not provide cost reimbursement for interested proposers in attendance. An online registration form and various other meeting details can be found at the registration website, <u>http://events.sa-meetings.com/AIMProposersDay</u>.

Participants are required to register no later than August 24, 2021 at 12:00 PM ET. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; there will be no onsite registration.

All foreign nationals, including permanent residents, must complete and submit a DARPA Form 60 "Foreign National Visit Request," which will be provided in the registration confirmation email.

Proposers Day Point of Contact: <u>AIM@darpa.mil</u> ATTN: DARPA-SN-21-37 675 North Randolph Street Arlington, VA 22203-2114

9. APPENDIX 1 – Volume II checklist

Volume II, Cost Proposal Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 of HR001121S0037. This worksheet must be included with the coversheet of the Cost Proposal.

1. Are all items from Section 4.2.2 (Volume II, Cost Proposal) of **HR001121S0037** included on your Cost Proposal cover sheet?

• YES • NO Appears on Page(s) [Type text] If reply is "No", please explain:

2. Does your Cost Proposal include (1) a summary cost buildup by Phase, (2) a summary cost buildup by Year, and (3) a detailed cost buildup of for each Phase that breaks out each task and shows the cost per month?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

3. Does your cost proposal (detailed cost buildup #3 above in item 2) show a breakdown of the major cost items listed below:

Direct Labor (Labor Categories, Hours, Rates)• YES• NOAppears on Page(s) [Type text]

Indirect Costs/Rates (i.e., overhead charges, fringe benefits, G&A)• YES• NOAppears on Page(s) [Type text]

Materials and/or Equipment • YES • NO

○ YES	• NO	Appears on Page(s) [Type text]
Subcontracts	s/Consultants	
○ YES	• NO	Appears on Page(s) [Type text]
Other Direct	Costs	
∘ YES	• NO	Appears on Page(s) [Type text]
Travel		
○ YES	\circ NO	Appears on Page(s) [Type text]

If reply is "No", please explain:

4. Have you provided documentation for proposed costs related to travel, to include purpose of trips, departure and arrival destinations and sample airfare?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

5. Does your cost proposal include a complete itemized list of <u>all</u> material and equipment items to be purchased (a priced bill-of-materials (BOM))?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

6. Does your cost proposal include vendor quotes or written engineering estimates (basis of estimate) for <u>all</u> material and equipment with a unit price exceeding \$5000?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

7. Does your cost proposal include a clear justification for the cost of labor (written labor basis-of-estimate (BOE)) providing rationale for the labor categories and hours proposed for each task?
 • YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

- 8. Do you have subcontractors/consultants? If YES, continue to question 9. If NO, skip to question 13. • YES • NO • Appears on Page(s) [Type text]
- 9. Does your cost proposal include copies of all subcontractor/consultant technical (to include Statement of Work) and cost proposals?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

10. Do all subcontract proposals include the required summary buildup, detailed cost buildup, and supporting documentation (SOW, Bill-of-Materials, Basis-of-Estimate, Vendor Quotes, etc.)?
 • YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

11. Does your cost proposal include copies of consultant agreements, if available? • YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

12. If requesting a FAR-based contract, does your cost proposal include a tech/cost analysis for all proposed subcontractors?

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

13. Have all team members (prime and subcontractors) who are considered a Federally Funded Research & Development Center (FFRDC), included documentation that clearly demonstrates work is not otherwise available from the private sector AND provided a letter on letterhead from the sponsoring organization citing the specific authority establishing their eligibility to propose to government solicitations and compete with industry, and compliance with the associated FFRDC sponsor agreement and terms and conditions.

• YES • NO Appears on Page(s) [Type text]

If reply is "No", please explain:

If reply is "No", please explain:

If reply is "No", please explain: