

Broad Agency Announcement Anesthetics for Battlefield Care (ABC) – Phases 1 and 2 BIOLOGICAL TECHNOLOGIES OFFICE HR001123S0038 June 9, 2023

TABLE OF CONTENTS

PART I: OVERVIEW INFORMATION	
PART II: FULL TEXT OF ANNOUNCEMENT	4
1. Funding Opportunity Description	4
1.1. Program Overview	4
1.2. Program structure and Technical Approach	6
1.3. Program Metrics, Milestones and Deliverables	8
1.4. General Requirements	9
2. Award Information	10
2.1. General Award Information	10
2.2. Fundamental Research	11
3. Eligibility Information	17
3.1. Eligible Applicants	17
3.2. Organizational Conflicts of Interest	
3.3. Cost Sharing/Matching	18
4. Application and Submission Information	19
4.1. Address to Request Application Package	19
4.2. Contact and Form of Application Submission	19
4.3. Funding Restrictions	
4.4. Other Submission Information	
5. Application Review Information	
5.1. Evaluation Criteria	
5.2. Review of Proposals	
5.2.4. Countering Foreign Influence Program (CFIP)	
6. Award Administration Information	
6.1. Submission Status Notifications	
6.2. Administrative and National Policy Requirements	
6.3. Reporting	
6.4. Electronic Systems	
7. Agency Contacts	40
8. Other Information	
8.1. Proposers Day	40
8.2. University Funding.	
9. APPENDIX I – Volume II checklist	42

PART I: OVERVIEW INFORMATION

- Federal Agency Name Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- Funding Opportunity Title Anesthetics for Battlefield Care (ABC) Phases 1 and 2
- Announcement Type Initial Announcement
- Funding Opportunity Number HR001123S0038
- North American Industry Classification System (NAICS) 541714
- Assistance Listing Number (ALN) 12.910 Research and Technology Development
- Dates
 - Posting Date: June 9, 2023
 - Proposers Day: June 16, 2023 https://sam.gov/opp/6d8334dabd2f4937a25feb5776f897bc/view
 - Proposal Abstract Due Date and Time: June 30, 2023, 4:00 PM ET
 - Full Proposal Due Date and Time: August 21, 2023, 4:00 PM ET
 - BAA Closing Date: August 21, 2023
- Concise description of the funding opportunity Anesthetics are remarkable drugs that have long-enabled surgical interventions, but their inherent lack of safety necessitates careful monitoring nearly exclusively within an operating room environment. The Anesthetics for Battlefield Care (ABC) program will test the hypothesis that therapeutic effects of anesthetics can be uncoupled/separated from deleterious effects. ABC endeavors to produce drugs for use in traumatic injury capable of safe, unmonitored anesthesia to enable earlier life-saving interventions, reduce the trauma associated with battlefield-injury, and thereby improve combat casualty outcomes.
- Anticipated individual awards Multiple awards are anticipated.
- **Types of instruments that may be awarded** Procurement contract, cooperative agreement, or Other Transaction (OT) for Prototype agreement.
- Agency contacts
 - o Technical POC: Michael Feasel, Program Manager, DARPA/BTO
 - E-Mail: <u>ABCare@darpa.mil</u>
 - Mailing Address: DARPA/BTO ATTN: HR001123S0038
 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 CFR § 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 generate anesthetics that can be used safely in cases of traumatic injury without physiological collapse. The envisioned approach will represent a paradigm shift, moving away from the administration of anesthetics with intense monitoring by highly-trained personnel to operational settings where such capabilities do not exist or cannot be afforded. A successful proposal will pursue the discovery of unappreciated anesthetic mechanisms, achieve anesthesia leveraging novel drugs or drugs as components of cocktails, and produce a formulated end product that exhibits increased safety compared to state-of-the-art drugs.

Specifically excluded are proposals that involve:

1. Establishing new biological models for trauma or related indications.

2. Sole reliance on reformulation and/or clinical development of existing drugs.

3. Exclusive focus on the development of devices or equipment intended to optimize drug delivery or monitoring.

4. Development of drugs solely with analgesic properties (i.e., the novel drug or cocktail component does not act as a hypnotic or sedative).

5. Neurostimulation or electrical stimulation modalities intended to be therapeutic (e.g., nerve stimulation, deep brain stimulation, transdermal/transcranial stimulation, etc.).

6. Use of local anesthetics or nerve block in phase 2 of the program.

7. End products that utilize genetic engineering strategies.

8. Research that generates incremental improvements to the existing state of anesthesia drug development.

1.1. PROGRAM OVERVIEW

Traumatic injury on the battlefield has relied almost entirely on rapid (<1 hour) medical evacuation, as demonstrated during sustained operations in Iraq and Afghanistan from 2001-2021. Significantly increased survival rates were seen in casualties who received critical care within 60 minutes post-injury, placing an emphasis of care on what is colloquially known as "the golden hour." That "golden hour", however, looks very much like it did in the Civil War: agonizing pain, limited access to therapeutics, and psychological trauma associated with the experience of the injury itself as well as the lifesaving intervention occurring without sedation or anesthesia. The golden hour however, may not be tractable in future conflict, creating the need for new tools to provide prolonged field care spanning 72 - 96 hours.

ABC aims to provide the warfighter with an anesthetic capability for cases of traumatic injury that require critical care or life-saving intervention at the point of injury, and to enhance prolonged

field care. ABC aims to accomplish these lofty goals by developing novel anesthetic(s) that are safer than the current state-of-the-art used in surgical settings and that are indicated in traumatic injury. Because of this large safety margin and utility in trauma, these new drugs will be able to be delivered by general forces safely and effectively. This, in turn, enables field medics and corpsmen to provide much-needed relief and comfort to their comrades in instances of traumatic injury on the battlefield.

Anesthetic drugs are currently only utilized exclusively in surgical settings, typically in Role 2 medical facilities or higher. These facilities not only have a clinical staff (anesthesiologists, nurse anesthetists, and other critical care/trauma support staff), but a plethora of life-support and monitoring equipment, as well as a pharmacy of drugs at their disposal to address dynamic and unstable physiologies. The reason anesthetics are exclusively used in this environment is due to their inherent lack of safety, represented by a low therapeutic index (e.g., propofol \sim 3.4). This narrow window for achieving desirable outcomes of anesthetics whilst avoiding deleterious outcomes (e.g., respiratory depression, adrenal suppression) underlines the need to develop drugs with cleaner mechanism of action.

All current anesthetics have been incidentally discovered rather than designed for the indication of interest. Intentional design of next-generation anesthetics has been hampered by significant gaps in knowledge spanning several scientific fields: the neuronal circuits that underlie the state of consciousness and perception are not established, the molecular and cellular targets of anesthesia are not well-understood, known anesthetic targets are not amenable to traditional structural techniques for intentional drug design, and safety in humans cannot be predicted. The work conducted under ABC will directly address these gaps in knowledge through deconvolution of anesthetic mechanisms of action. By the end of the program, it is envisioned that the performers will produce novel drug compounds capable of significantly safer anesthesia by engaging unappreciated neural and molecular targets.

Success with ABC will provide the warfighter with capabilities to do the following: 1) enable unmonitored anesthesia on the battlefield, 2) enable prolonged field care and lifesaving intervention, 3) reduce psychological trauma associated with combat injury, and 4) enable emergency critical care capabilities in the civilian sector.

Successful proposals must provide the following:

- 1. Rationale for selection of biological model system(s).
- 2. Justification for exploring the proposed molecular, cellular, or physiological target space.
- 3. Explicitly described workflow for down-selection and validation of anesthetic target hits.
- 4. Methods for exclusion of targets that contribute to undesirable effects of current anesthetics.
- 5. Rational approach for generation of novel chemical matter to achieve anesthetic endpoints.
- 6. A well-integrated experimental pipeline for optimization of lead compounds.

1.2. PROGRAM STRUCTURE AND TECHNICAL APPROACH

The ABC program is divided into two sequential phases totaling 60 months, with Phase 1 (Base) being 36 months and Phase 2 (Option) being 24 months. A Go/No-Go demonstration will occur at 36 months, and successful fulfillment of the criteria will be required for progression into phase 2 (Table 1.3). There are two Technical Areas (TAs): TA1 is Discovery, wherein anesthetic mechanistic discovery, target identification, and validation are conducted; TA2 is Medicinal Chemistry and involves the design of molecules and/or cocktails that work through the targets identified in TA1. At 36 months long, the Discovery TA spans the entirety of Phase 1, while TA2 will overlap both Phase 1 and Phase 2, and will be dependent on the selection of targets identified in TA1. The TAs are temporally overlapping to allow promising targets to be pursued with medicinal chemistry approaches as soon as they are identified and validated. Proposals must address both TAs for exactly five years (one 36-month Phase 1 and one 24-month Phase 2), along with the necessary expertise required for meeting the program milestones (Table 1.3). Proposals utilizing multiple teams should be assembled as a single research entity and must propose and report as such. Proposals that fail to address both technical areas across both phases will be considered non-conforming and will not be evaluated.

1.2.1. Technical Area 1 (TA1): Discovery

The goal of TA1 (Discovery) is to uncover novel targets and mechanisms that are involved in- and contribute to- anesthesia, and to validate those targets. The neural circuitry and molecular targets through which anesthesia occurs are incompletely understood. This current lack of mechanistic understanding represents a major road block to the development of anesthetics that lack potentially lethal side effects. To this end, performers will identify the required target landscape to drive the primary effects of anesthesia while avoiding or decoupling the adverse side effects on human physiology (e.g., hemodynamic instability, respiratory depression).

Work under this TA will require performers to advance the current understanding of molecular, neurological, and/or physiological mechanisms by which anesthetics work in order to leverage their beneficial effects as well as avoid negative effects. Proposed work to accomplish these goals can include top-down (complex biological models and phenotypic endpoints) and/or bottom-up approaches (reconstructing molecular pathway information, structure-guided drug discovery, etc.). Performers must provide justification for selection of established biological model systems. It is envisioned that identification of molecular, cellular and network level targets of anesthesia could involve, but is not limited to, large-unbiased molecular profiling efforts (e.g., mass spectrometry/sequencing-based methodologies), optogenetic manipulation of neural circuits, brain-activity profiling of human subjects, animal-based phenotyping, as well as cell type-specific profiling efforts (flow cytometry, mass cytometry, microscopy, etc.).

Phase 1 efforts will culminate in an *in vivo* demonstration of anesthetic effect through a novel molecular mechanism. Actionable targets must produce analgesia, immobility, and unconsciousness individually or in combination. Successful completion of this demonstration hinges on the ability to demonstrate that a given target (or set of targets) contributes to one or multiple anesthetic endpoints.

1.2.2. Technical Area 2 (TA2): Medicinal chemistry

The goal of TA2 is to design chemical compounds that specifically work through the targets and mechanisms of anesthesia identified in TA1 in order to achieve a safer anesthetic state. As opposed to the current paradigm of anesthetic drug discovery, compounds and drugs developed during TA2 will be intentionally selected and optimized based on the mechanistic information from TA1. Work under this TA will require performers to generate, optimize, formulate, and test anesthetic drugs with drastically improved therapeutic index compared to current state-of-the-art.

In Phase 1, TA2 efforts will be focused on identification of initial compound hits for anesthetic mechanisms that are discovered and validated in TA1. Multiple approaches are available for initial design and discovery of novel compounds against a given target. This could involve single-drug single target, single-drug multiple-targets, or multiple drugs interacting with multiple targets to accomplish the desired physiological effects of unconsciousness, immobility, analgesia, amnesia, etc. Approaches involved in initial identification may include but are not limited to large library drug screening (*in silico, in vitro, in vivo*) and structure-guided *de novo* drug design (either fragment-based or analogue approaches).

In Phase 2, TA2 efforts will be focused on optimizing chemical matter for improved therapeutic index, improved efficacy, and improved pharmacokinetic properties towards achieving safe anesthesia in a model of traumatic injury. Optimized chemical matter should act through effectors of anesthetic mechanism while avoiding established off-target molecular interactions (e.g., those associated with adrenal suppression, respiratory depression, cardiovascular collapse, etc.). Pharmacological interventions to be pursued may involve direct, orthosteric interactions, as well as non-canonical upstream modulatory pathways, including allosteric modulation, membrane-based domains, ion concentrations, etc. Pharmacokinetic and pharmacodynamic evaluation of drug candidates must be established, but can include early predictive *in silico* capabilities to accelerate drug optimization, prior to standard testing in animal models.

Following successful generation and optimization of novel chemical matter, performers will evaluate safety and Absorption, Distribution, Metabolism, Excretion (ADME) of candidate compounds by month 56 of the program. Physiological parameters to be measured in a healthy mammalian model include but are not limited to 1) hemodynamic stability, 2) lack of respiratory depression and 3) stability of intracranial pressure. Performers should provide detail in their proposals on what physiological parameters will be measured and how. Proposers should provide detailed justification for the selection of physiological assays to assess the safety of lead compounds. Drug candidates will be further compared to state-of-the-art anesthetic profiles for 1) partitioning of drug to the central nervous system, 2) bioavailability and 3) time of onset for achieving unconsciousness, analgesia, and immobility.

The Government will utilize Independent Validation and Verification (IV&V) partners to evaluate performer progress toward the end goals of the program (Month 56 - 60). In collaboration with performer groups, IV&V partners will evaluate clinical properties of drug candidates in an animal model of traumatic injury. Candidate compounds will be evaluated for safety, onset, and duration of anesthetic effect using two routes of administration, including one central, and one peripheral method. Performer groups will be required to send purified materials and dosing protocols to

IV&V partners for evaluation. Communications and engagement between IV&V and performers will occur starting in Phase 2 to ensure timely delivery of results and transfer of material.

1.3. PROGRAM METRICS, MILESTONES AND DELIVERABLES

Table 1.3. Milestones and Metrics for ABC						
Phase 1: 36 Months (Base)	 Milestone: Expand target space and demonstrate target contribution to anesthesia (unconsciousness, immobility, analgesia, etc.) 0-36 Months: Negotiated intermediate metrics based on individual performer approaches and goals 36 Months (Go/No-Go): Demonstrate novel and actionable targets that contribute to anesthesia 					
Phase 2: 24 Months (Option)	 Milestone: Produce battlefield ready intervention for inducing anesthesia 37- 55 Months: Negotiated intermediate metrics for optimization and testing of lead compounds 56 Month Demonstrate safety and efficacy of interventions in a healthy mammalian model Therapeutic index ≥ 10-fold greater than current state of the art (ketamine); Rapid onset (< 1 minute) 					
End of Program Evaluation	 60 Month End of Program IV&V Demonstration: Battlefield-ready novel anesthetic capable of safe and effective anesthesia Evaluate drug effect in a physiologically relevant model of traumatic injury; Efficacy with one central (e.g., intravenous, epidural) and one peripheral (e.g., transdermal, intramuscular) route of administration 					

.... ~

Note: Milestones and Metrics listed above apply to both TAs.

Progress towards the stated goals will be assessed throughout the program with Phase 2 progression dependent on both funding availability and performance towards the Phase 1-specific milestones. Quantitative intermediate metrics for months 0-36 must be tailored to the approach used in discovery and proposed by the performer. Finalized intermediate metrics will be negotiated with the Government prior to programmatic kick-off toward the following scientific areas: 1) establishing appropriate model systems, 2) producing a rank order list of previously unappreciated anesthetic targets, 3) down-selecting targets accounting for existing off-target physiological effects, 4) generating medicinal chemistry hits against targets, 5) establishing targets as necessary and/ or sufficient for producing anesthetic hallmark: unconsciousness, immobility, analgesia.

Intermediate metrics for Phase 2 will span months 37-55 and will focus on achieving the following: 1) optimizing novel compounds, 2) evaluating efficacy of lead compounds in higher order animal models, 3) improving bioavailability, 4) evaluating pharmacokinetic and pharmacodynamic properties, 5) verifying safety as it pertains to hemodynamic stability, respiratory function, or stability of intercranial pressure.

When appropriate, performers must propose specific deliverables (report, data, product, prototype, etc.) that demonstrate completion of a milestone or metric. The content of each deliverable will vary from task to task but must be designed such that the Government can evaluate performer progress towards the end goals of the program.

1.4. GENERAL REQUIREMENTS

Proposing Teams

It is expected that proposals will involve teams that have the expertise needed to achieve the goals of both TA1 and TA2. Specific content, communications, networking, and team formation are the sole responsibility of the proposer teams. Proposer teams must submit a single, integrated proposal led by a Principal Investigator (PI), under a single prime contractor that addresses all program Phases, as applicable.

DARPA will hold a Proposers Day (see <u>Section 8.1</u>) to facilitate the formation of proposer teams and enable sharing of information among interested proposers through the DARPA Opportunities Page.

Independent Verification and Validation

The Government is not soliciting IV&V proposals under HR001123S0038. To avoid potential conflicts of interest, performers for HR001123S0038 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), and/or other relevant domains capable of meeting the desired IV&V goals of the program as established by DARPA.

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, R Notebook, Spark) for evaluation and reproducibility.

Deliverables

All products – material and otherwise – to be provided to the Government as outcomes from conducted research should be defined in the proposal. Performers need to allot time and budget to fulfill obligations for travel to review meetings and the transmission of report documentation.

End of Phase reports: Three months prior to the end of Phase 1 (i.e., at Month 33) and one month prior to the end of Phase 2 (i.e., at Month 55), performers must draft and present to DARPA a written report of all research activities and metrics satisfied. This report will contain all relevant supporting data.

Monthly financial reports: Performers are required to provide financial status updates. The prime Performer shall include information for itself and all subawardees/subcontractors. These reports shall be in the form of an editable Microsoft (MS) ExcelTM file and shall provide financial data including, but not limited to:

- Program spend plan by Phase and task
- Incurred program expenditures to date by Phase and task
- Invoiced program expenditures to date by Phase and task

6-week technical progress reports: Performers are required to provide research Updates every 6 weeks in the form of a standardized slide presentation given to DARPA and discussed with the program management team via teleconference. Length and level of detail are at the discretion of the Program Manager.

Semi-annual program review meetings: Leadership from each performer team (with additional key personnel at the discretion of the PI) will be required to present research progress in person at program review meetings. The purpose of these reviews is to ensure adequate engagement with the DARPA team to discuss details that might otherwise fall outside the scope of a routine technical brief; progress towards milestones and scientific goals; and any ongoing technical or programmatic challenges that must be overcome to achieve the overarching program goals.

Final Program Report: When the final funding Phase closes out, performer teams must provide a final report summarizing all research activities and outcomes during the program; publications, research presentations, patent applications that result from the research pursued; and any additional deliverables requested by the contracting agent for this program.

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. § 4022(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.

University or non-profit research institution performance under this solicitation will include effort categorized as fundamental research. In addition to Government support for free and open scientific exchanges and dissemination of research results in a broad and unrestricted manner, the academic or non-profit research performer or recipient, regardless of tier, acknowledges that such research may have implications that are important to U.S. national interests and must be protected against foreign influence and exploitation. As such, the academic or non-profit research performer or recipient agrees to comply with the following requirements:

- (a) The University or non-profit research institution performer or recipient must establish and maintain an internal process or procedure to address foreign talent programs, conflicts of commitment, conflicts of interest, and research integrity. The academic or non-profit research performer or recipient must also utilize due diligence to identify Foreign Components or participation by Senior/Key Personnel in Foreign Government Talent Recruitment Programs and agree to share such information with the Government upon request.
 - i. The above described information will be provided to the Government as part of the proposal response to the solicitation and will be reviewed and assessed prior to award. Generally, this information will be included in the Research and Related Senior/Key Personnel Profile (Expanded) form (SF-424) required as part the proposer's submission through Grants.gov.
 - 1. Instructions regarding how to fill out the SF-424 and its biographical sketch can be found through Grants.gov.
 - ii. In accordance with USD(R&E) direction to mitigate undue foreign influence in DoD-funded science and technology, DARPA will assess all Senior/Key Personnel proposed to support DARPA grants and cooperative agreements for potential undue foreign influence risk factors relating to professional and financial activities. This will be done by evaluating information provided via the SF-424, and any accompanying or referenced documents, in order to identify and assess any associations or affiliations the Senior/Key Personnel may have with foreign strategic competitors or countries that have a history of intellectual property theft, research misconduct, or history of targeting U.S. technology for unauthorized transfer. DARPA's evaluation takes into consideration the entirety of the Senior/Key Personnel's SF-424, current and pending support, and biographical sketch, placing the most weight on the Senior/Key Person's professional and financial activities over the last 4 years. The majority of foreign entities lists used to make these determinations are publicly available. The DARPA Countering Foreign Influence Program (CFIP) "Senior/Key Personnel Foreign Influence Risk Rubric" details the various risk ratings and factors. The rubric can be seen at the following link:

https://www.darpa.mil/attachments/092021DARPACFIPRubric.pdf

- iii. Examples of lists that DARPA leverages to assess potential undue foreign influence factors include, but are not limited to:
 - Executive Order 13959 "Addressing the Threat From Securities Investments That Finance Communist Chinese Military Companies": <u>https://www.govinfo.gov/content/pkg/FR-2020-11-17/pdf/2020-25459.pdf</u>
 - 2. The U.S. Department of Education's College Foreign Gift and Contract Report: <u>College Foreign Gift Reporting (ed.gov)</u>

- 3. The U.S. Department of Commerce, Bureau of Industry and Security, List of Parties of Concern: <u>https://www.bis.doc.gov/index.php/policy-guidance/lists-of-parties-of-concern</u>
- 4. Georgetown University's Center for Security and Emerging Technology (CSET) Chinese Talent Program Tracker: <u>https://chinatalenttracker.cset.tech</u>
- 5. Director of National Intelligence (DNI) "World Wide Threat Assessment of the US Intelligence Community": <u>2021 Annual Threat Assessment of</u> <u>the U.S. Intelligence Community (dni.gov)</u>
- 6. Various Defense Counterintelligence and Security Agency (DCSA) products regarding targeting of US technologies, adversary targeting of academia, and the exploitation of academic experts: <u>https://www.dcsa.mil/</u>
- (b) DARPA's analysis and assessment of affiliations and associations of Senior/Key Personnel is compliant with Title VI of the Civil Rights Act of 1964. Information regarding race, color, or national origin is not collected and does not have bearing in DARPA's assessment.
- (c) University or non-profit research institutions with proposals selected for negotiation that have been assessed as having high or very high undue foreign influence risk, will be given an opportunity during the negotiation process to mitigate the risk. DARPA reserves the right to request any follow-up information needed to assess risk or mitigation strategies.
- i. Upon conclusion of the negotiations, if DARPA determines, despite any proposed mitigation terms (e.g. mitigation plan, alternative research personnel), the participation of any Senior/Key Research Personnel still represents high risk to the program, or proposed mitigation affects the Government's confidence in proposer's capability to successfully complete the research (e.g., less qualified Senior/Key Research Personnel) the Government may determine not to award the proposed effort. Any decision not to award will be predicated upon reasonable disclosure of the pertinent facts and reasonable discussion of any possible alternatives while balancing program award timeline requirements.
- (d) Failure of the academic or non-profit research performer or recipient to reasonably exercise due diligence to discover or ensure that neither it nor any of its Senior/Key Research Personnel involved in the subject award are participating in a Foreign Government Talent Program or have a Foreign Component with an a strategic competitor or country with a history of targeting U.S. technology for unauthorized transfer may result in the Government exercising remedies in accordance with federal law and regulation.
 - i. If, at any time, during performance of this research award, the academic or nonprofit research performer or recipient should learn that it, its Senior/Key Research Personnel, or applicable team members or subtier performers on this award are or are believed to be participants in a Foreign Government Talent Program or have Foreign Components with a strategic competitor or country with a history of targeting U.S. technology for unauthorized transfer , the performer or recipient

will notify the Government Contracting Officer or Agreements Officer within 5 business days.

- 1. This disclosure must include specific information as to the personnel involved and the nature of the situation and relationship. The Government will have 30 business days to review this information and conduct any necessary fact-finding or discussion with the performer or recipient.
- 2. The Government's timely determination and response to this disclosure may range anywhere from acceptance, to mitigation, to termination of this award at the Government's discretion.
- 3. If the University receives no response from the Government to its disclosure within 30 business days, it may presume that the Government has determined the disclosure does not represent a threat.
- ii. The performer or recipient must flow down this provision to any subtier contracts or agreements involving direct participation in the performance of the research.

(e) Definitions

- i. Senior/Key Research Personnel
 - This definition would include the Principal Investigator or Program/Project Director and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the award. These include individuals whose absence from the project would be expected to impact the approved scope of the project.
 - 2. Most often, these individuals will have a doctorate or other professional degrees, although other individuals may be included within this definition on occasion.
- ii. Foreign Associations/Affiliations
 - 1. Association is defined as collaboration, coordination or interrelation, professionally or personally, with a foreign government-connected entity where no direct monetary or non-monetary reward is involved.
 - 2. Affiliation is defined as collaboration, coordination, or interrelation, professionally or personally, with a foreign government-connected entity where direct monetary or non-monetary reward is involved.
- iii. Foreign Government Talent Recruitment Programs
 - 1. In general, these programs will include any foreign-state-sponsored attempt to acquire U.S. scientific-funded research or technology through foreign government-run or funded recruitment programs that target scientists, engineers, academics, researchers, and entrepreneurs of all nationalities working and educated in the U.S.
 - 2. Distinguishing features of a Foreign Government Talent Recruitment Program may include:

- a. Compensation, either monetary or in-kind, provided by the foreign state to the targeted individual in exchange for the individual transferring their knowledge and expertise to the foreign country.
- b. In-kind compensation may include honorific titles, career advancement opportunities, promised future compensation or other types of remuneration or compensation.
- c. Recruitment, in this context, refers to the foreign-state-sponsor's active engagement in attracting the targeted individual to join the foreign-sponsored program and transfer their knowledge and expertise to the foreign state. The targeted individual may be employed and located in the U.S. or in the foreign state.
- d. Contracts for participation in some programs that create conflicts of commitment and/or conflicts of interest for researchers. These contracts include, but are not limited to, requirements to attribute awards, patents, and projects to the foreign institution, even if conducted under U.S. funding, to recruit or train other talent recruitment plan members, circumventing merit-based processes, and to replicate or transfer U.S.-funded work in another country.
- e. Many, but not all, of these programs aim to incentivize the targeted individual to physically relocate to the foreign state. Of particular concern are those programs that allow for continued employment at U.S. research facilities or receipt of U.S. Government research funding while concurrently receiving compensation from the foreign state.
- 3. Foreign Government Talent Recruitment Programs DO NOT include:
 - a. Research agreements between the University and a foreign entity, unless that agreement includes provisions that create situations of concern addressed elsewhere in this section,
 - b. Agreements for the provision of goods or services by commercial vendors, or
 - c. Invitations to attend or present at conferences.
- iv. Conflict of Interest
 - 1. A situation in which an individual, or the individual's spouse or dependent children, has a financial interest or financial relationship that could directly and significantly affect the design, conduct, reporting, or funding of research.
- v. Conflict of Commitment
 - 1. A situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities.
 - 2. Common conflicts of commitment involve conflicting commitments of time and effort, including obligations to dedicate time in excess of

institutional or funding agency policies or commitments. Other types of conflicting obligations, including obligations to improperly share information with, or withhold information from, an employer or funding agency, can also threaten research security and integrity and are an element of a broader concept of conflicts of commitment.

- vi. Foreign Component
 - 1. Performance of any significant scientific element or segment of a program or project outside of the U.S., either by the University or by a researcher employed by a foreign organization, whether or not U.S. government funds are expended.
 - 2. Activities that would meet this definition include, but are not limited to:
 - a. Involvement of human subjects or animals;
 - b. Extensive foreign travel by University research program or project staff for the purpose of data collection, surveying, sampling, and similar activities;
 - c. Collaborations with investigators at a foreign site anticipated to result in co-authorship;
 - d. Use of facilities or instrumentation at a foreign site;
 - e. Receipt of financial support or resources from a foreign entity; or
 - f. Any activity of the University that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.
 - 3. Foreign travel is not considered a Foreign Component.
- vii. Strategic Competitor
 - 1. A nation, or nation-state, that engages in diplomatic, economic or technological rivalry with the United States where the fundamental strategic interests of the U.S are under threat.

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. Historically Black Colleges and Universities, Small Businesses, Small Disadvantaged Businesses and Minority Institutions are encouraged to submit proposals and join others in submitting proposals; however, no portion of this announcement will be set aside for these organizations' participation due to the impracticality of reserving discrete or severable areas of this research for exclusive competition among these entities.

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.§ 4892 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. DARPA will respond to abstracts providing feedback and indicating whether, after preliminary review, there is interest within BTO for the proposed work. DARPA will attempt to reply within 14 calendar days of receipt. Proposals may be submitted irrespective of comments or feedback received in response to the abstract. Proposals are reviewed without regard to feedback given as a result of abstract review. The time and date for submission of proposal abstracts are specified in Part I above.

The abstract is a concise version of the proposal comprising a maximum of **8** pages, including all figures, tables, and charts. 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. 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.

The page limit does NOT include:

- Official transmittal letter (optional);
- Cover sheet;
- Executive summary slide;
- Resumes; and
- Bibliography (optional).

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, e-mail, 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?

C. Executive Summary Slides: The slide template is provided as **Attachment 1** to the BAA posted at <u>https://SAM.gov</u>. Use of this template is required.

D. Technical Plan: Outline and address all technical areas and challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide specific objectives, metrics, and milestones at intermediate stages of the project to demonstrate a plan for accomplishment of the program goals. Propose additional appropriate qualitative and quantitative metrics specific to the approach, as needed. Outline of intermediary milestones should occur at no greater than 6-month increments. See Table 1.3 for Go/No-Go criteria and Demonstration requirements. Proposers will define quantitative intermediate Metrics between 0-36 months in order to evaluate technical progress ahead of the Go/No-Go. Additionally, in Phase 2, Months 37-56 will contain proposer-generated quantitative metrics to regularly evaluate progress towards the demonstration of drug efficacy and safety *in vivo*. Examples of regular intermediate metrics designed to satisfy criteria listed in the Program Go/NoGo and Demonstration are listed below. Deliverables in the proposer's Statement of Work should address Technical Areas 1 and 2.

FOR EXAMPLE ONLY **Phase 1 (Base):**

6 mos.: Implement at least two biological models for interrogation **12 mos.:** Select and classify \geq 3 canonical anesthetics, and demonstrate that \geq 1 novel feature(s) contributes to anesthetic response **18 mos.:** Generate a rank order list of \geq 10 anesthetic targets. Safety Screening: Identify contribution of \geq 1 anti-target to known negative effect of canonical anesthetics that were classified. **24 mos.:** Expand and validate anesthetic target space Recapitulate \geq 2 hallmarks of anesthesia through \geq 1 novel targets. Safety: Establish that novel target space does not overlap with established anesthetic off-target in an in vitro model

30 mos.: Identify and optimize ≥ 10 molecules against ≥ 3 lead targets, at least one of which is a novel target. Provide target engagement data for each individual target.

36 mos.: Satisfy demonstration and Go/NoGo criteria

Phase 2 (Option):

42 mos.: Improve and evaluate drug properties of ≥ 3 lead compounds in higher order model than 36 mos. Partitioning to the CNS \geq State of the art. Bioavailability and time to onset by peripheral administration \geq State of the art 52 mos.: Safety Profile: 1) hemodynamic stability ($\Delta BP \leq 10\%$), 2) lack of respiratory depression, 3) stable intracranial pressure 56 mos.: Satisfy demonstration criteria

E. Management and Capabilities: Provide a brief summary of expertise of the team, including subcontractors and key personnel.

A Principal Investigator for the project must be identified, and a description of the team's organization including a breakdown by Technical Area (TA). All teams are strongly encouraged to identify a Project Manager/Integrator to serve as the primary point of contact to communicate with the DARPA Program Manager, IV & V partner, and Contracting Officer's Representative, coordinate the effort across co-performer, vendor, and subcontractor teams, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables.

Include a description of the team's organization including roles and responsibilities. Team member descriptions should address the Technical Plan, describe the time and percent effort divisions for members participating across multiple TAs, and delineate individuals to avoid duplication of efforts.

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. Describe any specialized facilities to be used as part of the project, the extent of access to these facilities, and any biological containment, biosafety, and certification requirements.

F. Cost and Schedule: Provide a cost estimate for resources over the proposed timeline of the project, broken down by phase and major cost items (e.g., labor, materials, etc.). Include cost estimates for each potential subcontractor (may be a rough order of magnitude).

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 1 is 35 pages. The official transmittal letter is not included in the page count. Volume I should include the following components:

a. Volume I, Technical and Management Proposal

Section I. Administrative

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

- 1. BAA number (HR001123S0038);
- 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 Principle 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, cost sharing contract no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;
- 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 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.

C. Executive Summary Slides: The slide template is provided as Attachment 1 to the BAA posted at <u>https://SAM.gov</u>. Use of this template is required.

Section II. Detailed Proposal Information

- **A. Executive Summary:** Provide a synopsis of the proposed project, including answers to the following questions:
 - What is the proposed work attempting to accomplish or do?
 - How is it done today, and what are the limitations?
 - What is innovative in your approach?
 - What are the key technical challenges in your approach, and how do you plan to overcome these?
 - Who or what will be affected, and what will be the impact if the work is successful?
 - How much will it cost, and how long will it take?
- **B. Goals and Impact:** Clearly describe what the team is trying to achieve and the difference it will make (qualitatively and quantitatively) if successful. Describe the innovative aspects of the project in the context of existing capabilities and approaches, clearly delineating the uniqueness and benefits of this project in the context of the state of the art, alternative approaches, and other projects from the past and present. Describe how the proposed project is revolutionary and how it significantly rises above the current state-of-the-art. Describe the deliverables associated with the proposed project and any plans to commercialize the technology, transition it to a customer, or further the work.
- **C. Technical Plan:** Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) at intermediate stages of the program to demonstrate progress, plan for achieving the milestones, and must include a simple process flow diagram of their final system concept. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal. Discuss mitigation of technical risk.
- **D. Management Plan:** Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. A Principal Investigator

(PI) for the project must be identified, along with a description of the team's organization, including the breakdown by Technical Area. All teams are strongly encouraged to identify a Project Manager/Integrator to serve as the primary point of contact to communicate with the DARPA Program Manager, IV & V partner, and Contracting Officer's Representative, coordinate the effort across co-performer, vendor, and subcontractor teams, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables.

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

- **E. Capabilities:** Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Describe any specialized facilities to be used as part of the project, the extent of access to these facilities, and any biological containment, biosafety, and certification requirements. Discuss any work in closely related research areas and previous accomplishments.
- F. Statement of Work (SOW): The SOW should provide a detailed task breakdown, citing specific tasks for each Technical Area, and their connection to the milestones and program metrics. Each phase of the program should be separately defined. The SOW must not include proprietary information. <u>SOW is not included in the Volume 1 page count.</u>

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.

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

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

b. Volume II, Cost Management Proposal

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

- 1. BAA Number (HR001123S0038);
- 2. Lead Organization Submitting proposal;
- 3. Type of organization, selected 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 (if available), electronic mail (if available);
- 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 (if available), and electronic mail (if available);
- 9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract no fee, or other type of procurement contract (*specify*), GRANT, cooperative agreement, or other transaction;
- 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. Name, address, and telephone number of the proposer's cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
- 14. Name, address, and telephone number of the proposer's cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
- 15. Date proposal was prepared;
- 16. Unique Entity ID (<u>https://sam.gov/content/duns-uei</u>);
- 17. Taxpayer ID number (<u>https://www.irs.gov/Individuals/International-</u> Taxpayers/Taxpayer-Identification-Numbers-TIN);
- Commercial and Government Entity (CAGE) code (https://cage.dla.mil/Home/UsageAgree);
- 19. Proposal validity period

The Government requires that proposers* use the provided MS ExcelTM 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.

*University proposers requesting a grant, cooperative agreement, or Other Transaction for Research do not need to use the MS ExcelTM DARPA Standard Cost Proposal Spreadsheet. Instead, a proposed budget and justification may be provided using the SF-424 Research & Related Budget forms provided via <u>https://www.grants.gov</u>.

- (1) Total program, per phase (Phase 1 (Base) and Phase 2 (Option), and per task cost broken down by major cost items to include:
 - i. **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.
 - ii. **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.
 - iii. **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.

- iv. Animal Use Costs itemized list of all materials, animal purchases, and per diem costs, associated with proposed animal use; include documentation supporting daily rates.
- v. 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.
- vi. 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.
- vii. **Other Direct Costs** Consultants: provide executed Consultant Agreement that describes work scope, rate and hours.
- viii. **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).
 - ix. Indirect costs specific to a University performer: (1) Fringe Benefit Rate (provide current Department of Health and Human Services (DHHS) or Office of Naval Research (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 performer: (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).

- (2) A summary of total program costs by phases 1 and 2 and task.
- (3) 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 that verifies the proposed loaded daily/hourly rate.

- (4) 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.
- (5) A summary of projected funding requirements by month for all phases of the project.
- (6) A summary of tasks that have animal or human use funding.
- (7) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions that could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.
- (8) 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.).
- (9) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available).
- (10) 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 reasonably 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 (OT) Requests

All proposers requesting an OT must include a detailed list of milestones for each phase of the program (I, II, and III). 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* e-mail must be sent to the BAA mailbox requesting submission instructions from the Technical Office Program Security Officer (PSO). If a determination is made that the award instrument may result in access to classified information, a Security Classification Guide (SCG) and/or DD Form 254 will be issued by DARPA and attached as part of the award.

Controlled Unclassified Information (CUI) – if anticipated/applicable

For unclassified proposals containing controlled unclassified information (CUI), applicants will ensure personnel and information systems processing CUI security requirements are in place.

If an unclassified submission contains CUI or the suspicion of such, as defined by Executive Order 13556 and 32 CFR Part 2002, the information must be appropriately and conspicuously marked CUI in accordance with DoDI 5200.48. Identification of what is CUI about this DARPA program will be detailed in a DARPA CUI Guide and will be provided as an attachment to the BAA or may be provided at a later date.

Unclassified submissions containing CUI may be submitted via DARPA's BAA Website (<u>https://baa.darpa.mil</u>) in accordance with <u>Section 4.2.4</u> of this BAA.

Proposers submitting proposals involving the pursuit and protection of DARPA information designated as CUI must have, or be able to acquire prior to contract award, an information system authorized to process CUI information IAW NIST SP 800-171 and DoDI 8582.01.

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	Summary of	Basis for	Asserted Rights	Name of Person
Computer	Intended Use in	Assertion	Category	Asserting
Software To be	the Conduct of			Restrictions
Furnished With	the Research			
Restrictions				
(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)

For All Non-Procurement Contracts

Proposers responding to this BAA requesting a Cooperative 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: https://www.fsd.gov/sys_attachment.do?sys_id=c08b64ab1b4434109ac5ddb6bc4bcbb8.

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 HR001123S0038. <u>Submissions may not be sent 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.

Proposal Abstract Submission

Proposal Abstracts submitted in response to HR001123S0038 must be submitted via DARPA's BAA Website (https://baa.darpa.mil). Note: If an account has recently been created for the DARPA BAA Website, this account may be reused. Accounts are typically disabled and eventually deleted following 75-90 days of inactivity – if you are unsure when the account was last used, it is recommended that you create a new account. If no account currently exists for the DARPA BAA Website, 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 the 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 the submission process be started as early as possible.

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

Full Proposal Submission

For Procurement Contracts or Other Transactions only:

Proposers requesting procurement contracts or Other Transactions must submit proposals through one of the following methods: (1) via DARPA's BAA Website (<u>https://baa.darpa.mil</u>) (DARPA-preferred), or (2) hard copy mailed directly to DARPA. If proposers intend to use DARPA's BAA Website as their means of submission, then they must submit their entire proposal through <u>https://baa.darpa.mil</u>; applications cannot be submitted in part electronically and in part as a hard-copy. Proposers using <u>https://baa.darpa.mil</u> do not submit hard-copy proposals in addition to the electronic submission.

Note: If an account has recently been created for the DARPA BAA Website, this account may be reused. Accounts are typically disabled and eventually deleted following 75-90 days of inactivity – if you are unsure when the account was last used, it is recommended that you create a new account. If no account currently exists for the DARPA BAA Website, 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 the 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 (<u>https://baa.darpa.mil</u>), though proposers will likely still need to visit <u>https://baa.darpa.mil</u> 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 the submission process be 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: SF 424 Research and Related (R&R) Application for Federal Assistance, 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: The Research and Related Senior/Key Person Profile (Expanded) form, available on the Grants.gov website at

https://apply07.grants.gov/apply/forms/sample/RR_KeyPersonExpanded_3_0-V3.0.pdf, 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. 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:
 - Education and Training.
 - Research and Professional Experience.
 - Collaborations and Affiliations (for conflict of interest).
 - 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:
 - 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>.

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

Not applicable.

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 HR001123S0038 summary. Submit your question(s) via e-mail to <u>ABCare@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. The proposed technical team has the expertise and experience to accomplish the proposed tasks. 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

5.2.1. Review Process

It is the policy of DARPA to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed in Section 5.1. 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.

5.2.2. 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.

5.2.3. 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, 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.

5.2.4. Countering Foreign Influence Program (CFIP)

DARPA's CFIP is an adaptive risk management security program designed to help protect the critical technology and performer intellectual property associated with DARPA's research projects by identifying the possible vectors of undue foreign influence. The CFIP team will create risk assessments of all proposed Senior/Key Personnel selected for negotiation of a fundamental research grant or cooperative agreement award. The CFIP risk assessment process will be conducted separately from the DARPA scientific review process and adjudicated prior to final award.

6. Award Administration Information

6.1. SUBMISSION STATUS NOTIFICATIONS

Proposal Abstracts and Full Proposals submitted in response to HR001123S0038 will be evaluated following the submission deadlines listed in Part I. DARPA will respond as described below. These official notifications will be sent via e-mail to the Technical Point of Contact (POC) and/or Administrative POC identified on the submission coversheet.

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 all proposals 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. Performers 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 identification, marking, protecting, and control, to include processing on Non-DoD Information Systems, is incorporated herein and 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.

A small business joint venture offeror must submit, with its offer, the representation required in paragraph (c) of FAR solicitation provision 52.212-3, Offeror Representations and Certifications-Commercial Products and Commercial Services, and paragraph (c) of FAR solicitation provision 52.219-1, Small Business Program Representations, in accordance with 52.204-8(d) and 52.212-3(b) for the following categories: (A) Small business; (B) Service-disabled veteran-owned small business; (C) Women-owned small business (WOSB) under the WOSB Program; (D) Economically disadvantaged women-owned small business under the WOSB Program; or (E) Historically underutilized business zone small business.

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 (http://public.era.nih.gov/iedison).

7. Agency Contacts

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

The BAA Coordinator for this effort may be reached at:

ABCare@darpa.mil DARPA/BTO ATTN: HR001123S0038 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

8.1. PROPOSERS DAY

The Biological Technologies Office (BTO) of the Defense Advanced Research Projects Agency (DARPA) will host a virtual Proposer's Day for the potential proposer community in support of this Broad Agency Announcement (BAA) for the ABC Program on **June 16, 2023**. A link to the Special Notice announcing this Proposer's Day as well as information relayed during the event will be made available on the BTO section of the DARPA Opportunities page: <a href="https://www.darpa.mil/work-with-us/opportunitieshttp://www.darpa.mil/work-with-us/opportunitieshttp://www.darpa.mil/work-with-us/opportunitieshttp://www.darpa.mil/work-with-us/opportunities the pool of innovative proposal concepts, DARPA strongly encourages participation by non-traditional performers (e.g., small businesses, academic and research institutions, and first-time Government contractors).

The Proposer's Day goals will include:

- 1. Introduce the ABC program vision and goals to the research community;
- 2. Explain the mechanics of a DARPA program in general and the objectives and milestones of this program in particular; and
- 3. Encourage and promote teaming arrangements among organizations that have the relevant expertise, research facilities, and capabilities for executing research and development addressing the ABC program goals.

The Proposer's Day will include brief overview presentations by Government personnel as well as an information session to respond to questions from participants. Potential performers will be

able to highlight their technical capabilities through "lightning" talks such that teaming relationships can be developed. It is expected that ABC will require strong teaming efforts to successfully innovate and integrate critical technologies necessary to meet the metrics of the program. Potential performers will be able to publish profiles of their expertise and sought-after capabilities for prospective teammates to establish partnerships.

Proposers Day Point of Contact: <u>ABCare@darpa.mil</u> ATTN: DARPA-SN-23-61

8.2. UNIVERSITY FUNDING

In order to ensure that U.S. scientific and engineering students will be able to continue to make strategic technological advances, DARPA is committed to supporting the work and study of Ph.D. students and post-doctoral researchers that began work under a DARPA-funded program awarded through an assistance instrument. Stable and predictable federal funding enables these students to continue their scientific and engineering careers.

To that end, should a DARPA funded program awarded through a grant or cooperative agreement with a university or a Research Other Transaction pursuant to 10 U.S.C. § 4021 where the university is a participant end (due to termination or down-select) before the planned program completion, DARPA may continue to fund, for no more than two semesters (or equivalent), the documented costs to employ or sponsor Ph.D. students and/or post-doctoral researchers. Should such a circumstance arise, the following will take place:

- 1) The Government will provide appropriate notification to the University participant by the Agreements Office or through the prime performer.
- 2) The University must make reasonable efforts to find alternative research or employment opportunities for these students and researchers.
- Before any costs will be paid, the University must submit documentation describing their due diligence efforts in finding alternative arrangements that is certified by a University official.
- 4) In addition to this documentation, the affected students and researchers must submit statements of work describing what research activities they will pursue during the period of funding and the final deliverable they will submit when the funding is complete.
- 5) In determining these costs, DARPA will rely on information from the University's original proposal unless specific circumstances warrant requesting updated proposals. In no circumstances will this funding be provided when the program is ended because of suspected or actual fraud or negligence.

DARPA Down-Select Definition:

DARPA often structures programs in phases or options that include specific objectives and a designated period of performance. This may result in potentially issuing multiple awards to maximize the number of innovative approaches. This approach allows the Government to monitor progress and enables programmatic decision points based, at a minimum, against stated evaluation criteria, metrics, funding availability, and program goals and objectives. As a result, select performers may advance via award of a subsequent phase or through exercise of a planned option period.

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 cost volume. Full instructions appear in Section 4.2.2 of HR001123S0038. 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 **HR001123S0038** 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)

fo YES o NO Appears 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

• NO Appears on Page(s) [Type text]

Subcontracts/Consultants• YES• NOAppears on Page(s) [Type text]

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

 Travel

• YES • 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 basisof-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:

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: