Broad Agency Announcement

Biostasis

BIOLOGICAL TECHNOLOGIES OFFICE

HR001118S0034

March 16, 2018

TABLE OF CONTENTS

PART I: OVERVIEW INFORMATION

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office
- **Funding Opportunity Title –** Biostasis
- **Announcement Type –** Initial Announcement
- **Funding Opportunity Number –** HR001118S0034
- **Catalog of Federal Domestic Assistance Numbers (CFDA) – 12.910 Research and Technology Development**
- **Dates**
  - Posting Date: March 16, 2018
  - Proposal Abstracts are due by Tuesday, April 17, 2018, 4:00 PM ET
  - Full Proposals are due Tuesday, May 22, 2018, 4:00 PM ET
  - BAA Closing Date: Tuesday May 22, 2018
  - Proposers' Day Webinar: Tuesday, March 20, 2018, 12:30 PM ET

  https://www.fbo.gov/spg/ODA/DARPA/CMO/DARPA-SN-18-36/listing.html

- **Concise description of the funding opportunity:** DARPA seeks novel approaches to reversibly pause and/or slow the functions and preserve viability of living cells without reliance on cold temperature. This new technology aims to directly address needs within the Department of Defense to maintain and deliver biological therapeutics and extend the window of time for effective use of field forward therapeutics.
- **Anticipated individual awards** – Multiple awards are anticipated.
- **Types of instruments that may be awarded** – Procurement contract, cooperative agreement, or other transaction.
- **Any cost sharing requirements**- None
- **Agency contact**

  The BAA Coordinator for this effort may be reached at:
  Biostasis@darpa.mil
  DARPA/BTO
  ATTN: HR001118S0034
  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. The Defense Advanced Research Projects Agency (DARPA) often selects its research efforts through the BAA process. The BAA will appear first on the FedBizOpps website, http://www.fbo.gov, and the Grants.gov website http://www.grants.gov. The following information is for those wishing to respond to the BAA. Proposals received as a result of this BAA shall be evaluated in accordance with evaluation criteria specified herein through a scientific review process.

DARPA is soliciting innovative proposals to develop novel technology that will reversibly slow down and/or pause biological processes and protect the functional integrity of the biological system that has been slowed or paused without the use of temperature manipulation. Specifically excluded is research that primarily results in evolutionary improvements to the existing state of practice.

1.1. PROGRAM OVERVIEW

Biostasis aims to provide a new capability to military and civilian health operations as an adjunct/alternative to traditional responses to trauma and acute infection, and can also be applied to logistical issues related to the transport and use of biological reagents and therapeutics that rely on cold chain. Slowing the overall reaction rates of biochemical processes by lowering temperature is routinely applied via cryopreservation for simple systems (e.g., cell line preservation), but is impractical for use on more complex multicellular tissues. Rather, DARPA seeks to establish new capabilities for preserving biological viability without relying on temperature manipulation. The successful products of the Biostasis program represent a new class of medical interventions and countermeasures and will enable a significant paradigm shift in the treatment of the injured warfighter.

To achieve this capability, Biostasis will focus on developing and characterizing new molecular interventions that capitalize on fundamental principles of the biochemistry of life to slow down and/or pause cellular functions and preserve viability under challenging conditions; slowing life to save life. The ability to reversibly slow down and/or pause biological systems is desirable for immediate response to battlefield trauma, slowing of acute infection, and room temperature stabilization of diagnostic reagents, therapeutics, and blood products.

Recent discoveries in cryptobiology point to molecular mechanisms that can be leveraged in new ways to produce the desired effects with minimal reliance on environmental induction of stasis. For example, in these cryptobiotic organisms that exhibit exceptional environmental tolerance, there are traits that all share a common mechanistic component in that protection is conferred via collective chaperoning of subcellular constituents at the molecular level. This protective restriction in protein conformation enables the entire system to survive conditions that are

otherwise incompatible with life. Acknowledging this core component of the molecular nature of cryptobiosis is key to developing strategies that can be applied to multiple biological systems of varying complexity, from simple enzymes, to cells, to tissues, to entire organisms. The new approaches and interventions developed under Biostasis will need to globally restrict macromolecular processes without producing maladaptive responses that ultimately compromise the functional integrity of the biological system. Successful proposals will pursue chemical biology solutions that can be delivered passively to biological systems (i.e., do not require genetic manipulations or excessive specialized equipment for administration), to slow down and/or pause all critical biochemical processes, and exhibit reversal either by design or by secondary intervention.

Biostasis approaches should be generalizable across levels of biological complexity (e.g., biological reagents, biologics, cells, tissue, etc.). For example, preservation of simple biological products such as diagnostic reagents, vaccines, or therapeutic enzymes to extend shelf stability and protect activity while minimizing the infrastructure required for storage and/or transport could be as readily applied to a more complex system by optimizing factors for delivery and systemic tolerance for use as novel adjuvant therapies in critical care scenarios (e.g., acute infection and trauma).

1.2. PROGRAM STRUCTURE AND TECHNICAL APPROACH

The Biostasis research and development program is divided into four sequential Phases: Phase I (base effort) – 18 months, Phase II (option) – 12 months, Phase III (option) – 12 months, and Phase IV (option) – 18 months. Proposers must present a plan for no more than five years and a comprehensive approach to meeting all program milestones (see Table I). Proposals utilizing multiple teams (from the same or different institutions) and/or exploring multiple approaches to Biostasis should be assembled as a single research entity, and report as such.

Proposals must address both of the following major tasks:

Task 1: Design, build and test reversible Biostasis intervention(s).

> One of the critical aspects of the Biostasis program is the ability of performers to identify and optimize approaches that produce reliable states of slowed and/or paused cellular activity. Potential approaches to addressing this need are (but not limited to): 1) Assembly of intracellular polymers that mimic intracellular overcrowding; 2) Small molecules that act as promiscuous pharmacological chaperones and reversibly restrict protein conformational flexibility; and 3) Engineered intrinsically disordered proteins that can penetrate or be transported into cells and act as stress-responsive proteostasis effectors. Proposers should consider what type of approach they intend to apply and how it can be most effectively developed and profiled to demonstrate, in Task 2, efficacy and generalizability across biological systems of varying degrees of complexity. Proposers should also have a proven track record in the fundamental science underlying the approach they will pursue, and access to all of the research infrastructure required to meet the program milestones.

In Task 1, proposers will develop the molecular approaches they wish to pursue, and evaluate the performance of, in simple biomolecular systems. To gauge Task 1 progress on approach development, proposals must utilize five or more functionally disparate *in vitro* biomolecular assays to guide and warrant further evaluation in complex biological systems as described in Task 2, Phase II - IV. It is up to the proposer to select their preferred biomolecular assays that are amenable to their approach, but examples could be five different enzyme complexes, or five different transmembrane proteins expressed in artificial lipid bilayers, etc. Using simple screening chassis, proposers must also provide a plan to determine critical functional parameters that are suitable to their proposed biostasis approach, such as:

- Protein structural modeling and interactions
- In vitro enzyme activity and kinetics of reversible inhibition
- Protein chaperoning and protection from denaturation
- Bio-orthogonal polymerization
- Thermodynamics
- Conditions for induction and reversal of protein complex stabilization

Performers will submit to DARPA quantitative data and interpretation of one or more of the screening chassis as part of the required 6-week regular reports to demonstrate that forward progress is being made or if redirection of the approach is necessary.

It is anticipated that proposals will develop a plan for Task 1 similar to the following: during Phase I, molecular interventions based on cryptobiotic mechanisms are synthesized and profiled in biomolecular assays (≥5) for desired effects. In Phase II, lead interventions from the first phase are optimized and the molecular mechanisms by which these interventions induce cellular stasis are tested and verified. Once lead compounds/methods are established, in Phase III, interventions will be refined and improved to ensure optimal delivery of the intervention to a complex biological system (i.e., tissue, animals). Proposals should provide a detailed plan to optimize formulation of lead interventions. By the final Phase IV under this task, it is expected that refined and optimized intervention(s) and their molecular activity; kinetics of activity and reversibility will be fully characterized.

Quantitative metrics and milestones for successful phase transitions are provided by DARPA (see Table 1 and 2), but it is expected that proposers will have and describe intermediate metrics, milestones and demonstrations of progress (see section 1.3).

Task 2: Determine Safety, Efficacy, and Generalizability of Biostasis intervention(s).

Task 2 will test and evaluate the safety and efficacy of the interventions developed in Task 1. Additionally, proposals should include details on how the interventions will be tested for their safety and efficacy in slowing and/or pausing cellular activity in progressively more complex test systems (i.e., human cells, human organoids, animal models). In Phase I, proposals should describe a plan to first use simple human cell culture and/or *in vitro* systems (e.g., biologics, enzymes, protein complexes) to test

prototype compounds in high throughput fashion. Bioassays used should address parameters such as:

- Cell penetration (timecourse and mechanism)
- Intracellular distribution
- Kinetics and stability of cellular activities (e.g., metabolic markers, trafficking, etc.)
- Reversibility of the intervention in the system

Performers will submit to DARPA quantitative data and interpretation of one or more of the bioassay parameters as part of the required 6-week regular reports to demonstrate that forward progress is being made or if redirection of the approach is necessary.

It is anticipated that in Phase I, proposers will use these simple systems to design, build and test interventions to optimize stasis induction at room temperature. Proposals should include measurement parameters such as viability, metabolic response, toxicity, distribution, absorption, clearance, stability, and reversibility of interventions. As interventions are optimized, proposals should detail a plan to move into more complex human cell systems such as organoids and tissue constructs in Phases II and III and it is expected that quantitative parameters to determine safety and efficacy of the interventions will be measured (e.g., stasis induction, kinetics of stasis, reversibility, cell viability, etc.). For the last phase of the program, proposers should address a plan to test optimized interventions in *in vivo* animal models (*e.g.,* rodents, non-human primates) for safety and efficacy. Proposals will need to address the pharmacokinetics (how an organism affects a drug) and pharmacodynamics (how a drug affects an organism) of optimized interventions.

As the model system for Biostasis efficacy and safety demonstration increases in complexity, so too do the metrics for performance and maintenance of viability in the cell/tissue models. The terminal goal for model systems is maintenance of cell viability at 98% or greater; a quantitative metric necessary for subsequent human medical use. This specific milestone must be satisfied using an *in vitro* model prior to entry into the final 18-month phase of the program.

Feasibility

Proposals should describe the precedent for their technological approach and, where applicable, provide any preliminary data indicating the level of expertise applied to the research and development objectives of the Biostasis program. This estimate should be based not only on the theoretical strength of the proposed approach, but on real-world capabilities such as screening infrastructure, chemical synthesis and formulation capacity, and experience with progressively more complex biological model systems. A Gantt chart or similar diagram of a high-level representation of the sequence timeline for experiments and capability tests leading up to the phase transition demonstration should be included in the proposal.

1.3. END OF PHASE DEMONSTRATIONS

Prior to the end of each phase, performers will be required to demonstrate the ability of their approach(es) to initiate and maintain biostasis in their model system of choice. Ideally, this demonstration should be presented as a single, large-scale experiment that details the methods used to measure biological activity, the degree and duration of stasis induced, and the mechanisms by which stasis is produced and reversed. Challenges to the system will be selected by the performers in consultation with DARPA, and should be consistent with a desired end-user application space. It is not required that performers set aside a specific period of time for a demonstration, rather, the demonstration should be a test of Biostasis capability by the end of the phase.

At the end of each phase, the outcomes of the demonstration experiments should be presented to DARPA and invited representatives of other government agencies as a concise research study. High-level information on the nature of the approach, mechanistic understanding, and how the challenge conditions conceptualize a real-world application for the approach(es) should be the major foci of the presentation.

It is expected that the approach(es) to Biostasis will continually improve with respect to tolerance within the test system(s), reflected by the ability to surmount the viability percentage objective at each phase transition (Table 1). Moreover, metrics for mechanistic understanding and molecular coverage of Biostasis interventions also increase in complexity as the anticipated number of lead compounds/test scenarios decreases. This increase in the complexity of the reported mechanisms and the test system used to evaluate Biostasis performance should be reflected in the plans for future phases and include risk mitigation strategies for continued performance.

Model Systems

Performers may establish biological test beds of their choosing for any scenarios, provided that the complexity increases according to the metrics for Task 2 (see Table 1) with successful transitions across phases. It is anticipated that Task 1, Phase I will largely rely on simple in silico and *in vitro* test beds to design, build and test interventions, and will gradually incorporate larger scale mechanistic experiments using progressively more complex models as required in Task 2 and subsequent phases.

1.4. PROGRAM METRICS

Research proposals should describe efforts for the full 60 months of anticipated performance, according to the Table 1 below. Although the following minimum milestones and metrics are specified, the Government identifies these to bound the effort while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problems. Proposers are encouraged to add additional milestones or metrics based on the team's specific technical approach. Proposals must address all key milestones and technical metrics described in this section in Tables 1 and 2.

Table 1: Progression of Model Complexity and Potential DoD applications by phase

Phase	Model System	Primary Metrics (capability	Potential DoD application

		test)	
I	Simple cell/*in vitro* system, human cells	Stasis induction and viable cell recovery at 60%.	Biological reagents & therapeutics without cold chain
II	Complex human cell systems, organoids or tissue	Stasis induction and viable cell recovery at 85%.	Blood product, cell-based sensors/diagnostics
III	Human organoid or tissue	Stasis induction and viable cell recovery at 98%.	Tissue preservation
IV	Animal	Stasis induction and tolerance in animal model	Trauma and acute infection

It is suggested, but not mandatory, that proposals follow the below program structure:

> Phase I (base effort): Proposals will describe a technical plan to leverage the molecular mechanisms underlying cryptobiosis for cell stasis induction to generate lead compounds/interventions to induce stasis in living systems. Potential compounds will be deployed in simple cell model and/or human relevant *in vitro* systems. By the end of Phase I, performers will need to demonstrate that potential compounds can induce stasis and/or demonstrate temporary reduction of multiple functional outputs from simple cell model and/or *in vitro* systems with 60% viability when released from stasis.
>
> Phase II (option): Proposals will detail a plan that will optimize the performance of compounds in complex human cell model systems. Expected outcomes are compounds and delivery protocols capable of inducing reversible biological stasis and/or temporary reduction of multiple functional outputs with greater than 85% cell survival upon release from stasis.
>
> Phase III (option): Proposals will describe a plan to continue to optimize the performance of compounds in human organoid and/or human tissue with added phenotypic data detailing systems-wide effects, dose-response relationships, efficacy, kinetics of stasis, safety, and reversibility in cell systems. Performers must demonstrate at least 98% viability after stasis induction and upon release from stasis.
>
> Phase IV (option): Proposals will describe a detailed plan that tests optimized intervention(s) in multicellular animal models to demonstrate safety and efficacy of stasis induction, as well as optimize parameters and metrics for deployment under field conditions (formulation, stability, dosing requirements). Proposers should also explore the generalizability of stasis induction to determine if compounds can induce stasis under a variety of conditions (i.e., infection, trauma, labile biological reagents).

As described previously, successful transition into Phase IV means that Biostasis approaches are of sufficient *in vitro* performance to warrant safety evaluation and efficacy testing in complex mammalian organism systems. It is anticipated that, at this point, cellular viability is in excess of

98% following stasis induction, and that this level of performance is consistent across multiple model systems (e.g., purified protein complex, simple cell, model tissue). Proposals should address the model systems and potential applications by phase included in Table 1, as well as the metrics included in Table 2 below along with any additional intermediate research goals that will be reported to DARPA during regular meetings that address both major tasks. In the proposal metrics in Table 2 must be addressed by phase in the appropriate model system and include:

- Phase I: cell viability on recovery, <6 hours for initiation of cellular stasis, and DNA damage response.
- Phase II: cell viability on recovery, time course characterization for cellular stasis initiation and reversibility, DNA damage response, and cellular activity profiles for ≥ 12 different processes over time (e.g., membrane potential, ATP concentration, subcellular trafficking, cell cycle transition, enzyme activities, etc.).
- Phase III: 98% or greater cell viability on recovery from stasis intervention, time course characterization for cellular stasis initiation and reversibility, cellular activity profiles for ≥ 12 different processes over time in ≥ 4 different cell types, and metabolomic profiling.
- Phase IV: proposals must address the metrics described below in Table 2 and include a plan to characterize the pharmacokinetics and pharmacodynamics of Biostasis intervention(s) in an animal model.

Table 2. Program Metrics

Phase 1: 18 months	**Milestone:** Characterization of intervention-induced stasis in simple in vitro/human cell models. **Metrics:** • ≥5 in vitro biomolecular assays used to assess intervention performance. • 60% cell viability on recovery. • <6 hours for initiation of cellular stasis. • Genome integrity: <10% increase in DNA damage response.
Phase 2: 12 months	**Milestone:** Lead intervention(s) with enhanced efficacy and safety **Metrics:** • 85% cell viability on recovery in complex human cell systems (e.g., blood, organ on chip). • <4 hours for stasis induction and reversibility on demand or time course characterization. • Genome integrity: <5% increase in DNA damage response. • High throughput live cell activities: ≥12 different processes measured at S/N<10%.
Phase 3: 12 months	**Milestone:** Refined intervention(s) with sufficient safety and efficacy to warrant animal studies **Metrics:** • 98% cell viability on recovery in complex human systems (tissue or organoid model). • <2 hours for stasis induction and reversibility on demand or time course characterization. • High throughput live cell activities: ≥12 different processes measured from ≥4 cell types. • Quantify changes to metabolites covering 80% of known metabolic output.
Phase 4: 18 months	**Milestone:** Reversible stasis in multicellular organism **Metrics:** • 98% stabilization of cellular components and local effect onset in <1 hr (diffusion-limited). • *In vivo* physiological screen, quantitative pharmacokinetics (i.e., concentration, time course, distribution, clearance) and pharmacodynamics analysis. • Reversibility demonstrated *in vivo* on demand or time course characterization.

Deliverables

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

- End of Phase Reports: At the end of each funding period, prior to the initiation of a subsequent phase, performers must draft and present to DARPA a written report of all research activities and metrics satisfied. This report should contain as much supporting data for the establishment of Biostasis conditions as can be reasonably conveyed to academic reviewers.
- Monthly Financial Reports: performers are required to provide financial status updates. These reports will be in the form of an editable MS Excel™ file, and will provide financial data including, but not limited to, the following: spend plan by phase and task, encumbered expenditures to date by phase and task, and invoiced expenditures to date by phase and task.
- Six-Week Progress Reports: Every six (6) weeks (or as close to as scheduling permits), performers are required to provide research updates. These reports will be in the form of a standardized slide presentation given to DARPA and discussed with the program management team via telecon. Length and detail level will be at the discretion of the Program Manager.
- Quarterly Technical Reports: The reports shall be prepared and submitted in accordance with the procedures contained in the award document.
- Semi-Annual Reviews: Leadership from each performer team (with additional key personnel at the discretion of the Principal Investigator) will be required to present research progress in person, twice annually. The purpose of these reviews is to ensure adequate engagement with the DARPA team, and provide opportunities to discuss any ongoing issues or programmatic details that might otherwise fall outside the scope of a routine technical brief.
- Final Phase Report: When the final funding phase closes out, performer teams will need to provide a final report that summarizes all research activities, outcomes, and molecular mechanisms discovered during the program.
- Any publications, research presentations, patent applications that result from the research pursued as part of the Biostasis program.
- Any additional deliverables requested by the executive agent for this program (DARPA Contracts Management Office).

Transition

Biostasis is designed to develop and prove the efficacy and safety of novel molecular interventions that work within living cells to stabilize and reversibly pause and/or slow all biochemical processes; effectively providing “time on demand” for living things. As such, the reagents themselves as well as the methods developed to produce them represent not only a revolutionary capability to protect our service members but also a potentially lucrative commodity for the private sector. Performers are encouraged to engage with representatives from these areas after successful completion of the first phase in order to ensure proof-of-concept for the program is met. Since program products may also find use in humans, early communication with the appropriate regulatory agencies (Food and Drug Administration, United States

Department of Agriculture) is critical. Products that pass through the final development phase will be treated as medicines for use in humans and will be evaluated as such by the abovementioned agencies.

Proposers are expected to manage intellectual property (IP) rights so as to facilitate transition of the tools and methods developed under this program. Forms to be completed regarding intellectual property are in Section VIII.

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 fund a Phase option based on funding availability, an assessment of the research results, and a determination that awarding the option is in the best interest of the Government.
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 http://www.darpa.mil/work-with-us/contract-management#OtherTransactions.

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 BAA, 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 BAA. 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 BAA criteria for submissions. If proposals are selected for award that offer other than a fundamental research solution, the Government will either work with the proposer to modify the proposed statement of work to bring the research back into line with fundamental research or else the proposer will agree to restrictions in order to receive an award.
Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to select award instrument type and to negotiate all instrument terms and conditions with selectees. Appropriate clauses will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate. This clause 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 being performed by the awardee is restricted research, a subawardee may be conducting fundamental research. In those cases, it is the awardee's responsibility to explain in their proposal why its subawardee's effort is fundamental research

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

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

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

FFRDCs

FFRDCs are subject to applicable direct competition limitations and cannot propose to this BAA in any capacity unless they meet the following conditions: (1) FFRDCs must clearly demonstrate that the proposed work is not otherwise available from the private sector. (2) FFRDCs must provide a letter on official letterhead from their sponsoring organization citing the specific authority establishing their eligibility to propose to Government solicitations and compete with industry, and their compliance with the associated FFRDC sponsor agreement's terms and conditions. This information is required 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.

Authority and Eligibility

At the present time, DARPA does not consider 15 U.S.C. § 3710a to be sufficient legal authority to show eligibility. While 10 U.S.C.§ 2539b may be the appropriate statutory starting point for some entities, specific supporting regulatory guidance, together with evidence of agency approval, will still be required to fully establish eligibility. DARPA will consider FFRDC and Government entity eligibility submissions on a case-by-case basis; however, the burden to prove eligibility for all team members rests solely with the proposer.

3.1.2. Non-U.S. Organizations

Non-U.S. organizations and/or individuals may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances.

3.2. ORGANIZATIONAL CONFLICTS OF INTEREST

FAR 9.5 Requirements

In accordance with FAR 9.5, proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and *any* proposed team member (subawardee, consultant). Under this Section, the proposer is responsible for providing this disclosure with each proposal submitted to the BAA. 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 BAA 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.

For more information on potential cost sharing requirements for Other Transactions for Prototype, see http://www.darpa.mil/work-with-us/contract-management#OtherTransactions.

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 http://www.darpa.mil, contact the administrative contact listed herein.

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

All submissions, including abstracts and proposals, must be written in English with type no smaller than 12-point font. Smaller font may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11-inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title.

4.2.1. Proposal Abstract Format

Proposers are strongly encouraged to submit an abstract in advance of a proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. The abstract is a concise version of the proposal comprising a maximum of **8** pages including all figures, tables, and charts. The submission letter is not included in the page count. All submissions must be written in English with type no smaller than 12-point font. Smaller font may be used for figures, tables, and charts. The page limitation for abstracts includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11-inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title.

Abstracts must include the following components:

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

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

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

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

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

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

E. Cost and Schedule: Cost and schedule for the proposed research, including an estimate of (a) total cost, (b) cost for each task in each phase (as defined in Table 1) of the effort by prime and major subcontractors, and (c) any cost share (if applicable).

4.2.2. Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal.** All submissions must be written in English with type no smaller than 12-point font. 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 submission letter is not included in the page count. Volume I should include the following components:

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

a. Volume I, Technical and Management Proposal

Section I. Administrative

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

1. BAA number (HR001118S0034);
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 Grant Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, firm-fixed-price, cooperative agreement, other transaction, or other type (specify);
10. Place(s) of performance, including all subcontractors and consultants;
11. Period of performance;
12. Total funds requested from DARPA, total funds requested per phase (as defined in Table 1), and the amount of any cost share (if any);
13. Proposal validity period; AND
14. Date proposal was submitted.

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

B. Official Transmittal Letter.

Section II. Detailed Proposal Information

A. Executive Summary (1-2 pages): Provide a synopsis of the proposed project, including answers to the following questions:

- What is the proposed work attempting to accomplish or do?
- How is it done today, and what are the limitations?
- What is innovative in your approach? How is your approach better than the current state-of-the-art, alternative approaches, and previous efforts? Why do you think your approach will succeed? Summarize scientific rationale supporting your approach.
- What are the key technical challenges in your approach and how do you plan to overcome these?
- Who or what will be affected and what will be the impact if the work is successful?

- How much will it cost, and how long will it take? Ensure that the cost and schedule are aligned with the phases outlined in Section 1.4 Program Metrics and as outlined in Table 1 and Table 2.

B. Goals and Impact (1-2 pages): Clearly describe what the team is trying to achieve and the difference it will make (qualitatively and quantitatively) if successful. Describe the innovative aspects of the project in the context of existing capabilities and approaches, clearly delineating the uniqueness and benefits of this project in the context of the state of the art, alternative approaches, and other projects from the past and present. Describe how the proposed project is revolutionary and how it significantly rises above the current state-of-the-art. Describe the deliverables associated with the proposed project and any plans to commercialize the technology, transition it to a customer, or further the work.

C. Technical Plan (12-18 pages): Provide a detailed scientific rationale and description of the planned approach and execution plan. The technical plan should demonstrate a deep understanding of the scientific challenges and present a credible (even if risky) plan to achieve the program goals. The technical approach should address all applicable proposal content instructions in Sections 1.1- 1.4.

    1. Approach: Describe the scientific and technical approach. Hypotheses should be articulated clearly and include a rigorous test plan with quantitative metrics to yield unambiguous results. Provide appropriate measurable milestones (qualitative and quantitative) and program metrics (see Section 1.4) at each phase of the program to demonstrate progress, and a plan for achieving the milestones and metrics. Experimental designs and procedures must be described thoroughly, including aspects such as equipment, behavioral paradigms, animal models, approximate numbers of subjects, software, analysis plan, statistical reporting etc. Figures and diagrams that help illustrate the experimental design may be included.
    2. Rationale: Provide a clear rationale for the approach, including a justification for the feasibility of the proposed task. Proposers are highly encouraged to include supporting data when available, even if preliminary. Figures included within the proposal should be accompanied by a brief description of how data was collected, what analysis was performed, what the results mean, and why the result supports the feasibility of the proposed task.
    3. Schedule: Include a narrative overview of the timeline of the task/objective. Intermediate milestones and final completion criteria should be identified along with the quantitative metrics that will be used to evaluate progress. Include a one-page high-level graphical (Gantt or flow chart style) timeline of the outlined tasks/objectives described in the Scientific Approach and Plan.

4. Challenges and Risks: Articulate the scientific and technical challenges and risks facing this effort. Include a risk mitigation plan including possible solutions for overcoming potential hurdles or alternative approaches.
5. Personnel: Identify the personnel responsible for each major task (e.g., "led by Jane Smith with support from one graduate student at 50% effort").

D. Management Plan (2-3 pages): Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. Include an organization chart for the entire team which includes, as applicable: (1) the programmatic relationship of team member; (2) the unique capabilities of team members; (3) the task responsibilities of team members; (4) the teaming strategy among the team members; and (5) the key personnel along with the amount of effort to be expended by each person during each year. Resumes do not count against the proposal page count. Identify a principal investigator for the project. Provide a detailed plan for coordination including explicit guidelines for interaction among collaborators/subcontractors of the proposed effort.

E. Capabilities (1-3 pages): Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Discuss any work in closely related research areas and previous accomplishments. Include a description of the facilities that would be used for the proposed effort.

F. Statement of Work (SOW) (3-6 pages): The SOW must be read as a stand-alone document without references to text or figures included in Section B. Each Phase of the program (I through IV) should be defined separately and each task should be identified as Task 1 or 2. Dependencies between tasks and/or subtasks should be identified clearly. The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. The SOW must not include proprietary information.

   For each task/subtask, provide:

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

G. Transition Plan (0.5-1 pages): Proposals are encouraged to outline a plan for potential clinical translation of the products that are developed in Biostasis. While Biostasis is a fundamental research program, it is anticipated that the capabilities, knowledge, and products developed by the end of the program will be suitable for advanced development for medical use and for National Security purposes. The transition plan should be consistent with the goal of the Biostasis program and might include commercial ventures, licensing agreements, and/or journal publications of detailed plans and methods.

b. Volume II, Cost Management Proposal

Cover Sheet (labeled "PROPOSAL: VOLUME II") and Appendix 1 to include:

1. BAA number (HR001118S0034);
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 Grant 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*), 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. DUNS number (http://www.dnb.com/get-a-duns-number.html) ;
17. Taxpayer ID number (https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN;
18. CAGE code (https://cage.dla.mil/Home/UsageAgree);
19. Proposal validity period

Note that nonconforming proposals may be rejected without review.

Proposers that do not have a Cost Accounting Standards (CAS) compliant 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.gsa.gov/portal/forms/download/115778 and submit the completed form with the proposal. To complete the form, check the boxes on the second page, then provide a narrative explanation of your accounting system to supplement the checklist on page one. For more information, see (http://www.dcaa.mil/Home/Preaward).

The Government encourages proposers to complete an editable MS excel budget template that covers many of the items discussed below. This template document is provided as **Attachment 1** to this BAA. If proposers choose to use **Attachment 1**, submit the MS Excel template in addition to Volume I and II of their proposal. Volume II must include all other items discussed below that are not covered by the editable MS Excel budget template. Proposers are welcome to utilize an alternative format, provided the information requested below is clearly and effectively communicated.

(1) Total program costs broken down by phase (Phase I base, Phase II option, Phase III option, and Phase IV option) in Contractor Fiscal Year to include:

i. direct labor, including individual labor categories or persons, with associated labor hours and numbered direct labor rates;
ii. Indirect costs including Fringe Benefits, Overhead, General and Administrative Expense, Cost of Money, etc. (Must show base amount and rate)
iii. Travel – Number of trips, number of days per trip, departure and arrival destinations, number of people, etc. Per Diem Rates proposed should not exceed General Services Administration (GSA) Per Diem rates for the destination area;
iv. Materials and Supplies – itemized list which includes description of material, quantity, unit price, and total price by total program, per phase, and per task;
v. Equipment – itemized list which includes description of equipment, unit price, quantity, and total price by total program, per phase, and per task. Any equipment item with a unit price over $5,000 must include a vendor quote;
vi. Other Direct Costs – Should be itemized with costs or estimated costs. Backup documentation will be submitted to support proposed costs. 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;

(2) A summary of total program costs by task (1 or 2) under each phase;

(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 which 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;

(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 which could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each; and

(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) A summary of major program tasks by Government Fiscal Year (GFY = Oct 1-Sep 30)

(10) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available); and

(11) Proposers with a Government acceptable accounting system who are proposing a cost-type contract, must submit the DCAA document approving the cost accounting system.

The proposer should include supporting cost and pricing information in sufficient detail to substantiate the summary cost estimates and should include a description of the method used to estimate costs and supporting documentation. 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 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 cooperative agreement, or Other Transaction.)

4.2.3. Additional Proposal Information

Proprietary Markings

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

Unclassified Submissions

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

Human Research Subjects/Animal Use

Proposers that anticipate involving Human Research Subjects or Animal Use must comply with the approval procedures detailed at http://www.darpa.mil/work-with-us/additional-baa.

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.gsa.gov/portal/forms/download/115778 and submit the completed form with the proposal. To complete the form, check the boxes on the second page, then provide a narrative explanation of your accounting system to supplement the checklist on page one. For more information, see (http://www.dcaa.mil/preaward_accounting_system_adequacy_checklist.html).

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 http://www.darpa.mil/work-with-us/additional-baa for further information. If no restrictions are intended, the proposer should state "none." The table below captures the requested information:

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

For All Non-Procurement Contracts

Proposers responding to this BAA requesting a Cooperative Agreement 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 BAA. See http://www.darpa.mil/work-with-us/additional-baa for further information.

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 HR001118S0034. Submissions may not be submitted by fax or e-mail; any so sent will be disregarded.

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

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

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

Abstracts and Full Proposals sent in response to HR001118S0034 may be submitted via DARPA's BAA Website (https://baa.darpa.mil). Visit the website to complete the two-step registration process. Submitters will need to register for an Extranet account (via the form at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the abstract. Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process be started as early as possible.

All unclassified concepts submitted electronically through DARPA's BAA Website must be uploaded as zip files (.zip or .zipx extension). The final zip file should be no greater than 50 MB in size. Only one zip file will be accepted per submission. Classified submissions and proposals requesting assistance instruments (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 BAAT_Support@darpa.mil, and is typically available during regular business hours, (9:00 AM- 5:00 PM EST Monday-Friday).

Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process 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 https://www.grants.gov/applicants/apply-for-grants.html; 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: Proposers must submit the three forms listed below.

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

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. A§ 1681 Et. Seq.), the Department of Defense is using the two forms below to collect 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. Detailed instructions for each form are available on Grants.gov.

Research and Related Senior/Key Person Profile (Expanded), available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_KeyPersonExpanded_2_0-V2.0.pdf. *This form must be completed and submitted.*

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

Grants.gov Submissions: 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 http://www.darpa.mil/work-with-us/additional-baa.

Hard-copy Submissions: Proposers electing to submit grant or cooperative agreement proposals as hard copies must complete the SF 424 R&R form (Application for Federal Assistance,) available on the Grants.gov website http://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf.

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.

4.2.5. 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 http://www.darpa.mil/work-with-us/additional-baa#NPRPAC.

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://doi.org/10.6028/NIST.SP.800-171r1) that are in effect at the time the BAA 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.

4.3. FUNDING RESTRICTIONS

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

4.4. OTHER SUBMISSION REQUIREMENTS

Not Applicable.

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

Review Process

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

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

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

Handling of Source Selection Information

DARPA policy is to treat all submissions as source selection information (see FAR 2.101 and 3.104), and to disclose their contents only for the purpose of evaluation. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All DARPA

support contractors performing this role are expressly prohibited from performing DARPA-sponsored technical research and are bound by appropriate nondisclosure agreements. Subject to the restrictions set forth in FAR 37.203(d), input on technical aspects of the proposals may be solicited by DARPA from non-Government consultants/experts who are strictly bound by the appropriate non-disclosure requirements.

Federal Awardee Performance and Integrity Information (FAPIIS)

Per 41 U.S.C. 2313, as implemented by FAR 9.103 and 2 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.

6. Award Administration Information

6.1. SELECTION NOTICES

As soon as the evaluation of a proposal is complete, the proposers will be notified that 1) the proposal has been selected for funding pending contract negotiations, or 2) the proposal has not been selected. These official notifications will be sent via email to the Technical POC identified on the proposal 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 full proposals submitted using the published evaluation criteria and without regard to any comments resulting from the review of an abstract.

6.1.2. Full Proposals

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

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 http://www.darpa.mil/work-with-us/additional-baa.

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

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

6.2.3. Representations and Certifications

If a procurement contract is contemplated, prospective awardees will need to be registered in the SAM database prior to award and complete electronic annual representations and certifications consistent with FAR guidance at 4.1102 and 4.1201; the representations and certifications can be found at www.sam.gov. Supplementary representations and certifications can be found at http://www.darpa.mil/work-with-us/additional-baa.

.

6.2.4. Terms and Conditions

A link to the DoD General Research Terms and Conditions for Grants and Cooperative Agreements and supplemental agency terms and conditions can be found at http://www.darpa.mil/work-with-us/contract-management#GrantsCooperativeAgreements.

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 https://wawf.eb.mil, 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.

Points of Contact
The BAA Coordinator for this effort may be reached at:
Biostasis@darpa.mil
DARPA/BTO
ATTN: HR001118S0034
675 North Randolph Street
Arlington, VA 22203-2114

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

8. Other Information

DARPA will host a Proposers Day Webinar on Tuesday, March 20 at 12:30 PM ET, in support of the Biostasis program. This event will provide critical information on the program vision, program objectives, and opportunities associated with the development of an interdisciplinary proposal to respond to the BAA.

Participants must register to attend the Biostasis Webinar through the registration website: https://events.sa-meetings.com/BiostasisProposersDay. Advance registration is required for every individual intending to view the Webinar, regardless of whether said individuals will be watching the webcast as a group. The Webinar URL will be provided once participants have registered. Webinar registration is limited to **500** remote participants. There is no fee for the Webinar. The Webinar will cover technical and cost proposal instructions. Therefore, both technical/scientific staff and administrative/contracting representatives from the office of sponsored research/programs are encouraged to attend.

Proposers Day Point of Contact: DARPA-SN-18-36@darpa.mil

9. APPENDIX 1 – Volume II Checklist

Volume II, Cost Proposal
Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 beginning on Page 21 of HR001118S0034. This worksheet must be included with the coversheet of the Cost Proposal.

1. Are all items from Section 4.3.8.2 (Volume II, Cost Proposal) of **HR001118S0034** included on your Cost Proposal cover sheet?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]
   If reply is "No", please explain:

2. Does your Cost Proposal include (1) a summary cost buildup by Phase, (2) a summary cost buildup by Year, and (3) a detailed cost buildup of for each Phase that breaks out each task and shows the cost per month?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   If reply is "No", please explain:

3. Does your cost proposal (detailed cost buildup #3 above in item 2) show a breakdown of the major cost items listed below:
   Direct Labor (Labor Categories, Hours, Rates)
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   Indirect Costs/Rates (i.e., overhead charges, fringe benefits, G&A)
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   Materials and/or Equipment
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   Subcontracts/Consultants
   ○ **YES** ○ **NO** **Appears 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 all 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 all material and equipment with a unit price exceeding $5000?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   If reply is "No", please explain:

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

   If reply is "No", please explain:

8. Do you have subcontractors/consultants? If YES, continue to question 9. If NO, skip to question 13.
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

9. Does your cost proposal include copies of all subcontractor/consultant technical (to include Statement of Work) and cost proposals?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   If reply is "No", please explain:

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

    If reply is "No", please explain:

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

    If reply is "No", please explain:

12. If requesting a FAR-based contract, does your cost proposal include a tech/cost analysis for all proposed subcontractors?
    ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

    If reply is "No", please explain:

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

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

If reply is "No", please explain:

14. Does your proposal include a response regarding Organizational Conflicts of Interest?

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

If reply is "No", please explain:

15. Does your proposal include a completed Data Rights Assertions table/certification?

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

If reply is "No", please explain: