



Broad Agency Announcement

Panacea

BIOLOGICAL TECHNOLOGIES OFFICE

HR001119S0010

December 10, 2018

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PART I: OVERVIEW INFORMATION

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title** – Panacea
- **Announcement Type** – Initial Announcement
- **Funding Opportunity Number** – HR001119S0010
- **North American Industry Classification System (NAICS)** – 541714
- **Catalog of Federal Domestic Assistance Numbers (CFDA)** – 12.910 Research and Technology Development
- **Dates**
 - Posting Date: December 10, 2018
 - Proposal Abstract Due Date and Time: January 7, 2019, 4:00 pm Eastern Standard Time
 - Full Proposal Due Date and Time: February 22, 2019, 4:00 pm Eastern Standard Time
 - BAA Closing Date: February 22, 2019
 - Proposers' Day: December 14, 2018
- **Concise description of the funding opportunity** – Human physiology is a limiting factor in the operational readiness of the United States Department of Defense. When the human body is damaged or a physiological system is not functioning optimally, interventions are required to help mend the injury or support continued performance. DARPA seeks to develop new technological approaches in medicinal chemistry and systems pharmacology to expand the druggable proteome and discover new therapeutic tools in the areas of soft tissue pain/inflammation and metabolic stress that limit optimal physiological function. This new platform technology will directly address needs within the Department of Defense to support the unique physiological demands of the warfighter and provide proof-of-concept for novel drug discovery and development pipelines.
- **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** – Cost sharing may be required under applicable statutory regulations for other transactions for prototype projects awarded under the authority of 10 U.S.C. § 2371b.
- **Agency contact**

The BAA Coordinator for this effort may be reached at:
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DARPA/BTO
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PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

The Defense Advanced Research Projects Agency (DARPA) often selects its research efforts through the Broad Agency Announcement (BAA) process. The BAA will appear first on the FedBizOpps website, <http://www.fedbizopps.gov/>, and the Grants.gov website <http://www.grants.gov/>. The following information is for those wishing to respond to the BAA.

The Defense Advanced Research Projects Agency (DARPA) is soliciting innovative proposals that will integrate systems pharmacology and advanced medicinal chemistry approaches to expand the human drug target space for therapeutic interventions in the areas of acute management of pain and inflammation and the improvement of physiological endurance under oxygen-limited conditions or environments. Specifically excluded is research that primarily results in evolutionary improvements to the existing state of practice, that requires genetic manipulation of the intended recipient, or that relies on discovering novel pharmacodynamic space for known therapeutics to identify additional indications.

1.1. PROGRAM OVERVIEW

Human physiology is a limiting factor in the operational readiness of the United States Department of Defense (DoD). When the human body is damaged or a physiological system is not functioning optimally, interventions are required to help mend the injury or improve the underperforming system. Drugs represent one such intervention we use to influence physiological processes, but not all drugs are effective and safe, and not all complex conditions can be remedied with existing drugs. The ability of a drug to interact with and change the function of cellular components is the root of its therapeutic action. These effects cover many degrees of abstraction from the known primary molecular targets of the drug(s), and are observable across many levels of biological complexity within organisms.

Proteins represent the biological targets for the vast majority of drugs in the modern pharmacopoeia. The human proteome is composed of as many as 20,043 proteins and over 6 million estimated proteoforms; novel therapeutic gateways lay hidden within that space. Protein abundances and functions vary according to contexts, such as cell type, age, genetic background, and environmental conditions. Despite this rich landscape, only a tiny fraction (less than 4%) of the proteome is targeted by drugs to facilitate recuperation and support survival. Part of this paucity of drug target space arises from the fact that there is incomplete knowledge of the functional roles of all the proteins comprising the proteome. The focus on compounds with single targets in cell signaling networks (so called “magic bullet” drugs) is another reason the current drug target space is limited to a finite number of proteins and a restricted set of protein classes. Physiological systems are robust; their capability to resist change is a consequence of their evolutionarily acquired complexity. Successful intervention in complex biological systems may require functional modulation of multiple targets instead of just one, and some of those targets may have no known function or structure.

The Panacea program will support the development and proof-of-concept demonstration of a new integrated platform for the rapid prediction, synthesis and validation of pharmacological

interventions. DARPA seeks to bridge the gaps between the chemical space required to identify and produce novel pharmacological interventions and the complex biological space whose functions must be quantified in order to predict and validate the benefits of those interventions for the desired indications (i.e., pain/inflammation and metabolic stress). The success of the Panacea program will represent a paradigm shift in the new drug discovery process and provide new technology that enables more rapid, safe and effective therapeutic drug development for our military and civilian health.

The Panacea program aims to shift the focus of drug discovery toward a physiology-centered paradigm, as opposed to the minimalist, genome-centric model currently employed. Drug target prediction from genomic data has not produced the anticipated improvements over traditional drug discovery methods. Part of this discrepancy between predictive value and actual progress is due to the lack of organism-level model systems that are representative of human physiology. Another reason lies in the degree of abstraction from genomic data to physiological condition. Multiple studies have indicated that physiological traits and disease states are the result of highly complex interactions between genes and other biological entities within a living system, and that the presentation of a given condition is multifaceted. Therefore, the Panacea program seeks to move from the “one gene-one disease-one drug” model, and capture more of the inherent physiological complexity for the discovery and deployment of drugs for a given indication. The theory underlying the development of polypharmacy centers on the understanding that complex physiological processes are capable of adaptation to repeated perturbation, and that signaling plasticity must be acknowledged in order to improve therapeutic efficacy. The approaches leveraged in the Panacea program will address the need to apply novel pharmacological tools that arise from, and work with physiological complexity, rather than in spite of it.

DARPA is soliciting innovative proposals that will pursue cornerstone technologies that mechanistically dissect complex physiological processes and use novel medicinal chemistries to engage diverse molecular targets from empirically determined functional proteomic networks. These new interventions must address two urgent DoD needs:

- 1) Novel treatments to combat acute pain and inflammation (e.g., associated with soft tissue injury) without central nervous system side effects (e.g., addiction/reward) or impairment of natural tissue regenerative processes.
- 2) New drugs to support and protect continued service member performance by mitigating effects of metabolic stress.

Ideally, the drug properties outperform any single agent therapeutic for a given indication and the discovery process can be tailored to address any physiological condition that is effectively modeled at the organism level. Proposers are free to select one indication or propose pathways to address both, provided that the model systems used are accepted and validated as pre-clinical models, and that unique experimental designs, datasets, and drug candidates are produced that are specific to each indication.

1.2. PROGRAM STRUCTURE AND TECHNICAL APPROACH

The Panacea research and development program is divided into three sequential Phases: Phase 1 (Base) – 24 months, Phase 2 (Option) – 24 months, and Phase 3 (Option) – 12 months. Proposers

must present a plan for no more than five years and a comprehensive approach to meeting all program milestones (see Table 1). Proposals utilizing multiple teams (from the same or different institutions) and/or developing multiple approaches to addressing the Task goals should be assembled as a single research entity, and report as such.

Proposals must address both of the following major tasks:

Task 1: Predict and evaluate drug targets and effects.

In Task 1, proposers will determine the druggable space of a complex physiological system(s) using high-content analytical techniques and computational approaches. This physiological system(s) must faithfully recapitulate the complexity of the indication (i.e., pain/inflammation, metabolic stress) of interest. The goals are to describe the physiological landscape of the indication, to predict the target space for intervention development, and to evaluate the effectiveness of the novel interventions developed. This task should be subdivided into the following:

- 1) Analytical – techniques that enable measurements of physiological components (deep biomolecular profiling, signal transduction, and phenotypic monitoring) necessary to build the Panacea capability.
- 2) Informatics Components – computational approaches to enable empirically guided network construction to identify and define actionable sets of protein targets.

The analytical efforts will use multi-omic techniques (i.e., mass spectrometry-based metabolomics and proteomics coupled with transcriptomics) as well as traditional bioassays (e.g., enzyme activity, histology, biometrics, etc.) to generate high-content molecular maps of the physiological condition as well as its response to perturbation by pharmacological agents, both known and novel. The informatics effort will develop and use computational tools to generate directed networks of physiological processes incorporating all molecular and phenotypic data. Model systems must represent organism-level complexity, present multiple levels of phenotypic severity, and be consistent with accepted preclinical test platforms. Proposers will use these models of complex physiological conditions with direct clinical relevance to build empirically-derived networks and establish the target space for novel drug design and evaluation. The predicted target space should be agnostic with respect to prior knowledge about specific protein functional annotations and should include proteins of no known function (where appropriate) as dictated by the network dynamics. These model systems should be used to interrogate the physiological processes (indication) for intervention design, as well as the effects of therapeutic perturbations with known and novel drugs. From these experiments, it should be possible to determine mechanisms of action.

All proposals should detail the history and validity of their model system(s) with respect to the known molecular and physiological aspects relevant to the indication. Additionally, proposals should describe the analytical methods, informatics approaches, and the phenotypic evaluations that will be used to build the empirical networks, predict the targets of highest impact, and explain the heuristics used to make those determinations (see Table 2 for specific metrics and milestones for each task). The bioassays used to evaluate the efficacy of the interventions

predicted should be well-detailed. Analytical methods and phenotypic bioassays used should address parameters such as:

- Abundance, posttranslational modification and subcellular distribution of proteins
- Dynamics of protein-protein interactions
- Distribution of phenotypic severity
- Onset of drug effect and duration
- Pharmacokinetics and Pharmacodynamics (safety and efficacy)

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

Proposals should develop a detailed work plan for Task 1. For example, during Phase 1, indication-specific physiological system(s) should be selected and justified, then descriptions should be included on how this system will be used to construct content-rich networks using quantitative multi-omic analyses of multiple cell and tissue types as well as subcellular compartments. These systems-level networks contain potentially druggable targets: some structurally and functionally known, others unknown; they may represent protein posttranslational modifications and/or the formation or disruption of a protein-protein interaction. Computational tools must be developed or employed to derive empirical causality and guide selection of a subset of actionable putative targets that will provide the templates for drug synthesis in Task 2. In Phase 2, proposers should describe methods to validate novel network components identified in Phase 1, as well as develop and validate multi-target pharmacological compounds exhibiting robust phenotypic effects. A mid-phase exam will require proposers to validate the utility of their network analysis by predicting and demonstrating phenotypic effects of novel combination therapies with existing drugs/tool compounds. Phase 3 will involve further development and validation of a multi-target compound(s) (to be synthesized in Task 2) that exceeds state-of-the-art effectiveness via mechanisms involving proteins of unknown function and meets requirements for the submission of an IND per metrics established by the FDA.

Task 2: Novel intervention design and synthesis.

The goal of Task 2 in the Panacea program is the capability to build and optimize the activity of novel chemical compounds that functionally target multiple cellular proteins. In order for a drug to have efficacy, it must exert a functionally relevant effect on a protein, proteins, or protein-protein interactions. Tools must be developed in the Panacea program that enable the engagement of any protein in the human proteome, regardless of its predicted shape and functional role(s) in a cellular process. In Task 1, proposers will define the drug targets for a given indication (metabolic stress, pain/inflammation, or both) and provide empirical rationale for target prioritization. In Task 2, proposers must develop new approaches to identify/produce chemical compounds that recognize and bind to protein targets within empirically-determined

physiological system(s) networks. The methods used to generate these compounds must be agnostic to any predetermined structure or functional process of the target. Potential approaches to addressing this need are (but not limited to): 1) Kinetic target-guided synthesis methods that use cellular targets as scaffolds for the generation of novel ligands from functionalized fragment libraries with bio-orthogonal ligation reactions; 2) Chemi-informatic approaches that use protein structural homology to predict binding site geometries and apply in silico docking screens to identify fragments for subsequent empirical elaboration; and/or 3) Automated high-throughput barcoded screening and computation-aided structure prediction. It is possible that elements of multiple medicinal chemistry approaches are pursued in parallel or with iteration between them within a single team, but a description of the pipeline must be presented along with how the task will integrate and iterate with Task 1 (empirical network analysis for a physiological indication). Proposers should describe quantitative metrics for recurrent performance evaluations (e.g., yield, purity, composition) and experimental synthesis methods to meet quality standards and production metrics. Proposers should have experience with the approaches they intend to apply, as well as the laboratory infrastructure required for its efficient execution.

Proposals should develop a detailed work plan for Task 2. In Phase 1, proposers should develop and integrate novel drug design and synthesis methods to generate interventions that expand the druggable space. By the end of this phase, proposers must build and/or access the required compound libraries, construct and validate the screening and synthesis pipeline, and demonstrate efficient design of promising interventions in the context of pain or metabolic stress. In Phase 2, proposers must describe approaches to develop tools to accelerate the pace of novel chemical design and optimize the drug synthesis pipeline from the first phase. In addition, proposers must include a plan to evaluate the platform's ability to generate diverse molecular structures in less than 30 days from presentation with predicted protein targets, regardless of 3D structural information. Proposers must describe how they will optimize production of lead compounds and determine parameters of the active pharmaceutical ingredient such as physicochemical properties (e.g., melting point, boiling point, etc.), and stability. Once lead compounds are established, in Phase 3, proposers must outline their methods to refine, optimize and improve the formulation of the intervention for use in a preclinical model as a route towards entry into FDA IND approval.

Proposals must present a detailed work plan for Task 2. Key deliverables in Phase 1 will be related to library size, throughput, computational framework for structural repository and interaction prediction modules. In Phase 2, emphasis will be placed on optimization of synthesis following hit identification and prediction of lead compound elaboration. In Phase 3, the goal will be to have multiple high-value lead compounds produced from predicted targets within 60 days of network validation in Task 1 (see Table 2 for specific metrics and milestones for each task). Proposers must also provide a plan to determine critical properties and basic interaction space for each lead compound produced, such as:

- Physicochemical properties/formulation optimization
- Proteome-wide interaction
- Acute cytotoxicity

Quantitative metrics and milestones for successful phase transitions are provided by DARPA (see Table 1), and proposers must describe in detail intermediate metrics, milestones, and

demonstrations of progress (see section 1.3). For Task 2, all compounds produced that are prioritized as drug leads must be evaluated for acute effects in simple biological systems to provide quantitative assessments of dose-limiting toxicities before being considered for evaluation in animal models.

Feasibility

Given the interdisciplinary nature of the program, proposals should describe both the technical precedent for their approaches as well as evidence for the successful integration of the multiple teams. Where appropriate, provide biographical information detailing productive professional relationships between investigators, and describe any preliminary data supporting the ability to execute the proposed methods and communicate results between efforts. Proposals should include the designation of a principle investigator for each task (in addition to the project principal investigator (PI)) as well as a dedicated project manager for the entirety of the effort. Numbers of dedicated personnel at all hierarchical levels of the effort should reflect the substantial scale anticipated to meet the critical program objectives and contain detailed information about specific expertise (pharmacologists; cell/molecular biologists; computational biologists; statisticians; chemists: analytical, medicinal, formulation, etc.); these specific expertise areas should include the appropriate levels of support staff (e.g., postdocs and technicians: instrumentation, animal care, sample preparation, etc.). Proposals should contain evidence that the empirically-driven trajectory of Network-Prediction-Intervention-Validation will be followed and can be reasonably expected to be completed on site by the proposers. Experimental designs and procedures must be described thoroughly; of critical importance are aspects specific to capital equipment (to-be-purchased or existing), approximate numbers of subjects, analysis plans, statistical reporting, anticipated throughput and sample numbers for quantitative –omics and any advanced computational infrastructure requirements. Figures and diagrams that help illustrate the experimental design may be included. Applications utilizing the following approaches or tools will be deemed non-responsive and may *not* be considered for review:

- Existing proprietary chemical compounds or capabilities
- Gene editing or intervention at the genetic level
- Model systems not explicitly designed or validated as organism-level preclinical models
- Drug repurposing efforts

A Gantt chart illustrating a high-level representation of the sequence timeline for experiments and capability tests leading up to the phase transition demonstration must be included in the proposal.

1.3. END OF PHASE DEMONSTRATIONS

Prior to the end of each phase, a demonstration of program progress is required. It is not required that proposers set aside a specific period of time for a demonstration, rather, the demonstration should be a test of the platform capability by the end of the phase. Ideally, this demonstration should be presented as a report and in-person demo that details the advances on each major Technical Task within the timeframes and according to the specific metrics detailed in Table 2.

At the end of the phase, the outcomes of the demonstration experiments should be presented to DARPA and invited representatives of other government agencies as a concise research study. Lab demonstrations of how the technology works, animal/human results/effects, and illustrations of system integration are all expected. 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.

1.4. PROGRAM METRICS

Proposals should follow the program metric structure below:

Phase 1 (Base): Proposers will establish infrastructure for medicinal chemistry discovery and computational pipelines. Progress will be judged based on the throughput of known and novel protein targets (with structures or homology models) and *in silico*-to-*in vitro* compound design and build intervals. Proposers will interrogate physiotypic model systems and identify molecular protein targets that are known and unknown. Task 1 analytical techniques should be able to quantify >10,000 proteins (current SoA in a cell line) within the known and dark proteome for more than two tissue types and profile >500 protein-protein interactions (current SoA organ level). Experiment designs should be pre-registered and are anticipated to provide sufficient statistical power to resolve log₂ fold changes on the order of 0.5-1. Network analysis of the proteins from the physiotypic model system(s) should reconstruct a topological representation of the complex physiological state with at least 80% coverage of the canonical pathways (by Month 12). These functional multi-omic networks will then be used as road maps to targets for small molecules synthesized using novel chemistry methodologies from Task 2. The novel medicinal chemistry approaches proposed in Task 2 should be able to generate ≥ 30 small molecule candidates for a given target space by the end of this Phase. The proposers should show during Phase 1 the ability to assemble the molecular network and identify the target space within 60 days of primary data collection.

Phase 2 (Option): Proposers will accelerate the chemical synthesis platform and will optimize novel interventions to demonstrate superior predictive performance of the informatics pipeline compared to known clinical interventions. A midterm exam in this phase will validate the utility of Task 1 to outperform traditional drug target discovery by predicting novel combination therapies of existing drugs based on their interactions within the empirical network space. During this phase, proposers will also need to demonstrate the ability to generate molecular networks and identify the target space within 30 days of primary data collection as well as show the steps taken to prioritize targets according to specific network parameters. Proposers should synthesize at least 30 novel compounds within 30 days after target space identification and identify leads according to *in vitro* functional parameters (i.e., acute cytotoxicity, proteome binding assessments, etc.).

Phase 3 (Option): Proposers will test the safety and efficacy of optimized multi-target compounds. Novel multi-target drugs should engage >2 proteins of previously unknown function with predicted roles in the indication(s) and will show a therapeutic index

(effective dose/lethal dose) greater than standard of care or existing tool compounds. Proposers will generate data towards the submission of an IND Application and will identify a transition strategy or corporate partner to aid in future clinical trials. Proposers will also have the opportunity to assess if novel interventions developed using their platform technologies can be used for compassionate use cases towards the treatment of a seriously ill patient using a new, unapproved drug when no other treatments are available.

Table 1: Program Schedule and Demonstrations

	Phase 1 (24 Mo)	Phase 2 (24 Mo)	Phase 3 (12 Mo)
Technical Task	Task 1: Predict and Evaluate		
	Task 2: Novel Intervention Design		
Demos			
End of Phase Final Exams	<p>End of Phase 60 Day Final Exam:</p> <p>60 days to network assembly and identification of targets</p> <p>Build drug design infrastructure</p>	<p>End of Phase 60 Day Final Exam:</p> <p>30 days to validate targets</p> <p>30 days to build and test new drug candidate</p>	<p>Demo Outperforming Standard Care <i>in vivo</i></p> <p>IND Submission</p> <p>Examine options for compassionate use</p>

Table 2. Program Milestones Metrics

<p>Phase 1: 24 Months</p>	<p>Milestone: Previously unknown drug targets for metabolic stress and/or pain/inflammation. Metrics:</p> <ul style="list-style-type: none"> • Step 1: Build a functional network of >10,000 proteins and >500 protein-protein interactions quantified for multiple cell types in >2 tissues specific to indication. • Step 2: Define drug targets from functional protein networks. • Mid-Phase Exam (month 12): Show 80% coverage of canonical network and additional target space. • Task 1 Demo (month 24): Drug target space for metabolic stress and/or pain/inflammation in <60 days. • Task 2 Demo (month 24): Generate ≥30 small molecule candidates targeting protein networks for metabolic stress and pain/inflammation.
<p>Phase 2: 24 Months</p>	<p>Milestone: Functioning pipeline with <i>in vivo</i> validation of novel drug mechanism. Metrics:</p> <ul style="list-style-type: none"> • Task 1 Mid-Phase Exam (month 36): Validation of novel network by predicting and testing new drug combinations: e.g. 1) Improved function and/or tolerance under metabolic stress; 2) Control pain/inflammation post-insult model better than single drug therapy • Task 2 Mid-Phase Exam (month 36): Demonstration of target engagement for novel multi-target drugs. • Task 1 Demo (month 48): 30 days to network assembly and intervention identification for known/unknown targets. • Task 2 Demo (month 48): Synthesis platform to build novel drugs <30 days after target space definition.
<p>Phase 3: 12 months</p>	<p>Milestone: Multi-target drug for metabolic stress and/or pain/inflammation with effectiveness exceeding state of the art. Metrics:</p> <ul style="list-style-type: none"> • End of Program Goal (month 60): Novel multi-target drug with therapeutic index (toxic dose/effective dose) 1.5-2x greater than standard of care. <ul style="list-style-type: none"> • Effect onset in 2-40 minutes, duration of 12-24 hours without repeat dosing. • Drug interacts with >2 protein of previously unknown function. • Preclinical data for Pharmacology and Toxicology for IND. • Transition strategy and/or corporate partner for entry into clinical trial.

Table 2 captures the critical performance metrics for each Task and Phase transition. Some absolute quantitative metrics will be specific to proposed approaches for discovery and synthesis. Therefore, this table is not exhaustive and proposers must present relevant intermediate milestones for each Task.

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 Panacea 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.
- **6-Week Progress Reports:** Every 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 PI) 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 Panacea program.
- Any additional deliverables requested by the executive agent for this program (DARPA Contracts Management Office).

Transition

The technologies developed in Panacea will develop therapeutics towards complex physiological conditions that are better than standard of care. Since the methods, technologies, and products developed represent a potentially lucrative commercial commodity, the performers will need to describe the plans and capability to accomplish technology transition and commercialization. Proposers will provide a transition plan that outlines a path towards the submission of an IND to the FDA. Performers will be encouraged to engage with representatives from the FDA early on, especially if any interventions developed show potential as therapeutics which could be

considered for compassionate use. Performers are required to identify transition partners or a commercial strategy (e.g., startup company) for human clinical trials with a drug or drugs meeting FDA requirements for an IND. Updated transition plans will be required by the end of Phase 2.

Proposers are expected to manage intellectual property (IP) rights so as to facilitate transition of the tools and methods developed under this program. Additional information regarding intellectual property can be found in Section 4.2.3.

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 <http://www.darpa.mil/work-with-us/contract-management#OtherTransactions>.

In accordance with 10 U.S.C. § 2371b(f), the Government may award a follow-on production contract or Other Transaction (OT) for any OT awarded under this BAA 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 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.

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. CONTACT AND FORM OF APPLICATION SUBMISSION

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

4.2.1. Proposal Abstract Format

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

Abstracts must include the following components:

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

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

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

4.2.2. Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal**. All submissions must be written in English with type no smaller than 12-point font. A smaller font may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1- inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. **The maximum page count for Volume I is 35 pages.** The submission letter is not included in the page count. Volume I should include the following components:

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

a. Volume I, Technical and Management Proposal

Section I. Administrative

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

1. BAA number (HR001119S0010);
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-fee (CPFF), cost-award—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 -15 pages): Provide a detailed scientific rationale and description of the planned approach and execution plan. The technical plan should demonstrate a deep understanding of the scientific challenges and present a credible (even if risky) plan to achieve the program goals. The technical approach should address all applicable proposal content instructions in Sections 1.1 – 1.4.

- a. Approach:** Describe the scientific and technical approach. Hypotheses should be articulated clearly and include a rigorous test plan with quantitative metrics to yield unambiguous results. Experimental designs and procedures must be described thoroughly, including aspects such as equipment, behavioral paradigms, animal models, approximate numbers of subjects, software, analysis plan, statistical reporting etc. Figures and diagrams that help illustrate the experimental design may be included.
- b. Rationale:** Provide a clear rationale for the approach, including a justification for the feasibility of the proposed task. Proposers are highly encouraged to include supporting data when available, even if preliminary. Figures included within the proposal should be accompanied by a brief description of how data was collected, what analysis was performed, what the results mean, and why the result supports the feasibility of the proposed task.
- c. Schedule:** Include a narrative overview of the timeline of the task/objective. Intermediate milestones and final completion criteria should be identified along with the quantitative metrics that will be used to evaluate progress. Include a

one-page high-level graphical (Gantt or flow chart style) timeline of the outlined tasks/objectives described in the Scientific Approach and Plan.

- d. **Challenges and Risks:** Articulate the scientific and technical challenges and risks facing this effort. Include a risk mitigation plan including possible solutions for overcoming potential hurdles or alternative approaches.
 - e. **Personnel:** Identify the personnel responsible for each major task (e.g. “led by Jane Smith with support from one graduate student at 50% effort”).
- D. Management Plan (2-3 pages):** Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. Include an organization chart for the entire team which includes, as applicable: (1) the programmatic relationship of team member; (2) the unique capabilities of team members; (3) the task responsibilities of team members; (4) the teaming strategy among the team members; and (5) the key personnel along with the amount of effort to be expended by each person during each year. Resumes do not count against the proposal page count. Identify a principal investigator for the project. 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 should be defined separately: Phase 1 (Base); Phase 2 (Option); and Phase 3 (Option). Dependencies between tasks and/or subtasks should be identified clearly. The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. The SOW must not include proprietary information.

For each task/subtask, provide:

- A detailed description of the approach to be taken to accomplish each defined task/subtask.
- Identification of the primary organization responsible for task execution (prime contractor, subcontractor(s), consultant(s), by name).
- A measurable milestone, i.e., a deliverable, demonstration, or other event/activity that marks task completion. Include completion dates for all milestones. Include quantitative metrics.

- A definition of all deliverables (e.g., data, reports, software) to be provided to the Government in support of the proposed tasks/subtasks.

G. Schedule and Milestones (1-3 pages): Provide a detailed schedule showing tasks (task name, duration, work breakdown structure element as applicable, performing organization), milestones, and the interrelationships among tasks. The task structure must be consistent with that in the SOW. Measurable milestones should be clearly articulated and defined in time relative to the start of the project.

H. Transition Plan (0.5-1 pages): Proposals are encouraged to outline a plan for potential clinical translation of the products that are developed in Panacea. While Panacea is a fundamental research program, it is anticipated that the capabilities, knowledge, and products developed by the end of the program will be suitable for advanced development for medical use and for National Security purposes. It is DARPA's vision that by the end of the program, performers should have identified partners for transition into the clinic. Additionally, transition elements should include aspects of commercial ventures, licensing agreements, or other pathways from basic research into health and medical applications.

I. Summary Slides (Does not count towards page limit; two (2) slides maximum): PowerPoint slide(s) summarizing the proposed effort's vision, goals, impact, scientific/technical approach, and milestone schedule. Download and use the template provided in **Attachment 1** posted with the subject BAA. Submit the PowerPoint file in addition to Volume I and II of your proposal.

a. Volume II, Cost Management Proposal

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

1. BAA Number (HR001119S0010);
2. Technical area;
3. Lead Organization Submitting proposal;
4. Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
5. Proposer's reference number (if any);
6. Other team members (if applicable) and type of business for each;
7. Proposal title;
8. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);

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

Note that nonconforming proposals may be rejected without review.

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 2** to this BAA. If proposers choose to use **Attachment 2**, submit the MS Excel template in addition to Volume I and II of their proposal. The template is not a Volume II alternative. 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) Please submit any breakdown of expenses in an editable, MS EXCEL cost file.
- (2) Total program, per phase (Phase 1 (Base); Phase 2 (Option); and Phase 3 (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 DHHS or ONR negotiated rate package; if calculated by other than a rate, provide University documentation identifying fringe costs by position or HR documentation if unique to each person); (2) **F&A Indirect Overhead Rate** (provide current DHHS or ONR negotiated rate package); (3) **Tuition Remission** (provide current University documentation justifying per student amount); and (4) **Health Insurance/Fee** (provide current University documentation justifying per student amount, if priced separately from fringe benefits with calculations included in the EXCEL cost file).
 - x. **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).
- (3) A summary of total program costs by phase and task.
- (4) 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.

- (5) 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.
- (6) A summary of projected funding requirements by month for all phases of the project.
- (7) A summary of tasks that have animal or human use funding.
- (8) 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.
- (9) 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.).
- (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).
- (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.

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

Subawardee Proposals

The awardee is responsible for compiling and providing all subawardee proposals for the Procuring Contracting Officer (PCO)/Grants Officer (GO)/Agreements Officer (AO), as applicable. Subawardee proposals should include Interdivisional Work Transfer Agreements (ITWA) or similar arrangements. Where the effort consists of multiple portions which could reasonable be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.

All proprietary subawardee proposal documentation, prepared at the same level of detail as that required of the awardee’s proposal and which cannot be uploaded with the proposed awardee’s proposal, shall be provided to the Government either by the awardee or by the subawardee organization when the proposal is submitted. Subawardee proposals submitted to the

Government by the proposed subawardee should be submitted via e-mail to the address in Section I.

Other Transaction Requests

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

- milestone description,
- completion criteria,
- due date, and
- payment/funding schedule (to include, if cost share is proposed, awardee and Government share amounts).

It is noted that, at a minimum, milestones should relate directly to accomplishment of program technical metrics as defined in the BAA and/or the proposer's proposal. Agreement type, expenditure or fixed-price based, will be subject to negotiation by the Agreements Officer. Do not include proprietary data.

4.2.3. Additional Proposal Information

Proprietary Markings

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

Unclassified Submissions

DARPA anticipates that submissions received under this BAA will be unclassified. However, should a proposer wish to submit classified information, an *unclassified* email must be sent to the BAA mailbox requesting submission instructions from the Technical Office 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.

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.

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) 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.

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, Technology Investment Agreement, or Other Transaction for Prototypes shall follow the applicable rules and regulations governing these various award instruments, but, in all cases, should appropriately identify any potential restrictions on the Government’s use of any Intellectual Property contemplated under the award instrument in question. This includes both Noncommercial Items and Commercial Items. Proposers are encouraged to use a format similar to that described in the section above. If no restrictions are intended, then the proposer should state “NONE.”

System for Award Management (SAM) and Universal Identifier Requirements

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

International entities can register in SAM by following the instructions in this link: https://www.fsd.gov/bsd-gov/answer.do?syparm_kbid=dbf8053adb119344d71272131f961946&syparm_search=KB0013221.

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 HR001119S0010. 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 HR001119S0010 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 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 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 is started as early as possible.

For Cooperative Agreements only:

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

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

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

4.3. FUNDING RESTRICTIONS

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

4.4. OTHER SUBMISSION INFORMATION

DARPA will post a consolidated Frequently Asked Questions (FAQ) document. To access the posting go to: <http://www.darpa.mil/work-with-us/opportunities>. A link to the FAQ will appear under the HR001119S0010 summary. Submit your question(s) via e-mail to Panacea@darpa.mil.

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

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 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 to the mailbox listed below.

Points of Contact

The BAA Coordinator for this effort may be reached at:

Panacea@darpa.mil

DARPA/BTO

ATTN: HR001119S0010

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 in support of the Panacea program on December 14, 2018 at the Executive Conference Center (ECC; 4075 Wilson Blvd., Suite 300, Arlington, VA 22203). The purpose is to provide potential proposers with information on the Panacea program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and to encourage team formation.

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

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

To encourage team formation, interested proposers are encouraged to submit information to be shared with all potential proposers through the Proposers Day website and the DARPA

Opportunities Page. This information may include contact information, relevant publications, and a slide or poster to summarize the proposer's interests.

Participants are required to register no later than **December 7, 2018, 12:00 PM ET**. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; there will be no onsite registration.

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

Proposers Day Point of Contact:

DARPA-SN-19-12@darpa.mil

ATTN: DARPA-SN-19-12

675 North Randolph Street

Arlington, VA 22203-2114

9. APPENDIX 1 – Volume II checklist

Volume II, Cost Proposal Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 beginning on Page 22 of HR001119S0010. 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 **HR001119S0010** 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: