

Broad Agency Announcement ReVector BIOLOGICAL TECHNOLOGIES OFFICE HR001119S0056 May 14, 2019

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PART I: OVERVIEW INFORMATION

- Federal Agency Name Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- Funding Opportunity Title ReVector
- Announcement Type Initial Announcement
- Funding Opportunity Number HR001119S0056
- North American Industry Classification System (NAICS) 541714
- Catalog of Federal Domestic Assistance Numbers (CFDA) 12.910 Research and Technology Development
- Dates
 - o Posting Date: May 14, 2019
 - o Proposal Abstract Due Date and Time: June 4, 2019, 4:00 PM ET
 - o Full Proposal Due Date and Time: July 11, 2019, 4:00 PM ET
 - o BAA Closing Date: July 11, 2019
 - o Proposers' Day: May 17, 2019

https://fbo.gov/spg/ODA/DARPA/CMO/DARPA-SN-19-48/listing.html

- Concise description of the funding opportunity The ReVector program aims to develop methods to use human skin microbiomes to modulate chemical production in order to avoid mosquito attraction and feeding and reduce the threat of mosquito-borne disease to Warfighters. Human skin associated microbes interact with metabolites from the body and influence the volatile molecules of each individual, making some individuals more attractive to mosquitoes. This program seeks to develop advanced data analytics and microbiome modulation tools for engineering skin microbiomes and provide new options for the readiness and resiliency of military personnel.
- **Anticipated individual awards** Multiple awards are anticipated.
- Types of instruments that may be awarded Procurement contract, cooperative agreement, or other transaction.
- Agency contact

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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 to develop the ability to use human skin microbiomes to reduce attraction and feeding by mosquitoes or other disease vectors. Proposed research should investigate disruptive approaches to identify microbiome-based metabolites used by mosquitoes to locate humans; design targeted intervention plans to reduce attraction and/or feeding; and develop reliable and safe methods of manipulating the human skin microbiome to achieve desired metabolite production. The integration of these approaches to produce novel microbiome interventions should enable precise, safe and transient products that prevent or significantly reduce incidence of mosquito attraction and feeding to human skin.

1.1. PROGRAM OVERVIEW

Mosquitoes act as a vector for diseases like dengue and malaria that represent a significant danger to the readiness and resiliency of military personnel and more broadly public health. While multiple approaches to avoiding vector-borne disease exist (e.g., bed nets, repellants or anti-malarial therapeutics), they each have logistical burdens or side effects that make them impractical for use. In addition, these methods of avoiding disease vectors are not feasible during deployment or require frequent reapplication or dosing that can result in inconsistent protection. Methods of protecting against vector-borne disease that require minimal maintenance, equipment or training and lack deleterious side effects such as odor are required.

Volatiles emitted in human breath attract mosquitoes to the general area of the human. However, it is the heat and volatiles from the skin that direct mosquitoes to the sites on the skin where they feed, ultimately acting as a vector for agents of disease like bacteria, parasites, and viruses. Many volatiles that attract mosquitoes to the skin are produced by the metabolism of organisms in the human skin microbiome. The ReVector program will develop precise, safe, and efficacious technologies to modulate the profile of skin-volatiles by changing the organisms and/or metabolic processes that are present in the skin microbiome in order to reduce attraction and feeding by mosquitoes. It is the proposing team's responsibility to obtain all necessary federal, state, and local government permits and approvals, and abide by all applicable domestic and international regulations for the proposed work to be conducted. See section 1.4 for additional permitting and compliance requirements.

1.2. TECHNICAL APPROACH AND STRUCTURE

Performers under the ReVector program will develop deployable technologies that use the microbiome to reduce attraction and feeding by at least three genera (i.e., *Aedes*, *Anopheles*, and *Culex*) of disease vectors. For maximum impact, these technologies must be versatile enough to function on multiple representative and distinct microbiomes, to accommodate natural variability

over time and within a population. Development will require detailed characterization of the human volatilome (the combined volatile molecules given off by the skin) and microbiome to identify the common subset of metabolites, microbes, and pathways that attract mosquitoes searching for a potential blood meal to a human. Teams will need to model and implement safe, effective changes to the microbiome to reduce vector attraction and design interventions to carry out this transformation. This intervention model will need to be resilient and account for varying microbiome and volatile molecule profiles between individual humans.

Modulation of volatile profiles may be designed to actively repel mosquitoes or remove/repress volatiles used by mosquitoes to identify human targets. Mechanisms of engineering the microbiome to conform to a desired volatile profile could include probiotics (addition of beneficial microbes, natural or engineered); prebiotics (changing physiological factors that regulate the composition of the microbiome); precisely targeted antimicrobials to remove microbes; or synthetic biology techniques that change genes/pathways/gene expression of endogenous members of a microbiome. Any proposed mechanism for modifying the skin microbiome should be coupled to safety mechanisms to ensure maximum control and safety. For example, use of antimicrobials should minimize or remove chances of developing antimicrobial resistance, and steps to ensure that engineering endogenous members of the microbiome will also incorporate mechanisms for ensuring that engineered microbes are either transient or mechanisms are in place to remove them. Finally, a means of enabling the transition from the starting microbiome to the desired microbiome will need to be developed and validated. In order to advance the engineering of a human skin microbiome from early proof of concept to clinical translation, development of ReVector technologies will require innovation in several key areas. New predictive analysis and modeling algorithms will be needed to design microbiome modifications that will perform reliably across scales from metabolite to complex microbial community. Iterative discovery and testing will be required to determine efficacious microbial and metabolic targets and adapt to the dynamic nature of microbial community interactions and test the tools required for modifying the microbiome, and finally, developing or leveraging a system for deploying the modified microbiome onto a human. Performers may initially demonstrate their technologies on in vitro model microbiomes, but in vivo and/or human studies will be required by the completion of the program. Demonstrations of efficacy and safety will facilitate either human or non-human primate trials depending on Food and Drug Administration (FDA)/regulatory requirements by the end of the program.

The intervention and delivery strategy, once applied, should function without requiring additional application for at least two weeks. While the treatment is foreseen to be transient, it should be expected to persist under common hygiene practices (e.g., showering).

1.2.1. Program Structure

ReVector is structured into a four (4) year effort consisting of three (3) phases with Phase I (Base effort) lasting 18 months, Phase II (Option) lasting 18 months, and Phase III (Option) lasting twelve (12) months and two Technical Areas: Technical Area 1 (TA1) – Metabolite Identification and Design; Technical Area 2 (TA2) – Modulate and Deploy. <u>Interdisciplinary</u> teams must address both TAs in parallel to develop a platform technology capable of identifying

microbiome leverage points and engineering microbiomes capable of producing a microbiome that reduces attraction and feeding by disease causing vectors.

In Phase I, microbial or metabolic targets must be identified that produce molecules relevant to mosquito attraction and feeding and microbiome alterations will be designed that utilize these leverage points to produce the desired molecules in simplified in vitro communities (18 months). In Phase II, teams must integrate the tools developed in Phase I to move to animal models and more complex microbiome communities (18 months). Finally, in Phase III teams must perform final demonstrations in human or non-human primate (NHP) studies (12 months). In the case of NHP studies, performers must structure their research plan such that, if successful, they will have sufficiently robust data to justify advancement to human clinical trials by the end of the program. Total program duration is four (4) years.

TA1: Metabolite Identification and Design

TA1 is focused on developing platform technologies for identification of focused leverage points that influence mosquito attraction, specifically defining key metabolic components contributing to a common set of molecules for vector attractant or repellant. Secondly, performers will need to use TA1 technologies to develop a strategy that will use these leverage points for transforming the skin microbiome to reduce mosquito attraction and feeding. The complexity and diversity of the underlying systems creates challenges on several fronts including, but not limited to, olfactory systems of insect vectors, microbial diversity on and between individuals, and complexity of community interactions with respect to metabolism and overall community structure. Teams should generate systematic methods for overcoming these and other challenges to create an enabling technology for designing functional changes to complex microbiomes.

Mosquitoes and other insect vectors have sophisticated olfactory systems composed of hundreds of receptors, presenting a challenge to the identification of biologically active volatiles. Proposals should define high-throughput methods for determining the volatile compounds that mosquitoes use to identify human targets, and the microbes responsible for producing those compounds. The target space should take human and microbiome metabolism into account, and a set of target volatile compounds and corresponding molecular pathways and/or specific microbes must be identified. Proposals should account for the natural variability in skin microbiome and physiology within populations and over time. If a proposed method focuses on rendering a specific skin microbiome or volatilome unattractive to mosquitos, the proposal must also articulate how the insights from that test case will be generalized, rapidly and practically, to make the intervention transferable to a broader range of use cases. Additionally, if efforts to actively repel mosquitoes will be undertaken, suitable high-throughput methods to identify relevant genes/pathways/molecular products must be clearly articulated.

In parallel with target volatile molecule identification, performers must also develop models to help design effective strategies for microbiome manipulation that account for the complexity of the skin microbiome with regard to community composition, structure, and function. Proposers must develop a predictive modeling platform to design robust interventions for implementation and testing in TA2. Proposals must describe strategies for identifying key leverage points as well as techniques for minimizing the modifications and interventions required to produce a robust solution.

The diversity of individual host metabolism and secretions, as well as diversity of microbiomes on and between individuals, will complicate the design of a "universal" solution. Models must take natural human variability into account and design either a single overall intervention that works on all human skin microbiomes, or if a single intervention is not possible based on human variability, the smallest optimal number of interventions. Proposed technologies should be able to address complex variation including defining skin microbiome types that share molecular properties and corresponding intervention strategies.

Safety is of paramount importance, and models of the impact of the intervention on the microbiome's function should ensure that the modified microbiome achieves the desired molecular profile and has no negative consequences for the Warfighter (e.g., odor, irritation, infection).

The minimum performer objectives for TA1 are as follows:

- Deliver a clearly articulated plan for acquiring, processing, and storing data drawn from the research effort, as well as any relevant data from scientific literature.
- Deliver models and supporting data that must describe minimal interventions required to
 modify a microbiome to avoid mosquito attraction and feeding. The model should
 account for interactions between the host and microbiome, as well as those of individual
 microbes responsible for phenotypes of interest. The model should detail both the health
 and safety implications for the individual, as well as the consequences for the metabolite
 production.

Proposals must outline how the models and supporting data adequately capture natural variability within human metabolism and microbiomes.

TA2: Modulate and Deploy

TA2 will focus on development of techniques for precise and safe modification of the skin microbiome based on the TA1 design. When a successful intervention has been validated, the performer must then develop a deployment strategy that can be easily applied by the Warfighter while maintaining function for at least two weeks.

The proposal should describe computational and molecular technology required to facilitate microbiome modification. Methods of modification can incorporate (but are not limited to):

- Addition of microbes that possess a preferred phenotype such as probiotics.
- Removal of microbes through targeted means such as phages, antibiotics, CRISPR Cas9 etc.
- Prebiotics could be used to control conditions and select for desirable organisms/metabolic pathways or select against undesirable organisms/metabolic pathways.

• Synthetic biology could be used to modify genes or pathways in endogenous or engineered microbes. In this case, appropriate safety mechanisms for controlling transience or removal of the engineered organism should be addressed.

Many endogenous members of the human skin microbiome perform beneficial/commensal activities and proposals should articulate methods ensuring beneficial phenotypes will not be lost during microbiome modification. In addition, immunology studies of the proposed treatment's effects should be detailed to ensure that treatment does not result in a deleterious immune response.

Deployment of the final microbiome strategy onto the skin will be the final component of the ReVector platform. The following objectives must be addressed:

- Treatment should be technically simple to apply, without significant burden on the Warfighter—oral or manual delivery of interventions, for example, will be significantly preferred over delivery via intravenous injection or full-body-immersion.
- The treatment should be stable within 48 hours and persistent for at least 2 weeks given reasonable hygiene practices (e.g., showering and washing with non-antibiotic soap).
- FDA-approved as safe or ready for investigational new drug application (IND) and human clinical trials by the end of the program. All formulations (including those that qualify as Generally Recognized As Safe) will be required to work with the FDA to ensure both safety and efficacy are demonstrated to facilitate human trials. Proposed biotherapeutics that do not meet FDA requirements for human use will be considered unresponsive. Additional information about the FDA approval process for biotherapeutics can be found at: https://www.fda.gov/downloads/Biologi%E2%80%A6/UCM292704.pdf

Integration

TA1 and TA2 described above must be integrated into a single system capable of modifying a human's microbiome metabolite production. All proposing teams must address both TAs to ensure a complete, integrated system by the end of the program. Initial integration of the design and modifications required should be complete by the end of Phase I, while deployment strategy will be required for completion of Phase II. Each of the TAs will remain active for all three phases as it is anticipated that iterative improvement and optimization will be required throughout the project.

Independent Validation and Verification

Engineered microbiomes will be tested by third parties at the end of each phase to validate performance and accelerate the development and approval process. Independent labs from Department of Defense (DoD) or U.S. Government agencies will validate the ability of the engineered communities to successfully evade mosquitoes at the end of each Phase. If a microbiome expert is required to maintain the samples being tested by the independent verification and validation (IV&V) team, the proposers should account for tasks and costs associated with sending a team member to participate in IV&V activities in both the Statement of Work (SOW) and budget.

1.3. PROGRAM METRICS

In order for the Government to evaluate the effectiveness of a proposed solution in achieving the stated program objectives, proposers should note that the Government hereby promulgates the following program metrics that may serve as the basis for determining whether satisfactory progress is being made to warrant continued funding of the program. Although the following program metrics are specified, proposers should note that the Government has identified these goals with the intention of bounding the scope of effort, while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problem. Proposers are expected to define additional quantitative and qualitative success criteria as needed. Proposers must clearly and uniquely itemize tasks needed to accomplish planned milestones and deliverables.

Proposals should cite the quantitative and qualitative success criteria that the proposed effort will achieve by the time of each phase's program metric measurement.

Proposals must be written to address milestones in both TAs: Identify and Design (TA1) and Modulate and Deploy (TA2). Proposals that do not address both technical areas will be considered non-conforming and rejected without review. The milestones and metrics for each technical area and phase are outlined below. Proposers must explain quantitative success criteria for each milestone, and information on how it will be achieved, in their SOW.

Phase I (Base) (months 1 through 18): In vitro experiments using model systems

Technical Area 1: Identify and Design

Goal: Identify microbiome constituents and cognate metabolites which contribute to production of volatiles that are detectable by mosquitoes, or design a method for microbial production of a molecule or molecules capable of repelling disease vectors. Once specific targets are identified, performers will design an intervention that targets the most influential leverage points with the modifications needed to reproduce a microbiome that will reduce mosquito attraction to an in vitro model microbial community. The predicted interventions designed in this TA will be evaluated in TA2.

Milestones:

- (i) Identify key microbiome elements responsible for mosquito attraction or genes/pathways capable of repelling mosquitoes (6 months).
- (ii) Develop multiple in vitro model microbiomes for evaluation of interventions. (12 months)
- (iii) Generate a blueprint of modifications that would disrupt mosquito-attraction by removing/reducing metabolite and/or volatile production or generating a means of actively repelling mosquitoes (12 months).

Note: Final Phase I demonstration is associated with TA2 (18 months).

Metrics:

- (i) Identify ≥ 5 molecules associated with mosquito attraction and feeding, and associate them with their microbiome sources; alternatively, identify viable pathways for production of ≥ 5 candidate molecules that actively repel mosquitoes (6 months).
- (ii) Establish ≥ 5 distinct in vitro model microbial communities, based on human microbiomes that reflect natural variability within a population or over time, that either produce volatiles associated with mosquito attraction and feeding or produce molecules that repel mosquitoes (9 months).

Technical Area 2: Modulate and Deploy

Goal: In Phase I, the TA2 objective is to enable the modification of in vitro microbiomes to demonstrate the feasibility of controlling their volatile outputs or producing a repellant.

The reconfiguration of microbial communities can be mediated through a combination of biological, environmental, and genetic perturbations. The initial integration of the design and the modifications required should be complete by the end of Phase I. This integration will lead to insight into appropriate microbiome compositions that have the potential to reduce mosquito attraction and feeding.

Milestones:

- (i) Develop tools to modify in vitro model microbiome function and/or composition to either reduce production of volatiles that attract mosquitoes or repel mosquitoes in one in vitro model microbiome (12 months).
- (ii) Extend demonstration of these tools to at least five model microbiomes (18 months).

Metrics:

- (i) Achieve \geq 5-fold reduction of molecules associated with mosquito attraction, and/or achieve \geq 5-fold increase in repellant molecules; interventions should be demonstrated on a single in vitro microbiome (12 months).
- (ii) Achieve a \geq 5-fold modification of attractant/repellant volatiles from \geq 5 in vitro microbiomes (18 months). Successful demonstration of this modification and confirmation via IV&V is necessary for advancement to Phase II.

IV&V:

At month 18, performers must demonstrate an intervention that leads to \geq 5-fold reduction in mosquito attraction and feeding for in vitro model communities that the performers will provide to the IV&V team.

<u>Phase II (Option) (months 18 through 36):</u> Pre-clinical animal studies validating safety and efficacy.

Technical Area 1: Identify and Design

Goal: Establish and characterize modified animal model microbiomes, and continue the design-build-test cycle with TA2 as successive microbiome changes are made. Proposers must provide detailed justifications for the animal models that will be used. Once initial microbiome modifications have been tested in Phase I, performers will design improved interventions that incorporate this understanding of the most influential leverage points in order to further improve the efficacy of the modified microbiome.

Milestones:

Establish representative human microbiomes on relevant animal models and confirm the efficacy of mosquito attractant or repellant compounds depending on the approach taken (24 months).

Metrics:

- (i) Demonstrate relevant data (genome sequencing or otherwise) confirming establishment of ≥ 5 distinct model human microbiomes on relevant animal models (24 months).
- (ii) Demonstrate volatilome or empirical mosquito attraction data confirming that applied microbiomes reduce the quantity of volatile compounds associated with mosquito attraction produced by the skin microbiome of animal models. Alternatively, demonstrate that pathways for production of mosquito repelling molecules have been added to the skin microbiomes of the animal models (24 months).

Note: Final Phase II demonstration is associated with TA2 (36 months).

Technical Area 2: Modulate and Deploy

Goal: Develop multiple unique human microbiome models on animals and demonstrate a safe and efficacious intervention that is capable of reducing mosquito attraction and feeding. When a successful intervention has been validated, the performer will then develop a deployment strategy that has a low logistical burden on the Warfighter. Both the deployment strategy and the intervention will require validation as safe per FDA standards. The modifications should be stable within two (2) days and persist for at least two (2) weeks. In order to continue towards development for human use in Phase III, initial filings to approve human studies must be submitted by the end of Phase II.

Milestones:

- (i) Modify the skin microbiome of a single animal model hosting a human microbiome, to reduce mosquito attraction and feeding (30 months).
- (ii) Modify microbiome in animal models hosting 10 distinct human microbiomes to reduce mosquito attraction and feeding (36 months).
- (iii) Validate that the microbiome-altering intervention and molecular alterations are safe according to FDA standards in the appropriate animal model for pre-clinical testing; initial filings for human studies must be submitted to continue to Phase III (36 months).

Metrics:

- (i) Achieve \geq 10-fold reduction of molecules associated with mosquito attraction, and/or achieve \geq 10-fold increase in repellant molecules (30 months).
- (ii) Achieve a \geq 10-fold modification of relevant attractant/repellant compounds associated with mosquito attraction in 10 distinct human microbial communities hosted on animal models (36 months).

IV&V:

At month 36, performers must demonstrate an intervention that leads to \geq 10-fold reduction in mosquito attraction and feeding for \geq 10 distinct model communities provided to the IV&V team, on relevant animal models.

Phase III (Option) (months 36 through 48): Human or non-human primate trials and IV&V

Goal: Using an intervention based on the work in Phases 1 and 2, modify the innate human or non-human primate microbiome and demonstrate successful reduction of subjects to attraction and feeding by mosquitoes. In the instance of non-human primate studies, the final goal will be to have achieved optimal intervention performance and gained approval to progress to human clinical trials by the end of the program.

Milestones:

Demonstrate efficacy of a system for reducing mosquito attraction and feeding in humans or non-human primate model (48 months).

Metrics:

Upon treatment with microbiome intervention achieve a 100-fold reduction in mosquito attraction and feeding in 10 distinct human or non-human primates (48 months).

IV&V:

At month 48, the IV&V team will use the intervention developed by performer teams and demonstrate that it leads to \geq 100-fold reduction in mosquito attraction and feeding for 10 distinct human or non-human primate subjects.

1.4. PERMITS AND COMPLIANCE

It is the proposing team's responsibility to obtain all necessary federal, state, and local government permits and approvals and abide by all applicable laws where necessary for the proposed work to be conducted. All international laws must also be followed.

Proposing teams must design proposals so that they minimize any adverse effects on humans. Proposals must include sufficient documentation to demonstrate that all federal laws and regulations including FDA requirements for human clinical trials will be followed. If the proposal will use Generally Recognized as Safe (GRAS) organisms that do not require FDA approval, sufficient documentation of the GRAS status of the organisms proposed must be included. Please reference FDA 80 FR 17050, "Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information" for further guidance on the FDA regulatory process for live biotherapeutics:

https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM292704.pdf.

Failure to apply for and/or obtain federal, state and local permits, approvals, letters of agreement or failure to provide a path towards regulatory approval where necessary will delay award of funds if a project is selected for funding.

Proposing teams must design proposals so that they minimize any adverse effects on the environment. Proposals must have sufficient documentation to show the proposal is categorically excluded from further National Environmental Policy Act (NEPA) analysis or whether an Environmental Assessment or Environmental Impact Statement (EIS) will be necessary for the proposed work. Failure to apply for and/or obtain federal, state, and local permits, approvals, letters of agreement or failure to provide environmental analysis where necessary (e.g., NEPA, EIS) will delay award of funds if a project is selected for funding. See Sections 4.2.1(D)(11) and 4.2.2(a)-Section IIB for additional detail on required documentations.

DARPA does not consider the use of biological agents to be in the scope of this BAA, and all proposals shall discuss how the proposed technical approach is not a contravention of the Biological Weapons Convention. See https://www.state.gov/t/isn/bw/c48738.htm.

1.5. GENERAL REQUIREMENTS

In addition to the requirements above, proposers to the ReVector program must address each of the following:

1.5.1. Teaming

Proposers are responsible for assembling a complete team that has technical expertise, capabilities, and facilities to address all requirements of the program. Proposers must address both technical areas, which should run in parallel. A complete proposer team should therefore not only have the ability to meet the technical challenges of each TA and create an integrated platform for modeling and engineering human skin microbiome but also perform relevant experiments with animal models at appropriate biosafety level (BSL)/containment levels. It is also essential that proposer teams include members that have industrial and commercial experience to aid in focusing technology research and development strategy for eventual clinical translation. This could include, for example, expertise in medical product development or microbiome intervention (e.g., probiotics) for use in preclinical and clinical settings to effectively navigate the preparatory process for IND/Emergency Use Authorization (EUA), or equivalent, submission during the program effort. Proposers must describe any formal teaming agreements that are required to execute this program. All teams are encouraged to identify a Project Manager to serve as the primary point of contact to communicate with the DARPA Program Manager and Contracting Officer Representative, coordinate effort across performer teams, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables. For teams that are not physically co-located, proposers must articulate how logistical challenges will be overcome to ensure smooth collaboration and an integrated work product.

1.5.2. Controlled Unclassified Information (CUI)

To prevent the release of sensitive technical information, certain aspects of the proposed research may be considered CUI if they reveal host susceptibilities to threats or other vulnerabilities, and may require safeguarding or dissemination controls, pursuant to and consistent with applicable law, regulations, and government-wide policies. Proposals that anticipate the production of any such information must deliver a detailed risk mitigation plan to DARPA (see Section 4.2.2. Proposal Format Section II: I). Performers must partition potentially sensitive tasks from non-sensitive research efforts. All performers (prime contractor and subcontractor) desiring public release of project information that may contain CUI as defined above must submit a request for public release from DARPA/PRC in accordance with their contractual requirements.

1.5.3. Ethical, Legal, and Societal Implications (ELSI)

DARPA maintains its commitment to ensuring that efforts funded under this BAA adhere to ethical and legal regulations currently in place for Federal and DoD-funded research. Program developments will be discussed with a panel of expert external advisors with expertise in bioethical issues that may emerge as a consequence of advances in biomedical science and technology, including human microbiome engineering. Proposers to this BAA should address potential ethical, legal, and societal implications of the proposed technology, with a special emphasis on strategies to enable safe, transient, non-permanent human skin microbiome engineering.

1.5.4. Regulatory Strategy

Proposers must present a detailed plan for early and continued engagement with regulators (e.g., FDA, Environmental Protection Agency) throughout the program to discuss developing technologies and challenges in order to inform and improve the design of microbiome intervention strategies during the program, and to facilitate the eventual translation of the technology to field deployment. Ideally, proposers will identify the applicant for the Live Biotherapeutic IND submission at the time of proposal submission.

1.5.5. Transition Strategy

Proposers must present a detailed plan for transition of the technologies developed under the program for human testing and product formulation. It is anticipated that the ReVector microbiome engineering platform will be suitable for advanced development and licensing for many high impact applications in global health and pharmaceutical development. It is critical that ReVector platform technologies be developed in a manner that positions them for further development and deployment by the end of the program.

1.5.6. 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 Phase 1 and Phase II, prior to the initiation of the 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 as can be reasonably conveyed.

- Predictive analysis and modeling algorithms
- Monthly financial reports: Performers are required to provide financial status updates. These reports should be in the form of an editable MS Excel file, and should provide financial data including, but not limited to, the following: program spend plan by phase and task, incurred program expenditures to date by phase and task, and invoiced program expenditures to date by phase and task. The prime Performer is to include information for itself and all subawardees/subcontractors.
- Monthly technical progress reports: Each month (or as close to as scheduling permits),
 performers are required to provide research updates. These reports should be in the form
 of a standardized slide presentation given to DARPA and discussed with the program
 management team via teleconference. Length and detail level should be at the discretion
 of the Program Manager.
- Quarterly technical reports: The reports shall be prepared and submitted in accordance with the procedures contained in the award document.
- Semi-Annual Reviews: Leadership from each performer team (with additional key personnel at the discretion of the Principal Investigator (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 to discuss details that might otherwise fall outside the scope of a routine technical brief, and provide opportunities to discuss progress towards milestones and scientific goals, any ongoing technical or programmatic challenges that must be overcome to achieve the overarching goals of the program.
- Final Program Report: When the final funding phase closes out, performer teams will 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 ReVector program.
- Any additional deliverables requested by the Contracting agent for this program.

2. Award Information

2.1. GENERAL AWARD INFORMATION

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

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this solicitation and to make awards without discussions with proposers. The Government also reserves the right to conduct discussions if it is later determined to be necessary. If warranted, portions of resulting awards may be segregated into pre-priced options. Additionally, DARPA reserves the right to accept proposals in their entirety or to select

only portions of proposals for award. In the event that DARPA desires to award only portions of a proposal, negotiations may be opened with that proposer. The Government reserves the right to fund proposals in phases with options for continued work, as applicable.

The Government reserves the right to request any additional, necessary documentation once it makes the award instrument determination. Such additional information may include but is not limited to Representations and Certifications (see Section VI.B.2., "Representations and Certifications"). The Government reserves the right to remove proposers from award consideration should the parties fail to reach agreement on award terms, conditions, and/or cost/price within a reasonable time, and the proposer fails to timely provide requested additional information. Proposals identified for negotiation may result in a procurement contract, cooperative agreement, or other transaction, depending upon the nature of the work proposed, the required degree of interaction between parties, whether or not the research is classified as Fundamental Research, and other factors.

Proposers looking for innovative, commercial-like contractual arrangements are encouraged to consider requesting Other Transactions. To understand the flexibility and options associated with Other Transactions, consult 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 either cannot be met by proposers intending to perform fundamental research or the proposed research is anticipated to present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Therefore, the Government anticipates restrictions on the resultant research that will require the awardee to seek DARPA permission before publishing any information or results relative to the program.

Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to determine whether the proposed research shall be considered fundamental and to select the award instrument type. Appropriate language will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate. This language can be found at http://www.darpa.mil/work-with-us/additional-baa.

For certain research projects, it may be possible that although the research to be performed by a potential awardee is non-fundamental research, its proposed subawardee's effort may be fundamental research. It is also possible that the research performed by a potential awardee is fundamental research while its proposed subawardee's effort may be non-fundamental research. In all cases, it is the potential awardee's responsibility to explain in its proposal which proposed efforts are fundamental research and why the proposed efforts should be considered fundamental research.

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

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

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

FFRDCs

FFRDCs are subject to applicable direct competition limitations and cannot propose to this 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. This information is required for Government Entities proposing to be awardees or subawardees.

Authority and Eligibility

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

3.1.2. Non-U.S. Organizations

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

3.2. ORGANIZATIONAL CONFLICTS OF INTEREST

FAR 9.5 Requirements

In accordance with FAR 9.5, proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and *any* proposed team member (subawardee, consultant). Under this Section, the proposer is responsible for providing this disclosure with each proposal submitted to the 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 six (6) pages including all figures,

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

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?
- **C. Technical Plan:** Outline and address all technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide a plan for accomplishment of the milestones presented in Section 1.3.
- **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 or reports.
- **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 1 is 30 pages. The official transmittal letter is not included in the page count. Volume I should include the following components:

NOTE: Non-conforming submissions that do not address both Technical Areas and/or 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 (HR001119S0056);
- 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, email;
- 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, email;
- 9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, firm-fixed-price, cooperative agreement, other transaction, or other type (specify);
- 10. Place(s) of performance, including all subcontractors and consultants;
- 11. Period of performance;

- 12. Total funds requested from DARPA, total funds requested per phase 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.

C. Executive Summary Slide: Provide a one-slide summary in PowerPoint that effectively and succinctly conveys the main objective, key innovations, expected impact, and other unique aspects of the proposed project. The slide template is provided as Attachment 1 to the BAA posted at http://www.fbo.gov. Use of this template is required.

Section II. Detailed Proposal Information

- **A.** Executive Summary: Provide a synopsis of the proposed project, including answers to the following questions:
 - What is the proposed work attempting to accomplish or do?
 - How is it done today, and what are the limitations?
 - What is innovative in your approach?
 - What are the key technical challenges in your approach and how do you plan to overcome these?
 - Who or what will be affected and what will be the impact if the work is successful?
 - How much will it cost, and how long will it take?
- **B.** Goals and Impact: Clearly describe what the team is trying to achieve and the difference it will make (qualitatively and quantitatively) if successful. Describe the innovative aspects of the project in the context of existing capabilities and approaches, clearly delineating the uniqueness and benefits of this project in the context of the state of the art, alternative approaches, and other projects from the past and present. Describe how the proposed project is revolutionary and how it significantly rises above the current state-of-the-art. Describe the deliverables associated with the proposed project and any plans to commercialize the technology, transition it to a customer, or further the work.
- **C. Technical Plan:** Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) at intermediate stages of

the program to demonstrate progress, and a plan for achieving the milestones (see Part II, paragraph 1.3 of this BAA). The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal. Discuss mitigation of technical risk.

- **D. Management Plan:** Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. Resumes count against the proposal page count. Identify a principal investigator for the project. Provide a clear description of the team's organization including an organization chart that includes, as applicable: the programmatic relationship of team members; the unique capabilities of team members; the task responsibilities of team members, the teaming strategy among the team members; and key personnel with the amount of effort to be expended by each person during each year. Provide a detailed plan for coordination including explicit guidelines for interaction among collaborators/subcontractors of the proposed effort. Include risk management approaches. Describe any formal teaming agreements that are required to execute this program.
- **E. Capabilities:** Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Discuss any work in closely related research areas and previous accomplishments.
- **F. Statement of Work (SOW):** The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. Each phase (Phase I (Base), Phase II (Option), and Phase III (Option)) of the program should be separately defined, and all tasks/subtasks should be identified as TA1 or TA2. The SOW must not include proprietary information. It is strongly encouraged, though not required, to use the SOW template provided as **Attachment 2**. The SOW is not included in the Volume 1 page count.

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:** 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. Regulatory Plan:** Provide a detailed plan for early and continued engagement with regulators (e.g., FDA, EPA) throughout the program to discuss developing technologies and challenges in order to inform and improve the design of microbiome intervention strategies during the program, and to facilitate the eventual translation of the technology to field deployment. Ideally, proposers will identify the applicant for the Live Biotherapeutic IND submission at the time of proposal submission.
- **I. Technology Transfer Plan:** Proposers should provide a detailed plan, with milestones, showing how regulatory, safety, and transition aspects of the technology will be addressed. The plan should include descriptions of how potential DoD users will be engaged as well as paths for commercialization of the technology.

a. Volume II, Cost Management Proposal

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

- 1. BAA Number (HR001119S0056);
- 2. Lead Organization Submitting proposal;
- 3. Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
- 4. Proposer's reference number (if any);
- 5. Other team members (if applicable) and type of business for each;
- 6. Proposal title;
- 7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
- 8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
- 9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;
- 10. Place(s) of performance, including all subcontractors and consultants;
- 11. Period of performance;

- 12. Total funds requested from DARPA, total funds requested per phase (as defined in Table 1), and the amount of any cost share (if any);
- 13. Name, address, and telephone number of the proposer's cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
- 14. Name, address, and telephone number of the proposer's cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
- 15. Date proposal was prepared;
- 16. Data Universal Numbering System (DUNS) number (http://www.dnb.com/get-a-duns-number.html);
- 17. Taxpayer ID number (https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN);
- 18. Commercial and Government Entity (CAGE) code (https://cage.dla.mil/Home/UsageAgree);
- 19. Proposal validity period

NOTE: Non-conforming submissions that do not address both Technical Areas and/or follow the instructions herein may be rejected without further 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 3** to this BAA. If proposers choose to use **Attachment 3**, submit the MS Excel template in addition to Volume I and II of their proposal. The template is not a Volume II alternative. <u>Volume II must include all other items discussed below that are not covered by the editable MS excel budget template.</u> 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 I (Base); Phase II (Option); and Phase III (Option)), and per task cost broken down by major cost items to include:
 - i. **Direct labor** provide an itemized breakout of all personnel, listed by name or TBD, with labor rate (or salary), labor hours (or percent effort), and labor category. All senior personnel must be identified by name.
 - ii. **Materials and Supplies** itemized list which includes description of material, quantity, unit price, and total price. If a material factor is used based on historical purchases, provide data to justify the rate.
 - iii. **Equipment** itemized list which includes description of equipment, unit price, quantity, and total price. Any equipment item with a unit price over \$5,000 must include a vendor quote.
 - iv. **Animal Use Costs** itemized list of all materials, animal purchases, and per diem costs, associated with proposed animal use; include documentation supporting daily rates.
 - v. Travel provide an itemized list of travel costs to include purpose of trips, departure and arrival destinations, projected airfare, rental car and per GSA approved diem, number of travelers, number of days); provide screenshots from travel website for proposed airfare and rental car, as

- applicable; provide screenshot or web link for conference registration fee and note if the fee includes hotel cost. Conference attendance must be justified, explain how it is in the best interest of the project. **Plan for two** (2) **DARPA program review meetings per year.**
- vi. Other Direct Costs (e.g., computer support, clean room fees) Should be itemized with costs or estimated costs. Backup documentation and/or a supporting cost breakdown is required to support proposed costs with a unit price over \$5,000. An explanation of any estimating factors, including their derivation and application, must be provided. Please include a brief description of the proposers' procurement method to be used.
- vii. **Other Direct Costs** Consultants: provide executed Consultant Agreement that describes work scope, rate and hours.
- viii. **Indirect costs** including, as applicable, fringe benefits, overhead, General and Administrative (G&A) expense, and cost of money (see university vs. company specific requirements below).
- ix. Indirect costs specific to a University performer: (1) Fringe Benefit Rate (provide current Department of Health and Human Services (DHHS) or Office of Naval Research (ONR) negotiated rate package; if calculated by other than a rate, provide University documentation identifying fringe costs by position or HR documentation if unique to each person); (2) F&A Indirect Overhead Rate (provide current DHHS or ONR negotiated rate package); (3) Tuition Remission (provide current University documentation justifying per student amount); and (4) Health Insurance/Fee (provide current University documentation justifying per student amount, if priced separately from fringe benefits with calculations included in the EXCEL cost file).
- 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 I, II, and III 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 that 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 that 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 for each phase of the program (I, II, and III). Each milestone must include the following:

• milestone description,

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

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

4.2.3. Additional Proposal Information

Proprietary Markings

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

Unclassified Submissions

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

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 Subjects Research (HSR)/Animal Use

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

Approved Cost Accounting System Documentation

Proposers that do not have a Cost Accounting Standards (CAS) complaint accounting system considered adequate for determining accurate costs that are negotiating a cost-type procurement contract must complete an SF 1408. For more information on CAS compliance, see http://www.dcaa.mil/cas.html. To facilitate this process, proposers should complete the SF 1408 found at http://www.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	Summary of	Basis for	Asserted Rights	Name of Person
Computer	Intended Use in	Assertion	Category	Asserting
Software To be	the Conduct of			Restrictions
	the Research			

Furnished With				
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/fsd-gov/answer.do?sysparm_kbid=dbf8053adb119344d71272131f961946&sysparm_search=KB001 3221.

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 HR001119S0056. <u>Submissions may not be sent by fax or e-mail</u>; 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 HR001119S0056 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 <u>BAAT_Support@darpa.mil</u>, and is typically available during regular business hours, (9:00 AM- 5:00 PM EST Monday – Friday).

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

For Cooperative Agreements only:

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

<u>SF 424 Research and Related (R&R) Application for Federal Assistance</u>, 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 Personal Data 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.

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

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

<u>Hard-copy Submissions</u>: Proposers electing to submit cooperative agreement proposals as hard copies must complete the SF 424 R&R form (Application for Federal Assistance,) available on the Grants.gov website (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 HR001119S0056 summary. Submit your question(s) via e-mail to ReVector@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

6.1.2. Full Proposals

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

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

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

6.2.1. 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

In accordance with FAR 4.1102 and 4.1201, proposers requesting a procurement contract must complete electronic annual representations and certifications at https://www.sam.gov/. In addition, resultant procurement contracts will require supplementary DARPA-specific representations and certifications. See https://www.darpa.mil/work-with-us/additional-baa for further information.

6.2.4. Terms and Conditions

For terms and conditions specific to grants and/or cooperative agreements, see the DoD General Research Terms and Conditions (latest version) at http://www.onr.navy.mil/Contracts-Grants/submit-proposal/grants-proposal/grants-terms-conditions and the supplemental DARPA-specific terms and conditions 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:
ReVector@darpa.mil
DARPA/BTO
ATTN: HR001119S0056
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 ReVector program on May 17, 2019, at the Executive Conference Center (4075 Wilson Boulevard, Suite 300, Arlington, VA 22203). The purpose is to provide potential proposers with information on the ReVector program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and encourage team formation.

Interested proposers are not required to attend to respond to the ReVector 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/ReVectorProposersDay.

Participants are required to register no later than May 10, 2019, 12:00 PM ET. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; there will be no onsite registration.

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

Proposers Day Point of Contact: <u>DARPA-SN-19-48@darpa.mil</u>

ATTN: DARPA-SN-19-48

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 24 of HR001119S0056. This worksheet must be included with the coversheet of the Cost Proposal.

	coversneet of the Co	st Proposai.		
1.	Are all items from Sect Cost Proposal cover she • YES If reply is "No", ple	eet?	ne II, Cost Proposal) of HR001119S0056 included on your Appears on Page(s) [Type text]	
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?			
	o YES	○ NO	Appears on Page(s) [Type text]	
	If reply is "No", ple	ease explain:		
3.	Does your cost proposal (detailed cost buildup #3 above in item 2) show a breakdown of the major cost items listed below: Direct Labor (Labor Categories, Hours, Rates) fo YES NO Appears on Page(s) [Type text]			
	IO IES	0110	Appears on Page(s) [Type text]	
	Indirect Cost	s/Rates (i.e., ov	erhead charges, fringe benefits, G&A)	
	o YES	∘ NO	Appears on Page(s) [Type text]	
	Materials and	l/or Equipment		
	o YES	∘ NO	Appears on Page(s) [Type text]	
	Subcontracts	Consultants		
	∘ YES	∘ NO	Appears on Page(s) [Type text]	
	Other Direct	Costs		
	o YES	∘ NO	Appears on Page(s) [Type text]	
	Travel			
	\circ YES	\circ NO	Appears on Page(s) [Type text]	

If reply is "No", please explain:

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

	If reply is "No", p	lease explain:	
5.	Does your cost propos purchased (a priced bi • YES		olete itemized list of <u>all</u> material and equipment items to be OM))? Appears on Page(s) [Type text]
	If reply is "No", p	lease explain:	
6.			quotes or written engineering estimates (basis of estimate) for rice exceeding \$5000? Appears on Page(s) [Type text]
	If reply is "No", p	lease explain:	
7.			justification for the cost of labor (written labor basis-of- the labor categories and hours proposed for each task? Appears on Page(s) [Type text]
	If reply is "No", p	lease explain:	
8.	Do you have subcontro YES	ractors/consultants ○ NO	? If YES, continue to question 9. If NO, skip to question 13. Appears on Page(s) [Type text]
9.	Does your cost propos of Work) and cost pro		of all subcontractor/consultant technical (to include Statement
	• YES	o NO	Appears on Page(s) [Type text]
	If reply is "No",]	please explain:	
10			the required summary buildup, detailed cost buildup, and of-Materials, Basis-of-Estimate, Vendor Quotes, etc.)? Appears on Page(s) [Type text]
	If reply is "No",	please explain:	
11	Does your cost pr	oposal include cop	pies of consultant agreements, if available? Appears on Page(s) [Type text]
	If reply is "No",	please explain:	
12	2. If requesting a FA proposed subcontractor	·	does your cost proposal include a tech/cost analysis for all
	• YES	∘ NO	Appears on Page(s) [Type text]
	If reply is "No",	please explain:	

Appears on Page(s) [Type text]

o YES

 \circ NO

is sp ge	not otherwise available onsoring organization	le from the prival citing the speci s and compete w	DC), included documentation that clearly demonstrates work ate sector AND provided a letter on letterhead from the fic authority establishing their eligibility to propose to with industry, and compliance with the associated FFRDC tions.
•	o YES	o NO	Appears on Page(s) [Type text]
	If reply is "No", ple	ease explain:	
14.	Does your proposal o YES	include a responsible on NO	nse regarding Organizational Conflicts of Interest? Appears on Page(s) [Type text]
	If reply is "No", ple	ase explain:	
15.	Does your proposal o YES	include a compl	leted Data Rights Assertions table/certification? Appears on Page(s) [Type text]
	If reply is "No", ple	ase explain:	

Have all team members (prime and subcontractors) who are considered a Federally Funded

13.