



Broad Agency Announcement
Biological Control
BIOLOGICAL TECHNOLOGIES OFFICE
DARPA-BAA-16-17
February 18, 2016

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PART I: OVERVIEW INFORMATION

- **Federal Agency Name:** Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title:** Biological Control
- **Announcement Type:** Initial Announcement
- **Funding Opportunity Number:** DARPA-BAA-16-17
- **Catalog of Federal Domestic Assistance Numbers (CFDA):** 12.910 Research and Technology Development
- **Dates** (All times listed herein are Eastern Time.)
 - Posting Date: February 18, 2016
 - Proposal Abstract Due Date: Friday, March 18, 2016, 4:00 PM
 - Proposal Due Date: Friday, April 29, 2016, 4:00 PM
 - BAA Closing Date: Friday, April 29, 2016, 4:00 PM
 - Proposers' Day: February 22, 2016
- **Anticipated individual awards:** Multiple awards are anticipated.
- **Types of instruments that may be awarded:** Procurement contracts, cooperative agreements, or Other Transactions.
- **Agency contact**
 - Technical POC: Elizabeth Strychalski, Program Manager, DARPA/BTO
 - BAA Coordinator: DARPA-BAA-16-17@darpa.mil
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Arlington, VA 22203-2114
- **Teaming information:** See Section 3.3 and Section 8.2 for further information.

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. This BAA is being issued, and any resultant selection will be made, using procedures under Federal Acquisition Regulation (FAR) 35.016 and the Department of Defense Grant and Agreement Regulatory System (DoDGARS) Part 22 for Grants and Cooperative Agreements. Any negotiations and/or awards will use procedures under FAR 15.4, Contract Pricing, as specified in the BAA (including DoDGARS Part 22 for Grants and Cooperative Agreements). Proposals received as a result of this BAA shall be evaluated in accordance with evaluation criteria specified herein through a scientific review process.

DARPA BAAs are posted on the Federal Business Opportunities (FedBizOpps) website, <https://www.fbo.gov/>, and, as applicable, the Grants.gov website at <http://www.grants.gov/>. The following information is for those wishing to respond to this BAA.

DARPA is soliciting innovative research proposals in the area of control of biological systems. Proposed research should investigate innovative approaches that enable revolutionary advances. Specifically excluded is research that results primarily in incremental or evolutionary improvements to the existing state of practice.

1.1. PROGRAM OVERVIEW

The objective of the DARPA Biological Control program is to build new capabilities for the control of biological systems across scales—from nanometers to centimeters, seconds to weeks, and biomolecules to populations of organisms—using embedded controllers made of biological parts to program system-level behavior. This program will apply and advance existing control theory to design and implement generalizable biological control strategies analogous to conventional control engineering, for example, for mechanical and electrical systems. The resulting advances in fundamental understanding and capabilities will create new opportunities for engineering biology.

Specifically, the Biological Control program will demonstrate tools to rationally design and implement multiscale, closed-loop control of biological systems, through the development of biological controllers, testbeds to evaluate control of system-level behavior, and theory and models to predict and design effective control strategies. The resulting capabilities will be inherently generalizable to a variety of biological systems. Successful teams will integrate and apply these capabilities to demonstrate a practical proof-of-principle biological solution to a proposer-defined application relevant to the U.S. Department of Defense (DoD).

1.2. PROGRAM INTRODUCTION AND SCOPE

Control is essential to engineer a system of interacting components for a desired behavior. However, the tools and techniques needed to successfully design and build control into biological systems are prohibitively lacking, when compared with the variety and sophistication of those available for nonbiological systems. The innate control exhibited by biological systems, despite their inherent complexity, indicates that closing this gap is possible. While control of

biological systems has been a theme in research, most recently in the field of synthetic biology, major technical challenges remain. Efforts to design and implement effective control of biological systems have been hampered by difficulties in applying and adapting established theory from conventional control engineering, as well as a lack of adequate experimental tools to assemble biological parts into controllers with measurable, predictable performance, across the spatial, temporal, and organizational scales relevant to biological systems.

Today, biological control strategies are typically open-loop, use controllers assembled from a limited number of biological parts, and target behavior with minimal or uncharacterized effects across scales. For example, genetic circuits often control the production of small molecules or fluorescent proteins. Although these outputs may result in a system-level behavior—for example, the fluorescence of a cell or cell population—these typically serve as sensors only. To operate as controllers for this program, the resulting optical properties should directly enable the biological system to perform programmable work in a closed-loop manner at system-level spatial, temporal, and organizational scales relevant to meet a practical need. Furthermore, biological controllers today often require considerable *ad hoc*, empirical optimization, due to an overall lack of generalizability and adequate predictive capabilities for implementation in complex and/or undercharacterized biological systems. This program will leverage empirical measurements into predictive capabilities to inform the design and implementation of broadly-applicable approaches for biological control. Several studies¹⁻⁵ are representative of promising initial progress.

To advance capabilities beyond the state of the art, the Biological Control program will lay a theoretical and technological foundation for control of biological systems. Looking to control engineering for nonbiological systems, this program will apply and advance existing capabilities for implementation in biological systems. Realizing this vision will require experimentally-validated theories and models to aid the rational design of control strategies and controllers that operate across scales—from nanometers to centimeters, seconds to weeks, and biomolecules to populations of organisms—to target system-level behaviors relevant to practical applications. Rigorous characterization of the operation and performance of the controllers will further require testbeds consisting of a naturally simple or synthetically simplified biological system, as well as hardware for quantitative measurements and dynamic environmental control. The resulting measurements will enable empirical and unambiguous connection of input stimuli to output effects, to inform the prediction of system-level behavior. The program will leverage innate mechanisms for biological control and ensure reliable, generalizable, closed-loop control of system-level behavior compatible with the distinctive properties of biological systems, such as stochasticity, emergence, and complexity.

Biological systems have considerable economic and strategic impact for national security, and control of those systems has broad practical and intellectual implications, for example, to

¹ Ang, J., Bagh, S., Ingalls, B. P. & McMillen, D. R. Considerations for using integral feedback control to construct a perfectly adapting synthetic gene network. *J Theor Biol* **266**, 723–738 (2010).

² Mishra, D., Rivera, P. M., Lin, A., Del Vecchio, D. & Weiss, R. A load driver device for engineering modularity in biological networks. *Nat Biotechnol* **32**, 1268–1275 (2014).

³ Chandra, F. A., Buzi, G. & Doyle, J. C. Glycolytic oscillations and limits on robust efficiency. *Science* **333**, 187–192 (2011).

⁴ Harris, A. W. K., Dolan, J. A., Kelly, C. L., Anderson, J. & Papachristodoulou, A. Designing Genetic Feedback Controllers. *IEEE Trans Biomed Circuits Syst* (2015). doi:10.1109/TBCAS.2015.2458435.

⁵ Hsiao, V., de los Santos, E. L. C., Whitaker, W. R., Dueber, J. E. & Murray, R. M. Design and implementation of a biomolecular concentration tracker. *ACS Synth. Biol.* **4**, 150–161 (2015).

advance biotic-abiotic interfaces, control complex systems, develop active materials with life-like properties, understand complexity and life, and harness the tremendous promise of engineered biological systems for human use. Such capabilities and understanding will find initial practical application at the conclusion of this program, in a proof-of-principle demonstration of a biological solution to a proposer-defined application relevant to DoD, such as marine biofouling and biocorrosion on naval vessels or other problems of equivalent biological complexity and significant consequence to national security. To ensure the safe development of capabilities for control of biological systems, work performed in this program will proceed in laboratory settings only.

1.3. PROGRAM STRUCTURE

The Biological Control program is divided into three Phases to deliver increasingly sophisticated, broad, and practical capabilities for control of biological systems, culminating in a demonstration of a proposer-defined, proof-of-concept biological solution to an application of relevance to DoD. During Phase 1 (18 months), teams will develop an initial biological controller, testbed, and predictive models for the controller and its effects on the initial target system-level behavior. During Phase 2 (18 months), teams will develop additional controllers with more stringent performance criteria, target additional system-level behaviors, and demonstrate multiple controllers simultaneously. During Phase 3 (12 months), teams will build a proof-of-concept biological solution to a proposer-defined application of relevance to DoD, such as combating biofouling and/or biocorrosion, fighting antibiotic resistance, improving biomanufacturing platforms, or enabling environmental bioremediation. Phase 3 will emphasize translating capabilities built in Phase 1 and Phase 2 to demonstrate the application of biological control strategies and rational design of biological controllers for a specific practical application. The ability to predict system-level behavior from high-quality measurements and theoretical models is critical to the success of the Biological Control program and should be emphasized, along with a control theoretic perspective, in the proposed approach.

To accomplish the objectives of each Phase, three Technical Areas (TAs) will be addressed concurrently within each Phase: (TA1) biological controllers; (TA2) testbeds to evaluate controller performance; and, (TA3) theory and models to support the prediction of system-level behavior and design of biological control strategies. TA1 should consist primarily of wet laboratory research. TA2 should consist of both wet laboratory research and hardware development for measurement and environmental control. TA3 should consist primarily of theory, modeling, and computer simulation, emphasizing control theory, to develop predictive models and design control strategies for biological systems.

Each team must fully address all Phases and TAs. Successful teams will engage both theorists and experimentalists in active collaboration across TAs to meet the goals of the program, with approximately equal emphasis in the proposed approach on theoretical and experimental components. Proposals that address only a subset of Phases or TAs or that do not involve teams with deep expertise across the relevant theoretical and experimental fields of science and technology will be considered non-conforming.

DARPA expects that the proposer-defined, proof-of-concept demonstration in Phase 3 will be based on the capabilities developed in Phase 1 and expanded in Phase 2. For this reason, proposers should focus the technical discussion of their proposals primarily on the concepts and approaches for Phase 1 and Phase 2, while still outlining a clear and credible technical plan for

Phase 3. Experimentally, DARPA anticipates that the biological system comprising the testbed in Phase 1 and Phase 2 should be suited to developing understanding and capabilities for control of biological systems generally and may not be the same as the demonstration system in Phase 3, which should be suited to a specific proof-of-concept application relevant to DoD. However, DARPA expects that the capabilities from Phase 1 and Phase 2 will generalize and transfer readily, with minimal modifications, to the demonstration system in Phase 3. Therefore, strategies for integrating, expanding, and generalizing capabilities for control of biological systems, as well as fully leveraging experimental results and tools against predictive theory and models—and *vice versa*—should be elaborated throughout. Proposals should also discuss mitigation of technical challenges that may arise within each Phase and TA.

Throughout the program, teams will interact with an independent verification and validation (IV&V) team to test and validate progress. The IV&V team will consist of subject matter experts from Government, Federally Funded Research and Development Centers (FFRDCs), and/or academia and domain experts. This independent team will experimentally test the reproducibility and performance of capabilities for the control of biological systems developed in Phase 1 and Phase 2 for TA1 and TA2 of the Biological Control program. As teams will be expected to collaborate closely with the IV&V team, proposals must budget and include plans for delivering to the IV&V team all materials, protocols, and domain knowledge necessary to experimentally reproduce demonstrated capabilities for control in Phase 1 and Phase 2. Should duplication of the testbed and/or associated specialized equipment present an unreasonable cost, teams should outline a secondary plan to allow the IV&V team access to the team's laboratory, as necessary, to test and validate progress. IV&V team members will be required to complete appropriate nondisclosure agreements, to protect intellectual property. To avoid potential conflicts of interest, performers for DARPA-BAA-16-17 will not be allowed to compete for the IV&V contract. DARPA-BAA-16-17 is not soliciting proposals for IV&V.

To ensure the safe development of capabilities for control of biological systems, work performed in this program will proceed in laboratory settings only. Efforts to manipulate or study organisms in any context not completely insulated from the natural environment will be deemed non-conforming to this solicitation. Proposers must ensure and demonstrate throughout the program that all methods and demonstrations of capabilities comply with national guidance for manipulation of genes and organisms and follow all guidance for biological safety and biosecurity. Proposals should address any potential safety and security issues that the development of the proposed capabilities might pose and include a discussion of approaches and strategies to monitor, mitigate, and manage these risks during technology development. In addition, all proposed efforts must meet any applicable regulations designed to protect human health and the environment promulgated by the Environmental Protection Agency, the Food and Drug Administration, the Department of Agriculture, the Department of Health and Human Services, and any other cognizant agencies within the Government. Proposers must also comply with any applicable state or municipal regulations or ordinances governing biotechnology practices.

1.4. PROGRAM OBJECTIVES

DARPA anticipates that the Biological Control program will provide predictive, closed-loop, generalizable means for controlling various biological systems and programming diverse system-level behaviors across multiple scales. Examples of potential system-level behaviors to be

controlled include, but are not limited to, behaviors that may be decomposed, individually and/or in combination, into growth and reproduction, adaptation and evolution, sensing and responding, and metabolism. Control of these behaviors may be combined to achieve a desired overall system-level behavior for a target practical application. Approaches that emphasize generalizability of control strategies are strongly encouraged; capabilities for control of biological systems should find potential applicability beyond the specific biological system and demonstration application proposed. Regardless of the specific approach, proposed approaches to the Biological Control program must include the following features, with additional details provided in Section 1.5:

- **Biological Controller(s):** Control of system-level functions must be implemented using biological controller(s) comprised of biological parts and embedded in a biological system.
 - Must be constructed using natural and/or synthetic biological parts only, to the exclusion of nonbiological technologies, such as nanoparticles and NEMS/MEMS devices.
 - Must be consistent with closed-loop control, by providing measurements of the state of the biological system, comparing with and driving to the desired state, and maintaining that desired state within programmed limits. This control loop may not use nonbiological technologies.
 - Must effect output(s) that result ultimately in controlled system-level behaviors, regardless of the scales of the biological controller(s) and their components.
 - Must be sufficiently modular to allow simultaneous use of multiple controllers without significant loss of predictability or performance.
 - Should be generalizable and transferable to other biological systems with minimal modifications.
 - Should, to the extent possible, follow a rational design process based on theory and/or models; therefore, capabilities for control of biological systems developed primarily through screening or similar methods, with no basis in predictive theory and/or models, are inconsistent with the program goals.
- **Testbed:** The performance of the biological controller(s) must be measured and evaluated through the use of a testbed consisting of a biological system and hardware for quantitative measurements and dynamic environmental control.
 - Must include a biological system that is sufficiently simple so that predictable connections between input stimuli and output effects may be established with confidence from measurements and models.
 - Example biological systems include, but are not limited to, life-like systems (*e.g.*, cell-free systems, protocells, and genetically minimized cells), characterized microbes (*e.g.*, *E. coli* and *S. cerevisiae*), or multicellular systems (*e.g.*, roundworms and hydra).

- Must allow for reproducible, quantitative measurements of a variety of system parameters related to the controller inputs and outputs, system state, and target system-level behaviors to be controlled, sufficient to enable predictability across spatial, temporal, and organizational scales relevant to control.
- Must allow time-course measurements of dynamic behavior, in addition to end-point measurements.
- Must include environmental control sufficient to evaluate controller performance reproducibly and for a range of static and dynamic environmental conditions.
- Must be appropriate to study a variety of controllable system-level behaviors, consistent with the innate behaviors of the biological system.
- Must be chosen such that results for control are reasonably generalizable between different biological systems, beyond the specific biological system used for the testbed.
- **Theory and Models:** The rational design of biological controllers and associated control strategies must be grounded in theory and predictive mathematical models.
 - Must provide prediction to inform the design and implementation of biological controllers and control strategies, as opposed to merely describing experimental results.
 - Must model biological controllers that implement various control strategies that are grounded in and/or advance existing control theory.
 - Must provide testable quantitative predictions for testbed behavior and controller performance.
 - Should be readily adaptable and generalizable for modeling control for biological systems beyond that chosen for the testbed, including, but not limited to, the proposer-defined application of relevance to DoD.
 - Must identify methods of tuning controller output(s), as appropriate to the system-level behaviors targeted for control.
 - Should be implemented in computational tools to aid design and implementation of control strategies and biological controllers.
 - Should include the development of new control theory and modeling approaches, as appropriate.
- **Demonstration:** The program will culminate with a practical demonstration of biological control addressing a proposer-defined application relevant to DoD.
 - Should constitute a proof-of-concept demonstration at the laboratory scale.
 - Must proceed in closed laboratory environment only, without release of any kind into the environment.

- **IV&V:** The biological controllers and testbed must be made available for independent verification and validation (IV&V) to assess reproducibility and capabilities for control with respect to the program metrics and milestones.

1.5. PROGRAM METRICS AND MILESTONES

For DARPA to evaluate the effectiveness of a proposed approach to the stated program objectives, DARPA 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 DARPA 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.

Performer progress will be assessed against the milestones and metrics defined below, as well as end-of-period and intermediate milestones defined by the proposer. Certain specific metrics must be set by the proposers in their proposals (*e.g.*, percent error tolerance on steady-state measurement), based on what is believed to be attainable. Where such ‘proposer-defined metrics’ are expected is made explicit in the metrics and milestones defined below. Proposers are encouraged to provide additional qualitative and quantitative proposer-defined metrics, as appropriate, beyond those requested explicitly below, with a strong preference for quantitative metrics. Proposers should provide a technical and programmatic strategy that conforms to the Biological Control program schedule and presents an aggressive plan to fully address all program metrics and milestones, whether they are specified in this solicitation or proposer-defined. Proposals should cite explicitly the qualitative and quantitative criteria that the proposed effort will achieve in accordance with the metrics and milestones for each Phase and TA. Proposers must also include a detailed management plan that supports effective communication and collaboration within teams, across relevant fields of science and technology and between theorists and experimentalists. For the purposes of this solicitation, the following additional definitions and clarifications apply:

- **Complexity:**
 - Refers to the high degree of interconnectedness of the scales and components of a biological system, in a manner that complicates prediction and control of system-level behavior at the state of the art.
- **Generalizability:**
 - Control strategies based on system-agnostic theory and models, once well-understood and implemented in one biological system, should be straightforward to adapt for use in other biological systems.
- **Control across scales:**
 - Refers to mechanisms at one or more scales operating in such a way as to control a behavior at one or more different, typically larger, scales.
 - For example, for an application of DoD relevance involving marine biofouling, biomolecular mechanisms at nanometer characteristic scales may ultimately

control the system-level structural behavior of a biofilm at millimeter scales relevant to preventing biofouling and reducing drag.

- System-level behavior:
 - Behaviors targeted for control that manifest at the organizational level of a whole biological system, for example, a cellular community, multicellular organism, or ecosystem, given that the whole system is approximately centimeter-scale or smaller and compatible with laboratory scale experiments.
 - Examples include, but are not limited to, behaviors that may be decomposed, individually and/or in combination, into growth and reproduction, adaptation and evolution, sensing and responding, and metabolism, to facilitate generalization to other biological systems.

PHASE 1 (BASE) 18 MONTHS

- Deliver one or more biological controller(s) and testbed, with associated predictive theory and models, for which one or more system-level behavior(s) are demonstrably controlled in a closed-loop manner.

Phase 1 TA1: Controller(s)

- Design and build one or more biological controller(s) consistent with Phase 1 TA2 and Phase 1 TA3 capable of achieving closed-loop control of one or more proposer-defined, system-level behavior(s).
 - Compose controller(s) of biological parts only, and include biological mechanisms, such as sensors, for closed-loop control.
- Demonstrate input signals, which may take a variety of forms, including, but not limited to, chemical, thermal, mechanical, or optical, to program the controller, while outputs are biological and integral to the biological system in TA2.
- Demonstrate control of at least one system-level behavior, by achieving three (3) or more steady-state, proposer-defined outputs associated with the target behavior within proposer-defined tolerances in relevant quantities, such as time to achieve steady-state value and deviation from setpoint value.
- Integrate controller(s) into the testbed in TA2, to evaluate controller performance according to proposer-defined metrics, and demonstrate stable integration for a proposer-defined period of two or more times greater than a relevant system-level characteristic timescale (*e.g.*, doubling time for cells, passages for serial batch culture, or life cycle time for multicellular organisms).
- For biological controllers developed in Phase 1, provide detailed schematics, protocols, domain knowledge, and other information and/or materials as necessary and relevant to the IV&V team.

Phase 1 TA2: Testbed

- Develop a testbed, consisting of a biological system and hardware for measurements and environmental control, compatible with the target system-level behavior(s) and controller(s) in TA1.
 - Demonstrate a testbed that includes a biological system, which is a naturally simple or synthetically simplified biological system of appropriately reduced complexity to ascertain predictable connections with confidence between inputs and outputs for control from measurements and models in TA3.
- Demonstrate application of inputs to program the controller(s).
- Demonstrate measurement of one or more parameters at each scale of length, time, and/or organization relevant to control of the target system-level behavior(s).
 - Demonstrate measurands and measurement methods consistent with TA3, informative for evaluation of the control strategy and controller, and yielding measurements relevant to proposer-defined metrics.
 - Where possible and practical, use of orthogonal measurements is strongly encouraged.
- Demonstrate time-course measurements of dynamic behavior, in addition to end-point measurements.
- Demonstrate manipulation and measurement of a sufficient variety of proposer-defined environmental conditions (*e.g.* temperature, pH, salinity, flow rate, *etc.*) relevant to the biological systems and target system-level behavior(s).
- Demonstrate sufficient number and type of sensors to assess the state of the biological system and inform control of the target system-level behavior(s).
- Integrate controller(s) designed in TA1 into the testbed, evaluate controller performance according to proposer-defined metrics, and demonstrate stable integration for a proposer-defined period of time two or more times greater than a relevant system-level characteristic timescale (*e.g.*, doubling time for cells, passages for serial batch culture, or life cycle time for multicellular organisms).
- For the testbed developed in Phase 1, provide detailed schematics, protocols, domain knowledge, and other information and/or materials as necessary and relevant to the IV&V team.

Phase 1 TA3: Theory and Modeling

- Produce predictive, mathematical analytical and/or computational model(s) with biological significance grounded in control theory for the controller(s) in TA1 and testbed in TA2.
 - Explicitly include experimentally accessible inputs, outputs, biochemical or other relevant interactions between the controller(s) and testbed, and measurands to evaluate controller performance, in a manner interpreted readily by experimentalists in TA1 and TA2.

- Describe and predict the target system-level behavior(s) for control in the testbed, both without and with embedded biological controller(s).
- Apply theory and models to optimize controller(s) performance, with respect to relevant proposer-defined metrics in TA1.
- Demonstrate relevance for informing control strategies, including, but not limited to, those implemented in TA1 and TA2 and compatible with the controller(s), testbed, and target system-level behavior(s).
- Demonstrate agreement between predicted and measured controller performance, according to proposer-defined metrics, as well as system-level behavior(s) of the testbed, both without and with the embedded controller(s).
- Identify the need for and initiate development of new analytical tools grounded in control theory, as required, for design, analysis, and optimization of control strategies and controllers, with respect to relevant proposer-defined metrics.
- For each model or valid approximation thereof, according to proposer-defined metrics:
 - Characterize the relevant parameter space (*e.g.*, reaction rates, component concentrations, length and time scales, *etc.*), indicating the region(s) for which the proposed control strategy is valid for the controller embedded in the testbed.
 - Provide stability analysis, as well as analyses of controller robustness and stability margins, as appropriate.
 - Characterize sensitivity and show sufficient disturbance attenuation, as appropriate.
 - Analyze the response to three or more step input-type perturbations, for example, in terms of overshoot, rise time, settling time, and steady-state error.
 - Provide and evaluate additional proposer-defined performance metrics, as appropriate.

PHASE 2 (OPTION 1) 18 MONTHS

- For the testbed in Phase 1, develop additional biological controllers that meet more stringent performance criteria, implement additional control strategies, and control additional system-level behaviors.

Phase 2 TA1: Controllers

- Design and build three or more additional biological controllers to control the same system-level behavior(s) as in Phase 1 using alternative control strategies and/or additional proposer-defined, system-level behaviors.
 - Must meet metrics and milestones, as applicable, for Phase 1 TA1.
- Demonstrate control of system-level behavior(s) of interest by achieving five or more steady-state, proposer-defined outputs and five or more dynamic, proposer-defined outputs associated with the behavior of interest, within proposer-defined error tolerances in relevant quantities, such as time to achieve steady-state and deviation from the setpoint value.

- Demonstrate combinations of up to three or more controllers in the testbed in TA2, for simultaneous control of multiple system-level behaviors, to implement more sophisticated overall control and control strategies, according to proposer-defined metrics, than is possible for each controller operating independently.
- For biological controllers developed in Phase 2, provide detailed schematics, protocols, domain knowledge, and other information and/or materials as necessary and relevant the IV&V team.

Phase 2 TA2: Testbed

- Must meet metrics and milestones, as applicable, for Phase 1 TA2 but with regard to controllers developed in Phase 2 TA1.
- Integrate the controllers in TA1 into the testbed, evaluate controller performance according to proposer-defined metrics, and demonstrate stable integration for a proposer-defined period of time five or more times greater than a relevant system-level characteristic timescale (*e.g.*, doubling time for cells, passages for serial batch culture, or life cycle time for multicellular organisms).
- For biological control developed in Phase 2, provide detailed schematics, protocols, domain knowledge, and other information and/or materials as necessary and relevant to the IV&V team.

Phase 2 TA3: Theory and Modeling

- Must meet metrics and milestones, as applicable, for Phase 1 TA3 but with regard to controllers and testbeds developed in Phase 2 TA1 and Phase 2 TA2, respectively.
 - Additionally, Phase 2 proposer-defined metrics for controller performance must be more stringent than those in Phase 1 TA3.
- Implement models of controllers and testbed in a computational environment that is practical and accessible to experimentalists to aid rational design of control strategies and controllers.

PHASE 3 (OPTION 2) 12 MONTHS

- Demonstrate the applicability, generalizability, and predictability of capabilities for control of biological systems developed in Phases 1 and 2.

Phase 3 TA1: Controllers

- Design and implement controllers to enable a proposer-defined, practical, proof-of-concept demonstration of relevance to DoD.
- Demonstrate controllers that build on results from Phase 1 and Phase 2 and meet the metrics and milestones, as applicable, for Phase 2 TA1.
- Demonstrate, for the demonstration system in Phase 3 TA2, simultaneous control of multiple system-level behaviors according to proposer-defined metrics, to implement more sophisticated overall control and control strategies than is possible for each controller operating independently.

Phase 3 TA2: Testbed

- Design and build a demonstration system to serve as an application-specific testbed to evaluate controllers for the proposer-defined, practical, proof-of-concept demonstration relevant to DoD.
- Must meet metrics and milestones, as applicable, for Phase 2 TA2, but with regard to controllers developed in Phase 3 TA1.

Phase 3 TA3: Theory and Modeling

- Must meet metrics and milestones, as applicable, for Phase 2 TA3 but with regard to controllers and testbeds developed in Phase 3 TA1 and Phase 3 TA2, respectively.
- Demonstrate rapid transition of capabilities to the demonstration system through rational design of biological control strategies and biological controllers based on theory and modeling in Phase 1 TA3 and Phase 2 TA3.
- Participate in tests of the models' predictive capability. DARPA will determine and announce the details for this test no later than the conclusion of Phase 2.
 - Demonstrate correspondence between predictions and measurements obtained by the IV&V team.
 - Predictive capability will be evaluated and scored based upon the agreement between predictions and measurements.

2. Award Information

Multiple awards are anticipated. 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 at the end of one or more of the Phases.

Awards under this BAA will be made to proposers on the basis of the evaluation criteria listed below (see section labeled "Application Review Information", Sec. 5.), and program balance to provide overall value to the Government. The Government reserves the right to request any additional, necessary documentation once it makes the award instrument determination. Such additional information may include but is not limited to Representations and Certifications. The Government reserves the right to remove proposers from award consideration should the parties fail to reach agreement on award terms, conditions and cost/price within a reasonable time or the proposer fails to provide requested additional information in a timely manner. 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.

In all cases, the Government contracting officer shall have sole discretion to select award instrument type and to negotiate all instrument terms and conditions with selectees. Proposers are advised that if they propose cooperative agreements, DARPA may select other award instruments, as it deems appropriate. 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.

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 established the national policy for controlling the flow of scientific, technical, and engineering information produced in federally funded fundamental research at colleges, universities, and laboratories. The Directive defines fundamental research as follows:

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

As of the date of publication of this BAA, the Government expects that program goals as described herein may be met by proposers intending to perform fundamental research. The Government does not anticipate applying publication restrictions of any kind to individual awards for fundamental research that may result from this BAA. Notwithstanding this statement of expectation, the Government is not prohibited from considering and selecting research proposals that, while perhaps not qualifying as fundamental research under the foregoing definition, still meet the BAA criteria for submissions. If proposals are selected for award that offer other than a fundamental research solution, the Government will either work with the proposer to modify the proposed statement of work to bring the research back into line with fundamental research or else the proposer will agree to restrictions in order to receive an award. Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to select award instrument type and to negotiate all instrument terms and conditions with selectees. Appropriate clauses will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate.

For certain research projects, it may be possible that although the research being performed by the prime contractor is restricted research, a subawardee may be conducting fundamental research. In those cases, it is the prime contractor's responsibility to explain in its proposal why its subawardee's effort is fundamental research.

The following statement or similar provision will be incorporated into any resultant non-fundamental research procurement contract or other transaction:

There shall be no dissemination or publication, except within and between the contractor and any subawardees, of information developed under this contract or contained in the reports to be furnished pursuant to this contract without prior written approval of DARPA's Public Release Center (DARPA/PRC). All technical reports will be given proper review by appropriate authority to determine which Distribution Statement is to be applied prior to the initial distribution of these reports by the contractor. With regard to subawardee proposals for Fundamental Research, papers resulting from unclassified fundamental research are exempt from prepublication controls and this review requirement, pursuant to DoD Instruction 5230.27 dated October 6, 1987.

When submitting material for written approval for open publication, the contractor/awardee must submit a request for public release to the DARPA/PRC and include the following information: (1) Document Information: document title, document author, short plain-language description of technology discussed in the material (approx. 30 words), number of pages (or minutes of video) and document type (e.g., briefing, report, abstract, article, or paper); (2) Event Information: event type (conference, principal investigator meeting, article or paper), event date, desired date for DARPA's approval; (3) DARPA Sponsor: DARPA Program Manager, DARPA office, and contract number; and (4) Contractor/Awardee's Information: POC name, email and phone. Allow four weeks for processing; due dates under four weeks require a justification. Unusual electronic file formats may require additional processing time. Requests may be sent either via email to public_release_center@darpa.mil or by mail at 675 North Randolph Street, Arlington VA 22203-2114, telephone (571) 218-4235. Refer to the following for link for information about DARPA's public release process: <http://www.darpa.mil/work-with-us/contract-management/public-release>."

3. Eligibility Information

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

3.1. ELIGIBLE APPLICANTS

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

Federally Funded Research and Development Centers (FFRDCs) and Government entities (e.g., Government/National laboratories, military educational institutions, etc.) 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; and (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 prime contractors or subawardees. 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. 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. See Section 4.2.1 “Proprietary and Security Information” regarding the proposers capabilities to perform research and development at the classification level they propose.

Procurement Integrity, Standards of Conduct, Ethical Considerations, and Organizational Conflicts of Interest

Current federal employees are prohibited from participating in particular matters involving conflicting financial, employment, and representational interests (18 U.S.C. §§ 203, 205, and 208). Once the proposals have been received, and prior to the start of proposal evaluations, the Government will assess potential conflicts of interest and will promptly notify the proposer if any appear to exist. The Government assessment does NOT affect, offset, or mitigate the proposer’s responsibility to give full notice and planned mitigation for all potential organizational conflicts, as discussed below.

Without prior approval or a waiver from the DARPA Director, in accordance with FAR 9.503, a contractor cannot simultaneously provide scientific, engineering, technical assistance (SETA) or similar support and also be a technical performer. As part of the proposal submission, all members of the proposed team (prime proposers, proposed subawardees, and consultants) must affirm whether they (their organizations and individual team members) are providing SETA or similar support to any DARPA technical office(s) through an active contract or subcontract. All affirmations must state which office(s) the proposer, subawardees, consultant, or individual supports and identify the prime contract number(s). All facts relevant to the existence or potential existence of organizational conflicts of interest (FAR 9.5) must be disclosed. The disclosure must include a description of the action the proposer has taken or proposes to take to avoid, neutralize, or mitigate such conflict. If in the sole opinion of the Government after full consideration of the circumstances, a proposal fails to fully disclose potential conflicts of interest and/or any identified conflict situation cannot be effectively mitigated, the proposal will be rejected without technical evaluation and withdrawn from further consideration for award.

If a prospective proposer believes a conflict of interest exists or may exist (whether organizational or otherwise) or has questions on what constitutes a conflict of interest, the proposer should send his/her contact information and a summary of the potential conflict via

email to the BAA email address before time and effort are expended in preparing a proposal and mitigation plan.

3.2. 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 (*e.g.*, for any Other Transactions under the authority of 10 U.S.C. §2371). Cost sharing is encouraged where there is a reasonable probability of a potential commercial application related to the proposed research and development effort.

3.3. OTHER ELIGIBILITY REQUIREMENTS

While teaming is not required, teaming is *strongly encouraged* to meet the program goals across all Phases and TAs. DARPA *requires* teaming to be resolved before proposal submission and, as such, will facilitate the formation of teams with the expertise necessary to meet the goals of the program (see Section 8.2 below). However, specific content, communications, networking, and team formation are the sole responsibility of the proposers. Teams/collaborative efforts must submit a single, integrated proposal that addresses all program TAs and Phases, led by a single Principal Investigator (PI) or prime contractor. Proposers may join any number of teams as a subcontractor and still submit a separate proposal as the PI (with or without subcontractors). In all cases, collaborating team members must submit a unified proposal.

It is expected that successful teams will require deep expertise in both theoretical and experimental science and technology, for example, in fields of biology relevant to the proposed testbed and demonstration system, fields of engineering relevant to the proposed testbed and measurement methods, and control engineering.

4. Application and Submission Information

4.1. ADDRESS TO REQUEST APPLICATION PACKAGE

This solicitation contains all information required to submit a proposal. No additional forms, kits, or other materials are needed. This notice, with the classified addendum, constitutes the total solicitation. No additional information is available, except as provided at FBO.gov or Grants.gov, nor will a formal Request for Proposal (RFP) or additional solicitation regarding this announcement be issued. Requests for the same will be disregarded.

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

4.2.1. Proprietary and Security 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.

Submissions will not be returned. The original 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 at this office within five (5) days after notification that a proposal was not selected.

4.2.1.1 Proprietary Information

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.

4.2.1.2 Security Information

Classified submissions shall be transmitted in accordance with the following guidance. Additional information on the subjects discussed in this section may be found at <http://www.dss.mil/>.

If a submission contains Classified National Security Information as defined by Executive Order 13526, the information must be appropriately and conspicuously marked with the proposed classification level and declassification date. Similarly, when the classification of a submission is in question, the submission must be appropriately and conspicuously marked with the proposed classification level and declassification date. Submissions requiring DARPA to make a final classification determination shall be marked as follows:

“CLASSIFICATION DETERMINATION PENDING. Protect as though classified _____ (insert the recommended classification level, e.g., Top Secret, Secret or Confidential)”

NOTE: Classified submissions must indicate the classification level of not only the submitted materials, but also the classification level of the anticipated award.

Proposers submitting classified information must have, or be able to obtain prior to contract award, cognizant security agency approved facilities, information systems, and appropriately cleared/eligible personnel to perform at the classification level proposed. All proposer personnel performing Information Assurance (IA)/Cybersecurity related duties on classified Information Systems shall meet the requirements set forth in DoD Manual 8570.01-M (Information Assurance Workforce Improvement Program).

Proposers choosing to submit classified information from other collateral classified sources (*i.e.*, sources other than DARPA) must ensure (1) they have permission from an authorized individual at the cognizant Government agency (*e.g.*, Contracting Officer, Program Manager); (2) the proposal is marked in accordance with the source Security Classification Guide (SCG) from which the material is derived; and,, (3) the source SCG is submitted along with the proposal.

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).

Security classification guidance and direction via a SCG and/or DD Form 254, “DoD Contract Security Classification Specification,” will not be provided at this time, since DARPA is soliciting ideas only. If a determination is made that the award instrument may result in access to

classified information, a SCG and/or DD Form 254 will be issued by DARPA and attached as part of the award.

4.2.2. Submission Information

Proposers are *strongly encouraged* to submit a proposal abstract in advance of a proposal. This procedure is intended to minimize unnecessary effort in proposal preparation and review. The time and date for submission of abstracts and proposals is specified in Section 4.4 below. Abstracts and proposals should express a consolidated effort in support of all three TAs. Disjointed efforts should not be included into a single proposal. Abstracts and proposals not meeting the format described in the BAA may not be reviewed.

For Proposers Submitting Proposal Abstracts or Full Proposals through DARPA’s BAA Submission Portal:

Abstracts and Full Proposals sent in response to DARPA-BAA-16-17 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 (2) separate emails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the “Register your Organization” link along the left side of the homepage), view submission instructions, and upload/finalize the abstract. Proposers using the DARPA BAA website may encounter heavy traffic on the submission deadline date; it is highly advised that the submission process be started as early as possible.

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

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

For Proposers Requesting Cooperative Agreements:

Proposers requesting cooperative agreements may submit proposals through one of the following methods: (1) hard copy mailed directly to DARPA; or (2) electronic upload per the instructions at <http://www.grants.gov/applicants/apply-for-grants.html>. Cooperative agreement proposals may not be submitted through any other means. 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 the Grants.gov do not submit paper proposals in addition to the Grants.gov electronic submission.

Grants.gov requires proposers to complete a one-time registration process before a proposal can be electronically submitted. If proposers have not previously registered, this process can take between three (3) business days and four (4) weeks. See the Grants.gov registration checklist at

<http://www.grants.gov/documents/19/18243/GrantsgovOrganizationRegistrationGuide.pdf> for registration requirements and instructions.

Once Grants.gov has received a proposal submission, Grants.gov will send two (2) email messages to advise proposers as to whether or not their proposals have been validated or rejected by the system; **IT MAY TAKE UP TO TWO (2) DAYS TO RECEIVE THESE EMAILS.** The first email will confirm receipt of the proposal by the Grants.gov system; this email only confirms receipt, not acceptance, of the proposal. The second will indicate that the application has been successfully validated by the system prior to transmission to the grantor agency or has been rejected due to errors. If the proposal is validated, then the proposer has successfully submitted their proposal. If the proposal is rejected, the proposal must be corrected and resubmitted before DARPA can retrieve it. If the solicitation is no longer open, the rejected proposal cannot be resubmitted. Once the proposal is retrieved by DARPA, the proposer will receive a third email from Grants.gov. To avoid missing deadlines, proposers should submit their proposals in advance of the final proposal due date with sufficient time to receive confirmations and correct any errors in the submission process through Grants.gov. For more information on submitting proposals to Grants.gov, visit the Grants.gov submissions page at: <http://www.grants.gov/web/grants/applicants/apply-for-grants.html>

Upload six (6) separate documents as attachments to the application package: (i) Volume I, Technical, and Management Proposal; (ii) Volume II, Cost Proposal; (iii) Attachment 1, Summary Slides; Attachment 2, Statement of Work; Attachment 3, Gantt Chart; and, Attachment 4, Budget. **No other Grants.gov forms are required.** Please note that Grants.gov does not accept zipped or encrypted proposals. More detailed instructions for using Grants.gov can be found on the Grants.gov website. Technical support for Grants.gov submissions may be reached at 1-800-518-4726 or support@grants.gov.

Please note that submitters to Grants.gov will still need to visit <https://baa.darpa.mil> to register their organization concurrently to ensure the BAA office can verify and finalize their submission.

DARPA intends to use email for correspondence regarding DARPA-BAA-16-17. All administrative correspondence and questions on this solicitation, including requests for information on how to submit a proposal to this BAA, should be directed to the BAA Administrator at DARPA-BAA-16-17@darpa.mil.

Proposals and proposal abstracts may not be submitted by fax or email; any so sent will be disregarded. DARPA encourages use of the internet for retrieving the BAA and any other related information that may subsequently be provided.

4.2.3. Restrictive Markings on Proposals

All proposals should clearly indicate limitations on the disclosure of their contents. Proposers who include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall:

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this proposer as a result of, or in connection with, the submission of this data, the Government shall have the right to

duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and,,

(2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

Markings like "Company Confidential" or other phrases that may be confused with national security classifications shall be avoided.

4.3. FORMATTING CHARACTERISTICS

4.3.1. Proposal Abstract Format

Proposers are *strongly encouraged* to submit a proposal abstract in advance of a proposal. This procedure is intended to minimize unnecessary effort in proposal preparation and review. The time and date for submission of proposal abstracts is specified in Section 4.4.1 below. DARPA will acknowledge receipt of the submission and assign a control number that should be used in all further correspondence regarding the proposal abstract.

Abstracts and proposals not meeting the format described in the BAA may not be reviewed.

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

DARPA will attempt to reply to abstracts in writing within 21 calendar days of receipt.

Abstracts, if submitted, are required to address all Biological Control program requirements.

The abstract is a concise version of the proposal comprising a maximum of eight (8) pages including all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11 inch paper with 1" margins and in a typeface not smaller than 12 point. Smaller type may be used for figures, tables, and charts, but it is the proposer's responsibility to make sure that these are legible on a printed page without magnification. Submissions must be written in English. The page limit does NOT include:

1. Official transmittal letter (optional);
2. Cover sheet;
3. Executive summary slide;
4. Resumes (optional); and,,
5. Bibliography (optional). While not included in the overall page limit, the bibliography should not exceed two (2) pages.

Proposal abstracts must include the following components:

i. Cover Sheet (LABELED "ABSTRACT"):

1. BAA number (DARPA-BAA-16-17);
2. Lead organization (prime contractor) submitting proposal;
3. Team members (subcontractors);
4. Proposal abstract title;
5. Technical Point of Contact (POC) (Principal Investigator or Program Coordinator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, and email;
6. Administrative POC to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, and email;
7. Estimated cost; and,
8. Estimated period of performance.

ii. Executive Summary Slide: Provide a one-slide summary in PowerPoint that effectively and succinctly conveys the information requested in the slide template provided as **Attachment 1** to the BAA posted at <https://www.fbo.gov>. Use of this template is required.

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

1. What are you going to do? Articulate your objectives using no jargon.
2. How is it done today? What are the associated limitations?
3. What is innovative in your approach, and how does it compare to the state of the art?
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?

iv. Technical Plan: Summarize your plan for accomplishing the program technical goals. Be sure to address the three required TAs. In addition:

1. Describe the proposed biological controllers to be developed.
2. Describe the proposed testbed (Phase 1 and 2) and demonstration system (Phase 3), including environmental controls, system inputs, and relevant sensors and measurements.
3. Detail how the assembled system capabilities will enable system modeling and quantification and prediction of controller performance and behavior.
4. Identify the proposed system-level behavior(s) to be controlled in the experimental testbed (Phases 1 and 2) and in the demonstration system (Phase 3).
5. Describe your theoretical approach to enable the rational design of controllers and control strategies.
6. Detail how control of a biological system in the testbed and subsequent transition to the demonstration system will demonstrate the generalizability of your proposed control strategy.
7. Outline and address the areas of greatest technical risk inherent to the approach and strategies for mitigating these risks.
8. Propose appropriate and sufficient qualitative and quantitative metrics and milestones at intervals no greater than 6 months to demonstrate progress and a brief plan for their accomplishment.

v. Capabilities/Management Plan: It is expected that proposals will involve multidisciplinary teams that include expertise from, for example, the biology/synthetic biology community and the control theory/systems engineering community. Provide a brief summary of expertise of the team, including key personnel and any potential subcontractors. Identify the PI/ Program Coordinator and describe the team's organization. Describe the roles and responsibilities for each key team member. Describe any specialized facilities to be used.

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

vii. Resumes (Optional): If desired, include resumes of key team members.

viii. Bibliography (Optional): If desired, include a brief bibliography with links to relevant papers and reports. The bibliography should not exceed two (2) pages.

4.3.2. Proposal Format

NOTE (classification and handling markings): Confidential, Secret and Top Secret are classification markings used to control the dissemination of U.S. Government National Security Information (NSI) as dictated in Executive Order 13526 - "Classified National Security Information". When referencing business proprietary information in a response to this BAA, please refrain from using any combination of the NSI caveats unless the content is classified.

All full proposals must be in the format given below. Nonconforming proposals may be rejected without review. Proposals shall consist of two (2) volumes. All pages shall be formatted for printing on 8-1/2 by 11 inch paper with 1" margins and in a typeface not smaller than 12 point. Smaller type may be used for figures, tables, and charts, but it is the proposer's responsibility to make sure that these are legible on a printed page without magnification. The page limitation for full proposals includes all figures, tables, and charts. 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. Proposal submissions must be written in English. **The maximum page count for Volume 1 is 25 pages.** The official transmittal letter is not included in the page count. Volume I should include the following components:

4.3.2.1 Volume I, Technical and Management Proposal

Section I. Administrative

A. Cover Sheet (LABELED "PROPOSAL: VOLUME 1"):

1. BAA number (DARPA-BAA-16-17);

2. Lead organization (prime contractor) submitting proposal;
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. Reference number (if any);
5. Other team members (if applicable) and type of organization for each;
6. Proposal title;
7. Technical POC (Principal Investigator or Program Coordinator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, and email;
8. Contracting Officer to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, and email;
9. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, firm-fixed-price, cooperative agreement, other transaction, or other type (specify);
10. Place(s) and period(s) of performance;
11. Proposal validity period;
12. DUNS number (<http://www.dnb.com/get-a-duns-number.html>);
13. Taxpayer ID number (<https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN>);
14. CAGE code (<https://cage.dla.mil/search//FAQ.aspx>);

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 three-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**. Use of this template is required.

Section II. Detailed Proposal Information [25 pages]

A. Executive Summary: Provide a synopsis of the proposed project, including answers to the following questions:

- What are you going to do? Articulate your objectives using no jargon.
- How is it done today? What are the associated limitations?
- What is innovative in your approach, and how does it compare to the state of the art?
- What are the key technical challenges in your approach, and how do you plan to overcome these?
- Who will care, and what will the impact be if you are 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 or further the work.

- C. Technical Plan:** Outline and address technical challenges inherent in the approach and describe 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. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (if risky) plan to achieve the program goals. 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. Each team should be led by a single PI or full time Program Coordinator with an advanced technical degree in a related field who will take overall responsibility for the conduct of the funded research and serve as the technical point of contact with DARPA. 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 the proposed work.
- 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 Government requires proposers to complete an editable MS Word SOW template that covers much of the details discussed below; download and complete the template provided in **Attachment 2**, SOW Template, posted with the BAA. Clearly define the technical tasks/subtasks to be performed, their durations, and dependencies among them. The page length for the SOW will be dependent on the scope of the effort. 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 metric and/or milestone, *i.e.*, a deliverable, demonstration, or other event/activity that marks task completion. Include quantitative metrics, as appropriate.
 - A definition of all deliverables (*e.g.*, data, reports, software) to be provided to the Government in support of the proposed tasks/subtasks.
 - It is recommended that the SOW should be developed so that each Phase of the program is separately defined.

- Do not include any proprietary information in the SOW.

The Government requires proposers to complete an editable Excel Gantt Chart template that outlines the proposed tasks, subtasks, metrics, and milestones by each Phase; download and complete the template provided in **Attachment 3**, Gantt Template, posted with the BAA.

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 metrics and milestones should be clearly articulated and defined in time relative to the start of the project.

The Government requires proposers to complete the table found in the “Milestones and Deliverables” tab within **Attachment 4**, Cost Proposal Template; proposers are encouraged to copy this exact table into the milestones section of their Technical Proposal.

A cost summary table which breaks down costs by Technical Area, team, and Phase should be included in this section. Please refer to the following example:

	Phase 1 (18 months)	Phase 2 (18 months)	Phase 3 (12 months)	Total
TA1: Controller(s)				
Prime				\$-
Subcontractor				\$-
TA1 Total	\$-	\$-	\$-	\$-
TA2: Testbed				
Prime				\$-
Subcontractor				\$-
TA2 Total	\$-	\$-	\$-	\$-
TA3: Theory and Models				
Prime				\$-
Subcontractor				\$-
TA3 Total	\$-	\$-	\$-	\$-

Section III. Additional Information (Note: Does not count towards page limit)

A resume or “Biosketch” is required for key personnel.

A brief bibliography of relevant technical papers and research notes (published and unpublished) which document the technical ideas upon which the proposal is based. The bibliography should not exceed two (2) pages. Copies of not more than three (3) relevant papers can be included in the submission.

4.3.2.2 Volume II, Cost Proposal – {No Page Limit}

All proposers, including FFRDCs, must submit the following:

Cover sheet to include:

1. BAA number (DARPA-BAA-16-17);
2. Lead organization (prime contractor) 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. Reference number (if any);
5. Other team members and type of business for each;
6. Proposal title;
7. Contracting Officer to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and email;
8. Administrative POC to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and email;
9. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), or other transaction;
10. Place(s) and period(s) of performance;
11. Total proposed cost separated by basic award and option(s) (if any);
12. Name, address, and telephone number of the proposer’s cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
13. Name, address, and telephone number of the proposer’s cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
14. Date proposal was prepared;
15. DUNS number (<http://www.dnb.com/get-a-duns-number.html>) ;
16. Taxpayer ID number (<https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN>);
17. CAGE code (<https://cage.dla.mil/search//FAQ.aspx>);
18. Proposal validity period

Note that nonconforming proposals may be rejected without review.

NOTE: The Cost Volume Proposer Checklist (**Appendix 1**), must be included with the coversheet of the Cost Proposal.

Proposers without an accounting system considered adequate for determining accurate costs must complete an SF 1408 if a cost type contract is to be negotiated. To facilitate this process, proposers should complete the SF 1408 found at <http://www.gsa.gov/portal/forms/download/115778> and submit the completed form with the proposal. To complete the form, check the boxes on the second page, then provide a narrative explanation of your accounting system to supplement the checklist on page one. For more information, please see http://www.dcaa.mil/preaward_accounting_system_adequacy_checklist.html.

The Government encourages proposers to complete an editable MS excel budget template that covers items 1.i, 1.iv, 2, 3, 4, and 5 discussed below. This template document is provided as **Attachment 4** to this BAA. If you choose to use **Attachment 4**, submit the MS Excel template in addition to Volume I and II of your proposal. Volume II must include all other items discussed below that are not covered by the editable MS excel budget template. Proposers are welcome to utilize an alternative format, provided the information requested below is clearly and effectively communicated.

The detailed cost breakdown should include:

- (1) Total program cost broken down by major cost items to include:
 - i. Direct labor, including individual labor categories or persons, with associated labor hours and numbered direct labor rates;
 - ii. If consultants are to be used, proposer must provide consultant agreement or other document which verifies the proposed loaded daily/hourly rate;
 - iii. Indirect costs including Fringe Benefits, Overhead, General and Administrative Expense, Cost of Money, *etc.* (must show base amount and rate);
 - iv. Travel – Number of trips, number of days per trip, departure and arrival destinations, number of people, *etc.*; and,,
 - v. Other Direct Costs – Should be itemized with costs or estimated costs. Backup documentation will be submitted to support proposed costs. An explanation of any estimating factors, including their derivation and application, must be provided.
Please include a brief description of the proposer’s procurement method to be used.
- (2) Major program tasks by fiscal year.
- (3) Itemization of major subcontracts and equipment purchases, to include: a cost proposal as detailed as the prime contractor’s cost proposal.
- (4) Itemization of any information technology (IT) purchase, as defined in FAR Part 2.101.
- (5) Summary of projected funding requirements by month.
- (6) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions which could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.
- (7) Identification of pricing assumptions 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.*)

The Cost Volume should include supporting cost and pricing information in sufficient detail to substantiate the summary cost estimates and should include a description of the method used to estimate costs and supporting documentation. Per FAR 15.403-4, certified cost or pricing data shall be required if the proposer is seeking a procurement contract award per the referenced threshold, unless the proposer requests an exception from the requirement to submit cost or pricing data. Certified cost or pricing data are not required if the proposer proposes an award instrument other than a procurement contract (*e.g.*, a cooperative agreement, or other transaction.)

The prime contractor is responsible for compiling and providing all subcontractor proposals for the Procuring Contracting Officer (PCO). Subcontractor proposals should include Interdivisional Work Transfer Agreements (ITWA) or similar arrangements. Where the effort consists of multiple portions which could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each. NOTE: for IT and equipment purchases, include a letter stating why the proposer cannot provide the requested resources from its own funding.

All proprietary subcontractor proposal documentation should be prepared at the same level of detail as that required of the prime contractor. The prime and subcontractor proposals should be uploaded together if possible to DARPA’s BAA website (<https://baa.darpa.mil/>). If the subcontractor proposal contains proprietary information not releasable to the prime, the

subcontractor may upload their proposal separately but identify the proposal as a subcontract proposal and provide the name and proposal title of the prime contractor. If submitted directly by the subcontractor, the subcontractor must identify the proposal as a subcontract proposal and provide the name and proposal title of the prime contractor. Subcontractors must provide the same number of electronic proposals as is required of the prime contractor.

The Government strongly encourages that tables included in the cost proposal also be provided in an editable (*i.e.*, MS Excel™) format with calculations formulae intact to allow traceability of the cost proposal numbers across the prime and subcontractors (see **Attachment 4**, Cost Proposal Template). This includes the calculations and adjustments that are utilized to generate the Summary Costs from the source labor hours, labor costs, material costs, etc., input data. The Government prefers receiving cost data as Excel files; however, this is not a requirement. If the PDF submission differs from the Excel submission, the PDF will take precedence. Each copy must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title (short title recommended).

The Government also requests and recommends that the Cost Proposal include MS Excel™ file(s) that provide traceability between the Bases of Estimates (BOEs) and the proposed costs across all elements and Phases. This includes the calculations and adjustments that are utilized to generate the Summary Costs from the source labor hours, labor costs, material costs, etc. input data. It is requested that the costs and Subcontractor proposals be readily traceable to the Prime Cost Proposal in the provided MS Excel™ file(s). The Government prefers receiving cost data as Excel files; however, this is not a requirement.

All proposers requesting an 845 Other Transaction for Prototypes (OT) agreement must include a detailed list of milestones. Each such milestone must include the following: milestone description, completion criteria, due date, and payment/funding schedule (to include, if cost share is proposed, contractor and Government share amounts). It is noted that, at a minimum, such milestones should relate directly to accomplishment of program technical metrics as defined in the BAA and/or the proposer's proposal. Agreement type, fixed price or expenditure based, will be subject to negotiation by the Agreements Officer; however, it is noted that the Government prefers use of fixed price milestones with a payment/funding schedule to the maximum extent possible. Do not include proprietary data. If the proposer requests award of an 845 OT agreement as a nontraditional defense contractor, as so defined in the OSD guide entitled "Other Transactions (OT) Guide For Prototype Projects" dated January 2001 (as amended) (<http://www.acq.osd.mil/dpap/Docs/otguide.doc>), information must be included in the cost proposal to support the claim. Additionally, if the proposer requests award of an 845 OT agreement, without the required one-third (1/3) cost share, information must be included in the cost proposal supporting that there is at least one non-traditional defense contractor participating to a significant extent in the proposed prototype project. For information on 845 Other Transaction for Prototypes (OT) agreements, refer to <http://www.darpa.mil/work-with-us/contract-management>.

4.4. SUBMISSION DATES AND TIMES

4.4.1. Proposal Abstract Submission Deadline

The proposal abstract sent in response to DARPA-BAA-16-17 must be submitted to DARPA/BTO **on or before 4:00 p.m., ET, Friday, 18 March 2016**. Refer to Sections 4.2.2 and 4.3.1 Submission Information for instruction on abstract submission. Proposal abstracts received after this time and date may not be reviewed.

4.4.2. Full Proposal Submission Deadline

The full proposal sent in response to DARPA-BAA-16-17 must be submitted to DARPA/BTO **on or before 4:00 p.m., ET, Friday, 29 April 2016**. Refer to Sections 4.2.2 and 4.3.2 Submission Information for instruction on proposal submission.

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.

DARPA will post a consolidated Question and Answer list in response to any relevant and/or BAA clarification question(s) after **Monday, 22 February 2016**, before final full proposals are due. In order to receive a response to your question, submit your question by **Monday, 25 April 2016** to the BAA Coordinator at DARPA-BAA-16-17@darpa.mil.

4.5. FUNDING RESTRICTIONS

Not applicable.

4.6. OTHER SUBMISSION REQUIREMENTS

Not applicable.

5. Application Review Information

5.1. EVALUATION CRITERIA

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

5.1.1. Overall Scientific and Technical Merit

The proposed technical approach is feasible, achievable, complete and supported by a proposed technical team that 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 clearly defines feasible planned mitigation strategies and efforts to address those risks.

The proposal clearly explains the technical approach(es) that will be employed to meet or exceed performer and program defined metrics and milestones and provides ample justification as to why the approach(es) is/are feasible. Other factors to be considered will include the structure,

clarity, and responsiveness to the statement of work; the quality of proposed deliverables; and,, the linkage of the statement of work, technical approach(es), risk mitigation plans, costs, and deliverables of the prime contractor and all subcontractors through a logical, well-structured, and traceable technical plan.

Proposers should clearly address the generalizability and scalability of experimental and theoretical capabilities anticipated to result from their research. The proposer should describe how the proposed approaches are not limited to use in isolation or to solve a specific problem, and can be used in combination with existing and future technologies employed in characterizing, constructing, and controlling biological systems. In addition, the proposer should address potential technical challenges and risk mitigation strategies specifically associated with the integration of the proposed technologies with the state of the art, as applicable.

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 maintain the technological superiority of the U.S. military and prevent technological surprise from harming our national security by sponsoring revolutionary, high-payoff research that bridges the gap between fundamental discoveries and their application.

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).

The proposer's prior scientific and technical experience in similar or related efforts must clearly demonstrate an ability to meet the proposed technical performance within the proposed budget and schedule. The team has the expertise to manage the cost and schedule. Similar efforts completed/ongoing by the proposer in this area are fully described, including identification of other Government sponsors.

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

The costs are consistent with a proposed schedule that aggressively pursues performance metrics in the shortest timeframe and accurately accounts for that timeframe. The proposed schedule identifies and mitigates any potential schedule risk.

5.2. REVIEW AND SELECTION PROCESS

DARPA will conduct a scientific/technical review of each conforming proposal. 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, all factors considered, including the potential contributions of the proposed work to the overall research program and the availability of funding for the effort.

It is the policy of DARPA to ensure impartial, equitable, comprehensive proposal evaluations and to select the source (or sources) whose offer meets the Government's technical, policy, and programmatic goals. Pursuant to FAR 35.016, the primary basis for selecting proposals for acceptance shall be technical, importance to agency programs, and fund availability. In order to provide the desired evaluation, qualified Government personnel will conduct reviews and (if necessary) convene panels of experts in the appropriate areas.

For evaluation purposes, a proposal is the document described in "Proposal Format", Section 4.3.2. Other supporting or background materials submitted with the proposal will be considered for the reviewer's convenience only and not considered as part of the proposal.

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.

6. Award Administration Information

6.1. SELECTION NOTICES

As soon as the evaluation of a proposal is complete, the proposers will be notified that 1) the proposal has been selected for funding pending contract negotiations, or 2) the proposal has not been selected. These official notifications will be sent via email to the Technical POC identified on the proposal coversheet.

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

There will be a program kickoff meeting, and all key participants are required to attend. Performers should also anticipate regular program-wide meetings and periodic site visits at the Program Manager's discretion. 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. Performers should anticipate at least quarterly meetings, including teleconference calls, in-person program reviews, and site visits by the DARPA Program Manager and/or Government team. In addition, performers anticipate at least one site visit per Phase from the IV&V team to learn about Biological Control technologies for testing and evaluation. For travel budgeting purposes, proposers may assume program reviews at six (6) month intervals with alternating locations on the east and west coasts of the United States.

6.2.2. Human Subjects Research

All research selected for funding involving human subjects, to include use of human biological specimens and human data, must comply with the federal regulations for human subjects protection. Further, research involving human subjects that is conducted or supported by the DoD must comply with 32 CFR 219, Protection of Human Subjects (and DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (<http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>)).

Institutions awarded funding for research involving human subjects must provide documentation of a current Assurance of Compliance with Federal regulations for human subjects protection, such as a Department of Health and Human Services, Office of Human Research Protection Federal Wide Assurance (<http://www.hhs.gov/ohrp>). All institutions engaged in human subjects research, to include subawardees, must also hold a valid Assurance. In addition, all personnel involved in human subjects research must provide documentation of completion of human subjects research training.

For all proposed research that will involve human subjects in the first year or phase of the project, the institution must provide evidence of or a plan for review by an Institutional Review Board (IRB) upon final proposal submission to DARPA as part of their proposal, prior to being selected for funding. The IRB conducting the review must be the IRB identified on the institution's Assurance of Compliance with human subjects protection regulations. The protocol, separate from the proposal, must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. It is recommended that you consult the designated IRB for guidance on writing the protocol. The informed consent document must comply with federal regulations (32 CFR 219.116). A valid Assurance of Compliance with human subjects protection regulations along with evidence of completion of appropriate human subjects research training by all investigators and personnel involved with human subjects research should accompany the protocol for review by the IRB.

In addition to a local IRB approval, a headquarters-level human subjects administrative review and approval is required for all research conducted or supported by the DoD. The Army, Navy, or Air Force office responsible for managing the award can provide guidance and information about their component's headquarters-level review process. Note that confirmation of a current Assurance of Compliance with human subjects protection regulations and appropriate human subjects research training is required before headquarters-level approval can be issued.

The time required to complete the IRB review/approval process varies depending on the complexity of the research and the level of risk involved with the study. The IRB approval process can last between one and three months, followed by a DoD review that could last between three and six months. Ample time should be allotted to complete the approval process. DoD/DARPA funding cannot be used towards human subjects research until ALL approvals are granted.

6.2.3. Animal Use

Award recipients performing research, experimentation, or testing involving the use of animals shall comply with the rules on animal acquisition, transport, care, handling, and use as outlined in: (i) 9 CFR parts 1-4, Department of Agriculture rules that implement the Animal Welfare Act of 1966, as amended, (7 U.S.C. § 2131-2159); (ii) National Institutes of Health Publication No. 86-23, "Guide for the Care and Use of Laboratory Animals" (8th Edition); and (iii) DoD Instruction 3216.01, "Use of Animals in DoD Programs."

For projects anticipating animal use, proposals should briefly describe plans for Institutional Animal Care and Use Committee (IACUC) review and approval. Animal studies in the program will be expected to comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, available at <http://grants.nih.gov/grants/olaw/olaw.htm>.

All award recipients must receive approval by a DoD-certified veterinarian, in addition to an IACUC approval. No animal studies may be conducted using DoD/DARPA funding until the United States Army Medical Research and Materiel Command (USAMRMC) Animal Care and Use Review Office (ACURO) or other appropriate DoD veterinary office(s) grant approval. As a part of this secondary review process, the award recipient will be required to complete and submit an ACURO Animal Use Appendix, which may be found at https://mrmc-www.army.mil/index.cfm?pageid=Research_Protections.acuro&n=1.

6.2.4. Export Control

Per DFARS 225.7901-4, all procurement contracts, other transactions and other awards, as deemed appropriate, resultant from this solicitation will include the DFARS Export Control clause (252.225-7048).

6.2.5. Subcontracting

Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. § 637(d)), it is the policy of the Government to enable small business and small disadvantaged business concerns to be considered fairly as subcontractors to contractors performing work or rendering services as prime contractors or subcontractors under Government contracts, and to assure that prime contractors and subcontractors carry out this policy. Each proposer who submits a contract proposal and includes subcontractors is required to submit a subcontracting plan in accordance with FAR 19.702(a) (1) and should do so with their proposal. The plan format is outlined in FAR 19.704.

6.2.6. Electronic and Information Technology

All electronic and information technology acquired through this solicitation must satisfy the accessibility requirements of Section 508 of the Rehabilitation Act (29 U.S.C. § 794d) and FAR 39.2. Each proposer who submits a proposal involving the creation or inclusion of electronic and information technology must ensure that Federal employees with disabilities will have access to and use of information that is comparable to the access and use by Federal employees who are not individuals with disabilities and members of the public with disabilities seeking information or services from DARPA will have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

6.2.7. Employment Eligibility Verification

As per FAR 22.1802, recipients of FAR-based procurement contracts must enroll as federal contractors in E-verify and use the system to verify employment eligibility of all employees assigned to the award. All resultant contracts from this solicitation will include FAR 52.222-54, “Employment Eligibility Verification.” This clause will not be included in grants, cooperative agreements, or Other Transactions.

6.2.8. System for Award Management (SAM) and Universal Identifier Requirements

Unless the proposer is exempt from this requirement, as per FAR 4.1102 or 2 CFR 25.110 as applicable, all proposers must be registered in the System for Award Management (SAM) and have a valid Data Universal Numbering System (DUNS) number prior to submitting a proposal. All proposers must maintain an active registration in SAM with current information at all times during which they have an active Federal award or proposal under consideration by DARPA. All proposers must provide the DUNS number in each proposal they submit.

Information on SAM registration is available at www.sam.gov.

6.2.9. Reporting Executive Compensation and First-Tier Subcontract Awards

FAR clause 52.204-10, “Reporting Executive Compensation and First-Tier Subcontract Awards,” will be used in all procurement contracts valued at \$25,000 or more. A similar award term will be used in all grants and cooperative agreements.

6.2.10. Updates of Information Regarding Responsibility Matters

Per FAR 9.104-7(c), FAR clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters, will be included in all contracts valued at \$500,000 or more where the contractor has current active Federal contracts and grants with total value greater than \$10,000,000.

6.2.11. Representations by Corporations Regarding an Unpaid Delinquent Tax Liability or a Felony Conviction under any Federal Law

The following representation will be included in all awards:

(a) In accordance with section 101(a) of the Continuing Appropriations Act, 2016 (Pub. L. 114-53) and any subsequent FY 2016 appropriations act that extends to FY 2016 funds the same restrictions as are contained in sections 744 and 745 of division E, title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), none of the funds made available by this or any other Act may be used to enter into a contract with any corporation that

(1) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless the agency has considered suspension or debarment of the corporation and made a

determination that this further action is not necessary to protect the interests of the Government; or

(2) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless the agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(b) The Offeror represents that –

(1) It is [] is not [] a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability,

(2) It is [] is not [] a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

6.2.12. Cost Accounting Standards (CAS) Notices and Certification

As per FAR 52.230-2, any procurement contract in excess of the referenced threshold resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR 99), except those contracts which are exempt as specified in 48 CFR 9903.201-1. Any proposer submitting a proposal which, if accepted, will result in a CAS compliant contract, must submit representations and a Disclosure Statement as required by 48 CFR 9903.202 detailed in FAR 52.230-2. The disclosure forms may be found at http://www.whitehouse.gov/omb/procurement_casb.

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

Controlled Unclassified Information (CUI) refers to unclassified information that does not meet the standards for National Security Classification but is pertinent to the national interests of the United States or to the important interests of entities outside the Federal Government and under law or policy requires protection from unauthorized disclosure, special handling safeguards, or prescribed limits on exchange or dissemination. All non-DoD entities doing business with DARPA are expected to adhere to the following procedural safeguards, in addition to any other relevant Federal or DoD specific procedures, for submission of any proposals to DARPA and any potential business with DARPA:

- Do not process DARPA CUI on publicly available computers or post DARPA CUI to publicly available webpages or websites that have access limited only by domain or Internet protocol restriction.
- Ensure that all DARPA CUI is protected by a physical or electronic barrier when not under direct individual control of an authorized user

and limit the transfer of DARPA CUI to subawardees or teaming partners with a need to know and commitment to this level of protection.

- Ensure that DARPA CUI on mobile computing devices is identified and encrypted and all communications on mobile devices or through wireless connections are protected and encrypted.
- Overwrite media that has been used to process DARPA CUI before external release or disposal.

6.2.14. Safeguarding of Covered Defense Information and Cyber Incident Reporting

Per DFARS 204.7304, DFARS 252.204-7012, “Safeguarding of Covered Defense Information and Cyber Incident Reporting,” applies to this solicitation and all FAR-based awards resulting from this solicitation.

6.2.15. Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements

(a) In accordance with section 101(a) of the Continuing Appropriations Act, 2016 (Pub. L. 114-53) and any subsequent FY 2016 appropriations act that extends to FY 2016 funds the same restrictions as are contained in section 743 of division E, title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), none of the funds appropriated (or otherwise made available) by this or any other Act may be used for a contract with an entity that requires employees or subcontractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contactors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(b) The prohibition in paragraph (a) of this provision does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(c) *Representation.* By submission of its offer, the Offeror represents that it does not require employees or subcontractors of such entity seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contactors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

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. 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 materials will also be required as appropriate to document progress in accomplishing program metrics and milestones. 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. Representations and Certifications

In accordance with FAR 4.1201, prospective proposers shall complete electronic annual representations and certifications at <https://www.sam.gov/portal/SAM/>.

6.4.2. Wide Area Work Flow (WAWF)

Unless using another approved electronic invoicing system, performers will be required to submit invoices for payment directly via the internet/WAWF at <http://wawf.eb.mil>. Registration to WAWF will be required prior to any award under this BAA.

6.4.3. 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 (<https://public.era.nih.gov/iedison>).

7. Agency Contacts

Administrative, technical or contractual questions should be sent via email to DARPA-BAA-16-17@darpa.mil. All requests must include the name, email address, and phone number of a point of contact.

- **Technical POC:** Elizabeth Strychalski, Program Manager, DARPA/BTO
- **BAA Coordinator:** DARPA-BAA-16-17@darpa.mil

8. Other Information

8.1. INTELLECTUAL PROPERTY

8.1.1. Procurement Contract Proposers

8.1.1.1 Noncommercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS, shall identify all noncommercial technical data, and noncommercial computer software that it plans to generate, develop, and/or deliver under any proposed award instrument in which the Government will acquire less than unlimited rights, and to assert specific restrictions on those deliverables. Proposers shall follow the format under DFARS 252.227-7017 for this stated purpose. In the event that proposers do not submit the list, the Government will assume that it automatically has “unlimited rights” to all noncommercial technical data and noncommercial computer software generated, developed, and/or delivered under any award instrument. If mixed funding is anticipated in the development of noncommercial technical data, and noncommercial computer software generated, developed, and/or delivered under any award

instrument, then proposers should identify the data and software in question, as subject to Government Purpose Rights (GPR). In accordance with DFARS 252.227-7013 Rights in Technical Data - Noncommercial Items, and DFARS 252.227-7014 Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation, the Government will automatically assume that any such GPR restriction is limited to a period of five (5) years in accordance with the applicable DFARS clauses, at which time the Government will acquire “unlimited rights” unless the parties agree otherwise. Proposers are advised that the Government will use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer’s assertions. If no restrictions are intended, then the proposer should state “NONE.” It is noted an assertion of “NONE” indicates that the Government has “unlimited rights” to all noncommercial technical data and noncommercial computer software delivered under the award instrument, in accordance with the DFARS provisions cited above. Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

A sample list for complying with this request is as follows:

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

8.1.1.2 Commercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS, shall identify all commercial technical data, and commercial computer software that may be embedded in any noncommercial deliverables contemplated under the research effort, along with any applicable restrictions on the Government’s use of such commercial technical data and/or commercial computer software. In the event that proposers do not submit the list, the Government will assume that there are no restrictions on the Government’s use of such commercial items. The Government may use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer’s assertions. If no restrictions are intended, then the proposer should state “NONE.” Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

A sample list for complying with this request is as follows:

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

8.1.2. Non-Procurement Contract Proposers - Noncommercial and Commercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting an Other Transaction for Prototype shall follow the applicable rules and regulations governing that instrument, but in all cases should appropriately identify any potential restrictions on the Government's use of any Intellectual Property contemplated under that award instrument. This includes both Noncommercial Items and Commercial Items. Although not required, proposers may use a format similar to that described in Sections 8.1.1.1 and 8.1.1.2 above. The Government may use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE." Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

8.1.3. All Proposers – Patents

Include documentation proving your ownership of or possession of appropriate licensing rights to all patented inventions (or inventions for which a patent application has been filed) that will be utilized under your proposal for the DARPA program. If a patent application has been filed for an invention that your proposal utilizes, but the application has not yet been made publicly available and contains proprietary information, you may provide only the patent number, inventor name(s), assignee names (if any), filing date, filing date of any related provisional application, and a summary of the patent title, together with either: 1) a representation that you own the invention, or 2) proof of possession of appropriate licensing rights in the invention.

8.1.4. All Proposers-Intellectual Property Representations

Provide a good faith representation that you either own or possess appropriate licensing rights to all other intellectual property that will be utilized under your proposal for the DARPA program. Additionally, proposers shall provide a short summary for each item asserted with less than unlimited rights that describes the nature of the restriction and the intended use of the intellectual property in the conduct of the proposed research.

8.2. PROPOSERS DAY

DARPA will host a Proposers Day in support of the Biological Control program on **Monday, 22 February 2016** in the Arlington, VA area. The purpose is to provide potential proposers with information on the Biological Control program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and to encourage team formation. Interested proposers are not required to attend to respond to the Biological Control BAA, and relevant information and materials discussed at Proposers Day will be made available to all potential proposers in the form of a FAQ posed on the FBO.gov website. This event is not open to the Press. 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://www.sa-meetings.com/BiologicalControlproposersday>.

Participants are required to register no later than **Thursday, 11 February 2016** and will be accepted on a first come first serve basis, subject to room restrictions. The Proposers Day will be

open to members of the public who have registered in advance for the event; there will be no onsite registration. All foreign nationals, including permanent residents, must complete and submit a DARPA Form 60 “Foreign National Visit Request,” which will be provided in the registration confirmation email.

Proposers Day Point of Contact: DARPA-SN-16-19@darpa.mil

9. APPENDIX 1 – Volume II checklist

Volume II, Cost Proposal Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.3.2 beginning on Page 29 of DARPA-BAA-16-17. **This worksheet must be included with the coversheet of the Cost Proposal.**

1. Are all items from Section 4.3.2 (Volume II, Cost Proposal) of DARPA-BAA-16-17 included on your Cost Proposal cover sheet?

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

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

Direct Labor (Labor Categories, Hours, Rates)

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

Indirect Costs/Rates (i.e., overhead charges, fringe benefits, G&A)

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

Materials and/or Equipment

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

Subcontracts/Consultants

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

Other Direct Costs

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

Travel

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

7. Does your cost proposal include a clear justification for the cost of labor (written labor basis-of-estimate (BOE)) providing rationale for the labor categories and hours proposed for each task?

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

If reply is “No”, please explain:

8. Do you have subcontractors/consultants? If YES, continue to question 9. If NO, skip to question 13.

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

9. Does your cost proposal include copies of all subcontractor/consultant technical (to include Statement of Work) and cost proposals?

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

If reply is “No”, please explain:

10. Do all subcontract proposals include the required summary buildup, detailed cost buildup, and supporting documentation (SOW, Bill-of-Materials, Basis-of-Estimate, Vendor Quotes, etc.)?

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

If reply is “No”, please explain:

11. Does your cost proposal include copies of consultant agreements, if available?

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain: