



Broad Agency Announcement
ADvanced Acclimation and Protection Tool for
Environmental Readiness (ADAPTER)
BIOLOGICAL TECHNOLOGIES OFFICE

HR001120S0041

April 2, 2020

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PART I: OVERVIEW INFORMATION

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title** – **ADvanced Acclimation and Protection Tool for Environmental Readiness (ADAPTER)**
- **Announcement Type** – Initial Announcement
- **Funding Opportunity Number** – HR001120S0041
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- **Dates**
 - Posting Date: April 2, 2020
 - Proposal Abstract Due Date and Time: April 29, 2020, 4:00 PM ET
 - Full Proposal Due Date and Time: June 18, 2020; 4:00 PM ET
 - BAA Closing Date: June 18, 2020
 - Proposers' Day: April 15, 2020

<https://beta.sam.gov>
- **Concise description of the funding opportunity** – While jet lag and traveler's diarrhea are inconveniences for an average traveler, they are critical challenges to operational readiness for a warfighter and can be the difference between mission success or failure. To maximize warfighter performance, the ADvanced Acclimation and Protection Tool for Environmental Readiness (ADAPTER) program will develop systems to provide warfighters with control over their own physiology. This program will integrate therapeutic cellular factories and biomolecules into an internal, bioelectronics carrier that the warfighter can signal, as needed, to initiate the production and release of therapies that either eliminate the principal cause of traveler's diarrhea - pathogenic bacteria - or regulate disrupted circadian rhythms caused by jetlag or shift work schedules.
- **Anticipated individual awards** – Multiple awards are anticipated.
- **Types of instruments that may be awarded** – Procurement contract, cooperative agreement, or Other Transaction.
- **Agency contact**

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

1. Funding Opportunity Description

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and 2 CFR § 200.203. Any resultant award negotiations will follow all pertinent law and regulation, and any negotiations and/or awards for procurement contracts will use procedures under FAR 15.4, Contract Pricing, as specified in the BAA.

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

The Biological Technologies Office (BTO) is soliciting innovative proposals to enable the development of hybrid technology (bioelectronics and synthetic biology) for warfighter-controlled, on-demand enhanced management of circadian rhythms and mitigation of gastrointestinal stress caused by pathogenic bacteria. Proposed research should investigate innovative approaches that enable revolutionary advances in science, devices, or systems. Specifically excluded is research that primarily results in incremental improvements to the existing state of practice.

1.1. PROGRAM OVERVIEW

The ADvanced Acclimation and Protection Tool for Environmental Readiness (ADAPTER) program will develop a travel adapter for the human body, an implantable or ingestible bioelectronic carrier that contains therapeutic cellular factories and biomolecules which can provide warfighters control over their own physiology. The integrated system will house multiple capabilities that typically require lengthy preparation or cold chains such as instant antibiotic production, *in vivo* toxin removal from ingested resources, and enhanced warfighter acclimation to jet lag or shift lag. It will alleviate operational limitations imposed by human physiology for two high-priority military needs: (1) entraining the sleep cycle, either to a new time zone or back to a normal sleep pattern after night missions; and (2) eliminating bacteria that cause traveler's diarrhea, a perennial challenge for militaries noted as far back as the Peloponnesian War. ADAPTER will provide a transient, non-genetic means of extending and enhancing warfighter readiness.

Poor sleep can impair warfighter effectiveness by decreasing alertness, causing disorientation, and weakening athletic performance. Current mechanisms for physically adapting circadian rhythms to new environments focus on extensive pre-deployment preparation, sleep hygiene, and exposure to intense light; however, these interventions require precise timing and fixed equipment that can limit maneuverability and are impractical when coordinating large numbers of people. Consequently, such interventions rarely exceed the body's natural acclimation rate of one day for every hour the clock is shifted. Separately, some warfighters, such as pilots and special operators, perform night or extended tempo missions that greatly disrupt sleep and

require a prolonged period afterwards to reset healthy sleep patterns. Managing these warfighter’s circadian rhythm synchrony often results in reliance on chemical methods for wakefulness, which disrupt downstream sleep patterns and lead to exhaustion. Methods that expedite the reestablishment of a healthy sleep cycle would enhance performance, enable deployed warfighters to fight more effectively, and restore function to those whose sleep has been chronically disrupted.

For sustenance, warfighters are expected to rely on transported food, a logistical challenge since each warfighter needs approximately 4.5 lbs of food and 9 lbs of water every day. Pre-packaged meals are currently delivered to the warfighter at substantial cost in money, fuel, and exposure to enemy fire. During field forward deployments, carrying sustenance for several days overloads the warfighter, which can reduce their performance and generate chronic musculoskeletal injuries. Moreover, resupply logistics have not kept pace with increased warfighter mobility. Resources can be limited even with current best practices, forcing the warfighter to rely on local food and water, which can lead to otherwise preventable disease. From 2003 to 2004 in Iraq, roughly 1/3rd of personnel in combat experienced situations where ingesting degraded food was necessary. Consequently, 77% of troops in Iraq and 54% in Afghanistan contracted diarrhea, with 2/5ths of those cases requiring medical attention (Sanders et al., 2005). The challenges of obtaining food are likely to grow in the future as military missions become more dispersed and remote. According to the 2015 National Military Strategy, “We are more likely to face prolonged campaigns than conflicts that are resolved quickly” (Riesberg et al., 2017).

Advances in medical devices and synthetic biology could help address these limitations. The development of *in vivo* bioelectronic medical devices to augment deficient organs has advanced rapidly and now includes open-loop pacemakers to control blood pressure, closed-loop pumps to regulate blood glucose, and subcutaneously implanted circuits to deliver drugs. Additionally, ingestible bioelectronic sensors can now be used to monitor the gastrointestinal tract. These devices have been proven safe and effective and are approved by the U.S. Food and Drug Administration (FDA). Early-stage hybrid bioelectronics and synthetic biology approaches that combine the strengths of both device and synthetic biology show promise; however, these advances have not yet been applied to complicated challenges like circadian rhythm management or traveler’s diarrhea.

ADAPTER will manage a warfighter’s circadian rhythm, halving the time to reestablish normal sleep after a disruption such as jet lag or shift lag. It will also provide safe food and water by eliminating the top five bacterial sources of traveler’s diarrhea. Both will enhance the health and mobility of warfighters.

1.2. TECHNICAL APPROACH AND PROGRAM STRUCTURE

Performers for the ADAPTER program will develop *in vivo*, bioelectronic carriers that maintain and release therapies that provide warfighters control over their own physiology. The program focuses on engineering cells to produce these active therapies either by creating or removing compounds within the body. Developing the therapeutic systems will require two Technical Areas (TAs)—Accurate Therapies (TA1) and Carrier/Communication (TA2). The key technical problems addressed by ADAPTER include (i) hierarchical control systems based on a

bioelectronic “carrier” and cellular factories (engineered mammalian or bacterial cells that can deliver a defined dose or intervention *in vivo*), (ii) molecule production or intervention by the cellular factories at physiologically relevant time points and concentrations, (iii) securable communication through tissue and targeted power transfer, (iv) integration of the carrier and cellular factory into a system for effective *in vivo* interventions, and (v) stabilization of engineered organisms *in vivo*.

To focus this development, performers will choose one of two application tracks: (1) *in vivo* compound delivery to entrain circadian rhythm/restore sleep-cycles or (2) *in vivo* decontamination of food and water from bacterial causes of traveler’s diarrhea. An individual proposal must address both TAs and must address only one application track. Proposers may propose to both tracks but must provide separate proposals; although allowed, this is highly discouraged. To rapidly meet the milestones and metrics for the ADAPTER program TA1, performers should leverage known strategies, solutions, and molecules. **Any proposed therapy should have a published basis: new mechanistic or exploratory therapeutic studies are not of interest.**

Circadian Rhythm Management Track:

Performers will focus on developing mechanisms for *in vivo* production of compounds that entrain circadian rhythms and must address the following requirements:

- Develop at least one *in vivo* generation and delivery mechanism per therapy (≥ 2 therapies) for *in vivo* circadian rhythm entrainment.
- Develop or integrate a sensor that monitors the warfighter’s circadian rhythm.
- Therapies must decrease the time required to entrain a phase-shifted circadian rhythm to local time or a new shift schedule: **20% decrease by the end of Phase I and 50% decrease by the end of Phase II.**
- Therapies must have an additive or synergistic effect on entrainment, either directly on the rate of entrainment or indirectly through some related measurable benefit to the warfighter (i.e., reduction in related side effects).
- Therapies must be released from an integrated system.
- The system interface can guide the warfighter to wear eyewear to block sunlight at key times but cannot provide light therapy.

Decontamination Track:

Performers will focus on developing mechanisms for *in vivo* production of compounds that can remove bacterial threats and must address the following requirements:

- Develop at least one *in vivo* generation and delivery mechanism per *in vivo* therapy (≥ 2 therapies) to eliminate bacterial causes of traveler’s diarrhea.
- *In vivo* decontamination of pathogenic bacteria that cause traveler’s diarrhea. The Defense Health Agency lists these bacterial pathogens of interest: *Campylobacter* species, *Salmonella enterica*, *Shigella* species, Enterotoxigenic *E. coli* (ETEC), Enteroaggregative *E. coli* (EAEC), Enterohemorrhagic *E. coli* (EHEC), and Enteroinvasive *E. coli* (EIEC), Enteropathogenic *E. coli* (EPEC). Proposers may argue for other species. **One species should be degraded by 99% by the end of Phase I; Five**

species should be degraded by 99.9% by the end of Phase II. Species may be degraded either simultaneously or individually as long as they meet the timeline requirements.

- Therapies must be released from an integrated system.

Technical Areas

Each application track will address the same Technical Areas (TAs)—Accurate Therapies (TA1) and Carrier/Communication (TA2)—and will be developed over three phases. During Phase I (24 months), performers must engineer cells to execute the desired biological function. For example, these alterations might direct gut bacteria to generate melatonin to entrain the circadian rhythm or to produce antibiotics to decontaminate food. The delivery of the compound should be physiologically relevant, reproducible, and have an appropriate dose profile. Additionally, teams must develop a bioelectronic carrier, a modular device that can house the engineered cells and compounds (therapies) and deploy these therapies on demand via external activation. During Phase I, testing of the accurate therapies (TA1) **will be in small animals or large animals with the intent to scale up to large animals during Phase II.** Phase I testing of Carrier/Communication (TA2) must be in large animals.

During Phase II (18 month Option), performers must integrate the carrier and the engineered cells into a system that delivers physiologically relevant therapies in a **large animal model** and must successfully apply for a pre-IDE/pre-IND approval(s).

Finally, Phase III (12 month Option) will focus on human trials to demonstrate the safety of components of the ADAPTER system. **Total Time: 4.5 years.**

Technical Area 1: Accurate Therapies

Current implantable drug delivery systems can be limited in that the pre-packaged drugs are necessarily finite in quantity and must be stabilizable. To overcome these limitations, the developed systems must ultimately produce and deliver at least two therapies *in vivo*, necessitating accuracy in both the biological (TA1) and bioelectronic components (TA2). Example delivery mechanisms for the biological component, the living chassis, include bacterial or mammalian cells engineered to release an active biomolecule or, alternatively, release of the engineered cells directly to perform a function such as attacking pathogens. Physiologically relevant quantities must be delivered at precise time points and with necessary speed. Additionally, interventions and therapies must be accurate, reliable, and cease on demand. As mentioned above, to rapidly meet the milestones and metrics for the ADAPTER program, performers should leverage known strategies, solutions, and molecules. **Any proposed therapy should have a published basis: new mechanistic or exploratory studies are not of interest.** Finally, while *in vivo* production of therapies is required, the direct release of stored biomolecules from the system is allowed in order to augment therapy, trigger a kill switch, or otherwise assist in meeting the milestones.

Performers must integrate the biological components with the carrier (TA2) to address the following requirements:

- Interventions and dosing profiles must be relevant to the targeted physiological processes.
- The intervention or therapy produced *in vivo* must be amplified by at least 1:1::(load volume):(released dose) by the end of Phase I and by at least 1:4 by the end of Phase II.
- Interventions and therapies must be controllable by the system.
- All interventions and therapies must be safe and effective for the length of the therapy in small or large animals in Phase I and in large animals in Phase II.
- All engineered cells should have a kill switch or other mechanism to prevent viability beyond the duration of use.

Technical Area 2: Carrier and Communication

Performers will develop innovative carriers (devices/platforms) to maintain TA1 components and, when signaled by an external device controlled by the user, activate therapies. Carriers can be ingested or implanted subcutaneously, must sustain their localization within the body throughout the duration of use, and change shape, self-orient, or otherwise open when activated to release therapies. Testing will use both realistic, *in vitro* models, such as phantom tissues developed by the performers or others, and *in vivo* animal models.

Performers must address the following requirements for integration of carriers with biological interventions:

- Carriers must communicate through live tissue via mechanisms such as radio frequency (RF), ultrasound, magnetic field, etc., that are securable via either highly local signal propagation or through encryption.
- Carriers must remain functional within the relevant biological location *in vivo* (large animals) for the period of intervention, not to be less than 60 days by the end of Phase II.
- Carriers must maintain the viability of the living chassis cells or biomolecules for the duration of use and intervention delivery.
- Carriers must be operational and biocompatible for the duration of use and cause no appreciable harm upon removal (if removal is necessary).

Integration

Both TAs described above must be integrated into a single system that enhances warfighter capabilities through securable, accurate interventions. All proposing teams must address both TAs to ensure a complete system by the end of Phase II. To facilitate this, the teams must identify one or more team members as integrators of the different TA components. Additionally, teams must include milestones for a Preliminary Design Review (PDR) and Critical Design Review (CDR) in Phase I. The PDR should discuss the targeted therapeutics, describe device design and plans for system integration, and review risks and mitigation strategies. The CDR should update and solidify the plans provided in the PDR.

- Performers must develop design plans (PDR, CDR) for the integrated ADAPTER system.
- Performers must develop precise biological therapeutics (TA1) and compatible carriers (TA2) that can be successfully integrated within Phase II. Thus, carriers must house, maintain viability, and activate the therapies in large animals.
- Performers must have a successful pre-IDE/pre-IND submission for Phase III option execution.

Testing of Biocompatibility and Safety by a Contract Research Organization (CRO)

In order for this technology to be adopted, the end user must be assured that the technology is safe, will provide sufficient benefit to justify usage, and is under the user's control. Moreover, the technology should be developed in a fashion that will enable expansion of functionality. While the final system at the program's end will require a suite of at least two services targeting one application track, the long-term vision for ADAPTER is an internal "pharmacy" that could solve additional Department of Defense (DoD) adaptation and acclimation needs.

Proposals must include plans and budget for contracting third party groups to test carrier and intervention biocompatibility (e.g., acute and subacute toxicity), biofouling, and safety during Phases I and II. Proposals must describe the type and number of tests that will be necessary for regulatory evaluation and transition of the technology into humans.

Independent Verification and Validation (IV&V) of the Technology

Throughout the program, the performers will work with an independent verification and validation (IV&V) team established by DARPA. The IV&V team will consist of subject matter experts from the Government, Federally Funded Research and Development Centers (FFRDCs), academia and/or other relevant domains. The IV&V team will test and validate the ability of the ADAPTER technology to respond accurately to the appropriate external communication/activation and elicit a relevant physiological response in large animal models by the end of Phase II.

The milestone and metrics section below describes the schedule for CRO biocompatibility tests and delivery of biological interventions, carriers, integrated systems, and protocols to either the IV&V or CRO team for testing and evaluation.

To avoid potential conflicts of interest, performers for HR001120S0041 will not be allowed to compete for the IV&V contract. HR001120S0041 is not soliciting proposals for IV&V.

Schedule

The ADAPTER program spans 4.5 years and consists of a 24-month Phase I, 18-month Phase II Option, and 12-month Phase III Option. Progress towards the stated goals will be assessed throughout the program. Participation in Phase I does not guarantee funding in the Option Phases; the Government's unilateral determination to exercise an option will be contingent on performance in the previous phase and availability of funds.

During Phase I, performers will develop and demonstrate at least one therapy towards the chosen application track in small or large animals (TA1), and generate a separate carrier that can house, maintain, and deploy the biological therapy in large animals (TA2). By the end of Phase I, performers must demonstrate the ability to maintain the living chassis *in vivo* for at least 10 days, and biocompatibility of the carrier (TA2) in large animals for at least 30 days, and the safety and efficacy of at least one therapy.

During Phase II, performers must scale the developed therapies for use and efficacy in large animal models and integrate the biological components and carrier into a single, externally controlled system. By the end of Phase II, performers must demonstrate the safety and efficacy of at least two therapies, sustained performance of the integrated system in large animal models for at least 60 days, and successfully submit a pre-investigational device exemption (pre-IDE) and pre-investigational new drug (pre-IND) application to the FDA.

During Phase III, performers will complete clinical trials to assess the safety of the system in humans.

1.3. PROGRAM MILESTONES, METRICS, AND DELIVERABLES

Progress toward the program goal will be determined through the use of regular milestones, metrics, and deliverables. The Government specifies the following minimally-required milestones, metrics, and deliverables to bound the effort while still affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problems. Proposers are expected to define additional quantitative and qualitative success criteria as needed. Proposers must clearly and uniquely itemize tasks needed to accomplish planned milestones and deliverables.

Proposals must be written to address milestones in both TAs: Accurate Therapies (TA1) and Carrier and Communications (TA2) with metrics that align to one application track. **Proposals that do not address both technical areas or that attempt to address both application tracks will be considered non-conforming and may be removed from consideration (rejected without review).** The minimum milestones and metrics for each technical area and phase are outlined below. Proposers must explain quantitative success criteria for each milestone, and information on how it will be achieved, in their Statement of Work (SOW). Proposers are also encouraged to identify metrics beyond the minimum defined below.

For ease of reference, all of the technical requirements for each TA are listed for each track. A description of Phases I-III of the circadian rhythm management track is located on pp. 11-13. A description of Phases I-III of the decontamination track is located on pp. 13-16.

Circadian Rhythm Management: Technical Areas, Milestones and Metrics

Phase I (Months 1 through 24)

Phase I, *24 months*, will comprise the development of therapies and the carrier. At the end of Phase I, performers must demonstrate that at least one therapy is effective *in vivo* in small or large animals, and that the carrier can sustain a living chassis *in vivo* in large animals. To accomplish this, performers will demonstrate *in vitro* and *in vivo* production of therapies by the living chassis at physiologically relevant levels and activity, the ability of the carrier (TA2) to maintain a living chassis *in vivo* for at least 10 days, and the biocompatibility of the carrier in large animals for at least 30 days. The living chassis does not need to be controlled by the carrier in this Phase.

Goal: Performers must develop a system that delivers therapies that entrain circadian rhythms, at least one of which was synthesized *in vivo* using an engineered cell (living chassis). Performers must demonstrate that **physiologically relevant** levels are released and that the quantities released are precisely controlled.

Technical Area 1 (TA1): Accurate Therapies

Milestones and Metrics:

- Demonstrate 5-fold **induction of biosynthesis** of one biological therapy *in vitro*. (9 months)
- Demonstrate inducible delivery of **physiologically relevant** quantities of one therapy *in vitro*. (12 months)
- Demonstrate inducible delivery of **effective dose profile** for one therapy *in vitro*. Variability of therapy production or dose is between 50-200%. (15 months)
- Demonstrate inducible biosynthesis and delivery of physiologically relevant quantities of a second biological therapy *in vitro*. (15 months)
- Demonstrate delivery of effective dose profile for the second therapy *in vitro*. Variability of therapy production or dose is between 50-200%. (18 months)
- Demonstrate biosynthesis of at least one therapy in a relevant *in vivo* model- small or large animal. (18 months)
- Demonstrate amplification of at least one therapy is at least 1:1::(load volume):(released dose). (24 months)
- **Demonstrate therapy produces a $\geq 20\%$ reduction in duration to entrain circadian rhythm to local time or a new shift schedule in small or large animals.** (24 months)

Technical Area 2 (TA2): Carrier and Communication

Milestones and Metrics:

- Fabricate initial bioelectronic carrier prototype. (6 months)
- Demonstrate that the carrier maintains the viability of the living chassis for at least 10 days *in vitro*. (9 months)
- Demonstrate initial sensor prototype to monitor circadian rhythm (12 months). An existing commercial product may be adapted if appropriate. (12 months)
- Demonstrate that signals between the prototype and the external controller can propagate through a realistic physiological model (e.g., phantom tissues) with relevant thicknesses. (12 months)
- Demonstrate ability of the carrier to localize within phantom tissue or comparable model system. (12 months)
- Demonstrate specific localization within phantom tissue or comparable model system for ≥ 10 days. (18 months)
- Demonstrate that the carrier maintains $\geq 70\%$ viability of the living chassis in a large animal model for ≥ 10 days. (21 months)
- Demonstrate sensor prototype to monitor circadian rhythm in a large animal model. (21 months)

- **Demonstrate precise and controlled release of ≥ 1 therapy for targeted application in a large animal model. (24 months)**

Testing and Evaluation (CRO):

- Demonstrate biocompatibility for all TA2 components that will be in direct contact with tissue via third party CRO (or similar lab) to test for prolonged biocompatibility (30 days) in a large animal model. TA2 components should undergo tests such as cytotoxicity, acute toxicity, inflammatory response, degradation, and biofouling. (18 months)

Deliverables:

- Preliminary Design Review. (15 months)
- Submit the carrier components to a third party CRO (or similar lab) to test biocompatibility of the carrier in a large animal model for 30 days. (15 months)
- Report from a third party CRO (or similar lab) detailing the results of biocompatibility testing and confirming biocompatibility of the TA2 carrier. (18 months)
- Critical Design Review. (21 months)
- Submit integrated system and associated protocols to a third party CRO (or similar lab) to test safety and efficacy of ≥ 1 biological therapy. Efficacy will be measured by therapeutic or physiological impact. (24 months)

Phase II Option (Months 25 through 42)

Phase II Option, *18 months*, will cover integration of the TAs and refinement of capabilities. By the end of Phase II, the integrated system will demonstrate therapeutic efficacy in a large animal model. Since performance will be measured for the integrated system, the milestones and metrics for the two technical areas are also integrated.

Goal: Production of compounds that entrain circadian rhythms to new time zone or shift work schedules. Integrated system that works *in vivo* producing ≥ 2 physiologically relevant therapies in a large animal model for at least 60 days.

Milestones and Metrics:

- Demonstrate biofouling or fibrosis does not decrease efficacy of the carrier. Variability is within 50–200% of target dose for 10 days *in vivo*. (27 months)
- Demonstrate app-based operational software or GUI interface for external controller enabling precise dosing and controlled therapy deployment. (30 months)
- Demonstrate communication between external controller and integrated system to activate therapies *in vivo*. (30 months)
- Demonstrate delivery of physiologically relevant quantities from a single system *in vivo*. Dosing will decrease entrainment duration by $\geq 25\%$. (30 months)
- Demonstrate on demand complete termination of production within 6 hours. (30 months)
- Demonstrate specific localization of the system within a large animal model for ≥ 60 days. (36 months)
- Demonstrate the system maintains $\geq 90\%$ viability of the TA1 living chassis for ≥ 60 days *in vivo*. (36 months)
- Demonstrate effective delivery profiles of ≥ 2 therapies from integrated system *in vivo*.

- Variability of dosing is between 80-125%. (36 months)
- Submit pre-IND application to the FDA. (39 months)
- Submit pre-IDE application to the FDA. (39 months)
- Demonstrate amplification of at least one therapy is at least 1:4:: (load volume):(released dose). (42 months)
- **Demonstrate therapy released from the integrated system decreases time to entrain circadian rhythm by $\geq 50\%$ in a large animal model. (42 months)**

Testing and Evaluation (CRO and IV&V):

- CRO will demonstrate safety and efficacy of ≥ 1 biological therapy. Efficacy will be measured by therapeutic or physiological impact. (27 months)
- CRO will demonstrate safety and an IV&V team will demonstrate efficacy of ≥ 2 therapies *in vivo* when delivered from TA2 carrier in large animal model. (39 months)

Phase III Option (Months 43 through 54)

Phase III Option, *12 months*, will comprise first-in-human clinical trials to test the safety of TA1 therapies and TA2 carriers regardless of the chosen application track. For simplicity, the components from TA1 and TA2 will be tested and evaluated separately.

Deliverables:

- Report detailing the results of the first-in-human safety study of ≥ 1 therapy or service from TA1 (or IND enabling studies). (54 months)
- Report detailing the results of the first-in-human safety study of the carrier from TA2. (54 months)

Decontamination: Technical Areas, Milestones and Metrics

Phase I (Months 1 through 24)

Phase I, *24 months*, will comprise the development of therapies and the carrier. At the end of Phase I performers must demonstrate that at least one therapy is effective *in vivo* in small or large animals, and that the carrier can sustain a living chassis *in vivo* in a large animal model. To accomplish this, performers will demonstrate *in vitro* and *in vivo* production of therapies by the living chassis at physiologically relevant levels and activity, the ability of the carrier to maintain a living chassis *in vivo* for at least 10 days, and biocompatibility of the carrier in large animals for at least 30 days. The living chassis does not need to be controlled by the carrier in this Phase.

Goal: Removal of bacterial pathogens that cause traveler's diarrhea from contaminated food or water using engineered cells (living chassis) to precisely control synthesis and release of ≥ 1 therapy *in vivo*.

Technical Area 1 (TA1): Accurate Therapies

Milestones and Metrics:

- Demonstrate 5-fold **induction of biosynthesis** of one biological therapy *in vitro*. (9

- months)
- Demonstrate inducible delivery of **physiologically relevant** quantities of one therapy *in vitro*. (12 months)
 - In a mock community, reduce 1 species that causes traveler's diarrhea by 95% *in vitro*. Mock communities must comprise at least 3 different community members in addition to the species causing traveler's diarrhea. (12 months)
 - Demonstrate inducible delivery of **effective dose profile** for one therapy *in vitro*. Variability of therapy production or dose is between 50-200%. (15 months)
 - Demonstrate inducible biosynthesis and delivery of physiologically relevant quantities of a second biological therapy *in vitro*. (15 months)
 - In a mock community, reduce 5 species that cause traveler's diarrhea by 95% *in vitro*. (18 months)
 - Demonstrate delivery of effective dose profile for the second therapy *in vitro*. Variability of therapy production or dose is between 50-200%. (18 months)
 - Demonstrate biosynthesis of at least one therapy in a relevant *in vivo* model. (18 months)
 - Demonstrate amplification of at least one therapy is at least 1:1::(load volume):(released dose). (24 months)
 - Demonstrate in a small animal model that the therapy will not disrupt the beta diversity of the community >10% at 5 days post initiation of therapy. (Alternate measures of disruption may be proposed.) (24 months)
 - ***In vivo* reduction of 1 species that causes traveler's diarrhea by 99% in large or small animal models.** (24 months)

Technical Area 2 (TA2): Carrier and Communication

Milestones and Metrics:

- Fabricate initial bioelectronic carrier prototype. (6 months)
- Demonstrate that the carrier maintains the viability of the living chassis for at least 10 days *in vitro*. (9 months)
- Demonstrate that signals between the prototype and the external controller can propagate through a realistic physiological model (e.g., phantom tissues) with relevant thicknesses. (12 months)
- Demonstrate ability of the carrier to localize within phantom tissue or comparable model system. (12 months)
- Demonstrate specific localization within phantom tissue or comparable model system for ≥ 10 days. (18 months)
- Demonstrate that the carrier maintains $\geq 70\%$ viability of the living chassis in a large animal model for ≥ 10 days. (21 months)
- Demonstrate precise and controlled release of ≥ 1 therapy for targeted application in a large animal model. (24 months)

Testing and Evaluation (CRO):

- Demonstrate biocompatibility for all TA2 components that will be in direct contact with tissue via third party CRO (or similar lab) to test for prolonged biocompatibility (30 days) in a large animal model. TA2 components should undergo tests such as cytotoxicity, acute toxicity, inflammatory response, degradation, and biofouling. (18 months)

Deliverables:

- Preliminary Design Review. (15 months)
- Submit the carrier components to a third party CRO (or similar lab) to test biocompatibility of the carrier in a large animal model for 30 days. (15 months)
- Report from a third party CRO (or similar lab) detailing the results of biocompatibility testing and confirming biocompatibility of the TA2 carrier. (18 months)
- Critical Design Review. (21 months)
- Submit integrated system and associated protocols to a third party CRO (or similar lab) to test safety and efficacy of ≥ 1 biological therapy. Efficacy will be measured by therapeutic or physiological impact. (24 months)

Phase II Option (Months 25 through 42)

Phase II Option, *18 months*, will cover integration of the TAs and refinement of capabilities. By the end of Phase II the integrated system will demonstrate therapeutic efficacy in a large animal model. Since performance will be measured for the integrated system, the milestones and metrics for the two technical areas are also integrated.

Goal: Integrated system that works *in vivo*, producing ≥ 2 physiologically relevant therapies in a large animal model for at least 60 days.

Milestones and Metrics:

- Demonstrate biofouling or fibrosis does not decrease efficacy of the carrier. Variability is within 50–200% of target dose for 10 days *in vivo*. (27 months)
- Reduce 5 species that cause traveler’s diarrhea by 99% *in vivo*. Species may be degraded either simultaneously or individually as long as they meet the timeline requirements. (30 months)
- Demonstrate app-based operational software or GUI interface for precise dosing and controlled therapy deployment. (30 months)
- Demonstrate communication between external device and the system to activate therapies *in vivo*. (30 months)
- Demonstrate on demand complete termination of production within 6 hours. (30 months)
- Demonstrate sustained localization of the system within a large animal model for ≥ 60 days. (36 months)
- Demonstrate the system maintains $\geq 90\%$ viability of the TA1 living chassis for ≥ 60 days *in vivo*. (36 months)
- Demonstrate accurate delivery profiles of ≥ 2 therapies from integrated system *in vivo*. Variability of dosing is between 80-125%. (36 months)
- Reduce 5 species that cause traveler’s diarrhea by 99.9% *in vitro*. (36 months)
- Submit pre-IND application to the FDA. (39 months)
- Submit pre-IDE application to the FDA. (39 months)
- Demonstrate amplification of at least one therapy is at least 1:4:: (load volume):(released dose). (42 months)
- Demonstrate in a large animal model that the therapy will not disrupt the beta diversity of the community $>10\%$ at 3 days post initiation of therapy. (Alternate measures of

disruption may be proposed.) (42 months)

- **Reduce 5 species that cause traveler’s diarrhea by 99.9% in a large animal model. (42 months)**

Testing and Evaluation (CRO and IV&V):

- CRO will demonstrate safety and efficacy of ≥ 1 biological therapy. Efficacy will be measured by therapeutic or physiological impact. (27 months)
- CRO will demonstrate safety and an IV&V team will demonstrate efficacy of ≥ 2 therapies *in vivo* when delivered from TA2 carrier in a large animal model. (39 months)

Phase III Option (Months 43 through 54)

Phase III Option, *12 months*, will comprise first-in-human clinical trials to test the safety of TA1 therapies and TA2 carriers regardless of the chosen application track. For simplicity, the components from TA1 and TA2 will be tested and evaluated separately.

Deliverables:

- Report detailing the results of the first-in-human safety study of ≥ 1 therapy or service from TA1 (or IND enabling studies). (54 months)
- Report detailing the results of the first-in-human safety study of the carrier from TA2. (54 months)

1.4. GENERAL REQUIREMENTS

Proposing Teams

Proposer teams must address both TAs described above which should run in parallel. Consequently, it is expected that the teams will include experts from the multiple disciplines related to the program challenges and goal (e.g., bioelectronic carrier engineering, synthetic biology, control theory, infectious disease or sleep management). Because several different technologies must ultimately work together, teams must identify one or more members as project integrators who will ensure that team members focused on a specific TA are also appropriately working towards the overall program goal. The project integrator should also address all risks specifically associated with integration.

Specific content, communications, networking, and team formation are the sole responsibility of the proposer teams. Proposer teams must submit a single, integrated proposal led by a single Principal Investigator or prime contractor.

Human Subjects Research/Animal Use

Proposers that anticipate involving Human Research Subjects or Animal Use must comply with the approval procedures detailed in [Section 4.2.3](#) of the BAA.

Other Requirements

Performers are expected to attend semi-annual program reviews to provide updates to the DARPA program management team and other ADAPTER performers on progress towards their milestones and scientific goals on the ADAPTER program. Performers will also summarize outstanding challenges and limitations that must still be overcome to achieve the overarching goals of the program.

2. Award Information

2.1. GENERAL AWARD INFORMATION

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

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this solicitation and to make awards without discussions with proposers. The Government also reserves the right to conduct discussions if it is later determined to be necessary. If warranted, portions of resulting awards may be segregated into pre-priced options. Additionally, DARPA reserves the right to accept proposals in their entirety or to select only portions of proposals for award. In the event that DARPA desires to award only portions of a proposal, negotiations may be opened with that proposer. The Government reserves the right to fund proposals in phases with options for continued work, as applicable.

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

Proposers looking for innovative, commercial-like contractual arrangements are encouraged to consider requesting Other Transactions. To understand the flexibility and options associated with Other Transactions, consult <http://www.darpa.mil/work-with-us/contract-management#OtherTransactions>.

In accordance with 10 U.S.C. § 2371b(f), the Government may award a follow-on production contract or Other Transaction (OT) for any OT awarded under this BAA if: (1) that participant in the OT, or a recognized successor in interest to the OT, successfully completed the entire prototype project provided for in the OT, as modified; and (2) the OT provides for the award of a follow-on production contract or OT to the participant, or a recognized successor in interest to the OT.

In all cases, the Government contracting officer shall have sole discretion to select award instrument type, regardless of instrument type proposed, and to negotiate all instrument terms and conditions with selectees. DARPA will apply publication or other restrictions, as necessary, if it determines that the research resulting from the proposed effort will present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Any award resulting from such a determination will include a requirement for DARPA permission before publishing any information or results on the program. For more information on publication restrictions, see the section below on Fundamental Research.

2.2. FUNDAMENTAL RESEARCH

It is DoD policy that the publication of products of fundamental research will remain unrestricted to the maximum extent possible. National Security Decision Directive (NSDD) 189 defines fundamental research as follows:

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

As of the date of publication of this BAA, the Government expects that program goals as described herein may be met by proposers intending to perform fundamental research and does not anticipate applying publication restrictions of any kind to individual awards for fundamental research that may result from this BAA. Notwithstanding this statement of expectation, the Government is not prohibited from considering and selecting research proposals that, while perhaps not qualifying as fundamental research under the foregoing definition, still meet the BAA criteria for submissions. If proposals are selected for award that offer other than a fundamental research solution, the Government will either work with the proposer to modify the proposed statement of work to bring the research back into line with fundamental research or else the proposer will agree to restrictions in order to receive an award.

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

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

efforts are fundamental research and why the proposed efforts should be considered fundamental research.

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

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

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

FFRDCs

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

Government Entities

Government Entities (e.g., Government/National laboratories, military educational institutions, etc.) are subject to applicable direct competition limitations. Government Entities must clearly demonstrate that the work is not otherwise available from the private sector and provide written documentation citing the specific statutory authority and contractual authority, if relevant, establishing their ability to propose to Government solicitations and compete with industry. This information is required for Government Entities proposing to be awardees or subawardees.

Authority and Eligibility

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

3.1.2. Non-U.S. Organizations

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

3.2. ORGANIZATIONAL CONFLICTS OF INTEREST

FAR 9.5 Requirements

In accordance with FAR 9.5, proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and *any* proposed team member (subawardee, consultant). Under this Section, the proposer is responsible for providing this disclosure with each proposal submitted to the BAA. The disclosure must include the proposer's, and as applicable, proposed team member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4.

Agency Supplemental OCI Policy

In addition, DARPA has a supplemental OCI policy that prohibits contractors/performers from concurrently providing Scientific Engineering Technical Assistance (SETA), Advisory and Assistance Services (A&AS) or similar support services and being a technical performer. Therefore, as part of the FAR 9.5 disclosure requirement above, a proposer must affirm whether the proposer or *any* proposed team member (subawardee, consultant) is providing SETA, A&AS, or similar support to any DARPA office(s) under: (a) a current award or subaward; or (b) a past award or subaward that ended within one calendar year prior to the proposal's submission date.

If SETA, A&AS, or similar support is being or was provided to any DARPA office(s), the proposal must include:

- The name of the DARPA office receiving the support;
- The prime contract number;
- Identification of proposed team member (subawardee, consultant) providing the support; and
- An OCI mitigation plan in accordance with FAR 9.5.

Government Procedures

In accordance with FAR 9.503, 9.504 and 9.506, the Government will evaluate OCI mitigation plans to avoid, neutralize or mitigate potential OCI issues before award and to determine whether it is in the Government's interest to grant a waiver. The Government will only evaluate OCI mitigation plans for proposals that are determined selectable under the BAA evaluation criteria and funding availability.

The Government may require proposers to provide additional information to assist the Government in evaluating the proposer's OCI mitigation plan.

If the Government determines that a proposer failed to fully disclose an OCI; or failed to provide the affirmation of DARPA support as described above; or failed to reasonably provide additional information requested by the Government to assist in evaluating the proposer's OCI mitigation plan, the Government may reject the proposal and withdraw it from consideration for award.

3.3. COST SHARING/MATCHING

Cost sharing is not required; however, it will be carefully considered where there is an applicable statutory condition relating to the selected funding instrument. Cost sharing is encouraged where

there is a reasonable probability of a potential commercial application related to the proposed research and development effort.

4. Application and Submission Information

4.1. ADDRESS TO REQUEST APPLICATION PACKAGE

This announcement, any attachments, and any references to external websites herein constitute the total solicitation. If proposers cannot access the referenced material posted in the announcement found at <http://www.darpa.mil>, contact the administrative contact listed herein.

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

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

4.2.1. Proposal Abstract Format

Proposers are strongly encouraged to submit an abstract in advance of a full proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. DARPA will respond to abstracts providing feedback and indicating whether, after preliminary review, there is interest within BTO for the proposed work. DARPA will attempt to reply within 20 calendar days of receipt. Proposals may be submitted irrespective of comments or feedback received in response to the abstract. Proposals are reviewed without regard to feedback given as a result of abstract review. The time and date for submission of proposal abstracts are specified in Part I above.

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

The page limit does NOT include:

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

Abstracts must include the following components:

A. Cover Sheet (does not count towards page limit): Include the administrative and technical points of contact (name, address, phone, fax, e-mail, lead organization). Also

include the BAA number, title of the proposed project, primary subcontractors, estimated cost, duration of the project, and the label “ABSTRACT.”

B. Executive Summary Slide (does not count towards page limit): The slide template is provided as **Attachment 1** to the BAA posted at <https://beta.sam.gov>. Use of this template is required.

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

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

D. Technical Plan: Outline and address all technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate specific milestones (quantitative, if possible) at intermediate stages of the project to demonstrate progress and a brief plan for accomplishment of the milestones.

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

4.2.2. Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal**. All submissions must be written in English with type no smaller than 12-point font. A smaller font may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or

research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. **The maximum page count for Volume I is 35 pages.** The official transmittal letter is not included in the page count. Volume I should include the following components:

NOTE: Non-conforming submissions that do not address both technical areas and/or follow the instructions herein may be removed from consideration (rejected without further review).

a. Volume I, Technical and Management Proposal

Section I. Administrative

A. Cover Sheet (LABELED “PROPOSAL: VOLUME I”) to include:

1. BAA number (HR001120S0041);
2. Lead organization submitting proposal (prime contractor);
3. Type of organization, selected from among the following categories: “LARGE BUSINESS,” “SMALL DISADVANTAGED BUSINESS,” “OTHER SMALL BUSINESS,” “HBCU,” “MI,” “OTHER EDUCATIONAL,” OR “OTHER NONPROFIT”;
4. Proposer’s reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principle Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), e-mail (if available);
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), e-mail (if available);
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*), cooperative agreement, or other transaction;
10. Place(s) of performance, including all subcontractors and consultants;
11. Period of performance;
12. Total funds requested from DARPA, total funds requested per phase and the amount of any cost share (if any);
13. Proposal validity period; AND
14. Date proposal was submitted.

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

B. Official Transmittal Letter.

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

Section II. Detailed Proposal Information

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

- What is the proposed work attempting to accomplish or do?
- How is it done today, and what are the limitations?
- What is innovative in your approach?
- What are the key technical challenges in your approach, and how do you plan to overcome these?
- Who or what will be affected, and what will be the impact if the work is successful?
- How much will it cost, and how long will it take?

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

C. Technical Plan: Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) at intermediate stages of the program to demonstrate progress and a plan for achieving the milestones. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal. Discuss mitigation of technical risk.

D. Management Plan: Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. Resumes count against the proposal page count. Identify a principal investigator for the project. Provide a clear

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

- E. Capabilities:** Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Discuss any work in closely related research areas and previous accomplishments.
- F. Statement of Work (SoW) (does not count towards page limit):** The SoW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. Each phase of the program should be separately defined. The SOW must not include proprietary information. The SoW template is provided as **Attachment 2** to the BAA posted at <https://beta.sam.gov>. Use of this template is required.

For each task/subtask, provide:

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

NOTE: It is recommended that the SOW be developed so that each technical area and Phase of the program is separately defined.

Do not include any proprietary information in the SOW.

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

H. DARPA Embedded Entrepreneur Initiative (optional sub-section; does not count toward page count):

To catalyze the conversion of scientific discovery to impact, the Biological Technologies Office offers applicants the opportunity for additional funding and transition assistance through participation in the Embedded Entrepreneur Initiative. The DARPA Embedded Entrepreneur Initiative will provide additional funding, up to \$250,000, to employ one entrepreneur-in residence or one corporate business development lead. The entrepreneurial lead's ultimate goal is to develop a robust go to market strategy for entering into defense and commercial markets.

All commercialization and transition activities will be timed to suit the Performer's stage of maturity. Often, the Embedded Entrepreneurial work is most useful in year two or three of a Program. Activities conducted can include, but are not limited to; cost modeling, end user engagement, market analysis and mapping, competitive analysis, techno-economic analysis, manufacturing and scale-up strategy, IP securement strategy, and financial plan creation.

Embedded Entrepreneur participants will work closely with DARPA's Commercial Strategy team and their extensive network of U.S. investors, strategic partners, and mentors.

Proposers wishing to participate in the Embedded Entrepreneur Initiative must:

- Include an initial hypothesis describing how the proposed technology will transition from its current state to future integration into a product or capability.
- Include separately costed tasks describing plans to build and refine a viable Go to Market Strategy over the course of the DARPA program. Tasks contributing to the build of a robust Go to Market Strategy can include, but are not limited to; cost modeling, end user engagement, market analysis and mapping, competitive analysis, techno-economic analysis, manufacturing and scale-up strategy, IP securement strategy, and financial plan creation.

Participation in the Embedded Entrepreneur Initiative is voluntary but highly recommended.

Participants are not expected to form a new company or leave their current research positions to pursue transition, but are expected to, throughout the lifecycle of the proposed effort, identify appropriate partners for enabling transition. Embedded Entrepreneur Initiative funding requests should be consistent with the proposed work scope and proposed timeline, but are anticipated to be in the range of \$250,000 per Performer.

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

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

a. Volume II, Cost Management Proposal

Cover Sheet (LABELED “PROPOSAL: VOLUME II”):

1. BAA Number (HR001120S0041);
2. Lead organization submitting proposal;
3. Type of organization, selected among the following categories: “LARGE BUSINESS”, “SMALL DISADVANTAGED BUSINESS”, “OTHER SMALL BUSINESS”, “HBCU”, “MI”, “OTHER EDUCATIONAL”, OR “OTHER NONPROFIT”;
4. Proposer’s reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
9. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;
10. Place(s) of performance, including all subcontractors and consultants;
11. Period of performance;
12. Total proposed cost separated by Task Area and Phase (as defined in Figure 1), and the amount of any cost share (if any);
13. Name, address, and telephone number of the proposer’s cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
14. Name, address, and telephone number of the proposer’s cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
15. Date proposal was prepared;
16. Data Universal Numbering System (DUNS) number (<http://www.dnb.com/get-a-duns-number.html>);
17. Taxpayer ID number (<https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN>);
18. Commercial and Government Entity (CAGE) code (<https://cage.dla.mil/Home/UsageAgree>);
19. Proposal validity period

The Government strongly encourages that proposers use the provided MS Excel™ cost proposal spreadsheet (Attachment 3) in the development of their cost proposals. All tabs and tables in MS Excel™ cost proposal spreadsheet should be developed in an editable format with calculation formulas intact to allow traceability of the cost proposal numbers across the

spreadsheet. This MS Excel™ cost proposal spreadsheet should be used by the prime organization and all subcontractors. In addition to using the MS Excel™ cost proposal spreadsheet, Volume II still must include all other items discussed below that are not covered by the editable spreadsheet. Subcontractor MS Excel™ cost proposal spreadsheets may be submitted directly to the Government by the proposed subcontractor via e-mail to the address in Part I of this BAA. Using the provided MS Excel™ cost proposal spreadsheet will assist the Government in a rapid analysis of your proposed costs and, if your proposal is selected for award, speed up the negotiation and award execution process.

- (1) Total program, per phase (Phase I (Base), Phase II (Option), and Phase III (Option)) and per task cost broken down by major cost items to include:
 - i. **Direct labor** – provide an itemized breakout of all personnel, listed by name or TBD, with labor rate (or salary), labor hours (or percent effort), and labor category. All senior personnel must be identified by name.
 - ii. **Materials and Supplies** – itemized list, which includes description of material, quantity, unit price, and total price. If a material factor is used based on historical purchases, provide data to justify the rate.
 - iii. **Equipment** – itemized list, which includes description of equipment, unit price, quantity, and total price. Any equipment item with a unit price over \$5,000 must include a vendor quote.
 - iv. **Animal Use Costs** – itemized list of all materials, animal purchases, and per diem costs, associated with proposed animal use; include documentation supporting daily rates.
 - v. **Travel** – provide an itemized list of travel costs to include purpose of trips, departure and arrival destinations, projected airfare, rental car and GSA approved per diem, number of travelers, number of days); provide screenshots from travel website for proposed airfare and rental car, as applicable; provide screenshot or web link for conference registration fee and note if the fee includes hotel cost. Conference attendance must be justified, explain how it is in the best interest of the project. **Plan for two (2) DARPA program review meetings per year.**
 - vi. **Other Direct Costs (e.g., computer support, clean room fees)** – Should be itemized with costs or estimated costs. Backup documentation and/or a supporting cost breakdown is required to support proposed costs with a unit price over \$5,000. An explanation of any estimating factors, including their derivation and application, must be provided. Please include a brief description of the proposers' procurement method to be used.
 - vii. **Other Direct Costs** – Consultants: provide executed Consultant Agreement that describes work scope, rate and hours.
 - viii. **Indirect costs** including, as applicable, fringe benefits, overhead, General and Administrative (G&A) expense, and cost of money (see university vs. company specific requirements below).
 - ix. **Indirect costs specific to a University performer: (1) Fringe Benefit Rate** (provide current Department of Health and Human Services (DHHS) or Office of Naval Research (ONR) negotiated rate package; if calculated by other than a rate, provide University documentation identifying fringe

costs by position or HR documentation if unique to each person); (2) **F&A Indirect Overhead Rate** (provide current DHHS or ONR negotiated rate package); (3) **Tuition Remission** (provide current University documentation justifying per student amount); and (4) **Health Insurance/Fee** (provide current University documentation justifying per student amount, if priced separately from fringe benefits with calculations included in the EXCEL cost file).

- x. **Indirect costs specific to a Company performer:** (1) **Fee/Profit** (provide rationale for proposed fee/profit percentage using criteria found in DFARS 215.404-70); and (2) **Fringe Benefit/Labor OH/Material OH/G&A Rates** (provide current Forwarding Pricing Rate Proposal (FPRP) or DCMA/DCAA Forward Pricing Rate Recommendation or Agreement (FPRR or FPRA). If these documents are not available, provide company historical data, preferably two years, minimum of one, to include both pool and expense costs used to generate the rates).
- (2) A summary of total program costs by Phase I, II and III and task.
- (3) An itemization of Subcontracts. All subcontractor cost proposal documentation must be prepared at the same level of detail as that required of the prime. Subcontractor proposals should include Interdivisional Work Transfer Agreements (IWTA) or evidence of similar arrangements (an IWTA is an agreement between multiple divisions of the same organization). The prime proposer is responsible for compiling and providing all subcontractor proposals for the Procuring Contracting Officer (PCO). The proposal must show how subcontractor costs are applied to each phase and task. If consultants are to be used, proposer must provide consultant agreement or other document that verifies the proposed loaded daily/hourly rate.
- (4) An itemization of any information technology (IT) purchase (including a letter stating why the proposer cannot provide the requested resources from its own funding), as defined in FAR Part 2.101.
- (5) A summary of projected funding requirements by month for all phases of the project.
- (6) A summary of tasks that have animal or human use funding.
- (7) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions that could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.
- (8) Identification of pricing assumptions of which may require incorporation into the resulting award instrument (e.g., use of Government Furnished Property/Facilities/Information, access to Government Subject Matter Expert/s, etc.).
- (9) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available).
- (10) Proposers with a Government acceptable accounting system who are proposing a cost-type contract must submit the DCAA document approving the cost accounting system.

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

Subawardee Proposals

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

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

Other Transaction Requests

All proposers requesting an OT must include a detailed list of milestones for each phase of the program (I, II and III). Each milestone must include the following:

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

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

4.2.3. Additional Proposal Information

Proprietary Markings

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

Unclassified Submissions

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

Disclosure of Information and Compliance with Safeguarding Covered Defense Information Controls

The following provisions and clause apply to all solicitations and contracts; however, the definition of “controlled technical information” clearly exempts work considered fundamental research and therefore, even though included in the contract, will not apply if the work is fundamental research.

DFARS 252.204-7000, “Disclosure of Information”

DFARS 252.204-7008, “Compliance with Safeguarding Covered Defense Information Controls”

DFARS 252.204-7012, “Safeguarding Covered Defense Information and Cyber Incident Reporting”

The full text of the above solicitation provision and contract clauses can be found at <http://www.darpa.mil/work-with-us/additional-baa#NPRPAC>.

Compliance with the above requirements includes the mandate for proposers to implement the security requirements specified by National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, “Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations” (see <https://doi.org/10.6028/NIST.SP.800-171r1>) that are in effect at the time the BAA is issued.

For awards where the work is considered fundamental research, the contractor will not have to implement the aforementioned requirements and safeguards. However, should the nature of the work change during performance of the award, work not considered fundamental research will be subject to these requirements.

Human Subjects Research (HSR)/Animal Use

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

Approved Cost Accounting System Documentation

Proposers that do not have a Cost Accounting Standards (CAS) compliant accounting system considered adequate for determining accurate costs that are negotiating a cost- type procurement contract must complete an SF 1408. For more information on CAS compliance, see <http://www.dcaa.mil/cas.html>. To facilitate this process, proposers should complete the SF 1408 found at <http://www.gsa.gov/portal/forms/download/115778> and submit the completed form with the proposal.

Small Business Subcontracting Plan

Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. § 637(d)) and FAR 19.702(a)(1), each proposer who submits a contract proposal and includes subcontractors might be required to submit a subcontracting plan with their proposal. The plan format is outlined in FAR 19.704.

Section 508 of the Rehabilitation Act (29 U.S.C. § 749d)/FAR 39.2

All electronic and information technology acquired or created through this BAA must satisfy the accessibility requirements of Section 508 of the Rehabilitation Act (29 U.S.C. § 749d)/FAR 39.2.

Intellectual Property

All proposers must provide a good-faith representation that the proposer either owns or possesses the appropriate licensing rights to all intellectual property that will be utilized under the proposed effort.

(1) For Procurement Contracts

Proposers responding to this BAA requesting procurement contracts will need to complete the certifications at DFARS 252.227-7017. See <http://www.darpa.mil/work-with-us/additional-baa> for further information. If no restrictions are intended, the proposer should state “none.” The table below captures the requested information:

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

(2) For All Non-Procurement Contracts

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

System for Award Management (SAM) and Universal Identifier Requirements

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

International entities can register in SAM by following the instructions in this link:

https://www.fsd.gov/fsd-gov/answer.do?sysparm_kbid=dbf8053adb119344d71272131f961946&sysparm_search=KB0013221.

4.2.4. Submission Information

DARPA will acknowledge receipt of all submissions and assign an identifying control number that should be used in all further correspondence regarding the submission. DARPA intends to use electronic mail correspondence regarding HR001120S0041. Submissions may not be sent by fax or e-mail; any so sent will be disregarded.

Submissions will not be returned. An electronic copy of each submission received will be retained at DARPA, and all other non-required copies destroyed. A certification of destruction may be requested, provided the formal request is received by DARPA within five (5) business days after notification that a proposal was not selected.

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

Proposal Abstracts (for any award instrument) and Full Proposals (requesting procurement contracts or other transactions) sent in response to HR001120S0041 may be submitted via DARPA's BAA Website (<https://baa.darpa.mil>). Visit the website to complete the two-step registration process. Submitters will need to register for an Extranet account (via the form at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the abstract. Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process be started as early as possible.

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

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

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

For Cooperative Agreements only:

Proposers requesting cooperative agreements must submit proposals through one of the following methods: (1) electronic upload per the instructions at <https://www.grants.gov/applicants/apply-for-grants.html>; or (2) hard-copy mailed directly to DARPA. If proposers intend to use Grants.gov as their means of submission, then they must submit their entire proposal through Grants.gov; applications cannot be submitted in part to Grants.gov and in part as a hard-copy. Proposers using Grants.gov do not submit hard-copy proposals in addition to the Grants.gov electronic submission.

Submissions: Proposers must submit the three forms listed below.

Form 1: SF 424 Research and Related (R&R) Application for Federal Assistance, available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf. This form must be completed and submitted.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et.seq.), the Department of Defense (DoD) is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering or mathematics disciplines. In addition, the National Defense Authorization Act (NDAA) for FY 2019, Section 1286, directs the Secretary of Defense to protect intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security and limit undue influence, including foreign talent programs by countries that desire to exploit United States' technology within the DoD research, science and technology, and innovation enterprise. This requirement is necessary for all research and research-related educational activities. The DoD is using the two forms below to collect the necessary information to satisfy these requirements. Detailed instructions for each form are available on Grants.gov.

The Research and Related Senior/Key Person Profile (Expanded) form will be used to collect the following information for all senior/key personnel, including Project Director/Principal

Investigator and Co-Project Director/Co-Principal Investigator, whether or not the individuals' efforts under the project are funded by the DoD:

- Degree Type and Degree Year.
- Current and Pending Support, including:
 - A list of all current projects the individual is working on, in addition to any future support the individual has applied to receive, regardless of the source.
 - Title and objectives of the other research projects.
 - The percentage per year to be devoted to the other projects.
 - The total amount of support the individual is receiving in connection to each of the other research projects or will receive if other proposals are awarded.
 - Name and address of the agencies and/or other parties supporting the other research projects
 - Period of performance for the other research projects.

Additional senior/key persons can be added by selecting the “Next Person” button at the bottom of the form. Note that, although applications without this information completed may pass Grants.gov edit checks, if DARPA receives an application without the required information, DARPA may determine that the application is incomplete and may cause your submission to be rejected and eliminated from further review and consideration under the BAA. DARPA reserves the right to request further details from the applicant before making a final determination on funding the effort.

Form 2: Research and Related Senior/Key Person Profile (Expanded), available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_KeyPersonExpanded_2_0-V2.0.pdf. This form must be completed and submitted.

Form 3: Research and Related Personal Data, available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_PersonalData_1_2-V1.2.pdf. Each applicant must complete the name field of this form, however, provision of the demographic information is voluntary. Regardless of whether the demographic fields are completed or not, this form must be submitted with at least the applicant's name completed.

Grants.gov Submissions: Grants.gov requires proposers to complete a one-time registration process before a proposal can be electronically submitted. First-time registration can take between three (3) business days and four (4) weeks. For more information about registering for Grants.gov, see <http://www.darpa.mil/work-with-us/additional-baa>.

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

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

Failure to comply with the submission procedures may result in the submission not being evaluated. DARPA will acknowledge receipt of complete submissions via e-mail and assign control numbers that should be used in all further correspondence regarding proposals.

4.3. FUNDING RESTRICTIONS

Not applicable.

4.4. OTHER SUBMISSION INFORMATION

DARPA will post a consolidated Frequently Asked Questions (FAQ) document. To access the posting go to <http://www.darpa.mil/work-with-us/opportunities>. A link to the FAQ will appear under the HR001120S0041 summary. Submit your question(s) via e-mail to ADAPTER@darpa.mil.

5. Application Review Information

5.1. EVALUATION CRITERIA

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

5.1.1. Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, achievable, and complete. The proposed technical team has the expertise and experience to accomplish the proposed tasks. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible.

5.1.2. Potential Contribution and Relevance to the DARPA Mission

The potential contributions of the proposed effort are relevant to the national technology base. Specifically, DARPA's mission is to make pivotal early technology investments that create or prevent strategic surprise for U.S. National Security.

5.1.3. Cost Realism

The proposed costs are realistic for the technical and management approach and accurately reflect the technical goals and objectives of the solicitation. The proposed costs are consistent with the proposer's Statement of Work and reflect a sufficient understanding of the costs and level of effort needed to successfully accomplish the proposed technical approach. The costs for the prime proposer and proposed subawardees are substantiated by the details provided in the proposal (e.g., the type and number of labor hours proposed per task, the types and quantities of materials, equipment and fabrication costs, travel and any other applicable costs and the basis for the estimates).

It is expected that the effort will leverage all available relevant prior research in order to obtain the maximum benefit from the available funding. For efforts with a likelihood of commercial

application, appropriate direct cost sharing may be a positive factor in the evaluation. DARPA recognizes that undue emphasis on cost may motivate proposers to offer low-risk ideas with minimum uncertainty and to staff the effort with junior personnel in order to be in a more competitive posture. DARPA discourages such cost strategies.

5.2. REVIEW OF PROPOSALS

Review Process

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

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

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

Handling of Source Selection Information

DARPA policy is to treat all submissions as source selection information (see FAR 2.101 and 3.104) and to disclose their contents only for the purpose of evaluation. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All DARPA support contractors performing this role are expressly prohibited from performing DARPA-sponsored technical research and are bound by appropriate nondisclosure agreements.

Subject to the restrictions set forth in FAR 37.203(d), input on technical aspects of the proposals may be solicited by DARPA from non-Government consultants/experts who are strictly bound by the appropriate nondisclosure requirements.

Federal Awardee Performance and Integrity Information (FAPIIS)

Per 41 U.S.C. § 2313, as implemented by FAR 9.103 and 2 CFR § 200.205, prior to making an award above the simplified acquisition threshold, DARPA is required to review and consider any information available through the designated integrity and performance system (currently FAPIIS). Awardees have the opportunity to comment on any information about themselves entered in the database, and DARPA will consider any comments, along with other information in FAPIIS or other systems prior to making an award.

6. Award Administration Information

6.1. SELECTION NOTICES

6.1.1. Proposal Abstracts

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

6.1.2. Full Proposals

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

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

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

6.2.2. FAR and DFARS Clauses

Solicitation clauses in the FAR and DFARS relevant to procurement contracts and FAR and DFARS clauses that may be included in any resultant procurement contracts are incorporated herein and can be found at <http://www.darpa.mil/work-with-us/additional-baa>.

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

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

6.2.4. Representations and Certifications

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

6.2.5. Terms and Conditions

For terms and conditions specific to grants and/or cooperative agreements, see the DoD General Research Terms and Conditions (latest version) at <http://www.onr.navy.mil/Contracts-Grants/submit-proposal/grants-proposal/grants-terms-conditions> and the supplemental DARPA-specific terms and conditions at <http://www.darpa.mil/work-with-us/contract-management#GrantsCooperativeAgreements>.

6.3. REPORTING

The number and types of reports will be specified in the award document but will include at a minimum monthly financial status reports, monthly technical status reports, annual reports, and an end-of-phase report. The reports shall be prepared and submitted in accordance with the procedures contained in the award document and mutually agreed on before award. Reports and briefing material will also be required as appropriate to document progress in accomplishing program metrics. A Final Report that summarizes the project and tasks will be required at the conclusion of the performance period for the award, notwithstanding the fact that the research may be continued under a follow-on vehicle.

6.4. ELECTRONIC SYSTEMS

6.4.1. Wide Area Work Flow (WAWF)

Performers will be required to submit invoices for payment directly to <https://wawf.eb.mil>, unless an exception applies. Performers must register in WAWF prior to any award under this BAA.

6.4.2. I-EDISON

The award document for each proposal selected for funding will contain a mandatory requirement for patent reports and notifications to be submitted electronically through i-Edison (<http://public.era.nih.gov/iedison>).

7. Agency Contacts

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

Points of Contact

The BAA Coordinator for this effort may be reached at:

ADAPTER@darpa.mil

DARPA/BTO

ATTN: HR001120S0041

675 North Randolph Street

Arlington, VA 22203-2114

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

8. Other Information

DARPA will host a Proposers Day in support of the ADAPTER program on April 15, 2020 via Webinar. The purpose is to provide potential proposers with information on the ADAPTER program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and encourage team formation.

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

An online registration form and various other meeting details can be found at the registration website, <https://events.sa-meetings.com/ADAPTERProposersDay>.

Participants are required to register no later than **April 10, 2019**. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; there will be no real-time registration.

Proposers Day Point of Contact:
DARPA-SN-20-42@darpa.mil
ATTN: DARPA-SN-20-42

9. APPENDIX 1 – Volume II checklist

**Volume II, Cost Proposal
Checklist and Sample Templates**

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 of HR001120S0041. This worksheet must be included with the coversheet of the Cost Proposal.

1. Are all items from Section 4.2.2 (Volume II, Cost Proposal) of **HR001120S0041** 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: