Broad Agency Announcement

Bridging the Gap Plus (BG+)

BIOLOGICAL TECHNOLOGIES OFFICE

HR001120S0004

October 30, 2019

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- **Federal Agency Name –** Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title –** Bridging the Gap Plus (BG+)
- **Announcement Type –** Initial Announcement
- **Funding Opportunity Number –** HR001120S0004
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- **Catalog of Federal Domestic Assistance Numbers (CFDA) –** 12.910 Research and Technology Development
- **Dates**
    - Posting Date: October 30, 2019
    - Proposal Abstract Due Date and Time: November 25, 2019, at 5pm EST
    - Full Proposal Due Date and Time: January 22, 2020, at 5pm EST
    - BAA Closing Date: January 22, 2020
    - Proposers' Day: November 5-6, 2019

  http://fbo.gov/spg/ODA/DARPA/CMO/DARPA-SN-20-02/listing.html
- **Concise description of the funding opportunity –** The Bridging the Gap Plus (BG+) program will focus on new approaches to treating spinal cord injury by developing systems that address acute injury stabilization, regenerative therapy, and chronic functional restoration.
- **Anticipated individual awards –** Multiple awards are anticipated.
- **Types of instruments that may be awarded –** Procurement contract, grant, cooperative agreement, or Other Transaction.
- **Agency contact**

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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 FedBizOpps website, http://www.fedbizopps.gov/, and the Grants.gov website http://www.grants.gov/. The following information is for those wishing to respond to the BAA.

1.1. PROGRAM OVERVIEW

Spinal cord injury is a complex condition that causes partial or complete loss of function below the location of injury. Those who are injured often face lifelong paralysis and increased long-term morbidity due to factors such as sepsis or functional complications. According to the United States (U.S.) Department of Veterans Affairs, tens of thousands of U.S. veterans live with some form of spinal cord injury. The injury profile is often unique to the individual and typically progresses through three major phases, each with different characteristics. The acute phase (typically 0-48 hours) includes hemorrhage and inflammation at the site of injury, often requiring surgery to minimize secondary injury. The sub-acute phase (typically 2-14 days) follows, during which there is an expanded zone of damage as the cells that were not impacted by the initial injury begin to die within the increasingly cytotoxic environment. The chronic phase (beyond 14 days) exhibits vasculature and neural reorganization, stabilization, and limited nerve regrowth in very specific circumstances.

While considerable research efforts have been devoted toward restorative and therapeutic technologies, significant challenges remain. For example, devices designed for restoring various functions typically do not deliver the appropriate sensory feedback (e.g., proprioception) to the user or the nervous system, thus limiting their effectiveness and usability. With respect to regenerative medicine, efforts have focused on regenerating/repairing nerve projections using electrical stimulation, pharmacology, cell therapy, and scaffolds. These approaches have been difficult to translate into the clinic and do not leverage neuronal feedback mechanisms or biomarker information to track progress and adjust treatment paradigms.

The Bridging the Gap Plus (BG+) program will develop new approaches to treating spinal cord injury by integrating injury stabilization, regenerative therapy, and functional restoration. To achieve this combinatorial approach, BG+ teams will build two systems of implantable and adaptive devices. The first system will reduce injury effects during the acute and subacute phases of spinal cord injury. This system will consist of active devices that will perform real-time biomarker monitoring and intervention to stabilize – and where possible, rebuild – the neural communications pathways at the site of injury, providing the clinician with previously unavailable diagnostic information for automated or clinician-directed interventions. The second

system will primarily address recovery of function in the chronic phase and will involve stimulation and/or recording devices that may be deployed anywhere on the nervous system or relevant end organs to effectively "bridge the gap" of the spinal cord injury.

DARPA is soliciting innovative proposals for the BG+ program that will mitigate the early effects of injury, lead to improved awareness and interactive therapies at the penumbral zone to preserve neural function, and restore multiple functions (e.g., movement/sensation, posture/proprioception, bladder, bowel, respiratory). The final deliverables will adapt to the change in injury profile over time, inform new standards of care for the acute effects of injury, minimize secondary complications, and address the long-term dysfunctions that remain for years after injury.

1.2. TECHNICAL AREAS

BG+ includes two Technical Areas (TAs) that will run concurrently throughout the five-year program. The overall program timeline and technical milestones for the program are listed in Section 1.6.

Proposers must apply to **both** TAs listed below:

Technical Area 1 (TA1). Injury Stabilization and Therapeutic Stimulation
Teams will develop devices that focus on stabilizing and reducing the initial effects of injury during the acute and subacute phases. Teams will focus on the following activities:

- Develop a device/devices that is/are implanted at the injury site (the penumbral zone) to do the following:
    - Track biomarkers specific to spinal cord injury.
    - Provide therapeutic stimulation (e.g., drug delivery, cell therapy, neural stimulation) to drive the regeneration and sustainment of damaged neural tissue
- Develop methods to allow the device to communicate to an external user interface that will provide clinicians and researchers with previously unavailable diagnostic information about the injury site.
- Consider methods that could enable device deployment at medical treatment facilities for military personnel, likely during the acute phase of injury and associated decompression surgery.

Technical Area 2 (TA2). Functional Recovery
Teams will develop systems that focus on functional restoration during the chronic phase of injury. Teams will focus on the following activities:

- Develop embedded devices that can be deployed on the central or peripheral nervous system as well as relevant end organs (e.g., muscles, bladder) to intelligently "bridge the gap" of spinal cord injury.
- Address at least three functions in animals and demonstrate at least two in human research participants. Functions of interest include movement with somatosensory feedback, posture with proprioceptive feedback, bladder, bowel, respiratory, and cardiovascular function.

1.3. PHASE DESCRIPTIONS

Technical Area 1: Injury Stabilization and Therapeutic Stimulation

TA1 | Phase 1 (Base – 18 months): Device Development

Teams will develop the subcomponents (e.g., sensors, stimulators, algorithms) necessary to develop a fully implantable device(s) that will monitor biomarkers at, or near, the site of the spinal cord injury. The subcomponents must be able to provide intervention for therapeutic stimulation to encourage regeneration, either through drug/biologic delivery (e.g., anti-inflammatory, anti-coagulation agents), cell delivery, or neural stimulation (e.g., electrical, optical, or other modalities). To enable animal experiments, Statement of Work milestones must account for the timelines needed for local Institutional Animal Care and Use Committee (IACUC) approval as well as DoD Animal Care and Use Review Office (ACURO) review.

Biomarker tracking and reporting: Proposals must identify the target biomarkers of interest and describe their relevance to spinal cord injury as currently understood. A biomarker is defined as a measurable substance or indicator that provides awareness of the state of the biological tissue of interest. Example biomarkers include physiological signals (e.g., mean arterial pressure, oxygen), markers of inflammation, growth factors, proteins, cytokines, etc. Exploration of new biomarkers is out of scope for this program. However, since research in understanding spinal cord injury is ongoing, proposals must describe how device design will account for future discovery of relevant biomarkers (i.e., changes of the sensor itself). Each tracked biomarker must be unambiguously linked to one specific aspect of the injury or to the state of the injury site. Proposals must describe how the system will report biomarker data and use the information to stabilize the injury site and/or reduce secondary effects. Biomarker information must be delivered to an external user interface and should be delivered directly to the therapeutic component of the device. The external user interface can be an already available device, such as a smart phone or medical computer.

Therapeutic stimulation for regeneration: Proposals must identify the method of providing therapeutic stimulation to encourage neural regeneration. Therapeutic stimulation may include drug delivery, cell therapy, or neural stimulation (e.g., electrical, optical, magnetic, etc.). Stimulation should be informed by one or more biomarkers. Similar to the biomarker tracking component, the proposals must describe how the device design will account for future changes in best practices on how to best respond to the injury and changes in desired therapy (e.g., changes in drugs used or stimulation parameters).

Device characteristics: The final system may include one single device or multiple, networked devices at or near the injury location to effectively monitor the site, dictate intervention, and deliver therapeutic stimulation. Proposals must include a fabrication plan. The plan should indicate how long the system is intended to last, along with a strategy for removal from the patient's body when the device is no longer needed. If the team's selected biomarkers are only relevant for the early phases of injury, biodegradable sensors are in scope, and proposals should describe the mechanism of how the device will biodegrade and be eliminated from the body. Proposers may choose to design a permanent device(s) that will play an active role in the chronic phase of injury. Due to the critical nature of spinal cord injury and the need for diagnostic

imaging, the final TA1 system must be compatible with 1.5 and 3 Tesla clinical Magnetic Resonance Imaging (MRI) scanners. Proposals should describe the safety measures that will be evaluated for the appropriate level of MRI compatibility (MR Conditional or MR Safe) as well as other safety considerations for biocompatibility in the body defined by the appropriate Food and Drug Administration (FDA) guidelines.

Military relevance: Proposals should describe how the system design is amenable to implantation in a stateside civilian trauma hospital as well as a down range combat hospital. The system should be robust enough to be stored and utilized in a combat zone. Proposals should also describe how the design will minimize additional operative time and the need for additional implantation equipment.

Algorithm development: Proposers must describe and justify the class of algorithms that will interpret and provide responses to incoming data from the system. Proposals must also describe and quantify the number of information channels that will be streamed in real time to an external user interface for each biomarker.

Design reviews: Teams must include Statement of Work milestones for a Preliminary Design Review (PDR) and Critical Design Review (CDR) at months 12 and 15 after award, respectively. The PDR should describe device design, plans for system integration, a discussion of the targeted injury type, and a review of risks and mitigation strategies. The PDR should also describe ways to adapt the devices to support a changing scientific biomarker and therapeutic stimulation landscape. The CDR should solidify the plans provided in the PDR and describe early plans for a software development kit (SDK) that will allow interoperability with the system in an open and standardized manner.

Phase 1 demonstration: Teams must demonstrate the performance of their system subcomponents (e.g., sensors, stimulators, algorithms) in an animal model. The demonstration must address the metrics described in Table 1. Key metric definitions are provided in Table 2. Proposals must describe the experiment and justify the choice of animal model for the demonstration, which should include describing the similarities and differences between the animal model and humans. Proposals must also describe how demonstration results are expected to translate into the clinic.

TA1 | Phase 2 (Option – 24 months): Integration and Assessment

Teams will focus on device integration and evaluation of the full system in animal models.

Device integration: Proposers must describe their plan to integrate and demonstrate a fully implantable system. The final system may include separate devices, but they must be functionally integrated. If the TA1 system is designed so that it can inform the TA2 system, proposals should describe how the two systems will communicate. Teams must provide open-source standards for allowing other potential device manufacturers and R&D teams to use, modify, or interact with the technology. To this end, Statement of Work deliverables must include the development of an SDK and a benchtop testbed that is amenable to testing by a third-party, such as an Independent Verification and Validation (IV&V) team.

Regenerative capabilities: Proposals must describe experiments to demonstrate the capability of the integrated system to deliver therapeutic intervention.

Algorithm refinement: Proposals must describe how the team will refine their algorithms to improve system performance.

Regulatory activities: Proposers must describe a plan to engage the FDA early and often throughout the development of their technology. Proposers must plan to submit at least one round of a pre-submission (Investigational Device Exemption [IDE] and/or an Investigational New Drug [IND]) to the FDA. Per FDA guidance, teams must plan to conduct safety and efficacy studies in animals ahead of clinical studies. Proposers must describe these experiments and justify the chosen animal models. Teams must also conduct appropriate longevity (i.e., accelerated aging) tests to quantify the potential lifetime of the system and should justify their chosen test.

Phase 2 demonstration: Teams must demonstrate the performance of their integrated system in animal models. This demonstration must include all chosen biomarkers and therapeutic stimulation modalities. Proposals must justify the animal model for this demonstration and describe how the devices and results shown may translate into the clinic. The demonstration must show the capability of the technology compared to the metrics described in Table 1.

TA1 | Phase 3 (Option – 18 months): Clinical Studies

Team activities will include submission and approval of an IDE and/or an IND from the FDA and a clinical demonstration in at least one human research participant. Challenges include participant recruitment and demonstrating how the technology advances clinical outcomes over current standard of care. Statement of Work milestones must account for the general timelines associated with local Institutional Review Board (IRB) approval as well as DoD Human Research Protection Office (HRPO) review.

Animal studies: Proposers may continue animal studies to continue to prove out the capabilities of the technology. Proposals should describe these experiments and their scientific motivation.

Recruitment plan: Proposers must plan to submit an IDE and/or IND, and proposals should describe a recruitment plan for human research participants. This plan should include a brief overview of inclusion and exclusion criteria, particularly the level of injury and the American Spinal Injury Association grade of the target cohort. Due to challenges in identifying and recruiting participants, teams should present two viable recruitment strategies in the proposal (i.e., different recruitment sites or materials) and must demonstrate collaboration with a strong clinical partner (e.g., a rehabilitation hospital, the U.S. Department of Veteran's Affairs).

Phase 3 demonstration: Teams must demonstrate the performance of the system in at least one human research participant. Proposals must describe the details of the clinical experiment and the anticipated timeline. It is anticipated that the final device will be implanted during the surgical decompression procedure that often happens in the acute phase of spinal cord injury. An acute

demonstration of device function during decompression surgery is within scope, but teams that choose acute experiments should plan to demonstrate system capability in more than one participant. While the device must have the ability to provide therapeutic stimulation and the teams are encouraged to demonstrate this capability, for regulatory reasons the teams may choose to demonstrate the device's ability to monitor biomarkers only. Biomarker data must be transmitted to an external interface per the external information channels metric described in Table 1. Beyond demonstrating performance against the metrics in Table 1, proposals must describe quantitative measures that can demonstrate the improved standard of care that is facilitated by this new system.

Technical Area 2 – Functional Recovery

TA2 | Phase 1 (Base – 18 months): Device Development

Teams must develop the subcomponents (e.g., sensors, stimulators, algorithms) necessary to develop a technology that will provide functional restoration in the chronic phase of injury. To enable animal experiments, Statement of Work milestones must account for the timelines needed for local IACUC approval as well as DoD ACURO review.

Neural interface for functional restoration: Proposals must design a technology that addresses the restoration of at least 3 separate functions. Examples of functions that are in scope include: movement with somatosensory feedback, posture control with proprioceptive feedback, bladder, bowel, respiratory and cardiovascular function. Proposals should describe the advances that their proposed technology provides over state-of-the-art methods. Systems for restoration of movement and posture control must be bidirectional per the Table 2 definition. Systems for bladder, bowel, respiratory, and cardiovascular function must be closed-loop per the definition in Table 2 and should be bidirectional.

Device characteristics: The final deliverable may include one or many devices, as needed, to address each function. The set of devices to address each function will make up a "system". The final program deliverable is a "system of systems" that addresses multiple functions. Proposals must describe a fabrication plan for the system subcomponents, such as a plan for Good Manufacturing Practices (GMP). Early interaction with the FDA must help inform the necessary standards to follow for appropriate device development. Due to the critical nature of spinal cord injury and the need for diagnostic imaging, the final systems much be compatible with 1.5 and 3 Tesla clinical MRI scanners if they will be implanted in the acute or subacute phases of injury. If the systems will be implanted in the chronic phase of injury, they should be compatible with 1.5 and 3 Telsa scanners. Proposals should describe the safety measures that will be evaluated for the appropriate level of MRI compatibility (MR Conditional or MR Safe) as well as other safety considerations for biocompatibility in the body defined by the appropriate FDA guidelines.

Algorithm development: Proposers must describe and justify the algorithms that will be used to provide functional recovery, including neural decoders to interpret neural commands and neural encoders to dictate appropriate stimulation parameters. Proposers should describe algorithmic strategies for selectively recording and stimulating neural circuits or end organs of interest.

Challenges related to movement restoration: Proposers that are planning to address movement restoration must describe their approach to overcome classic issues related to muscle fatigue and the ability to recruit large muscles. These proposers must include a separate experiment in Phase 1 to demonstrate the improvements of their approach over state-of-the-art functional electrical stimulation (e.g., fatigue testing). Ideas that are in scope include the development of novel hardware to facilitate more sophisticated stimulation paradigms, or the use of modalities beyond electrical stimulation (e.g., optical, magnetic, acoustic) that could be approved for human use by the end of the program.

Design reviews: Teams must include Statement of Work milestones for a Preliminary Design Review (PDR) and Critical Design Review (CDR) at months 12 and 15 after contract award, respectively. The PDR should describe device design, plans for system integration, a description of how the system will restore function, a discussion of the targeted injury type, and a review of risks and mitigation strategies. The CDR should solidify the plans provided in the PDR and describe early plans for a software development kit (SDK) that will allow interoperability with the system in an open and standardized manner.

Phase 1 demonstration: Teams must demonstrate the performance of their system subcomponents (e.g., sensors, stimulators, algorithms) in an animal model. System components may be percutaneous at this point in the program. The demonstration must address the metrics described in Table 1. Proposals must describe the experiments and justify the choice of animal model for this demonstration, which includes describing the similarities and differences between the animal model and humans. Proposals must also describe how demonstration results will translate into the clinic.

TA2 | Phase 2 (Option – 24 months): Integration and Assessment

Teams will focus on device integration and evaluation of the full system of systems in animal models. The final system must include embedded devices that do not include percutaneous leads or connectors.

Device integration: Proposals must describe a plan to integrate and demonstrate fully implantable and networked systems. Proposals must describe experiments that will validate the efficacy and validity of the full system of systems to restore multiple functions. Proposals should also describe a plan to develop a higher-level master controller and device communication architecture and hierarchy that can oversee and coordinate between the systems (e.g., shut off bladder system during locomotion). Teams must also conduct longevity (e.g., accelerated aging) tests on the integrated system to quantify its potential lifetime. Proposals must justify their longevity chosen test.

System modularity: To allow for the technology to address additional categories of functional restoration in the future, the team's system must be modular. Proposals must describe a technical plan for allowing additional neuroprosthetic components to be added to or removed from the system (i.e., devices to address new functions). Teams must provide open-source standards for allowing other potential device manufacturers and R&D teams to use, modify, or interact with the technology. To this end, Statement of Work deliverables must include the development of an

SDK and a benchtop testbed that is amenable to testing by a third-party, such as an Independent Verification and Validation (IV&V) team.

Algorithm refinement: Proposals must describe how the team will refine their algorithms to improve system performance.

Regulatory activities: Proposers must describe a plan to engage the FDA early and often throughout the development of their technology. Proposers must plan to submit at least one round of a pre-submission (IDE and/or IND) to the FDA. Per FDA guidance, teams must conduct safety and efficacy studies in animals in this Phase. Proposers must describe these series of experiments, including a description of the specific animal models to be used.

Phase 2 demonstration: At the end of Phase 2, teams must demonstrate the performance of their integrated system in animal models. Proposals must justify the animal model for this demonstration and describe how the devices and results shown may translate into the clinic. The demonstration must show the capability of the technology compared to the metrics described in Table 1.

TA2 | Phase 3 (Option – 18 months): Clinical Studies

Team activities will include submission and approval of an IDE and/or IND from the FDA and clinical experiments. While the proposals must describe plans to demonstrate recovery of all 3 chosen functions, teams will demonstrate 2 functions in a human research participant. The top 2 functions will be chosen by DARPA based on the results presented during the Phase 2 demonstration. Challenges in Phase 3 will include participant recruitment and demonstrating how the technology advances clinical outcomes over current standard of care. Statement of Work milestones must account for the general timelines associated with local IRB approval as well as DoD HRPO review.

Animal studies: Proposers may continue animal studies in this phase to continue to prove out the capabilities of the technology. Proposals should describe these experiments and their scientific motivation.

Recruitment plan: Proposers must plan to submit an IDE and/or IND, and proposals should describe a recruitment plan for human research participants. This plan should include a brief overview of inclusion and exclusion criteria, particularly the level of injury and the American Spinal Injury Association grade of the target cohort. Due to challenges in identifying and recruiting participants, teams should present two viable recruitment strategies in the proposal (i.e., different recruitment sites or materials) and must demonstrate collaboration with a strong clinical partner (e.g., a rehabilitation hospital, the U.S. Department of Veteran's Affairs).

Phase 3 demonstration: Teams must demonstrate the performance of the final technology in a human research participant by the end of the program. Teams are encouraged to demonstrate all the technology in a single participant but may demonstrate each system in separate participants for regulatory reasons. If the team will combine system use with rehabilitation, the proposal should outline the general exercise protocol. Proposals must describe and justify the anticipated

experimental timeline (e.g., number of weeks or months). Beyond demonstrating performance against the metrics in Table 1, proposals must describe quantitative measures that will be used to demonstrate the functional improvements that will be facilitated by the final deliverable.

1.4. KEY PROGRAM COMPONENTS

Proposals must include a strategic plan for the key program components described below.

Ethical, Legal, and Societal Implications (ELSI)

Proposers must include an ELSI section in the proposal that discusses the salient considerations associated with the study. Proposers should consider and discuss the ethical treatment of both animals and human research participants, and may include a budget for research animal retirement where possible. Proposers are encouraged to embed an ethical consultant on their team who can facilitate ELSI discussions. The ethical consultant may be a trainee (e.g., ethics graduate student) who helps with or attends experiments throughout the program in order to remain knowledgeable on the project.

Neural Data Security

Proposers must describe their plan for protecting data transfer and stimulation protocols, especially when data is wirelessly transmitted to and from the user.

Transition Strategy

Proposals must describe a detailed Technology Transition Plan to transition BG+ technologies for further development or to larger clinical trials. Proposers should identify potential transition partners and provide a timeline for discussion and collaboration with relevant parties. To increase the likelihood of technology transition, the Technology Transition Plan should describe transition for the fully embedded version of the system as well as a less invasive approach to achieving similar outcomes.

As part of the Technology Transition Plan, proposers should also consider the cost-effectiveness of the final system, which may contribute to wider adoption of the technology. Proposers are encouraged to interface with the Center for Medicare and Medicaid Services (CMS) early and often during technology development.

1.5. PROGRAM METRICS

Although the following program metrics are specified, proposers should note that the Government has identified these goals with the intention of bounding the scope of effort, while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problem. Proposals and Statements of Work should include the quantitative and qualitative success criteria that the proposed effort will achieve at each Phase end. Table 1 below outlines the BG+ program end-of-phase metrics, and Table 2 provides detailed definitions for each metric.

Table 1. BG+ End-of-Phase Metrics

Technical Areas	**Phase 1 (18 Mo)** Device Development	**Phase 2 (24 Mo)** Integration and Assessment	**Phase 3 (18 Mo)** Clinical Studies
TA 1: Injury stabilization and therapeutic stimulation	**Biomarkers tracked** ≥ 3 **Therapeutic stimulation channels** ≥ 3 (e.g. electrical stim, drug elution) **Sensor accuracy** within ± 20% of ground truth concentration **Sensor precision** within ± 20% signal coefficient of variation	**Fully implantable device** **Sampling rate** ≥ Nyquist for relevant biomarker **Therapeutic stimulation latency** ≤ kinetics of the stimulation modality **MRI compatibility** implants compatible with 1.5 and 3T	**Clinical transition** ≥ 1 clinical sponsor **External information channels** ≥ 1 per biomarker
TA 2: Functional recovery	**# of functions addressed in animals** ≥3 bidirectional **Full system channel count** ≥ 64 ch **System latency** 50 ms	**System latency** 10 ms **Longevity studies** implanted components >10 year life **Functional improvement in animals** 3x over baseline (e.g. respiration: from 3 to 9 unassisted breaths/min)	**Clinical transition** ≥ 1 clinical sponsor **# of functions addressed in humans** ≥ 2 **Functional improvement in humans** 3x over baseline

Table 2. Definitions

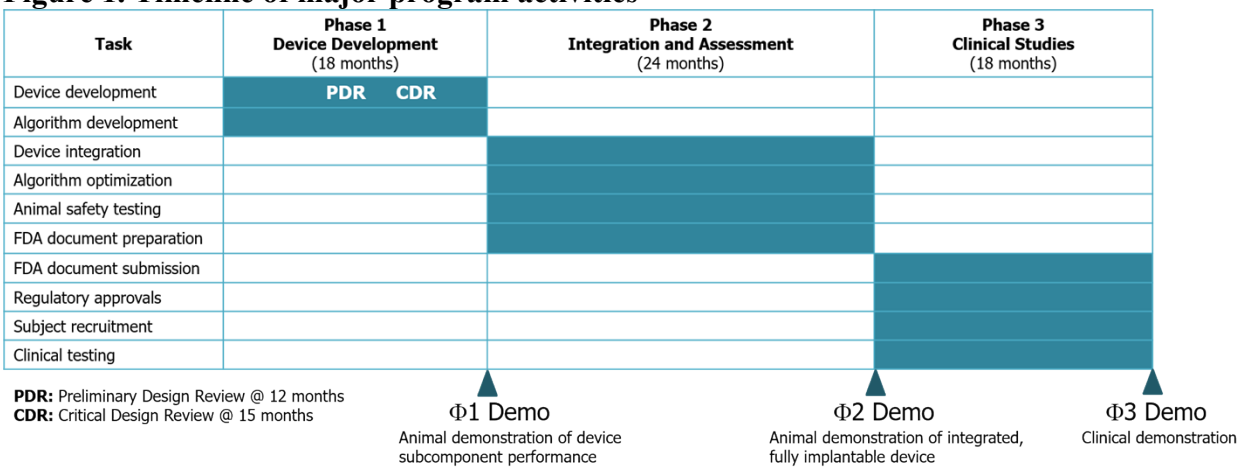
Number of functions addressed	Examples of categories of function include: Movement with somatosensory feedback, posture with proprioceptive feedback, bladder, bowel, respiratory and cardiovascular function. Systems for restoration of movement and posture-control must be bidirectional. Systems for bladder, bowel, respiratory, and cardiovascular function must be closed-loop and should be bidirectional.
Bidirectional system	A bidirectional system uses neural commands for control and provides appropriate feedback about the system's state back to the nervous system via nerve, spinal cord or brain stimulation.
Biomarkers tracked	The device(s) will monitor biomarkers that have relevance to spinal cord injury. A biomarker here is defined as a measurable substance or indicators that provide awareness of the state of the biological tissue of interest. Example biomarkers include physiological signals (e.g. mean arterial pressure, oxygen), markers of inflammation, growth factors, proteins, cytokines, et cetera.
Clinical transition	Proposers must identify and substantiate a relationship with clinical transition partner who will support further technological development and/or larger clinical trials.
Closed-loop system	A closed-loop system is one that can provide **automated** control or intervention for a given system based on its state (e.g. signals from the relevant end effector such as bladder pressure).
External information channels	External information channels are biomarker data that are delivered to an external user interface to be evaluated by a clinician and/or researcher.
Full system channel count	The total channel count of the different devices used for TA2 must meet or exceed 64. The channels may be divided among the devices and separated into recording/stimulating/full-duplex channels as deemed appropriate by the team.
Functional improvement	For each function addressed by the TA2 system, proposers must describe a key baseline measure (e.g. number of unassisted breaths/minute, standing time) and justify how it is functionally relevant. The restored function must be 3x this baseline measure. If the baseline capability is zero, Proposers must quantify the amount of recovery and demonstrate its functional relevance using a clinically accepted metric.
Longevity studies	Proposers must choose and justify an appropriate longevity (e.g. accelerated aging) test to demonstrate that the system is robust in vivo.

MRI compatible implants	Proposers must demonstrate that the TA1 and TA2 device can safely function (e.g., minimal tissue heating), in both a 1.5T and a 3T MRI scanner.
Fully implantable device	Sensors and stimulators must be embedded within the body without percutaneous leads are connectors. Processors should be embedded but may be external.
Sampling rate	Proposers must identify the appropriate time course for each individual biomarker and demonstrate that the device can monitor each biomarker with an appropriate sampling rate.
Sensor accuracy	Sensor accuracy is agreement between reported value and a ground truth value. Proposals must define and justify the chosen technology for ground truth determination in an animal model.
Sensor precision	Sensor precision is the variability across replicate measurements, to include within assay variability, repeatability (within-day variability), and reproducibility (day-to-day variability).
System latency	The system must be able to record residual commands and stimulate the injured circuit within the defined latency.
Therapeutic stimulation channels	Therapeutic stimulation must encourage regrowth of injured neurons. Therapeutic stimulation may be in the form of drug delivery, cell therapy (e.g. growth factors, stem cells), or neural stimulation (e.g. electrical, optical, or other modalities). Teams may choose one or multiple types of stimulation modalities.
Therapeutic stimulation latency	Proposers must define the intervention's window of therapeutic efficacy and demonstrate how the device(s) will deliver stimulation within an appropriate time course.

1.6. PROGRAM TIMELINE AND TECHNICAL MILESTONES

A snapshot of the high-level program activities is shown in Figure 1 below.

Figure 1. Timeline of major program activities



Major technical milestones with the associated month after contract (MAC) are outlined below:

Phase 1: Device Development

- Early feasibility tests for each sensor/stimulator at MAC 6
- Preliminary Design Review at MAC 12
- Critical Design Review at MAC 15
- Phase 1 final demo and final report at MAC 18

Phase 2: Integration and Assessment

- Initiate safety studies at MAC 28
- Pre-IDE/Pre-IND Submission at MAC 36
- Deliverable of software development kit (SDK) and benchtop testbed at MAC 40
- Phase 2 demo and final report at MAC 42

Phase 3: Clinical Studies

- Submit IDE/IND at MAC 44
- Initiate first clinical study at MAC 52
- Release updated SDK at MAC 60
- Phase 3 demo and final report at MAC 60

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. CONTACT AND FORM OF APPLICATION SUBMISSION

All submissions, including abstracts and proposals, must be written in English with type no smaller than 12-point font. Smaller font may be used for figures, tables, and charts. The page limitations include all figures, tables, and charts.

4.2.1. Proposal Abstract Format

Proposers are strongly encouraged to submit an abstract in advance of a proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. 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 30 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 **8 pages** including all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11-inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal abstract title.

The page limit does NOT include:

- Official transmittal letter (optional);
- Cover sheet;
- Executive summary slide;
- 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. Goals and Impact: Clearly describe what is being proposed and what difference it will make (qualitatively and quantitatively), including brief answers to the following questions:

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

C. Executive Summary Slides: The slide template is provided as **Attachment 1** to the BAA posted at http://www.fbo.gov. Use of this template is required.

D. Technical Plan: Briefly address the BAA technical areas and challenges inherent in the approach and possible solutions for overcoming potential problems. Provide specific objectives, metrics, and milestones at intermediate stages of the project to demonstrate a plan for accomplishment of the program goals. Provide a description of system design including the anticipated location of the interfaces and how they will influence the appropriate system (theory of operation). List the potential biomarkers and functions to be addressed. Propose additional appropriate qualitative and quantitative metrics specific to the approach as needed. Outline of intermediary milestones should occur at no greater than 6-month increments. Address anticipated approach safety and regulatory challenges. Identify tentative collaborators and their areas of expertise.

E. Management and Capabilities: Provide a brief summary of expertise of the team, including subcontractors and key personnel.

A principal investigator for the project must be identified, along with a description of the team's organization (including a breakdown by TA). All teams are strongly encouraged to identify a Project Manager/Integrator to serve as the primary point of contact to communicate with the DARPA Program Manager, IV&V partner, and Contracting Officer's Representative, coordinate the effort across co-performer, vendor, and subcontractor teams, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables.

Include a description of the team's organization including roles and responsibilities. Team member descriptions should address the Technical Plan, describe the time and percent effort divisions for members participating across multiple TAs, and delineate individuals to avoid duplication of efforts.

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. Describe any specialized facilities to be used as part of the project, the extent of access to these facilities, and any biological containment, biosafety, and certification requirements.

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

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.** The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an

attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. **The maximum page count for Volume 1 is 35 pages.** The official transmittal letter is not included in the page count. Volume I should include the following components:

NOTE: Non-conforming submissions that do not address both Technical Areas and/or follow the instructions herein may be rejected without further review.

a. Volume I, Technical and Management Proposal

Section I. Administrative

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

1. BAA number (HR001120S0004);
2. Lead organization submitting proposal (prime contractor);
3. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
4. Proposer's reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principle Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), grant, 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 Slides: The slide template is provided as **Attachment 2** to the BAA posted at http://www.fbo.gov. Use of this template is required.

Section II. Detailed Proposal Information

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

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

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

C. Technical Plan: Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) at intermediate stages of the program to demonstrate progress, plan for achieving the milestones, and must include a simple process flow diagram of their final system concept. 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. This section should also include the ELSI and Neural Data Security plans.

D. Management Plan: Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. A Principal Investigator (PI) for the project must be identified, along with a description of the team organization including the breakdown by Technical Area. All teams are strongly encouraged to identify a Project Manager/Integrator to serve as the primary point of contact to communicate with the DARPA Program Manager, IV&V partner, and Contracting Officer's Representative, coordinate the effort across co-performer, vendor, and subcontractor teams, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables.

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. Describe any specialized facilities to be used as part of the project, the extent of access to these facilities, and any biological containment, biosafety, and certification requirements. Discuss any work in closely related research areas and previous accomplishments.

F. Statement of Work (SOW) NOT INCLUDED IN PAGE COUNT: The SOW should provide a detailed task breakdown, citing specific tasks for each Technical Area, and their connection to the milestones and program metrics. Each phase of the program should be separately defined. The SOW must not include proprietary information. It is encouraged, though not required, to use the SOW template provided as **Attachment 3**. SOW is not included in the Volume 1 page count.

For each task/subtask, provide:

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

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

It is recommended that the SOW be developed so that each Technical Area and Phase of the program is separately defined.

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. Technology Transition Plan: Provide information regarding the types of partners (e.g., government, private industry) that will be pursued and submit a timeline with incremental milestones toward successful engagement (see Section 1.4: Key Program Components). The plan should include a description of how DARPA will be included in the development of potential technology transfer relationships. If the Technology Transfer Plan includes the formation of a start-up company, a business development strategy must also be provided.

a. Volume II, Cost Management Proposal

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

1. BAA Number (HR001120S0004);
2. Lead Organization Submitting proposal;
3. Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
4. Proposer's reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), grant, cooperative agreement, or Other Transaction;
10. Place(s) of performance, including all subcontractors and consultants;

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

The Government strongly encourages that proposers use the provided MS Excel™ cost proposal spreadsheet 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 per General Services Administration (GSA) approved diem, number of travelers, number of days); provide screenshots from travel website for proposed airfare and rental car, as applicable; provide screenshot or web link for conference registration fee and note if the fee includes hotel cost. Conference attendance must be justified, explain how it is in the best interest of the project. **Plan for two (2) DARPA program review meetings per year.**

vi. **Other Direct Costs (e.g., computer support, clean room fees) –** Should be itemized with costs or estimated costs. Backup documentation and/or a supporting cost breakdown is required to support proposed costs with a unit price over $5,000. An explanation of any estimating factors, including their derivation and application, must be provided. Please include a brief description of the proposers' procurement method to be used.

vii. **Other Direct Costs** – Consultants: provide executed Consultant Agreement that describes work scope, rate and hours.

viii. **Indirect costs** including, as applicable, fringe benefits, overhead, General and Administrative (G&A) expense, and cost of money (see university vs. company-specific requirements below).

ix. **Indirect costs specific to a University performer:** (1) **Fringe Benefit Rate** (provide current Department of Health and Human Services (DHHS) or Office of Naval Research (ONR) negotiated rate package; if calculated by other than a rate, provide University documentation identifying fringe costs by position or HR documentation if unique to each person); (2) **F&A Indirect Overhead Rate** (provide current DHHS or ONR negotiated rate package); (3) **Tuition Remission** (provide current University documentation justifying per-student amount); and (4) **Health Insurance/Fee** (provide current University documentation justifying per student amount, if priced separately from fringe benefits with calculations included in the EXCEL cost file).

x. **Indirect costs specific to a Company performer:** (1) **Fee/Profit** (provide rationale for proposed fee/profit percentage using criteria found in DFARS 215.404-70); and (2) **Fringe Benefit/Labor OH/Material OH/G&A Rates** (provide current Forwarding Pricing Rate Proposal (FPRP) or DCMA/DCAA Forward Pricing Rate Recommendation or Agreement (FPRR or FPRA). If these documents are not available, provide company historical data, preferably two years, minimum of one, to include both pool and expense costs used to generate the rates).

(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 (OT) 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) complaint accounting system considered adequate for determining accurate costs that are negotiating a cost- type procurement contract must complete an SF 1408. For more information on CAS compliance, see http://www.dcaa.mil/cas.html. To facilitate this process, proposers should complete the SF 1408 found at http://www.gsa.gov/portal/forms/download/115778 and submit the completed form with the proposal.

Small Business Subcontracting Plan

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

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

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

Grant Abstract

Per Section 8123 of the Department of Defense Appropriations Act, 2015 (Pub. L. 113-235), all grant awards must be posted on a public website in a searchable format. To comply with this requirement, proposers requesting grant awards must submit a maximum one (1) page abstract that may be publicly posted and explains the program or project to the public. The proposer should sign the bottom of the abstract confirming the information in the abstract is approved for public release. Proposers are advised to provide both a signed PDF copy, as well as an editable (e.g., Microsoft word) copy. Abstracts contained in grant proposals that are not selected for award will not be publicly posted.

Intellectual Property

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

For Procurement Contracts

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

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

For All Non-Procurement Contracts

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

System for Award Management (SAM) and Universal Identifier Requirements

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

International entities can register in SAM by following the instructions in this link: https://www.fsd.gov/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 HR001120S0004. 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 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.

All Proposal Abstracts, and Full Proposals requesting procurement contracts or Other Transactions, sent in response to HR001120S0004 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 Grants or Cooperative Agreements only:

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

Submissions: Proposers must submit the three forms listed below.

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

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. A§ 1681 Et. Seq.), the Department of Defense is using the two forms below to collect certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, or mathematics disciplines. Detailed instructions for each form are available on Grants.gov.

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

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

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

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

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

Failure to comply with the submission procedures may result in the submission not being evaluated. DARPA will acknowledge receipt of complete submissions via 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 HR001120S0004 summary. Submit your question(s) via e-mail to BGPlus@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; 5.1.3 Cost Realism; 5.1.4 Realism of Proposed Schedule; and 5.1.5 Plans and Capabilities to Accomplish Technology Transition.

5.1.1. Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, achievable, and complete.
The proposed technical team has the expertise and experience to accomplish the proposed tasks. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible. The timeline for achieving major milestones is aggressive but rationally supported with a clear description of the requirements and risks. The proposer's prior experience in similar efforts must clearly demonstrate an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule.

5.1.2. Potential Contribution and Relevance to the DARPA Mission

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

5.1.3. Cost Realism

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

It is expected that the effort will leverage all available relevant prior research in order to obtain the maximum benefit from the available funding. For efforts with a likelihood of commercial application, appropriate direct cost sharing may be a positive factor in the evaluation. DARPA recognizes that undue emphasis on cost may motivate proposers to offer low-risk ideas with minimum uncertainty and to staff the effort with junior personnel in order to be in a more competitive posture. DARPA discourages such cost strategies.

5.1.4. Realism of Proposed Schedule

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

5.1.5. Plans and Capability to Accomplish Technology Transition

The proposer clearly demonstrates its capability to transition the technology to the research, industrial, and/or operational military communities in such a way as to enhance U.S. defense. In addition, the evaluation will take into consideration the extent to which the proposed intellectual property (IP) rights will potentially impact the Government's ability to transition the technology.

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

6.1.2. Full Proposals

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

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

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

6.2.1. FAR and DFARS Clauses

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

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

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

6.2.3. Representations and Certifications

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

6.2.4. Terms and Conditions

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

6.3. REPORTING

The number and types of reports will be specified in the award document, but will include as a minimum monthly financial status reports, 6-week technical status reports, and quarterly technical status reports. The reports shall be prepared and submitted in accordance with the procedures contained in the award document and mutually agreed on before award. Reports and

briefing material will also be required as appropriate to document progress in accomplishing program metrics. A Final Report that summarizes the project and tasks will be required at the conclusion of the performance period for the award, notwithstanding the fact that the research may be continued under a follow-on vehicle.

6.4. ELECTRONIC SYSTEMS

6.4.1. Wide Area Work Flow (WAWF)

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

6.4.2. I-EDISON

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

7. Agency Contacts

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

Points of Contact

The BAA Coordinator for this effort may be reached at:
BGPlus@darpa.mil
DARPA/BTO
ATTN: HR001120S0004
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 Bridging the Gap Plus (BG+) program on November 5-6, 2019, in Arlington, VA. The purpose is to provide potential proposers with information on the BG+ 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 BG+ BAA, and relevant information and materials discussed at Proposers Day will be made available to all potential proposers in the form of a FAQ posted on the DARPA Opportunities Page.

DARPA will not provide cost reimbursement for interested proposers in attendance. An online registration form and various other meeting details can be found at the registration website, insert link.

Participants are required to register no later than October 29, 2019, 12:00 PM ET. We will continue to accept webinar only registrations through November 1, 2019, or until webinar capacity is reached, whichever comes first. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; there will be no onsite registration.

Proposers Day Point of Contact:
DARPA-SN-20-02@darpa.mil
ATTN: DARPA-SN-20-02

9. APPENDIX 1 – Volume II checklist

Volume II, Cost Proposal
Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 beginning on Page 36 of HR001120S0004. 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 **HR001120S0004** 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)
   f○ **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: