



Broad Agency Announcement
Bioelectronics for Tissue Regeneration (BETR)
BIOLOGICAL TECHNOLOGIES OFFICE
HR001119S0027
February 22, 2019

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PART I: OVERVIEW INFORMATION

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title** – Bioelectronics for Tissue Regeneration
- **Announcement Type** – Initial Announcement
- **Funding Opportunity Number** – HR001119S0027
- **North American Industry Classification System (NAICS)** – 541714
- **Catalog of Federal Domestic Assistance Numbers (CFDA)** – 12.910 Research and Technology Development
- **Dates**
 - Posting Date: February 22, 2019
 - Proposal Abstract Due Date and Time: March 21, 2019, 4:00 ET
 - Full Proposal Due Date and Time: April 18, 2019, 4:00 PM ET
 - BAA Closing Date: April 18, 2019
 - Proposers' Day: March 1, 2019

<https://fbo.gov/spg/ODA/DARPA/CMO/DARPA-SN-19-24/listing.html>
- **Concise description of the funding opportunity** – DARPA believes that recent advances in biosensors, actuators, and artificial intelligence could be extended and integrated to dramatically improve tissue regeneration. To achieve this, the new Bioelectronics for Tissue Regeneration (BETR) program asks researchers to develop bioelectronics that closely track the progress of the wound and then stimulate healing processes in real time to optimize tissue repair and regeneration.
- **Anticipated individual awards** – Multiple awards are anticipated.
- **Types of instruments that may be awarded** – Procurement contract, cooperative agreement, or other transaction.
- **Any cost sharing requirements** – Cost sharing may be required under applicable statutory regulations for other transactions for prototype projects awarded under the authority of 10 U.S.C. § 2371b.
- **Agency contact**

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PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

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

The Defense Advanced Research Projects Agency (DARPA) is soliciting innovative proposals to develop technology that improves wound healing via adaptive and dynamic closed-loop systems using biochemical and biophysical monitoring and intervention. Proposed research should investigate approaches that enable revolutionary advances in bioelectronics, artificial intelligence (AI), biosensors, tissue engineering, and cellular regeneration with the ultimate goal of improving human healing. Specifically excluded is research that primarily results in evolutionary improvements to the existing state of practice.

1.1. PROGRAM OVERVIEW

The Bioelectronics for Tissue Regeneration (BETR) program aims to increase warfighter resilience by decreasing the time between injury and re-deployment using dynamic, adaptive interventions for wound healing. Specifically, BETR will establish bidirectional communication between the body and a bioelectronic interface that will guide and expedite tissue healing and regeneration after an injury. The envisioned closed-loop adaptive system would consist of: biological actuators to stimulate healing tissue with appropriate biochemical and biophysical signals transmitted precisely over space and time, sensors to track the body's complex biochemical and biophysical responses, and adaptive learning approaches to integrate and process downstream data for dynamic healing. Successful systems will integrate state-of-the-art optical, biochemical, bioelectronic, and/or mechanical sensors and actuators with artificial intelligence to adapt and drive optimal growth and repair of tissues in real-time. The BETR program will thus provide a responsive platform for human medical interventions, enabling restorative repair and healing of complex tissues after injury. The final prototype will repair Department of Defense (DoD)-relevant blast and burn injuries—bone, skin, nerves, etc.—with increased speed and efficiency as compared to current state of the art therapies. Proposals that address osseointegration are encouraged.

Current medical practice relies on passive recovery. Physicians provide the conditions and time for the body to either heal itself (for tissues with regenerative capacity) or to accept and heal around direct transplantations (for tissues incapable of regeneration). Typical interventions include creating static scaffolds to stabilize self-regenerating tissues (e.g., casts) and transplanting healthy ligaments or organs from donors to replace torn or diseased non-regenerative tissues (e.g., ACL reconstruction, heart transplants). Such passive approaches can lead to slow healing of recalcitrant wounds, incomplete healing with scarring, and abnormal tissue regeneration with little to no healing. This is particularly true for military injuries, such as blast wounds. Research has shown that military blast injuries result in wounds that will not close in 23% of cases and abnormal bone growth in soft tissue, called heterotopic ossification, in 64% of cases (Alfieri et al., 2012).

Recent advances in experimental medicine have attempted to expedite healing through new static interventions. Some of these mechanisms include: wettable bandages that emit a continuous weak electric field or locally-deliver drugs, hydrogel scaffolds laced with a drug or recruitment factors for stem cells, and decellularized tissue re-seeded with donor cells from the patient. While such experimental approaches can enhance growth of non-regenerative tissue, they cannot adapt to the changing state of the wound, thus limiting their overall impact. For example, current practice for treating a simple cut often includes the use of antibiotics; however, while antibiotics will aid healing of an infected wound it can impair healing of a sterile wound.

To address the deficiencies of static strategies, other efforts have sought to actively assess the wound state and expedite or guide the body's own dynamic healing and regeneration system. While recent methods that use pH and temperature as actuators are noteworthy for closing the sensing-actuation loop, communication with the body was limited and focused only on bacterially-induced changes. An integrated, dynamic, adaptive closed-loop system for humans still remains elusive despite several promising sensing and actuating technologies. The BETR program aims to integrate state-of-the-art optical, biochemical, bioelectronic, and/or mechanical processes, increase both the number of independent signals that can be monitored and the number of stimuli that can be administered to the wound, and improve spatiotemporal resolution of actuators and sensors for a more complete, expedited healing process.

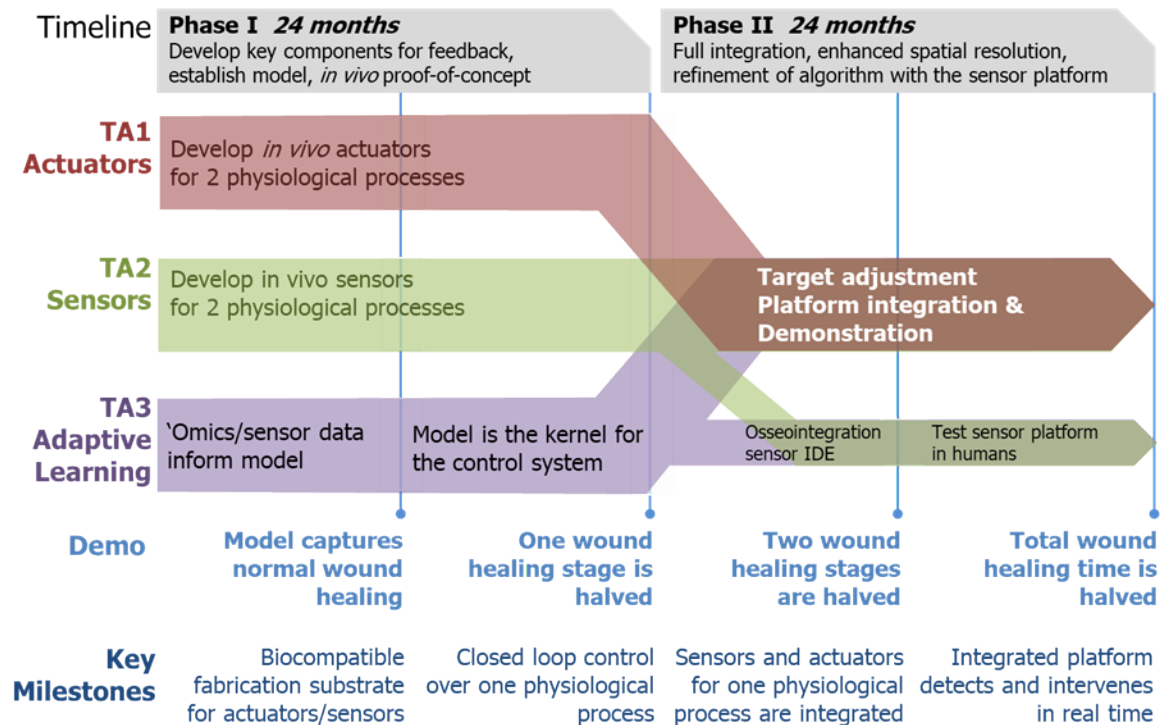
1.2. TECHNICAL APPROACH AND SCHEDULE

The BETR program will move tissue regeneration and wound healing away from static, pre-programmed approaches and toward dynamic, adaptive, and personalized human therapies. Central to this effort is the development of multiple actuators that expedite healing (Technical Area (TA1)) using precise biochemical and biophysical interventions. These actuators must intervene in various physiological processes (angiogenesis, stem-cell migration, etc.) at relevant time points. Examples of actuator function include modulating the immune system response, recruiting certain cell types to the wound, and/or directing stem-cell differentiation to expedite healing. As the tissue heals, the wound conditions will evolve, and interventions need to respond accordingly. Therefore, it will be critical to have biochemical and biophysical sensors that precisely determine the current wound state (Technical Area (TA2)). While many strategies for actuating and sensing the wound state could successfully perform in such a system, they must not result in permanent genetic modification. Lastly, an adaptive learning system is required to connect sensors and actuators (Technical Area (TA3)) for optimal and directed temporal and spatial responses. The closed-loop adaptive system provided by BETR must yield either faster healing of recalcitrant wounds, superior scar-free healing, or the ability to redirect abnormally healing wounds toward a pro-resolving pathway. BETR aims to advance the state-of-the-art from open-loop static interventions to a closed-loop, dynamic system that works with and augments the body's natural healing processes. The specific types of wounds addressed by this program will be DoD-relevant blast and burn injuries affecting various tissues including bone, skin, and nerves.

Achieving a dynamic, closed-loop system will require integrating recent advances in biochemical or biophysical actuators, biosensing, microelectronics, and machine learning into an end-to-end system that can interface directly with the body. The sensors should assess the wound state via

inflammatory markers or other immunological and physiological responses—e.g., chemokine and interleukin release, growth factor release, angiogenesis, immune cell invasion or changes in local oxygenation and pH. These signals should be processed using machine learning methods (e.g., deep learning and adaptive neural networks) to generate a predictive, adaptive model. The machine learning algorithms would then direct actuators of these same processes to expedite healing. The sensors and actuators could be in direct contact with the tissue, such as in electronic bandages, or in indirect contact, such as optically activated or interrogated nanoparticles.

The BETR technology will be implemented in two ways. First, the program will deliver closed-loop systems that automatically determine and implement optimal interventions in animal models to establish a pre-clinical foundation. A second, clinical track will integrate just the sensor devices and machine learning algorithms through a Food and Drug Administration Investigational Device Exemption (IDE) to track osseointegration healing in humans. For this clinical effort, the algorithms must convey the wound state to the clinician, aiding them in expediting healing or enabling more complete healing of wounds with hindered or abnormal regeneration. Moreover, over the course of the program, promising intervention results and regulatory evaluation of the animal model data will be continuously reviewed by the DARPA team for potential transition to humans.



Technical Area 1 (TA1): Multiplexed Local Interventions

New, high-resolution devices should be developed for prolonged real-time interventions to promote wound healing. Interventions must modulate physiological processes relevant to the wound model studied in an *in vivo* mammalian model. Proposers must address the following

requirements for integration of platforms/devices for the various physiological processes:

- Integrated devices/platforms must modulate at least two primary physiological processes relevant to wound healing, such as angiogenesis, inflammation, stem-cell differentiation, innervation, and extracellular matrix production and organization. To achieve closed-loop control, the actuated physiological processes must be the same as those sensed in TA2.
- Integrated devices/platforms must transmit at least one biochemical and one biophysical signal per physiological process. Since two physiological processes must be tracked, a total of at least four different actuators should be produced.
- Devices must be operational and biocompatible for the duration of the wound healing process and cause no appreciable harm upon removal (if removal is necessary).

Technical Area 2 (TA2): Real-Time Measure of Regenerative State

Performers must develop new, high-resolution devices for prolonged real-time measurement of key markers of wound healing in vivo. Markers being measured should report on the status of physiological processes relevant to the chosen wound model and so inform wound-repair interventions. Sensing multiple physiological processes in vivo, using both biochemical and biophysical mechanisms, are essential for directing the actuation of the wound (TA1).

Performers must achieve the following:

- Integrated devices/platforms must collectively assess the state of at least two of the physiological processes requisite for wound healing, such as: angiogenesis, inflammation, stem-cell differentiation, nerve innervation, and extracellular matrix production and organization. Physiological processes sensed must be the same as those actuated (TA1).
- Integrated devices/platforms must sense at least one biochemical and biophysical signal per physiological process, resulting in at least four (4) different sensor types.
- Sensors must sample the state of wound healing with sufficient temporal resolution to enable stable feedback.
- Devices must be operational and biocompatible for the duration of the wound healing process and cause no appreciable harm upon removal (if removal is necessary).

Technical Area 3 (TA 3): System of Systems Model for Real-time Decisions

Innovative models must be developed to predict and adapt to the wound's regenerative state and trajectory in real-time. Models must determine the necessary intervention to achieve faster healing and/or reroute abnormal tissue growth towards healthy tissue. Performers must achieve the following:

- Algorithms/models proposed must collectively address, either directly or indirectly, the following: heterogeneous signals, hierarchical structure (from cellular to tissue level; multiple physiological processes), spatiotemporal resolution, and sparse data.
- Models and algorithms must both predict and adapt to tissue regeneration in real-time.

- Models and algorithms must identify the key leverage points within the physiological processes that enable faster or better healing.
- Models must provide sufficient information and be explainable such that a clinician can understand reasoning behind recommended interventions.
- The model must be integrated with both sensing and intervention platforms.
- Models can be built either from the top-down (e.g., from the literature) or from the bottom-up (e.g., from omics), but must include relevant data. Bottom-up models might include, for example, tracking small mammal wound models using bioanalytical techniques including multi-omics and the proposed sensor arrays.

Clinical Track

DARPA will evaluate and choose successful Phase I efforts to enter into the clinical track Option during Phase II in conjunction with clinicians at the Walter Reed National Military Medical Center (Walter Reed). The clinical group at Walter Reed will be working with wounded soldiers, treating blast injuries and extremity loss via osseointegration surgery and recovery, concurrently with the BETR program. Performers selected for the clinical track must adapt their sensor platforms developed in Phase I to work with either lower or upper extremities as part of the clinical study (dependent upon subject availability); sensor platforms should be formatted to work with either a 17mm or 22mm implant, be mechanically flexible, and allow for patient mobility. The clinical track option will include a cohort of ≈ 10 subjects, as determined by the collaborating facility, and will last for approximately 30 days. Performers must prepare for sensor platforms to be changed every 2-3 days to conform to current clinical practices. Additionally, performers should plan for subject mobility during data capture. During the 30-day clinical testing, performers will work closely with the clinical team to address and meet the needs requisite for effective wound monitoring and prediction, bandage generation, data download, and AI model prediction.

Testing of Biocompatibility by a Contract Research Organization (CRO)

Performers addressing the TAs described above are required to contract and budget for third-party groups to test biocompatibility of devices. Proposals must describe the type and number of tests that will be necessary for regulatory evaluation and transition of the technology to humans.

Independent Verification and Validation (IV&V)

Throughout the program, performers will work with an independent verification and validation (IV&V) team established by DARPA. The IV&V team will consist of subject matter experts from Government and/or other relevant domains, and will help test and validate performer's progress.

The milestone and metrics section below describes the schedule for both biocompatibility testing, delivery of devices and protocols to the IV&V team, and an additional human trial testing sensor devices.

To avoid potential conflicts of interest, performers selected under this BAA (HR001119S0027) will not be allowed to compete for the IV&V contract. This BAA is not soliciting proposals for IV&V.

Schedule

The BETR program consists of two sequential phases, each 24 months in length. Progress towards the overall program goal will be assessed via deliverables and demonstrations throughout each phase. During Phase I, performers must develop and demonstrate effective sensors of and actuators for the wound healing process, paired with an adaptive learning model that can track and simulate wound progression. By the end of Phase I, performers must demonstrate closed-loop control over at least one physiological process. During Phase II, performers must integrate and validate technology from the three task areas—sensing, actuation, and adaptive modeling—to achieve tissue regeneration in half the time of standard clinical interventions. Additionally, an effort to integrate and scale-up the developed sensing and adaptive modeling capabilities into a wound monitoring system for osseointegration will occur during Phase II. The focus of this additional track will be to sense and report on the osseointegrative healing state to clinicians during clinical trials.

1.3. PROGRAM MILESTONES, METRICS, AND DELIVERABLES

Progress toward the program goal will be determined through the use of regular milestones, metrics, and deliverables. The Government specifies the following minimally-required milestones, metrics, and deliverables in order to direct the effort while still affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problems.

Proposers are expected to define additional quantitative and qualitative success criteria as needed. Additionally, proposers must clearly and uniquely itemize tasks needed to accomplish planned milestones and deliverables.

Proposals must be written to address the milestones of all three TAs: Multiplexed Local Interventions (TA1), Real-Time Measure of Regenerative State (TA2), and System of Systems Model for Real-Time Decisions (TA3). **Proposals that do not address all three technical areas will be considered non-conforming and rejected without review.** The milestones and metrics for each technical area and phase are outlined below. Proposers must explain both quantitative success criteria for each milestone and how it will be achieved in their Statement of Work (SOW).

Phase I (Months 1 through 24)

Phase I, *24 months*, will cover Actuation, Sensing, Model Construction and Adaptive Machine Learning. At the end of Phase I, the time to transit one of the latter stages of healing (inflammation, proliferation, maturation, etc.) must be halved.

To accomplish this, performers must demonstrate actuators that provide *in vivo* release of both biochemical (enzymes, growth factors, etc.) and biophysical (light, mechanical stress, electric field, etc.) interventions, and sensors that collect relevant biochemical and biophysical markers for at least two physiological processes *in vivo*. Performers must demonstrate a computational model that recapitulates tissue-level spatial and hierarchical structure and temporal patterns.

Technical Area 1: Multiplexed Local Interventions

Goal:

Demonstrate actuators that modulate the wound healing process via multiple mechanisms and that are compatible with the fully-integrated device targeted at the end of the program.

Milestones:

- Demonstrate reliable operation of actuators for an initial physiological process in an *in vitro* model. Reliability is defined in metrics below. (9 months)
- Demonstrate biocompatibility for all TA1 components that will be in direct contact with tissue via third-party CRO to test limited, 24-hr biocompatibility. Tests for biocompatibility must be relevant to the proposed usage (e.g., cytotoxicity, degradation, acute toxicity, material-mediated pyrogenicity). (9 months)
- Demonstrate reliable operation of initial actuators in a mammalian animal wound model. (12 months)
- Demonstrate reliable operation of actuators to a second physiological process in an *in vitro* model. (15 months)
- Demonstrate reliable operation of actuators to a second physiological process in a mammalian animal wound model. (18 months)
- Demonstrate selected actuators effectively target the key leverage points for directing the healing state for respective physiological processes. (21 months)
- Demonstrate biocompatibility for all TA1 components that will be in direct contact with tissue via third party CRO to test for prolonged biocompatibility, 7-30 days. Tests for biocompatibility must be relevant to the proposed usage (e.g., cytotoxicity, degradation, acute toxicity, material-mediated pyrogenicity). (21 months)
- Demonstrate improved wound healing for one wound healing stage. (24 months)
- In conjunction with TA2 and TA3, demonstrate closed loop control over at least one physiological process. (24 months)

Metrics:

- For reliability, devices and signals released must be biocompatible for the period of time associated with the wound. Performers will need to supply and justify measures/metrics for both *in vitro* and *in vivo* biocompatibility.
- For reliability, devices must deliver sufficient signal to establish closed-loop feedback control throughout the duration of its association with the wound.

- Performers must produce arrays of at least 16 actuators (e.g., 4x4 array) for the physiological processes actuated in TA2. Two different actuator classes must be produced, 1 biophysical and 1 biochemical, for each physiological process.
- Physiological responses to intervention occur in the predicted direction (i.e., signal input elicits increase in X and/or signal input elicits decrease in Y, etc.).
- Responses elicited are repeatable; variation between similar actuation responses does not differ significantly. Performers must show actuator/response curves highlighting level of accuracy and dynamic range.
- Expedited/improved healing will be measured via time to/from stage peak and/or half the deleterious effects to current state of practice.
- Devices must be operational and biocompatible for the duration of the wound healing process.
- Sensor removal after healing, if required, does not significantly damage the wound. Specifically, removal should not cause the wound to regress more than 15% of the typical wound healing duration.

Deliverables:

- Report (from a third party CRO or similar lab) detailing the results of biocompatibility testing and confirming biocompatibility of the TA1 components. (9 months)
- Report (from a third party CRO or similar lab) detailing the results of biocompatibility testing and confirming biocompatibility of the TA1 components. (21 months)
- Devices and associated protocols comprising a functional *in vivo* actuator system for delivery to the IV&V team. (24 months)

Technical Area 2: Real-Time Measure of Regenerative State

Goal:

Establish sensors that can operate reliably in a wound context and report on biophysical and biochemical signals for multiple physiological processes associated with wound healing. Sensors must be compatible with the fully-integrated device targeted at the end of the program. Performers must identify thresholds that indicate the onset and termination of the wound healing stages for their chosen markers.

Milestones:

- Demonstrate reliable operation of sensors for an initial physiological process in an *in vitro* model. Reliability is defined in the metrics below. (9 months)
- Demonstrate biocompatibility for all TA2 components that will be in direct contact with tissue via third-party CRO to test limited, 24-hr biocompatibility. Tests for biocompatibility must be relevant to the proposed usage (e.g., cytotoxicity, degradation, acute toxicity, material-mediated pyrogenicity). (9 months)

- Demonstrate reliable operation of sensors to initial physiological processes *in vivo*. (12 months)
- Demonstrate reliable sensor operation for a second physiological process in an *in vitro* model. (15 months)
- Demonstrate reliable sensor operation to a second physiological process *in vivo*. (18 months)
- Demonstrate biocompatibility for all TA2 components that will be in direct contact with tissue via third-party CRO to test prolonged biocompatibility, 7-30 days. Tests for biocompatibility must be relevant to the proposed usage (e.g., cytotoxicity, degradation, acute toxicity, material-mediated pyrogenicity). (21 months)
- Demonstrate collective sensors accurately capture healing state as described by performer identified thresholds. (21 months) Accuracy of sensors will be subsequently confirmed by IV&V team.
- Demonstrate sensor data is effectively captured throughout the healing process. (24 months)
- Demonstrate improved wound healing for one stage (24 months)
- In conjunction with TA1 and TA3, demonstrate closed-loop control over at least one physiological process. (24 months)

Metrics:

- For reliability, device and sensors must be biocompatible for the duration associated with the wound. Performers will need to supply and justify measures/metrics for both *in vitro* and *in vivo* biocompatibility.
- The test-retest reliability of the sensors should be sufficiently high that the TA3 algorithms can reproducibly determine the wound state.
- Performers must produce arrays of at least 16 sensors (e.g., 4x4 array) for the physiological processes to be monitored. Two different sensor classes must be produced, 1 biophysical and 1 biochemical, for each physiological process.
- Sensors should be sufficiently sensitive that tracking their chosen marker enables them to measure the duration of a wound healing stage with <10% error. Performers must show response/sensor curves highlighting the level of sensor accuracy and dynamic range.
- Sensors must collect sufficient data to demarcate wound-relevant stages of healing.
- Expedited/improved healing will be measured via time to transit healing stage and/or half the deleterious effects to current state of practice.
- Sensor removal after healing, if required, does not significantly damage the wound. Specifically, removal should not cause the wound to regress more than 15% of the typical wound healing duration.

Deliverables:

- Report (from a third party CRO or similar lab) detailing the results of biocompatibility testing and confirming biocompatibility of the TA1 components. (9 months)
- Report (from a third party CRO or similar lab) detailing the results of biocompatibility testing and confirming biocompatibility of the TA2 components. (21 months)
- Devices and associated protocols comprising a functional *in vivo* sensor system capable of accurately reporting the wound state will be delivered to the IV&V team. (21 months)

Technical Area 3: System of Systems Model for Real-time Decisions**Goal:**

Establish feasible approaches for integrating sensory data with actuation to guide tissue healing. Show that the model can correctly identify the state of healing from sensory data and predict wound trajectory.

Milestones:

- Generate initial model using available bioanalytical data, additional omics, and/or other data collected by TA2 sensors that captures tissue-level hierarchy, spatial structure, and temporal patterns. (9 months)
- Demonstrate that the model captures natural progression of the wound healing states in humans. If the model uses data from a system other than humans, demonstrate low error (e.g., root mean square error) when using human data. (12 months)
- Identify candidate markers/signals as regenerative state leverage points for sensing and/or intervention to direct the healing process; i.e., integral nodes. (12 months)
- Demonstrate that the model can determine a wound's current stage of healing. (15 months)
- Identify—through full analysis of model and regenerative state data—the optimal set of sensors and actuators targeting key leverage points. (18 months)
- Demonstrate model robustness; accurate inference with missing data/variable starting points. (21 months)
- Demonstrate that the model predicts wound stage from *in vivo* test data with 80% accuracy from baseline. (24 months)
- In conjunction with TA1 and TA2, demonstrate closed loop control over at least one physiological process. (24 months)

Metrics:

- Model must incorporate at least 1 biophysical and 1 biochemical input per physiological process with the necessary level of hierarchical complexity and spatiotemporal resolution. If using discrete measures, data must be translatable into a continuous model.
- Performers must supply and justify measures of model success and accuracy relevant to their model design, e.g., root mean square error. If no relevant human data is available for model validation, performers must provide metrics for model efficacy in humans.

- Model predictions must be validated using a secondary method (i.e., histology, microscopy, FACS, etc.). Model predictions must not differ significantly from the observed secondary method physiological state or markers.
- Performers must identify leverage points relevant to their wound system. This includes:
 - a) identification and justification of the specific number of time-points necessary to assess wound trajectory;
 - b) identification and justification for the minimum number of sensors/signals required for maximum gain of information;
 - c) identification and justification for the minimum number of actuators/signals required for effective control and/or gain/loss of function.

Deliverables:

- All computer code and simulation files developed during Phase I. (24 months)
- Comprehensive report detailing model performance. (24 months)

Phase II (Months 25 through 48)

Phase II, *24 months*, will cover integration and validation of the three task areas—sensing, actuation, and adaptive modeling – for responsive tissue regeneration. The device will lead to either a halving of the total healing time by the program end, or a 95% reduction of deleterious effects by the completion of Phase II.

Additionally, to begin validation of the technology in humans, only the team(s) with a high-performing sensor suite will be selected to pursue the clinical track during Phase II. During months 25-36, this track will integrate sensing and adaptive modeling capabilities for at least two physiological processes to form a wound monitoring system for osseointegration. The safety of this system will be established through the Investigational Device Exemption application process for an Early Feasibility Study. During months 37-48, these sensor platforms will be used in clinical studies in conjunction with a government partner. Specifically, platforms will need to report on the wound healing process in humans post osseointegration surgery and explain suggested interventions to clinicians.

Technical Areas 1 and 2: Multiplexed Local Interventions, and Real-Time Measure of Regenerative State

Goal:

Integrate sensing and actuation mechanisms into a unified device that can improve wound healing outcomes: **either a 50% reduction in overall healing time by program completion or, for abnormal wounds, 95% reduction in deleterious effects within a standard healing time.**

Milestones:

- Integrate sensors and actuators for one physiological process into a single platform (33 months)
- Demonstrate the improved healing for 2 stages (36 months)

- Demonstrate biocompatibility of fully-integrated platform via third party CRO. Tests for biocompatibility must be relevant to the proposed usage (e.g., cytotoxicity, degradation, acute toxicity, material-mediated pyrogenicity). (39 months)
- Integrate sensors and actuators for all physiological processes into a single *in vivo* platform (42 months)
- Demonstrate overall improved healing relative to current state of the practice. (48 months)

Metrics:

- Integrated device (sensors and actuators) must be biocompatible for the relevant time device is associated with the wound. Performers will need to supply and justify measures/metrics for both *in vitro* and *in vivo* biocompatibility.
- Half the time to heal of two healing stages or 25% of the deleterious effects per stage for two stages. This will be measured via time to/from stage peak and/or half the deleterious effects to current state of practice (36 months).
- Performers must integrate sufficient sensors (≥ 1 biophysical or biochemical) and actuators (≥ 1 biophysical or biochemical) into a cluster that can establish closed loop control over a physiological process. The system must have at least 64 clusters (e.g., an 8x8 array) across the wound area. (36 months).
- Each of the ≥ 64 clusters in the device must have sufficient sensors and actuators to establish closed loop control over two physiological processes (42 months).
- Half the overall time to heal or 5% of the deleterious effects of two stages (95% decrease of abnormal growth). This will be measured via time between stage peaks or half the deleterious effects to current state of practice (48 months).
- Platform removal after healing, if required, does not cause significant damage to the wound.

Deliverables:

- Reports (from a third party CRO or similar lab) detailing results of biocompatibility testing and confirming biocompatibility of fully-integrated platform. (39 months)
- Devices and associated protocols comprising a functional and fully-integrated system capable of improving wound healing are delivered to IV&V team. (45 months)

Technical Area 3: System of Systems Model for Real-time Decisions

Goal:

Integrate the algorithm with the final platform developed in TA1 and TA2. Demonstrate algorithm efficacy for predictability informing the device's guidance of the wound healing process. Suggested interventions are explainable to clinicians.

Milestones:

- Initial integrated model for multi-systems interventions. Demonstrate that model (i) incorporates all necessary biophysical and biochemical signals for each physiological process, (ii) captures hierarchical complexity relevant to the wound, and (iii) has the spatiotemporal resolution required for expedited healing. (27 months)
- Algorithms predict with sufficient speed to enable stable feedback. Demonstrate accuracy is not sacrificed for speed. (33 months)
- Demonstrate algorithm prediction accuracy improves to 85%. (36 months)
- Demonstrate algorithm prediction accuracy improves to 90%. (48 months)
- System must be able to provide to clinicians sufficient and acceptable justifications for the proposed interventions. (48 months)

Metrics:

- Performers must justify biophysical and biochemical signals, and show how hierarchical complexity and spatiotemporal resolution are addressed within their model.
- Performers must supply and justify measures of success and accuracy relevant to their model design, e.g., root mean square error.

Deliverables:

- Comprehensive report detailing improved model performance over Phase I, and including results of benchmark testing and confirming sufficiency and acceptability of justifications for proposed interventions. (48 months)
- All computer code and simulation files developed during Phase II. (48 months)

Optional Clinical Track: Multiplexed real-time measure of osseointegration healing state

Goal:

To begin to show the validity of this technology in humans, during the second phase one team will be allowed to pursue a clinical study tracking osseointegration wounds. **All teams must propose to this Option.** This effort will integrate TA2 and TA3 for real-time tracking of the wound healing process post osseointegration surgery. The goal will be to demonstrate the efficacy and accuracy of the sensing and predictive capabilities of the device as compared to clinician opinions.

Milestones:

- An Investigational Device Exemption or Early Feasibility Study for a First-in-Human trial is prepared in collaboration with government partners. (33 months)
- Sensors are integrated and scaled-up into a compatible platform able to track the healing process of osseointegrated prosthetics in clinical trials. (36 months)
- Sensor platform accurately describes healing state. (48 months)

Metrics:

- Model and sensors track at least two physiological processes (e.g., inflammatory state and angiogenesis) along with bioburden of *in vivo* osseointegration model.
- Platform removal should not cause the wound to regress more than 15% of the typical wound healing duration.
- Device-generated reports of osseointegration healing state must have comparable or increased accuracy as compared to a clinician.

Deliverables:

- Sensor platform and integrated adaptive model are delivered to the government partner for real-time tracking of osseointegration healing in clinical trials. (37 months)
- Report detailing device capabilities including side-by-side comparison with standard clinical assessment and performance. (39 months)

1.4. GENERAL REQUIREMENTS**Proposing Teams**

Proposer teams must address all three technical areas described above which should run in parallel. Consequently, it is expected that the teams will include experts from the multiple disciplines related to the program challenges and goal (e.g., bioelectronic device engineering, wound healing, immunology, advanced imaging techniques, machine learning algorithms). Because several different technologies must ultimately work together, teams should identify one or more members as project integrators who will ensure that team members focused on a specific TA are also appropriately working towards the overall program goal. The project integrator should also address all risks specifically associated with integration.

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

DARPA will hold a Proposers Day (see Section 8, Other Information) to help facilitate the formation of proposer teams and to enable sharing of information among interested parties through the DARPA Opportunities Page and the Proposers Day registration website.

Data Sharing

DARPA anticipates that a large amount of data will be generated under this program by each performer and that model construction will be strengthened by compiling and integrating non-proprietary data collected (e.g., omics, histology, etc.) across performers. Therefore, proposals must include a description of ways to share data with teams internally before publications, and a timeline for release of non-proprietary data for internal sharing among other performer teams.

Plans to facilitate data sharing and exchange of data will then be formalized in an Associate Contractor Agreement (ACA), to be included in the contract or agreement awarded. DARPA encourages sharing of data generated in the course of this program, as well as data aggregated for the system of systems model from pre-existing work or research funded by other sources.

Animal Model

As the core of the program requires acceleration of the wound healing process via biochemical and biophysical stimuli, the scope of the fully integrated BETR device will be limited strictly to animal models.

All research involving animal models will be subject to Institutional Animal Care and Use Committee (IACUC) and Animal Care and Use Review Office (ACURO) approval before commencing.

Human Clinical Trials

The scope of the BETR program *osseointegration track* is to move an integrated sensor and adaptive model device into human clinical trials. This program will be working in conjunction with a Federal lab to perform federally regulated clinical trials.

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

Other Requirements

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

2. Award Information

2.1. GENERAL AWARD INFORMATION

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

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this solicitation and to make awards without discussions with proposers. The Government also reserves the right to conduct discussions if it is later determined

to be necessary. If warranted, portions of resulting awards may be segregated into pre-priced options. Additionally, DARPA reserves the right to accept proposals in their entirety or to select only portions of proposals for award. In the event that DARPA desires to award only portions of a proposal, negotiations may be opened with that proposer. The Government reserves the right to fund proposals in phases with options for continued work, as applicable.

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

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

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

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

2.2. FUNDAMENTAL RESEARCH

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

‘Fundamental research’ means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific

community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.

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

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

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

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

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

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

FFRDCs

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

Government Entities

Government Entities (e.g., Government/National laboratories, military educational institutions, etc.) are subject to applicable direct competition limitations. Government entities must clearly demonstrate that the work is not otherwise available from the private sector and provide written documentation citing the specific statutory authority and contractual authority, if relevant, establishing their ability to propose to Government solicitations.

Authority and Eligibility

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

3.1.2. Non-U.S. Organizations

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

3.2. ORGANIZATIONAL CONFLICTS OF INTEREST

FAR 9.5 Requirements

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

Agency Supplemental OCI Policy

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

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

- The name of the DARPA office receiving the support;

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

Government Procedures

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

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

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

3.3. COST SHARING/MATCHING

Cost sharing is not required; however, it will be carefully considered where there is an applicable statutory condition relating to the selected funding instrument. Cost sharing is encouraged where there is a reasonable probability of a potential commercial application related to the proposed research and development effort.

4. Application and Submission Information

4.1. ADDRESS TO REQUEST APPLICATION PACKAGE

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

4.2. CONTACT AND FORM OF APPLICATION SUBMISSION

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

4.2.1. Proposal Abstract Format

Proposers are strongly encouraged to submit an abstract in advance of a proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. The abstract is a concise version of the proposal comprising a maximum of **8** pages including all figures, tables, and charts. All submissions must be written in English with type no smaller than 12-point font.

Smaller font may be used for figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11 inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal abstract title.

Abstracts must include the following components:

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

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

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

C. Technical Plan: Outline and address all technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide a plan for accomplishment of the milestones presented in Section 1.3.

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

E. Cost and Schedule: Cost and schedule for the proposed research, including an estimate of (a) total cost, (b) cost for each task in each phase of the effort by prime and major subcontractors, and (c) any cost share (if applicable).

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

4.2.2. Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal**. All submissions must be written in English with type no smaller than 12-point font. A smaller font may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1- inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. **The maximum page count for Volume 1 is 40 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 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 (HR001119S0027);
2. Lead organization submitting proposal (prime contractor);
3. Type of organization, selected from among the following categories: “LARGE BUSINESS,” “SMALL DISADVANTAGED BUSINESS,” “OTHER SMALL BUSINESS,” “HBCU,” “MI,” “OTHER EDUCATIONAL,” OR “OTHER NONPROFIT”;
4. Proposer’s reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principle Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
9. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, firm-fixed-price, cooperative agreement, other transaction, or other type (specify);
10. Place(s) of performance, including all subcontractors and consultants;

11. Period of performance;
12. Total funds requested from DARPA, total funds requested per phase and the amount of any cost share (if any);
13. Proposal validity period; AND
14. Date proposal was submitted.

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

B. Official Transmittal Letter.

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

Section II. Detailed Proposal Information

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

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

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

C. Technical Plan: Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide

appropriate measurable milestones (quantitative if possible) at intermediate stages of the program to demonstrate progress, and a plan for achieving the milestones. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal. Discuss mitigation of technical risk.

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

For each task/subtask, provide:

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

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

H. Technology Transfer Plan: Provide information and submit a timeline with incremental milestones toward successful engagement. The plan should include a description of how DARPA will be included in the development of potential technology transfer relationships.

a. Volume II, Cost Management Proposal

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

1. BAA Number (HR001119S0027);
2. Lead Organization Submitting proposal;
3. Type of organization, selected among the following categories: “LARGE BUSINESS”, “SMALL DISADVANTAGED BUSINESS”, “OTHER SMALL BUSINESS”, “HBCU”, “MI”, “OTHER EDUCATIONAL”, OR “OTHER NONPROFIT”;
4. Proposer’s reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
9. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;
10. Place(s) of performance, including all subcontractors and consultants;
11. Period of performance;
12. Total funds requested from DARPA, total funds requested per phase (as defined in Table 1), and the amount of any cost share (if any);
13. Name, address, and telephone number of the proposer’s cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
14. Name, address, and telephone number of the proposer’s cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
15. Date proposal was prepared;

16. Data Universal Numbering System (DUNS) number (<http://www.dnb.com/get-a-duns-number.html>);
17. Taxpayer ID number (<https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN>);
18. Commercial and Government Entity (CAGE) code (<https://cage.dla.mil/Home/UsageAgree>);
19. Proposal validity period

Note that nonconforming proposals may be rejected without review.

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

- (1) Please submit any breakdown of expenses in an editable, MS EXCEL cost file.
- (2) Total program, per phase (Phase 1 (Base); Phase 2 (Option); and Phase 3 (Option)), and per task cost broken down by major cost items to include:
 - i. **Direct labor** – provide an itemized breakout of all personnel, listed by name or TBD, with labor rate (or salary), labor hours (or percent effort), and labor category. All senior personnel must be identified by name.
 - ii. **Materials and Supplies** – itemized list which includes description of material, quantity, unit price, and total price. If a material factor is used based on historical purchases, provide data to justify the rate.
 - iii. **Equipment** – itemized list which includes description of equipment, unit price, quantity, and total price. Any equipment item with a unit price over \$5,000 must include a vendor quote.
 - iv. **Animal Use Costs** – itemized list of all materials, animal purchases, and per diem costs, associated with proposed animal use; include documentation supporting daily rates.
 - v. **Travel** – provide an itemized list of travel costs to include purpose of trips, departure and arrival destinations, projected airfare, rental car and per GSA approved diem, number of travelers, number of days); provide screenshots from travel website for proposed airfare and rental car, as applicable; provide screenshot or web link for conference registration fee and note if the fee includes hotel cost. Conference attendance must be justified, explain how it is in the best interest of the project. **Plan for two (2) DARPA program review meetings per year.**
 - vi. **Other Direct Costs (e.g., computer support, clean room fees)** – Should be itemized with costs or estimated costs. Backup documentation and/or a supporting cost breakdown is required to support proposed costs with a unit price over \$5,000. An explanation of any estimating factors, including

- their derivation and application, must be provided. Please include a brief description of the proposers' procurement method to be used.
- vii. **Other Direct Costs** – Consultants: provide executed Consultant Agreement that describes work scope, rate and hours.
 - viii. **Indirect costs** including, as applicable, fringe benefits, overhead, General and Administrative (G&A) expense, and cost of money (see university vs. company specific requirements below).
 - ix. **Indirect costs specific to a University performer:** (1) **Fringe Benefit Rate** (provide current Department of Health and Human Services (DHHS) or Office of Naval Research (ONR) negotiated rate package; if calculated by other than a rate, provide University documentation identifying fringe costs by position or HR documentation if unique to each person); (2) **F&A Indirect Overhead Rate** (provide current DHHS or ONR negotiated rate package); (3) **Tuition Remission** (provide current University documentation justifying per student amount); and (4) **Health Insurance/Fee** (provide current University documentation justifying per student amount, if priced separately from fringe benefits with calculations included in the EXCEL cost file).
 - x. **Indirect costs specific to a Company performer:** (1) **Fee/Profit** (provide rationale for proposed fee/profit percentage using criteria found in DFARS 215.404-70); and (2) **Fringe Benefit/Labor OH/Material OH/G&A Rates** (provide current Forwarding Pricing Rate Proposal (FPRP) or DCMA/DCAA Forward Pricing Rate Recommendation or Agreement (FPRR or FPRA). If these documents are not available, provide company historical data, preferably two years, minimum of one, to include both pool and expense costs used to generate the rates).
- (3) A summary of total program costs by phase and task.
 - (4) An itemization of Subcontracts. All subcontractor cost proposal documentation must be prepared at the same level of detail as that required of the prime. Subcontractor proposals should include Interdivisional Work Transfer Agreements (IWTA) or evidence of similar arrangements (an IWTA is an agreement between multiple divisions of the same organization). The prime proposer is responsible for compiling and providing all subcontractor proposals for the Procuring Contracting Officer (PCO). The proposal must show how subcontractor costs are applied to each phase and task. If consultants are to be used, proposer must provide consultant agreement or other document that verifies the proposed loaded daily/hourly rate.
 - (5) An itemization of any information technology (IT) purchase (including a letter stating why the proposer cannot provide the requested resources from its own funding), as defined in FAR Part 2.101.
 - (6) A summary of projected funding requirements by month for all phases of the project.
 - (7) A summary of tasks that have animal or human use funding.
 - (8) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions that could reasonably be partitioned for purposes of

- funding, these should be identified as options with separate cost estimates for each.
- (9) Identification of pricing assumptions of which may require incorporation into the resulting award instrument (e.g., use of Government Furnished Property/Facilities/Information, access to Government Subject Matter Expert/s, etc.).
 - (10) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available).
 - (11) Proposers with a Government acceptable accounting system who are proposing a cost-type contract must submit the DCAA document approving the cost accounting system.

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

Subawardee Proposals

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

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

Other Transaction Requests

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

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

It is noted that, at a minimum, milestones should relate directly to accomplishment of program technical metrics as defined in the BAA and/or the proposer’s proposal. Agreement type,

expenditure or fixed-price based, will be subject to negotiation by the Agreements Officer. Do not include proprietary data.

4.2.3. Additional Proposal Information

Proprietary Markings

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

Unclassified Submissions

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

Disclosure of Information and Compliance with Safeguarding Covered Defense Information Controls

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

DFARS 252.204-7000, “Disclosure of Information”

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

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

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

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

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

Human Research Subjects/Animal Use

Proposers that anticipate involving Human Research Subjects or Animal Use must comply with the approval procedures detailed at <http://www.darpa.mil/work-with-us/additional-baa>.

Approved Cost Accounting System Documentation

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

Small Business Subcontracting Plan

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

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

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

Intellectual Property

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

For Procurement Contracts

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

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

For All Non-Procurement Contracts

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

System for Award Management (SAM) and Universal Identifier Requirements

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

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

https://www.fsd.gov/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 HR001119S0027. Submissions may not be submitted by fax or e-mail; any so sent will be disregarded.

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

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

Abstracts and Full Proposals sent in response to HR001119S0027 may be submitted via DARPA's BAA Website (<https://baa.darpa.mil>). Visit the website to complete the two-step registration process. Submitters will need to register for an Extranet account (via the form at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the abstract. Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process be started as early as possible.

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

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

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

For Cooperative Agreements only:

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

Submissions: Proposers must submit the three forms listed below.

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

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

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

Research and Related Personal Data, available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_PersonalData_1_2-V1.2.pdf. *Each applicant must complete the name field of this form, however, provision of the*

demographic information is voluntary. Regardless of whether the demographic fields are completed or not, this form must be submitted with at least the applicant's name completed.

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

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

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

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

4.3. FUNDING RESTRICTIONS

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

4.4. OTHER SUBMISSION INFORMATION

DARPA will post a consolidated Frequently Asked Questions (FAQ) document. To access the posting go to <http://www.darpa.mil/work-with-us/opportunities>. A link to the FAQ will appear under the HR001119S0027 summary. Submit your question(s) via e-mail to BETR@darpa.mil.

5. Application Review Information

5.1. EVALUATION CRITERIA

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

5.1.1. Overall Scientific and Technical Merit

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

deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule.

5.1.2. Potential Contribution and Relevance to the DARPA Mission

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

5.1.3. Cost Realism

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

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

5.2. REVIEW OF PROPOSALS

Review Process

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

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

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

Handling of Source Selection Information

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

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

Federal Awardee Performance and Integrity Information (FAPIIS)

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

6. Award Administration Information

6.1. SELECTION NOTICES

6.1.1. Proposal Abstracts

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

6.1.2. Full Proposals

As soon as the evaluation of 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

If a procurement contract is contemplated, prospective awardees will need to be registered in the SAM database prior to award and complete electronic annual representations and certifications consistent with FAR guidance at 4.1102 and 4.1201; the representations and certifications can be found at www.sam.gov. Supplementary representations and certifications can be found at <http://www.darpa.mil/work-with-us/additional-baa>.

6.2.4. Terms and Conditions

A link to the DoD General Research Terms and Conditions for Grants and Cooperative Agreements and supplemental agency terms and conditions can be found at <http://www.darpa.mil/work-with-us/contract-management#GrantsCooperativeAgreements>.

6.3. REPORTING

The number and types of reports will be specified in the award document, but will include as a minimum monthly financial status reports, 6-week technical status reports, and quarterly technical status reports. The reports shall be prepared and submitted in accordance with the procedures contained in the award document and mutually agreed on before award. Reports and briefing material will also be required as appropriate to document progress in accomplishing program metrics. A Final Report that summarizes the project and tasks will be required at the conclusion of the performance period for the award, notwithstanding the fact that the research may be continued under a follow-on vehicle.

6.4. ELECTRONIC SYSTEMS

6.4.1. Wide Area Work Flow (WAWF)

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

6.4.2. I-EDISON

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

7. Agency Contacts

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

Points of Contact

The BAA Coordinator for this effort may be reached at:

BETR@darpa.mil

DARPA/BTO

ATTN: HR001119S0027

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 BETR program on March 1, 2019, at the Executive Conference Center (ECC; 4075 Wilson Blvd., Suite 300, Arlington, VA 22203). The purpose is to provide potential proposers with information on the BETR program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and to encourage team formation.

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

DARPA will not provide cost reimbursement for interested proposers in attendance. An online registration form and various other meeting details can be found at the registration website, <http://www.cvent.com/d/r6qnsj>.

To encourage team formation, interested proposers are encouraged to submit information to be shared with all potential proposers through the Proposers Day website and the DARPA Opportunities Page. This information may include contact information, relevant publications, and a slide or poster to summarize the proposer's interests.

Participants are required to register for physical attendance no later than **February 25, 2019, 4:00 PM ET**. Webinar registration will close on **February 27, 2019, 12:00 PM ET**. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; there will be no onsite registration.

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

Proposers Day Point of Contact:

DARPA-SN-19-24@darpa.mil

ATTN: DARPA-SN-19-24

675 North Randolph Street

Arlington, VA 22203-2114

9. APPENDIX 1 – Volume II checklist

Volume II, Cost Proposal Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 beginning on Page 27 of HR001119S0027. 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 **HR001119S0027** included on your Cost Proposal cover sheet?

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

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

Direct Labor (Labor Categories, Hours, Rates)

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

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

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

Materials and/or Equipment

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

Subcontracts/Consultants

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

Other Direct Costs

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

Travel

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

If reply is “No”, please explain:

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

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

If reply is "No", please explain:

5. Does your cost proposal include a complete itemized list of all material and equipment items to be purchased (a priced bill-of-materials (BOM))?
 YES **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

6. Does your cost proposal include vendor quotes or written engineering estimates (basis of estimate) for all material and equipment with a unit price exceeding \$5000?
 YES **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

7. Does your cost proposal include a clear justification for the cost of labor (written labor basis-of-estimate (BOE)) providing rationale for the labor categories and hours proposed for each task?
 YES **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

8. Do you have subcontractors/consultants? If YES, continue to question 9. If NO, skip to question 13.
 YES **NO** **Appears on Page(s)** [Type text]

9. Does your cost proposal include copies of all subcontractor/consultant technical (to include Statement of Work) and cost proposals?
 YES **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

10. Do all subcontract proposals include the required summary buildup, detailed cost buildup, and supporting documentation (SOW, Bill-of-Materials, Basis-of-Estimate, Vendor Quotes, etc.)?
 YES **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

11. Does your cost proposal include copies of consultant agreements, if available?
 YES **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

12. If requesting a FAR-based contract, does your cost proposal include a tech/cost analysis for all proposed subcontractors?
 YES **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

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

If reply is "No", please explain: