



Broad Agency Announcement

Neural Engineering System Design (NESD)

BIOLOGICAL TECHNOLOGIES OFFICE

DARPA-BAA-16-09

January 21, 2016

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PART I: OVERVIEW INFORMATION

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office
- **Funding Opportunity Title** – Neural Engineering System Design (NESD)
- **Announcement Type** – Initial Announcement
- **Funding Opportunity Number** – DARPA-BAA-16-09
- **Catalog of Federal Domestic Assistance Numbers (CFDA)** - 12.910 Research and Technology Development
- **Dates**
 - Posting Date – **January 21, 2016**
 - Proposal Abstract Due Date – **February 25, 2016**
 - Proposal Due Date – **April 14, 2016**
 - BAA Closing Date – **April 14, 2016**
 - Proposers Days – **February 2-3, 2016**

<https://www.fbo.gov/spg/ODA/DARPA/CMO/DARPA-SN-16-16/listing.html>
- **Concise description of the funding opportunity** – DARPA seeks proposals to design, build, demonstrate, and validate a neural interface system capable of recording from more than one million neurons and stimulating more than one hundred thousand neurons in proposer-defined regions of the human sensory cortex (e.g., visual cortex or auditory cortex). The complete system must demonstrate high-precision detection, transduction, and encoding of neural activity.
- **Total amount of money to be awarded** – Total funding up to approximately \$60M will be awarded. The actual amount of resources available will depend on the quality of proposals received, successful achievement of milestones and availability of funds.
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** – None
- **Agency contact**

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PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

The Defense Advanced Research Projects Agency often selects its research efforts through the Broad Agency Announcement (BAA) process. This BAA is being issued, and any resultant selection will be made, using procedures under Federal Acquisition Regulation (FAR) 35.016 and the Department of Defense Grant and Agreement Regulatory System (DoDGARS) Part 22 for Grants and Cooperative Agreements. Any negotiations and/or awards will use procedures under FAR 15.4, Contract Pricing, as specified in the BAA (including DoDGARS Part 22 for Grants and Cooperative Agreements). Proposals received as a result of this BAA shall be evaluated in accordance with evaluation criteria specified herein through a scientific review process. DARPA BAAs are posted on the Federal Business Opportunities (FedBizOpps) website, <https://www.fbo.gov/>, and, as applicable, the Grants.gov website at <http://www.grants.gov/>. The following information is for those wishing to respond to the BAA.

The most advanced neural interfaces approved to date by the Food and Drug Administration (FDA) for use in human clinical studies are based on electrical recording and stimulation through implants with, at most, hundreds of passive wire electrodes substantially larger in size and pitch than the underlying neurons, drastically limiting the amount and quality of information that can be read from, or stimulated, within the brain.

DARPA's Neural Engineering System Design (NESD) program is seeking innovative research proposals to design, fabricate and demonstrate safe, scalable, high-precision and fully-implantable next-generation neural interface systems. It is anticipated that these systems will leverage significant advances in other disciplines including microelectronics and photonics along with advances in scalable neural encoding and processing algorithms to demonstrate the transformation of high-definition sensory stimuli to and from proposer-specified human sensory-cortex areas, bridging physiological and electronic neural activity representations.

Specifically excluded is research that primarily results in incremental improvements to the existing state of practice. Proposals with external partners should include letters of support, specific tasking, and a cost breakdown for each proposed subcontractor.

Program Overview

The Neural Engineering System Design (NESD) program seeks innovative research proposals to design, build, demonstrate, and validate in animal and human subjects a neural interface system capable of recording from more than one million neurons, stimulating more than one hundred thousand neurons, and performing continuous, simultaneous full-duplex (read and write) interaction with at least one thousand neurons in regions of the human sensory cortex. In addition to achieving substantial advances in scale of interface (independent channel count), proposed systems must also demonstrate simultaneous high-precision in neural activity detection, transduction, and encoding, with single-neuron spike-train precision for each independent channel.

While the NESD program will initially focus on proposer-selected areas of the human sensory cortex (e.g., primary visual cortex [V1] or primary auditory cortex [A1]) that are physically accessible and have a solid scientific foundation on which to build, the fundamental objective of the program is to develop a modular and scalable interface system with the capability to serve a multiplicity of applications to monitor and modulate large-scale activity in the central nervous system. NESD hardware components and algorithms must be modular in design with clear, well-defined hardware interconnect and software Application Programming Interfaces (APIs) that can easily accommodate upgrades to componentry, new neural signal transduction modalities, and/or algorithms to enable their use as foundational engineering platforms for future research and development. DARPA expects that subsequent to this program, there will be a variety of uses for the NESD system beyond these initial proposer-defined applications.

In parallel with hardware developments and innovations in neural transduction techniques, the NESD program seeks to advance the state of the art in algorithms to identify neurons, neural circuits, and patterns of population-coded activity that represent and encode specific sensory stimuli and transform this neural-coded information to and from the digital electronic domain. New mathematical transformation algorithms will need to accommodate the increased scale of neural input/output, and leverage the developed NESD hardware systems to validate simultaneous high-bandwidth and high-precision, bi-directional information transfer between the system and animal/human subjects.

Successful NESD proposals must culminate in the delivery of complete, functional, implantable neural interface systems and the functional demonstration thereof. The final system must read at least one million independent channels of single-neuron information and stimulate at least one hundred thousand channels of independent neural action potentials in real-time. The system must also perform continuous, simultaneous full-duplex interaction with at least one thousand neurons. While DARPA desires a single 1 cm³ device that satisfies all of these capabilities (read, write, and full-duplex), proposers may propose a design wherein each capability is embodied in separate 1 cm³ devices. Proposed implementations must not require tethers or percutaneous connectors for powering or facilitating communication between the implanted and external portions of the system.

Proposals are strongly encouraged to address all NESD program requirements.

Program Structure

Integrated Neural Engineering System Design [NESD]

The NESD program is fundamentally an integrated systems design and innovation program that will require scientific and technical advances in two major Technical Areas (TA 1: **Neural Transducers and Algorithms**, and TA 2: **Hardware, Prototyping, and Manufacture**) to be fully integrated in a functioning system. The program is scheduled to span four years in three phases with critical milestones and deliverables expected in each phase. Phase 1 is scheduled for 12 months, Phase 2 for 12 months, and Phase 3 for 24 months (See Table 1).

In order to receive an FDA Investigational Device Exemption (IDE) for Early Feasibility Studies in humans, proposals must clearly define a specific target therapeutic neural interface application

and its associated target sensory cortical region(s). System requirements must be driven by the proposer-defined application and used to derive, define, and quantify additional specifications, including necessary levels of precision and area of cortical coverage. Proposers are encouraged to focus on cortical sensory pathways where deterministic neural activity encoding and computation models are best understood and can most easily be tested against precise yet complex stimuli. DARPA strongly prefers applications that highlight the benefits and improved functionality enabled by the scale and precision afforded by the proposed NESD systems compared to the state of the art, and would not be possible without the proposed innovations.

NESD systems should leverage leading academic and industrial expertise and fabrication capabilities in key technical areas of the system. In taking a systems-level approach, designs should leverage the strengths of one component technology against the weaknesses of others to produce a fully integrated system that performs better than the sum of its parts. Proposals wherein essential components or algorithms either lag behind, or fail to utilize, state-of-the-art techniques from that discipline may be considered non-conforming.

Proposed system demonstration designs must explain the tradeoffs between component performance, size, maturity, modularity, and energy consumption relative to achievable scale and precision necessary in order to keep the implantable power budget within thermal and emissions^a safety limits for the duration of any proposed trial. Proposing teams must include individuals with expertise managing system design tradeoffs between components and disciplines, and bringing interdisciplinary products from concept through manufacture to market.

All proposals must include a detailed schedule with clear interim milestones and dependencies, as well as a thorough risk analysis in order to prevent delays in the NESD program timeline, particularly those associated with rapid translation into first-in-human trials. Teams must include individuals or groups with demonstrated expertise in bringing highly integrated medical products to market (see the Evaluation Criteria in Section 5.1.1). Proposers that do not include team members with the necessary expertise to address all program requirements must include a plan for dealing with commercial transition and be prepared to enter into Associate Contractor Agreements (ACA) or other contractual vehicles with other DARPA-selected performers in order to contribute to a joint, complete system that meets the NESD program goals.

The final NESD deliverables must include a fully implantable device (i.e., no percutaneous leads for data or power), safe for semi-chronic or longer (> 30 days) human use, integrated with components and packing from TA2 and neural transducers^b and algorithms developed in TA1, and demonstrate reliable power and data telemetry supporting full-duplex system functionality in animals and humans.

^a Proposers are encouraged to read IEC 60601-1, IEC 60601-1-2, and IEC 14708-3.

^b “Neural transducer” is the portion of the proposed approach that encompasses the conversion of neural activity between individual neurons and an intermediate form of information. For example, photons, ions, magnetic fields, or ultrasonic vibrations. The neural transducer and intermediate form of information must be developed in conjunction with the manufactured transducers in the implanted portion of the system. For example, voltage-sensitive proteins, the intensity and wavelength of light emitted, and photo-detectors must all be compatible.

Quantitative Metric Requirements

Table 1. NESD Target System Performance Metrics			
	Phase 1 Bench Demo 12 months	Phase 2 Integrated Device 12 months	Phase 3 Final Integrated Systems 24 months
System	<i>proposer-defined quantitative metrics</i>	< 3 cm ³ ; < 5 Watt; < 20 ms latency; <i>proposer-defined safety metrics</i>	< 1 cm ³ ; < 1 °C rise in tissue; < 10 ms latency; <i>proposer-defined safety metrics</i>
Transducer	Read and write to individual neurons within region of interest (ROI) of > 0.1 cm ² cortex ^c ; < 100 µm spatial resolution	10 ⁵ read channels; > 0.75 cm ² cortex ROI; < 50 µm resolution	10 ⁶ read, 10 ⁵ write, 10 ³ full-duplex; 2 cm ² cortex ROI; < 25 µm resolution; 60 dB channel isolation
Representation and protocols <i>(proposer-defined quantitative metrics)</i>	Energy budget for representation and compression	Precision of representation reversibility; energy and link budget	Energy and link budget

Note: “proposer-defined quantitative metrics” indicates that all proposals must include measurable metrics for the performance of the proposed system that are appropriate to demonstrate significant advances in scale and precision, but are ultimately guided by and defined by the proposer-specified target sensory application and its associated cortical region function. Non-quantified and/or purely qualitative metrics may be considered non-conforming.

Regulatory Plans and Execution

A regulatory plan must be included in all proposals, and must define a credible pathway to human use. Proposers are required to partner with individuals or groups with demonstrated expertise in the regulatory process. Proposers should ensure that the study design has taken into account a power analysis to guarantee an appropriate sample size, describe planned inclusion/exclusion criteria for participants, and provide quantifiable and independently validated minimally clinically important differences (MCID) for each outcome measure^d. Include study success criteria and patient success criteria. Proposers must satisfy all FDA requirements in characterizing and addressing expected risks to patients (i.e., mitigate or document the severity and likelihood) in a worst-case scenario prior to pre-submission at the beginning of Phase 3.

Human and Animal Validation

Proposals must contain a comprehensive test plan encompassing all safety and complete NESD system performance and validation trials. Proposers must justify their choice of animal model(s) and duration of trials for the safety studies. For any human trials within the program timeline,

^c Surface of the cortex accessible to measurement, with transduction to/from all of the pyramidal layers.

^d Proposers are encouraged to read FDA guidance UCM106757:

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm106757.htm>

proposers must provide compelling arguments defining the specific trials, expected outcomes, and justification regarding the lack of an appropriate animal model.

Proposers are strongly encouraged to include a detailed plan to develop and use quality assurance processes to support later efforts including eventual translation to clinical products.

Security

Proposers must use approaches that ensure confidentiality, integrity, and availability (CIA triad) to prevent spoofing, tampering, or denial of service. While the NESD system is intended to be an investigational device, it will be necessary to adequately secure the connection between the NESD system and a subject's brain. Therefore, proposers must incorporate inherently safe techniques into the wireless and electronic portions of their system and must describe the specific protocols and techniques to be used. A security audit will be performed by an independent third-party security specialist during Phase 3. DARPA will work with performers to identify appropriate security standards based on the platforms that are proposed.

System Transition

Proposers must define and publish hardware and software APIs, protocols, and semantics for interoperability between NESD components and systems, making them available to all DARPA-selected performers. Note that this provision is not meant to require disclosure of otherwise proprietary internal component or process IP. DARPA requires distribution of all of the external interface specifications and data necessary for connecting the proposed developed components to other systems to facilitate third-party utilization of the developed technologies.

Proposers should consider how to enable rapid and broad deployment of NESD systems and technologies once an IDE is granted. Proposals should include tasks articulating plans for the wide distribution, use of, and reimbursement for production and distribution expenses, of NESD systems.

Proposers must complete the attached **Specifications Spreadsheet** (attachment 3) itemizing the anticipated capabilities and performance metric targets of their final proposed NESD system including clear functional diagrams detailing the expected interrelations of all major components, and the expected dimensions and materials for any implantable packaging.

Technical Area 1 - Neural Transducers and Algorithms

TA1 focuses on the scientific and technical advances along with their proofs of principle and function to inform and enable the final design of the NESD system.

Neural Transducer Refinement

Strategies to optimize and increase the scalability and precision of the NESD interfaces will depend on the transduction method employed.

Optical interface approaches may require molecular and synthetic biology development to improve efficacy and/or establish safety for human use. Proposed approaches should consider signal detectability with respect to background noise, channel independence, energy efficiency,

spectral diversity, methods to improve the safety and control of tissue transfection, and use of infrared wavelengths and/or luminescent complexes to reduce background noise.

In contrast, electronic interface approaches require advances in materials, insertion techniques, scale of hermetic package feed-through, and neural source localization and signal isolation algorithms to achieve NESD program scale and precision targets, without exciting an immune response severe enough to significantly degrade the neural signals over time and/or prevent semi-chronic use.

These two transduction modalities are listed as examples to illustrate the varied distinct technical challenges specific to each method. The list is not exclusive or exhaustive and DARPA is agnostic to the proposed interface modality and technical approach.

Sensory Data Transformation Algorithms

Proposers must develop algorithms to identify neurons, neural circuits, patterns of activity, and functional regions of the sensory cortex that represent specific information and transform this information into the digital electronic domain at the new levels of scale and precision enabled by the proposed NESD hardware. This is a brain-to-digital transformation algorithm. Additionally, proposers must develop the inverse algorithms for digital-to-brain transformation. It may be necessary to customize the transformations to each neural transducer mechanism and/or target cortical sensory region.

Proposers must demonstrate that brain-to-digital and digital-to-brain transformation algorithms can be used to convey complex sensory stimuli between the cortical neural population activity domain and the digital domain. The developed algorithms should transform artificial electronic input signals originating as, for example, spatial images and video pixel data, or MP3 audio files, into spatiotemporal patterns of neural activity to be induced in the cortex. Similarly, the inverse brain-to-digital transformation algorithm should convert spatiotemporal patterns of neural population activity into inferred digital stimulus files that, as accurately as possible, reconstruct the original electronic stimuli.

These models should incorporate how those neural population activity patterns change and adapt over time due to variations in stimulus and neural plasticity. While it is not required that these methods are invertible, they should be reversible and deterministic (i.e., passing a stimulus through a brain-to-digital then a digital-to-brain series of transformations should result in a recognizably similar stimulus).

Specifically excluded from the NESD program are transformation algorithms that do not accurately model the naturalistic activity of ensembles of individual neurons as the foundation for higher-level information representation. While general abstractions and higher-level statistical representations describing aggregate grouped neural activity are useful for independent applications, they are not sufficient to interface directly with individual neurons using new NESD system precision. The new algorithms should specify how each individual neuron and ensemble populations thereof should be read or stimulated moment-by-moment in order to encode specific precise and deterministic stimuli.

Neural Activity Representation and Protocols

Proposers must develop new methods to significantly reduce the quantity of data necessary to represent neural activity at scale in order to effect energy-efficient wireless telemetry delivery. These methods must be validated to ensure that there is no functional loss when utilizing the compressed neural information, and the impact on NESD system energy and thermal budgets must be demonstrated. For example, JPEG and MPEG file formats are lossy, but due to accurate psychophysical models they can compress data by two to three orders of magnitude while preserving perceptually important underlying information.

Technical Area 2: Hardware, Prototyping, and Manufacture

TA2 will focus on the design, prototyping, integration, fabrication, and test/validation of the NESD components and overall system.

Electronics and Signal Processing

Proposers must employ efficient ultra-low-power digital computation methods to sample, process, and telemeter one million channels of neural information. DARPA is agnostic to the technical approach. Proposers are encouraged to incorporate elements of life-cycle requirements for the development of medical software from IEC 62304.

Optical Interface Approaches

If constructing a NESD system with a photonic neural transducer, proposers must match optical sensing, emitting, and focusing components to the biological properties of both the neural light-transducing mechanisms in the cortex as well as the materials properties in the implant package where new transparent materials must be proven to meet FDA hermeticity and non-toxicity requirements.

Electronic and Other Interface Approaches

If constructing a NESD system with an electrical or other type of neural transducer, proposers must demonstrate scalable high-density package feed-throughs and external interfaces to electronics, as well as assembly and interface manufacture procedures that will satisfy FDA implantable device requirements.

Medical Materials and Device Packaging

Proposals will be considered non-conforming if they do not include provisions to package the final NESD deliverable entirely in a self-contained, biocompatible, sterilizable, hermetic package suitable for semi-chronic implantation in humans^e. Careful attention must be paid to all aspects of semi-chronic bio-compatibility including tissue response and power dissipation into tissue and related thermal limits. Electromagnetic compatibility and electrical safety will be required. The NESD system is not required to meet MRI compatibility standards. Proposers are strongly encouraged to partner with individuals or groups having demonstrated expertise with implantable medical device design, fabrication, and testing.

^e Proposers are encouraged to read ISO 10993, which provides guidance for selecting the tests to evaluate the biological response to medical devices, and FDA guidance UCM348890:
<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf>

Prototyping and Design for Manufacturing [DFM]

Future manufacturability at ever-increasing scales of production must shape design choices throughout the program, beginning with the initial stages and proposed system designs. The aggressive schedule of NESD will require fast design, optimization, and product development cycles. Proposers are strongly encouraged to include a detailed strategy to develop manufacturing, testing, and quality assurance processes applicable to eventual volume commercialization.

To facilitate and support the use of state-of-the-art capabilities across all technical disciplines, DARPA expects to announce the organization of a NESD Industry Group to facilitate participants' pre-competitive access to intellectual property, services, and facilities that can accelerate the prototyping and manufacture of advanced neuro-engineering components and services. Supported areas will include: state-of-the-art electronics, photonics, computing, fabrication, assembly, medical materials and packaging, clinical procedures, testing, and regulatory support. If Industry Group member services and capabilities are required to complete the proposed NESD system, proposers are strongly encouraged to independently establish contractual relationships with and among their collaborating team members. Proposals must clearly articulate relevant role, tasks and budget responsibility information, i.e., each participating Industry Group member must be clearly identified as a prime contractor, subcontractor, or vendor.

Proposals must include letter(s) of support from key partners and subcontractors if these capabilities are critical for the completion of the proposed work.

Program Milestones and Schedule

DARPA anticipates down-selecting and/or condensing teams at the end of Phases 1 and 2. Performers that do not pass preliminary (three months after contract) and critical (12 months after contract) design reviews conducted by DARPA and demonstrate convincing technical achievement *in vitro* will not advance to subsequent phases of the program. See Figure 1.

Proposers are encouraged to expand upon these required milestones and to add new milestones and deliverables specific to the approaches being proposed. For example, if it is expected that the proposed effort will require an Investigational New Drug (IND) exemption, relevant tasks should have a clearly delineated set of milestones associated with that objective. Proposals must also include application-specific milestones.

Note: intermediate milestones may use a limited number of percutaneous leads to demonstrate portions of the system.

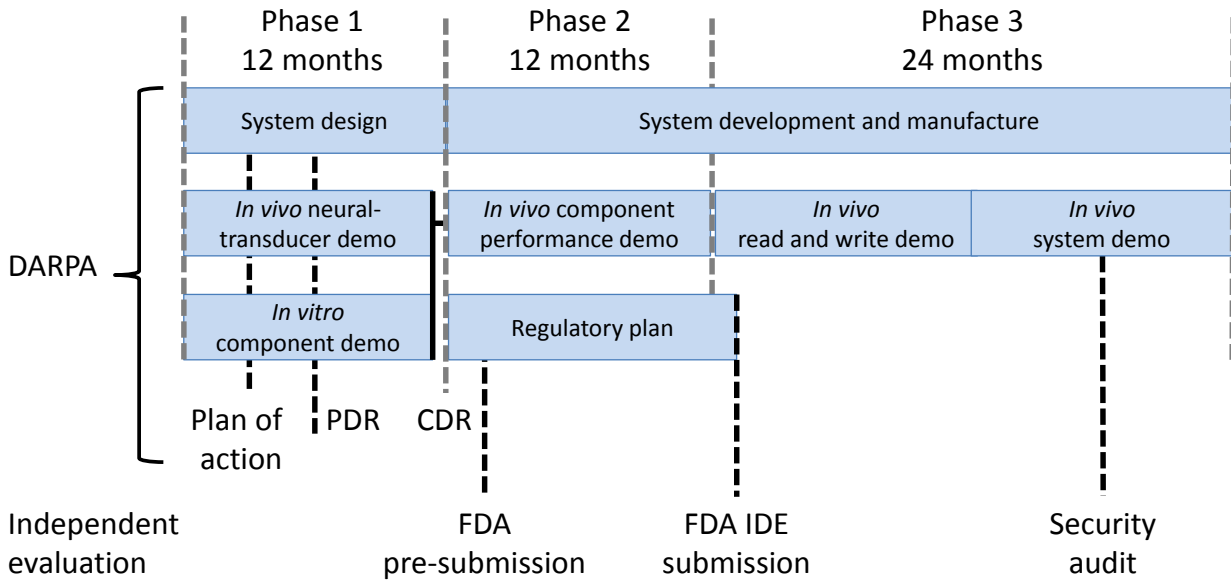


Figure 1 - NESD Program Plan and Milestones

Abstracts and Proposals

Proposers are encouraged to submit an abstract that clearly identifies a target sensory cortical area and the demonstration application that will drive complete system requirements and outlines including overall architectural descriptions and diagrams that clearly articulate fundamental system tradeoffs, expected scalability, precision and performance metric targets.

Proposers are strongly encouraged to submit abstracts and proposals that meet **all** NESD program requirements.

Smaller proposals for individual technical area explorations and developments that offer critical technology leverage and support for the entire NESD performer community will be considered but are a lower priority to DARPA.

Milestones

Performers are expected to achieve the technical objectives in Table 1, and these results must be integrated into the system prototyping and timeline in Figure 1.

Phase 1: 1-12 months after contract (MAC)

1. Plan of Action and Milestones (POAM) (3 MAC)

Milestone: Document the POAM, setting forth specific measurable milestones that DARPA can use to evaluate progress towards a fully compliant Preliminary Design Review (PDR).

Deliverable: POAM to DARPA Program Manager (PM), to include:

- a. Detailed execution plan for integration of prime contractor, subcontractors, collaborators, and vendors
 - b. Detailed technology-to-market plan including transition strategy, IP strategy, manufacturing plan and initial business plan
 - c. Measurable weekly milestones
2. Preliminary Design Review (6 MAC)
Milestone: Design review demonstrating that the proposed system design will credibly meet the NESD program objectives. All system requirements, specifications, regulatory plans, test and validation plans, and manufacturing plans must be reported.

Deliverable: Briefing to DARPA PM, to include
 - a. Design verification
 - b. Plan to fabricate the required prototypes
 - c. Plans to validate prototypes in animal and human subjects
 - d. Risk analysis – identify all risks, their severity, likelihood, and the approach to mitigate
 - e. Anticipated performance specifications based on *in vitro* experiments
3. Critical Design Review (12 MAC)
Milestone: Design review demonstrating that the proposed system design will meet the NESD program objectives on time and on budget. All system requirements, specifications, regulatory plans, and manufacturing plans must be completed.

Deliverable: Briefing to DARPA PM, to include
 - a. Design validation
 - b. Detailed risk analysis – retired risks; the severity and likelihood of remaining risks; approaches to mitigate remaining risks
 - c. System energy budget
 - d. System link budget
 - e. Scalability analysis for every aspect of the NESD system
 - f. Roadmap for manufacture of the NESD components and integration of the system
 - g. Device Evaluation Strategy (DES)
 - h. Test plan for safety, biocompatibility, and emissions
4. Phase 1 Demo (12 MAC)
Milestone: Demonstrate bench prototype NESD components *in vitro* or *in vivo*. Demonstrate proofs of principle for the scalability and precision of the neural transducer *in vivo* and neural representation and compression. Metrics are specified in Table 1.

- Deliverable:** Briefing to DARPA PM, to include
- Detailed component and system description
 - Trials performed, metrics tested against
 - Results measured, metrics achieved

Phase 2: 13-24 MAC

5. Regulatory pre-submission (no later than 15 MAC)

Milestone: Finalize DES, safety testing procedures and pre-submission documentation.

Deliverable: Submit DES and pre-submission request to the FDA.

6. Regulatory plan finalized (no later than 24 MAC)

Milestone: Complete a draft of the regulatory submission, which incorporates results from Phase 1 and Phase 2 safety studies and pre-submission discussions with the FDA.

Deliverable: Draft submission delivered to DARPA PM for review.

7. Phase 2 Demo (24 MAC)

Milestone: Demonstrate *in vivo* that the proposed biological transducer and algorithms can achieve the required performance specifications, scalability and precision. Demonstrate *in vivo* functionality of a first-generation prototype NESD system. Performance of individual components may be verified independently of the entire system. Metrics are specified in Table 1.

Deliverable: Five prototype NESD systems delivered to DARPA for independent validation and verification (IVV). Briefing to DARPA PM, to include

- Detailed component and system description
- Trials performed, metrics tested against
- Results measured, metrics achieved

Phase 3: 25-48 MAC

8. Regulatory submission (no later than 26 MAC)

Milestone: Finalize documentation to support first-in-human trials.

Deliverable: IDE submitted to the FDA, following Early Feasibility Study guidelines.

9. Phase 3 Interim Demo (36 MAC)

Milestone: Demonstrate *in vivo* reading from one hundred thousand neurons and writing to one hundred thousand neurons using a fully integrated second-generation NESD

prototype. Other metrics are performer-specified.

Deliverable: Five prototype NESD systems delivered to DARPA for IVV. Briefing to DARPA PM, to include

- a. Detailed component and system description
- b. Trials performed, metrics tested against
- c. Results measured, metrics achieved

10. Security Audit (42 MAC)

Milestone: Analysis of the methods used to protect the confidentiality, integrity and availability of a prototype NESD system.

Deliverable: Two prototype NESD electronic subsystems delivered to independent security evaluators. Briefing to DARPA PM, to include

- a. Trials performed, metrics tested against
- b. Results measured, metrics achieved
- c. Security flaws identified
- d. Actions required to rectify security flaws
- e. Plan of action to rectify critical flaws before the Phase 3 Final Demo

11. Phase 3 Final Demo (48 MAC)

Milestone: Demonstrate *in vivo* the safety and efficacy of the final human-ready NESD system. Metrics are specified in Table 1. Demonstrate application-specific capabilities.

Deliverable: Five prototype NESD systems delivered to DARPA for IVV. Briefing to DARPA PM, to include

- a. Detailed component and system description
- b. Trials performed, metrics tested against
- c. Results measured, metrics achieved
- d. Actions taken to rectify security flaws identified in Milestone 10

12. Regulatory Approval (48 MAC)

Milestone: Attain FDA approval to conduct controlled trials in human subjects using the complete NESD system.

Ethical, Legal, and Societal Implications

All proposers are expected to comport themselves in accordance with the highest ethical standards, particularly with regards to animal and human trials. In addition to fulfilling all Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), and IDE requirements for animal and human studies, all animal testing will require approval from

Animal Care and Use Review Office (ACURO) prior to release of funds related to animal testing and continuous monitoring thereafter as specified by the relevant oversight bodies. Human trials will require approval and continuous monitoring from a secondary DoD agency, to be identified by DARPA, prior to release of funds related to human subjects. NESD efforts involving development of new biologic treatments may be required to attain an IND exemption from the FDA. All NESD efforts will be required to attain an IDE and/or IND from the FDA by the end of the program.

In preparation for IRB and other regulatory reviews, and to facilitate timely consideration of the relevant safety, efficacy and other issues by regulators, proposers are encouraged to engage with independent bioethics experts. It is incumbent upon all NESD performers to consider, establish, and work within ethical boundaries that take into account such foundational principles as fully informed consent, privacy, and personal autonomy. DARPA encourages proposers to explore the Gray Matters project at <http://bioethics.gov/studies>.

2. 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 at the end of one or more of the phases.

Awards under this BAA will be made to proposers on the basis of the evaluation criteria listed below (see section labeled “Application Review Information”, Sec. 5.), and program balance to provide overall value to the Government. The Government reserves the right to request any additional, necessary documentation once it makes the award instrument determination. Such additional information may include but is not limited to Representations and Certifications. The Government reserves the right to remove proposers from award consideration should the parties fail to reach agreement on award terms, conditions and cost/price within a reasonable time or the proposer fails to timely provide requested additional information. Proposals identified for negotiation may result in a procurement contract, grant, cooperative agreement, or other transaction depending upon the nature of the work proposed, the required degree of interaction between parties, whether or not the research is classified as Fundamental Research, and other factors.

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

instruments, as it deems appropriate. DARPA will apply publication or other restrictions, as necessary, if it determines that the research resulting from the proposed effort will present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Any award resulting from such a determination will include a requirement for DARPA permission before publishing any information or results on the program. For more information on publication restrictions, see the section below on Fundamental Research.

Fundamental Research

It is DoD policy that the publication of products of fundamental research will remain unrestricted to the maximum extent possible. National Security Decision Directive (NSDD) 189 established the national policy for controlling the flow of scientific, technical, and engineering information produced in federally funded fundamental research at colleges, universities, and laboratories. The Directive defines fundamental research as follows:

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

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

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

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

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

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

3. Eligibility Information

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

3.1. ELIGIBLE APPLICANTS

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

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

Government entities must clearly demonstrate that the work is not otherwise available from the private sector and provide written documentation citing the specific statutory authority and contractual authority, if relevant, establishing their ability to propose to Government solicitations. At the present time, DARPA does not consider 15 U.S.C. § 3710a to be sufficient legal authority to show eligibility. While 10 U.S.C. § 2539b may be the appropriate statutory starting point for some entities, specific supporting regulatory guidance, together with evidence of agency approval, will still be required to fully establish eligibility. DARPA will consider FFRDC and Government entity eligibility submissions on a case-by-case basis; however, the burden to prove eligibility for all team members rests solely with the proposer.

3.1.2. Non-U.S. Organizations

Non-U.S. organizations are/or individuals may participate to the extent that such participants comply with any necessary nondisclosure agreements, security regulations, export control laws, and other governing statutes applicable under the circumstances. See Section 4.2 “Security and Proprietary Issues” regarding the proposers capabilities to perform research and development at the classification level they propose.

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

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

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

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

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

3.2. COST SHARING/MATCHING

Cost sharing is not required; however, it will be carefully considered where there is an applicable statutory condition relating to the selected funding instrument (e.g., for any Other Transactions under the authority of 10 U.S.C. § 2371). Cost sharing is encouraged where there is a reasonable probability of a potential commercial application related to the proposed research and development effort.

4. Application and Submission Information

4.1. ADDRESS TO REQUEST APPLICATION PACKAGE

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

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

4.2.1. Proprietary and Security Information

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

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

4.2.1.1 Proprietary Information

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

4.2.1.2 Security Information

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

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

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

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

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

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

DARPA anticipates that submissions received under this BAA will be unclassified. However, should a proposer wish to submit classified information, an *unclassified* email must be sent to the BAA mailbox requesting submission instructions from the Technical Office PSO.

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

4.2.2. Submission Information

Proposers are highly 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 time and date for submission of proposal abstracts is specified in Section 4.5.1 below. DARPA will

acknowledge receipt of the submission and assign a control number that should be used in all further correspondence regarding the proposal abstract. DARPA will attempt to respond within 30 calendar days of receipt.

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

The typical proposal should express a consolidated effort in support of one or more related technical concepts or ideas. Disjointed efforts should not be included into a single proposal.

Proposals not meeting the format described in the BAA may not be reviewed.

For Proposers Submitting Proposal Abstracts or Full Proposals as Hard Copies/On CD-ROM:

Proposers must submit an original hardcopy and one (1) electronic copy of the abstract or proposal in PDF (preferred) on a CD-ROM to the mailing address listed in Part I. Each copy must be clearly labeled with DARPA-BAA-16-09, proposer organization, technical point of contact, and proposal title (short title recommended).

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

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

Abstracts and Full Proposals sent in response to DARPA-BAA-16-09 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 assistance instruments (grants 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 submission process be started as early as possible.

For Proposers Requesting Grants or Cooperative Agreements:

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

Grants.gov requires proposers to complete a one-time registration process before a proposal can be electronically submitted. If proposers have not previously registered, this process can take between three business days and four weeks. See the Grants.gov registration checklist at <http://www.grants.gov/documents/19/18243/OrganizationRegChecklist.pdf> for registration requirements and instructions.

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

Upload two separate documents, Volume I, Technical and Management Proposal and Volume II, the Cost Proposal, as attachments to the application package. **No other Grants.gov forms are required.** Please note that Grants.gov does not accept zipped or encrypted proposals. More detailed instructions for using Grants.gov can be found on the Grants.gov website.

Proposers electing to submit grant or cooperative agreement proposals as hard copies must complete the SF 424 R&R form (Application for Federal Assistance, Research and Related) available on the Grants.gov website

http://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf. Technical support for Grants.gov submissions may be reached at 1-800-518-4726 or support@grants.gov.

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

For All:

All administrative correspondence and questions on this solicitation, including requests for information on how to submit a proposal to this BAA, should be directed to one of the administrative addresses below; e-mail is preferred.

BAA Administrator

E-mail: DARPA-BAA-16-09@darpa.mil

DARPA/BTO

ATTN: DARPA-BAA-16-09

675 North Randolph Street

Arlington, VA 22203-2114

Office Website: <http://www.darpa.mil/about-us/offices/bto>

Solicitations Page: <http://www.darpa.mil/work-with-us/opportunities>

DARPA intends to use electronic mail for correspondence regarding DARPA-BAA-16-09. Proposals and proposal abstracts may not be submitted by fax or e-mail; any so sent will be disregarded. DARPA encourages use of the Internet for retrieving the BAA and any other related information that may subsequently be provided.

4.2.3. Restrictive Markings on Proposals

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

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

‘This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this proposer as a result of, or in connection with, the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]’; and

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

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

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

4.3. FORMATTING CHARACTERISTICS

4.3.1. Proposal Abstract Format

The abstract is a concise version of the proposal comprising a maximum of 7 pages including the cover sheet and all figures, tables, and charts. The (optional) submission letter is not included in the page count. All pages shall be formatted for printing on 8-1/2 by 11 inch paper with font size not smaller than 12 point. Smaller font sizes may be used for figures, tables, and charts.

Submissions must be written in English.

Abstracts must include the following components:

A. Cover Sheet: 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 are you trying to do?
2. What is innovative in your approach and how does it compare to SOA?
3. How much will it cost and how long will it take?

C. Technical Plan: Provide an outline of the proposed statement of work. This should include all major tasks and subtasks, as well as estimates of the cost and duration for each task. Outline the critical risks (technical and programmatic) inherent in the proposed approach and potential solutions to mitigate these risks. The technical plan should provide specific milestones (quantitative, if appropriate) at key stages of the project to demonstrate progress towards the NESD goals. Provide a clear description or graphic identifying the key innovations/system components and how they interrelate.

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. Include a description of the team’s organizational structure, including roles and responsibilities. Since at least one key team member must have a demonstrated history of having successfully converted innovations into commercial products, provide a brief description of their previous product designs. Since regulatory approval is

essential to NESD, provide a description of the investigational or marketed devices that at least one key team member has received human use approval. If desired, include a brief bibliography with links to relevant papers or reports.

4.3.2. Proposal Format

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

All full proposals must be in the format given below. Nonconforming proposals may be rejected without review. Proposals shall consist of two volumes. All pages shall be printed on 8-1/2 by 11 inch paper with type not smaller than 12 point. Fonts no smaller than 8 point may be used for figures, tables and charts. The page limitation for full proposals includes all figures, tables, and charts. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished), which document the technical ideas and approaches 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 15 pages for responses to a single technical area, and 30 pages for a full program response.** Proposers may respond to a single technical area, or both of them, though DARPA has a strong preference for proposals that address both technical areas in parallel. A submission letter is optional and is not included in the page count. Volume I should include the following components:

- a. Volume I, Technical and Management Proposal

Section I. Administrative

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

1. BAA number (DARPA-BAA-16-09);
2. Technical area;
3. Lead organization (prime proposer);
4. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
5. Proposer's reference number (if any);
6. All subcontracted team members (if applicable) and type of organization for each;
7. Proposal title;

8. 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;
9. Administrative point of contact (Contracting Officer or Grant Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
10. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, firm-fixed-price, cooperative agreement, other transaction, or other type (specify);
11. Total proposed cost separated by basic award and option(s) (if any);
12. Place(s) and period(s) of performance;
13. Proposal validity period;
14. DUNS number (<http://www.dnb.com/get-a-duns-number.html>);
15. Taxpayer ID number (<https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN>);
16. CAGE code (<https://cage.dla.mil/search/FAQ.aspx>);

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

B. Official Transmittal Letter.

Section II. Detailed Proposal Information

- A. Executive Summary:** Provide a succinct synopsis of the proposed project, including final deliverables and answers to the following questions:

- What is the proposed work attempting to accomplish?
- 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 to complete the major tasks?

- 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 plans to gain regulatory approval for use as an investigational tool in human use, manage intellectual property, commercialize the technology, manufacture it, and

transition it to customers.

- C. Comparison with existing research:** Discuss any relevant work, indicating advantages and disadvantages of the proposed effort; discuss the proposer's previous accomplishments and work in closely related research areas. Proposers should address the state-of-the-art technology and current limitations.
- D. Technical Plan:** Provide a detailed technical plan, which fully-addresses all applicable proposal instructions in Section 1.1, "Program Overview." The technical plan must provide specific milestones at key stages of the program to demonstrate progress towards the NESD goals, and a detailed plan for achieving the milestones. Describe the metrics used to measure progress, in accordance with the "NESD Milestones and Metrics" (Table 1 of Section 1.1). Quantitative metrics are strongly preferred over metric to be quantified in the future, or qualitative metrics. In addition to the specified NESD goals, proposers are encouraged to develop and propose additional metrics and milestones.

The technical plan should demonstrate a deep understanding of the technical challenges and present a credible plan to achieve the program goal. Detail the critical risks (technical, regulatory, and programmatic) inherent in the proposed approach, potential solutions to mitigate these risks, and indicate when the risks are expected to be retired.

- E. Statement of Work (SOW):** Provide a condensed summary of the SOW in Volume I, and attach an editable and fully-detailed SOW in MS Word format, using the SOW template in Attachment 4 posted with the subject BAA. The SOW attachment does not count towards the page limit. The SOW should provide a detailed task breakdown in plain English, 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.

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. Quantitative metrics are strongly preferred over quantifiable or qualitative metrics.
- A definition of all deliverables (e.g., data, reports, software) to be provided to the Government in support of the proposed tasks/subtasks.

- F. Schedule and Milestones:** Provide a detailed, but readable, schedule showing tasks (task name, duration, work breakdown structure element as applicable, performing organization, and cost), milestones, and the dependencies between 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.
- G. Program Organization:** Provide a readable Work Breakdown Structure chart, where each element includes the tasks/subtask number from the SOW, Phase(s), lead organization, key personnel, and cost. This section should also include, in plain English, a description of the facilities and unique capabilities to be utilized by the team, as well as a summary of each key individual and their responsibilities. Provide detailed descriptions for the Principal Investigator, lead project manager, commercial translation expert, and regulatory coordinator.
- H. Summary slides (does not count towards page limit):** No more than four PowerPoint slides summarizing the proposed effort's vision, goals, impact, scientific/technical approach, and milestone schedule. Provide a graphic identifying the key innovations/system components and how they interrelate. Download and use the template provided in Attachment 1 posted with the subject BAA. Submit the PowerPoint file in addition to Volume I and II of your proposal.

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

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

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

All proposers, including FFRDCs, must submit the following:

Cover sheet to include:

1. BAA number;
2. Technical area;
3. Lead Organization Submitting proposal;
4. Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
5. Proposer's reference number (if any);
6. Other team members (if applicable) and type of business for each;
7. Proposal title;
8. 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;

9. Administrative point of contact (Contracting Officer or Grant Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
10. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), or other transaction;
11. Place(s) and period(s) of performance;
12. Total proposed cost separated by basic award and option(s) (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. 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. CAGE code (<https://cage.dla.mil/search/FAQ.aspx>);
19. Proposal validity period.

Note that nonconforming proposals may be rejected without review.

Proposers without an accounting system considered adequate for determining accurate costs must complete an SF 1408 if a cost type contract is to be negotiated. To facilitate this process, proposers should complete the SF 1408 found at:

<http://www.gsa.gov/portal/forms/download/115778> and submit the completed form with the proposal. To complete the form, check the boxes on the second page, then provide a narrative explanation of your accounting system to supplement the checklist on page one. For more information, please see:

http://www.dcaa.mil/preaward_accounting_system_adequacy_checklist.html.

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

- (1) total program cost broken down by major cost items to include:
 - i. direct labor, including individual labor categories or persons, with associated labor hours and numbered direct labor rates
 - ii. If consultants are to be used, proposer must provide consultant agreement or other document which verifies the proposed loaded daily/hourly rate

- iii. Indirect costs including Fringe Benefits, Overhead, General and Administrative Expense, Cost of Money, etc. (Must show base amount and rate)
 - iv. Travel – Number of trips, number of days per trip, departure and arrival destinations, number of people, etc.
 - v. Other Direct Costs – Should be itemized with costs or estimated costs. Backup documentation will be submitted to support proposed costs. An explanation of any estimating factors, including their derivation and application, must be provided. Please include a brief description of the proposers' procurement method to be used;
- (2) major program tasks by phase;
 - (3) an itemization of major subcontracts and equipment purchases, to include: a cost proposal as detailed as the Proposer's cost proposal;
 - (4) an itemization of any information technology (IT) purchase, as defined in FAR Part 2.101;
 - (5) a summary of projected funding requirements by month;
 - (6) the source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions which could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each; and
 - (7) 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.).

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

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

All proprietary subcontractor proposal documentation, prepared at the same level of detail as that required of the prime. The prime and subcontractor proposals should be uploaded together if possible to DARPA's BAA Website (<https://baa.darpa.mil/>). If the subcontractor proposal contains proprietary information not releasable to the prime, the subcontractor may upload their proposal separately but identify the proposal as a subcontract proposal and provide the name and proposal title of the prime contractor. Subcontractor proposals submitted by hard copy can be submitted in a sealed envelope by the prime or directly by the subcontractor. If submitted directly by the subcontractor the subcontractor must identify the proposal as a subcontract proposal and provide the name and proposal title of the prime proposer. Subcontractors must

provide the same number of hard copies and/or electronic proposals as is required of the prime proposer.

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

4.4. SUBMISSION DATES AND TIMES

4.4.1. Proposal Abstract Submission Deadline

The proposal abstract (original and (designated number) of hard and electronic copies) must be submitted to DARPA/BTO), 675 North Randolph Street, Arlington, VA 22203-2114 (Attn.: DARPA-BAA-16-09) **on or before 4:00 p.m., ET, February 25, 2016**. Proposal abstracts received after this time and date may not be reviewed.

4.4.2. Full Proposal Submission Deadline

The full proposal (original and (designated number) of hard and electronic copies) must be submitted to DARPA/BTO), 675 North Randolph Street, Arlington, VA 22203-2114 (Attn.: DARPA-BAA-16-09) **on or before 4:00 p.m., ET, April 14, 2016**.

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

DARPA will post a consolidated Question and Answer list in response to any relevant and/or BAA clarification question(s) after (date), before final full proposals are due. This list will appear on the DARPA Solicitations page: <http://www.darpa.mil/work-with-us/opportunities>. In order to receive a response to your question, submit your question by (date) to DARPA-BAA-16-09@darpa.mil.

4.5. FUNDING RESTRICTIONS

Not applicable.

5. Application Review Information

5.1. EVALUATION CRITERIA

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

5.1.1. Overall Scientific and Technical Merit

The proposed technical approach is feasible, achievable, complete and supported by a proposed technical team that has the expertise and experience to accomplish the proposed tasks.

Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible. The proposed team includes individuals with demonstrated experience bringing highly-integrated medical products to market.

5.1.2. Potential Contribution and Relevance to the DARPA Mission

The potential contributions of the proposed effort are relevant to the national technology base. Specifically, DARPA's mission is to maintain the technological superiority of the U.S. military and prevent technological surprise from harming our national security by sponsoring revolutionary, high-payoff research that bridges the gap between fundamental discoveries and their application.

5.1.3. Cost Realism

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

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 AND SELECTION PROCESS

DARPA will conduct a scientific/technical review of each conforming proposal. Proposals will not be evaluated against each other since they are not submitted in accordance with a common work statement. DARPA's intent is to review proposals as soon as possible after they arrive; however, proposals may be reviewed periodically for administrative reasons.

Award(s) will be made to proposers whose proposals are determined to be the most advantageous to the Government, all factors considered, including the potential contributions of the proposed work to the overall research program and the availability of funding for the effort.

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

For evaluation purposes, a proposal is the document described in "Proposal Information", Section 4.4.2. Other supporting or background materials submitted with the proposal will be considered for the reviewer's convenience only and not considered as part of the proposal.

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

6. Award Administration Information

6.1. SELECTION NOTICES

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

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

There will be a program kickoff meeting in the Arlington, VA vicinity and all key participants are required to attend. Performers should also anticipate two annual program-wide PI meetings per year in the Arlington, VA vicinity. In addition, performers should anticipate periodic site visits to the site of performance, specifically, the Preliminary Design Review six months after contract award, and at the end of each Phase. All key participants will be required to attend these site visits.

Proposers shall include within the content of their proposal details and costs of any travel or meetings they deem to be necessary throughout the course of the effort, to include periodic status reviews by the government.

6.2.2. Human Subjects Research

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

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

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

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

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

6.2.3. Animal Use

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

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

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

6.2.4. Export Control

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

6.2.5. Subcontracting

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

6.2.6. Electronic and Information Technology

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

6.2.7. Employment Eligibility Verification

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

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

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

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

6.2.9. Reporting Executive Compensation and First-Tier Subcontract Awards

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

6.2.10. Updates of Information Regarding Responsibility Matters

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

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

The following representation will be included in all awards:

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

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

the tax liability, where the awarding agency is aware of the unpaid tax liability, unless the agency has considered suspension or debarment of the corporation and made a determination that this further action is not necessary to protect the interests of the Government; or

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

(b) The Offeror represents that –

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

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

6.2.12. Cost Accounting Standards (CAS) Notices and Certification

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

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

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

- Do not process DARPA CUI on publicly available computers or post DARPA CUI to publicly available webpages or websites that have access limited only by domain or Internet protocol restriction.
- Ensure that all DARPA CUI is protected by a physical or electronic barrier when not under direct individual control of an authorized user and limit the transfer of DARPA CUI to subawardees or teaming partners with a need to know and commitment to this level of protection.
- Ensure that DARPA CUI on mobile computing devices is identified and encrypted and all communications on mobile devices or through wireless connections are protected and encrypted.
- Overwrite media that has been used to process DARPA CUI before external release or disposal.

6.2.14. Safeguarding of Unclassified Controlled Technical Information

Per DFARS 204.7303, DFARS 252.204-7012, Safeguarding of Unclassified Controlled Technical Information, applies to this solicitation and all FAR-based awards resulting from this solicitation.

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

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

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

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

6.3. REPORTING

The number and types of reports will be specified in the award document, but will include as a minimum monthly financial status reports and quarterly technical 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, specifically the Preliminary Design Review three months after contract award, and at the end of each Phase. 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. Reference 4.4.1.6 for a sample list for complying with this request.

6.4. ELECTRONIC SYSTEMS

6.4.1. Representations and Certifications

In accordance with FAR 4.1201, prospective proposers shall complete electronic annual representations and certifications at <http://orca.bpn.gov>.

6.4.2. Wide Area Work Flow (WAWF)

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

6.4.3. i-EDISON

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

7. Agency Contacts

Administrative, technical or contractual questions should be sent via e-mail to DARPA-BAA-16-09@darpa.mil.

Points of Contact

The BAA Coordinator for this effort may be reached at:

DARPA-BAA-16-09@darpa.mil.

DARPA/BTO

ATTN: DARPA-BAA-16-09

675 North Randolph Street

Arlington, VA 22203-2114

8. Other Information

8.1. INTELLECTUAL PROPERTY

8.1.1. Procurement Contract Proposers

8.1.1.1 Noncommercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS, shall identify all noncommercial technical data, and noncommercial computer software that it plans to generate, develop, and/or deliver under any proposed award instrument in which the Government will acquire less than unlimited rights, and to assert specific restrictions on those deliverables. Proposers shall follow the format under DFARS 252.227-7017 for this stated purpose. In the event that proposers do not submit the list, the Government will assume that it automatically has “unlimited rights” to all noncommercial technical data and noncommercial computer software generated, developed, and/or delivered under any award instrument. If mixed funding is anticipated in the development of noncommercial technical data, and noncommercial computer software generated, developed, and/or delivered under any award instrument, then proposers should identify the data and software in question, as subject to Government Purpose Rights (GPR). In accordance with DFARS 252.227-7013 Rights in Technical Data - Noncommercial Items, and DFARS 252.227-7014 Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation, the Government will automatically assume that any such GPR restriction is limited to a period of five (5) years in accordance with the applicable DFARS clauses, at which time the Government will acquire “unlimited rights” unless the parties agree otherwise. Proposers are advised that the Government will use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer’s assertions. If no restrictions are intended, then the proposer should state “NONE.” It is noted an assertion of “NONE” indicates that the Government has “unlimited rights” to all noncommercial technical data and noncommercial computer software delivered under the award instrument, in accordance with the DFARS provisions cited above. Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

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

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

8.1.1.2 Commercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS, shall identify all commercial technical data, and commercial computer software that may be embedded in any noncommercial deliverables contemplated under the research effort, along with any applicable restrictions on the Government’s use of such commercial technical data and/or commercial computer software. In the event that proposers do not submit the list, the Government will assume that there are no restrictions on the Government’s use of

such commercial items. The Government may use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE." Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

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

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

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

Proposers responding to this BAA requesting a cooperative agreement or Other Transaction for Prototype shall follow the applicable rules and regulations governing that instrument, but in all cases should appropriately identify any potential restrictions on the Government's use of any Intellectual Property contemplated under that award instrument. This includes both Noncommercial Items and Commercial Items. Although not required, proposers may use a format similar to that described in Paragraphs 1.a and 1.b above. The Government may use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE." Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

8.1.3. All Proposers – Patents

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

8.1.4. All Proposers-Intellectual Property Representations

Provide a good faith representation that you either own or possess appropriate licensing rights to all other intellectual property that will be utilized under your proposal for the DARPA program. Additionally, proposers shall provide a short summary for each item asserted with less than

unlimited rights that describes the nature of the restriction and the intended use of the intellectual property in the conduct of the proposed research.

9. APPENDIX 1 – Volume II checklist

Volume II, Cost Proposal Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.3.2 beginning on Page 30 of DARPA-BAA-16-09. **This worksheet must be included with the coversheet of the Cost Proposal.**

1. Are all items from Section 4.3.2 (Volume II, Cost Proposal) of DARPA-BAA-16-09 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: