Broad Agency Announcement

Detect It with Gene Editing Technologies (DIGET)

BIOLOGICAL TECHNOLOGIES OFFICE

HR001120S0016

November 27, 2019

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- **Federal Agency Name –** Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title – Detect It with Gene Editing Technologies (DIGET)**
- **Announcement Type –** Initial Announcement
- **Funding Opportunity Number –** HR001120S0016
- **North American Industry Classification System (NAICS) –** 541714
- **Catalog of Federal Domestic Assistance Numbers (CFDA) –** 12.910 Research and Technology Development
- **Dates**
    - Posting Date: November 27, 2019
    - Proposal Abstract Due Date and Time: January 7, 2020, 4:00 PM ET
    - Full Proposal Due Date and Time: February 25, 2020, 4:00 PM ET
    - BAA Closing Date: February 25, 2020
    - Proposers Day: December 11, 2019

    DARPA-SN-20-12 on beta.SAM.gov
- **Concise description of the funding opportunity –** The goal of the DIGET program is to leverage advances in gene editing technologies to develop low-cost, high-trust, sensitive, multiplexed, rapidly reconfigurable, and fieldable diagnostics and biosurveillance technologies to address the need for timely and comprehensive threat detection surveillance to support Department of Defense (DoD) stabilization missions and outpace infectious disease.
- **Anticipated individual awards –** Multiple awards are anticipated.
- **Types of instruments that may be awarded –** Procurement contract, cooperative agreement, or other transaction.
- **Agency contact**

    The BAA Coordinator for this effort may be reached at:
    DIGET@darpa.mil
    DARPA/BTO
    ATTN: HR001120S0016
    675 North Randolph Street
    Arlington, VA 22203-2114

PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

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

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

DARPA is soliciting innovative proposals to develop distributed point-of-need and massively multiplexed gene editing-based nucleic acid detection capabilities for diagnostics and biosurveillance that address the following areas for technical innovation: (1) development of *in silico* tools to aid in design of gene editing guides, tools, and assays for detection of pathogen and host biomarker targets, (2) development of foundational enzymes and reporters to enable sensitive and specific detection of nucleic acid targets, (3) incorporation of detection reagents into assays that yield high sensitivity and specificity results in 15 minutes or less and can be rapidly reconfigured for new targets, (4) integration of detection assays into point-of-need diagnostics and massively multiplexed detection (MMD) devices, and (5) algorithms and analytics tools to assist interpretation of complex assays with clearly presented and easily understood results for decision making. Proposed research should develop innovative technologies to enable usage in field-forward locations and rapid reconfiguration of assays in response to new and emergent threats. Specifically excluded is research that primarily results in incremental improvements to the existing state of practice.

1.1. PROGRAM OVERVIEW

Exposure to regional endemic diseases, global pandemic outbreaks, or other emergent threats can degrade the health and preparedness of U.S. military forces and civilians alike, contributing to the spread of disease and further destabilization of already fraught regions. Therefore, it is critical that field-forward personnel have access to tools that yield unequivocally trusted diagnostic and biosurveillance results to enable rapid and informed decision-making regarding medical support and interventions to prevent or mitigate illnesses and epidemics.

State of the art diagnostics (Dx) and biosurveillance (BSV) systems are unable to keep pace with disease outbreaks, fail to provide high trust information to support decision making at the time and place of need, and do not address disease severity. These shortcomings stem from a lack of the right balance of cost, reagent and equipment needs, inability to easily update for new targets, slow time to answer, low number of targets per test, and, most importantly, underperformance on two key metrics important for trustworthy detection – sensitivity (correctly identify a true positive sample) and specificity (correctly identify a true negative sample). Most point-of-need detection is performed with lateral flow immunoassays – a low complexity test in which

antibodies patterned on nitrocellulose or other media bind protein targets in samples such as clinical specimens (e.g., blood, serum, urine) or other environmental samples (e.g., mosquito lysate, livestock biofluids, etc.). While these low-cost (<$1) tests are easy to operate and tolerate a wide variety of storage conditions, they suffer from poor sensitivity and specificity and are slow to reconfigure for new targets. More complex molecular assays and genetic testing – including PCR, microarrays, and whole genome sequencing – can provide higher sensitivity and specificity and greater multiplex capacity, but are largely incompatible with field-forward stabilization missions due to reagent and equipment needs and/or the time needed to yield an answer (hours to days). In moderate resource conditions, such testing is limited to a few systems in centralized laboratories akin to traditional clinical Dx. BSV workflows similarly require shipment of samples to a centralized laboratory for these more complex molecular assays, slowing sample to answer turnaround time and adding significant cost. Additionally, current assays for detecting host biomarkers that can assess disease severity are primarily lab-based and are not widely available outside of research settings, leaving a significant unmet need for both the military and public health institutions.

In recent years, gene editing technologies have proven to be a promising molecular tool for the detection and modification of genetic material in a manner that is precise, sensitive, rapid, cost-effective, and broadly accessible. Fundamental advances in gene editing technologies have been extended to include detection of disease-relevant nucleic acid targets in samples with high sensitivity and specificity, highlighting their potential utility for a range of Dx and BSV applications. For example, the Cas13-based SHERLOCK[1] (Specific High-sensitivity Enzymatic Reporter unLOCKing) and Cas12-based DETECTR[2] (DNA Endonuclease Targeted CRISPR Trans Reporter) platforms can differentiate between nucleic acid sequences that differ by a single nucleotide and rely on the collateral activity of the gene editing enzymes to boost signal and assay sensitivity.

Pre-amplification of the target nucleic acids is still typically required to reach single-molecule detection sensitivity, and gene-editing-based diagnostic platforms employ a variety of isothermal target amplification techniques, such as recombinase polymerase amplification (RPA) and loop-mediated isothermal amplification (LAMP). However, progress has been made toward rendering pre-amplification unnecessary. For example, the CRISPR-Chip system, which uses CRISPR-Cas9 immobilized on a graphene field-effect transistor to enable electrical detection of nucleic acids, is able to yield results within 15 minutes with femtomolar sensitivity and without target amplification or bulky instrumentation[3], and the SHERLOCK platform utilizes effector enzymes in tandem to boost sensitivity by 3.5-fold[4]. Additional advances directly impact the potential of gene editing-based diagnostics in the field, including INSPECTR[5] (Internal Splint-Pairing Expression Cassette Translation Reaction), which employs synthetic biology-based gene

[1] Gootenberg *et al*., Nucleic acid detection with CRISPR-Cas13a/C2c2. *Science*. 2017 April; 356: 438-442.
[2] Chen *et al*., CRISPR-Cas12a target binding unleashes indiscriminate single-stranded DNase activity. *Science.* 2018 April; 360: 436-439.
[3] Hajian *et al.,* Detection of unamplified target genes via CRISPR-Cas9 immobilized on a graphene field-effect transistor. *Nature Biomedical Engineering.* 2019 June; 3: 427-437.
[4] Gootenberg *et al.*, Multiplexed and portable nucleic acid detection platform with Cas13, Cas12a, and Csm6. *Science*. April 2018; 360: 439-444.
[5] Pardee *et al.,* Rapid, Low-Cost Detection of Zika Virus Using Programmable Biomolecular Components. *Cell*. 2016 May: 165: 1255-1266.

networks to create a paper-based, shelf-stable, diagnostic that works at ambient temperatures, and HUDSON[6] (Heating Unextracted Diagnostic Samples to Obliterate Nucleases), a rapid pre-treatment method that enables nucleic acid detection directly from clinical samples, such as bodily fluids, without additional sample preparation. The availability of orthogonal reporter molecules and orthogonal Cas enzymes can also facilitate multiplexing[4]. Taken together, these recent advances indicate that gene editor-mediated nucleic acid detection technologies have the potential to provide a powerful, flexible new capability for rapid Dx and BSV in the field.

While initial proofs of concept in support of future fieldable gene-editing based detection are encouraging, there remains significant technology innovation and development that is required to deliver the intended radically improved Dx and BSV capabilities. To achieve this goal, DIGET will design, develop, prototype, and deploy two novel nucleic acid detection devices for the simultaneous detection of multiple targets: 1) a disposable point-of-need diagnostic for up to 10 targets, and 2) a massively multiplexed detection (MMD) device for 1,000 or more targets. Both devices must be simple to operate, low-cost, and rapidly reconfigurable to provide high impact, high quality, and trusted information that enhances decision-making. The devices will share a common upstream assay development pipeline and will have different but complementary uses in the field where they could be used individually or together depending on need. The disposable point-of-need device will improve the speed and efficacy of triage and treatment and enhance the standard of care for the military and public health domains; and the MMD device will enable a more comprehensive analysis for early threat detection, high throughput low-volume analysis of samples, assessment of patient status, and improved situational awareness to improve standard of care and inform countermeasure deployment. Successful DIGET technologies will be versatile enough for use in active combat zones, disaster response, and Role/Echelon 1 (point-of-need) and Role/Echelon 2 (MMD) medical settings worldwide.

1.2. TECHNICAL OBJECTIVES AND PROGRAM STRUCTURE

DIGET will encompass a four-year effort organized as two sequential two-year phases of increasing technical complexity. During Phase I, performer teams will establish and integrate the fundamental chemistry and hardware tools necessary to address each of the Technical Areas and will build benchtop (point-of-need) and breadboard (MMD) device prototypes to provide laboratory proof-of-concept for the point-of-need and MMD platforms. Phase II will focus on further development of prototypes, testing with a broad range of clinical and environmental samples, manufacturing, and ultimately field testing to generate data in support of submissions for Food and Drug Administration (FDA) approval. Intermediate and end-of-phase milestones, as outlined in this BAA, will be required in each phase to evaluate progress throughout the program.

The program consists of two Technical Areas (TAs) to be addressed concurrently:

1. Technical Area 1 (TA1): Detection assay design and development;

2. Technical Area 2 (TA2): Device development and deployment.

[6] Myhrvold *et al*., Field-deployable viral diagnostics using CRISPR-Cas13. *Science.* 2018 April; 360: 444-448.

The objective of TA1, **detection assay design and development**, is to establish the foundational chemistries to support gene editing-based detection tools and assays for pathogen and host nucleic acid targets. Proposers must target nucleic acids for detection, broadly defined to include DNA and RNA from pathogens for diagnostic purposes and host biomarkers (e.g., cell-free circulating DNA, mRNA transcripts) for prognostic purposes. The objective of TA2, **device development and deployment**, is to establish the requisite hardware and engineering advances to implement the detection assay chemistries in a low-cost, disposable point-of-need device and a simple, rugged MMD device. Proposers must also develop the front- and back-end bioinformatics pipelines required to design sensitive and specific nucleic acid detection assays and generate actionable data from massively multiplexed (≥1,000 targets) assays. Proposers must also plan to verify performance of both the point-of-need and MMD devices in Capability Demonstrations and a field test and submit a regulatory approval package to the FDA for a proposer-defined, DoD-relevant indication prior to completion of the program.

Both TAs must be developed concurrently over the duration of the effort. Proposers are responsible for ensuring their team has the requisite technical expertise, capabilities, and facilities to address both TAs. Proposals that fail to address both TAs and DoD-relevant indications will be considered non-responsive and not considered for review.

1.2.1. Technical Areas

TA1. DETECTION ASSAY DESIGN AND DEVELOPMENT

In TA1, proposers should focus on the foundational chemistries and tools required for the development of sensitive and specific detection assays to be used in point-of-need and MMD devices. This development will include generation of the enzymes, reporters, probes, and the associated upstream computational pipeline to support reagent and assay design. Proposed approaches must be compatible with multiplexed assays (i.e., ≥10 targets for point-of-need devices and ≥1000 targets for massively multiplexed approaches) and yield assays that are interoperable (i.e., adaptable for use on both point-of-need and MMD devices) and rapidly reconfigurable (i.e., components can be updated to respond to new targets in less than a day). Proposed reagents must be able to be generated in outbreak relevant timescales (<24 hours) and quantities to meet manufacturing goals of increasing speed and scale throughout the program. Proposers must design their reagents and assays to address DoD relevant panels of targets, and it is anticipated that multiple panels will be proposed. There may be panels of the proposer's choosing, but the panels developed must also include panels of DoD relevant targets. These targets must specifically include pathogens and disease biomarkers associated with at least two of the following:

- respiratory illnesses (e.g., severe acute respiratory syndrome, influenza),
- febrile illnesses (e.g., viral hemorrhagic fevers),
- vector-borne illnesses (e.g., malaria, viral encephalitis),
- gastrointestinal illnesses (e.g., cholera, giardiasis), and/or
- sepsis (e.g., bacterial, viral, fungal).

Of the two or more panels of DoD relevant targets selected by the proposer, at least one of these panels must also address host biomarkers to report severity of disease. Proposers may also choose to explore panels of targets of commercial interest. Proposers must clearly define the

make-up of their target panels, provide technical rationale for their selections, and include targets that will report comprehensive information about a given threat type (e.g., pathogen subtype, host biomarkers for disease severity, antimicrobial or anti-viral resistance).

It is anticipated that the core nucleic acid detection and signal amplification enzymes will be gene editing-based systems (e.g., Cas12[2], Cas13[1], or other novel editors); however, any technology that can achieve the desired assay sensitivity and specificity and other DIGET performance metrics in the form factors required will be considered. For proposers planning to use gene editing enzymes, proposals must describe current enzyme performance (e.g., off-target frequency, turnover, amplification, multiplex compatibility, etc.) and identify strategies for iteration/optimization and troubleshooting/risk mitigation. Because of the desired multiplexing capability, enzymes must operate in an orthogonal manner and not interfere with each other.

In order to detect specific nucleic acid targets in RNA and DNA, proposers must define the probes necessary for identifying the target nucleic acids within a sample, most likely guide RNAs or crRNAs for compatibility with gene editing-based detection strategies. Both broad probes (i.e., targeting sequences that are present across a number of strains/biomarkers) and specific probes (i.e., targeting unique sequences that can identify subtype, rare mutations, and host biomarkers of disease severity) are necessary and must be compatible with both point-of-need and MMD devices. These probes must be designed to maximize orthogonality to other targets and avoid unintended non-specific activity or spontaneous or erratic signal amplification.

Design and discovery of broad and specific target probes for thousands of pathogens and host biomarkers will require a bioinformatics pipeline to support the development of DIGET technologies. Recent advances have demonstrated a wide array of *in silico* tools to aid in gene editing tool creation and target refinement. Proposers must define their *in silico* pipeline, including any specific machine learning and artificial intelligence tools required for probe, enzyme, and/or assay design. Proposers must also include strategies to leverage pre-existing data sets to inform their design strategies, indicate how reference genes will be utilized, and how pathogen and host variability will be addressed in their design of universal Dx and BSV tools. *In silico* models should also support the enzyme design, build, and test process and help optimize overall *in vitro* assay performance. Modeling and simulation results should complement experimental investigation that quantifies the enzyme system efficacy and characterizes both on-target and off-target system activities. Furthermore, proposers must describe how the *in silico* pipeline and assay workflows will be agile enough to rapidly (less than a day) design assays for novel or emergent threats, including timelines for designing, building, testing, and validation of new probes from the moment a new target is identified to the time a new test is delivered. This computational pipeline could be adapted from existing, publically available tools or a novel pipeline developed for the DIGET program. If used, reference genomes or other data sets used to build these informatics tools must be specified in the proposal.

To enable sensitive detection of nucleic acid targets, signal amplification will be necessary. Phase I approaches may be coupled with target amplification (e.g., LAMP, RPA); however, proposers should clearly explain how pre-amplification could be phased out by the Phase I demonstration prior to Phase II. Signal amplification may include approaches that leverage the collateral activity of gene editing enzymes to activate reporter molecules, synthetic biology-

based genetic circuit reporters, or other robust approaches. Proposers must define their reporter molecules and strategies to develop assays that have utility for both the point-of-need and MMD devices, which may require different sets of reporters to generate results. Proposers must measure and report the dynamic range of assays, as well as limit of detection (LOD) for each target tested (see Tables 1 and 2: >4-logs dynamic range, <10 copies LOD).

Proposals must clearly define a simple single-step user-performed or automated assay workflow and include strategies that are compatible with collection methods of small sample volume (e.g., finger stick, mouth or nasal swab, sputum specimen, in-stream urine testing), require little-to-no sample preparation (preferred), and approaches to overcome the current state of the art need for pre-amplification of nucleic acid targets in the sample (by the end of Phase I). Assays must be generalizable, that is, compatible with a variety of sample types (e.g., clinical, environmental, and other lab samples) and matrices (e.g., blood, saliva, water, mosquito lysate) that could be encountered in the field. Further, the ability to detect multiple targets simultaneously (i.e., multiplex) is a key feature of both the point-of-need and MMD assays. It is anticipated that the point-of-need assays will measure 10 unique nucleic acid targets per sample tested by the end of the program. For MMD assays, proposers should describe strategies to achieve measurement of 1000 unique targets in a single sample, as well as a single target across 1000 unique samples and variations therein, to provide a maximally versatile tool for field and biosurveillance use.

Proposers should specifically articulate the sample volume requirements for the assays to achieve program goals for sensitivity and specificity, not to exceed 150 ul volume for point-of-need, or 1.5 mL for MMD, consistent with Role/Echelon 1 and Role/Echelon 2 settings, respectively. Proposers must describe their method of sample collection, and justify sample volume requirements with statistical analysis for probability of detection (e.g., probit curve or confidence interval) of a given sequence at clinically relevant concentrations. Biofluid sample collection should focus on non-invasive or minimally invasive procedures. In order to enable rapid detection using small sample volumes, proposers are encouraged to consider advances in microfluidic technologies that have demonstrated ultrafast kinetics, thousands of reaction compartments at nanoliter scale, and a variety of form factors ranging from media-based, lab-on-a-disk, and lab-on-a-chip at the point-of-need. Proposers must also ensure that compartmentalization of samples into microfluidic droplets will not compromise the sensitivity of the assays, and provide statistical data analysis to support proposed strategies.

By the end of the DIGET program, assays must meet program goals outlined in Table 1. Proposers must describe how assay performance metrics such as sensitivity, specificity, dynamic range, and time to result will be achieved, and how performance will improve over the course of the program. Proposers must also identify how they will access a variety of benchmark and testing samples that will be used to inform and facilitate detection assay development and to allow demonstration of the reproducibility, generalizability, and performance of the developed assays with real world samples. Samples should be relevant to the chosen concept of operations and of increasing complexity throughout the program. For example, development may begin with contrived and spike-in samples, but must ultimately perform with complex, neat samples. Assay performance must be regularly assessed against gold standards (e.g., FDA approved tests or error-free reference standards) for the proposer-chosen targets. If no gold standard exists, performers must detail how they will quantitatively evaluate performance using approaches based on method(s) that will be acceptable for regulatory review. Proposers must justify their

choice of approach, based on the degree of deviation from the classical paradigm and/or goal metrics (e.g., acceptable reference standard available versus reference standard is imperfect versus reference standard does not exist).

Table 1. Final DIGET Program Goals.

Feature	Goal
Limit of Detection	<10 copies of nucleic acid target
Diagnostic Sensitivity and Specificity	≥98%
Dynamic Range	>4 logs
Target Nucleic Acid Similarity	Detect single-nucleotide differences
Time (Sample to Answer)	<15 minutes
Multiplex	≥10 per point-of-need; ≥1000 per MMD
Sample Volume	Point-of-need: <150 µL; MMD: <1.5 mL
Sample Preparation	Online or simple single step
Sample Throughput	Point-of-need: one-use disposable; 1000s samples per day MMD: >1,000 tests/disposable component; up to ~ 100,000 tests/day from a single device
Cost	<$1 per point-of-need run; <$10 per MMD run
Target Pre-Amplification	None
Generalizability	Compatible with >1 sample type/matrix (e.g., blood, sputum, environmental lysates)
Reconfigurability	<24 h
Interoperability	Assays compatible with point-of-need and MMD devices
Stability and Ruggedness	Shelf-stable, minimal/no power requirements
Integration	Fully integrated sample prep, TA1 Assays, and TA2 hardware

Phase I (Base, 24 months): Detection Assay Design and Development

Phase I should yield new computational, chemical, and/or biochemical methods to detect target DNA and RNA, develop novel foundational detection reagents (e.g., enzymes, reporters), integrate these reagents into generalizable assays, stabilize the reagents for ambient temperature storage, and demonstrate one-step, rapid, and sensitive detection.

Proposers will develop reagents that will enable assays with low limits of detection, robust dynamic range, high sensitivity and specificity, and same-hour results. These reagents must be designed with both the point-of-need diagnostic and the MMD devices in mind, enabling multiplex detections across a variety of samples. Proposers will identify/develop computational pipelines for probe and enzyme designs. High throughput screening techniques may complement *in silico* tools to identify, design, and optimize functional enzymes for detection chemistry in an iterative manner.

Proposers will develop strategies to measure and mitigate potential failure modes, which must be identified and accompanied with proposer-defined characterization and risk mitigation plans.

Some examples of potential failure modes may include, but are not limited to: off-target activity, lack of multiplex compatibility, unsuccessful activation or inactivation of signal amplification, or presence of inhibitors/confounders in samples. The entire design and validation approach, including the *in silico* pipeline and experimental investigations, must also allow for the revision of a reagent set or development of a new one within a single day by the end of the program.

Proposers will test their assays against a variety of sample and matrix types, including matrices/samples spiked with target nucleic acids to ensure their assays are generalizable across likely field samples. In order to maximize impact and assess reconfigurability, proposers must select two panels of targets with relevance to DARPA/DoD, and test the assays developed in this TA with real world samples appropriate to the proposed use case. These tests can include internal testing performed during development and must include the capability demonstration in Month 22, as described in Section 1.2.5, Capability Demonstrations and Fielding. Proposers should clearly articulate the source, type, and numbers of samples that would be tested in this phase, the quality of data associated with the samples (e.g., clinical outcomes, data from gold standard reference tests already completed), and if these samples are banked or would need to be collected. Sample types must be justified based on their relevance to a defined DoD need (e.g., tropical febrile panel, biosurveillance in a given geographic region, etc.). Proposers will also complete necessary activities to support delivery of DIGET tools to the Independent Verification and Validation (IV&V) teams for testing prior to the completion of Phase I.

By the end of Phase I, performers are expected to:

- identify and develop the enzymes, probes, and reporters required for a point-of-need and MMD nucleic acid detection capability that is:
    - specific – e.g., exhibits activity only for intended targets and correctly identifies true negative samples without ambiguity;
    - sensitive – e.g., detects low abundance samples in complex sample matrices and correctly identifies true positive samples without ambiguity;
    - multiplexable – e.g., compatible with simultaneous measurement of multiple nucleic acid targets; and
    - reconfigurable – e.g., probes can be swapped into assays with ease to detect new targets with minimal re-optimization of assays;
- establish an *in silico* pipeline for probe and assay design, *in vitro* validations, and rapid reconfigurations;
- demonstrate generalizability by being able to perform with at least two different sample types/matrices;
- identify risks and mitigation plans for assay integration into the devices and Phase II assay optimization; and
- define DARPA/DoD-relevant application (e.g., respiratory, febrile, vector-borne, gastrointestinal panel, or host disease severity) and associated samples for testing and establish approach for IV&V.

Phase II (24 months): Detection Assay Development

In addition to the development of a second DARPA/DoD-relevant panel and any required optimization and validation of the detection assays, the majority of Phase II efforts will involve integrating the assays into the point-of-need and MMD device prototypes and field testing. Please see Section 1.2.4, Integration, and Section 1.2.5, Capability Demonstrations and Fielding for additional information.

TA2. DEVICE DEVELOPMENT AND DEPLOYMENT

TA2 activities should focus on the development of the novel hardware and engineering strategies required to package the detection assays from TA1 into field-forward, deployable devices. The proposers must address both the point-of-need and MMD platforms - two separate devices must be developed in parallel by each proposer team. Both the point-of-need device and MMD must address the following features: unambiguous results in ≤15 minutes, ≥98% sensitivity and specificity, integrated sample processing (as necessary), reconfiguration in <1 day, compatibility with a wide range (>2) of samples and sample types (e.g., clinical samples, environmental samples), and a low-cost, disposable component (e.g., consumable assay cartridges/devices).

As described in the TA1 section, there is a preference for both no reliance pre-amplification of nucleic acids and for little-to-no sample preparation. Thus, the proposal must detail an approach to increase the likelihood of reagent-target reaction without further concentration or purification of the target and in a manner that will ultimately enable detection within 15 minutes. The proposal must also include a detailed description of how both devices will be generalizable across a range of sample types. For example, for a respiratory application, the device would be able to handle samples with dynamic, non-Newtonian viscoelastic properties (e.g., mucus), which would make precise metering challenging. Similarly, devices that sample blood would need to contend with variabilities in clotting, hematocrit, and other properties which could confound results.

Proposals should clearly describe sample handling (i.e., how the user will input the sample to the device), sample preparation (i.e., how the nucleic acid content of the sample will be accessed), if required, and sample requirements for successful detection (e.g., volume, sample matrix compatibility, types of samples) to maximize broad compatibility across use cases. Ideally, sample preparation will not be necessary, but, if included in the proposal, sample preparation should be one-step, simple (e.g., neat sample added to lysis buffer and invert prior to application on device) and clearly described. For the point-of-need device, ideally there is only an application of a small volume of saliva, blood, or other raw sample type directly to the device. If a sample preparation strategy is proposed for the MMD device, it should ideally be in-line and automated. Proposers must define this strategy, including whether it employs novel or off-the-shelf technologies, and how sample preparation will be integrated into the end device and workflow.

The point-of-need diagnostic must be compatible with a one-step operation (e.g., application of the sample) and a *visual* output of results that is non-ambiguous with sharp cut-offs and a wide dynamic range. The device also must be able to detect at least 10 different targets simultaneously while being handheld, low-cost, and disposable. All technologies and form factors meeting these requirements will be considered. Recent studies have demonstrated rapid, instrument-free nucleic acid detection using paper-based and shelf-stable materials[5], lateral flow technology compatible

with gene editing tools[6], and a graphene-based field-effect transistor[3]. There has not been a demonstration of a low-cost (i.e., <$1), disposable device that can detect up to 10 different targets, and achieving this degree of multiplexing will likely require novel materials, reagents, and/or surface chemistries.

The MMD device must incorporate a low-cost (i.e., <$10), disposable component (e.g., cartridge) for single-step operation by the user (i.e., it contains all reagents and fluidic components necessary for automated sample preparation and detection). Further, the disposable component must allow for massive multiplexing of greater than 1,000 simultaneous detection assays. The proposers must also define the companion equipment that will rapidly read the assay results, generate a clear, simple but detailed visualization of the results, include geographic metadata as part of the results, identify secondary infections, and upload the raw data to a biosurveillance network (e.g., cloud-based) for additional analysis and trend prediction. The companion equipment must be compatible with field use, and proposers must address how they will achieve power source, weight, size, and ruggedness fit for this purpose. Based on the scale of the disposable component and the design of the companion equipment, the proposal must include estimates of sample throughput (i.e., how many samples can be analyzed per unit time and per device/disposable component). Proposals should also address arrangement of the targets and if the system enables random-access (e.g., load samples and consumables on the fly with operator walkaway capability). Sample throughput is of special concern during outbreaks/emergencies when the number of samples to be tested increases dramatically.

Proposers must consider manufacturing and scale in the device designs. In order to meet DoD needs and timelines, DIGET devices must be able to be produced at scale (e.g., tens to hundreds of thousands of consumables, hundreds to thousands of companion MMD devices) and devices/consumables must be reconfigurable in order to react and respond to emerging threat information on time scales able to impact a disease outbreak (e.g., days). Proposers must have a manufacturing plan and detail the expected cost of the platforms proposed as well as justify those costs (e.g., bill of materials, current cost of goods). Agile, rapid reconfiguration (<1 day), and arbitrary arrangement of targets (e.g., from the chosen panels of DoD relevance) of the platform must also be described in the proposal, as well as time to manufacture (preferably less than a week) and distribute. Proposers must also clearly articulate approaches for reconfiguration (i.e., how the devices are reconfigured) and at what stage of deployment the reconfiguration can take place (i.e., where the devices can be reconfigured).

Proposers must justify their device hardware, algorithms, and workflow choices using design principles, data, and appropriate technical rationale, based on:

- simplicity and ease of use,
- the ability to rapidly reconfigure the devices to target new nucleic acids,
- the ability to meet manufacturing goals,
- user-friendly readouts,
- the ability to report on emergent threats,
- sample throughput, and
- ruggedness.

Proposers must address both the point-of-need and MMD platforms. Proposals that focus on the generation of only the point-of-need or the MMD device will be considered non-responsive and not considered for review.

Phase I (Base, 24 months): Device development

In Phase I, proposers will establish, design, build, and test prototype point-of-need and MMD devices that incorporate assays developed in TA1 as described above. Depending on the proposer-defined DARPA-relevant applications, the types of devices, the form factors of the device, and the user interface may vary. Concurrent with assay development activities in TA1, performers will gather requirements for successful execution of those assays in TA2 devices, as available. Workflows from candidate assays developed in TA1 should be mapped to corresponding manipulations on the device side. For example, sample processing, handling, preparation (including nucleic acid extraction and clean up) may be workflows from the bench which need to be translated onto the device platform. Target identification, subsequent signal amplification steps, and detection should similarly follow.

For the point-of-need device, performers may need to iteratively design, build, and test prototypes to optimize performance. The use of computer-aided design tools, multiphysics simulation of fluid dynamics, and other computational packages may be used to accelerate device design and predict performance. Materials science development and leveraging advances in chromatography may be necessary to enable the detection assay features defined in TA1, especially multiplexing for 10 different targets. Proposals including point-of-need devices that require an additional reader will be considered non-responsive, but non-instrument readers that produce visual outputs without the need for external power sources, such as instant film, will be considered. The type of reporter developed under TA1 (e.g., gene circuit, nanoparticle, precipitating dye) must be arranged on the device such that the results are easily read and understood, making an effective decision-making tool. For example, this could involve spacing lines or dots on a lateral flow test strips with different chromogenic readouts.

For the MMD device, performers may first establish the standalone modules (e.g., sample handling, sample processing, and detection/readout) for performance of detection assays. Sample handling and processing modules must be compatible with a wide range of sample types and sample matrices. The modules must also be capable of metering/routing the sample throughout the assay process to achieve one step operation for the user by the end of Phase I. During Phase I, nucleic acid amplification steps are not preferred, but will be permitted to achieve sensitivity/limit of detection requirements, and these steps should be incorporated into the device platform. It is expected that the approach for amplification would leverage recent advances to miniaturize and accelerate reactions beyond benchtop formats to meet requirements for sensitivity and speed. The detector, or detection modality, must enable rapid, sensitive, and specific detection of the target sequences.

The MMD companion equipment will house the hardware necessary for the back-end algorithmic analysis. The equipment should have a user-friendly interface, and results from massively multiplexed assays should be reported in simple readouts that clearly communicate the identity and levels of the pathogens detected, and the identity and levels of host biomarkers responsible for the disease severity assessment. Additionally, the companion equipment should

be able to integrate into existing BSV networks (e.g., upload assay results to existing biosurveillance networks in a compatible format), allowing for further analyses and immediate trend prediction. By the end of Phase I, proposers will develop breadboards that will enable sample analysis with minimal user manipulation and input, using the assays developed in TA1. At this milestone in the program, the various modules that may be required for sample-to-answer must be co-located on the same breadboard, and capable of automatically and directly accepting the input from the preceding module versus existing as standalone modules that require user intervention.

By the end of Phase I, performers are expected to:

- manufacture 500 units of a 10-plex, handheld, instrument-free prototype point-of-need device,
- integrate MMD device modules into a breadboard-level prototype with 500-plex capabilities,
- achieve ≥85% sensitivity and specificity,
- achieve detection of 1,000 copies of target nucleic acids or fewer
- demonstrate data analytics and capability to upload results, and
- have coordinated technology onboarding with IV&V partners, shipped platform to partner site, and successfully demonstrated performance in the hands of IV&V partners.

Phase II (24 months): Device deployment

In Phase II, the performers will prototype and ultimately test in the field integrated, deployable, field-forward point-of-need and MMD devices. Please see Section 1.2.4, Integration and Section 1.2.5, Capability Demonstrations and Fielding for additional information.

1.2.4. Integration

The component capabilities from the TAs must work as an integrated whole to generate point-of-need and MMD devices that meet final DIGET program goals and metrics (Tables 1 & 2). Therefore, proposals must address two integration efforts in Phase II of each TA: 1) full integration of the assays into point-of-need and MMD devices for TA1 and 2) the integration of MMD device modules into a field-forward device that will fit into a mobile platform (e.g., smaller than a Pelican case) for TA2. Integration plans must include any optimization steps, expected risks and risk mitigation strategies, and testing plans to demonstrate successful performance once components are integrated into their prototype formats. Testing plans must include evaluations of the integrated prototypes using the guidelines outlined in previous sections and allow for third-party testing performed by the IV&V teams that will be coordinated by DARPA. Given the goal of submission to the FDA (e.g., for an Investigational Device Exemption (IDE)), internal testing of integrated devices should be based on guidance that will be recognized as a trusted source by FDA.

The integrated, FDA-relevant product will be an end-to-end system including front-end bioinformatics for design and reconfiguration, sample application, sample preparation, target nucleic-acid detection, signal amplification and readout; and back-end computation for assay

data analysis and upload. In order to achieve this goal, the integration of TA1 assays and TA2 prototypes into streamlined point-of-need and MMD devices will require transitioning solution-based assays into formats suitable for long-term storage and performance at field forward locations without the benefits of laboratory equipment and personnel. Additionally, for the MMD device, this effort will include integration of its laboratory-based breadboard components into a fieldable platform. Proposals must describe methods for incorporating all necessary reagents into a shelf-stable format compatible with the requirements and performance metrics for the point-of-need and MMD devices. Proposals must describe how they will ensure long-term stability (i.e., 1 year) of their integrated assays when stored at a range of ambient temperatures and humidity conditions, and how device performance may deteriorate over time at these conditions. Format, stabilization approaches, and integration approach must be justified based on their ability to enable one-step assay execution in the point-of-need and MMD devices with no significant loss in assay performance and the longevity of the assay when stored at ambient temperatures. Proposals should also describe any optimizations to improve assay performance to meet Phase II goals.

Both the integrated point-of-need and MMD devices must meet or exceed ruggedization metrics in Section 1.3, Program Metrics. Proposals must describe the materials and designs that will be used to mitigate the effects of potential stresses (e.g., drops, vibration, particulates, temperature, etc.), explain why certain conditions are not expected to cause adverse effects, and/or identify stresses that would cause significant to total loss of performance. Proposals must identify the standard to which they are designing (e.g., MIL-STD-810) and detail how resistance to relevant stresses will be evaluated. Ruggedization approaches must be justified based on the number of stresses the final form is expected to mitigate while still meeting the necessary size, weight, power and cost requirements. Furthermore, the integrated forms for both the point-of-need and MMD devices must be produced at an increasing scale in a timely (less than one week) and cost-effective manner.

By the end of Phase II performers are expected to:

- demonstrate assay and component integration into final, field-forward point-of-need and MMD devices;
- demonstrate sensitive and specific detection of target nucleic acids constituting two DARPA/DoD-relevant panels (respiratory, febrile, vector-borne, or gastrointestinal);
- demonstrate ruggedization of devices (metrics detailed in Section 1.3, Program Metrics);
- demonstrate detection of <10 copies of target nucleic acid;
- demonstrate ≥98% sensitivity and specificity;
- define the deterioration of device prototype performance after 1-year storage at multiple, proposer-defined temperature and humidity conditions;
- demonstrate manufacturing of 50,000 units of the point-of-need device;
- demonstrate manufacturing of 10 units of the MMD device and 1,000 disposable components; and
- demonstrate successful transfer and testing by IV&V partners.

1.2.5. **Capability Demonstrations and Fielding**

The integration of novel biochemical assays with prototype devices in an interoperable, deployable platform is critical to the success of the DIGET program. During the four-year program, DIGET performers will complete Capability Demonstrations in each program year to detect nucleic acid sequences from samples of increasing complexity and in decreasing timeframes, to manufacture the point-of-need device in increasing scale, and to demonstrate MMD system performance with an increasingly integrated platform in order to achieve the overall goals of the DIGET program. Devices that are manufactured to meet program metrics are anticipated to be used as consumables for Capability Demonstrations and Field Tests.

During Phase I of the program, individual assays and device module performance will be assessed by Capability Demonstrations at 12 and 22 months, although final integration will not yet be required (i.e., air-gapped modules are acceptable during Phase I). An alpha-prototype of the integrated system will be assessed in the Month 30 Capability Demonstration. By the Field Tests in Month 40, performers must demonstrate end-to-end detection on a fully contained and integrated prototype system.

Phase I, Milestones:	Month 12
Phase I, Capability Demo 1:	Month 22
Phase II, Capability Demo 2:	Month 30
Phase II, Field Test:	Month 40

Specific metrics associated with each Technical Area in the Capability Demonstrations are discussed below in Section 1.3, Program Metrics, Table 2. Importantly, subsequent to each Capability Demonstration and Field Test, proposers must transfer their technology to IV&V teams that DARPA will organize for third-party performance assessment and testing. Proposers must include a plan to facilitate transfer of reagents, tools and devices either in parallel or immediately following each Capability Demonstration. Field Tests will comprise testing of point-of-need and MMD devices at domestic and international sites. At a minimum, proposers must define a single domestic or international site for the Year 4 Field Test. In parallel, IV&V teams will test point-of-need and MMD devices at 4 additional sites, to be determined with DARPA, for a total of 5 Field Type sites for each proposer team by the end of the DIGET program. For each Field Test site, teams must test a minimum of 1000 point-of-need tests, and 50 disposable components across 2 MMD devices for a given DoD relevant panel(s), to be agreed upon by the DARPA PM.

In Phase I, proposers should leverage pre-existing sample collections or commercially available samples for testing wherever possible. Later Capability Demonstrations may involve samples collected prospectively for DIGET purposes; however, proposers must clearly indicate how sample collection timelines will not put technology development timelines at risk. Samples for testing must be chosen to approximate what could be seen in the field, such as clinical samples (e.g., flu season samples), environmental samples (e.g., insect vector or animal reservoir samples), and/or unexpected organisms (e.g., lab strains, engineered viruses). The performance evaluations will include measurement of sensitivity, specificity, and robustness to confounders as compared to gold standard state of the art assays, as available.

Following each Capability Demonstration, and at the start of Field Tests, proposers will deliver prototype devices to IV&V teams for third-party performance evaluation. In Phase II, the IV&V team will validate the proposer-performed Capability Demonstrations of the integrated device prototypes and domestic and international Field Tests with the final device prototypes. The IV&V team will generate reports describing the performance of the assays at each benchmark test so that DARPA can become aware of potential issues before proceeding on to further development, and so that proposer teams may iterate and improve upon device designs and performance. Phase I and II proposer and IV&V data will support FDA submissions. Phase II evaluations will also assess prototype ruggedness.

Performers must define a plan to work with the third-party IV&V team and must include in the proposed budget allowance for such work (e.g., sample/device shipment, training materials, labor, travel, etc.). Proposals must also include a plan and budget for field testing at domestic and international locations.

For budget planning purposes, assume device shipping and personnel travel for one domestic or international site of the proposer's choosing, and four IV&V trials: two domestic trials (one per coast) and two international trials (e.g., Europe, Asia, South America, etc.). Performers will be responsible for ensuring all regulatory requirements are met and all permits are received. Because testing at international locations is expected, proposals must list the specific information, assay and system components, software, etc., that are subject to export controls and identify which export control regime applies (e.g., Export Administration Regulations [EAR]).

1.3. PROGRAM METRICS

In order for the Government to evaluate the effectiveness of a proposed solution in achieving the stated DIGET program objectives, the Government has identified Metrics (Table 2) with the intention of bounding the scope of the effort, while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problem set. Proposals should cite the quantitative and qualitative success criteria that the effort will achieve by each Phase's program milestone and intermediary metric measurement.

Phase I Metrics – Development and Prototyping, Months 1-24
Phase I will include milestone metrics at Month 12 and one Capability Demonstration at Month 22. These metrics are established below in Table 2. At Month 18, teams are required to initiate FDA engagement (e.g., pre-pre-IDE submission to the Center for Devices and Radiological Health [CDRH]) to define the regulatory pathway for the DIGET platforms. Outcomes of the meetings with relevant FDA centers will inform the path to the initial submission required at the end of program (Phase II).

Phase II Metrics – Integration and Validation, Months 25-48
Phase II will include testing of the integrated point-of-need and MMD prototypes at a Month 30 Capability Demonstration and conclude with a Field Test at Month 40. The Field Test will demonstrate a fully integrated, rugged, end-to-end diagnostics and biosurveillance platforms. In addition, each team is required to complete a submission to the FDA (e.g., IDE) by Month 48 for the point-of-need DIGET device. Submission of the MMD device to the FDA is encouraged but not required.

Use of DIGET devices in field-forward settings and austere environments where U.S. military teams deploy requires that the devices be rugged and mobile. Constraints on Size, Weight, and Power (SWaP) help ensure that these requirements are met. In addition to the metrics above, performer teams will be required to meet the following **ruggedization** goals:

- Size: the point-of-need device shall be hand-held. The MMD device shall be able to fit into a case smaller than approximately 18.5 x 12 x 8 cm.
- Power: the MMD device companion equipment shall be battery operated, with the battery being rechargeable through a generator. Point-of-need should not require any power input.
- Both devices shall be capable of withstanding long duration (about 1 month) across a range of extreme temperatures: -20C to 50C (-4F to 122F), and a minimum of 1 year at ambient room temperature.
- The MMD device shall be able to withstand 5 drops from 1.5-m onto a hard surface (e.g., concrete).
- These metrics will be evaluated according to appropriate standards (e.g., MIL-STD-810H).

Table 2. Program Metrics.

	Year 1	Year 2	Year 3	Year 4
	Phase I: Assay/Device Development		Phase II: Integration	
Timeline	Milestones: 12 months	Capability Demo 1: 22 months	Capability Demo 2: 30 months	Field Test: 40 months
TA1 Metrics	Clinical metrics: • Detection: 5,000 copies • **≥85% Sens./Spec.** • Spike-in samples	Clinical metrics: • Detection: 1,000 copies • **≥90% Sens./Spec.** • Clinical/environmental samples	Clinical metrics: • Detection: 100 copies • **≥95% Sens./Spec.** • Blinded clinical/ environmental samples	Clinical metrics: • Detection: <10 copies • **≥98% Sens./Spec.** • Blinded clinical/ environmental samples
TA2 Metrics	• Detection: 5,000 copies • **≥80% Sens./Spec** Point-of-need: 5-plex, **100 units** MMD: **100-plex** Standalone modules • Sample handling • Sample processing • Detection/readout	• Detection: 1,000 copies • **≥85% Sens./Spec** Point-of-need: 10-plex, **500 units** MMD: **500-plex** Integrated modules Breadboard	• Detection: 100 copies • **≥90% Sens./Spec** Point-of-need: 10-plex, **5,000 units** MMD: **1,000-plex** Integrated platform Distributed environment (2 devices); 250 disposable components	• Detection: <10 copies • **≥98% Sens./Spec** Point-of-need: 10-plex, **50,000 units** MMD: **>1,000-plex** Integrated platform Operational environment (5 x 2 MMD devices); 1,000 disposable components
IVV	Sample coordination and technology onboarding	Benchtop assay and breadboard validation	Device prototype validation	Device Field Test
	Final deliverable: Point-of-need device suitable for FDA submission, validated MMD device			

1.4. GENERAL REQUIREMENTS

1.4.1. Proposing Teams

Proposers are responsible for assembling a complete team that has technical expertise, capabilities, and facilities to address all requirements of the program. Proposers must address

both TAs, which should run in parallel. Specific content, communications, networking, and team formation are the sole responsibility of the proposer teams. Proposer teams must submit a single, integrated proposal led by a single Principal Investigator, Program Integrator/Manager, under a single prime contractor that addresses all program phases, as applicable.

The Program Integrator/Manager shall serve as the primary point of contact to communicate with the DARPA PM and Contracting Officer Representative (COR), coordinate effort across performer teams, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables. For teams that are not physically co-located, proposers must articulate how logistical challenges will be overcome to ensure smooth collaboration and an integrated work product.

DARPA will hold a Proposers Day (see Section 8, Other Information) to facilitate the formation of proposer teams with the expertise necessary to meet the goals of the program and enable sharing of information among interested proposers through the DARPA Opportunities Page.

1.4.2. **Regulatory Strategy**

Proposers must present a detailed plan for early and continued engagement with U.S. regulatory agencies appropriate for use case/indication (e.g., Clinical Laboratory Improvement Amendments, FDA) to discuss the developing technologies and challenges. This engagement is necessary to meet the program regulatory milestones (e.g., IDE), to inform and to improve the design of the Capability Demonstrations, and to facilitate technological advancement and the eventual transition of the technology to field deployment. Ideally, proposers will identify the applicant for regulatory agency submission (e.g., IDE, Emergency Use Authorization, EUA) at the time of proposal submission. Additionally, although pre-EUA activities may be pursued they should not replace efforts to develop diagnostic devices for FDA approval through the appropriate pathways, and, where possible, EUA activities should proceed in parallel. It is anticipated that the point-of-need, handheld device will be the first device from this program suitable for FDA submission, and this submission must be for a DoD-relevant indication. Ideally, proposers will identify this indication, or a strategy to identify this indication, at the time of proposal submission.

1.4.3. **Ethical, Legal, and Societal Implications (ELSI) Strategy**

DARPA maintains its commitment to ensuring that efforts funded under this BAA adhere to ethical and legal regulations currently in place for Federal and DoD-funded research. Program developments will be discussed with a panel of expert external advisors organized by DARPA with expertise in bioethical issues. Proposers must include an ELSI section in the proposal that discusses the salient considerations associated with the study. Proposers should consider and discuss the ethical treatment of both animals and human research participants. Proposers may choose to embed an ethical consultant on their team who can facilitate ELSI discussions regarding issues that may arise with use of a point-of-need or massively multiplexed diagnostics or detection device. The ethical consultant may be a trainee (e.g., ethics graduate student) who helps with or attends experiments throughout the program in order to remain knowledgeable on the project.

1.4.4. **Informatics and Data Sharing**

DARPA anticipates that a large amount of data will be generated under this program by each proposer and that data analyses will be strengthened by compiling and integrating information across all teams. Therefore, the DIGET program will require that information be shared with DARPA, other DIGET performer teams, DIGET IV&V teams, U.S. Government stakeholders, and ultimately the broader research community. Proposers must include the description of a plan to provide data to DARPA, approximate timelines for data release, data and metadata types and formats, and total estimated data sizes.

1.4.5. **Transition and Commercialization Strategy**

Proposers must present a detailed plan for transition of the technologies developed during the program for testing, validation, and product formulation to the defense community, as well as other stakeholder entities and industry. It is critical that the DIGET devices be developed in a manner that positions them for further development and deployment by the end of the program with DoD transition partners identified and engaged throughout the course of the program. Engagement with IV&V partners (see section 1.4.6 below), in conjunction with DoD stakeholders, will enhance the utility of these devices for DoD use and enable rapid adoption by DoD components for advanced development activities. It is anticipated that DIGET devices will be relevant not only for defense but also for public health as viable candidates for clinical translation, commercialization, and technology transfer for other high impact applications. To further support transition and commercialization goals, performers may consider inclusion of qualified personnel to support these activities in order to increase a performer team's ability to move technology from the lab to a sustainable business that can provide new capabilities to the military.

1.4.6. **Independent Verification and Validation (IV&V)**

DIGET performers will interact throughout the program with IV&V teams established by DARPA that will help validate progress. The IV&V teams will consist of subject matter experts from Government, Federally Funded Research and Development Centers (FFRDCs), and/or other relevant domains. To assess progress toward achieving program metrics and milestones, performers must make their detection assays and device prototypes available for third-party testing by IV&V teams over the course of the program. During these evaluations, IV&V teams will analyze samples using the protocols provided by the performers. Protocols must be written in a manner that enables assay execution and result interpretation by IV&V team personnel without assistance from performers. Proposals must budget and include plans for shipping assays/prototypes and, if necessary, travel.

To avoid potential conflicts of interest, performers for DIGET will not be allowed to compete for an IV&V contract. DARPA is not soliciting proposals for IV&V under HR001120S0016. Government teams interested in participating in IV&V should NOT respond to this BAA, but rather indicate their interest in the DIGET program via email at DIGET@darpa.mil for further details.

1.4.7. **Deliverables**

All products, material and otherwise, to be provided to the Government as outcomes from conducted research should be defined in the proposal. Performers need to allot time and budget to fulfill obligations for travel to review meetings and the transmission of report documentation.

Monthly financial reports: Performers are required to provide financial status updates on a monthly basis. The prime Performer shall include information for itself and all subawardees/subcontractors. These reports should be in the form of an editable Microsoft (MS) Excel™ file, and should provide financial data including, but not limited to:

- Current spend plan
- Incurred program expenditures to date
- Invoiced program expenditures to date
- Explanation of spend plan deviations of +/-15%
- Mitigation plan for spend plan deviations of +/-15%

Technical progress reports: Performers are required to provide technical research updates in the form of a standardized slide presentation given to DARPA and discussed with the program management team via teleconference every 6 weeks. The length and detail level is at the discretion of the Program Manager.

Quarterly technical reports: The reports shall be prepared and submitted in accordance with the procedures contained in the award document.

End of Phase reports: At the end of Phase 1, prior to the initiation of the subsequent phase, performers must draft and present to DARPA a written report of all research activities and metrics satisfied. This report should contain as much supporting data as can be reasonably conveyed to academic reviewers.

Semi-Annual Reviews: Leadership from each performer team (with additional key personnel at the discretion of the Principal Investigator (PI)) will be required to present research progress in person, twice annually. The schedule for these reviews will alternate between an annual PI review meeting with all performer teams attending and an interim site visit at the performer location. The purpose of these reviews is to ensure adequate engagement with the DARPA team to discuss details that might otherwise fall outside the scope of a routine technical brief, and provide opportunities to discuss progress towards milestones and scientific goals, any ongoing technical or programmatic challenges that must be overcome to achieve the overarching goals of the program. At the beginning of the program, there will be a kick-off meeting at a location central to the performer teams, and all key participants are required to attend.

Final Program Report: When the final funding phase closes out, performer teams must provide a final report summarizing all research activities, outcomes, devices, and novel gene editing tools and mechanisms discovered during the program

Other Deliverables: Publications, research presentations, patent applications that result from the research pursued; any additional deliverables requested by the Contracting agent for this program.

2. Award Information

2.1. GENERAL AWARD INFORMATION

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

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

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

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

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

In all cases, the Government contracting officer shall have sole discretion to select award instrument type, regardless of instrument type proposed, and to negotiate all instrument terms and conditions with selectees. DARPA will apply publication or other restrictions, as necessary, if it determines that the research resulting from the proposed effort will present a high likelihood

of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Any award resulting from such a determination will include a requirement for DARPA permission before publishing any information or results on the program. For more information on publication restrictions, see the section below on Fundamental Research.

2.2. FUNDAMENTAL RESEARCH

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

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

As of the date of publication of this BAA, the Government expects that program goals as described herein may be met by proposed efforts for fundamental research and non-fundamental research. Some proposed research may present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Based on the anticipated type of proposer (e.g., university or industry) and the nature of the solicited work, the Government expects that some awards will include restrictions on the resultant research that will require the awardee to seek DARPA permission before publishing any information or results relative to the program.

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

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

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

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

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

FFRDCs

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

Government Entities

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

Authority and Eligibility

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

3.1.2. Non-U.S. Organizations

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

3.2. ORGANIZATIONAL CONFLICTS OF INTEREST

FAR 9.5 Requirements

In accordance with FAR 9.5, proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and *any* proposed team member (subawardee, consultant). Under this Section, the proposer is responsible for providing this disclosure with each proposal submitted to the BAA. The disclosure must include the proposer's, and as applicable, proposed team member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the

existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4.

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

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

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

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

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

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

3.3. COST SHARING/MATCHING

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

4. Application and Submission Information

4.1. ADDRESS TO REQUEST APPLICATION PACKAGE

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

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

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

4.2.1. **Proposal Abstract Format**

Proposers are strongly encouraged to submit an abstract in advance of a full proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. DARPA will respond to abstracts providing feedback and indicating whether, after preliminary review, there is interest within BTO for the proposed work. DARPA will attempt to reply within 30 calendar days of receipt. Proposals may be submitted irrespective of comments or feedback received in response to the abstract. Proposals are reviewed without regard to feedback given as a result of abstract review. The time and date for submission of proposal abstracts are specified in Part I above.

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

The page limit does NOT include:

- Official transmittal letter (optional);
- Cover sheet;
- Executive summary slides;
- Resumes; and
- Bibliography (optional).

Abstracts must include the following components:

A. Cover Sheet (does not count towards page limit):

1. BAA number (HR001120S0016);
2. Lead organization (prime contractor);
3. Other team members/subcontractors (if applicable);
4. Proposal Abstract title;
5. 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;
6. Administrative point of contract to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
7. Estimated cost; and
8. Estimated period of performance

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

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

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

D. Technical Plan: Outline and address all Technical Areas and challenges inherent in the approach and possible solutions for overcoming potential problems in each TA, as well as in the Capability Demonstrations, platform integration, IV&V engagement, and fielding of the technology. This section should provide appropriate specific milestones (quantitative) at intermediate stages of the project to demonstrate progress and a brief plan for accomplishment of the milestones. In addition:

1. Describe and justify the choice of targets, assay design, and instrument/device design, demonstrating relevance to public health and national security.
2. Describe and justify the experimental approach for each TA and for each Capability Demonstration, to include targets investigated, sensitivity, specificity, multiplex, and relevant clinical, environmental, or other samples that will be used for validation.
3. Provide qualitative and quantitative metrics and milestones that will be used to measure progress against program goals, including a detailed strategy to

integrate into a platform capability to generate novel detection capability and quantitative metrics of how successful integration will be measured.
4. Outline a plan for FDA engagement, culminating in a submission in accordance with FDA regulations (e.g., IDE, 510k) submission by the end of the program.
5. Outline a plan for technology transition for continued advanced development during the program, and following completion of the program.

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

A principal investigator for the project must be identified, and a description of the team's organization, including a breakdown by TA. It is expected that proposals will involve multidisciplinary teams that include expertise from multiple complementary disciplines, for example, synthetic biology, computational biology, genome editing, hardware engineering, etc. All teams are strongly encouraged to identify a Project Manager/Integrator to serve as the primary point of contact to communicate with the DARPA PM, IV&V partners, and COR, coordinate the effort across co-performer, vendor, and subcontractor teams, organize regular performer meetings or discussions, facilitate data sharing, and ensure timely completion of milestones and deliverables.

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

Describe the organizational experience in this area, existing intellectual property required to complete the project, and any specialized facilities to be used as part of the project. List Government-furnished materials or data assumed to be available. Describe any specialized facilities to be used as part of the project, the extent of access to these facilities, and any biological containment, biosafety, and certification requirements.

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

G. Resumes (do not count towards page limit): Include (no more than 2) resumes of key team members.

H. Bibliography (Optional, does not count towards page limit): If desired, include a brief bibliography with links to relevant papers and reports. The bibliography should not exceed two (2) pages.

4.2.2. **Full Proposal Format**

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal.** All submissions must be written in English with type no smaller than 12-point font. A smaller font

may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials, along with the proposals, is strongly discouraged and will not be considered for review. **The maximum page count for Volume I is 25 pages.** The official transmittal letter is not included in the page count. Volume I should include the following components:

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

a. Volume I, Technical and Management Proposal

Section I. Administrative

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

1. BAA number (HR001120S0016);
2. Lead organization submitting proposal (prime contractor);
3. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
4. Proposer's reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), e-mail (if available);
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), e-mail (if available);
9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;
10. Place(s) of performance, including all subcontractors and consultants;
11. Period of performance;
12. Total funds requested from DARPA, total funds requested per phase and the amount of any cost share (if any);
13. Proposal validity period; AND
14. Date proposal was submitted.

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

B. Official Transmittal Letter.

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

D. Specific Program Plan: (does not count towards page limit): Provide a summary list of technical information as requested in **Attachment 2**. Use of this Excel template is required.

Section II. Detailed Proposal Information

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

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

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

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

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

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

E. Capabilities: Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Describe any specialized facilities to be used as part of the project, the extent of access to these facilities, and any biological containment, biosafety, and certification requirements. Discuss any work in closely related research areas and previous accomplishments.

F. ELSI Strategy: In addition to agreeing to support DARPA ELSI activities, such as semi-annual teleconference calls with the ELSI Panel, identify personnel who will be responsible for ELSI oversight, strategies for maintaining compliance, and how issues will be addressed and documented to prevent reoccurrence.

G. Statement of Work (SOW): The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. Each phase of the program should be separately defined. The SOW must not include proprietary information. The task structure must be consistent with that in Section H. Schedule and Milestones and Volume II Cost Proposal summary of program costs by phase, TA and task. The Government encourages proposers to complete an editable MS Word document, and this template document is provided as **Attachment 3** to this BAA. If you choose to use Attachment 3, submit the MS Word document template in addition to Volume I and II of your proposal. The SOW is not included in the Volume 1 page count.

For each task/subtask, provide:

- A detailed description of the approach to be taken to accomplish each defined task/subtask.

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

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

Do not include any proprietary information in the SOW.

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

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

b. Volume II, Cost Management Proposal

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

1. BAA Number (HR001120S0016);
2. Lead Organization Submitting proposal;
3. Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
4. Proposer's reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);

8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;
10. Place(s) of performance, including all subcontractors and consultants;
11. Period of performance;
12. Total proposed cost separated by Task Area and Phase (as defined in Figure 1), and the amount of any cost share (if any);
13. Name, address, and telephone number of the proposer's cognizant Defense Contract Management Agency (DCMA) administration office (*if known)*;
14. Name, address, and telephone number of the proposer's cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
15. Date proposal was prepared;
16. Data Universal Numbering System (DUNS) number (http://www.dnb.com/get-a-duns-number.html);
17. Taxpayer ID number (https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN);
18. Commercial and Government Entity (CAGE) code (https://cage.dla.mil/Home/UsageAgree);
19. Proposal validity period

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

The Government strongly encourages that proposers use the provided MS Excel™ cost proposal spreadsheet in the development of their cost proposals. All tabs and tables in MS Excel™ cost proposal spreadsheet should be developed in an editable format with calculation formulas intact to allow traceability of the cost proposal numbers across the spreadsheet. This MS Excel™ cost proposal spreadsheet should be used by the prime organization and all subcontractors. In addition to using the MS Excel™ cost proposal spreadsheet, Volume II still must include all other items discussed below that are not covered by the editable spreadsheet. Subcontractor MS Excel™ cost proposal spreadsheets may be submitted directly to the Government by the proposed subcontractor via e-mail to the address in Part I of this BAA. Using the provided MS Excel™ cost proposal spreadsheet will assist the Government in a rapid analysis of your proposed costs and, if your proposal is selected for award, speed up the negotiation and award execution process.

(1) Total program, per phase Phase I (Base) and Phase II (Option 1), and per task cost broken down by major cost items to include:

i. **Direct labor** – provide an itemized breakout of all personnel, listed by name or TBD, with labor rate (or salary), labor hours (or percent effort), and labor category. All senior personnel must be identified by name.

ii. **Materials and Supplies** – itemized list which includes description of material, quantity, unit price, and total price. If a material factor is used based on historical purchases, provide data to justify the rate.

iii. **Equipment** – itemized list which includes description of equipment, unit price, quantity, and total price. Any equipment item with a unit price over $5,000 must include a vendor quote.

iv. **Animal Use Costs** – itemized list of all materials, animal purchases, and per diem costs, associated with proposed animal use; include documentation supporting daily rates.

v. Travel – provide an itemized list of travel costs to include purpose of trips, departure and arrival destinations, projected airfare, rental car and per GSA approved diem, number of travelers, number of days); provide screenshots from travel website for proposed airfare and rental car, as applicable; provide screenshot or web link for conference registration fee and note if the fee includes hotel cost. Conference attendance must be justified, explain how it is in the best interest of the project. **Plan for two (2) DARPA program review meetings per year.**

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

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

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

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

x. **Indirect costs specific to a Company performer:** (1) **Fee/Profit** (provide rationale for proposed fee/profit percentage using criteria found in DFARS 215.404-70); and (2) **Fringe Benefit/Labor OH/Material OH/G&A Rates** (provide current Forwarding Pricing Rate Proposal (FPRP) or DCMA/DCAA Forward Pricing Rate Recommendation or Agreement (FPRR or FPRA). If these documents are not available,

provide company historical data, preferably two years, minimum of one, to include both pool and expense costs used to generate the rates).

(2) A summary of total program costs by Phase I (Base), Phase II (Option 1) and task.
(3) An itemization of Subcontracts. All subcontractor cost proposal documentation must be prepared at the same level of detail as that required of the prime. Subcontractor proposals should include Interdivisional Work Transfer Agreements (IWTA) or evidence of similar arrangements (an IWTA is an agreement between multiple divisions of the same organization). The prime proposer is responsible for compiling and providing all subcontractor proposals for the Procuring Contracting Officer (PCO). The proposal must show how subcontractor costs are applied to each phase and task. If consultants are to be used, proposer must provide consultant agreement or other document that verifies the proposed loaded daily/hourly rate.
(4) An itemization of any information technology (IT) purchase (including a letter stating why the proposer cannot provide the requested resources from its own funding), as defined in FAR Part 2.101.
(5) A summary of projected funding requirements by month for all phases of the project.
(6) A summary of tasks that have animal or human use funding.
(7) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions that could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.
(8) Identification of pricing assumptions of which may require incorporation into the resulting award instrument (e.g., use of Government Furnished Property/Facilities/Information, access to Government Subject Matter Expert/s, etc.).
(9) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available).
(10) Proposers with a Government acceptable accounting system who are proposing a cost-type contract must submit the DCAA document approving the cost accounting system.

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

Subawardee Proposals

The awardee is responsible for compiling and providing all subawardee proposals for the Procuring Contracting Officer (PCO)/Grants Officer (GO)/Agreements Officer (AO), as applicable. Subawardee proposals should include Interdivisional Work Transfer Agreements (ITWA) or similar arrangements. Where the effort consists of multiple portions which could

reasonable be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.

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

Other Transaction Requests

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

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

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

4.2.3. Additional Proposal Information

Proprietary Markings

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

Unclassified Submissions

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

Disclosure of Information and Compliance with Safeguarding Covered Defense Information Controls

The following provisions and clause apply to all solicitations and contracts; however, the definition of "controlled technical information" clearly exempts work considered fundamental

research and therefore, even though included in the contract, will not apply if the work is fundamental research.

DFARS 252.204-7000, "Disclosure of Information"
DFARS 252.204-7008, "Compliance with Safeguarding Covered Defense Information Controls"
DFARS 252.204-7012, "Safeguarding Covered Defense Information and Cyber Incident Reporting"

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

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

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

Human Subjects Research (HSR)/Animal Use

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

Approved Cost Accounting System Documentation

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

Small Business Subcontracting Plan

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

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

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

Intellectual Property

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

(1) For Procurement Contracts

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

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

(2) For All Non-Procurement Contracts

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

System for Award Management (SAM) and Universal Identifier Requirements

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

International entities can register in SAM by following the instructions in this link: https://www.fsd.gov/fsd-gov/answer.do?sysparm_kbid=dbf8053adb119344d71272131f961946&sysparm_search=KB0013221.

4.2.4. Submission Information

DARPA will acknowledge receipt of all submissions and assign an identifying control number that should be used in all further correspondence regarding the submission. DARPA intends to use electronic mail correspondence regarding HR001120S0016. Submissions may not be sent by fax or e-mail; any so sent will be disregarded.

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

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

Abstracts and Full Proposals sent in response to HR001120S0016 may be submitted via DARPA's BAA Website (https://baa.darpa.mil). Visit the website to complete the two-step registration process. Submitters will need to register for an Extranet account (via the form at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the abstract. Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process be started as early as possible.

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

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

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

For Cooperative Agreements only:

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

Submissions: Proposers must submit the three forms listed below.

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

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

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

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

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

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

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

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

4.3. FUNDING RESTRICTIONS

Not applicable.

4.4. OTHER SUBMISSION INFORMATION

DARPA will post a consolidated Frequently Asked Questions (FAQ) document. To access the posting go to http://www.darpa.mil/work-with-us/opportunities. A link to the FAQ will appear under the HR001120S0016 summary. Submit your question(s) via e-mail to DIGET@darpa.mil.

5. Application Review Information

5.1. EVALUATION CRITERIA

Proposals will be evaluated using the following criteria, listed in descending order of importance: 5.1.1 Overall Scientific and Technical Merit; 5.1.2 Potential Contribution and Relevance to the DARPA Mission; 5.1.3 Realism of Proposed Schedule; 5.1.3 Plans and Capabilities to Accomplish Technology Transition; and 5.1.5 Cost Realism.

5.1.1. **Overall Scientific and Technical Merit**

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

5.1.2. **Potential Contribution and Relevance to the DARPA Mission**

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

5.1.3. **Realism of Proposed Schedule**

The proposed schedule aggressively pursues performance metrics in the shortest timeframe and accurately accounts for that timeframe. The proposed schedule identifies and mitigates any potential schedule risk. The proposed team has the expertise to manage the cost and schedule.

5.1.4. **Plans and Capability to Accomplish Technology Transition**

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

5.1.5. **Cost Realism**

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

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

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

5.2. REVIEW OF PROPOSALS

Review Process

It is the policy of DARPA to ensure impartial, equitable, comprehensive proposal evaluations based on the evaluation criteria listed in Section 5.1. and to select the source (or sources) whose offer meets the Government's technical, policy, and programmatic goals.

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

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

Handling of Source Selection Information

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

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

Federal Awardee Performance and Integrity Information (FAPIIS)

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

6. Award Administration Information

6.1. SELECTION NOTICES

6.1.1. Proposal Abstracts

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

6.1.2. Full Proposals

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

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

There will be a program kickoff meeting and semi-annual program-wide meetings in a location central to the performer teams (assume alternating U.S. coasts for budgeting purposes), that all key participants are required to attend. Proposers shall include within the content of their proposal details and costs of any travel or meetings they deem to be necessary throughout the course of the effort. Performers should anticipate monthly meetings by teleconference, in-person program reviews, and at least annual site visits by DARPA Program Manager and/or Government team.

6.2.2. FAR and DFARS Clauses

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

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

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

6.2.4. Representations and Certifications

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

6.2.5. Terms and Conditions

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

6.3. REPORTING

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

6.4. ELECTRONIC SYSTEMS

6.4.1. Wide Area Work Flow (WAWF)

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

6.4.2. I-EDISON

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

7. Agency Contacts

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

Points of Contact
The BAA Coordinator for this effort may be reached at:
DIGET@darpa.mil

DARPA/BTO
ATTN: HR001120S0016
675 North Randolph Street
Arlington, VA 22203-2114

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

8. Other Information

DARPA will host a Proposers Day in support of the DIGET program on December 11, 2019, at the Hyatt Regency Atlanta, 265 Peachtree Street, Atlanta, GA. The purpose is to provide potential proposers with information on the DIGET program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and encourage team formation.

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

DARPA will not provide cost reimbursement for interested proposers in attendance. An online registration form and various other meeting details can be found at the registration website, https://events.sa-meetings.com/DIGETProposersDay.

Participants are required to register no later than December 2, 2019. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; there will be no onsite registration.

Proposers Day Point of Contact:
DARPA-SN-20-12@darpa.mil
ATTN: DARPA-SN-20-12

9. APPENDIX 1 – Volume II checklist

Volume II, Cost Proposal
Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 of HR001120S0016. This worksheet must be included with the coversheet of the Cost Proposal.

1. Are all items from Section 4.2.2 (Volume II, Cost Proposal) of **HR001120S0016** included on your Cost Proposal cover sheet?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]
   If reply is "No", please explain:

2. Does your Cost Proposal include (1) a summary cost buildup by Phase, (2) a summary cost buildup by Year, and (3) a detailed cost buildup of for each Phase that breaks out each task and shows the cost per month?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   If reply is "No", please explain:

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

   Direct Labor (Labor Categories, Hours, Rates)
   f○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   Indirect Costs/Rates (i.e., overhead charges, fringe benefits, G&A)
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   Materials and/or Equipment
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   Subcontracts/Consultants
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   Other Direct Costs
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

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

   If reply is "No", please explain:

4. Have you provided documentation for proposed costs related to travel, to include purpose of trips, departure and arrival destinations and sample airfare?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

   If reply is "No", please explain:

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

   If reply is "No", please explain:

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

   If reply is "No", please explain:

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

   If reply is "No", please explain:

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

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

   If reply is "No", please explain:

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

    If reply is "No", please explain:

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

If reply is "No", please explain:

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

If reply is "No", please explain:

13. Have all team members (prime and subcontractors) who are considered a Federally Funded Research & Development Center (FFRDC), included documentation that clearly demonstrates work is not otherwise available from the private sector AND provided a letter on letterhead from the sponsoring organization citing the specific authority establishing their eligibility to propose to government solicitations and compete with industry, and compliance with the associated FFRDC sponsor agreement and terms and conditions.
○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

14. Does your proposal include a response regarding Organizational Conflicts of Interest?
○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain:

15. Does your proposal include a completed Data Rights Assertions table/certification?
○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

If reply is "No", please explain: