



Broad Agency Announcement
Personalized Protective Biosystem (PPB)
BIOLOGICAL TECHNOLOGIES OFFICE
HR001120S0015
November 26, 2019

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PART I: OVERVIEW INFORMATION

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title – Personalized Protective Biosystem (PPB)**
- **Announcement Type** – Initial Announcement
- **Funding Opportunity Number** – HR001120S0015
- **North American Industry Classification System (NAICS)** – 541714
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- **Dates**
 - Posting Date: November 26, 2019
 - Proposal Abstract Due Date and Time: **January 7, 2020, 4:00 PM ET**
 - Full Proposal Due Date and Time: **February 20, 2020, 4:00 PM ET**
 - BAA Closing Date: **February 20, 2020**
 - Proposers’ Day: **December 4, 2019**
[DARPA-SN-20-10 on beta.SAM.gov](#)
- **Concise description of the funding opportunity** – The Personalized Protective Biosystem (PPB) program will develop an integrated ensemble that simultaneously reduces protective equipment needs while increasing protection for the individual against existing and future chemical and biological (CB) threats. The capability to provide unburdened CB protection will maximize time on target for the warfighter and the stability operator, provide operational flexibility, extend mission duration, and enable military operations in austere environments regardless of the threat. PPB will consist of lightweight materials that protect the warfighter from exposure to any CB threat while simultaneously providing a second layer of protection, at the tissue barrier, with bio-molecular, commensal organisms, or other technologies that protect the skin, eyes, and airway from CB threats. PPB will improve mission execution by solving the current (“state of the art”) protective equipment limitations, including threat-specific vulnerabilities, thermal/logistical burdens, exposure risks during equipment removal/decontamination, and on-demand availability during unexpected threat situations.
- **Anticipated individual awards** – Multiple awards are anticipated.
- **Types of instruments that may be awarded** – Procurement contract or Other Transaction.
- **Agency contact**

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PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

This publication constitutes a Broad Agency Announcement (BAA) as contemplated in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016. 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>. The following information is for those wishing to respond to the BAA.

The Defense Advanced Research Projects Agency (DARPA) is soliciting innovative proposals to address the following areas: (1) novel textiles that prevent chemical and biological (CB) agent access to the body; and (2) a tissue barrier countermeasure (BCM) that neutralizes CB agents should they come in contact with the skin, airway, or eyes. Proposed research should investigate approaches that enable revolutionary advances in the development of wearable, lightweight, and smart materials that resist CB agent penetration/attachment. The goal for the PPB ensemble is to remain effective for deployments of up to 30 days and provide on-demand CB protection for missions of up to 12 hours at any time within the 30-day window. The BCM component should utilize host-compatible and high-efficiency protection strategies such as: chemical and biological agent-degrading enzymes, reconfigurable/robust expression chassis with commensal organisms, or highly stable biological nanoparticles. To administer BCM technologies, performers should develop delivery methods that can be self-administered from hand-held devices. The Personalized Protective Biosystem (PPB) will provide on-demand, broad-spectrum protection that can evolve at the pace of emerging threats.

The protective products currently in use, biological or otherwise, focus on one-threat countered by one-countermeasure, are not intrinsically adaptable, and rely on bulky, thick materials with respirators/ocular protection for sensitive tissue barrier protection. The PPB program will provide a dynamic response to multiple threats in a way that takes cues from natural systems capable of protecting against a diverse array of threats. For example, shark skin's inherent anti-fouling capabilities can be harnessed by mimicking the shark skin-texture on a wide variety of materials for antimicrobial applications. Further, bacterial communities that currently live in the human body can sense and respond, protecting against environmental bacterial and fungal infection. Molecular, nano, and other material solutions, when coupled with lessons from natural systems, will be integral for PPB technologies to protect against current and future CB threats.

1.1. PROGRAM OVERVIEW

The goal of the PPB program is to develop an integrated ensemble that simultaneously eliminates protective equipment needs while increasing protection for the individual against all CB threats. The capability to provide unburdened CB protection will reduce the logistical burden on the warfighter, provide operational flexibility, and sustain military operations in remote theaters, which may include diverse, unpredictable, and unknown threats.

The current CB threat environment consists of broadly acting, highly pathogenic, and sometimes immediately lethal threats that are capable of entering the body via multiple pathways, including skin, airway, ocular, and the gastrointestinal tract. Despite substantial financial investments and advances in the CB Defense enterprise over many decades, current personal protective equipment (PPE) solutions add logistical, mobility, and thermal challenges to the warfighter/stability operations care provider, which place their missions at risk. For example, typical PPE consists of cumbersome suits and respirators that require assistance and infrastructure for proper donning and doffing, and decontamination procedures to avoid contamination from agents that may still be present on the PPE. In a humanitarian assistance setting, the hours needed to don, doff, and decontaminate PPE leaves roughly two hours in an eight hour work day for a care provider to spend with patients, as seen in the Ebola 2014 (West Africa) and 2017 (Congo) outbreaks. These procedures limit the efficacy of stability operations workers in pandemic outbreak scenarios. Even with standard decontamination procedures and protective measures in place, hundreds of care providers have been infected with life-threatening biological agents, ranging from Ebola to Tuberculosis, due to PPE failures. In a military context, standard military PPE constrains vision, mobility, and “time on target,” thereby negatively impacting warfighter lethality. Moreover, PPE is not instantaneously available for individuals operating in austere or poorly resourced environments with no logistics infrastructure. Finally, current PPE is not designed with a robust second line of defense, should the outer layer(s) fail. Current, second-line technology includes topical treatments that are applied after agent exposure or that simply block but do not neutralize threat agents during exposure; these treatments are not designed to work in concert with existing PPE. Rather, the state-of-the-art strategy has been to build thicker, heavier, and more logistically burdensome PPE.

The PPB program is directed at providing a two-part solution to support the individual in the following operational scenarios: (a) mission execution with minimal to zero logistical footprint, while engaging in an unanticipated multiplexed threat environments; and (b) humanitarian assistance and disaster relief (HADR) during pathogenic outbreaks in austere environments without logistical support.

The PPB program envisions two technical areas (TAs) for development under this BAA. From the outset, proposed approaches and developed technologies should identify outputs that align to both Technical Area 1 (TA1) and Technical Area 2 (TA2) as described in Figure 1. TA1 technologies will ***prevent contact*** between the body and CB agents using protective, smart materials with near-zero logistical burden. TA2 technologies will ***neutralize threats at vulnerable tissue barriers*** using a configurable BCM.

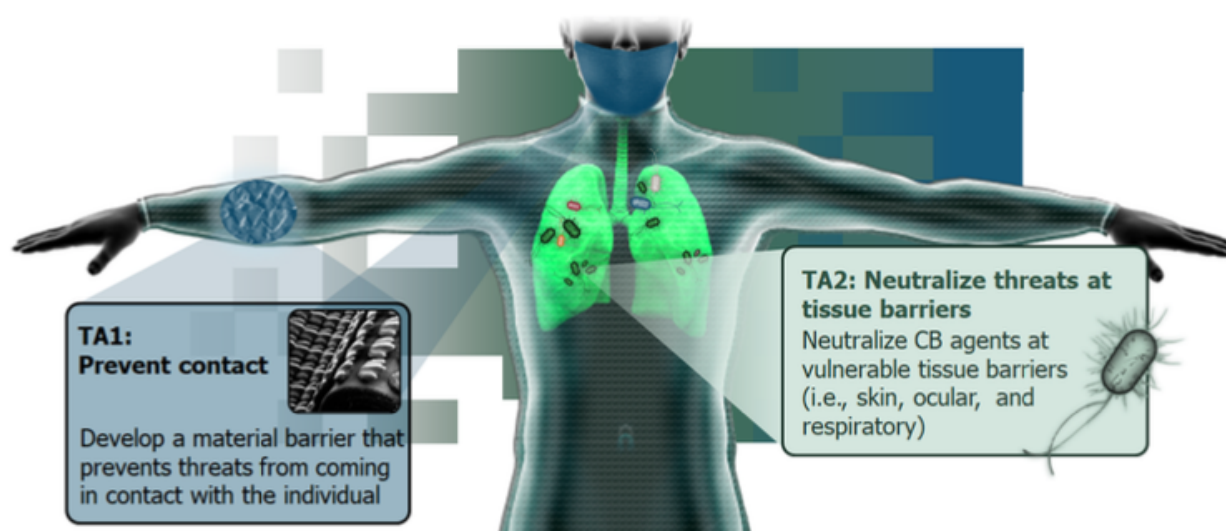


Figure 1 Schematic of PPB program objectives

By program completion, PPB platforms should be capable of immediately protecting the operator against **multiple** CB agents (see Program Milestones, Metrics and Schedule for specific details). Technologies should function in austere and/or isolated environments (e.g., far forward positions with limited infrastructure) for prolonged deployments of up to 30 days.

Revolutionary approaches directed at increasing CB protection while unburdening the operator will be necessary to accomplish the program goals. PPB platforms should be tested iteratively and optimized against various threat challenges with increasing complexity and performance requirements as the program progresses. Testing protocols will be developed to place the PPB ensemble on a path towards clinical translation and regulatory approval. Performers will be expected to attain Food and Drug Administration (FDA) Investigational New Drug (IND) approval by the end of the program for relevant PPB components. Further, performers will be required to engage with the FDA and other regulatory groups for design guidance on day one of the program.

1.2. TECHNICAL AREAS

The PPB program is structured as a five (5) year effort consisting of three (3) phases: (Phase I (Base), Phase II (Option One), and Phase III (Option Two)).

As designs will be heavily influenced by testing results, a significant investment has been made by DARPA to support an Independent Verification and Validation (IV&V) testing infrastructure that will enable an iterative developmental approach for the performers detailed further in the “PPB Testing” section.

Proposed efforts must describe a plan to address both of the TAs over the entire program duration (60 months). At the end of the program, performers will have developed a PPB ensemble capable of providing 100% survival against lethal exposure from 11 separate chemical and biological agents (10 for TA1, and 5 (4 of which overlap with TA1) for TA2, Table 1).

Tables 2 and 3 describe the schedule of evaluations and program assessment events that will drive programmatic decisions throughout the program.

The technical areas are described below:

- **TA1 Prevent contact:** Performers will develop materials that, when applied or worn, prevent the wearer from coming in contact with CB threats, while reducing donning processes to less than 10 minutes to provide full body coverage. Additionally, these TA1 technologies will be available to the warfighter or stability operations operator with near-zero logistical burden (e.g., no respirator, contamination-free donning and doffing). Further, accidental cross-contamination should be eliminated by the material's ability to inactivate, sequester, and/or eliminate attachment of agents.
- **TA2 Neutralize threats at tissue barriers:** This technical area will neutralize agent at one or all of the potential airway, ocular, or skin interfaces, as necessary, to protect against agent exposure. This will supplement TA1's protective barrier by providing persistent, offsetting, and orthogonal protection against threats that may penetrate the outer layer material or contact the wearer during doffing procedures. Newly adapted BCM technologies must increase CB protection breadth and specificity without sacrificing the protection against the original catalog of CB agents.

Teams must propose to both TA1 and TA2. Fully integrated teams should be assembled early in the proposal process, and the integration of both scientific and managerial responsibilities should be conveyed in the submission. Integrated teams should describe the organizational structure within the team, complete with a dedicated project manager (separate from the principal investigator) to show distribution of responsibilities, lines of communication, and technical tasks throughout the proposal. Teams should structure themselves to support continuous, active engagement with regulatory agencies to ensure a path towards clinical translation and regulatory application approvals such as IND or Emergency Use Authorization (EUA) as appropriate.

1.3. TECHNICAL APPROACH

Technical Area 1 (TA1): Prevent Contact

TA1 objectives must be achieved using technologies that prevent agent access to the wearer by blocking, degrading, or otherwise sequestering agent away from the body while also eliminating active agent binding on the material itself post-exposure. Materials that may accomplish this goal might include enzymatic, molecular, nanopore, or other technology and material combinations. Regardless of approaches proposed, the performers must specify the anticipated dynamic range of protection across threat concentrations and environmental conditions in their proposals. The ability to protect against large "mass-action" effects (at levels equal to or in excess of lethal doses) when large quantities of agent are encountered is a critical feature of the TA1 component. Materials or barriers requiring application of active coatings should be long lasting, durable, and weather resistant. TA1 materials should be lightweight and impose negligible thermal burden or mobility restriction in relation to work rate, duration, or environmental considerations. Garment engineering approaches should consider use in austere and low-infrastructure environments as part of the initial design constraints. Detailed design goals for TA1 are below (further details and specific metrics can be found in Tables 2, 3) and should be achieved by the end of the program:

- Protect against a broad spectrum (Table 1) of CB threats simultaneously with no impact on mission execution and time on target when compared to operators who do the same tasks without protective materials.
- Insignificant logistical or thermal burden during normal military or patient care operations.
- Protective materials developed should have evaporative resistance and permeability consistent with current military duty uniforms, such as the Army Combat Uniform (ACU).
- Material technologies will have physical performance equivalent to standard-issue military uniforms across all operating conditions to include extreme temperatures, precipitation, humidity, and other environmental scenarios (high dust or other environmental particulates).
- Solutions should innovate above standard hydrostatic resistance performance of waterproof fabrics.
- Reduce agent attachment to limit exposure risk during donning/doffing.
- Durability should exceed the performance criteria of current military duty uniforms (such as the ACU) relative to impact abrasion, seam burst strength, and impact cut resistance.
- Rapid don/doff, while also eliminating the risk of contamination to the wearer from incidental exposure to any agent that may have remained on the TA1 components.
- System should withstand usage (including repeated donning/doffing) for the entire duration of any deployment.
- The system as an ensemble of multiple garments, or as one continuous material should be lightweight, offering protection to the entire head, body, and extremities.

The IV&V team will administer tests as described below in Phase I and Phase II, culminating in key TA1 program milestones, metrics, and program assessment events (Tables 2, 3).

Technical Area 2 (TA2): Neutralize Threats at Tissue Barriers

TA2 is focused on the innovation and development of a BCM that neutralizes multiple threats encountered by vulnerable tissue barriers (ocular, respiratory, dermal). Proposers should submit potential solutions to neutralizing agent at airway, eye, and skin vulnerabilities, with the end goal of ensuring 100% protection in preclinical models against agents listed in Table 1. BCM will (a) provide simultaneous protection against diverse CB agents; (b) have the ability to add protection against novel threats (as they emerge) to the original catalog of threat protection; (c) be enabled by commensal, synthetic biological and/or nanoparticle-based components; and (d) possess multiple user-controlled safeguards (on/off capability). Proposers should develop innovative approaches to counter CB threats using high-throughput, scalable, molecular and biological production methodologies. Proposals should also describe solutions to TA2 that are allogeneic.

Successful completion of TA2 milestones and metrics will yield a BCM platform capability that can provide on-demand, rapid, and adaptable protection at tissue barriers. Newly adapted BCM platforms will increase CB protection breadth and specificity without sacrificing the protection against the original catalog of CB agents. The list below summarizes the primary design goals for the TA2 BCM, with specific metrics detailed in Tables 2 and 3:

- Neutralize against a broad spectrum (Table 1) of CB threats simultaneously at vulnerable tissue barriers (protecting ocular, respiratory, dermal).
- Contain safeguards, such as an on/off switch, that can be used to personalize the duration of protection and be deactivated with user-administered treatments that are non-toxic and FDA-cleared.
 - BCM's built-in responsive capability should provide two immediate benefits: (1) serve as a proactive tool to enhance the safety of BCM for the end user, and (2) provide on-demand and personalized temporal protection.
- Adapt the system to add protection against new threats without compromising existing breadth of protection.
- Platforms that are shelf-stable (for up to 2 years) without cold chain at room temperature at standard temperature and pressure (STP), mass produced in a Good Manufacturing Practices (GMP) setting, and able to obtain FDA clearance for a self-administered, hand-held device (e.g., eye-dropper, inhaler).
- Platforms that provide ease of delivery, safety, rapid activation, and long lasting protection.

Proposed protection system(s) and approach(es), including the details for living or non-living solutions and the method(s) mediating protection, are required. The list below summarizes the potential details proposers should address in their proposal as it relates to their specific TA2 solution:

- a) Platform(s) to be used such as: nanoparticles, biologics, small molecules, bacteria, fungi, protozoa, metazoa, virus, biologics, etc.
- b) Dose per kg body weight in terms of: mass of compound, total particles, colony forming units (CFU), propagules, parasitic burden, active units, viral particles, etc.
- c) Dynamic range and associated pharmacokinetics/pharmacodynamics of platform-mediated countermeasure production, if the platform actively produces countermeasures
- d) Safeguards, i.e., on/off regulation of countermeasure expression, maintenance and or clearance of chassis from operator.
- e) Platform delivery mechanism and residual anatomical localization, i.e., systemic, tissue, organ specific retention.
- f) Characteristics of platform residence time. Define if, when, rate of platform shedding/clearance, and transmission mitigation strategies as appropriate.

It is critical that proposers provide a solution that results in zero injury, toxicity, immunogenicity, or other adverse effects to the host.

PPB Testing

The first 24 months of the program are designed as a **Design-Test-Refine** strategy, organized for teams to develop and evaluate PPB design approaches and enable the teams to iteratively improve their approaches. Teams will have the opportunity to conduct feasibility studies and tests in collaboration with the IV&V team during the first 18 months. These evaluations are **not considered downselection events**. Rather, these evaluations are considered opportunities for

performer teams to iteratively refine technology prior to the 24-month Protection and Adaptation IV&V testing milestone (Figure 2, Phase 1).

Prior to 24 months proposer teams are encouraged to prepare for success by actively engaging PPB IV&V teams, co-developing testing methodologies, and performing in-house or outside facility testing of **numerous** design prototypes proactively defining ranges of protection and failure. Lastly, tests may be performed at any time; however, completion is required by the month stated as outlined in Table 2, and 3: PPB program milestones, metrics and assessment metrics.

Throughout the program there will be two types of testing, Safety and Regulatory Testing and CB Testing, detailed below.

Safety and Regulatory Testing:

The PPB system (both TA1 materials and TA2 platforms) must be characterized for a variety of performance metrics beyond protection against agent. All metrics are detailed in Tables 2 and 3. A significant portion of this characterization should happen in concert with FDA guidance and will require a testing plan to be created by the proposing teams in concert with the IV&V partners. Performance assessments that do not involve CB agent protection are expected to occur in parallel with milestone tests and must increase in complexity and comprehensiveness with each subsequent Phase (see **IV&V Testing and Evaluation (T&E) of PPB System**). The execution of non-agent tests can utilize the IV&V test team facilities or be conducted independently by the performers with IV&V oversight. These assessments should provide an in-depth understanding of the mechanisms of protection, failure modes, host toxicity, on- and off-target activity within the host, host-immunity (or autoimmunity), host-toxicity, and other factors that will affect performance/safety of all components of the PPB system. Many of these factors will be TA specific and should involve preclinical models with and without protection, under both ‘on’ and ‘off’ conditions (chemical removal or inactivation of TA2 platform components). Safety testing should demonstrate that preclinical models donned with TA1 and TA2 components (under all states; ‘on’, ‘off’) remain within pre-defined ‘normal physiologies’. The results and analysis accumulated throughout Safety and Regulatory Testing should be used to periodically update the FDA during pre-submission meetings, incorporating FDA feedback in any updates to the testing plan as it progresses. This entire dataset will then be used as part of the IND or other submissions prior to human testing in accordance with regulatory guidance.

Proposed safety testing must, at minimum, include:

- Months 0–12: Acute responses (minutes to hours)
 - Proposers must define the kinetics of PPB mediated protection, PPB mediated toxicity, and establish a baseline for acute responses related to:
 - temporal requirements for, and magnitude of, PPB protection;
 - on/off capability, and associated toxicities (with on- and off-states) at the level of cell, tissue, and organ; (TA2)
 - physiological responses raised by PPB platforms, including thermal stress and immune responses developed against PPB (i.e., immune cell activation, inflammatory response, and cytokine release);
 - standard toxicology studies; and

- molecular and histological analyses of tissues.
- Months 12–24: Persistent responses (days to weeks)
 - behavioral responses in preclinical models to include waking, sleeping, feeding, grooming, etc.;
 - delivery device development;
 - route of administration; and
 - dosage.
- Months 25–36: Chronic responses (months) and extensive longer-term safety characterization of PPB ensemble including:
 - toxicology;
 - reproductive toxicity;
 - shelf stability; and
 - ease of delivery.

Proposers must assess, beyond survival/death, the impact of PPB platforms on all of the subcategories (acute, persistent, and chronic) and symptoms relevant to the specific threat(s) investigated. Specifically, performers should ensure that there is an absence of clinical symptoms post-exposure to CB agents for an observation period of 30 days. Proposers must also quantitatively define and describe a method to measure duration and magnitude of the TA2 PPB protective response *in vivo*, and demonstrate the removal of PPB TA2 platforms, i.e., clearance through excretion, host mediated clearance, or pharmacological means.

CB Agent Testing:

Proposers will develop PPB platforms to protect against CB threats listed in Table 1. Development of platforms against select threats should remain consistent throughout the program, with the exception of Adaptation Tests. Performers may utilize surrogates for CB agents as systems are under development; however, all testing will be reviewed, approved, and monitored or conducted by IV&V partners. All live agent tests will be conducted by IV&V partners in a facility permitted to work with these agents and will use CB agents explicitly listed in (Table 1). As PPB platforms represent an entirely new approach to individual CB agent protection, new testing methodologies will need to be developed and will build on existing standards, such as the Test and Evaluation Capabilities and Methodologies Integrated Process Team (TECMIPT) test operations procedures TTOP08-2-109 and TTOP20141201-1. Finally, it is not within the scope of this program to propose research of chemical or biological agents not explicitly listed in Table 1.

Table 1 indicates the list of threats that are within the scope of the program. Within Table 1, all proposals should, at a minimum, demonstrate PPB functionality against either active, or simulant of specified threats as indicated. Proposers should develop platforms that can protect against all threats listed in Table 1.

Table 1 List of CB agents for TA1 & TA2

Class	Agents	TA1*	TA2*
Bacterial	Bacillus anthracis (Anthrax)	x	x
Bacterial	Staphylococcus aureus (MRSA, VSA)		
Bacterial	Francisella tularensis		
Chemical	Sulfur mustards	x	
Chemical	Organophosphates (GB, VX)	x	x
Chemical	Ammonia (CAS# 7664-41-7)	x	
Chemical	Hydrogen cyanide (CAS#74-90-8)		
Chemical	Chlorine (CAS# 7782-50-5)	x	
Chemical	Methyl chloroformate (CAS# 79-22-1)		
Chemical	Sulfur dioxide (CAS# 2025884)		
Chemical	Nitrogen dioxide (CAS# 10102-44-0)		
Chemical	Methylene chloride (CAS#75-09-2)	x	
Parasite	Malaria (P. falciparum, P. malariae, P. ovale, P. vivax)		
Toxin	Synthetic opioid analgesic (Carfentanil, Remifentanil)	x	
Toxin	Ricin Toxin (Ricin)	x	
Toxin	Marine neurotoxin (TTX, STX, DA)		x
Toxin	Botulinum toxin (BTX)		
Viral	Venezuelan equine encephalitis virus (VEE)		
Viral	Viral hemorrhagics (Ebola, Marburg, Lassa, Yellow fever)	x	x
Viral	Influenza (Type A, B, C, D)	x	x
Viral	Rhinovirus (RV)		
Viral	Coronavirus (Alpha, Beta, MERS, SARS)		
		*Required	

IV&V for Testing & Evaluation (T&E) of PPB System:

IV&V teams will support proposers as a Government-furnished service for all agent testing leading up to program milestones and will conduct all agent testing for evaluation against program metrics/milestones.

Simulant and Agent Testing: IV&V teams, with performer input, will design and provide a standardized testing plan for evaluation of PPB components exposed to CB agents at levels equal to or in excess of lethal doses (LD) or concentrations resulting in immediate danger to life or health (IDLH). Test designs will be submitted to DARPA six (6) months prior to agent challenges as indicated in Tables 2 and 3.

Analog tests (i.e., inactivated, simulant, or surrogate agents) will be designed and executed in collaboration with IV&V as a part of milestone/metric evaluations. As a part of this, proposers will collaboratively identify clinically relevant *ex vivo* and *in vitro* systems with the IV&V team, based on feedback from FDA interactions at the beginning of the program.

For each *in vivo* model challenge, IV&V teams will work with performers to identify clinically relevant small or large preclinical models. Selection of *in vivo* models will also consider relevance for the chosen CB threat type as it relates to human response and etiology (e.g., mode and magnitude of exposure, citation of literature supporting the model with physiological and molecular responses relevant to human exposure).

TA1-specific testing: Assessments that do not involve CB agent protection, such as wear, thermal, and breathability evaluations, are expected to occur in parallel with milestone tests and must increase in complexity and comprehensiveness with each subsequent Phase to meet the metrics in Tables 2 and 3 by the end of the program. The execution of non-agent tests can utilize either the IV&V test team facilities or be conducted independently by the performers with IV&V oversight, ensuring compliance with the IV&V-defined test plan.

1.4. PROGRAM SCHEDULE, MILESTONES & METRICS

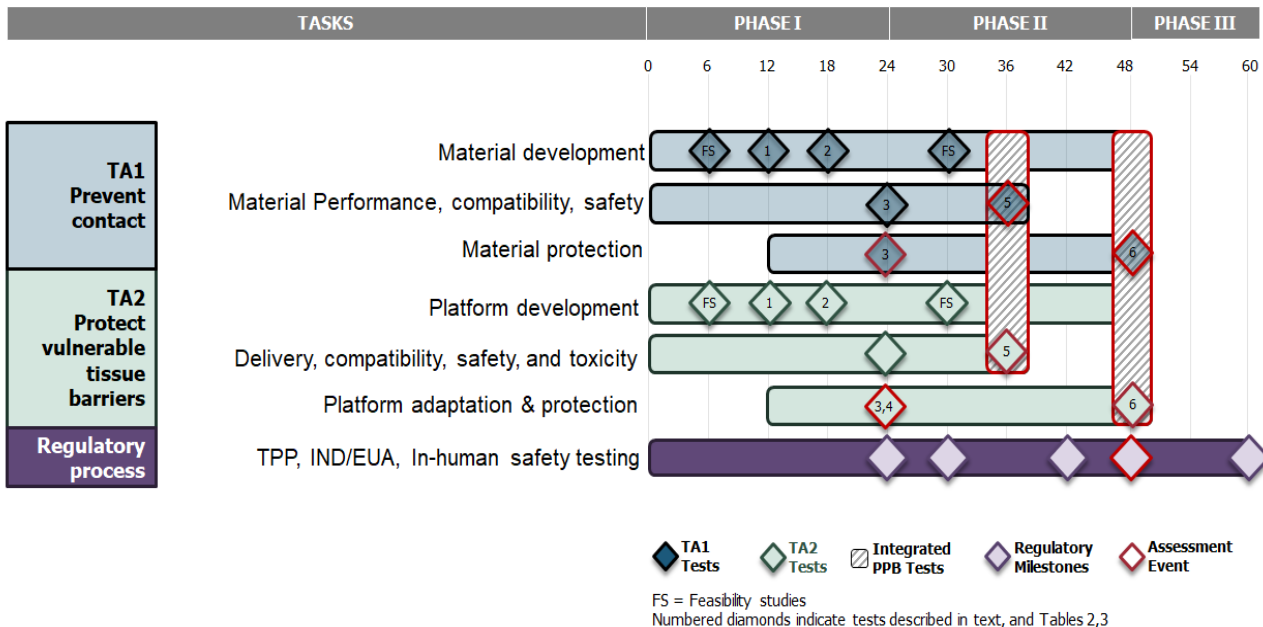


Figure 2: PPB PROGRAM SCHEDULE

Phase I (Base Period)

During Phase I, proposers will develop platforms that prevent (TA1) and neutralize (TA2) broad spectrum CB threats from accessing the body at vulnerable tissues (i.e., ocular, respiratory, dermal).

Feasibility Study (6 months) – TA1 and TA2

Performers will conduct feasibility studies within 6 months of being on contract. Feasibility studies will demonstrate 1) active team-IV&V communication, 2) fundamental technical aim components (e.g., chemical reactive groups, organisms, nanomaterials), and that technologies 3) can function in a manner that is consistent with program goals. Data will allow IV&V teams and DARPA program management to provide guidance in the design process and experimental procedures. This feasibility study will also facilitate early establishment of important working-relationships (IV&V, teaming, FDA).

Test 1 (12 months) – TA1 & TA2: Material and Platform Development

Performers will demonstrate capability of protection with up to three (3) designs consisting of materials (TA1)/platforms (TA2) in *ex vivo*/*in vitro* models against relevant simulants as approved by IV&V. Further details are outlined in Table 2: PPB program milestones, metrics, and program assessment metrics Phase I.

Test 2 (18 months) – TA1 & TA2: Material and Platform development

Demonstrate *in vivo* protection against threats as listed in Table 1 and outlined in Table 2. TA2 platforms will be required to demonstrate responsiveness and functionality with simulants and active agents as approved by IV&V (Table 1), in preparation for Test 3.

Test 3 (24 months) – TA1 Material Performance (Testing to occur at IV&V facility)

By 24 months, TA1 designs will be required to pass thermal, mechanical, and environmental tests designed by IV&V teams to evaluate compatibility with both strenuous activity and outdoor conditions without agent present using material swatches or equivalent constructs. Details are outlined in Table 2. Environmental and functional tests will be conducted as technologies mature in Phase 1 and will continue into Phase II with fully developed, wearable constructs. This is not a program assessment component of the Test 3 event.

Test 3 (24 months) – TA1 & TA2 Material and Platform Protection (Testing to occur at IV&V facility)

TA1 and TA2 technologies will be functionally transitioned into *in vivo* models. IV&V teams will test at most three (3) individual materials and three (3) platforms **per team (3, TA1 and 3, TA2)** against one (1) performer selected chemical agent and one (1) performer selected biological agent, achieving 100% protection *in vivo*.

Protection tests will require administration/donning of candidate PPB platforms (where donning is possible; otherwise tests will be done via barrier testing), followed by an immediate (within 1 hour) threat challenge to an *in vivo* model. Over a 30-day monitoring period multiple CB agent exposures (lasting no more than 12 hours) will be conducted in order to validate the duration of protection. Each platform submitted for Protection Tests should meet defined metrics (Table 2).

Exposure routes for BCM Protection Tests will be performer selected but limited to vulnerable tissue barriers (i.e., ocular, respiratory, dermal). The outcome of candidate PPB platform Protection Tests should demonstrate (1) long-term, (2) broad-spectrum, and (3) durable protection capability, as defined in Table 2.

Test 4 (24 months) – TA2 Platform Adaptation & Protection

By 24 months, TA2 proposers will participate in a second *in vivo* test assessing the ability of BCM candidate platforms to adapt and provide 100% protection against a proposer-unknown, DARPA-specified agent at IV&V determined concentrations and durations. Assessment will be

based on pre-defined metrics (Table 2) in IV&V assessment as well as all accessory data generated up to 24 months. Performers may submit up to three (3) individual BCM platforms for assessment. DARPA will announce a selected agent from Table 1 and IV&V teams will select appropriate preclinical models. Performers will have 21 days to ‘adapt’ BCM candidate platforms to protect against the ‘new threat’ and deliver BCM platforms to IV&V teams for challenge testing.

IV&V teams will select the vulnerable tissue barrier to challenge (i.e., ocular, respiratory, epithelial). IV&V teams will don/administer BCM platforms using *in vivo* models, where appropriate (noting the need for barrier tests where donning is not possible with certain models), and perform the challenge immediately (after 1 hour of donning). Sequential agent challenges (lasting less than 12 hours) will be administered over a 30 day period to ensure BCM mediated protection against novel threats, as well as safety, compatibility, and tolerability of BCM platforms. The outcome of candidate BCM platform Adaptation Tests will demonstrate (1) long-term effectiveness (30 days), (2) adaptability, and (3) durable protection capability (metrics in Table 2).

Regulatory process

During Phase I, proposers must actively engage the FDA/regulatory agencies, prior to drafting and submitting a Target Product Profile (See Tables 2 and 3). Active engagement may be informal or formal (e.g., FDA pre-pre-IND and/or EUA discussions) and will aid in the development of PPB, guidance in GMP manufacturing and fabrication, and clinical translation. Rigorous safety testing throughout Phase I will be within FDA guidance, TPP submission, and IND or EUA application drafting.

Phase II (Option One)

During Phase II, proposers will focus on optimizing and expanding the capabilities of their PPB platforms. Up to three (3) platforms for each TA, per team, may move forward into Phase II to best integrate TA1 and TA2 into a PPB ensemble.

Safety, efficacy, specificity, and transience of the integrated PPB ensemble *must* be tested *in vivo* during every test. A series of sequential tests of increasing difficulty will be designed to assess the ability of the PPB ensemble to protect against selected threats prophylactically (pre-exposure) in healthy threat-relevant preclinical models. Tests will demonstrate greater *in vivo* protection and a greater understanding of the mechanism of PPB protection and failure.

Feasibility Study (30 months) – TA1 and TA2 Ensemble

Performers will conduct an early Phase II feasibility study, in collaboration with IV&V partners, to demonstrate TA1 and TA2 integration efforts produce a PPB ensemble capable of functioning in a manner consistent with program goals. This study will enable performers to test and guide their technical designs. Data will allow IV&V and DARPA program management to provide feedback for the design process.

Test 5 (36 months) – TA1 & TA2 PPB Ensemble Safety

Proposers will continue to improve on technology metrics while scaling up CB agent protection and material performance on TA1 and TA2. Safety and toxicity tests (such as those outlined in **Safety and Regulatory Testing**) will be the focus of months 25-36. Proposers will outline (with guidance and testing support from IV&V) specific assays.

Test 6 (48 months) -- TA1 & TA2 PPB Ensemble Protection

By 48 months after contract award, proposers will demonstrate integrated PPB ensemble protection (100% survival) with appropriate preclinical *in vivo* models challenged against two **DARPA**-selected CB agents and **DARPA**-selected exposure routes, at threat-relevant agent concentrations determined by IV&V. Selected CB agents will not be announced to performers.

One PPB ensemble per team may be submitted for the PPB Ensemble Protection Test in the surety environment provided by IV&V teams. PPB Ensemble Protection Test will run a minimum of 30 days with exposures lasting up to 12 hours during the 30-day period. IV&V teams will equip preclinical models and/or robotic humanoid manikins with the PPB ensemble, challenge immediately (within hours) with both of the unannounced agent challenges (derived from the agent list in Table 1) periodically over the 30-day period. The outcome of candidate PPB platform Protection Tests will demonstrate (1) long-term, (2) broad-spectrum, and (3) durable protection against unannounced threats with zero adverse health effects from even low-level agent exposures to meet metrics in Table 3.

By the end of Phase II, the PPB ensemble should be capable of protecting a human, with regulatory (FDA) approval for in-human testing in Phase III of the program. Individually, TA1 solutions should be wear and weather resistant, pose near-zero thermal or logistical burden to the wearer, and protect against the pre-defined list of agents (Table 1) in accordance with metrics listed in Tables 2 and 3. TA2 solutions will be on-demand with hand-held delivery (e.g., eye-drops, inhalation, topical application, etc.).

Regulatory process

In the middle of Phase II (months 30-42), proposers will finalize all necessary IND/EUA application submission requirements, data analysis, platform optimization, and plans for technology transition. Proposers will demonstrate increased formulation versatility (shelf-stability, mass-producibility) and device delivery. At the end of Phase II, proposers will demonstrate the ability to develop PPB platform components in a GMP environment. Pre-EUA activities are not required but may proceed in parallel to the required FDA approval through IND pathways.

Safety testing of integrated PPB platform components such as those outlined in **Safety and Regulatory Testing** may be performed independently or coincide with IV&V tests. Rigorous safety testing throughout Phase II of the PPB ensemble will be within FDA guidance, in conjunction with robust on-going regulatory (i.e., FDA) engagement.

Phase III (Option Two)

In-human safety testing of PPB

The primary objective at the end of Phase III will be to translate the integrated PPB ensemble into human subjects for safety testing. The program will conclude with clinical in-human or on-human (as appropriate) safety study completion and transition of technology(ies). The end-objective for Phase III will be EUA granted from the FDA following a successful human study.

Milestones & Metrics

In order for the government to evaluate the effectiveness of proposed PPB technologies in achieving the stated program objectives, proposers should note that the government hereby promulgates the following program metrics that may serve as the basis for determining whether satisfactory progress is being made to warrant continued funding of the program. Although the following program metrics are specified, proposers should note that the government has identified these goals with the intention of bounding the scope of effort, while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problem.

Quantitative metrics are expected to vary for each proposer-selected threat area and system. Some exemplary milestones and metrics are included below for proposers to consider, but proposers should adjust accordingly for their given threat and system. Final metrics are to be determined at the time of award negotiation and are subject to DARPA approval. Proposers should note that program metrics may serve as the basis for determining whether satisfactory progress is being made to warrant continued funding of the program (i.e., assessment).

In addition to the tests and system demonstration milestones, performers will be required to participate in program review meetings every 6 months. All performers will attend these Technical Interchange Meetings (TIMs) to brief their latest results and progress toward program goals. The meetings will include government participation from FDA, Defense Threat Reduction Agency (DTRA), program agents, defense laboratories, and the potential customers including United States Special Operations Command (USSOCOM), U.S. Army Combat Capabilities Development Command Chemical Biological Center (CCDC CBC), U.S. Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD), and other interagency end-users. Government sidebars will be held to provide individual feedback to the performers and to ensure they are developing relevant technologies. Teleconferences will be held with each team at monthly intervals. Site visits will be conducted at the Program Manager's discretion. Tables 2 and 3 are a summary of the milestones and metrics for each team throughout the PPB program.

Table 2: PPB program milestones, metrics and Phase I assessment metrics

Phase I			
	Milestone	IV&V	Metric
6 months	TA1 & TA2 • Demonstrate feasibility	• Platform Feasibility Study	TA1 • Near instantaneous (within 10 minutes) protection • Meet pre-determined acceptable protection factor and/or breakthrough properties (as determined in consultation with the IV&V teams) against 5 CB threats or simulants
12 months	TA1 • Determine material protection factor and break through properties in consultation with IV&V teams • Demonstrate protection against 5 CB agents or simulants • Provide data describing acute responses (minutes to hours) as outlined in Safety and Regulatory Testing TA2 • Demonstrate neutralization of 2 CB agents or simulants • Provide data describing acute responses (minutes to hours) as outlined in Safety and Regulatory Testing	• Test 1: Material and Platform Development (TA1&TA2)	TA2 • Active within 10 minutes • Neutralizes 2 CB agents or simulants • Safeguard activated, gene expression shut off, or removal of platform (i.e. on/off control) demonstrated within 1 hour
18 months	TA1 • Translate platform from <i>ex vivo</i> to <i>in vivo</i> • Test plan developed in collaboration with IV&V, submitted to DARPA in preparation for Test 3 TA2 • Translate platform from <i>in vitro</i> to <i>in vivo</i> • <i>In vivo</i> on/off capability demonstrated within one hour • Test plan developed in collaboration with IV&V, submitted to DARPA in preparation for Test 3 and Test 4	• Test 2: Material and Platform Development (TA1&TA2)	
24 months	TA1 • Safety studies to ensure host compatibility for TA1 technologies as appropriate. Performers must include inflammatory profiles preclinical models. Safety studies should run a minimum of the duration of protection (at least 30 days), and include the characterization while donned with PPB TA1 technologies • Persistent responses (days to weeks);	• Test 3: Material Performance (TA1) • Test 3: Material and Platform Protection (TA1 & TA2)	TA1 and TA2 • Assessment metrics: 100% survival of preclinical models for at least 30 days against a lethal dose of 1 proposer-selected chemical, and 1 proposer-selected biological agent at IV&V defined exposure levels

	<p>such as those outlined in Safety and Regulatory Testing</p> <p>TA2</p> <ul style="list-style-type: none"> • Safety and toxicity studies to ensure host compatibility for TA2 technologies as appropriate. Performers must include characterization of toxicity and inflammatory profiles in preclinical models. Safety studies should run a minimum of the duration of protection (at least 30 days), and include the characterization of host under activation and deactivation of PPB platform components • Persistent responses (days to weeks); such as those outlined in Safety and Regulatory Testing <p>Regulatory</p> <ul style="list-style-type: none"> • TPP submission to DARPA 		
24 months	<p>TA1</p> <ul style="list-style-type: none"> • Demonstrate material technologies result in: <ul style="list-style-type: none"> • Near-zero burden • Weather and wear resistance <p>TA2</p> <ul style="list-style-type: none"> • Demonstrate BCM platform can be delivered on-demand by hand-held delivery device (e.g., eye-dropper, inhaler) <p>Regulatory</p> <ul style="list-style-type: none"> • Active engagement with FDA, and follow FDA guidance for IND/EUA application (minimum 2 meetings) 	<ul style="list-style-type: none"> • Test 4: Platform Adaptation & Protection (TA2) 	<p>TA1</p> <ul style="list-style-type: none"> • Core body temperature does not elevate above 100.4°F • Thermal insulation values are <0.7 clo • Permeability (index 0.20-0.25) • Logistical weight < 1.0 lb. • Hydrostatic resistance and breathability in excess of ACU performance • Impact abrasion, seam burst strength, impact cut resistance exceed EN 13595:2002 protection and integrity standards (EN 13595-1 through EN 13595-4) • Reduced attachment of agent (4-orders of magnitude, relative to ACU) <p>TA2</p> <ul style="list-style-type: none"> • Assessment metrics: Demonstrate BCM platform adaptation to a new biological or chemical threat within 21 days, providing comparable protection (100% protection, at least 30 days) in appropriate preclinical models model(s)

Table 3: PPB program milestones, metrics, and Phase II & Phase III assessment metrics

Phase II			
	Milestone	IV&V	Metric
30 months	<p>Integrated TA1 and TA2</p> <ul style="list-style-type: none"> Platform components (TA1 & TA2) integrated into one PPB ensemble and compatible with appropriate large preclinical model(s) Test plan developed in collaboration with IV&V, submitted to DARPA in preparation for Test 5 	<ul style="list-style-type: none"> Feasibility Study (TA1 & TA2 Ensemble) 	<p>TA1</p> <ul style="list-style-type: none"> Near instantaneous (within 10 minutes) protection Protection against 10 CB threats (survival at IV&V-specified agent exposure levels) under conditions ranging from -20-+45 °C, 0-100% RH, and up to 60 kts wind speed <p>TA2</p> <ul style="list-style-type: none"> Active within 10 minutes Neutralizes 5 CB agents Safeguard activated, gene expression shut off, or removal of platform (i.e. on/off control) demonstrated within 1 hour
36 months	<p>Integrated TA1 and TA2</p> <ul style="list-style-type: none"> Proposers will continue to perform specific assessment and reiteratively innovate PPB ensemble technologies in large preclinical models for weather resistance, wear resistance, and reduced burden (thermal, logistical) metrics Safety and toxicity parameters (such as CBC, chemistries, cardiac, renal, and hepatic function) will be defined by appropriate large preclinical models, ensuring models are donned with the PPB ensemble remain within pre-defined 'normal physiologies' Chronic responses (months); such as those outlined in Safety and Regulatory Testing Test plan developed in collaboration with IV&V, submitted to DARPA in preparation for Test 6 <p>Regulatory (complete by 42 months)</p> <ul style="list-style-type: none"> Finalize all necessary IND/EUA application submission requirements, data analysis, platform optimization, and plans for technology transition 	<ul style="list-style-type: none"> Test 5: PPB Ensemble Safety 	<p>Integrated Ensemble</p> <ul style="list-style-type: none"> Assessment metrics: Demonstrate PPB ensemble compatibility, safety, and zero toxicity for at least 30 days in large preclinical models

Phase II			
	Milestone	IV&V	Metric
48 months	<ul style="list-style-type: none"> • Demonstrate ability to produce BCM (TA2 component) in a GMP environment <p>Regulatory</p> <ul style="list-style-type: none"> • Assess, beyond survival/death, the impact of PPB platforms on all of the subcategories (acute, persistent, chronic) of potential impacts on the user of the PPB system to include autoimmune, adverse user experience, or other qualitative impacts 	<ul style="list-style-type: none"> • Test 6: PPB Ensemble Protection 	<p>Integrated Ensemble</p> <ul style="list-style-type: none"> • Assessment metrics: PPB provides 100% protection of preclinical models for at least 30 days when challenged with a lethal dose of CB agent
Phase III			
	Milestone	IV&V	Metric
60 months	<p>Integrated Ensemble, in-human</p> <ul style="list-style-type: none"> • Penetration testing using TECMIPT or similar DUSA T&E environments for aerosol and vapor break-through testing <p>Regulatory</p> <ul style="list-style-type: none"> • Submission of PPB platform for FDA regulatory approval to support EUA and fielding of system through commercial or military acquisition systems 	<ul style="list-style-type: none"> • Provide human and/or manikin model testing environment, as necessary 	<p>Integrated Ensemble</p> <ul style="list-style-type: none"> • Zero adverse effects by human subjects • Zero breakthrough of aerosol or vapor in human or manikin testing • Don/Doff <10minutes

1.5. GENERAL REQUIREMENTS

Controlled Unclassified Information (CUI) Statement

To prevent the release of sensitive technical information, certain aspects of the proposed research may be considered CUI if they reveal host susceptibilities to threats or other vulnerabilities, and may require safeguarding or dissemination controls, pursuant to and consistent with applicable law, regulations, and government-wide policies. Proposals that anticipate the production of any such information must deliver a detailed risk mitigation plan to DARPA (see Section 4.2.2. Proposal Format Section II: I). Performers must partition potentially sensitive tasks from nonsensitive research efforts. All performers (prime contractor and subcontractor) desiring public release of project information that may contain CUI as defined above must submit a request for public release from DARPA in accordance with their contractual requirements.

The PPB program will involve the development of PPE material technologies (TA1), which falls under Export Administration Regulations (EARs), and the research related to it will be treated as CUI for this program. The program will only investigate known threats (Table 1). TA2 developed technologies will have the potential to be rapidly reconfigured in order to mitigate or eliminate risks posed by novel CB agents. Details for TA2 platform reconfiguration will be considered CUI. Additionally, TA2 platforms will involve safeguards, with the potential for controlling activation and deactivation of TA2 provided protection. Safeguard controls, such as pharmacological sensitivity or induction/repression of protection, will be considered CUI.

To prevent the release of sensitive technical information, certain aspects of the PPB program may be considered CUI and may require safeguarding or dissemination controls, pursuant to and consistent with applicable law, regulations, and government-wide policies. As such, organizations that can comply with DoD CUI requirements must be part of the proposed team. CUI and Controlled Technical Information (CTI) are to be marked with one of the distribution statements B through F, in accordance with Department of Defense Instruction 5230.24, "Distribution Statements on Technical Documents." The terms CUI and CTI do not apply to information that is lawfully publicly available without restrictions. DARPA anticipates that pre-publication restrictions will apply to all funded research and/or CUI.

Data Sharing

DARPA anticipates that a large amount of data will be generated under this program by each proposer, and the PPB program will require that information be shared with DARPA and US Government stakeholders. It is anticipated data analyses will be strengthened by compiling and integrating information across all teams, and while teams are encouraged to share their data with other PPB teams and the broader research community, it is not required. Proposers must include the description of a plan to provide data to DARPA, approximate timelines for release of data, types and formats of (meta) data, and total estimated data sizes. Academic proposers considered to be conducting fundamental research on this program on campus may publish papers describing scientific or engineering advances that are general in nature and adhere to the above guidance. Should the character of the research change during award performance so that the research is no longer considered fundamental, the award will be modified to impose the restrictions on public release and dissemination of information that apply to those research efforts that are no longer considered fundamental research. For additional information on fundamental research, please see Section 2.2. Non-academic proposers shall submit any

publications to DARPA's Public Release Center to process for pre-publication review. All proposers desiring to publish papers that may contain CUI (see above) shall submit them in advance in accordance with contractual requirements.

Teaming

Proposers are responsible for assembling a complete team that has technical expertise, capabilities, and facilities to address all objectives of the program. Proposers must address both TAs which should run in parallel. A complete proposer team should, therefore, not only have the ability to meet the technical challenges of each TA and create an integrated platform PPB production, but also have the ability to protect against selected threats in threat-relevant preclinical models at appropriate containment levels. It is also encouraged that proposer teams include members that have industrial and commercial experience to aid in focusing on technology research and development strategy for eventual clinical translation. This could include, for example, expertise in medical product development and Good Laboratory Practice (GLP) or GMP manufacturing of medical countermeasures for use in preclinical and clinical settings to effectively navigate the preparatory process for IND/EUA, or equivalent, submission during the program effort. Describe any formal teaming agreements that are required to execute this program. All teams are encouraged to identify a Project Manager to serve as the primary point of contact to communicate with the DARPA Program Manager and Contracting Officer Representative, 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.

Ethical, Legal, and Social Implications (ELSI)

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 with expertise in bioethical issues that may emerge as a consequence of advances in biomedical science and technology, including human gene modulation. Proposers to this BAA should address potential ethical, legal, and societal implications of the proposed technology, with a special emphasis on strategies to enable safe, transient, non-permanent PPB. Industry proposers that are considering the development of PPB solutions to address opioid challenges should additionally consider the following ethical considerations for industry partnerships in this space:

https://acd.od.nih.gov/documents/presentations/032018_opioids-draft-report.pdf

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 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 either cannot be met by proposers intending to perform fundamental research or the proposed research is anticipated to present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Therefore, the Government anticipates 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. A smaller font may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11-inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title.

4.2.1. Proposal Abstract Format

Proposers are strongly encouraged to submit an abstract in advance of a full proposal to minimize effort and reduce the potential expense of preparing an out of scope proposal. DARPA will respond to abstracts providing feedback and indicating whether, after preliminary

review, there is interest within BTO for the proposed work. DARPA will attempt to reply within 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. A smaller font may be used for figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11-inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal abstract title.

The page limit does NOT include:

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

Abstracts must include the following components:

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

B. Goals and Impact (1 page): Clearly describe what is being proposed and what difference it will make (qualitatively and quantitatively), including brief answers to the following questions:

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

C. Technical Plan (3-4 pages): Outline and address all technical areas and challenges inherent in the approach and possible solutions for overcoming potential problems.

D. Capabilities (0.5-1 page): 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. Include a description of

the team's organization including roles and responsibilities. Describe the organizational experience in this area, existing intellectual property required to complete the project, and any specialized facilities. List Government-furnished materials or data assumed to be available. If desired, include a brief bibliography with links to relevant papers, reports, or resumes of key performers. Do not include more than two resumes as part of the abstract. Resumes count against the abstract page limit.

E. Budget (0.5 page): Please provide a rough order of magnitude of the costs of accomplishing the goals of the PPB program. Costs should be broken out by technical area and phase. Any anticipated government furnished equipment should be identified.

4.2.2. Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal**. All submissions must be written in English with type no smaller than 12-point font. A smaller font may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1- inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. **The maximum page count for Volume I is 25 pages.** A submission letter is optional and 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 (HR001120S0015);
2. Lead organization submitting proposal (prime contractor);
3. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
4. Proposer's reference number (if any);
5. Other team members (if applicable) and type of business for each;

6. Proposal title;
7. Technical point of contact (Program Manager or Principle Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), e-mail (if available);
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), e-mail (if available);
9. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-award—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), 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 Provide a one-slide summary in PowerPoint that effectively and succinctly conveys the main objective, key innovations, expected impact, and other unique aspects of the proposed project. The slide template is provided as **Attachment 1**. Use of this template is required.

Section II. Detailed Proposal Information

A. Executive Summary (1-2 pages): 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 (1-2 pages): 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 (7-10 pages):** Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) at intermediate stages of the program to demonstrate progress and a plan for achieving the milestones. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal. Discuss mitigation of technical risk.
- D. Management Plan (1-2 pages):** Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. Resumes count against the proposal page count. Identify a principal investigator (PI) for the project, and include an on-site program manager if the PI will contribute less than 50% time/effort to the project. Provide a clear description of the team's organization, including an organization chart that contains, as applicable: the programmatic relationship of team members, team members' unique capabilities/expertise, team members' task responsibilities, the teaming strategy among the team members, collaborators, subcontractors, etc., 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, etc., of the proposed effort. Include risk management approaches. Describe any formal teaming agreements that are required to execute this program.
- E. Capabilities (1-2 pages):** Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Discuss any work in closely related research areas and previous accomplishments.
- F. Statement of Work (SOW) (4-5 pages):** 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 (Phase I base, Phase II option, and Phase III option) should be separately defined. The SOW must not include proprietary information.

For each task/subtask, provide:

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

G. Schedule and Milestones (1-2 pages): Provide a detailed schedule (Gantt chart preferred) 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. If the Gantt chart cannot fit on a standard 8 ½ by 11” page, you are permitted to include it as an addendum/appendix.

H. Transition Plan (.5-1 page): As this program is expecting a prototype system at the end of 60 months; proposals must address a plan to complete, beta-test, and market the deployable platform to the military and commercial partners. Proposals should include a rough order of magnitude of the prototype system and disposables cost. If off-the-shelf technologies were proposed, proposals should address intellectual property (IP) licensing and associated risks.

Section III. CUI Risk Mitigation Plan (Note: Does not count towards page limit)

Required for proposers who anticipate generating work that may be considered CUI in accordance with Section 1.5 “Controlled Unclassified Information”: Provide a detailed plan for how the organization and its subcontractors will meet CUI safeguarding requirements **using Attachment 3**. The plan should provide a detailed strategy to protect CUI without unnecessarily compartmentalizing information flow within or among performer teams. This plan must describe safeguard procedures for generating any sensitive program deliverables.

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

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

a. Volume II, Cost Management Proposal

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

1. BAA Number (HR001120S0015);
2. Lead organization submitting proposal;
3. Type of organization, selected among the following categories: “LARGE BUSINESS”, “SMALL DISADVANTAGED BUSINESS”, “OTHER SMALL BUSINESS”, “HBCU”, “MI”, “OTHER EDUCATIONAL”, OR “OTHER NONPROFIT”;
4. Proposer’s reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
9. Award instrument requested: cost-plus-fixed-fee (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), or other transaction;
10. Place(s) of performance, including all subcontractors and consultants;
11. Period of performance;
12. Total proposed cost separated by Task Area and Phase (as defined in Figure 1), and the amount of any cost share (if any);
13. Name, address, and telephone number of the proposer’s cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
14. Name, address, and telephone number of the proposer’s cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
15. Date proposal was prepared;
16. Data Universal Numbering System (DUNS) number (<http://www.dnb.com/get-a-duns-number.html>);
17. Taxpayer ID number (<https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN>);
18. Commercial and Government Entity (CAGE) code (<https://cage.dla.mil/Home/UsageAgree>);
19. Proposal validity period

The Government strongly encourages that proposers use the provided MS Excel™ cost proposal spreadsheet in the development of their cost proposals. All tabs and tables in MS

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

- (1) Total program, per phase (Phase I (Base); Phase II (Option 1); and Phase III (Option 2), 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. Any materials or supplies item with a unit price over \$5,000 must include a vendor quote.
 - iii. **Equipment** – itemized list, which includes description of equipment, unit price, quantity, and total price. Any equipment item with a unit price over \$5,000 must include a vendor quote.
 - iv. **Animal Use Costs** – itemized list of all materials, animal purchases, and per diem costs, associated with proposed animal use; include documentation supporting daily rates.
 - v. **Travel** – provide an itemized list of travel costs to include purpose of trips, departure and arrival destinations, projected airfare, rental car and per GSA approved diem, number of travelers, number of days; provide screenshots from travel website for proposed airfare and rental car, as applicable; provide screenshot or web link for conference registration fee and note if the fee includes hotel cost. Conference attendance must be justified, explain how it is in the best interest of the project. **Plan for two (2) DARPA program review meetings per year.**
 - vi. **Other Direct Costs (e.g., computer support, clean room fees)** – Should be itemized with costs or estimated costs. Backup documentation and/or a supporting cost breakdown is required to support proposed costs with a unit price over \$5,000. An explanation of any estimating factors, including their derivation and application, must be provided. Please include a brief description of the proposers’ procurement method to be used.
 - vii. **Other Direct Costs** – Consultants: provide executed Consultant Agreement that describes work scope, rate and hours.
 - viii. **Indirect costs** including, as applicable, fringe benefits, overhead, General and Administrative (G&A) expense, and cost of money (see university vs. company specific requirements below).

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

- (9) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available).
- (10) Proposers with a Government acceptable accounting system who are proposing a cost-type contract must submit the DCAA document approving the cost accounting system.

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

Subawardee Proposals

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

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

Other Transaction Requests

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

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

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

4.2.3. Additional Proposal Information

Proprietary Markings

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

Unclassified Submissions

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

Disclosure of Information and Compliance with Safeguarding Covered Defense Information Controls

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

DFARS 252.204-7000, “Disclosure of Information”

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

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

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

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

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

Human Subjects Research (HSR)/Animal Use

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

Approved Cost Accounting System Documentation

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

Small Business Subcontracting Plan

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

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

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

Intellectual Property

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

(1) For Procurement Contracts

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

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

(2) For All Non-Procurement Contracts

Proposers responding to this BAA requesting an 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 HR001120S0015. Submissions may not be sent by fax or e-mail; any so sent will be disregarded.

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

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

Abstracts and Full Proposals sent in response to HR001120S0015 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 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.

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 HR001120S0015 summary. Submit your question(s) via e-mail to PPB@darpa.mil.

5. Application Review Information

5.1. EVALUATION CRITERIA

Proposals will be evaluated using the following criteria, listed in descending order of importance: 5.1.1 Overall Scientific and Technical Merit; 5.1.2 Potential Contribution and Relevance to the DARPA Mission; 5.1.3 Cost Realism; and 5.1.4 Realism of Proposed Schedule.

5.1.1. Overall Scientific and Technical Merit

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

5.1.2. Potential Contribution and Relevance to the DARPA Mission

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

5.1.3. **Cost Realism**

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

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

5.1.4. **Realism of Proposed Schedule**

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

5.2. **REVIEW OF PROPOSALS**

Review Process

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

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

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

Handling of Source Selection Information

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

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

Federal Awardee Performance and Integrity Information (FAPIS)

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 FAPIS). 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 FAPIS or other systems prior to making an award.

6. Award Administration Information

6.1. SELECTION NOTICES

6.1.1. Proposal Abstracts

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

6.1.2. Full Proposals

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

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

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

deem to be necessary throughout the course of the effort, to include periodic status reviews by the government.

6.2.2. FAR and DFARS Clauses

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

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

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

6.2.4. Representations and Certifications

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

6.2.5. Terms and Conditions

6.3. REPORTING

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

6.4. ELECTRONIC SYSTEMS

6.4.1. Wide Area Work Flow (WAWF)

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

6.4.2. I-EDISON

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

7. Agency Contacts

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

Points of Contact

The BAA Coordinator for this effort may be reached at:

PPB@darpa.mil

DARPA/BTO

ATTN: HR001120S0015

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 Personalized Protective Biosystem (PPB) program on December 4th, 2019, at the George Mason University Auditorium in Arlington, VA. The purpose is to provide potential proposers with information on the PPB program, promote additional discussion on the topic, address questions, provide a forum to present their capabilities, and to encourage team formation.

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

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

To encourage team formation, interested proposers are encouraged to submit information to be shared with all potential proposers through the Proposers Day website and the DARPA Opportunities Page. This information may include contact information, a brief description of their technical capabilities, and the desired expertise from other teams, as applicable.

Participants are required to register no later than **Tuesday, November 26, 2019** for the event. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; **there will be no onsite registration.**

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

Proposers Day Point of Contact DARPA-SN-20-10@darpa.mil.

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 HR001120S0015. 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 **HR001120S0015** included on your Cost Proposal cover sheet?

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

If reply is “No”, please explain:

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

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

If reply is “No”, please explain:

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

Direct Labor (Labor Categories, Hours, Rates)

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

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

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

Materials and/or Equipment

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

Subcontracts/Consultants

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

Other Direct Costs

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

Travel

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

If reply is “No”, please explain:

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

If reply is “No”, please explain:

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

If reply is “No”, please explain:

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

If reply is “No”, please explain:

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

If reply is “No”, please explain:

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

If reply is “No”, please explain: