Broad Agency Announcement

Fieldable Solutions for Hemorrhage with bio-Artificial Resuscitation Products (FSHARP)

BIOLOGICAL TECHNOLOGIES OFFICE

HR001121S0027

MAY 28, 2021

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PART I: OVERVIEW INFORMATION

- **Federal Agency Name –** Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title –** Fieldable Solutions for Hemorrhage with bio-Artificial Resuscitation Products (FSHARP)
- **Announcement Type –** Initial Announcement
- **Funding Opportunity Number –** HR001121S0027
- **North American Industry Classification System (NAICS) –** 541714
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- **Dates**
    - Posting Date:
    - Proposal Abstract Due Date and Time: June 22, 2021, 4:00 PM ET
    - Full Proposal Due Date and Time: August 10, 2021, 4:00 PM ET
    - BAA Closing Date: **August 10, 2021**
    - Proposers Day: **June 2, 2021**

    https://beta.sam.gov/opp/968e8c1d81244cdda48606dade821826/view
- **Concise description of the funding opportunity –** The goal of the FSHARP program is to leverage advances in bio-artificial blood substitute technologies to develop field deployable, shelf-stable hemorrhage countermeasures to sustain warfighters and civilian casualties in austere, pre-hospital settings.
- **Anticipated individual awards –** Multiple awards are anticipated.
- **Types of instruments that may be awarded –** Procurement contract, cooperative agreement, or other transaction.
- **Agency contact**

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PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

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

The Defense Advanced Research Projects Agency (DARPA) is soliciting innovative proposals to develop a deployable, shelf-stable, universal whole blood substitute as a hemorrhage countermeasure to sustain injured warfighters and civilians in austere, pre-hospital settings. Proposals should address the following areas for technical innovation: (1) development of bio-artificial resuscitation products that perform the therapeutic functions of blood components important for resuscitation (e.g., oxygen delivery; hemostasis, or cessation of bleeding; volume expansion); (2) integration of products into formulations that enable co-administration to achieve near-parity to whole blood functionality with no adverse effects; (3) preservation processes that impart months-long shelf-stability in a variety of expected operational conditions without cold-chain requirement; and (4) manufacturing processes and technologies that enable quick, scalable, and consistent production of formulations. Proposed research should develop innovative technologies to enable cost-effective production of resuscitative formulations suitable for use in field-forward locations. Specifically excluded is research that primarily results in incremental improvements to the existing state of practice.

1.1. PROGRAM OVERVIEW

In military and many civilian settings, hemorrhage is the leading cause of potentially survivable, traumatic pre-hospital death. [1,2,3] The foundation of treatment is transfusion of blood products, which includes individual blood components (e.g., red blood cells, platelets, clotting factors, plasma) or whole blood (i.e., blood with all of its components), considered the preferred resuscitation fluid in tactical combat casualty care. [4] Unfortunately, there are various logistical challenges that limit the use of whole blood in far-forward operations, including cold storage requirements and shelf-life of about a month. In emergencies, blood can be transfused from pre-identified on-site donors, but this typically is a small proportion of the population and depends on the donors not requiring blood themselves.[5]

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[1] Eastridge BJ, Mabry RL, Sguin P, et al. Death on the battlefield (2001-2011): implications for the future of combat casualty care. J Trauma Acute Care Surg 2012; 73:S431.
[2] Callcut RA, Kornblith LZ, Conroy AS, et al. The why and how our trauma patients die: a prospective multicenter Western Trauma Association study. J Trauma Acute Care Surg 2019; 96:864.
[3] Koh EY, Oyeniyi BT, Fox EE, et al. Trends in potentially preventable trauma deaths between 2005-2006 and 2012-2013. Am J Surg 2019; 218:50.
[4]Butler FK, Holcomb JB, Shackelford S, et al. Advanced resuscitative care in tactical combat casualty care: TCCC guidelines change 18-01:14 October 2018. J Spec Oper Med 2018; 18:37.
[5] Joint Trauma System. Clinical Practice Guideline. Whole blood transfusion (CPG ID: 21). 15 May 2018.

No product has been developed that performs all of the key resuscitative functions of whole blood, but DARPA and others have attempted to increase the availability of blood components. Treatments using hemoglobin, the oxygen-carrying molecule in red blood cells, date back to the 1940s.[6] Some of these reached human trials but were associated with side effects, such as cardiovascular complications that may result from cell-free hemoglobin's propensity to inhibit the vasodilator nitric oxide (NO).[7] DARPA's Blood Pharming program (2008-2014) took a different approach and grew red blood cells in the laboratory, though this did not alleviate the cold-chain requirement. An important recent innovation is freeze-dried plasma, which maintains function for 1-2 years without refrigeration, but does not simulate the crucial role of platelets in stopping bleeding or red blood cells in delivering oxygen.

Besides limited blood product availability, an additional challenge in hemorrhage resuscitation is trauma-induced coagulopathy (TIC), a spectrum of disordered clotting in traumatic hemorrhage and traumatic brain injury (TBI).[8] TIC ranges from excessive clot breakdown that exacerbates bleeding to suppressed clot breakdown that causes life-threatening off-target clots. TIC varies across patients and over time since injury.[9] One primary treatment for TIC is tranexamic acid (TXA), which inhibits clot breakdown systemically. But TXA was associated with increased mortality when given > 3 hours post-injury, possibly by enhancing clotting in patients with already-suppressed clot-breakdown.[10]

In summary, there is a need for shelf-stable products that comprehensively recapitulate the critical functions of whole blood, and that can be tailored to specific TIC treatment needs. Development of shelf-stable whole blood alternatives has not been attempted previously, but recent technical advances lay the foundation for innovations to overcome impediments to their successful development.

Multiple therapeutically-active components may be needed to approximate whole blood. Efforts may draw on recent innovations in semi- or fully-synthetic nanoparticle-based approaches to develop components for oxygen delivery, hemostasis, correction of TIC, and other therapeutic functions. For example, new experimental blood component substitutes have been developed using highly tunable nanoparticle design strategies, coupled with a new understanding of hemorrhage and TIC physiology, that achieve favorable safety and efficacy profiles in pre-clinical studies. These approaches, along with new computational and *in vitro* testing platforms, facilitate rapid prototyping and optimization for mutual material and functional compatibility among components and tailoring to specific trauma physiologies. Efforts may also draw on innovative approaches to preservation of blood components and substitutes, such as incorporation of agents that stabilize solutions during freezing or drying, and to nanoparticle manufacturing, such as scalable, continuous-flow methods.

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[6] Ambderson WR, Jennings JJ, Rhode CM. Clinical experience with hemoglobin-saline solutions. J Applied Physiol 1949; 7:469.
[7] Chen Q, Guo H, Gan Q, et al. Assessing hemorrhagic shock: feasibility of using an ultracompact photoacoustic microscope. J Biophotonics 2018; 12:e201800348.
[8] Galvagno SM, Fox EE, Appana SN, et al. Outcomes following concomitant traumatic brain injury and hemorrhagic shock: A secondary analysis from the PROPPR trial. J Trauma Acute Care Surg 2017; 83:668.
[9] Moore HB, Moore EM. Temporal changes in fibrinolysis following injury. Thromb Haemo 2020; 46:189.
[10] The CRASH-2 collaborators. The importance of early treatment with tranexamic acid in bleeding trauma patients: an exploratory analysis of the CRASH-2 randomised controlled trial. Lancet 2011; 377:1096.

FSHARP links component design with manufacturing and stabilization technology to meet DoD needs for whole blood simulants that overcome the logistical challenges of whole blood in forward settings. Additionally, through the development of bio-artificial resuscitation solutions, FSHARP begins to alleviate dependence on donations for blood products, so that ultimately production may be scaled as needed regardless of donor supply.

1.2. TECHNICAL OBJECTIVES AND PROGRAM STRUCTURE

FSHARP is a four-year effort, organized as two sequential 24-month phases (Phase I and Phase II), with a potential option for a Phase III (12 months) that would allow for pre-clinical studies to support an Investigational New Drug (IND) application to the Food and Drug Administration (FDA). During Phase I, performer teams will establish proof-of-concept for developing bio-artificial blood components and combination formulations via efficacy and safety testing in *in vitro/ex vivo* (e.g., organs-on-chip) models and relevant animal models of hemorrhage. In addition, performers will develop approaches for enabling shelf-stability and manufacturing scale-up of the bio-artificial blood products. Phase II focuses on demonstrating efficacy and safety of the blood simulant formulations in large animal models of complex trauma (e.g., hemorrhage with TBI, hemorrhage with TIC); long-term storage of formulations in a variety of expected operational conditions, including extreme heat and cold, without loss of efficacy; and manufacturing scale-up consistent with Good Manufacturing Practices (GMP). As outlined in this BAA, successful completion of intermediate and end-of-phase milestones, will be required in each phase to evaluate progress throughout the program. Progress toward meeting these milestones will be used to evaluate the continuation of performers and program at the end of Phase I.

Phase III would be reserved for pre-clinical studies to support an IND application to the FDA. Thus, proposers should plan for obtaining pharmacological and toxicological safety data in an appropriate animal model and demonstrating the capability to produce sufficient quantities of bio-artificial blood products for clinical testing within GMP guidelines. While the program does not currently have resources to continue into Phase III, a fully priced option is requested in order to allow for continuation should additional resources become available.

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

- Technical Area 1 (TA 1): Blood Substitute Development
- Technical Area 2 (TA 2): Manufacturing and Stabilization

The objective of TA1, Blood Substitute Development, is to develop multiple therapeutically-active bio-artificial components that will address three primary lifesaving functions of whole blood in resuscitation: oxygen delivery, hemostasis, and volume expansion. Performers may also develop adjunct therapies to aid or complement the above functions. These components will be integrated into combinations that will allow for co-administration to approximate comprehensive whole blood functionality without causing adverse effects. The objective of TA2, Manufacturing and Stabilization, is to develop chemical modifications and manufacturing approaches that enable the products developed in TA1 to be produced in an easily portable form that can be maintained under a range of environmental conditions likely to be encountered in military

operations and in sufficient quantities on a timescale that meets DoD needs. Proposers must plan to verify the effectiveness and safety of their bio-artificial blood substitutes in relevant models of hemorrhage in studies that could support submission of an FDA IND application. Proposers must also plan to demonstrate manufacturing capabilities in concordance with GMP guidelines.

Proposers must propose to both TAs, and both TAs must run concurrently over the duration of the effort. Proposers are responsible for ensuring their team has the requisite technical expertise, capabilities, and facilities to address all aspects of both technical areas. Proposals that fail to address both technical areas will be considered non-conforming and will not be evaluated.

1.2.1. TA1: Blood Substitute Development

In TA1, proposers must focus on the development of safe bio-artificial products to approximate whole blood functionality as co-administered formulations. As the intent is to allow for co-administration of alternatives to approximate whole blood, products must achieve material (physical) compatibility with each other early in the effort. Proposed approaches must ultimately provide functionality with near parity to whole blood (i.e., within 10% of whole blood function for medically relevant oxygenation, hemostatic, and hemodynamic parameters) with no adverse effects.

Proposers must define the modality by which the proposed alternatives will achieve the necessary resuscitative functions (e.g., will the oxygenation alternative be hemoglobin-based or use another approach); current performance characteristics, if known; and a strategy for achieving program metrics. For formulations that may include wholly donor-derived components (e.g., freeze-dried plasma), proposers must describe their pathogen removal strategy and detail the supply chain of the product to assure safety and availability. In addition, proposers must clearly explain the rationale of using a wholly donor-derived product (versus an artificial or bio-artificial product) for a component. However, formulations composed entirely of donor-derived products (i.e., no bio-artificial components are included) and formulations that do not address all three resuscitative functions are outside of the scope of this program.

In addition to hemorrhage, FSHARP seeks to address complex pathologies such as hemorrhage with TBI and hemorrhage with TIC, which may benefit from adjunct therapeutics; for example, agents that improve survival by protecting or restoring organ function, or treat coagulopathy. Therefore, proposals may include development and integration of adjunct therapeutics into the formulations to supplement the whole blood simulant's function in these complex clinical scenarios. However, proposals that focus primarily on the development of such therapeutics without addressing development of the bio-artificial blood substitutes are outside of the scope of this program.

Design, discovery, and preliminary testing of products may involve *in silico* modeling to support development and optimization of blood product alternatives and combined formulations. Further testing for compatibility and safety will be assessed using *in vitro/ex vivo* models (e.g., cell studies, organs-on-chip) and appropriate animal models, data from which could be used to support FDA IND submission. Performance comparisons to the gold standard (i.e., whole blood) will also be required. Therefore, proposals must describe the entire design and test process, including any *in silico* tools or pipeline expected to be used to aid in TA1 development; source

of animal models; justifications for the *in vitro, ex vivo,* and animal models and assays used; source of whole blood samples; and justifications for the comparative studies allowing performance quantification in relation to whole blood. Testing strategies must address how they will yield data sufficient for an FDA IND submission, including justification for chosen function and safety characteristics that will be monitored. Proposers will select assays for safety testing and justify those selections based on the design and function of the products and relevant FDA guidance. The assays should provide evidence needed for regulatory evaluation of product safety.

By the end of Phase II, components and formulations must meet the final program goals outlined in Table 1 below, as well as achieving interim goals noted in Table 3 of Section 1.3, Program Metrics. Proposers must describe how each goal will be achieved, how progress will be assessed, and how performance of the components and formulations will improve over the course of the program.

Table 1. TA1 Goals

Metric	Goal
Functionality of whole blood alternative	Within 10% of whole blood function (hemodynamics, oxygenation, and hemostasis)
Safety	No safety anomalies compared to whole blood

Phase I (Base, 24 months): Development and Initial Demonstration of Blood Substitutes
Phase I should yield novel blood substitutes that in combination enable resuscitation nearly on par with whole blood, defined as within 10% of whole blood function in head-to-head comparison for hemodynamic measures, oxygenation, and hemostasis. The products also should exhibit zero increase compared to whole blood in standard measures used to assess safety anomalies of blood component substitutes—at a minimum, immune activation, off-target clotting, and nitric oxide inhibition for hemoglobin-based oxygen carriers. Performers will define the specific assays to assess these functionality and safety parameters quantitatively based on the experimental model and the expected physiological effects of their products, and must justify the choices. Relevant FDA guidance should be cited where applicable to the proposed product. Novel therapeutic targeting strategies may also be developed but are not the primary focus for this program. As the TA1 products will be the subjects of shelf-stability and manufacturability enhancements in TA2, they must be designed with compatibility for proposed preservation and manufacturing approaches in mind.

Successful proposals must describe strategies to measure and mitigate potential failures, which should be identified and accompanied with proposer-defined characterization and risk mitigation plans. Some examples of potential failures may include, but are not limited to, insufficient functionality when compared to whole blood, cytotoxicity, component incompatibility in mixtures, and off-target clotting. The entire design and testing/validation approach must allow for the revision of components or development of new ones without significant schedule risk.

Proposals must address approaches to test products in various models to assess efficacy and safety, and drive toward demonstration of near functional parity when compared to whole blood. Proposers must define the efficacy and safety parameters they will be evaluating during testing

and provide justification for these choices. Efficacy and safety evaluation can include interim testing executed by performers during development and must include demonstrations of milestone achievement described in Section 1.3, Program Metrics. For Phase I, demonstrations will be in *in vitro/ex vivo* models, such as organs-on-chip during Year 1, and small and/or large animal models in Year 2. For proposers planning a Year 2 milestone demonstration in a large animal, initial proof in a small animal model is desired. Proposers must clearly define the models used for all testing and provide justification for their choices, including the likelihood of regulatory acceptance and physiological relevance. Proposers will be expected to have the capability to perform necessary studies at their or a subcontractor's facilities and should plan their teams accordingly.

Selected proposers will also be required to complete necessary activities to support delivery of blood substitute formulations to the Independent Verification and Validation (IV&V) teams for third-party validation of performance claims each year during milestone demonstrations. See Section 1.2.3, Milestone Demonstrations and IV&V, for additional information.

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

- develop bio-artificial blood substitute components that work in concert to mimic natural, whole blood in functionality and safety;
- identify risks and develop mitigation plans for Phase II optimizations, including those related to TA2 efforts to improve shelf-stability and manufacturability; and
- engage with the IV&V team to review and refine protocols for Phase II complex trauma large animal testing.

Progress against the Phase I milestones in Table 3 of Section 1.3 will be used to determine progression into Phase II.

Phase II (Option, 24 months): Optimization and Complex Trauma Demonstration
The majority of Phase II efforts will involve optimization of components and formulations to increase their efficacy without sacrificing safety and enable extension to complex trauma presentations, namely hemorrhage with TBI and hemorrhage with TIC. However, while addressing the aforementioned will be mandatory, proposers are free to propose additional complex presentations for which their products could be beneficial, provided the presentations are well defined and DoD relevance is established. Proposals that address only the mandatory presentations will not be viewed less favorably than those including additional, relevant presentations. For Years 3 and 4, proposers must plan for demonstrations in large animal models of complex presentations. As in Phase I, justification for the models must be provided, and proposers must have facilities for executing planned tests. IV&V teams will validate performer results in Years 3 and 4 in relevant models as proposed. See Section 1.2.3, Milestone Demonstrations and IV&V for additional information.

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

- demonstrate efficacy and safety of optimized bio-artificial blood substitute components in complex trauma presentations; and
- identify risks and develop mitigation plans for a potential FDA IND submission.

Progress against Phase II goals will be one of the criteria used to determine progression to Phase III.

Phase III (Option, 12 months): IND Submission
The focus of this phase is to prepare for an FDA IND application by obtaining pharmacological and toxicological data in a relevant animal model, demonstrating that FSHARP products are safe for human testing. No human trials would occur during this phase.

1.2.2. TA2: Manufacturing and Stabilization

In TA2, proposers will focus on the development of manufacturing and stabilization (preservation) processes that will enable the products and formulations from TA1 to be produced in shelf-stable formats that can be easily and cost-effectively scaled up to meet DoD needs. Proposed approaches must ultimately enable products to be stored at a range of conditions expected in operational environments, for up to 6 months and without significant degradation in functionality when compared to fresh product. In addition, manufacturing and stabilization approaches must yield products that meet the same safety criteria as fresh product. Manufacturing approaches must ultimately be compliant with standards. Stabilization approaches must yield products that are easily and thoroughly reconstituted with fluid, such as water or saline, without mechanical agitation (e.g., must be accomplished by simple manual shaking, squeezing, or inversion). The combined weight of 1 unit of the stabilized product and the required reconstitution fluid must be no more than a unit of whole blood in standard packaging. Formulations must be designed for intravenous and/or intraosseous administration. As both manufacturing and stabilization are part of TA2, each approach must take the other into consideration to ensure compatibility and a unified route to creating a shelf-stable product.

Proposers must detail the manufacturing approach for achieving scalable production, including a detailed description of the method and systems involved, current performance characteristics, and a strategy with traceable engineering changes to enable meeting program goals and GMP guidelines. Proposers must also detail their entire design and test process and how testing will increase in difficulty to demonstrate progress toward program goals. Testing approaches must address how compound composition, production rate, and any other proposer-chosen criteria to demonstrate consistent production capability, will be assessed. Proposers must provide justification for all proposer-chosen criteria and for assays to assess performance against the criteria, including how both increase the likelihood of regulatory acceptance. Manufacturing approaches must also detail controls and the setup of a quality management system (QMS).

Proposers must detail the stabilization approaches for preserving TA1 products, including a detailed description of the process, equipment, and excipients involved in creating shelf-stable formulations. Proposers must describe the expected form of the stabilized formulation (e.g., loose powder, tablet) and reconstitution method. Proposers must detail their design and test process, including how testing will increase in difficulty to demonstrate progress toward program goals. Testing plans must detail the assays, models, and characteristics that will be used to assess the effects of stabilization on the preserved products when compared to fresh TA1 product.

By the end of FSHARP, TA2 approaches must meet the program goals in Table 2 below, as well as achieving interim goals noted in Table 3 of Section 1.3, Program Metrics. Proposers must describe how each goal will be achieved, how progress will be assessed, and how performance of the manufacturing and stabilization approaches will improve over the course of the program.

Table 2. TA2 Goals

Metric	Goal
Production Rate	50 units in ≤1 week
Stability	Storage for 6 months at 4, 25, 40 °C with functional loss ≤ 10%
Reconstitution	Reconstitution without mechanical agitation
Safety	No safety anomalies (e.g., immune activation, off-target clotting, nitric oxide inhibition)
Cost	≤ whole blood
Weight (with reconstitution fluid)	≤ whole blood

Phase I (Base, 24 months): Development and Initial Demonstration of Manufacturing and Stabilization Approaches

Phase I should yield manufacturing and stabilization approaches that enable TA1 products to be made in shelf-stable formats in a timely, cost-effective manner. As the products in TA1 will be the focus of TA2 efforts, manufacturing and stabilization approaches should be designed with compatibility for the TA1 products in mind. However, approaches with potential applicability to other similar compounds are encouraged.

Successful proposals must describe strategies to measure and mitigate potential failures, which should be identified and accompanied with proposer-defined characterization and risk mitigation plans. Some examples of potential failures may include, but are not limited to, low yield after manufacturing, unacceptably high size dispersity, inconsistent composition, instability of preserved product at high temperature, and loss of function due to preservation. The entire design and testing/validation approach must allow for the revision of manufacturing and stabilization approaches without significant schedule risk.

Successful proposals must describe manufacturing approaches to demonstrate consistent production of adequate amounts within desired timescales, with an ultimate goal of demonstrating the capability of sufficient production to support clinical studies. Proposers should describe approaches to assess the products yielded by the TA2 manufacturing and stabilization approach for demonstration of near functional parity when compared to fresh TA1 products. Testing can include interim testing executed by performers during development and must clearly define the assays used for each milestone demonstration. Efficacy and safety testing of the stabilized products must also be included and described. Proposers will be required to complete necessary activities to support the delivery of blood substitute products that have been manufactured and stabilized by proposed methods to the IV&V teams for third-party validation of performance claims.

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

- develop a manufacturing and stabilization approach that confers shelf-stability to TA1 products without loss of function;
- identify risks and develop mitigation plans for Phase II optimizations; and
- identify traceable optimizations for the manufacturing and stabilization approach to meet Phase II goals.

Progress against the Phase I milestones in Table 3 of Section 1.3 will be used to determine progression to Phase II.

Phase II (Option, 24 months): Optimization
The majority of Phase II efforts will involve optimization of the manufacturing and stabilization approach to increase shelf-stability and production rate without sacrificing functionality, safety, or consistency of the TA1 products. Preserved products will be tested in large animal models of complex trauma presentations, see Section 1.2.3, Milestone Demonstrations and IV&V for additional information.

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

- demonstrate manufacturing and stabilization approaches that enable meeting the metrics for TA2; and
- identify additional processes and traceable optimizations that would allow for compliance with GMP and would enable further improvements to production consistency and rate.

Progress against Phase II goals will be one of the criteria used to determine continuation to Phase III.

Phase III (Option, 12 months): IND Submission
The focus of this phase is to prepare for an FDA IND application by preparing required manufacturing information pertaining to composition, stability, manufacturer, and controls used during manufacturing. Plans for this phase should include demonstrating the capability of TA2 to adequately produce and supply consistent batches of the stabilized TA1 products.

1.2.3. Milestone Demonstrations and IV&V

During Phase I and Phase II, FSHARP performers will complete demonstrations in each year to show their capability of meeting the milestones and progressing toward ultimate program goals. For TA1, the demonstrations will involve models of increasing injury complexity and increasingly challenging criteria for the safety and functionality metrics when comparing TA1 products to whole blood. For TA2, the demonstrations will involve decreasing timeframes for production of increasing amounts of product, increasing timeframes for stability over expected operational conditions, and increasing functionality goals when comparing stabilized and reconstituted TA1 product to fresh TA1 product. Progression from Phase I to Phase II is

dependent on successful completion of Phase-specific performance metrics and demonstrations as described below and outlined in Table 3 in Section 1.3.

During Phase I, performance of blood product substitutes, both fresh and preserved, and manufacturing capability will be assessed by demonstrations at 12 and 20 months. Phase II demonstrations will occur in months 36 and 45.

Demonstrations of product efficacy and safety will occur in models of increasing complexity. In Year 1, performers will conduct initial demonstrations using computer modeling and *in vitro/ex vivo* models, such as organs-on-chip, with *in vitro/ex vivo* data prioritized for the milestone demonstration. In Year 2, demonstrations will occur in animal models of hemorrhage. Proposers must define the expected animal model and provide a rationale for their choice. In Years 3 and 4, demonstrations will involve large animal models of hemorrhage, hemorrhage + TBI, and hemorrhage + TIC. Performers will demonstrate efficacy of their formulations against hemorrhage and one complex presentation (either hemorrhage + TBI or hemorrhage + TIC) in Year 3 but must demonstrate efficacy against all three presentations in Year 4. If performers have chosen to address additional complex presentations, efficacy against such presentations will be assessed in Year 3 via performer-chosen models and assays against program metrics.

If Phase III occurs, it will have one milestone demonstration, which includes the completion of pharmacological, toxicological, and any other studies required by the FDA for IND submission, and demonstration of adequate consistent manufacturing capability to support clinical studies. It is expected that the data and information supporting the submission would be obtained by month 59.

Specific metrics associated with each TA for the milestone demonstrations are discussed below in Section 1.3, Program Metrics.

In addition to milestone demonstrations, performers will be expected to provide their products to IV&V teams for third-party testing for each milestone. Therefore, proposals must budget for shipping products to IV&V teams. For budget planning purposes, assume the shipping of enough blood substitute products for one IV&V partner to conduct testing once a year on five (5) animal subjects per formulation tested. Performers will be responsible for ensuring products are shipped to IV&V teams and providing adequate documentation for proper reconstitution of products without performer involvement.

1.3. PROGRAM METRICS

For the Government to evaluate how effectively a proposed solution will achieve the stated program objectives, the Government hereby promulgates the following program metrics that may serve as the basis for determination of satisfactory progress to warrant continued funding. Although the 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 to proposed solutions to the stated problem. Proposals should cite the quantitative and qualitative success criteria that the effort will achieve by each Phase's program milestone and intermediary metric measurement.

Table 3. FSHARP Phase I and Phase II Metrics

	Phase I: Development and Initial Demonstration		Phase II: Optimization and Complex Trauma Applications	
	Year 1	**Year 2**	**Year 3**	**Year 4**
Demos	Mid-Phase Demo: Month 12	End of Phase Demo: Month 20	Mid-Phase Demo: Month 36	End of Phase Demo: Month 45
Models	*In vitro/ex vivo* models (e.g., organs on chip)	Small/Large animal models of hemorrhage	Large animal models of hemorrhage + TBI or hemorrhage +TIC	Large animal models of hemorrhage + TBI and hemorrhage +TIC
TA 1	• Physical* parameters for each component in the combination within 10% of pre-combined component • Functional† measures within 40% of whole blood • Safety‡ measures within 10% of whole blood	• Functional measures within 30% of whole blood • No safety anomalies	• Demo in 2 trauma models (H, H+TBI, or H+TIC) • Functional measures within 20% of whole blood • No safety anomalies	• Demo in 3 trauma models (H, H+TBI, and H+TIC) • Functional measures within 10% of whole blood • No safety anomalies
TA 2	• 10 units in ≤4 weeks • Storage for 1 month at 4 and 25 °C: functional measures ≤ 30% ↓	• 50 units in ≤4 weeks • Storage for 1 month at 4, 25, and 40 °C: functional measures ≤ 20% ↓	• 50 units in ≤2 weeks • Storage for 3 months at 4, 25, and 40 °C: functional measures ≤ 20% ↓ • Cost ≤ 2x whole blood	• 50 units in ≤1 week • Storage for 6 months at 4, 25, and 40 °C: functional measures ≤ 10% ↓ • Reconstitution w/o mechanical agitation • Cost ≤ 1x whole blood • Weight w/reconstitution fluid ≤ whole blood
FDA	Pre-IND Consultation Program (initiated by Month 3)			

*Physical: E.g., size, shape, surface.
†Functional: E.g., hemodynamics, oxygenation, hemostasis.
‡Safety: E.g., Immune activation, off-target clotting, NO inhibition.

Table 4 shows the program metrics expected for Phase III, should it occur.

Table 4. FSHARP Phase III Metrics

	Phase III: IND Submission
	Year 5
Demos	End of Phase Demo: Month 59
Models	Large animal models of hemorrhage, hemorrhage + TBI, and hemorrhage + TIC
TA 1	• *In vivo* demonstration of no adverse effects • Additional IND-enabling studies as required
TA 2	• Demonstration of GMP manufacturing and scale suitable for clinical studies
FDA	IND Submission

1.4. GENERAL REQUIREMENTS

1.4.1. Proposing Teams

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

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

The Program Integrator/Manager shall serve as the primary point of contact to communicate with the DARPA 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.

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

1.4.2. Regulatory Strategy

Proposers must present a detailed plan for early and continued engagement with FDA to discuss the developing technologies and challenges. This engagement is necessary to meet the ultimate goal of IND submission, to inform and to improve the design of the milestone demonstrations, and to facilitate technological advancement and the eventual transition of the technology to clinical studies and, ultimately, field deployment.

1.4.3. ELSI Strategy

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

1.4.4. Informatics and Data Sharing

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

1.4.5. Transition and Commercialization Strategy

Proposers must present a detailed plan for transition of the technologies developed during the program for testing, validation, and product formulation to the defense community, as well as other stakeholder entities and industry. It is critical that the FSHARP products, including blood alternatives, manufacturing approaches, and stabilization approaches, be developed in a manner that positions them for further development and deployment by the end of the program with DoD transition partners identified and engaged throughout the course of the program. Engagement with IV&V partners in conjunction with DoD stakeholders will enhance the utility of these products for DoD use and enable rapid adoption by DoD components for advanced development activities. It is anticipated that FSHARP products will be relevant not only for defense, but also for public health as viable candidates for clinical translation, commercialization, and technology transfer for other high-impact applications. To further support transition and commercialization goals, performers may consider inclusion of qualified personnel to support these activities in order to increase a performer team's ability to move technology from the lab to a sustainable business that can provide new capabilities to the military. The ease of access to products afforded to the Government by proposer IP assertions will be part of evaluations of proposal contribution and relevance to the DARPA mission (see Section 5.1.2, Potential Contribution and Relevance to DARPA Mission).

1.4.6. Independent Verification and Validation (IV&V)

IV&V teams established by DARPA will help validate progress. The IV&V teams will consist of subject matter experts from Government, Federally Funded Research and Development Centers (FFRDCs), and/or other relevant domains. To assess progress toward achieving program metrics and milestones, performers must make their products available for third-party testing by IV&V teams over the course of the program. During these evaluations, IV&V teams will analyze products in preclinical models, which will include reconstitution and administration of products in accordance with performer protocols. Protocols must be written in a manner that enables reconstitution and administration by IV&V team personnel without assistance from performers. Proposals must budget and include plans for shipping products to IV&V partners.

To avoid potential conflicts of interest, performers for FSHARP will not be allowed to compete for an IV&V contract. DARPA is not soliciting proposals for IV&V under HR001121S0027. Government teams interested in participating in IV&V should NOT respond to this BAA, but rather indicate their interest in the FSHARP program via e-mail at FSHARP@darpa.mil for further details.

1.4.7. Deliverables

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

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

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

Technical progress reports: Performers are required to provide technical research updates in the form of a standardized slide presentation given to DARPA and discussed with the program management team via teleconference every 4 weeks. Length and detail levels are at the discretion of the Program Manager.

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

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

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

Final Program Report: When the final funding phase closes out, performer teams must provide a final report summarizing all research activities, outcomes, and innovations discovered during the program.

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

2. Award Information

2.1. GENERAL AWARD INFORMATION

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

The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this solicitation and to make awards without discussions with

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

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

Proposers looking for innovative, commercial-like contractual arrangements are encouraged to consider requesting Other Transactions. To understand the flexibility and options associated with Other Transactions, consult http://www.darpa.mil/work-with-us/contract-management#OtherTransactions.
In accordance with 10 U.S.C. § 2371b(f), the Government may award a follow-on production contract or Other Transaction (OT) for any OT awarded under this solicitation 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 solicitation, the Government expects that program goals as described herein may be met by proposed efforts for fundamental research and non-fundamental research. Some proposed research may present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Based on the anticipated type of proposer (e.g., university or industry) and the nature of the solicited work, the Government expects that some awards will include restrictions on the resultant research that will require the awardee to seek DARPA permission before publishing any information or results relative to the program.

Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to determine whether the proposed research shall be considered fundamental and to select the award instrument type. Appropriate language will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate. This language can be found at http://www.darpa.mil/work-with-us/additional-baa.
For certain research projects, it may be possible that although the research to be performed by a potential awardee is non-fundamental research, its proposed subawardee's effort may be fundamental research. It is also possible that the research performed by a potential awardee is fundamental research while its proposed subawardee's effort may be non-fundamental research. In all cases, it is the potential awardee's responsibility to explain in its proposal which proposed efforts are fundamental research and why the proposed efforts should be considered fundamental research.

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

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

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

FFRDCs

FFRDCs are subject to applicable direct competition limitations and cannot propose to this solicitation 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 non-disclosure 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 solicitation. 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 solicitation evaluation criteria and funding availability.

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

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

3.3. COST SHARING/MATCHING

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

4. Application and Submission Information

4.1. ADDRESS TO REQUEST APPLICATION PACKAGE

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

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

All submissions, including abstracts and proposals, must be written in English with type no smaller than 12-point font. Smaller fonts 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 BAA number (HR001121S0027), proposer organization, and submission title.

4.2.1. Proposal Abstract Format

Proposers are **strongly** encouraged to submit an abstract in advance of a proposal to minimize effort and reduce the potential expense of preparing an out-of-scope proposal. 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 **20** 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 **10** pages including all figures, tables, and charts.

The page limit does NOT include:

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

Abstracts must include the following components:

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

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

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

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

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

1. Describe and justify the experimental approach for each TA and for each Milestone Demonstration, including justification for all models and assays used to determine metric achievement. If a third complex presentation is proposed in addition to the required two presentations (i.e., hemorrhage + TBI

and hemorrhage + TIC), the abstract must describe the DoD relevance of this optional presentation.

2. Provide qualitative and quantitative metrics and milestones that will be used to measure progress against program goals.
3. Outline a plan for FDA engagement and pre-clinical IND trials for Phase III.
4. Outline a plan for technology transition for continued advanced development during the program and following completion of the program.

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

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

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

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

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

G. Resumes (do not count towards page limit)**:** Include (no more than 2) resumes of key team members, one of which must be from/for the Principal Investigator.

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

4.2.2. Full Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal.** All submissions must be written in English with type no smaller than 12-point font. A smaller font may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. **The maximum page count for Volume 1 is 25 pages.** The official transmittal letter and Statement of Work are not included in the page count. Volume I should include the following components:

NOTE: Non-conforming submissions that do not follow the instructions herein may be rejected without further review.

a. Volume I, Technical and Management Proposal

Section I. Administrative

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

1. BAA number (HR001121S0027);
2. Lead organization submitting proposal (prime contractor);
3. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
4. Proposer's reference number (if any);
5. Other team members (if applicable) and type of business for each;
6. Proposal title;
7. Technical point of contact (Program Manager or Principle Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction;

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

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

B. Official Transmittal Letter.

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

Section II. Executive Summary

A. Technical rationale, technical approach, and constructive plan for accomplishment of technical goals in support of innovative claims and deliverable creation. (In the full proposal, this section should be supplemented by a more detailed plan in Section III of the Technical and Management Proposal.)
B. Innovative claims for the proposed research. This section is the centerpiece of the proposal and should succinctly describe the uniqueness and benefits of the proposed approach relative to the current state-of-art alternate approaches.
C. Deliverables associated with the proposed research and the plans and capability to accomplish technology transition and commercialization. Include in this section all proprietary claims to the results, prototypes, intellectual property, or systems supporting and/or necessary for the use of the research, results, and/or prototype. If there are no proprietary claims, this should be stated. For forms to be completed regarding intellectual property, see SectionIV.B.3.h of this BAA. There will be no page limit for the listed forms.
D. General discussion of other research in this area.
E. A clearly defined organization chart for the program team which includes, as applicable: (1) the programmatic relationship of team member; (2) the unique capabilities of team members; (3) the task of responsibilities of team members; (4) the teaming strategy among the team members; and (5) the key personnel along with the amount of effort to be expended by each person during each year.

Section III. Detailed Proposal Information

A. Goals and Impact: Clearly describe what the team is trying to achieve, including the final deliverables, 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 and other similar efforts. This should also address mitigation of life-cycle and sustainment risks associated with transitioning intellectual property for U.S. military applications, if applicable. See also Section 4.2.3 of this BAA, "Intellectual Property."

B. Technical Plan: Provide a detailed technical approach enhancing and completing the Summary of Proposal. 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 high-risk, plan to achieve the program goal. Discuss mitigation of technical risk.

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

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

Description of Security Management architecture and/or approach for the proposed effort. Detail unique additional security requirements information system certification expertise for controlled unclassified information (CUI) or classified processing, OPSEC, program protection planning, test planning, transportation plans, work being performed at

different classification levels, and/or utilizing test equipment not approved at appropriate classification level (may not be applicable for fundamental research).

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

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

F. Statement of Work (SOW) NOT INCLUDED IN PAGE COUNT: The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. Each phase of the program should be separately defined. The task structure must be consistent with that in Section G (Schedule and Milestones) and Volume II summary of program costs by phase/TA/task. The Government encourages proposers to complete the editable MS Word SOW template (**Attachment 2**), and submit it in addition to Volume I and II of your proposal.

For each task/subtask, provide:

- A general description of the objective (for each defined task/activity);
- A detailed description of the approach to be taken to accomplish each defined task/activity;
- Identification of the primary organization responsible for task execution (prime organization, 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/activities; and
- Clearly identify any tasks/subtasks that will be completed (by the prime organization or a subcontractor) on-campus at a University, if applicable.

Note: It is recommended that the SOW should be developed so that each Phase of the program is separately defined.

NOTE: Do not include any proprietary information in the SOW.

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

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

Section III. Additional Information (Note: Does not count towards page limit)
Provide 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 (HR001121S0027).
2. Lead Organization Submitting proposal.
3. Type of organization, selected among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT."
4. Proposer's reference number (if any).
5. Other team members (if applicable) and type of business for each.
6. Proposal title.
7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available).
8. Administrative point of contact (Contracting Officer or Award Officer) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available).
9. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost-sharing contract – no fee, or other type of procurement contract (*specify*), cooperative agreement, or other transaction.
10. Place(s) of performance, including all subcontractors and consultants.
11. Period of performance.

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

NOTE: Non-conforming submissions that do not follow the instructions herein may be rejected without further review.

The Government requires that proposers use the provided MS Excel™ DARPA Standard Cost Proposal Spreadsheet in the development of their cost proposals. A customized cost proposal spreadsheet may be an attachment to this solicitation. If not, the spreadsheet can be found on the DARPA website at http://www.darpa.mil/work-with-us/contract-management (under "Resources" on the right-hand side of the webpage). All tabs and tables in the cost proposal spreadsheet should be developed in an editable format with calculation formulas intact to allow traceability of the cost proposal. This cost proposal spreadsheet should be used by the prime organization and all subcontractors. In addition to using the cost proposal spreadsheet, the cost proposal still must include all other items required in this announcement that are not covered by the editable spreadsheet. Subcontractor 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 solicitation. **Using the provided cost proposal spreadsheet will assist the Government in a rapid analysis of your proposed costs and, if your proposal is selected for a potential award, speed up the negotiation and award execution process**.

(1) Total program, per phase (Phase I (Base); Phase II (Option); and Phase III (Option)), and per task cost broken down by major cost items to include:
   i. **Direct labor** – provide an itemized breakout of all personnel, listed by name or TBD, with labor rate (or salary), labor hours (or percent effort), and labor category. All senior personnel must be identified by name.
   ii. **Materials and Supplies** – itemized list which includes description of material, quantity, unit price, and total price. If a material factor is used based on historical purchases, provide data to justify the rate.
   iii. **Equipment** – itemized list which includes description of equipment, unit price, quantity, and total price. Any equipment item with a unit price over $5,000 must include a vendor quote.

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

v. Travel – provide an itemized list of travel costs to include purpose of trips, departure and arrival destinations, projected airfare, rental car and per 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 one (1) DARPA program review meeting 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).

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 year, to include both pool and expense costs used to generate the rates).

(2) A summary of total program costs by phase I, II, and III and task.

(3) An itemization of Subcontracts. All subcontractor cost proposal documentation must be prepared at the same level of detail as that required of the prime. Subcontractor proposals should include Interdivisional Work Transfer Agreements (IWTA) or evidence of similar arrangements (an IWTA is an

agreement between multiple divisions of the same organization). The prime proposer is responsible for compiling and providing all subcontractor proposals for the Procuring Contracting Officer (PCO). The proposal must show how subcontractor costs are applied to each phase and task. If consultants are to be used, proposer must provide consultant agreement or other document that verifies the proposed loaded daily/hourly rate.

(4) An itemization of any information technology (IT) purchase (including a letter stating why the proposer cannot provide the requested resources from its own funding), as defined in FAR Part 2.101.
(5) A summary of projected funding requirements by month for all phases of the project.
(6) A summary of tasks that have animal or human use funding.
(7) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions that could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.
(8) Identification of pricing assumptions of which may require incorporation into the resulting award instrument (e.g., use of Government Furnished Property/Facilities/Information, access to Government Subject Matter Expert/s, etc.).
(9) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available).
(10) Proposers with a Government acceptable accounting system who are proposing a cost-type contract must submit the DCAA document approving the cost accounting system.

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

DARPA Embedded Entrepreneur Initiative (EEI)

Awardees pursuant to this solicitation may be eligible to participate in the DARPA Embedded Entrepreneur Initiative (EEI) during the award's period of performance. EEI is a limited scope program offered by DARPA, at DARPA's discretion, to a small subset of awardees. The goal of DARPA's EEI is to increase the likelihood that DARPA-funded technologies take root in the U.S. and provide new capabilities for national defense. EEI supports DARPA's mission "to make pivotal investments in breakthrough technologies and capabilities for national security" by accelerating the transition of innovations out of the lab and into new capabilities for the Department of Defense (DoD). EEI investment supports development of a robust and deliberate Go-to-Market strategy for selling technology to government and commercial markets and positions DARPA awardees to attract U.S. investment. The following is for informational and planning purposes only and does not constitute solicitation of proposals to the EEI.

There are three elements to DARPA's EEI: (1) A Senior Commercialization Advisor (SCA)

from DARPA who works with the Program Manager (PM) to examine the business case for the awardee's technology and uses commercial methodologies to identify steps toward achieving a successful transition of technology to the government and commercial markets; (2) Connections to potential industry and investor partners via EEI's Transition Working Groups; and (3) Additional funding for awardees to hire an embedded entrepreneur to achieve specific commercialization milestones and work towards the delivery of a robust transition plan for both defense and commercial markets. This embedded entrepreneur's qualifications should include business experience within the target industries of interest, experience in commercializing early stage technology, and the ability to communicate and interact with technical and non-technical stakeholders. Funding for EEI is typically no more than $250,000 per awardee over the duration of the award. An awardee may apportion EEI funding to hire more than one embedded entrepreneur, if achieving the milestones requires different expertise that can be obtained without exceeding the awardee's total EEI funding. The EEI effort is intended to be conducted concurrent with the research program without extending the period of performance.

EEI Application Process:
After receiving an award under the solicitation, awardees interested in being considered for EEI should notify their DARPA PM during the period of performance. Timing of such notification should ideally allow sufficient time for DARPA and the awardee to review the awardee's initial transition plan, identify commercial milestones to deliver under EEI, modify the award, and conduct the work required to achieve such milestones within the original award period of performance. These steps may take 18-24 months to complete, depending on the technology. If the DARPA PM determines that EEI could be of benefit to transition the technology to product(s) the Government needs, the PM will refer the performer to DARPA's Commercial Strategy team.

DARPA's Commercial Strategy team will then contact the performer, assess fitness for EEI, and in consultation with the DARPA technical office, determine whether to invite the performer to participate in the EEI. Factors that are considered in determining fitness for EEI include DoD/Government need for the technology; competitive approaches to enable a similar capability or product; risks and impact of the Government's being unable to access the technology from a sustainable source; Government and commercial markets for the technology; cost and affordability; manufacturability and scalability; supply chain requirements and barriers; regulatory requirements and timelines; Intellectual Property and Government Use Rights, and available funding.

Invitation to participate in EEI is at the sole discretion of DARPA and subject to program balance and the availability of funding. EEI participants' awards may be subsequently modified bilaterally to amend the Statement of Work to add negotiated EEI tasks, provide funding, and specify a milestone schedule that will include measurable steps necessary to build, refine, and execute a Go-to-Market strategy aimed at delivering new capabilities for national defense. Milestone examples are in the attachment to this solicitation.

Awardees under this solicitation are eligible to be considered for participation in EEI, but selection for award under this solicitation does not imply or guarantee participation in EEI.

Subawardee Proposals

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

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

Other Transaction Requests

All proposers requesting an OT must include a detailed list of milestones for each phase of the program (I, 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.

Controlled Unclassified Information (CUI)
For unclassified proposals containing CUI, applicants will ensure personnel and information systems processing CUI security requirements are in place.

If an unclassified submission contains CUI or the suspicion of such, as defined by Executive Order 13556 and 32 C.F.R. Part 2002, the information must be appropriately and conspicuously marked CUI in accordance with DoD Instruction (DoDI) 5200.48. Identification of what is CUI about this DARPA program will be detailed in a DARPA CUI Guide and will be provided as an attachment to the BAA or may be provided at a later date.

Unclassified submissions containing CUI may be submitted via DARPA's BAA Website (https://baa.darpa.mil) in accordance with Section 4.2.4 of this BAA.

Proposers submitting proposals involving the pursuit and protection of DARPA information designated as CUI must have, or be able to acquire prior to contract award, an information system authorized to process CUI information IAW NIST SP 800-171 and DoDI 8582.01.

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) and DoDI 8582.01 that are in effect at the time the solicitation 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.

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

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

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 (Pre-award Survey of Prospective Contractor (Accounting System)). For more information on CAS compliance, see http://www.dcaa.mil/cas.html. To facilitate this process, proposers should complete the SF 1408 found at http://www.gsa.gov/portal/forms/download/115778 and submit the completed form with the proposal.

Small Business Subcontracting Plan

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

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

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

Intellectual Property

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

For Procurement Contracts

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

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

Furnished With Restrictions				
(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)

For All Non-Procurement Contracts

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

System for Award Management (SAM) and Universal Identifier Requirements

All proposers must be registered in SAM unless exempt per FAR 4.1102. FAR 52.204-7, "System for Award Management" and FAR 52.204-13, "System for Award Management Maintenance" are incorporated into this solicitation. 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 HR0011210S0027. Submissions may not be sent by fax or e-mail; any so sent will be disregarded.

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

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

Abstracts and Full Proposals sent in response to HR001121S0027 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 the submission process be started as early as possible.

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

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

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

For Cooperative Agreements Only:

Proposers requesting cooperative agreements must submit proposals through one of the following methods: (1) electronic upload per the instructions at https://www.grants.gov/applicants/apply-for-grants.html (DARPA-preferred); or (2) hard-copy mailed directly to DARPA. If proposers intend to use Grants.gov as their means of submission, then they must submit their entire proposal through Grants.gov; applications cannot be submitted in part to Grants.gov and in part as a hard-copy. Proposers using Grants.gov do not submit hard-copy proposals in addition to the Grants.gov electronic submission.
Submissions: In addition to the volumes and corresponding attachments requested elsewhere in this solicitation, proposers must also submit the three forms listed below.
Form 1: SF 424 Research and Related (R&R) Application for Federal Assistance, available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf. *This form must be completed and submitted.*
To evaluate compliance with Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et.seq.), the Department of Defense (DoD) is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering or mathematics disciplines. In addition, the National Defense Authorization Act (NDAA) for FY 2019, Section 1286, directs the Secretary of Defense to protect intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security and limit undue influence, including foreign talent programs by countries that desire to exploit United States' technology within the DoD research, science and technology, and innovation enterprise. This requirement is necessary for all research and research-related educational activities. The DoD is using the two forms below to collect the necessary information to satisfy these requirements. Detailed instructions for each form are available on Grants.gov.
Form 2: Research and Related Senior/Key Person Profile (Expanded), available on the Grants.gov website at

https://apply07.grants.gov/apply/forms/sample/RR_KeyPersonExpanded_2_0-V2.0.pdf. *This form must be completed and submitted.*
The Research and Related Senior/Key Person Profile (Expanded) form will be used to collect the following information for all senior/key personnel, including Project Director/Principal Investigator and Co-Project Director/Co-Principal Investigator, whether or not the individuals' efforts under the project are funded by the DoD:

- Degree Type and Degree Year.
- Current and Pending Support, including:
    - A list of all current projects the individual is working on, in addition to any future support the individual has applied to receive, regardless of the source.
    - Title and objectives of the other research projects.
    - The percentage per year to be devoted to the other projects.
    - The total amount of support the individual is receiving in connection to each of the other research projects or will receive if other proposals are awarded.
    - Name and address of the agencies and/or other parties supporting the other research projects
    - Period of performance for the other research projects.

Additional senior/key persons can be added by selecting the "Next Person" button at the bottom of the form. Note that, although applications without this information completed may pass Grants.gov edit checks, if DARPA receives an application without the required information, DARPA may determine that the application is incomplete and may cause your submission to be rejected and eliminated from further review and consideration under the solicitation. DARPA reserves the right to request further details from the applicant before making a final determination on funding the effort.
Form 3: Research and Related Personal Data, available on the Grants.gov website at https://apply07.grants.gov/apply/forms/sample/RR_PersonalData_1_2-V1.2.pdf. *Each applicant must complete the name field of this form, however, provision of the demographic information is voluntary. Regardless of whether the demographic fields are completed or not, this form must be submitted with at least the applicant's name completed.*

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

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

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

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

4.3. FUNDING RESTRICTIONS

Not applicable.

4.4. OTHER SUBMISSION INFORMATION

DARPA will post a consolidated Frequently Asked Questions (FAQ) document. To access the posting go to http://www.darpa.mil/work-with-us/opportunities. A link to the FAQ will appear under the HR001121S0027 summary. Submit your question(s) via e-mail to FSHARP@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. Proposed animal models are relevant and strong justification for their use is provided. The proposal identifies major technical risks, and planned mitigation efforts are clearly defined and feasible. The proposer's prior experience in similar efforts must clearly demonstrate an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule.

5.1.2. Potential Contribution and Relevance to the DARPA Mission

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

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

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 an efficient time frame that accurately accounts for the anticipated workload. The timeline for achieving major milestones is aggressive, but rationally supported with a clear description of the requirements and risks. The proposed schedule identifies and mitigates any potential schedule risk. The proposed team has the expertise to manage the schedule.

5.2. REVIEW OF PROPOSALS

Review Process

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

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

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

Handling of Source Selection Information

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

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

Federal Awardee Performance and Integrity Information (FAPIIS)

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

6. Award Administration Information

6.1. SUBMISSION STATUS NOTIFICATIONS

Proposal Abstracts and Full Proposals submitted in response to HR001121S0027 will be evaluated as they are received. DARPA will respond as described below. These official notifications will be sent via e-mail to the Technical POC and/or Administrative POC identified on the submission coversheet.

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 a proposal 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.

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

There will be a program kickoff meeting and semi-annual program-wide meetings either held virtually or in the Washington, D.C. metropolitan area, that all key participants are required to attend. Proposers shall include within the content of their proposal details and costs of any travel or meetings they deem to be necessary throughout the course of the effort. Performers should anticipate monthly meetings by teleconference, in-person program reviews, and, provided no travel restrictions, at least annual site visits by DARPA Program Manager and/or Government team.

6.2.1. Solicitation Provisions and Award Clauses, Terms and Conditions

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

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

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

6.2.3. Representations and Certifications

In accordance with FAR 4.1102 and 4.1201, proposers requesting a procurement contract must complete electronic annual representations and certifications at https://www.sam.gov/.
In addition, all proposers are required to submit for all award instrument types supplementary DARPA-specific representations and certifications at the time of proposal submission. See http://www.darpa.mil/work-with-us/reps-certs for further information on required representation and certification depending on your requested award instrument.

6.2.4. Terms and Conditions

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

6.3. REPORTING

See Section 1.4.7 for reporting information/requirements.

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:
FSHARP@darpa.mil
DARPA/BTO
ATTN: HR001121S0027
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 FSHARP program on June 2, 2021, via webcast. The purpose is to provide potential proposers with information on the FSHARP program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and encourage team formation.

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

An online registration form and various other meeting details can be found at the registration website, https://events.sa-meetings.com/FSHARPProposersDay.

Proposers Day Point of Contact:
DARPA-SN-21-23@darpa.mil
ATTN: DARPA-SN-21-23

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 HR001121S0027. 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 **HR001121S0027** included on your Cost Proposal cover sheet?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]
   If reply is "No", please explain:

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

   If reply is "No", please explain:

3. Does your cost proposal (detailed cost buildup #3 above in item 2) show a breakdown of the major cost items listed below:
   Direct Labor (Labor Categories, Hours, Rates)
   f○ **YES** ○ **NO** **Appears on Page(s)** [Type text]

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

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

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

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

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

   If reply is "No", please explain:

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

   If reply is "No", please explain:

5. Does your cost proposal include a complete itemized list of <u>all</u> 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: