Broad Agency Announcement

Reimagining Protein Manufacturing (RPM)

BIOLOGICAL TECHNOLOGIES OFFICE

HR001121S0038

August 23, 2021

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- **Federal Agency Name –** Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office (BTO)
- **Funding Opportunity Title – Reimagining Protein Manufacturing** (RPM)
- **Announcement Type –** Initial Announcement
- **Funding Opportunity Number –** HR001121S0038
- **North American Industry Classification System (NAICS) –** 541714
- **Catalog of Federal Domestic Assistance Numbers (CFDA) –** 12.910 Research and Technology Development
- **Dates**
  - Posting Date: **August 23, 2021**
  - Proposal Abstract Due Date and Time: **September 23, 2021, 4:00 PM ET**
  - Full Proposal Due Date and Time: **November 16, 2021, 4:00 PM ET**
  - BAA Closing Date: **November 16, 2021**
  - Proposers' Day: **August 26, 2021**

  https://sam.gov/opp/e552cf52e2654fe6bf9d9c17e965bb3b/view
- **Concise description of the funding opportunity –** The Reimagining Protein Manufacturing (RPM) program aims to ensure timely Department of Defense (DoD) access to critical medical countermeasures (MCMs) by establishing the foundational technologies needed for fully distributed, on-demand manufacturing of protein-based MCMs and associated raw materials. To achieve this goal, RPM will develop technologies to enable immediate synthesis (lead time approximately 24 hours) of bioactive protein MCMs and raw material production enzymes at a yield corresponding to ≥ 500 doses per week. This technology will allow the DoD to rapidly secure access to both therapeutic proteins and enzymes needed for nucleic acid-based MCM synthesis, and reduce reliance on complex supply chains.
- **Anticipated individual awards –** Multiple awards are anticipated.
- **Types of instruments that may be awarded –** Procurement contract, grant, 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 C.F.R. § 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.

1.1. PROGRAM OVERVIEW

DoD access to critical proteins is currently limited by the slow response times of protein production methods. State-of-the-art (SOA) protein-based MCM production relies on massive centralized infrastructure and complex pipelines that require lengthy cellular engineering, sufficient growth of cells for production, and intensive purification and quality control. Current response times are several months for production alone, with additional time needed for dispersing MCMs to vulnerable populations. Distributed manufacturing paradigms may transform these timelines into those relevant to DoD response, especially in denied, degraded, or disrupted operational environments.

Other DARPA programs have invested in distributed manufacturing of pharmaceuticals and nucleic acids. Here, RPM focuses on protein production (which is generally complex) and bioactivity (which relies on correct folding *and* post-translational modifications [PTMs]). Establishing a distributed protein production platform involves two broad types of challenges: engineering and biochemistry. RPM seeks to overcome difficult upstream biochemistry challenges associated with protein production (i.e., RPM will not develop a fully automated system or device for production).

To significantly advance the DoD's ability to rapidly manufacture proteins in a fully distributed setting, RPM will address the following biochemistry challenges: (1) achieving relevant quantities of MCM (≥ 500 doses per week); (2) ensuring protein production lead time within ~24 hours of receiving DNA/RNA template (including reagent generation and reaction set-up); and (3) producing fully bioactive proteins with complex folding and controlled PTMs.

1.2. TECHNICAL APPROACH AND STRUCTURE

1.2.1. Technical Areas

The RPM program will develop technologies to enable high-yield synthesis of protein MCMs with short lead times and correct PTMs. To this end, the RPM program is focused on two technical areas:

- Technical Area 1 (TA1): Production Yield and Time. Protein synthesis technologies for near-immediate synthesis of proteins at high yields.

- Technical Area 2 (TA2): Post-Translational Modifications. Protein production approaches to add PTMs in a controlled manner to ensure the final product is bioactive and of high quality.

Protein quality characteristics will be evaluated throughout the program to ensure the developed technologies produce a high-quality product. Both technical areas must be developed and integrated concurrently over the duration of the effort**. Proposals that fail to address both technical areas will be deemed non-conforming and may be rejected without further review.**

TA1: Production Yield and Time.

On-demand synthesis modalities must rapidly achieve relatively high yields to be broadly adapted for distributed protein manufacturing devices. Today's commercial protein production platforms require months to years for stable cell line creation, followed by weeks to months for protein production. This paradigm is not conducive to on-demand distributed protein production.

TA1 seeks to create new protein production paradigms that can operate with immediately (~24 hours) available reaction components and supplies. Performers may pursue cell-based, cell-free, or other approaches for protein synthesis. However, by the end of the program, the established method must be capable of initiating protein synthesis within approximately 24 hours of obtaining DNA or RNA template (i.e., the time needed to procure template sequence does not count toward the 24-hour lead timeline).

TA1 also seeks to synthesize at least 500 doses per week of critical protein-based MCMs, drugs, or reagents. RPM will produce at least five classes of proteins, including (but not limited to) subunit or conjugate vaccines, monoclonal antibodies, clotting factors, raw material enzymes for nucleic acid production, and other therapeutic proteins. Yield metrics vary depending on the protein – see details under TA1 metrics (Section 1.3).

The novel protein production approach must meet the following specifications:

- Production Run Initiation: Protein synthesis methods must be able to begin operation within 24 hours of receiving DNA or RNA sequence template.
- Production Run Length: Increased yields can be achieved by operating a single production run for a week or by a series of shorter or continuous runs. Methods that produce initial doses within days are preferred.
- Reactor Volume: The chosen synthesis approach must achieve the yield metrics with a reactor volume < 10 L.
- Starting Materials:
    - Footprint: Given the anticipated downstream, distributed applications of this technology, it is important that the starting material quantity and footprint do not create logistical burden (i.e., should not exceed an approximately 4-ft^3 pallet in size).
    - Product Specificity: Technologies where the same starting materials can produce all classes of protein are preferred. However, approaches in which varied starting materials are used for different classes of protein are acceptable (e.g., reagent/cell line A is used for monoclonal antibodies while reagent/cell line B is used for subunit vaccines) as long as the rapid lead time is maintained.

- Reproducibility: Starting materials should be defined and well-characterized to ensure a reproducible protein production process.

Throughout the program, performers will utilize a variety of approaches to increase protein synthesis yield while decreasing the time for production. Some of these approaches may include, but are not limited to:

1) Optimizing reaction conditions or reaction vessels.
2) Engineering the source of cell lysate (if cell-free).
3) Modifying the host organism (if cell-based).
4) Engineering the RNA or DNA encoding the protein of interest.
5) Utilizing a stable integration site (landing pad) for cell-line stabilization (if cell-based).
6) Using non-model/non-traditional organisms for protein synthesis.

Proposers must provide the following information in the proposal:

- Approaches to increase yield;
- Initial lead time to production and a plan to reduce lead time to approximately 24 hours;
- Initial production run time and a plan for reduced run time not to exceed 1 week;
- Reagents required for protein production (include reagent source information);
- Anticipated footprint of protein production starting materials (e.g., cell lysates and excipients; final footprint should not exceed volume of a 4-ft^3 pallet);
- Details of the reaction vessel (e.g., volume, batch vs. continuous, monitoring capabilities, etc.);
- Host used for protein production (if cell-based);
- Source of cell lysate (if cell-free; e.g., CHO, *E. coli*, wheat germ, etc.);
- Methods to characterize starting materials to ensure reproducibility;
- Approximate reactor volume needed to create appropriate cell lysates (if cell-free; reactor volumes must not exceed 300 L);
- Methods for protein purification; and
- Methods for maintaining and assuring sterility during production.

TA1 metrics (Section 1.3) will increase in difficulty and complexity over the course of the RPM program. To prove technical progress, performers will complete capability demonstrations at roughly 12-month intervals. Performers will send purified material from the production reaction to a government-provided Independent Verification & Validation (IV&V) team for downstream analysis. To ensure reproducibility of the performer approach, the IV&V team will also produce the target protein from performer-supplied starting material. The IV&V team will compare and contrast IV&V- and performer-produced protein to assess transferability of the protein production process.

TA2: Post-Translational Modifications.

Correct protein function typically relies on the presence of PTMs decorating the structure. PTMs pose a challenge to protein production because there are multiple types and variations of modifications, and their addition involves non-template driven cellular processes. Even though PTM importance is known, SOA protein production methods have not been able to add PTMs in a controlled, consistent manner. Therefore, current manufacturing approaches result in MCMs with a distribution of modifications that must be extensively characterized post-production before subsequent product use. The SOA method for protein modification hinders rapid manufacturing – every material production lot must use tightly controlled reaction conditions to ensure similar distribution of modifications lot-to-lot. Often, lot-to-lot similarity is not achieved, resulting in failed production runs, lost time, and increased cost. For RPM, on-demand synthesis modalities must achieve controlled addition of PTMs to ensure simplified downstream purification and analysis, and bioactivity of the resulting protein product.

TA2 seeks to produce proteins with controlled addition of PTMs that improve protein quality characteristics. PTMs of interest include, but are not limited to, N- and O-linked glycosylation, γ-carboxylation, β-hydroxylation, sulfation, and phosphorylation. For N-linked glycosylation specifically, approaches must be capable of adding both simple glycans (e.g., terminal mannose or galactose) and complex glycans (e.g., terminal sialic acid or branched glycans). The PTMs can occur either during (preferred) or after protein synthesis reactions. Technologies developed under this TA should represent an advancement of the SOA with respect to the addition of PTMs to protein MCMs. Given this, it is anticipated that approaches will be capable of reproducibly adding the desired PTMs, with downstream analysis showing low batch-to-batch variance.

Performers must be able to simultaneously achieve the time and yield metrics laid out in TA1 and PTM metrics laid out in TA2.

Throughout the program, performers will utilize a series of approaches to facilitate the addition of PTMs. Some of these approaches may include, but are not limited to:

1) Utilizing endogenous or exogenous biosynthetic machinery to facilitate addition of PTMs.
2) Genome mining to identify new biosynthetic pathways for addition of new/complex modifications.
3) Engineering of host cell lines.
4) Chemical modification.
5) Using engineered non-model/non-traditional organisms.

Proposers must describe the following in the proposal:

- Types of PTMs planned;
- Approach for adding each type of PTM, including whether endogenous or exogenous machinery will be used;
- Rational design approach for enhancing protein characteristics; and

- Analytics capabilities for measuring PTMs and assessing characteristics of the modified protein.

TA2 metrics (Section 1.3) will increase in difficulty and complexity over the course of the RPM program. To prove technical progress, performers will complete capability demonstrations at roughly 12-month intervals. Performers will send purified content from the production reaction to an IV&V team for downstream analysis. To ensure the reproducibility of the performer approaches, the IV&V team will also produce the target protein using performer-supplied starting material. The IV&V team will compare and contrast the IV&V and performer-produced protein to assess transferability of the post-translational protein modification process.

Protein Quality Characteristics.

RPM aims to develop technologies to produce therapeutic proteins and enzymes needed for nucleic acid-based MCM synthesis on a rapid timescale and at high yields. If successful, RPM will result in novel protein production technologies not previously deployed. It should be noted that the ultimate use case for the novel protein product technologies is the production of MCMs intended for use in human patients. As such, it is critical that quality proteins are produced throughout the program; RPM will assess protein quality characteristics as part of each capability demonstration. The quality characteristics will be selected in accordance with current release criteria (based on current manufacturing practices) and will include (but are not limited to) potency, purity, target binding/activity, glycosylation profile, composition, bioburden, and endotoxin concentrations (see Section 1.3 for details).

1.2.2. Program Target Proteins

Selected protein targets must include DoD-relevant proteins from each of the five listed classes, including (but not limited to) vaccine subunits, monoclonal antibodies, clotting factors, raw material nucleic acid production enzymes (e.g., T7 RNA polymerase or MutS), and other therapeutic proteins (e.g., G-CSF).

During Phase 1, performers will choose DoD-relevant proteins to produce during the annual capability demonstrations. Performers must select one protein > 5 kDa for year 1 and 2 proteins > 30 kDa for year 2. Each protein must represent a different class (i.e., three classes of proteins will be produced during Phase 1). Demonstrated PTMs must include O-linked glycosylation during year 1 and both N-linked and O-linked glycosylation during year 2 – if different modifications are proposed, a rationale must be provided. The proposal must list the selected proteins.

During Phase 2, performers will produce DARPA-selected proteins. DARPA will select complex proteins that contain N- and O-linked glycosylation and two additional types of PTMs. At least one protein selected for the capability demonstrations during years 3 and 4 will be > 150 kDa. It should be noted that not all therapeutic proteins require glycosylation, but RPM performers will be required to demonstrate the ability to glycosylate proteins.

1.2.3. Program Structure

The RPM program will be accomplished over two sequential Phases of increasing technical complexity (see Figure 1). Phases 1 and 2 are 26 and 24 months long, respectively. **Progression to Phase 2 depends on funding availability and performance towards Phase 1-specific goals in capability demonstrations 1 and 2 as described below and outlined in Tables 2, 3, 5, and 6.**

Phase 1 (Base, 26 months): Proof of Concept

During the 26-month Phase 1, performers will demonstrate a proof-of-concept technology for immediate synthesis (lead time < 5 days) of proteins from different classes (vaccine subunits, monoclonal antibodies, clotting factors, raw material enzymes, and other therapeutic proteins). During Phase 1 of the program, performers must choose proteins from at least three different classes to demonstrate the broad applicability of the proposed technology. Performers must select one protein > 5 kDa for year 1 and 2 proteins for year 2 of which 1 is >30kDa. The proteins must be produced at high yields (TA1) and with the appropriate PTMs (TA2).

Goals of Phase 1 (metrics defined in Section 1.3):

- Demonstrate protein synthesis on a small scale (> 1 mL)
- Demonstrate fast protein synthesis
- Show that high yield of different classes of proteins can be achieved
- Demonstrate that PTMs of the protein compare to SOA
- Demonstrate protein quality characteristics are equivalent to SOA by multiple metrics (e.g., potency, purity, target binding/activity, glycosylation profile, composition, bioburden, and endotoxin concentrations)

Phase 2 (Option, 24 months): Prototype

During the 24-month Phase 2, performers will demonstrate a prototype technology for immediate, high-yield protein synthesis (lead time under 24 hours) of complex proteins from all five classes with PTMs required for bioactivity. At least one protein selected for the capability demonstrations during years 3 and 4 will be > 150 kDa.

Goals of Phase 2 (metrics defined in Section 1.3):

- Demonstrate protein synthesis at scale (< 10 L)
- Demonstrate that immediate protein synthesis can be achieved (lead time ~ 24 hours)
- Show that high yield production of complex proteins can be achieved
- Demonstrate correct PTM of the produced protein
- Demonstrate produced proteins are improved over SOA by measuring protein quality characteristics (e.g., potency, purity, target binding/activity, glycosylation profile, composition, bioburden, and endotoxins concentrations)

Pre-Program	Phase I - Proof of Concept 26 months								Phase II - Prototype 24 months									
FY21	FY22				FY23				FY24				FY25				FY26	
Q2 Q3 Q4	Q1 Q2 Q3 Q4				Q1 Q2 Q3 Q4				Q1 Q2 Q3 Q4				Q1 Q2 Q3 Q4				Q1 Q2	
Timeline	Capability Demonstration 1 11 months				Capability Demonstration 2 22 months				Capability Demonstration 3 38 months				Capability Demonstration 4 48 months					
TA1 Metrics for Capability Demonstration	Produce: • 1 performer-selected protein[1] • > 5 kDa • Reactor > 1mL • Purity > 80% • Lead time < 14 days • Yield see table 3				Produce: • 2 performer-selected proteins[1] • > 30 kDa • Reactor > 1mL • Purity > 85% • Lead time < 5 days • Yield see table 3				Produce: • 3 program-selected proteins[1] • > 150 kDa[2] • Reactor <10L • Purity > 90% • Lead time < 3-5 days • Yield see table 3				Produce: • 3 program-selected proteins[1] • > 150 kDa[2] • Reactor < 10L • Purity > 95% • Lead time ~24 hours • Yield see table 3					
TA2 Metrics for Capability Demonstration	Protein modifications • O-linked Glycans Protein Quality Characteristics • Equivalent to relevant SOA metric[3]				Protein modifications • O-linked & N-linked glycans • > 1 site (same or different modification) Protein Quality Characteristics • Equivalent to relevant SOA metric[3]				Protein modifications • O-linked & N-linked glycans • > 2 sites (same or different modification) Protein Quality Characteristics • Better than relevant SOA metric[3]				Protein modifications • O-linked & N-linked glycans • 2 additional types of PTM at > 3 sites Protein Quality Characteristics • Better than relevant SOA metric[3]					
IV&V	Function, stability, and composition of the proteins produced during each capability demonstration will be assessed through a series of field recognized analytical techniques																	
	Performance by the end of 50 months: **Production at a rate of ≥ 500 doses/week**																	

[1] Proteins will be chosen from five classes (vaccine subunits, monoclonal antibodies, clotting factors, raw material nucleic acid production enzymes, and other therapeutic proteins) – each chosen protein must come from a different class
[2] At least one protein selected for the capability demonstrations 3 and 4 will be > 150 kDa
[3] See Table 6

Figure 1. Program Structure and General Overview

1.2.4. Capability Demonstrations

During the 50-month program, RPM performers will complete a series of four capability demonstrations at months 11, 22, 38, and 48. During the capability demonstrations and throughout the RPM program, performers will synthesize a variety of DoD-relevant proteins from five classes (vaccine subunits, monoclonal antibodies, clotting factors, raw material enzymes, and other therapeutic proteins). For capability demonstrations 1 and 2 at months 11 and 22, respectively, performers will be challenged to synthesize proteins of their choice. Performers must select one protein > 5 kDa for capability demonstration 1 and two proteins > 30 kDa for capability demonstration 2. All proteins must be chosen from a different class. To demonstrate flexibility of the platform, DARPA will select DoD-relevant proteins for capability demonstrations 3 and 4 at months 38 and 48, respectively.

Specific metrics associated with each Technical Area in the capability demonstrations are discussed below in Section 1.3 and Tables 2, 3, 5, and 6. A government-provided IV&V team will conduct a series of field-recognized analytical techniques to evaluate the purity (e.g., assessment of aggregation, fragments, % dimers, etc.), functionality, efficacy, and composition of the purified proteins produced during each capability demonstration. The characteristics of the produced proteins will be demonstrated in both Phases through *in vivo* efficacy studies and quality control assays for metrics such as potency, purity, target binding/activity, glycosylation profile, composition, bioburden, and endotoxin concentrations. Chosen MCM targets should be not only DoD-relevant but should also have defined assays for assessing efficacy (in vivo and/or in vitro); it is outside the scope of RPM to develop new efficacy assays. If the product is a raw material production enzyme and not for direct therapeutic use, activity will be demonstrated through downstream production capability or by measuring enzymatic activity. To ensure the reproducibility of the performer approaches, the IV&V team will use the respective performer's process to produce the proteins selected for the capability demonstrations. The IV&V team will

compare and contrast the IV&V and performer-produced proteins to assess transferability of the production process.

1.3. PROGRAM METRICS

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 below, proposers should note that the Government has identified these goals with the intention of bounding the scope of effort while affording maximum flexibility, creativity, and innovation of 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.

TA1 Metrics and Objectives

The overall program goals for TA1 are listed in Table 1. Performers will conduct a series of capability demonstrations throughout the program to ensure program goals are being met. TA1 metrics for each capability demonstration are listed in Table 2. Yield metrics will vary by protein class as the protein needed per dose varies dramatically for each MCM (see Table 3). Given the varied quantity per dose of each MCM, some variation in quantity metrics is anticipated depending on the chosen protein. Proposals must include relevant yield metrics for each performer-proposed protein to be produced in Phase 1. Should a performer choose a protein for which the metrics laid out in Table 3 are either inappropriate or vary greatly from those listed, the performer should propose an appropriate metric and rationale.

Table 1. TA1 Overall Program Goals

Protein classes	Ability to synthesize five classes of protein-based molecules including vaccine subunits, monoclonal antibodies, clotting factors, raw material enzymes, and other therapeutic proteins
Protein size	> 150 kDa
Reactor size	< 10 L
Purity	> 95%
Yield	≥ 500 doses on demand per week
Lead time to production	Start producing protein within 24 hours after obtaining DNA or RNA template for production

Table 2. TA1 metrics for each capability demonstration

Metric	**11 months**	**22 months**	**38 months**	**48 months**
Number of proteins	1 performer-selected proteins	2 performer-selected proteins	3 DARPA-selected proteins	3 DARPA-selected proteins
Protein size	> 5 kDa	> 30 kDa	> 150 kDa*	> 150kDa*
Reactor size	> 1 mL	> 1 mL	< 10 L	< 10 L
Purity	> 80%	> 85%	> 90%	> 95%
Lead time	< 14 days	< 5 days	3-5 days	~24 hours

*During capability demonstrations 3 & 4, performers will be required to produce at least one protein > 150 kDa.

Table 3. TA1 yield metrics by program Phase*

Product Type	**11 months**	**22 months**	**38 months**	**48 months**
Antibodies	3 grams (g)/week (10 doses/week)	15 g/week (50 doses/week)	75 g/week (250 doses/week)	150 g/week (500 doses/week)
Subunit vaccine	2 mg/week (100 doses/week)	11 mg/week (500 doses/week)	55 mg/week (2500 doses/week)	110 mg/week (5000 doses/week)
Production enzymes	0.1 g/week	0.5 g/week	2.5 g/week	5 g/week
Clotting factors	50 mg/week (10 doses/week)	250 mg/week (50 doses/week)	1250 mg/week (250 doses/week)	2500 mg/week (500 doses/week)
Therapeutic proteins (e.g., scFv, nanobodies, GCSF)	Performer-determined metric that aligns with above prescribed metrics	Performer-determined metric that aligns with above prescribed metrics	Performer-determined metric that aligns with above prescribed metrics	Performer-determined metric that aligns with above prescribed metrics

*Proposed doses are approximate and are listed as broadly as possible – proposals should include appropriate quantity (grams of material) for the relevant proposed MCM dose. Some variation in quantity metrics is anticipated depending on the chosen protein.

TA2 Metrics and Objectives

The overall program goals for TA2 are described in Table 4. Performers will be evaluated and monitored over the duration of the program through a series of capability demonstrations to ensure program goals are being met. TA2 metrics for each capability demonstration are listed in Table 5. RPM performers will be required to modify proteins with N-linked and O-linked glycans. Proposals should list two additional types of PTMs that the proposed approach can achieve and the rationale for the selection. Approaches must be capable of reproducibly adding

the desired PTMs, and downstream analysis must be performed (at performer site and/or IV&V site) to show low batch-to-batch variance.

It is anticipated that the controlled addition of PTMs will increase certain quality characteristics associated with the resulting protein product. For example, reproducible glycosylation with increased presence of certain glycans may have an effect not only on aggregation but also on the *in vivo* half-life of a protein MCM. Therefore, as part of Phase 2, RPM performers will need to demonstrate the ability to improve protein characteristics typically associated with PTMs. These characteristics may be drawn from the suggested quality characteristics in Table 6, or different characteristics may be proposed with their appropriate metrics.

Table 4. TA2 Overall Program Goals

Post-translational modification	Ability to perform N- and O-linked glycosylation, and 2 other types of PTMs such as γ-carboxylation, β-hydroxylation, sulfation, and phosphorylation
Number of sites	Perform PTMs at > 3 sites
Protein quality characteristics (Table 6)	Better than relevant SOA metric

Table 5. TA2 metrics for each capability demonstration

Metric	**11 months**	**22 months**	**38 months**	**48 months**
Glycans	O-linked glycans	N- and O-linked glycans	N- and O-linked complex glycans	N- and O-linked complex glycans
Other types	-	-	-	2 additional types
Number of sites	-	> 1 site	-	> 3 sites
Protein quality characteristics (Table 6)	Equivalent to relevant SOA metric	Equivalent to relevant SOA metric	Better than relevant SOA metric	Better than relevant SOA metric

Protein Quality Control Metrics and Objectives

To ensure the quality of products, performers must show SOA equivalence to all characteristics listed in Table 6 during the capability demonstrations (or other relevant proposed characteristics if rationale is provided for why Table 6 metrics do not apply). Table 6 includes example metrics for a standard release assay – however, these metrics may deviate depending on the specific product. Therefore, for each proposed protein to be produced in Phase 1, proposals should include a discussion of the quality attributes that are most relevant. Proposals must specify the SOA protein characteristic metric that will be used for SOA comparison and the rationale for the metric selection. Final quality attributes can be discussed in consultation with the IV&V team (arranged by DARPA) and will be ultimately measured by the IV&V team.

Table 6. Protein Quality Characteristics

Protein Quality Characteristic	**Example Quantitative Metric**
Composition	> 95% target product
Purity	< 5% dimers, aggregates, fragments
Target binding/activity	50-150% relative potency
Glycosylation profile	< 10% variance between batches
Potency/*in vivo* efficacy	Proposer defined efficacy metric*
Bioburden	0 CFU/mL
Endotoxin	< 0.5 EU/mL

*Given the variation in SOA efficacy for different MCMs, proposals should include appropriate efficacy metric

Performers must show SOA equivalence to appropriate metrics during capability demonstrations. During capability demonstrations 3 and 4, performers must select at least one characteristic upon which to improve. While the goal of RPM is to improve the quality characteristics during Phase 2 through controlled PTMs, other metrics based on TA1 technologies could also show significant improvements. These include overall downstream process yield or percent yield per input of starting material; therefore, these relevant measures of success should be discussed in the proposal.

Phase 1 Metrics – Proof of Concept, Months 1-26
Phase 1 will include two capability demonstrations at months 11 and 22 of increasing complexity with required metrics as listed in Tables 2, 3, 5, and 6.

Phase 2 Metrics –Prototype, Months 27-50
Phase 2 will include two capability demonstrations at months 38 and 48 of increasing complexity with required metrics established above in Tables 2, 3, 5, and 6.

1.4. GENERAL REQUIREMENTS

1.4.1. Proposing Teams

It is expected that proposals will involve teams that have the expertise needed to achieve the goals of both TA1 and TA2. 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 Principal Investigator (PI), under a single prime contractor that addresses all program Phases, as applicable.

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

1.4.2. IV&V

The Government is not soliciting IV&V proposals under HR001121S0038. To avoid potential conflicts of interest, performers for HR001121S0038 will not be allowed to compete for the IV&V contract. Throughout the program, the performers will work with a Government-furnished IV&V team. This partnership will be facilitated by the Government. The IV&V team will consist of subject matter experts from the Government, Federally Funded Research and Development Centers (FFRDCs), academia and/or other relevant domains capable of meeting the desired IV&V goals of the program as established by DARPA.

1.4.3. Transition Strategy

RPM aims to establish the foundational technologies needed for fully distributed, on-demand manufacturing of protein-based medical countermeasures (MCM), critical protein-based reagents, and associated raw materials. While no formal transition plan is required for the proposal, it should be noted that the technologies developed during RPM may lay the groundwork for follow-on development of a distributed platform for protein manufacturing.

1.4.4. 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.

End of Phase reports: Three months prior to the end of Phase 1 (i.e., at Month 23) and one month prior to the end of Phase 2 (i.e., at Month 49), performers must draft and present to DARPA a written report of all research activities and metrics satisfied. This report will contain all relevant supporting data.

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

- Program spend plan by Phase and task
- Incurred program expenditures to date by Phase and task
- Invoiced program expenditures to date by Phase and task

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

Quarterly technical progress reports: Performers are required to provide quarterly research updates in the form of a written report describing all research activities and metrics achieved during the quarter. Length and level of detail are at the discretion of the Program Manager.

Mid-Phase and End of Phase reviews: Leadership from each performer team (with additional key personnel at the discretion of the PI) will be required to present research progress in person at program review meetings. 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; progress towards milestones and scientific goals; and any ongoing technical or programmatic challenges that must be overcome to achieve the overarching program goals.

Final Program Report: When the final funding Phase closes out, performer teams must provide a final report summarizing all research activities, outcomes, and molecular mechanisms discovered during the program; publications, research presentations, patent applications that result from the research pursued; and 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 proposers intending to perform fundamental research and does not anticipate applying publication restrictions of any kind to individual awards for fundamental research that may result from this solicitation. Notwithstanding this statement of expectation, the Government is not prohibited from considering and selecting research proposals that, while perhaps not qualifying as fundamental research under the foregoing definition, still meet the solicitation criteria for submissions. If proposals are selected for award that offer other than a fundamental research solution, the Government will either work with the proposer to modify the proposed statement of work to bring the research back into line with fundamental research or else the proposer will agree to restrictions in order to receive an award.

Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to 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. CONTACT AND FORM OF APPLICATION SUBMISSION

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

4.2.1. Proposal Abstract Format

Proposers are strongly encouraged to submit an abstract in advance of a proposal to minimize effort and reduce the potential expense of preparing an out-of-scope proposal. 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 **15** calendar days of receipt. Proposals may be submitted irrespective of comments or feedback received in response to the abstract. Proposals are reviewed without regard to feedback given as a result of abstract review. The time and date for submission of proposal abstracts are specified in Part I above.

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

The page limit does NOT include:

- Official transmittal letter (optional);
- Cover sheet;
- Executive summary 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. Goals and Impact: Clearly describe what is being proposed and what difference it will make (qualitatively and quantitatively), including brief answers to the following questions:

1. What is the proposed work attempting to accomplish or do?
2. How is it done today? And what are the limitations?
3. What is innovative in your approach, and how does it compare to the current SOA?
4. What are the key technical challenges in your approach, and how do you plan to overcome these?
5. How much will it cost, and how long will it take?

C. Executive Summary Slides: The slide template is provided as **Attachment 1** to the BAA posted at https://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. This section should provide specific objectives, metrics, and milestones at intermediate stages of the project to demonstrate a plan for accomplishment of the program goals. Propose additional appropriate qualitative and quantitative metrics specific to the approach, as needed. Outline of intermediary milestones should occur at no greater than 6-month increments.

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

A PI for the project must be identified, and a description of the team's organization, including a breakdown by Technical Area (TA). 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 team, 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 delineate individuals to avoid duplication of efforts.

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

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

4.2.2. Proposal Format

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

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal.** All submissions must be written in English with type no smaller than 12-point font. A smaller font may be used for figures, tables, and charts. The page limitation includes all figures, tables, and charts. All pages shall be formatted for printing on 8-1/2 by 11- inch paper. Margins must be 1-inch on all sides. Copies of all documents submitted must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title/proposal short title. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and approach upon which the proposal is based. Copies of not more than three (3) relevant papers may be included with the submission. The bibliography and attached papers are not included in the page counts given below. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. **The maximum page count for Volume 1 is 40 pages.** The official transmittal letter is not included in the page count. Volume I should include the following components:

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

a. Volume I, Technical and Management Proposal

Section I. Administrative

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

1. BAA number (HR001121S0038);
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*), GRANT, 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. Detailed Proposal Information

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

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

B. Goals and Impact: Clearly describe what the team is trying to achieve and the difference it will make (qualitatively and quantitatively) if successful. Describe the innovative aspects of the project in the context of existing capabilities and approaches, clearly delineating the uniqueness and benefits of this project in the context of the state

of the art, alternative approaches, and other projects from the past and present. Describe how the proposed project is revolutionary and how it significantly rises above the current state-of-the-art. Describe the deliverables associated with the proposed project and any plans to commercialize the technology, transition it to a customer, or further the work.

C. Technical Plan: Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) at intermediate stages of the program to demonstrate progress, plan for achieving the milestones, and must include a simple process flow diagram of their final system concept. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal. Discuss mitigation of technical risk.

D. Management Plan: Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. A PI for the project must be identified, along with a description of the team's 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 team, 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.

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

F. Statement of Work (SOW) NOT INCLUDED IN PAGE COUNT: The SOW should provide a detailed task breakdown, citing specific tasks for each Technical Area, and their connection to the milestones and program metrics. Each Phase of the program should be separately defined. The SOW must not include proprietary information. It is encouraged, though not required, to use the SOW template provided as **Attachment 2**. SOW is not included in the Volume I page count.

For each task/subtask, provide:

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

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

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.

a. Volume II, Cost Management Proposal

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

1. BAA Number (HR001121S0038);

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 PI) 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*), GRANT, 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); and
19. Proposal validity period.

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

The Government 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 1 [Base] and Phase 2 [Option]), and per task cost broken down by major cost items to include:

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

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

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

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

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

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

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

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

ix. **Indirect costs specific to a University performer:** (1) **Fringe Benefit Rate** (provide current Department of Health and Human Services (DHHS) or Office of Naval Research (ONR) negotiated rate package; if calculated by other than a rate, provide University documentation identifying fringe

costs by position or HR documentation if unique to each person); (2) **Facilities &Administrative 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, to include both pool and expense costs used to generate the rates).

(2) A summary of total program costs by Phase (1 and 2) 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 another document that verifies the proposed loaded daily/hourly rate.
(4) An itemization of any information technology (IT) purchase (including a letter stating why the proposer cannot provide the requested resources from its own funding), as defined in FAR Part 2.101.
(5) A summary of projected funding requirements by month for all Phases of the project.
(6) A summary of tasks that have animal or human use funding.
(7) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions that could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each.
(8) Identification of pricing assumptions of which may require incorporation into the resulting award instrument (e.g., use of Government Furnished Property/Facilities/Information, access to Government Subject Matter Expert/s, etc.).
(9) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available).
(10) Proposers with a Government acceptable accounting system who are proposing a cost-type contract must submit the DCAA document approving the cost accounting system.

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

Subawardee Proposals

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

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

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.

Other Transaction (OT) Requests
All proposers requesting an OT must include a detailed list of milestones for each Phase of the program (1 and 2). Each milestone must include the following:

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

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

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

4.2.3. Additional Proposal Information

Proprietary Markings

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

Unclassified Submissions

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

Disclosure of Information and Compliance with Safeguarding Covered Defense Information Controls

The following provisions and clause apply to all solicitations and contracts; however, the definition of "controlled technical information" clearly exempts work considered fundamental research and therefore, even though included in the contract, will not apply if the work is fundamental research.
DFARS 252.204-7000, "Disclosure of Information"
DFARS 252.204-7008, "Compliance with Safeguarding Covered Defense Information Controls"
DFARS 252.204-7012, "Safeguarding Covered Defense Information and Cyber Incident Reporting"
The full text of the above solicitation provision and contract clauses can be found at http://www.darpa.mil/work-with-us/additional-baa#NPRPAC.
Compliance with the above requirements includes the mandate for proposers to implement the security requirements specified by National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations" (see https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-171r2.pdf) 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.

Approved Cost Accounting System Documentation

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

Small Business Subcontracting Plan

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

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

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

Grant Abstract

Per Section 8123 of the Department of Defense Appropriations Act, 2015 (Pub. L. 113-235), all grant awards must be posted on a public website in a searchable format. To comply with this requirement, proposers requesting grant awards must submit a maximum one (1) page abstract that may be publicly posted and explains the program or project to the public. The proposer should sign the bottom of the abstract confirming the information in the abstract is approved for public release. Proposers are advised to provide both a signed PDF copy, as well as an editable (e.g., Microsoft word) copy. Abstracts contained in grant proposals that are not selected for award will not be publicly posted.

Intellectual Property

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

For Procurement Contracts

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

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

For All Non-Procurement Contracts

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

System for Award Management (SAM) and Universal Identifier Requirements

All proposers must be registered in SAM unless exempt per FAR 4.1102. FAR 52.204-7, "System for Award Management" and FAR 52.204-13, "System for Award Management Maintenance" are incorporated into this 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/sys_attachment.do?sys_id=c08b64ab1b4434109ac5ddb6bc4bcbb8.

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 HR001121S0038. 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 HR001121S0038 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 Grants or Cooperative Agreements only:

Proposers requesting grants or 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 HR001120S0038 summary. Submit your question(s) via e-mail to RPM@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; 5.1.4 Realism of Proposed Schedule; and 5.1.5 Proposer's Capability and/or Related Experience.

5.1.1. Overall Scientific and Technical Merit

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

5.1.2. Potential Contribution and Relevance to the DARPA Mission

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

5.1.3. Cost Realism

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

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

5.1.4. Realism of Proposed Schedule

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

5.1.5. Proposer's Capabilities and/or Related Experience

The proposer's prior experience in similar efforts clearly demonstrates an ability to deliver products that meet the proposed technical performance within the proposed budget and schedule. The proposed team has the expertise to manage the cost and schedule. Similar efforts completed/ongoing by the proposer in this area are fully described, including identification of other Government sponsors.

5.2. REVIEW OF PROPOSALS

Review Process

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

DARPA will conduct a scientific/technical review of each conforming proposal. Conforming proposals comply with all requirements detailed in this 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 HR001121S0038 will be evaluated following the submission deadlines listed in Part 1. DARPA will respond as described below. These official notifications will be sent via e-mail to the Technical Point of Contact (POC) and/or Administrative POC identified on the submission coversheet.

6.1.1. Proposal Abstracts

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 in the Arlington, VA vicinity, and all key participants are required to attend. Performers should also anticipate regular program-wide PI meetings and periodic site visits at the Program Manager's discretion to the Arlington, VA vicinity. Proposers shall include within the content of their proposal details and costs of any travel or meetings they deem to be necessary throughout the course of the effort, to include periodic status reviews by the government.

6.2.1. 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

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

6.4. ELECTRONIC SYSTEMS

6.4.1. Wide Area Work Flow (WAWF)

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

6.4.2. I-EDISON

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

7. Agency Contacts

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

Points of Contact
The BAA Coordinator for this effort may be reached at:
RPM@darpa.mil
DARPA/BTO
ATTN: HR001121S0038
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 virtual Proposers Day in support of the RPM program on August 26, 2021. The purpose is to provide potential proposers with information on the RPM program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and encourage team formation.

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

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

Participants are required to register no later than **August 23, 2021, 12:00 PM ET**. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; there will be no onsite registration.

Proposers Day Point of Contact:
RPM@darpa.mil
ATTN: DARPA-SN-21-38

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 HR001120S0038. 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 **HR001120S0038** included on your Cost Proposal cover sheet?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]
   If reply is "No", please explain:

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

   If reply is "No", please explain:

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

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

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

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

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

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

   If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

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

If reply is "No", please explain: