

Broad Agency Announcement PREventing EMerging Pathogenic Threats (PREEMPT) BIOLOGICAL TECHNOLOGIES OFFICE HR001118S0017 January 19, 2018

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PART I: OVERVIEW INFORMATION

- Federal Agency Name Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office
- Funding Opportunity Title PREventing EMerging Pathogenic Threats
- Announcement Type Initial
- Funding Opportunity Number HR001118S0017
- Catalog of Federal Domestic Assistance Numbers (CFDA) 12.910 Research and Technology Development
- Dates
 - Posting Date January 19, 2018
 - Proposal Abstract Due Date and Time February 13, 2018 4:00 ET
 - Proposal Due Date and Time March 27, 2018 4:00 ET
 - o BAA Closing Date March 27, 2018
 - Proposers' Day January 30, 2018

https://www.fbo.gov/spg/ODA/DARPA/CMO/DARPA-SN-18-18/listing.html

- Concise description of the funding opportunity DARPA is soliciting innovative proposals to develop novel and scalable approaches to preempt viral spillover and transmission from animals or vectors into humans.
- Anticipated individual awards Multiple awards are anticipated.
- Types of instruments that may be awarded Procurement contract, cooperative agreement or other transaction.
- Any cost sharing requirements Cost sharing may be required under applicable statutory regulations for other transactions for prototype projects awarded under the authority of 10 U.S.C. § 2371b.
- Agency contact
 - Points of Contact James Gimlett, Ph.D. Program Manager Biological Technologies Office

The BAA Coordinator for this effort may be reached at: <u>PREEMPT@darpa.mil</u> DARPA/BTO ATTN: HR001118S0017 675 North Randolph Street

PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

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

DARPA is soliciting innovative proposals for research to develop new tools and models to quantify the likelihood of a virus to jump from an animal host into humans, and to develop and validate new scalable technologies to target potential human-capable viral pathogens in wild reservoirs and/or mosquito vectors to prevent transmission to humans.

1.1. PROGRAM OVERVIEW

Introduction

During U.S. international operations, military forces are deployed to remote locations around the globe, often in areas where endemic and emerging diseases are prevalent¹. Most of these emerging and re-emerging diseases originate in animal reservoirs and then jump into humans. Numerous trends, including the increased interactions between human, animal and insect populations due to increased population densities, globalization, densification of livestock production, and rising human encroachment into animal habitats, have increased the risks of new viral outbreaks in those regions where Department of Defense (DoD) personnel are typically deployed. Often, DoD personnel are among the first responders in outbreak situations. Emerging infectious diseases, for which few medical countermeasures are available, represent a major threat to the warfighter and national security and could have devastating impacts on U.S. public health.

Despite biosurveillance efforts around the globe, new viral outbreaks continue to outpace preparedness efforts and show no signs of abating. During the first three quarters of 2017 outbreaks of avian influenza A (H7N9), Chikungunya, MERS coronavirus, Ebola, Seoul virus, Hepatitis E, Hepatitis A, Yellow Fever, Lassa, and Zika viruses were recorded². While current biosurveillance strategies focus on detection of known pathogens within the human population following an infectious outbreak event, there is a dearth of research and surveillance on sentinel or reservoir animals³. Animal-specific viruses that have the potential to infect humans (*namely* "human-capable" pathogens), but have not yet spilled over into human populations, are rarely considered. As a result, infectious agents are detected only *after* an outbreak—that is, after an animal pathogen has adapted to become capable of infecting humans. Consequently, the outbreak response is largely reactive and not initiated until after an epidemic has already begun. The PREEMPT program represents a radical departure from current practice, aiming to target viral

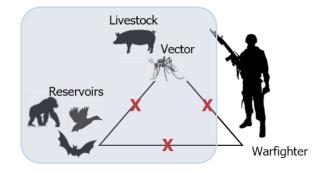
¹ Halliday Jo E.B. et al. (2017). Driving improvements in emerging disease surveillance through locally relevant capacity strengthening. Science.

² World Health Organization (2017). <u>http://www.who.int/csr/don/archive/year/2017/en/.</u>

³ Metcalf, J.E. and Lessler, J. (2017). Opportunities and challenges in modeling emerging infectious diseases. Science.

biothreats within the animal reservoirs where they originate and preempt their entry into human populations *before* an outbreak occurs.

Recently, the scientific community has advanced its understanding of host-pathogen genetics and mechanisms of adaptation across hosts^{4,5}, developed analytic tools to predict animal hosts of new and potential human-transmissible viruses, and learned how to identify "hot spot" geographic regions where an animal-to-human virus jump is imminent^{6,7}. This understanding is empowered by new high-throughput data generation capabilities and sophisticated analytic and computational tools. Together, this new understanding and capability hold great promise for the development of advanced integrated models that can assess and likely provide guidance for action that prevents human virus emergence before the virus gains entry to the human population. The PREEMPT program aims to develop new tools and models to quantify the likelihood of a virus quasispecies (QS) to jump from an animal host into humans. In parallel, PREEMPT seeks to develop and validate new scalable technologies that prevent transmission of viral pathogens in wild reservoirs and/or mosquito vectors to humans or to bridge animals that serve as intermediary hosts prior to virus jump into humans.



Research Objectives

PREEMPT research objectives are structured along two Technical Areas (TAs). Both Technical Areas must be performed in parallel by vertically integrated, interdisciplinary teams. Proposers must present a plan to address both Technical Areas and meet key milestone decision points that occur at the end of year 2.

- 1) TA1: Develop and validate integrated, multiscale models that quantify the likelihood a human-capable virus will emerge from an animal reservoir residing in a "hot spot" geographic region.
- 2) TA2: Develop scalable approaches that target and suppress the animal virus in its reservoir(s) and/or vector(s), to reduce the likelihood of virus transmission into humans.

Technical Area 1 (TA1)

⁴ Lloyd-Smith, J.O. (2010). Identifying genetic markers of adaptation for surveillance of viral host jumps. Nature Reviews Microbiology.

⁵ Plowright, R.K. et al. (2017). <u>Pathways to zoonotic spillover</u>. Nature Reviews Microbiology.

⁶ Olival, K.J. et al. (2017). Host and viral traits predict zoonotic spillover from mammals. Nature.

⁷ Han, B.A. et al. (2016). Undiscovered Bat Hosts of Filoviruses. PLoS Negl Trop Dis.

Studies within TA1 must produce and validate models that: (a) quantify the likelihood of a virus to jump into a new animal species and/or humans, (b) identify opportunities for proactive intervention, and (c) determine likely efficacy, scalability, and sustainability of prevention strategies.

Proposers are expected to leverage high-throughput virus screening methods, metagenomics, ecological surveillance, and advanced modeling tools to generate risk models for species jump that will enable near real-time data analysis and identification of potential risks and risk factors. This far-forward biosurveillance system should also identify opportunities for preemptive intervention, assessing likely efficacy, scalability, safety, and sustainability of preemptive strategies to target viral threats in animal reservoirs and/or vectors before they enter the human population.

TA1 Components

Proposers should address, at minimum, the following aspects:

- 1) Selection of zoonotic or vector-borne viral pathogen(s) (multiple viruses within the same family may be addressed if they share a common animal reservoir and/or vector)
- 2) Field data collection
- 3) Multi-species field samples studied in a controlled laboratory setting
- 4) Data analysis, integration, and model development
- 5) Real-time data sharing and analysis
- 6) Model outputs
- 7) Experimental validation of model predictions in a controlled, environment-simulated laboratory setting

1. Selection of zoonotic or vector-borne viral pathogen

This BAA only will consider proposals focused on zoonotic and/or vector-borne viruses. Microorganisms other than viruses are not responsive to this announcement. A rationale for the viruses selected is required. Virus selection may be based on, but is not limited to, the following factors: high frequency of re-emergence (*e.g.* avian influenza virus), patterns of virus host range or host breadth (predicted zoonotic potential), potential for rapid spread due to vector-mediated transmissibility, severity of disease pathology, and likelihood of pandemic threat.

2. Field data collection

Proposers must identify and justify suitable geographic "hotspots" within which they will collect field data. Proposers must consider <u>all</u> of the following criteria when selecting geographic hot spots for field data collection:

- 1) Previous evidence of geographic distribution of zoonotic reservoirs and/or vectors for known or unknown human viruses; these maps may be based on epidemiological, phylogenetic, ecological, biogeographic, socio-economic data, or other;
- 2) Evidence of past species jump events in or near the selected geographic location;

- 3) Demonstrated capabilities and infrastructure to perform research in the selected geographic region and/or collaboration with an established DoD or Department of Health and Human Services (DHHS) partner (*e.g.*, a Naval Medical Research Unit site, Armed Forces Research Institute of Medical Sciences, or Centers for Disease Control), such that the performer can coordinate far-forward surveillance activities and access local lab and analytics capabilities;
- 4) Appropriate levels of in-country government approval, cooperation, infrastructure and logistical support where samples will be collected and analyzed; and
- 5) Rationale for reservoirs/species to be sampled.

Where applicable, proposers must consider seasonal distribution (e.g., wet-dry seasons for mosquito), temporal ecological factors (e.g., time of fruiting for fruit bats), and temporal behavioral traits (e.g., sexual maturation) of zoonotic species for field sampling. Potential geographic areas may include, but are not limited to, endemic regions; those undergoing ecological shifts (thus increasing risk for spillover due to changes in animal-human interactions); those harboring host species with high zoonotic potential that are in proximity to human populations and "bridge" animal hosts (e.g., human-bat-swine ecosystems); and prior sites of spillover events or outbreaks. The selection of geographic areas of common military deployment that also meet the above criteria is strongly encouraged. Proposers should describe feasible approaches to increase the probability of detecting viruses within animal reservoirs and/or vectors-residing in selected geographic areas-that have the potential to become humancapable. Proposers should describe sample collection methods in detail, being sure to include longitudinal sampling frequency. Development of novel and rapid sampling approaches for the real-time continuous screening of emerging or re-emerging pathogens at the human-animal interface is encouraged. Proposers are encouraged to identify field samples that were collected during past outbreak events, or field data already generated, that could be accessed for retrospective analyses. In such cases, proposers should describe how and where the data were collected, and establish quality control methods for data evaluation and use. Although human use research will not be funded by PREEMPT, the use of human samples or data from prior outbreaks obtained through other programs may be included in the research plan as long as samples are appropriately de-identified (see, for example, https://humansubjects.nih.gov/humanspecimens-cell-lines-data).

3. Multi-species laboratory testing of field samples

Proposers should discuss protocols to determine and quantify the virus population QS diversity from the vector or reservoir at the time of sample collection (t=0) in a manner that minimizes QS alterations, which commonly result from cell line passaging. Proposers should assess the need for longitudinal collection of samples to understand viral QS temporal dynamics (temporal changes in sequence and fitness landscapes) in field virus populations. The initial viral QS isolated from a field sample (t=0) will be hereon annotated as "QS₀". Proposers must describe *in vitro* and/or *in vivo* experiments to assess jump potential of the QS₀ population to a relevant new host. Experimental approaches to monitor viral species jump may include, but are not limited to: changes in viral population QS during cell line passaging between relevant species; infection of appropriate animal models; infection of natural animal hosts; and controlled, multi-species laboratory ecosystems. Lab testing should determine the key parameters influencing the probability of a viral QS_0 to jump and adapt to a new host species. Potential parameters across different host animals or vectors may include, but are not limited to:

- 1) QS diversity profiles
- 2) Rates of virus infection and amplification
- 3) Virus incubation period
- 4) Viremia and viral shedding
- 5) Transmission bottlenecks
- 6) Animal host evolutionary and immune pressures

The data generated should enable the development of genotype-to-phenotype maps and the determination of mutation(s) associated with virus jump to a new host. *4. Data analysis, integration, and model development*

Proposers should identify the relevant data needed for developing integrated models of risk assessment. Proposers should discuss the development of probabilistic models of virus jump using advanced computational methods and tools, including both model-driven and data-driven approaches. Models should integrate multi-scale and cross-host species data, including but not limited to, field and experimental data (*e.g.*, QS dynamics), ecological data (*e.g.*, demographic, socio-economic, epidemiological, biogeographical, and other metadata), and other relevant data available, especially that generated from past spillover events. Models should consider all factors associated with pathogen emergence and transmission, particularly multi-host immunological landscapes. Models should also capture viral evolutionary trajectories, fitness landscapes in zoonotic and/or vector species, and quantify the transmission dynamics underlying species jump.

5. Real-time data sharing and analysis

The PREEMPT program is expected to generate significant amounts of data, primarily from next generation sequencing (NGS) of viral populations and analysis of host molecular signatures. Proposers should identify methods for near-real-time data sharing and analysis.

6. Model outputs

Proposers should explain how they will develop probabilistic models and machine learning techniques that integrate multi-scale and cross-species data (*e.g.*, molecular signatures, demographic, ecological, socio-economic, epidemiological, weather, climate, and other metadata) to quantify a pathogen's likelihood to cross species barriers and infect humans. Models should capture viral evolutionary trajectories and mutations that govern species jump. Models should quantify transmission dynamics, accounting for the diversity of viral QS. Models should identify key parameters of the pathogen, host species, vector dynamics, and ecological interactions contributing to species jump, and should inform a preemption strategy by identifying optimal pressure points (*e.g.*, jump-enabling mutations, stochastic transmission bottlenecks, and viral amplification requirements) that can be targeted to reduce the likelihood of species jump. For proposals addressing vector-borne viruses, proposers should describe methods to quantify

the likelihood of virus adaptation to a new vector and propose experimental methods to validate these predictions. Proposers should discuss metrics for grading model accuracy, sensitivity, and specificity. Models should be able to receive dynamic biosurveillance inputs and accommodate virus QS changes.

7. Experimental validation of model predictions

Proposers must describe in detail a plan to establish relevant *in vivo*, multi-species experimental approaches to validate model outputs. Experimental testing may closely resemble or recapitulate real-life settings (*e.g.*, climate, phylogenetically adjacent host species, and vector "biting" patterns) to enable the quantification of the probability of spillover and/or transmission events in a controlled manner. Approaches that closely recapitulate real-life ecosystems and natural hosts are strongly encouraged. To improve model accuracy, sensitivity, and specificity, performers must iterate both theoretical and empirical experiments.

TA1 Key Outputs

The key outputs for TA1 must include the following:

- 1) Integrated models that quantify likelihood of virus jump and can be easily adapted to receive dynamic surveillance and virus data input.
- 2) Stochastic models quantifying bottlenecks (e.g., transmission, cell entry, and infection rates) and mutational fitness maps (e.g., enabler mutations and their frequency).
- 3) Identification and assessment of potential preemptive intervention targets to preempt virus jump from the reservoir and/or vector.

Technical Area 2 (TA2)

Studies within this technical area aim to develop deployable and scalable methods to preempt viral jump across species.

TA2 Components

Technical Area 2 aims to develop deployable and scalable methods to preempt viral jump to other species. Proposers must address, at minimum, <u>all</u> of the following aspects:

- 1) Proof-of-concept preemption approaches;
- 2) Scalable delivery methods;
- 3) Analysis of long-term sustainability; and
- 4) Experimental validation.

1. Proof-of-concept preemption approaches

Proposers should describe how the output of TA1 *in silico* models will guide preventive method design, and how quantitative information of virus-host species barriers and transmission bottlenecks will be used to develop strategies to preempt emergence of human-capable viruses. Models should guide the selection of: host species to be treated (*e.g.*, wild animals, "bridge"

animals, vectors, and livestock); potential molecular targets (*e.g.*, key mutation(s) enabling receptor binding in a new host); targets associated with transmission cycle dynamics (*e.g.*, reduction of viral load within the reservoir and/or vector that would preclude transmission); and other relevant factors identified by the models. Proposers should describe the preemptive methods that address different model outputs. Examples of preemptive approaches include but are not limited to:

- 1) Specific disruption of jump-capable genes from virus QS in reservoirs and/or vectors using small interfering RNAs or CRISPR/Cas-based targeted deletions.
- 2) Suppression of virus jump to a new host through antibody-mediated virus neutralization.
- 3) Suppressed reservoir and/or vector viremia using virus defective interfering particles (DIPs) to outcompete virus replication.
- 4) Suppressed transmission among animal reservoirs through induced immunity (*e.g.*, vaccinate the animal).
- 5) Alternative methods informed by experimental and theoretical models. The development of novel preemptive approaches are strongly encouraged.

2. Scalable delivery methods

Proposers must describe scalable approaches to deliver the preemptive therapeutic to achieve animal and/or vector population-level control of the targeted virus, including strategies for reaching less accessible animal reservoirs (*e.g.*, rodents or non-human primates). Approaches that enable host-to-host therapeutic distribution (*i.e.*, do not require individual treatment) that are self-limiting, only activate when the viral pathogen target is present, and/or have a controllable "on/off-switch" are encouraged. Potential scalable methods of inoculation may include, but are not limited to:

- 1) Self-disseminating treatments or preventives (*e.g.*, transmissible recombinant vaccines, therapeutic interfering particles, or self-spreading antiviral therapies).
- 2) Bait vaccination or treatment of wild or domestic animals.
- 3) Spray-based methods.

Approaches that utilize genetic modifications of vectors (*e.g.*, engineered mitochondrial DNA) are acceptable. The proposed method of inoculation must be justified. The proposer must describe strategies for closely controlling preemptive delivery and spread.

3. Analysis of long-term safety and efficacy

Proposers must establish initial methods to assess the long-term safety and efficacy of preemptive approaches (*e.g.*, determine the mechanism by which species specificity of a vaccine is maintained, and assess evolutionary stability and ecological safety).

4. Experimental validation

Proposers must describe approaches to validate preemptive methods of choice in controlled experimental models. Multi-species experimental platforms that closely recapitulate real-life ecosystems and use natural hosts are strongly encouraged.

TA2 Key Outputs

The key outputs of TA2 must include the validation of new "block-before-jump" preemption technologies for one of the following:

- 1) Validate suppression of virus jump from wild animal reservoir to humans and/or an intermediate animal carrier (*e.g.*, domestic livestock).
- 2) Validate suppression of virus jump or transmission from wild reservoir to vector, vector to a different vector species, and/or from vector to human.

Period of Performance

DARPA anticipates that the PREEMPT program will provide up to three and a half years of funding for research and development to be performed over Phase I (base) and II (option) periods of 24 and 18 months, respectively.

Timeline

PREEMPT spans a 42-month effort with a 24-month Phase I (base) and an 18-month Phase II (option). In general, Phase I should provide early validation of zoonosis risk models, and Phase II should establish efficacy and scalability of zoonosis prevention approaches.

Phase I (Base period)

Phase I efforts aim to develop experimental and mathematical models to quantify the likelihood a virus will jump from one host species to another, identify potential targets for spillover preemption, and develop scalable methods of preemption. During Phase I, performer teams will:

- 1) Identify the genetic adaptations that enable species jump.
- 2) Develop mathematical models to quantify the likelihood of species jump based on:
 - a. Molecular data (e.g., viral QS data from deep sequencing) and
 - b. Ecological data *(e.g.,* immune state of the host population before pathogen emergence, species relatedness, etc.).
- 3) Identify bottlenecks for intervention (e.g.. transmission, cell entry, viral amplification, infection rate, and other mechanisms associated with viral cross-species compatibility).
- 4) Develop initial scalable platforms that target viruses in reservoirs and/or vectors to prevent viral jump into other animals or humans.

By the end of year 1 (Phase I) performers will be expected to have:

- 1) Identified signatures of fitness and spillover potential of a pathogen between two species.
- 2) Quantified the genetic and transmission factors requirements of viral QS to jump to a new host (*e.g.*, develop genotype-to-phenotype maps, identify specific mutations, etc.) using far-forward biosurveillance data from selected high-risk regions.

By the end of year 2 (Phase I) performers will be expected to have:

- 1) Initially demonstrated that models can quantify the probability of human-capable virus pathogens to jump from one species to another species.
- 2) Demonstrated proof of concept methods for targeting human-capable virus pathogens in the reservoirs and/or vectors to reduce the probability of virus jump.
- 3) Provided initial strategies to scale up preemption methods.

Phase II (Option period)

Phase II efforts aim to develop probabilistic models for intra- and inter-species viral amplification and transmission dynamics, integrated models for risk assessment, and experimental validation of new approaches to preempt species jump. During Phase II, performer teams will extend Phase I modeling efforts to:

- 1) Quantify intra- and inter-species viral amplification dynamics and transmission.
- 2) Develop integrated models that quantify the probability of a virus QS to jump to bridge animal species or to humans.
- 3) Experimentally validate scalable methods for their ability to preempt zoonotic spillover.

By the end of year 3.5 (Phase II) performers will be expected to:

- 1) Demonstrate accuracy of risk assessment and preemption models in a relevant multispecies experimental setting.
- 2) Demonstrate the ability to suppress viral jump to a new species in controlled experimental settings.

It is recognized that appropriate milestones and metrics may depend upon the type of virus, the reservoir, the mechanisms of species jump, and the proposed preemption methods. Proposers must offer quantitative milestones and metrics (see Tables 1 and 2 below for notional metrics) for their proposed proof-of-principle use case. Proposers must demonstrate relevant research experience in the required technical areas. Proposals involving multiple teams and/or experimental approaches should be structured as unified efforts that address the program Technical Areas in parallel, in an integrated manner.

1.2. PROGRAM METRICS

In order for the Government to evaluate the effectiveness of a proposed solution in achieving the stated program objectives, proposers should note that the Government hereby promulgates the following program metrics that may serve as a guideline for assessing program progress, risk and impact. Although the following program metrics are provided, proposers should note that the Government has identified these goals with the intention of bounding the scope of effort while affording the maximum flexibility, creativity, and innovation in proposing solutions to the stated problem. Proposers should offer more appropriate and specific metrics for their particular use case and technical approach, including intermediate metrics (i.e. every 6 months, or sooner) to help further evaluate progress. Final metrics are to be negotiated at the time of contracting.

Table 1: Notional Milestones, Deliverables, and Program Metrics for TA1

Phase	Milestones and Deliverables	Program Metric
I	Collected field surveillance data:	Quantitative measures of:
	 Virus QS molecular data (<i>e.g.</i> from deep sequencing) and metadata from longitudinal samples (<i>e.g.</i> obtained from selected high-risk areas (<i>e.g.</i> bat cave) and/or from prior outbreak event Host species immune molecular data 	 Longitudinal viral population QS (QS_{t=0}, QS_{t=6 months}, QS_{t=12 months},) diversity in selected high-risk areas (<i>e.g.</i> frequency of mutations, evolutionary trajectories) (6 months) Viral QS diversity in samples obtained from animal, vector, and/or human from prior outbreak event (<i>e.g.</i> frequency of species-specific mutations) (9 months) Immune molecular signatures from host reservoir or intermediate reservoir species (12 months)
	Multi-species lab test data:	Quantitative measures of:
	 Virus QS genotype-phenotype maps for at least 2 relevant host species 	 Cell entry and adaptation across species in vitro and/or in vivo (e.g. QS diversity during passage across species) (18 months)
	Initial mathematical models that assess risk	Model capability to describe/predict:
	of virus jump	 Virus QS evolutionary trajectories between 2 relevant species (9 months) Key molecular factors that could be targeted to prevent virus jump <i>in vitro</i> and/or <i>in vivo</i> (<i>e.g.</i> signatures of fitness of a pathogen between two relevant host species) (18 months) Molecular targets for preemption (24 months)
	Established testbeds for validation of model predictions	Testbeds mimic natural environment as quantified by performer-defined parameters (24 months)
II	 Multi-species lab test data Quantify virus QS transmission factors between two species <i>in vivo</i> 	 Quantitative measures of: Virus amplification and transmission dynamics (<i>e.g.</i> rate of infection vs. viremia, amplification rates, and incubation time) (30 months)
	 Advanced mathematical models that assess risk of virus jump Integration of molecular data and virus amplification/transmission dynamics Integration of host immune evolutionary pressures and virus QS dynamics 	 Models predict: Intra- and inter-species transmission dynamics (36 months) Probability of spillover (risk assessment) (42 months) Top 2 targets to reduce probability of transmission between two species to

Phase	Milestones and Deliverables	Program Metric
		inform TA2 (42 months)
	Further validation of model prediction in established testbeds	Validated model prediction accuracy in multispecies environment (42 months)

Table 2: Notional Milestones, Deliverables, and Program Metrics for TA2

Phase	Milestones and Deliverables	Program Metric
1	Proof-of-concept demonstration of preemptive approach that reduces either the probability of virus jump or the frequency of virus QS variants at high risk for species jump	 Quantitative validation of preemptive approach as established by performer (24 months) Examples: Frequency of high-risk mutation within virus QS in reservoir reduced >3X Virus incubation period in vector extended >3X Virus amplification rate in reservoir or vector reduced >3X Viremia in host or vector reduced >5X
II	Demonstrated efficacy of preemption method	Reduced probability of transmission between two species by >5X <i>in vivo</i> for top 2 targets (36 months)
	Demonstrated scalability of preemption method	Quantitative scalability as established by performer (42 months)

Data Sharing

Proposers must ensure all technical data items (including experimental findings, processed data, methods of processing, research reports, and publications) and software (source code and executables) generated from PREEMPT program funding are made available to DARPA. Regularly submitted reports (*e.g.*, monthly or quarterly) should contain all relevant project data, including (but not limited to) raw and analyzed data and any necessary annotations and interpretation. Data and/or samples collected from de-identified human volunteers/patients from previous outbreak events must include associated anonymized metadata (*e.g.*, signs/symptoms, diagnostic test results, interventions, clinical observations, and outcomes). All raw data and metadata should be recorded according to approved experimental standards.

To gain enhanced scientific value from open collaboration in fundamental research, DARPA may seek permission to share some or all program-generated data with the broader research community as open data (including the possibility of accessing, reusing, and redistributing under appropriate licensing terms) to the extent permitted by applicable laws and regulations (*e.g.*, privacy, security, and export control).

DARPA anticipates that a large amount of data will be generated under this program by each performer and that the analyses and validation will be strengthened by compiling and integrating

information across all performers. Performers are strongly encouraged to establish the appropriate agreements to enable collaboration and data sharing. DARPA encourages sharing of pre-existing data, including those generated through funding by other sources, although this is not a requirement of the program.

As feasible, DARPA intends to share data within the PREEMPT performer community to promote program goals. To facilitate sharing and exchange of data items, performers will be required to enter an Associate Contractor Agreement (ACA); an ACA clause will be included in the contract or agreement awarded.

PREEMPT Transition Plan

Proposers must include a PREEMPT Technology Transition Plan. Proposers must indicate the types of partners (*e.g.*, government, private industry, non-profit) they plan to pursue and submit a timeline with incremental milestones toward successful engagement. Proposers should begin transition activities during the early stages of the program (Phase I). Awardees must include DARPA in the development of transition relationships. If the transition plan includes a start-up company, a business development strategy must be included as well. The extent by which the proposed intellectual property (IP) rights will impede the Government's ability to transition the technology will be considered in the proposal evaluation.

1.3. ETHICAL, LEGAL, AND SOCIETAL IMPLICATIONS (ELSI)

DARPA is committed to ensuring that efforts funded under this BAA adhere to ethical and legal regulations currently in place for federally and DoD-funded research. Program developments will be discussed with a panel of expert external advisors with expertise in bioethical and biosafety issues that may emerge as a consequence of advances in biomedical science and technology. Proposers to this BAA should address potential ethical, legal, and societal implications of the proposed technology.

1.4. PROTECTION OF SENSITIVE INFORMATION

PREEMPT is a 6.1 fundamental research program aimed at enhanced biosurveillance and novel approaches to preempt viral pathogens in animal reservoirs from jumping into human populations. DARPA follows current DoD policy for contracted fundamental research. DARPA recognizes, however, that PREEMPT program components aimed at understanding and quantifying mechanisms for viral zoonotic spillover could potentially generate sensitive information that could be misused. Since this is a fundamental research program, the risk of misuse currently cannot be reasonably evaluated. However, proposers are notified that during proposal evaluation and/or program performance, when such a risk reasonably can be evaluated, DARPA may determine that risk of misuse creates exceptional circumstances, compelling reasons, and/or national security reasons under current DoD policy for contracted fundamental research. DARPA therefore expects that proposers to this program understand and will comply with various government guidance regarding potential gain-of-function research of concern (GOFROC)⁸ and dual use research of concern (DURC)^{9,10,11,12,13}. See https://www.phe.gov/s3/dualuse/Pages/default.aspx for further information.

⁸ Gain-of-Function Research (GOFROC) refers to studies with the potential to generate pathogens with pandemic potential exhibiting high transmissibility and high virulence.

DARPA requires that proposals include a Risk Mitigation Plan that will be incorporated into any resulting agreements or contracts and includes the following information:

- 1) An assessment of potential risks to public health, agriculture, plants, animals, the environment, and national security.
- 2) Proposed guidelines that the proposer will follow to ensure maximal biosafety and biosecurity during the course of the research.
- 3) A communication plan that addresses content, timing, and the extent of distribution of potentially sensitive dual-use information. The plan must also address how input from DARPA, other government, and community stakeholders will be taken into account in decisions regarding communication and publication of potentially sensitive dual-use information.

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 fund a Phase II option based on funding availability, an

⁹ Dual Use Research of Concern (DURC) refers to life sciences research that can be reasonably anticipated to provide knowledge, information, products or technology that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

¹⁰ Proposed framework for the oversight of dual use life sciences research: strategies for minimizing the potential misuse of research information, National Science Advisory Board for Biosecurity (NSABB). June 2007.

¹¹ Recommendations for the evaluation and oversight of proposed gain-of-function research by the National Science Advisory Board for Biosecurity (NSABB). May 2016.

¹² Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern: A Companion Guide to the United States Government Polices for Oversight of Life Sciences Dual Use Research of Concern. NIH. September 2014.

¹³ United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern. DURC Policy. March 2012.

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

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 <u>http://www.darpa.mil/work-with-us/contract-management#OtherTransactions</u>.

In all cases, the Government contracting officer shall have sole discretion to select award instrument type, regardless of instrument type proposed, and to negotiate all instrument terms and conditions with selectees. DARPA will apply publication or other restrictions, as necessary, if it determines that the research resulting from the proposed effort will present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Any award resulting from such a determination will include a requirement for DARPA permission before publishing any information or results on the program. For more information on publication restrictions, see the section below on Fundamental Research.

2.2. FUNDAMENTAL RESEARCH

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

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

As of the date of publication of this BAA, the Government expects that program goals as described herein may be met by proposers intending to perform fundamental research and proposers not intending to perform fundamental research or the proposed research may present a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense. Based on the nature of the performer and the nature of the work, the Government anticipates that some awards will include restrictions on the resultant research that will require the awardee to seek DARPA permission before publishing any information or results relative to the program.

Proposers should indicate in their proposal whether they believe the scope of the research included in their proposal is fundamental or not. While proposers should clearly explain the intended results of their research, the Government shall have sole discretion to select award instrument type and to negotiate all instrument terms and conditions with selectees. Appropriate clauses will be included in resultant awards for non-fundamental research to prescribe publication requirements and other restrictions, as appropriate. This clause 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 being performed by the awardee is restricted research, a subawardee may be conducting fundamental research. In those cases, it is the awardee's responsibility to explain in their proposal why its subawardee's effort is fundamental research

3. Eligibility Information

3.1. ELIGIBLE APPLICANTS

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

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

FFRDCs

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

Authority and Eligibility

At the present time, DARPA does not consider 15 U.S.C. § 3710a to be sufficient legal authority to show eligibility. While 10 U.S.C.§ 2539b may be the appropriate statutory starting point for some entities, specific supporting regulatory guidance, together with evidence of agency approval, will still be required to fully establish eligibility. DARPA will consider FFRDC and

Government entity eligibility submissions on a case-by-case basis; however, the burden to prove eligibility for all team members rests solely with the proposer.

3.1.2. Non-U.S. Organizations

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

3.2. ORGANIZATIONAL CONFLICTS OF INTEREST

FAR 9.5 Requirements

In accordance with FAR 9.5, proposers are required to identify and disclose all facts relevant to potential OCIs involving the proposer's organization and *any* proposed team member (subawardee, consultant). Under this Section, the proposer is responsible for providing this disclosure with each proposal submitted to the BAA. The disclosure must include the proposer's, and as applicable, proposed team member's OCI mitigation plan. The OCI mitigation plan must include a description of the actions the proposer has taken, or intends to take, to prevent the existence of conflicting roles that might bias the proposer's judgment and to prevent the proposer from having unfair competitive advantage. The OCI mitigation plan will specifically discuss the disclosed OCI in the context of each of the OCI limitations outlined in FAR 9.505-1 through FAR 9.505-4.

Agency Supplemental OCI Policy

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

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

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

Government Procedures

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

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

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

3.3. COST SHARING/MATCHING

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

For more information on potential cost sharing requirements for Other Transactions for Prototype, see <u>http://www.darpa.mil/work-with-us/contract-management#OtherTransactions</u>

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 <u>http://www.darpa.mil</u>, contact the administrative contact listed herein.

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

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

Submissions must be written in English.

Abstracts must include the following components:

A. Cover Sheet (does not count towards page limit): Include the administrative and technical points of contact (name, address, phone, fax, email, lead organization). Also

include the BAA number, title of the proposed project, primary subcontractors, estimated cost, duration of the project, and the label "ABSTRACT."

B. Executive Summary Slide: Provide a one slide summary in PowerPoint that effectively and succinctly conveys the main objective, key innovations, expected impact, and other unique aspects of the proposed project. Proposers should use the slide template provided as Attachment 1 to the BAA posted at http://www.fbo.gov.

C. 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 current practice and state-of-the-art (SOA)?
- 4. What are the key technical challenges in your approach and how do you plan to overcome these?
- 5. Who will care and what will the impact be if you are successful?
- 6. How much will it cost and how long will it take?

D. Technical Plan: Outline and address all technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate specific milestones (quantitative, if possible) at intermediate stages of the project to demonstrate progress and a brief plan for accomplishment of the milestones.

E. Capabilities: Provide a brief summary of expertise of the team, including subcontractors and key personnel. A principal investigator for the project must be identified, and a description of the team's organization. Include a description of the team's organization including roles and responsibilities. Describe the organizational experience in this area, existing intellectual property required to complete the project, and any specialized facilities to be used as part of the project. List Government-furnished materials or data assumed to be available. If desired, include a brief bibliography with links to relevant papers, reports, or resumes of key performers. Do not include more than two resumes as part of the abstract. Resumes count against the abstract page limit.

4.2.2. Proposal Format

All full proposals must be in the format given below. Proposals shall consist of two volumes: 1) **Volume I, Technical and Management Proposal**, and 2) **Volume II, Cost Proposal**. All pages shall be printed on 8-1/2 by 11-inch paper with type not smaller than 12 point. Smaller font may be used for figures, tables and charts. The page limitation for full proposals includes all figures, tables, and charts. Volume I, Technical and Management Proposal, may include an attached bibliography of relevant technical papers or research notes (published and unpublished) which document the technical ideas and 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. <u>The submission of other</u> <u>supporting materials along with the proposals is strongly discouraged and will not be considered</u> <u>for review.</u> **The maximum page count for Volume 1 is 36 pages.** A submission letter is optional and is not included in the page count. Volume I should include the following components:

NOTE: Non-conforming submissions that do not 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 (HR001118S0017);
- 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 Grant 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, firm-fixed-price, grant, cooperative agreement, other transaction, or other type (specify);
- 10. Place(s) and period(s) of performance ;
- 11. Proposal validity period;
- 12. Total funds requested from DARPA, and the amount of cost share (if any); AND
- 13. Date proposal was submitted.

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

B. Official Transmittal Letter.

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.** Executive Summary Slide: Provide a one slide summary in PowerPoint that effectively and succinctly conveys the main objective, key innovations, expected impact, and other unique aspects of the proposed project. Proposers should use the slide template provided as **Attachment 1** to the BAA posted at https://www.fbo.gov.
- **C.** 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.
- **D.** 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) and program metrics (see Section 1.2) at intermediate stages of the program to demonstrate progress, and a plan for achieving the milestones. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal. Discuss mitigation of technical risk. The technical plan should address the TA1 and TA2 proposal content requirements detailed in Section 1.1.
- **E.** Management Plan: Provide a summary of expertise of the team, including any subcontractors, and key personnel who will be doing the work. Resumes count against the proposal page count. Identify a principal investigator for the project. 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.

- **F.** Capabilities: Describe organizational experience in relevant subject area(s), existing intellectual property, specialized facilities, and any Government-furnished materials or information. Discuss any work in closely related research areas and previous accomplishments.
- **G.** Statement of Work (SOW): The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. Each phase of the program (Phase I base and Phase II option) should be separately defined in the SOW and each task should be identified by TA (1 or 2). The SOW must not include proprietary information.

For each task/subtask, provide:

- A detailed description of the approach to be taken to accomplish each defined task/subtask.
- Identification of the primary organization responsible for task execution (prime contractor, subcontractor(s), consultant(s), by name).
- A measurable milestone, i.e., a deliverable, demonstration, or other event/activity that marks task completion. Include 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.
- H. Schedule and Milestones: Provide a detailed schedule showing tasks (task name, duration, work breakdown structure element as applicable, performing organization), milestones, and the interrelationships among tasks. The task structure must be consistent with that in the SOW. Measurable milestones should be clearly articulated and defined in time relative to the start of the project.
- I. PREEMPT Transition Plan (see Section 1.2): Proposers must indicate the types of partners (e.g., government, private industry, non-profit) they plan to pursue and submit a timeline with incremental milestones toward successful engagement. Proposers should begin transition activities during the early stages of the program (Phase I). The plan should describe any potential DARPA roles. If the plan includes a start-up company, a business development strategy must be included as well.

- **J.** PREEMPT Risk Mitigation Plan (see Section 1.4): Proposers must provide a risk mitigation plan that addresses the following:
 - An assessment of potential risks to public health, agriculture, plants, animals, the environment, and national security.
 - Proposed guidelines that the proposer will follow to ensure maximal biosafety and biosecurity during the course of the research.
 - A communication plan that addresses content, timing, and the extent of distribution of potentially sensitive dual-use information. The plan must also address how input from DARPA, other government, and community stakeholders will be taken into account in decisions regarding communication and publication of potentially sensitive dual-use information.
- **K.** Ethical, Legal, and Societal Implications (ELSI) (see Section 1.3): Proposers should address potential ethical, legal, and societal implications of the proposed technology.

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

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

a. Volume II, Cost Management Proposal

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

- 1. BAA number;
- 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), CAGE Code(s), and type of business for each;
- 6. Proposal title;
- 7. Technical point of contact (Program Manager or Principal Investigator) to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
- 8. Administrative point of contact (Contracting Officer or Grant 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) and period(s) of performance;
- 11. Total proposed cost separated by basic award and option(s) (if any);
- 12. Name, address, and telephone number of the proposer's cognizant Defense Contract Management Agency (DCMA) administration office (*if known*);
- 13. Name, address, and telephone number of the proposer's cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
- 14. Date proposal was prepared;
- 15. DUNS number (<u>http://www.dnb.com/get-a-duns-number.html</u>);
- 16. Taxpayer ID number (<u>https://www.irs.gov/Individuals/International-</u> <u>Taxpayers/Taxpayer-Identification-Numbers-TIN</u>;
- 17. CAGE code (<u>https://www.dlis.dla.mil/bincs/FAQ.aspx</u>);
- 18. Proposal validity period

Note that nonconforming proposals may be rejected without review.

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. To complete the form, check the boxes on the second page, then provide a narrative explanation of your accounting system to supplement the checklist on page one. For more information, see

(http://www.dcaa.mil/preaward accounting system adequacy checklist.html).

The Government strongly encourages that tables included in the cost proposal also be provided in an editable (e.g., MS Excel) format with calculation formulas intact to allow traceability of the cost proposal numbers across the prime and subcontractors.

The Government requires that the proposer provide a detailed cost breakdown to include:

- (1) Total program cost broken down by Phase I (Base) and Phase II (Option) in Contractor Fiscal Year to include:
 - i. Direct Labor Including individual labor categories with associated labor hours and direct labor rates. If selected for award, be prepared to submit supporting documentation to justify labor rates. (i.e., screenshots of HR databases, comparison to NIH or other web-based salary database);
 - ii. Consultants If consultants are to be used, proposer must provide a copy of the consultant's proposed SOW as well as a signed consultant agreement or other document which verifies the proposed loaded daily / hourly rate, hours and any other proposed consultant costs (e.g., travel);

- iii. Indirect Costs Including Fringe Benefits, Overhead, General and Administrative Expense, Cost of Money, Fee, etc. (must show base amount and rate), if available, provide current Forward Pricing Rate Agreement or Forward Pricing Rate Proposal. If not available, provide 2 years historical data to include pool and expense costs used to generate the rates. For academia, provide DHHS or ONR negotiated rate package or, if calculated by other than a rate, provide University documentation identifying G&A and fringe costs by position;
- iv. Travel Provide the purpose of the trip, number of trips, number of days per trip, departure and arrival destinations, number of people, estimated rental car and airfare costs, and prevailing per diem rates as determined by gsa.gov, etc.; Quotes must be supported by screenshots from travel websites;
- v. Other Direct Costs Itemized with costs including tuition remission, animal per diem rates, health insurance/fee; back-up documentation is to be submitted to support proposed costs;
- vi. Equipment Purchases Itemization with individual and total costs, including quantities, unit prices, proposed vendors (if known), and the basis of estimate (e.g., quotes, prior purchases, catalog price lists, etc.); any item that exceeds \$5,000 must be supported with back-up documentation such as a copy of catalog price lists or quotes prior to purchase (NOTE: For equipment purchases, include a letter stating why the proposer cannot provide the requested resources from its own funding), and;
- vii. Materials Itemization with costs, including quantities, unit prices, proposed vendors (if known), and the basis of estimate (e.g., quotes, prior purchases, catalog price lists, etc.); any item that exceeds \$5,000 must be supported with back-up documentation such as a copy of catalog price lists or quotes prior to purchase.
- (2) A summary of total program costs by major task;
- (3) A summary of projected funding requirements by month;
- (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) 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);
- (6) The source, nature, and amount of any industry cost-sharing. Where the effort consists of multiple portions which could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each;
- (7) Identification of pricing assumptions of which may require incorporation into the resulting award instrument (e.g., use of Government Furnished Property/Facilities/Information, access to Government Subject Matter Expert/s, etc.);
- (8) Any Forward Pricing Rate Agreement, DHHS rate agreement, other such approved rate information, or such documentation that may assist in expediting negotiations (if available); and
- (9) Proposers with a Government acceptable accounting system who are proposing a cost-type contract must submit the DCAA document approving the cost accounting system.

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* email must be sent to the BAA mailbox requesting submission instructions from the Technical Office PSO. If a determination is made that the award instrument may result in access to classified information, a SCG and/or DD Form 254 will be issued by DARPA and attached as part of the award.

Human Research Subjects/Animal Use

Proposers that anticipate involving Human Research Subjects or Animal Use must comply with the approval procedures detailed at <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

Small Business Subcontracting Plan

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

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

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

Intellectual Property

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

For Procurement Contracts

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

The table below captures the requested information:

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

For All Non-Procurement Contracts

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

System for Award Management (SAM) and Universal Identifier Requirements

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

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 HR001118S0017. <u>Submissions may not be submitted by fax or e-mail; any so sent will be disregarded.</u>

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.

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

Proposers must submit an original hardcopy and one (1) electronic copy of the abstract or proposal in PDF (preferred) on a CD-ROM to the mailing address listed in Part I. Each copy must be clearly labeled with HR001118S0017, proposer organization, technical point of contact, and proposal title (short title recommended).

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

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

Abstracts and Full Proposals sent in response to HR001118S0017 may be submitted via DARPA's BAA Website (https://baa.darpa.mil). Visit the website to complete the two-step registration process. Submitters will need to register for an Extranet account (via the form at the URL listed above) and wait for two separate e-mails containing a username and temporary password. After accessing the Extranet, submitters may then create an account for the DARPA BAA website (via the "Register your Organization" link along the left side of the homepage), view submission instructions, and upload/finalize the abstract. Proposers using the DARPA BAA Website may encounter heavy traffic on the submission deadline date; it is highly advised that submission process be started as early as possible.

All unclassified concepts submitted electronically through DARPA's BAA Website must be uploaded as zip files (.zip or .zipx extension). The final zip file should be no greater than 50 MB in size. Only one zip file will be accepted per submission. Classified submissions and proposals requesting assistance instruments (grants or cooperative agreements) should NOT be submitted through DARPA's BAA Website (<u>https://baa.darpa.mil</u>), though proposers will likely still need to visit <u>https://baa.darpa.mil</u> 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 <u>BAAT_Support@darpa.mil</u>, and is typically available during regular business hours, (9:00 AM- 5:00 PM EST Monday – Friday).

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

For Full Proposals Requesting Cooperative Agreements:

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

<u>Grants.gov Submissions:</u> 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 <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

<u>Hard-copy Submissions</u>: Proposers electing to submit grant or cooperative agreement proposals as hard copies must complete the SF 424 R&R form (Application for Federal Assistance,) available on the Grants.gov website http://aaply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf.

nup://aapiy07.grants.gov/appiy/forms/sample/KK_SF424_2_0-v2.0.pdf.

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

4.2.5. 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 <u>http://www.darpa.mil/work-with-us/additional-baa#NPRPAC</u>.

Compliance with the above requirements includes the mandate for proposers to implement the security requirements specified by National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations" (see https://doi.org/10.6028/NIST.SP.800-171rl) that are in effect at the time the BAA is issued, or as authorized by the Contracting Officer, not later than December 31, 2017.

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.

4.3. FUNDING RESTRICTIONS

Not Applicable.

4.4. OTHER SUBMISSION REQUIREMENTS

Not Applicable.

5. Application Review Information

5.1. EVALUATION CRITERIA

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

5.1.1. Overall Scientific and Technical Merit

The proposed technical approach is innovative, feasible, achievable, and complete.

Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed deliverables clearly defined such that a final outcome that achieves the goal can be expected as a result of award. The proposal identifies major technical risks and planned mitigation efforts are clearly defined and feasible. The proposed PREEMPT Risk Mitigation Plan effectively provides the following: an assessment of potential risks; proposed guidelines to ensure maximal biosafety and biosecurity; a risk management plan for responsible communications; and a plan to address how input from the Government and community stakeholders will be considered regarding communication and publication of potentially sensitive dual-use information.

5.1.2. Potential Contribution and Relevance to the DARPA Mission

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

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

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.

5.2. REVIEW OF PROPOSALS

Review Process

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

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

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

Handling of Source Selection Information

DARPA policy is to treat all submissions as source selection information (see FAR 2.101 and 3.104), and to disclose their contents only for the purpose of evaluation. Restrictive notices notwithstanding, during the evaluation process, submissions may be handled by support contractors for administrative purposes and/or to assist with technical evaluation. All DARPA support contractors performing this role are expressly prohibited from performing DARPA-sponsored technical research and are bound by appropriate nondisclosure agreements. Subject to the restrictions set forth in FAR 37.203(d), input on technical aspects of the proposals may be solicited by DARPA from non-Government consultants/experts who are strictly bound by the appropriate non-disclosure requirements.

Federal Awardee Performance and Integrity Information (FAPIIS)

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

6. Award Administration Information

6.1. SELECTION NOTICES

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

6.1.1. Proposal Abstracts

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

6.1.2. Full Proposals

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

6.2. ADMINISTRATIVE AND 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. FAR and DFARS Clauses

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

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

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

6.2.3. Representations and Certifications

If a procurement contract is contemplated, prospective awardees will need to be registered in the SAM database prior to award and complete electronic annual representations and certifications consistent with FAR guidance at 4.1102 and 4.1201; the representations and certifications can be found at www.sam.gov. Supplementary representations and certifications can be found at <u>http://www.darpa.mil/work-with-us/additional-baa</u>.

6.2.4. Terms and Conditions

A link to the DoD General Research Terms and Conditions for Grants and Cooperative Agreements and supplemental agency terms and conditions can be found 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 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 <u>https://wawf.eb.mil</u>, 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 (<u>http://public.era.nih.gov/iedison</u>).

7. Agency Contacts

Communication via e-mail is preferred.

Points of Contact The BAA Coordinator for this effort may be reached at: <u>PREEMPT@darpa.mil</u> DARPA/BTO ATTN: HR001118S0017 675 North Randolph Street Arlington, VA 22203-2114

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

8. Other Information

DARPA will host a Proposers Day in support of the PREEMPT program on **January 30, 2018**, at the Executive Conference Center in Arlington, VA. The purpose is to provide potential

proposers with information on the PREEMPT program, promote additional discussion on this topic, address questions, provide a forum to present their capabilities, and to encourage team formation.

Interested proposers are not required to attend to respond to the PREEMPT 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. The event will be webcast for those who would like to participate remotely.

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, <u>https://events.sa-meetings.com/PREEMPTProposersDay</u>.

To encourage team formation, interested proposers are encouraged to submit information to be shared with all potential proposers through the Proposers Day website and the DARPA Opportunities Page. This information may include contact information, relevant publications, and a slide or poster to summarize the proposer's interests.

Participants are required to register no later than **January 23, 2018**, for physical attendance, and **January 26, 2018**, for the webcast. This event is not open to the Press. The Proposers Day will be open to members of the public who have registered in advance for the event; **there will be no onsite registration**.

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

Proposers Day Point of Contact: DARPA-SN-18-18@darpa.mil.

9. Appendix 1 – Volume II checklist

Volume II, Cost Proposal Checklist and Sample Templates

The following checklist and sample templates are provided to assist the proposer in developing a complete and responsive cost volume. Full instructions appear in Section 4.2.2 beginning on Page 25 of HR001118S0017. 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 **HR001118S0017** 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:

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

Direct Labor (Labor Categories, Hours, Rates)			
○ YES	• NO	Appears on Page(s) [Type text]	
Indirect Costs/R	ates (i.e., overhe	ad 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/Con	nsultants		
• YES	• NO	Appears on Page(s) [Type text]	
120	110		
Other Direct Cos	ts		
• YES	• NO	Appears on Page(s) [Type text]	
○ 1E5		Appears on rage(s) [rype text]	
Travel			
• YES	• NO	Appears on Paga(s) [Type text]	
U LES		Appears on Page(s) [Type text]	

If reply is "No", please explain:

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

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

If reply is "No", please explain:

5. Does your cost proposal include a complete itemized list of <u>all</u> material and equipment items to be purchased (a priced bill-of-materials (BOM))?

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

If reply is "No", please explain:

6. Does your cost proposal include vendor quotes or written engineering estimates (basis of estimate) for <u>all</u> 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:

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:

If reply is "No", please explain:

If reply is "No", please explain: