Broad Agency Announcement

INTERfering and Co-Evolving Prevention and Therapy

BIOLOGICAL TECHNOLOGIES OFFICE

DARPA-BAA-16-35

April 28, 2016

TABLE OF CONTENTS

PART I: OVERVIEW INFORMATION

- **Federal Agency Name** – Defense Advanced Research Projects Agency (DARPA), Biological Technologies Office
- **Funding Opportunity Title –** INTERfering and Co-Evolving Prevention and Therapy
- **Announcement Type –** Initial announcement
- **Funding Opportunity Number –** DARPA-BAA-16-35
- **Catalog of Federal Domestic Assistance Numbers (CFDA) – "12.910 Research and Technology Development"**
- **Dates**
  - Posting Date **(Date Posted to FBO and/or Grants.gov – to be completed by CMO)**
  - Proposal Abstract Due Date – **Thursday, May 19 4:00 PM ET**
  - Proposal Due Date – **Thursday, July 7, 2016 4:00 PM ET**
  - Proposers' Day – **Thursday, April 28, 2016**

Concise description of the funding opportunity - DARPA is soliciting innovative proposals for research to explore and develop therapeutic interfering particles as a novel approach to address infections from fast evolving viral pathogens.

- **Anticipated individual awards** - Multiple awards are anticipated.
- **Types of instruments that may be awarded** - Procurement Contract, Cooperative Agreement, Grant, or Other Transaction.
- **Agency contact**
  - Points of Contact
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PART II: FULL TEXT OF ANNOUNCEMENT

1. Funding Opportunity Description

The Defense Advanced Research Projects Agency often selects its research efforts through the Broad Agency Announcement (BAA) process. This BAA is being issued, and any resultant selection will be made, using procedures under Federal Acquisition Regulation (FAR) 35.016 and the Department of Defense Grant and Agreement Regulatory System (DoDGARS) Part 22 for Grants and Cooperative Agreements. Any negotiations and/or awards will use procedures under FAR 15.4, Contract Pricing, as specified in the BAA (including DoDGARS Part 22 for Grants and Cooperative Agreements). Proposals received as a result of this BAA shall be evaluated in accordance with evaluation criteria specified herein through a scientific review process.

DARPA BAAs are posted on the Federal Business Opportunities (FedBizOpps) website at https://www.fbo.gov and, as applicable, the Grants.gov website at http://www.grants.gov. The following information is for those wishing to respond to the BAA.

DARPA is soliciting innovative research proposals to explore and evaluate the potential of a radically different therapeutic and preventative approach to combat and outpace fast-evolving viral pathogens based on viral therapeutic interfering particles.

1.1. PROGRAM OVERVIEW

Current preventive and therapeutic approaches to address viral pathogens, including vaccines and anti-virals, are designed to target the virus in its circulating state or at the time of diagnosis. However, pathogens mutate and evolve over time, becoming resistant to many therapies. Fast-evolving viruses with changing/heterogeneous surface antigens or complex immunopathogenesis among multiple serotypes (e.g., influenza and dengue, respectively) are particularly challenging. The current paradigm of static therapeutics and preventives relies on repeated and time-consuming development, manufacturing, and testing of new therapies and vaccines. This results in major health response gaps, economic burden, and limited capability to respond rapidly to emerging strains and bio threats. For many viral diseases there are no approved vaccines and few (if any) therapeutic options. The goal of the INTERfering and Co-Evolving Prevention and Therapy (INTERCEPT) program is to explore and evaluate virus-based therapeutic interfering particles (TIPs) that parasitize, interfere, and co-evolve with viral targets as a means of adaptively preventing, controlling, and eliminating acute or chronic infection.

The novel path explored in this program is based upon previously reported Defective Interfering Particles (DIPs), viral-derived particles with partially deleted genomes that arise during a natural infection. DIPs lack genes encoding replication enzymes and capsid proteins, and thus require co-infection with the wildtype parent virus to replicate and mobilize.[1] DIPs have been isolated from numerous viral infections and shown to interfere with the replication and packaging processes through stoichiometric competition for essential viral components.[2] It has been

[1] Huang, A. S. & Baltimore, D. (1970). Defective viral particles and viral disease processes. Nature (Review).

suggested that DIPs may have therapeutic and protective potential and may serve as a broad range treatment approach to combat respiratory infections. For example, a cloned Influenza-A DIP was effective in protecting from infection by Influenza-A, as well as by heterologous respiratory viruses in small animal models.[3] In addition, given their transmission potential, it has been proposed that interfering viral particles may serve as anti-viral therapies to reduce disease incidence and thus control epidemics.[4]

The INTERCEPT program aims to explore and evaluate the potential of TIPs as a therapeutic and/or preventive approach for the long term control of a broad range of fast-evolving viruses. The program will address the key technical challenges and risks of TIP safety, efficacy, long-term co-evolution, and generalizability, by leveraging novel molecular and genetic design tools, high throughput genomic technologies, and advanced computational methods in a multidisciplinary, multi-team effort.

To explore the TIP concept as a potential therapeutic and/or preventive platform that can keep pace with fast-evolving pathogens, INTERCEPT will address four fundamental questions:

1. Safety & efficacy: Can TIPs be built that are safe and out-compete the pathogen to control infections short-term?
2. Co-evolution: Can TIPs evolve and keep pace with evolving pathogens to control an infection long-term?
3. Population-scale efficacy: Can TIPs co-transmit alongside pathogen to help control the spread of infectious disease across populations?
4. Generalizability: Can the TIP concept be extended across multiple viruses and for multiple acute and chronic infectious diseases?

DARPA anticipates that the INTERCEPT program will encompass a four year effort organized in two phases of two years duration each. During the Phase I period, performer teams will establish proof-of-concept of TIPs safety, broad range efficacy, and initial TIP-pathogen co-evolution using *in vitro* and *in vivo* models of viral infection, as well as mathematical models of TIP-pathogen-host dynamics. The Phase II period will focus on the validation of long-term TIP safety and efficacy, long-term co-evolution studies, and TIP co-transmission dynamics for population-scale disease control.

INTERCEPT research objectives are structured along three Technical Areas (TAs), to be addressed concurrently: (1) TIP development and *in vitro* screening; (2) TIP optimization and *in vitro* and *in vivo* assessment of long-term safety; efficacy, and co-evolution with parent wildtype virus; and (3) mathematical modeling of TIP-pathogen-host dynamics to support TIP optimal design and predict TIP long-term safety, efficacy, co-evolution and co-transmission.

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[2] Dimmock N.J. & Easton A.J. (2014). Defective interfering influenza virus RNAs: time to reevaluate their clinical potential as broad-spectrum antivirals? J Virol (Review).
[3] Easton AJ, Dimmock NJ. (2015). Cloned Defective Interfering Influenza RNA and a Possible Pan-Specific Treatment of Respiratory Virus Diseases. Viruses (Review).
[4] Metzger, V. T., Lloyd-Smith, J. O. & Weinberger, L. S. (2011). Autonomous targeting of infectious superspreaders using engineered transmissible therapies. PLoS Comput Biol.

Proposers must address one of the following:

- All three Technical Areas;
- Technical Areas 2 and 3; or
- Technical Area 3.

Proposals that focus solely on Technical Area 1 or solely on Technical Area 2 will not be considered for funding. Proposers selected to pursue Technical Area 3 independently must identify one or more collaborators with whom they could team with to address Technical Area 2 before the end of the first year of contract.

Milestones will be negotiated between proposers and DARPA and structured to provide early validation results (see Table 2, page 14 for notional metrics); Phase II of the program will focus on those pathogens of interest and TIP approaches that successfully meet initial safety and efficacy targets and are most likely to advance the TIP platform.

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.

Technical Area 1 (TA1): TIP engineering and screening

Studies within this Technical Area aim to generate TIP prototypes demonstrating safety and broad range efficacy in short term *in vitro* assays. Proposers should select one or more pathogens from the provided list of viral pathogens of interest (Table 1), and describe a technical approach for building several virus-specific TIP prototype candidates, and for testing the TIPs for short-term safety and efficacy using conventional *in vitro* methods. Proposers should justify choice of virus candidates using data, models, and reasoned explanations, based on: (1) likelihood of successful TIP therapy; (2) plausible path for TIP design, development, and optimization; and (3) availability or ease of developing suitable models for testing. The INTERCEPT program aims to explore the TIP approach for either or both chronic and acute infectious diseases (see Table 1).

TIP design: Proposers should outline a detailed approach to generate TIPs using state-of-the-art cloning and molecular techniques. For the purpose of this BAA, TIPs are defined as engineered virus-like particles that depend on the wildtype parent virus to replicate and mobilize. Proposers should consider TIP designs that adhere to the following criteria: (1) contain parental viral proteins; (2) contain part of the parental viral genome; (3) require complementation by a non-defective homologous virus for replication; (4) interfere specifically with replication of the parental wildtype virus; and (5) target the same cell/tissue as the parental wildtype virus. Approaches to TIP generation may include (but are not limited) to: (a) random deletion libraries; (b) site-directed deletions; (c) alterations of naturally emerging DI particles; (d) reverse genetics; and (e) hybrid approaches involving multiple techniques. TIPs should also be designed to enable tracking of specific TIP candidates and TIP molecular sequences (i.e. through molecular tagging, barcoding, fluorescent labeling, or other). Proposers should identify adequate methods to package, isolate and/or enrich TIPs from parental wildtype virus populations.

TIP efficacy: Proposers should describe how they will quantitatively assess TIP candidates for their ability to reduce viral load using established *in vitro* assays (e.g., viral infectivity assays,

ratio of TIP to viral genomes, and viral particle counts) at various multiplicity of infections (MOI) and for a range of TIP concentrations. Proposers should also describe how they will investigate mechanisms for TIP-mediated interference of viral replication, such as competition for essential viral components or activation of anti-viral immunity pathways. In addition, proposers should describe a plan to assess the TIP prototype candidates for broad efficacy across pathogen strain variants within a given species (e.g., HIV strain variants) and/or within a genus sub-group (e.g., multiple dengue serotypes).

TIP safety: A key safety requirement is that TIPs cannot replicate in uninfected cells and should remain dormant until the host cell is co-infected by the associated wildtype pathogen. Proposers should plan to investigate if TIP prototypes affect cell viability, and whether TIPs are transcriptionally silent, do not replicate, and are not mobilized either in the absence of the wildtype virus or in the presence of viral strains unrelated to the parent virus. These assessments should be conducted at various multiplicity of infections (MOI), for a range of TIP concentrations, and when exposed pre- and post-infection with the wildtype virus.

TIP prototype molecular design and testing may be further optimized based on design parameter requirements predicted from modeling studies in Technical Area 3 and on long-term *in vitro* and/or *in vivo* assessment studies from Technical Area 2.

Table 1. Viral pathogens of interest, including the National Institute of Allergy and Infectious Diseases category A, B, and C pathogens for which limited vaccines or therapies are available. (http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Pages/CatA.aspx).

HIGH PRIORITY VIRAL PATHOGHENS			
Dengue	SARS-CoV	Ebola	JC virus
Zika	MERS-CoV	Crimean Congo HV	BK virus
Hantaviruses	Lassa	Lujo	Chapare
Nipah	Junin	Machupo	Guanarito
Hendra	Sabia	Caliciviruses	West Nile
Rift Valley Fever	St. Louis encephalitis	LaCrosse encephalitis	California encephalitis
Western equine encephalitis	Eastern equine encephalitis	Enterovirus 68	Enterovirus 71
Chikungunya	Hepatitis C	Herpes simplex	HIV
Japanese encephalitis	Venezuelan equine encephalitis	Influenza	Hepatitis E
Crimean Congo Hemorrhagic Fever	Marburg	Severe Fever with Thrombocytopenia Syndrome	Heartland
Omsk Hemorrhagic Fever	Alkhurma virus	Kyasanur Forest	Tickborne encephalitis complex flaviviruses

By the end of Phase I (year 2), performers are expected to have completed the proposed *in vitro* efficacy and safety studies with one or more rounds of optimization of virus-specific TIP candidates for each selected pathogen. Performers should demonstrate broad-range efficacy of optimized TIPs across multiple pathogen strain variants and/or within various pathogen

serotypes. Proposers should provide yearly intermediate metrics and milestones specific to their proposed approach (see Table 2). The proposed number and depth of proposed studies should allow for completion within the 24-month Phase I period. TA1 efforts may continue into years 3 and 4 if further TIP optimizations are prescribed based upon the empirical testing results of TA2 and the modeling results of TA3.

Technical Area 2 (TA2): Optimization for long-term TIP safety, efficacy, and co-evolution

Studies under this Technical Area should address the long-term efficacy, safety, evolutionary stability, and transmission of TIP prototypes developed in TA1, and the long-term effects of TIPs on wildtype virus evolution, persistence, and transmission. Proposers may choose to test selected TIP prototypes directly in animal models, without previous assessment in long-term dynamic *in vitro* systems (this selected path should be fully justified).

Long-term in vitro monitoring: Traditional *in vitro* cell culture systems may not be suitable for continuous, long-term assessment of virus and TIP co-evolution. Proposers should devise dynamic, *in vitro* platforms that sustain continuous virus evolution for extended periods of time (weeks to months). The proposed system should enable continuous operation and control of critical parameters while closely emulating physiological conditions (*e.g.*, maintain a steady state target cell population and exponential or otherwise appropriate growth/replication of wildtype virus and TIPs). The proposed dynamic *in vitro* system should be used to assess wildtype virus-TIP co-evolution in a time-dependent and systematic manner. In the context of this BAA, co-evolution of wildtype virus and TIP is defined as the accumulation of hereditary genetic changes during the lifespan of both wildtype virus and TIP, arising from replication errors and adaptations to changing environment, including TIP and the wildtype virus selective pressures. In addition, the dynamic *in vitro* system should be used to optimize and/or select for TIP candidates with high efficacy (*e.g.*, isolating and enriching for promising low frequency TIP candidates, implementing controlled selective pressures, or other proposed techniques). Examples of dynamic *in vitro* systems may include, but are not limited to: (1) bioreactors that sustain continuous feeding of healthy cells and removal of dead cells with controlled wildtype virus and TIP removal; (2) high-throughput microfluidic systems that can track viral evolution at the single cell level; and (3) organ-on-a-chip infection models (provided the system has been developed previously and is available for use with minimal modifications). The use of continuous cell passaging may be used only if well-justified.

Quantifying virus and TIP co-evolution: Proposers should outline approaches to quantify wildtype virus and TIP genetic diversity at given time points, as well as longitudinal diversification, TIP genetic stability, and wildtype virus escape via monitoring of mutation rates, recombination rates, replication rates, stoichiometric competition, and/or other parameters established by the proposer. Appropriate approaches, including possible use of markers, reporters, and new sequencing technologies, as well as experimental controls should be described. Proposers should provide a plan to assess and quantify the long-term stability, safety, and efficacy of TIP prototypes in the dynamic *in vitro* system under different conditions, *e.g.*, different target cell lines, various times of TIP introduction, multiple MOIs and/or other parameters established by the proposer. Long-term, wide-range efficacy against pathogen-related strains also should be addressed in the dynamic *in vitro* system. The exploration of TIP cocktails

to broaden TIP efficacy to a range of viral strains and/or serotypes, and to prevent viral escape, is encouraged.

Long-term in vivo assessment: Proposers should describe appropriate animal models of chronic and/or acute infection and a reasonable plan to investigate TIP safety, stability, co-evolution, and efficacy at varied TIP dose range and exposure times pre- and/or post-infection. Proposers should determine the most promising TIP prototype or TIP prototype cocktails to be tested in animal models based on *in vitro* results from TA1 and/or TA2 safety and efficacy studies. TIP prototype selection and animal study design (*e.g.*, TIP dose and exposure time range to be tested) may also be informed by within-host mathematical model predictions from TA3.

In vivo safety and stability: Animal studies should address any potential long-term toxicity of selected TIP candidates in the absence of parent virus and/or in the presence of non-parent virus. TIP safety monitoring may include, but is not limited to: (1) adverse effects on host health; (2) innate and adaptive host immune responses; (3) TIP distribution and specificity to target cells/tissues; (4) TIP activation in the absence of parent wildtype virus; and (5) TIP clearance from the host. Studies addressing TIP stability in the presence of wildtype parent virus may include, but are not limited to: (1) TIP genome recombination and reversion to an infectious state; (2) TIP genome co-packaging with wildtype virus; and (3) TIP diversification from parent wildtype virus (*e.g.*, TIP no longer competes for viral factors). Appropriate metrics to determine TIP safety and stability *in vivo* should be established by the proposer.

In vivo efficacy: Proposers should provide sound approaches to quantify long-term efficacy of TIP prototypes in chronic animal models of infection and/or short-term efficacy in acute animal models of infection. These studies should examine dose-dependent kinetics of TIP activation, stoichiometric competition, and efficacy (*e.g.*, reduced viral replication/titers, clinical improvement, reduced viral shedding, and increased viral clearance) as a function of days post infection (dpi) and viral MOI. In addition, suitable routes of TIP delivery should be identified and/or investigated (*e.g.*, intranasal, intramuscular, and/or intradermal). Proposers should explore TIP feasibility as a preventive modality in acute and/or chronic infection settings, for example, by testing TIP latency, physical stability (*i.e.*, half-life), and competition when administered within a measured timeframe prior to infection with wildtype virus. TIP preventive or therapeutic efficacy may depend on cell/tissue/organ tropism, routes of administration, viral MOI, and dose and timing parameters, all of which should be explained in the experimental approach. Proposers should outline appropriate metrics to determine *in vivo* efficacy.

Virus, TIP, and host immune response dynamics: Proposers should provide a well-reasoned approach to study co-evolution between wildtype virus and TIP under the influence of the host immune response. Studies that exploit non-traditional technologies are strongly encouraged. These may include, but are not limited to, longitudinal assessment of TIP and wildtype virus evolution at the single molecule level, advanced imaging and metrics to quantify wildtype virus and TIP amplification within the host, and tracking single molecule mutation trajectories (*e.g.*, single molecule labeling, virus reporters, and real-time detection by whole body imaging). These studies may also be informed by within-host mathematical model predictions from TA3.

TIP transmission: Transmission studies to assess TIP efficacy to control disease spread at the population level may be explored in experimental animal models of chronic and/or acute infection. Such studies should address wildtype virus and TIP co-transmission kinetics, and identify relevant parameters involved. These may include, but are not limited to: (1) wildtype virus and TIP load thresholds for co-transmission; (2) mechanisms of co-transmission; and (3) kinetics of co-transmission (including cell/tissue/organ tropism).

Vector-mediated mechanisms: Proposers are encouraged to explore vector-mediated (*e.g.*, mosquito) TIP transmission and evolution. It has been suggested that DIPs, while reducing infectivity, may enhance persistence of wildtype virus infections (*e.g.*, for certain flaviviruses) in cell culture and *in vivo*.[5,6] Proposers should address whether and how TIPs may affect wildtype virus persistence within the host, and/or within the vector using appropriate models. Proposals that describe approaches for reducing TIP-mediated long-term persistence of the wildtype virus, and TIP-mediated suppression of wildtype virus in the vector, are encouraged. Proposers should provide a well-reasoned plan to study wildtype virus and TIP co-evolution, stability, and persistence, as well as mechanisms of co-transmission within vectors and associated reservoirs. These studies also may be informed by population-level mathematical model predictions from TA3.

Proposers must identify all animal study vendors and facilities, including the appropriate biosafety level (BSL), and provide a letter of intent for each subcontractor at the time of proposal submission. Contracted service vendors should demonstrate capability for accommodating the animal species to be tested as outlined in proposed experimental plan, including small and large animals.

Human use studies will be considered if proposers: (1) describe a feasible path by which they can obtain the prerequisite toxicity, safety, and dosage data from animal studies; (2) outline a detailed plan for obtaining all necessary human use approvals within the program time frame; and (3) provide a well-reasoned plan to address TA3 with results obtained from human subjects (*i.e.* develop *in silico* models of TIP safety, efficacy, and co-evolution).

TA2 studies may span the 4-year program duration. The outputs of TA2 should include empirical, quantitative data on TIP long-term stability, safety, efficacy, and co-evolution dynamics with the pathogen. Data from these experiments should inform the *in silico* model developments in TA3 and also may inform TIP design optimization in TA1. Proposers should outline reasonable yearly program metrics and milestones, such as those suggested in Table 3.

[5] Salas-Benito J.S. and De Nova-Ocampo M. (2015). Viral Interference and Persistence in Mosquito-Borne Flaviviruses. Journal of Immunology Research (Review).
[6] Ke R et al. (2013). Phylodynamic Analysis of the Emergence and Epidemiological Impact of Transmissible Defective Dengue Viruses. PLoS Pathogens.

Technical Area 3 (TA3): Mathematical modeling

Mathematical models have been reported that describe dynamics of wildtype virus and DIPs at the single cell, host, and population levels. [4,6,7,8] A critical component of the INTERCEPT program is the development of a quantitative, multiscale, *in silico* model that can map and predict long-term co-evolutionary dynamics of the wildtype virus, TIP, and host interactions. Proposers may leverage and build upon existing mathematical models of viral evolution and transmission. It is expected that models developed in the INTERCEPT program will move beyond the standard pathogen-host dynamics to include TIP dynamics, and to account for the large spectrum of wildtype virus and TIP variants that co-exist at any given time within the host and in a population.

Single cell modeling: Proposers should describe their approach to building computational tools to simulate intracellular wildtype virus and TIP dynamics as well as the cell output of wildtype virus and TIP progeny. These models should aim to capture the kinetics of wildtype virus and TIP replication, wildtype virus and TIP production ratios, TIP persistence, TIP interference, molecular dynamics of competition between wildtype virus and TIP, mutational rates and evolution of wildtype virus and TIP within a cell, cell-to-cell variability, and/or other parameters relevant to the system.

Within-host modeling: Proposers should describe their approach to modeling the long-term co-evolution of wildtype virus and TIP, as well as TIP safety and efficacy within a host. Model outputs may include, but are not limited to: (1) TIP impact on viral loads (efficacy) as a function of TIP dosage and time of intervention; (2) probability of wildtype virus escape under TIP selective pressure; (3) probability of a TIP to revert to virulence (e.g., recombination between wildtype virus and TIP or other means); (4) TIP impact on viral persistence; and (5) within-host TIP spatial dynamics (e.g., distribution to target organ). The role of host immune response as a natural selection pressure on long-term wildtype virus and TIP co-evolutionary dynamics should be incorporated into the models. The mathematical models should also describe cell and host variability and their potential impact to TIP design and requisites for optimal TIP-to-virus production ratios.

Population modeling: Proposers should describe their approach to population-scale modeling of TIP dynamics within a population. These models should predict TIP impacts on viral transmission dynamics and the potential to control disease spread. Models should predict wildtype virus and TIP long-term co-evolution rates and trajectories within a population, wildtype virus and TIP co-transmission dynamics, and/or the role of vectors on co-evolution and co-transmission dynamics (e.g., mosquito-borne diseases). Data from population-level modeling should further inform TIP design and constraints to enable TIP effectiveness across populations (e.g., provide the TIP-to-virus stoichiometric production ratio across viral strains required for population-scale disease control). Proposer should provide a plan for generalizing these multi-scale models for applicability to other viruses and associated TIPs. Models may also describe

[7] Reichl U et al. (2016). Modeling the intracellular replication of influenza A virus in the presence of defective interfering RNAs. Virus Research.

[8] Ke R and Loyd-Smith J. (2012). Evolutionary Analysis of Human Immunodeficiency Virus Type 1 Therapies Based on Conditionally Replicating Vectors. PLOS Comp Bio.

and predict TIP capability as a complementary therapy to traditional anti-viral therapies and/or vaccines, or for slowing disease progression while the host mounts an effective immune response.

Studies in this Technical Area may span the entire 4-years duration of the program. It is expected that TA3 will be informed by empirical data obtained in TA1 and TA2, but proposers are also encouraged to utilize any accessible pre-existing retrospective datasets from animal and human infectious diseases studies that may assist in analysis and validation of the models generated. Data and results obtained from the *in silico* models should guide optimal TIP design and dosage parameters for TIP optimization in TA1 and TA2. Proposers should outline reasonable yearly program metrics and milestones, such as those suggested in Table 4.

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 INTERCEPT 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 interpretations. Data obtained from human volunteers must be provided in a coded format that protects subject identities, but must contain diagnosis (signs/symptoms), interventions, technical observations, diagnostic tests/results, and outcomes. All raw data and metadata should be recorded appropriately following approved experimental standards.

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

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 (with permission to access, reuse, and redistribute under appropriate licensing terms) to the extent permitted by applicable law and regulations (e.g., privacy, security, and export control).

The proposers must describe a plan to share data with teams both internally to the INTERCEPT performer group and externally with the broader research community. Proposers should demonstrate an understanding of data file types, sizes, annotations, and other metadata components associated with the experiment(s) proposed. Proposers should indicate the extent of their team's familiarity with open data and open-access journals. Proposers should provide timelines for dataset availability to the broader research community.

Period of Performance:

DARPA anticipates that the INTERCEPT program will provide up to four years of funding for research and development to be performed in two phase periods of 2 years each.

1.1.1. Phase I

Phase I efforts aim to establish proof-of-concept TIP safety, broad-range efficacy, and short-term co-evolution capability. By the end of Phase I performers will be expected to:

1. Demonstrate proof-of-concept that engineered and optimized TIP prototypes are safe and can effectively outcompete the virus(es) of choice *in vitro* and/or *in vivo*.
2. Demonstrate understanding of TIP molecular mechanisms.
3. Provide initial evidence of TIP short-term coevolution with the pathogen.
4. Demonstrate TIP efficacy against a broad range of viral strains and/or subtypes closely related to the parental wildtype virus.
5. Demonstrate initial *in silico* models that describe virus and TIP dynamics at the single cell level, and long-term safety, efficacy, and co-evolutionary stability at the host level.

1.1.2. Phase II

Phase II efforts aim to explore TIPs safety, efficacy, and co-evolution in long-term assessments. Phase II efforts also aim to evaluate TIP transmissibility and use in population-scale control of disease. By the end of Phase II performers will be expected to:

1. Demonstrate long-term safety and efficacy of optimized TIP(s) in a dynamic *in vitro* system and in animal models of chronic and/or acute infection.
2. Demonstrate long-term co-evolution of wildtype virus and TIP, and establish proof-of-concept TIP co-transmission in animal models.
3. Demonstrate TIP long-term stability and efficacy, and, for vector-borne pathogens, dynamics of virus and TIP co-transmission and co-evolution within the vector.
4. Demonstrate host-scale *in silico* models that describe and integrate dynamics among TIP, wildtype virus, and host immune response.
5. Demonstrate population-scale models that predict long-term TIP safety, efficacy, and evolution within a population, and define critical feedback metrics for population-level virus control via TIP co-transmission.

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 may 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 time of contracting.

Table 2: Milestones, Deliverables, and Program Metrics for TA1

Phase	Milestones **and Deliverables**	**Program Metric**
I	Initial TIP prototypes that: • Out-compete virus *in vitro* • Cannot replicate, and mobilize in absence of parent wildtype virus Mechanisms of TIP functional efficacy elucidated (Encouraged)	Quantitative measures of: • Short-term TIP efficacy for a range of virus MOI and TIP doses • Short-term TIP safety in cell culture for a range of virus MOI and TIP doses • Broad-range efficacy to out-compete multiple virus strain variants
	TIP design strategies for targeting a second or third selected viruses of one or more broad types (based on Baltimore classification) (Optional)	(Same as above for a second and/or third virus-specific TIP *in vitro)*
II	Further optimization of TIP prototypes: • Genome sequences of Phase I TIPs further optimized based on modelling data (TA3) • Long-term evaluation of safety and efficacy in bioreactor and/or animal models	(Same as above, to include all progressive improvements with advancing optimizations)

Table 3: Milestones, Deliverables, and Program Metrics for TA2

Phase	Milestones and Deliverables	Program Metric
I	Demonstrated dynamic *in vitro* system capable of maintaining long-term viral infection Demonstrated TIP efficacy *in vit*ro Assessed wildtype virus and TIP co-evolution *in vitro*	• Sustained steady-state infection for at least 1 month based on cell and molecular studies • Quantitative measure of long term safety and efficacy (metrics established by the proposer) • Quantitative assessment of long term co-evolution (metrics established by the proposer)
	Demonstrated initial TIP safety and stability in animal models	• TIPs are not toxic, and do not over-stimulate an immune response as demonstrated by histopathology, immunological studies, and/or other metric established by the proposer • Quantitative measure of TIPs stability and clearance over a period determined by proposer (e.g. two weeks for *acute* infection, or two months for *chronic* infection)
II	Demonstrated TIP efficacy and co-evolution at different TIP doses and viral strains in continuous **dynamic *in vitro* systems**	• Quantitative measure of long-term efficacy established and justified by proposer (*e.g.*, TIP-mediated stable reduction of virus loads at least 90% for at least 4 months) • Quantitative measures of pathogen and TIP co-evolution (*e.g.*, rates of mutations, recombination events, or other determined by the proposer)
	Demonstrated long-term TIP safety and efficacy in **animal models** of *chronic /acute* infection Assessment of co-evolution and co-transmission in **animal models** of *chronic /acute* infection Demonstrated TIP stability and co-evolution in vector-born viral infection	• Quantitative measure of long-term TIPs safety and efficacy in animal models of *chronic/acute* infection • Quantitative measure of pathogen and TIP co-evolution (*e.g.*, rates of mutation, emergence of virus and TIP variants, or other determined by the proposer) • Quantitative measure of pathogen and TIP co-transmission (*e.g.*, ratios of TIP-to-pathogen loads in target organ during transmission studies) • Quantitative measure of TIP loads and TIP-virus co-evolution in vector studies

Table 4: Milestones, Deliverables, and Program Metrics for TA3

Phase	Milestones and Deliverables	Program Metric
I	Cell scale models that predict parameters for TIPs safety and efficacy: • TIP-virus dynamics as a function of TIP dosage and time of intervention • Probability of TIP reversion to virulence	Model predicts: • Critical parameters for TIP out-competition (TIP/pathogen genomic ratios, TIP length, sequence, stoichiometric ratios) • Safety (*e.g.*, probability of TIP and virus recombination and TIP reversion to infectious particle) • Kinetic variability across various cell types Quantitative predictions feed back to TA1 and TA2 and guide TIP design and dosage parameters
	Host-scale models that predict long-term *safety* and *efficacy* of TIPs: • Within-host co-evolutionary stability • Within-host spatial and temporal dynamics of TIPs and pathogen • TIP and pathogen co-evolution dynamics	Model predicts: • Critical parameters for long-term TIP stability at target organ (*e.g.*, dosage, time of introduction, or other) • Critical parameters for long-term efficacy (*e.g.*, dosage, time of introduction, or other) • Probability of virus escape under TIP evolutionary pressure • Inter-host variability Quantitative predictions feed back to TA1 and TA2 on TIP optimal design constraints and dosage parameters for long-term stability and efficacy
II	Host-scale models incorporate host immune response with TIP-to-pathogen dynamic models generated in Phase I	Model predicts: • Effect of host immune response on long-term TIP and pathogen co-evolutionary dynamics and TIP stability • Probability of virus escape from TIP under selective pressure of host immune response • Probability of TIP cocktails to enable broad efficacy of TIPs across viral strains and serotypes • Probability of TIP cocktails to prevent viral escape
	Population-scale models of pathogen and TIP co-evolution and co-transmission dynamics across population	Model predicts: • Critical parameters for TIP safety and efficacy across populations for *acute* and/or *chronic* infections • Relevant parameters in TIP design and dosage to control pathogen escape at the population level • Critical parameters for optimal co-transmission dynamics for pathogen control across a population (reduce incidence) Quantitative predictions feed back to TA1 and TA2 on TIP optimal design and dosage parameters for optimal TIP transmission to serve as long-term, single-shot therapies
	Vector-based disease models that predict co-transmission and co-evolution dynamics of pathogen and TIP	Model predicts: • Critical parameters for TIP co-transmission with pathogen within vector and host • Probability to reduce epidemic as compared to other therapies or vaccines • Probability of TIP stability and virus escape within vector and reservoir

2. 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 at the end of one or more of the phases.

Awards under this BAA will be made to proposers on the basis of the evaluation criteria listed below (see section labeled "Application Review Information", Sec. 5.), and program balance to provide overall value to 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. The Government reserves the right to remove proposers from award consideration should the parties fail to reach agreement on award terms, conditions and cost/price within a reasonable time or 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.

In all cases, the Government contracting officer shall have sole discretion to select award instrument type and to negotiate all instrument terms and conditions with selectees. Proposers are advised that regardless of the instrument type proposed, DARPA personnel, in consultation with the Government contracting officer, may select other award instruments, as they deem appropriate. 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.

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 established the national policy for controlling the flow of scientific, technical, and engineering information produced in federally funded fundamental research at colleges, universities, and laboratories. The Directive 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. The Government does not anticipate applying publication restrictions of any kind to individual awards for fundamental research that may result from this BAA. Notwithstanding this statement of expectation, the Government is not prohibited from considering and selecting research proposals that, while perhaps not qualifying as fundamental research under the foregoing definition, still meet the BAA criteria for submissions. If proposals are selected for award that offer other than a fundamental research solution, the Government will either work with the proposer to modify the proposed statement of work to bring the research back into line with fundamental research or else the proposer will agree to restrictions in order to receive an award.

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

For certain research projects, it may be possible that although the research being performed by the prime contractor is restricted research, a subawardee may be conducting fundamental research. In those cases, it is the prime contractor's responsibility to explain in its proposal why its subawardee's effort is fundamental research.

The following statement or similar provision will be incorporated into any resultant non-fundamental research procurement contract or other transaction:

> There shall be no dissemination or publication, except within and between the contractor and any subawardees, of information developed under this contract or contained in the reports to be furnished pursuant to this contract without prior written approval of DARPA's Public Release Center (DARPA/PRC). All technical reports will be given proper review by appropriate authority to determine which Distribution Statement is to be applied prior to the initial distribution of these reports by the contractor. With regard to subawardee proposals for Fundamental Research, papers resulting from unclassified

fundamental research are exempt from prepublication controls and this review requirement, pursuant to DoD Instruction 5230.27 dated October 6, 1987.

When submitting material for written approval for open publication, the contractor/awardee must submit a request for public release to the DARPA/PRC and include the following information: (1) Document Information: document title, document author, short plain-language description of technology discussed in the material (approx. 30 words), number of pages (or minutes of video) and document type (e.g., briefing, report, abstract, article, or paper); (2) Event Information: event type (conference, principal investigator meeting, article or paper), event date, desired date for DARPA's approval; (3) DARPA Sponsor: DARPA Program Manager, DARPA office, and contract number; and (4) Contractor/Awardee's Information: POC name, email and phone. Allow four weeks for processing; due dates under four weeks require a justification. Unusual electronic file formats may require additional processing time. Requests may be sent either via email to public_release_center@darpa.mil or by mail at 675 North Randolph Street, Arlington VA 22203-2114, telephone (571) 218-4235. Refer to the following for link for information about DARPA's public release process: http://www.darpa.mil/work-with-us/contract-management/public-release."

3. Eligibility Information

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

3.1. ELIGIBLE APPLICANTS

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

Federally Funded Research and Development Centers (FFRDCs) and Government entities (e.g., Government/National laboratories, military educational institutions, etc.) 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; and (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 prime contractors or subawardees. 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. 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 are/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. See Section 4.2 "Security and Proprietary Issues" regarding the proposers capabilities to perform research and development at the classification level they propose.

3.1.3. Procurement Integrity, Standards of Conduct, Ethical Considerations, and Organizational Conflicts of Interest

Current federal employees are prohibited from participating in particular matters involving conflicting financial, employment, and representational interests (18 U.S.C. §§ 203, 205, and 208). Once the proposals have been received, and prior to the start of proposal evaluations, the Government will assess potential conflicts of interest and will promptly notify the proposer if any appear to exist. The Government assessment does NOT affect, offset, or mitigate the proposer's responsibility to give full notice and planned mitigation for all potential organizational conflicts, as discussed below.

Without prior approval or a waiver from the DARPA Director, in accordance with FAR 9.503, a contractor cannot simultaneously provide scientific, engineering, technical assistance (SETA) or similar support and also be a technical performer. As part of the proposal submission, all members of the proposed team (prime proposers, proposed subawardees, and consultants) must affirm whether they (their organizations and individual team members) are providing SETA or similar support to any DARPA technical office(s) through an active contract or subcontract. All affirmations must state which office(s) the proposer, subawardees, consultant, or individual supports and identify the prime contract number(s). All facts relevant to the existence or potential existence of organizational conflicts of interest (FAR 9.5) must be disclosed. The disclosure must include a description of the action the proposer has taken or proposes to take to avoid, neutralize, or mitigate such conflict. If in the sole opinion of the Government after full consideration of the circumstances, a proposal fails to fully disclose potential conflicts of interest and/or any identified conflict situation cannot be effectively mitigated, the proposal will be rejected without technical evaluation and withdrawn from further consideration for award.

If a prospective proposer believes a conflict of interest exists or may exist (whether organizational or otherwise) or has questions on what constitutes a conflict of interest, the proposer should send his/her contact information and a summary of the potential conflict via email to the BAA email address before time and effort are expended in preparing a proposal and mitigation plan.

3.2. 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 (e.g., for any Other Transactions

under the authority of 10 U.S.C. § 2371). Cost sharing is encouraged where there is a reasonable probability of a potential commercial application related to the proposed research and development effort.

4. Application and Submission Information

4.1. ADDRESS TO REQUEST APPLICATION PACKAGE

This solicitation contains all information required to submit a proposal. No additional forms, kits, or other materials are needed. This notice, with the classified addendum, constitutes the total solicitation. No additional information is available, except as provided at FBO.gov or Grants.gov, nor will a formal Request for Proposal (RFP) or additional solicitation regarding this announcement be issued. Requests for the same will be disregarded.

4.2. CONTENT AND FORM OF APPLICATION SUBMISSION

4.2.1. Proprietary and Security 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.

Submissions will not be returned. The original 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 at this office within 5 days after notification that a proposal was not selected.

4.2.1.1 Proprietary Information

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.

4.2.1.2 Security Information

Classified submissions shall be transmitted in accordance with the following guidance. Additional information on the subjects discussed in this section may be found at http://www.dss.mil/.

If a submission contains Classified National Security Information as defined by Executive Order 13526, the information must be appropriately and conspicuously marked with the proposed

classification level and declassification date. Similarly, when the classification of a submission is in question, the submission must be appropriately and conspicuously marked with the proposed classification level and declassification date. Submissions requiring DARPA to make a final classification determination shall be marked as follows:

> "CLASSIFICATION DETERMINATION PENDING. Protect as though classified_____(insert the recommended classification level, e.g., Top Secret, Secret or Confidential)"

NOTE: Classified submissions must indicate the classification level of not only the submitted materials, but also the classification level of the anticipated award.
Proposers submitting classified information must have, or be able to obtain prior to contract award, cognizant security agency approved facilities, information systems, and appropriately cleared/eligible personnel to perform at the classification level proposed. All proposer personnel performing Information Assurance (IA)/Cybersecurity related duties on classified Information Systems shall meet the requirements set forth in DoD Manual 8570.01-M (Information Assurance Workforce Improvement Program).

Proposers choosing to submit classified information from other collateral classified sources (i.e., sources other than DARPA) must ensure (1) they have permission from an authorized individual at the cognizant Government agency (e.g., Contracting Officer, Program Manager); (2) the proposal is marked in accordance with the source Security Classification Guide (SCG) from which the material is derived; and (3) the source SCG is submitted along with the proposal.

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.

Security classification guidance and direction via a Security Classification Guide (SCG) and/or DD Form 254, "DoD Contract Security Classification Specification," will not be provided at this time, since DARPA is soliciting ideas only. 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.

4.2.2. Submission Information

Proposers are strongly encouraged to submit a proposal abstract in advance of a proposal. This procedure is intended to minimize unnecessary effort in proposal preparation and review. The time and date for submission of proposal abstracts is specified in Section 4.5.1 below. DARPA will acknowledge receipt of the submission and assign a control number that should be used in all further correspondence regarding the proposal abstract.

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.

The typical proposal should express a consolidated effort in support of one or more related technical concepts or ideas. Disjointed efforts should not be included into a single proposal.

Restrictive notices notwithstanding, proposals may be handled, for administrative purposes only, by a support contractor. This support contractor is prohibited from competition in DARPA technical research and is bound by appropriate nondisclosure requirements. Proposals and/or proposed abstracts may not be submitted by fax or e-mail; any so sent will be disregarded.

Proposals not meeting the format described in the BAA 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 DARPA-BAA-16-35, 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 https://baa.darpa.mil to register their organization concurrently to ensure the BAA office can verify and finalize their submission.

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

Abstracts and Full Proposals sent in response to DARPA-BAA-16-35 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 (https://baa.darpa.mil), though proposers will likely still need to visit https://baa.darpa.mil to register their organization (or verify an existing registration) to ensure the BAA office can verify and finalize their submission.

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

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

For Proposers Requesting Grants or Cooperative Agreements:

NOTE: Proposal Abstracts CANNOT be submitted via Grants.gov.

Proposers requesting grants or 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 http://www.grants.gov/applicants/apply-for-grants.html. Grant or 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.

Grants.gov requires proposers to complete a one-time registration process before a proposal can be electronically submitted. If proposers have not previously registered, this process can take between three business days and four weeks. See the Grants.gov registration checklist at http://www.grants.gov/documents/19/18243/OrganizationRegChecklist.pdf for registration requirements and instructions.

Once Grants.gov has received a proposal submission, Grants.gov will send two email messages to advise proposers as to whether or not their proposals have been validated or rejected by the system; IT MAY TAKE UP TO TWO DAYS TO RECEIVE THESE EMAILS. The first email will confirm receipt of the proposal by the Grants.gov system; this email only confirms receipt, not acceptance, of the proposal. The second will indicate that the application has been successfully validated by the system prior to transmission to the grantor agency or has been rejected due to errors. If the proposal is validated, then the proposer has successfully submitted their proposal. If the proposal is rejected, the proposed must be corrected and resubmitted before DARPA can retrieve it. If the solicitation is no longer open, the rejected proposal cannot be resubmitted. Once the proposal is retrieved by DARPA, the proposer will receive a third email from Grants.gov. To avoid missing deadlines, proposers should submit their proposals in advance of the final proposal due date with sufficient time to receive confirmations and correct any errors in the submission process through Grants.gov. For more information on submitting proposals to Grants.gov, visit the Grants.gov submissions page at: http://www.grants.gov/web/grants/applicants/apply-for-grants.html

Upload two separate documents, Volume I, Technical and Management Proposal and Volume II, the Cost Proposal as attachments to the application package. **No other Grants.gov forms are required.** Please note that Grants.gov does not accept zipped or encrypted proposals. More detailed instructions for using Grants.gov can be found on the Grants.gov website.

Proposers electing to submit grant or cooperative agreement proposals as hard copies must complete the SF 424 R&R form (Application for Federal Assistance, Research and Related) available on the Grants.gov website http://apply07.grants.gov/apply/forms/sample/RR_SF424_2_0-V2.0.pdf. Technical support for Grants.gov submissions may be reached at 1-800-518-4726 or support@grants.gov.

Please note that submitters to Grants.gov will still need to visit https://baa.darpa.mil to register their organization concurrently to ensure the BAA office can verify and finalize their submission.

All administrative correspondence and questions on this solicitation, including requests for information on how to submit a proposal to this BAA, should be directed to one of the administrative addresses below; e-mail is preferred.

BAA Administrator
E-mail: DARPA-BAA-16-35@darpa.mil

DARPA/BTO
ATTN: DARPA-BAA-16-35
675 North Randolph Street
Arlington, VA 22203-2114
Office Website: http://www.darpa.mil/about-us/offices/bto
Solicitations Page: http://www.darpa.mil/work-with-us/opportunities

DARPA intends to use electronic mail for correspondence regarding DARPA-BAA-16-35. Proposals and proposal abstracts may not be submitted by fax or e-mail; any so sent will be disregarded. DARPA encourages use of the Internet for retrieving the BAA and any other related information that may subsequently be provided.

4.2.3. Restrictive Markings on Proposals

All proposals should clearly indicate limitations on the disclosure of their contents. Proposers who include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall-

(1) Mark the title page with the following legend:

> This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this proposer as a result of, or in connection with, the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

> Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

Markings like "Company Confidential" or other phrases that may be confused with national security classifications shall be avoided.

4.3. FORMATTING CHARACTERISTICS

4.3.1. Proposal Abstract Format

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

The abstract is a concise version of the proposal comprising a maximum of 8 pages including all figures, tables, and charts. 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.

Page limit includes:	Page limit does NOT include:
– All figures	– Official transmittal letter (optional)
– All tables	– Cover Sheet
– All charts	– Executive summary slide
– Resumes. Do not include more than two resumes as part of the abstract.	– Bibliography (optional). While not included in the overall page limit, the bibliography should not exceed 2 pages.

Submissions must be written in English.

Abstracts must include the following components:

> A. Cover Sheet: 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 are you trying to 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 SOA?
4. Who will care and what will the impact be if you are successful?
5. How much will it cost and how long will it take?

D. Technical Plan: Outline and address key 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. Where possible, substantiate the proposed technical approach with supporting arguments, calculations, data and/or modeling.

E. Capabilities/Management Plan: 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. No more than two resumes should be included as part of the abstract. 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.

F. Provide a cost estimate for resources over the proposed timeline of the project, broken down by year. For purposes of costing, assume an October 1, 2016 start date. Include labor, materials, a list of deliverables and delivery schedule. Provide rough cost estimates for each subcontractor.

G. Bibliography (Optional): If desired, include a brief bibliography with links to relevant papers and reports.

4.3.2. Full Proposal Format

NOTE (classification and handling markings): Confidential, Secret and Top Secret are classification markings used to control the dissemination of US Government National Security Information (NSI) as dictated in Executive Order 13526 - "Classified National Security Information". When referencing business proprietary information in a response to this BAA, please refrain from using any combination of the NSI caveats unless the content is classified.

All full proposals must be in the format given below. Nonconforming proposals may be rejected without review. Proposals shall consist of two volumes. 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. The submission of other supporting materials along with the proposals is strongly discouraged and will not be considered for review. Proposers are encouraged to submit concise, but descriptive, proposals. Specific examples of problems, approaches, and goals are preferred to qualitative generalities. **The maximum page count for Volume 1 is 34 pages.** A submission letter is optional and is not included in the page count. Volume I should include the following components:

a. Volume I, Technical and Management Proposal

Section I. Administrative

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

1. BAA number (DARPA-BAA-16-35);
2. Technical area;
3. Lead organization (prime contractor);
4. Type of organization, selected from among the following categories: "LARGE BUSINESS," "SMALL DISADVANTAGED BUSINESS," "OTHER SMALL BUSINESS," "HBCU," "MI," "OTHER EDUCATIONAL," OR "OTHER NONPROFIT";
5. Proposer's reference number (if any);
6. Other team members (if applicable), organization type, and Technical point of contact (e-mail/phone) for each;
7. Proposal title;
8. 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;
9. Contracting Officer or Grant Officer to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax, e-mail;
10. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, firm-fixed-price, grant, cooperative agreement, other transaction, or other type (specify);
11. Place(s) and period(s) of performance ;
12. Proposal validity period;
13. DUNS number (http://www.dnb.com/get-a-duns-number.html);
14. Taxpayer ID number (https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN;
15. CAGE code (https://www.dlis.dla.mil/bincs/FAQ.aspx);

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

B. Official Transmittal Letter.

Section II. Detailed Proposal Information

A. Executive Summary {2 pages max}: 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 {1 page max}: 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 {4 pages max}: 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 expected outcomes associated with the proposed project and any plans to commercialize the technology, transition it to a customer, or further the work.

D. Technical Plan {15 pages max}: Outline and address technical challenges inherent in the approach and possible solutions for overcoming potential problems. This section should provide appropriate measurable milestones (quantitative if possible) at intermediate stages of the program to demonstrate progress, and a plan for achieving the milestones. The technical plan should demonstrate a deep understanding of the technical challenges and present a credible (even if risky) plan to achieve the program goal.

E. Management Plan {3 pages max}: 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 {2 pages max}: 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) {4 pages max}: The SOW should provide a detailed task breakdown, citing specific tasks and their connection to the interim milestones and program metrics. Each phase of the program should be separately defined. The SOW must not include proprietary information.
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.

Schedule and Milestones {3 pages max}: 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. Proposers should use the template provided as **Attachment 2** to the BAA posted at https://www.fbo.gov.

A cost summary table listing costs according to Technical Area, team, and Phase should be included in this section. Please refer to the following example:

	Phase I (24 months)	Phase II (24 months)	Total
TA1: TIP Design			
Prime			$-
Subcontractor			$-
(repeat above row for additional subcontractors)			
TA1 Total	$-	$-	$-
TA2: Safety, Efficacy & Co-evolutionary Testing			
Prime			$-
TA2.1: *in vitro* testing			$-
TA2.2: *in vivo* testing			$-
Subcontractor			$-
TA2.1: *in vitro* testing			$-
TA2.2: *in vivo* testing			$-
(repeat above rows for additional subcontractors)			
TA2 Total	$-	$-	$-
TA3: Modeling			
Prime			$-
Subcontractor			$-
(repeat above row for additional subcontractors)			
TA3 Total	$-	$-	$-

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

A resume or "Biosketch" is required for key personnel.

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.

4.4.2.2 Volume II, Cost Proposal – {No Page Limit}
All proposers, including FFRDCs, must submit the following:

Cover sheet to include:

1. BAA number;
2. Technical area;
3. Lead Organization Submitting proposal;
4. Type of organization, selected among the following categories: "LARGE BUSINESS", "SMALL DISADVANTAGED BUSINESS", "OTHER SMALL BUSINESS", "HBCU", "MI", "OTHER EDUCATIONAL", OR "OTHER NONPROFIT";
5. Proposer's reference number (if any);

6. Other team members (if applicable), organization type, and Technical point of contact (e-mail/phone) for each;
7. Proposal title;
8. Technical point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), electronic mail (if available);
9. Administrative point of contact to include: salutation, last name, first name, street address, city, state, zip code, telephone, fax (if available), and electronic mail (if available);
10. Award instrument requested: cost-plus-fixed-free (CPFF), cost-contract—no fee, cost sharing contract – no fee, or other type of procurement contract (*specify*), or other transaction;
11. Place(s) and period(s) of performance;
12. Total proposed cost separated by basic award and option(s) (if any);
13. Name, address, and telephone number of the proposer's cognizant Defense Contract Management Agency (DCMA) administration office (*if known)*;
14. Name, address, and telephone number of the proposer's cognizant Defense Contract Audit Agency (DCAA) audit office (*if known*);
15. Date proposal was prepared;
16. DUNS number (http://www.dnb.com/get-a-duns-number.html);
17. Taxpayer ID number (https://www.irs.gov/Individuals/International-Taxpayers/Taxpayer-Identification-Numbers-TIN;
18. CAGE code (https://www.dlis.dla.mil/bincs/FAQ.aspx); and
19. Proposal validity period.

Note that nonconforming proposals may be rejected without review.

Proposers without an accounting system considered adequate for determining accurate costs must complete an SF 1408 if a cost type contract is to be negotiated. 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, please see http://www.dcaa.mil/preaward_accounting_system_adequacy_checklist.html.

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

(1) Total program cost broken down by major cost items to include:

i. direct labor, including individual labor categories or persons, with associated labor hours and numbered direct labor rates;

ii. If consultants are to used, proposer must provide consultant agreement or other document which verifies the proposed loaded daily/hourly rate;

iii. Indirect costs including Fringe Benefits, Overhead, General and Administrative Expense, Cost of Money, etc. (Must show base amount and rate);
iv. Travel – Number of trips, number of days per trip, departure and arrival destinations, number of people, etc.; and
v. Other Direct Costs – Should be itemized with costs or estimated costs. Backup documentation will be submitted to support proposed costs. An explanation of any estimating factors, including their derivation and application, must be provided. Please include a brief description of the proposers' procurement method to be used.

(2) Major program tasks by fiscal year.
(3) An itemization of major subcontracts and equipment purchases, to include: a cost proposal as detailed as the Proposer's cost proposal.
(4) An itemization of any information technology (IT) purchase, as defined in FAR Part 2.101.
(5) A summary of projected funding requirements by month.
(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.).

The proposer should include supporting cost and pricing information in sufficient detail to substantiate the summary cost estimates and should include a description of the method used to estimate costs and supporting documentation. Per FAR 15.403-4, certified cost or pricing data shall be required if the proposer is seeking a procurement contract award per the referenced threshold, unless the proposer requests an exception from the requirement to submit cost or pricing data. Certified cost or pricing data" are not required if the proposer proposes an award instrument other than a procurement contract (e.g., a grant, cooperative agreement, or other transaction.)

The prime contractor is responsible for compiling and providing all subcontractor proposals for the Procuring Contracting Officer (PCO). Subcontractor proposals should include Interdivisional Work Transfer Agreements (ITWA) or similar arrangements. Where the effort consists of multiple portions which could reasonably be partitioned for purposes of funding, these should be identified as options with separate cost estimates for each. NOTE: for IT and equipment purchases, include a letter stating why the proposer cannot provide the requested resources from its own funding.

All proprietary subcontractor proposal documentation, prepared at the same level of detail as that required of the prime. The prime and subcontractor proposals should be uploaded together if possible to DARPA's BAA Website (https://baa.darpa.mil/). If the subcontractor proposal contains proprietary information not releasable to the prime, the subcontractor may upload their proposal separately but identify the proposal as a subcontract proposal and provide the name and proposal title of the prime contractor. Subcontractor proposals submitted by hard copy can be submitted in a sealed envelope by the prime or directly by the subcontractor. If submitted

directly by the subcontractor the subcontractor must identify the proposal as a subcontract proposal and provide the name and proposal title of the prime contractor. Subcontractors must provide the same number of hard copies and/or electronic proposals as is required of the prime contractor.

The Government strongly encourages that tables included in the cost proposal also be provided in an editable (i.e., MS Excel™) format with calculations formulae intact to allow traceability of the cost proposal numbers across the prime and subcontractors. This includes the calculations and adjustments that are utilized to generate the Summary Costs from the source labor hours, labor costs, material costs, etc., input data. The Government prefers receiving cost data as Excel files; however, this is not a requirement. If the PDF submission differs from the Excel submission, the PDF will take precedence. Each copy must be clearly labeled with the DARPA BAA number, proposer organization, and proposal title (short title recommended).

The Government also requests and recommends that the Cost Proposal include MS Excel™ file(s) that provide traceability between the Bases of Estimates (BOEs) and the proposed costs across all elements and phases. This includes the calculations and adjustments that are utilized to generate the Summary Costs from the source labor hours, labor costs, material costs, etc. input data. It is requested that the costs and Subcontractor proposals be readily traceable to the Prime Cost Proposal in the provided MS Excel™ file(s). The Government prefers receiving cost data as Excel files; however, this is not a requirement.

All proposers requesting an Other Transaction (OT) for Prototypes must include a detailed list of milestones. Each milestone must include the following: milestone description, completion criteria, due date, and payment/funding schedule (to include, if cost share is proposed, contractor and Government share amounts). It is noted that, at a minimum, milestones should relate directly to accomplishment of program technical metrics as defined in the BAA and/or the proposer's proposal. Agreement type, fixed price or expenditure based, will be subject to negotiation by the Agreements Officer; however, it is noted that the Government prefers use of fixed price milestones with a payment/funding schedule to the maximum extent possible. Do not include proprietary data. If the proposer requests award of an OT for Prototype as a non-traditional contractor (defined as an entity that is not currently performing or has not performed in the last one-year period any contract or subcontract for the Department of Defense that is subject to full CAS coverage), information must be included in the cost proposal to support the claim.

Per Section 8123 of the Department of Defense Appropriations Act, 2015 (Division C of the Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. 113-235), all grant awards must be posted on a public website in a searchable format. To facilitate this task, proposers requesting grant awards must submit a maximum one (1) page abstract that may be publicly posted to comply with the requirement of Section 8123. This abstract should explain the project or program to the public and should only contain information that the proposer confirms is releasable to the public; DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR INFORMATION THAT CANNOT BE DISPLAYED ON A PUBLIC WEBSITE. The proposer should sign the bottom of the abstract confirming the information in the abstract is approved for public release. Proposers are advised to provide both a signed PDF

copy, as well as an editable (e.g., Microsoft word) copy. Abstracts contained in grant proposals that are not selected for award will not be publicly posted.

4.4. SUBMISSION DATES AND TIMES

4.4.1. Proposal Abstract Submission Deadline

The proposal abstract (original and (designated number) of hard and electronic copies) must be submitted to DARPA/BTO), 675 North Randolph Street, Arlington, VA 22203-2114 (Attn.: DARPA-BAA-16-35) **on or before 4:00 p.m., ET, May 19, 2016**. Proposal abstracts received after this time and date may not be reviewed.

4.4.2. Full Proposal Submission Deadline

The full proposal (original and (designated number) of hard and electronic copies) must be submitted to DARPA/BTO), 675 North Randolph Street, Arlington, VA 22203-2114 (Attn.: DARPA-BAA-16-35) **on or before 4:00 p.m., ET, July 7, 2016**.

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.

DARPA will post a consolidated Question and Answer list in response to any relevant and/or BAA clarification question(s) after **May 3, 2016**, before final full proposals are due. In order to receive a response to your question, submit your question by **June 28, 2016** to DARPA-BAA-16-35@darpa.mil.

4.5. FUNDING RESTRICTIONS

Not applicable.

4.6. OTHER SUBMISSION REQUIREMENTS (IF APPLICABLE. IF THERE ARE NONE, WRITE "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 feasible, achievable, complete and supported by a proposed technical team that has the expertise and experience to accomplish the proposed tasks.

The work proposed is novel, innovative, and if successful can lead to new approaches, therapies and preventatives to counter fast-evolving viral pathogens and biothreats. Research approach for quantitative experimental work and predictive modeling is innovative and clearly described. Task descriptions and associated technical elements provided are complete and in a logical sequence with all proposed objectives and 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 describes a plausible approach to achieve a compelling outcome despite these risks.

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 maintain the technological superiority of the U.S. military and prevent technological surprise from harming our national security by sponsoring revolutionary, high-payoff research that bridges the gap between fundamental discoveries and their application.

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).

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 AND SELECTION PROCESS

DARPA will conduct a scientific/technical review of each conforming proposal. 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, all factors considered, including the potential contributions of the proposed work to the overall research program and the availability of funding for the effort.

It is the policy of DARPA to ensure impartial, equitable, comprehensive proposal evaluations and to select the source (or sources) whose offer meets the Government's technical, policy, and programmatic goals. Pursuant to FAR 35.016, the primary basis for selecting proposals for

acceptance shall be technical, importance to agency programs, and fund availability. In order to provide the desired evaluation, qualified Government personnel will conduct reviews and (if necessary) convene panels of experts in the appropriate areas.

For evaluation purposes, a proposal is the document described in "Proposal Information", Section 4.4.2. Other supporting or background materials submitted with the proposal will be considered for the reviewer's convenience only and not considered as part of the proposal.

Restrictive notices notwithstanding, proposals may be handled for administrative purposes by support contractors. These support contractors are prohibited from competition in DARPA technical research and are bound by appropriate non-disclosure requirements.

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.

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.

6.2. ADMINISTRATIVE AND NATIONAL POLICY REQUIREMENTS

6.2.1. Meeting and Travel Requirements

There will be a program kickoff meeting in the Arlington, VA vicinity and all key participants are required to attend. Proposers 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.

6.2.2. Human Subjects Research

All research selected for funding involving human subjects, to include use of human biological specimens and human data, must comply with the federal regulations for human subjects protection. Further, research involving human subjects that is conducted or supported by the DoD must comply with 32 CFR 219, Protection of Human Subjects (and DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf).

Institutions awarded funding for research involving human subjects must provide documentation of a current Assurance of Compliance with Federal regulations for human subjects protection, such as a Department of Health and Human Services, Office of Human Research Protection

Federal Wide Assurance (http://www.hhs.gov/ohrp). All institutions engaged in human subjects research, to include subawardees, must also hold a valid Assurance. In addition, all personnel involved in human subjects research must provide documentation of completion of human subjects research training.

For all proposed research that will involve human subjects in the first year or phase of the project, the institution must provide evidence of or a plan for review by an Institutional Review Board (IRB) upon final proposal submission to DARPA as part of their proposal, prior to being selected for funding. The IRB conducting the review must be the IRB identified on the institution's Assurance of Compliance with human subjects protection regulations. The protocol, separate from the proposal, must include a detailed description of the research plan, study population, risks and benefits of study participation, recruitment and consent process, data collection, and data analysis. It is recommended that you consult the designated IRB for guidance on writing the protocol. The informed consent document must comply with federal regulations (32 CFR 219.116). A valid Assurance of Compliance with human subjects protection regulations along with evidence of completion of appropriate human subjects research training by all investigators and personnel involved with human subjects research should accompany the protocol for review by the IRB.

In addition to a local IRB approval, a headquarters-level human subjects administrative review and approval is required for all research conducted or supported by the DoD. The Army, Navy, or Air Force office responsible for managing the award can provide guidance and information about their component's headquarters-level review process. Note that confirmation of a current Assurance of Compliance with human subjects protection regulations and appropriate human subjects research training is required before headquarters-level approval can be issued.

The time required to complete the IRB review/approval process varies depending on the complexity of the research and the level of risk involved with the study. The IRB approval process can last between one and three months, followed by a DoD review that could last between three and six months. Ample time should be allotted to complete the approval process. DoD/DARPA funding cannot be used towards human subjects research until ALL approvals are granted.

6.2.3. Animal Use

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

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

All award recipients must receive approval by a DoD-certified veterinarian, in addition to an IACUC approval. No animal studies may be conducted using DoD/DARPA funding until the United States Army Medical Research and Materiel Command (USAMRMC) Animal Care and Use Review Office (ACURO) or other appropriate DoD veterinary office(s) grant approval. As a part of this secondary review process, the award recipient will be required to complete and submit an ACURO Animal Use Appendix, which may be found at https://mrmc-www.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1.

6.2.4. Export Control

Per DFARS 225.7901-4, all procurement contracts, other transactions and other awards, as deemed appropriate, resultant from this solicitation will include the DFARS Export Control clause (252.225-7048).

6.2.5. Subcontracting

Pursuant to Section 8(d) of the Small Business Act (15 U.S.C. § 637(d)), it is the policy of the Government to enable small business and small disadvantaged business concerns to be considered fairly as subcontractors to contractors performing work or rendering services as prime contractors or subcontractors under Government contracts, and to assure that prime contractors and subcontractors carry out this policy. Each proposer who submits a contract proposal and includes subcontractors is required to submit a subcontracting plan in accordance with FAR 19.702(a) (1) and should do so with their proposal. The plan format is outlined in FAR 19.704.

6.2.6. Electronic and Information Technology

All electronic and information technology acquired through this solicitation must satisfy the accessibility requirements of Section 508 of the Rehabilitation Act (29 U.S.C.§ 794d) and FAR 39.2. Each proposer who submits a proposal involving the creation or inclusion of electronic and information technology must ensure that Federal employees with disabilities will have access to and use of information that is comparable to the access and use by Federal employees who are not individuals with disabilities and members of the public with disabilities seeking information or services from DARPA will have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

6.2.7. Employment Eligibility Verification

As per FAR 22.1802, recipients of FAR-based procurement contracts must enroll as federal contractors in E-verify and use the system to verify employment eligibility of all employees assigned to the award. All resultant contracts from this solicitation will include FAR 52.222-54, "Employment Eligibility Verification." This clause will not be included in grants, cooperative agreements, or Other Transactions.

6.2.8. System for Award Management (SAM) and Universal Identifier Requirements

Unless the proposer is exempt from this requirement, as per FAR 4.1102 or 2 CFR 25.110 as applicable, all proposers must be registered in the System for Award Management (SAM) and have a valid Data Universal Numbering System (DUNS) number prior to submitting a proposal. All proposers must maintain an active registration in SAM with current information at all times during which they have an active Federal award or proposal under consideration by DARPA. All proposers must provide the DUNS number in each proposal they submit.

Information on SAM registration is available at www.sam.gov.

6.2.9. Reporting Executive Compensation and First-Tier Subcontract Awards

FAR clause 52.204-10, "Reporting Executive Compensation and First-Tier Subcontract Awards," will be used in all procurement contracts valued at $25,000 or more. A similar award term will be used in all grants and cooperative agreements.

6.2.10. Updates of Information Regarding Responsibility Matters

Per FAR 9.104-7(c), FAR clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters, will be included in all contracts valued at $500,000 or more where the contractor has current active Federal contracts and grants with total value greater than $10,000,000.

6.2.11. Representations by Corporations Regarding an Unpaid Delinquent Tax Liability or a Felony Conviction under any Federal Law

The following representation will be included in all awards:

(a) In accordance with section 101(a) of the Continuing Appropriations Act, 2016 (Pub. L. 114-53) and any subsequent FY 2016 appropriations act that extends to FY 2016 funds the same restrictions as are contained in sections 744 and 745 of division E, title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), none of the funds made available by this or any other Act may be used to enter into a contract with any corporation that —

> (1) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless the agency has considered suspension or debarment of the corporation and made a determination that this further action is not necessary to protect the interests of the Government; or
>
> (2) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless the

agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(b) The Offeror represents that –

(1) It is [ ] is not [ ] a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability,

(2) It is [ ] is not [ ] a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.

6.2.12. Cost Accounting Standards (CAS) Notices and Certification

As per FAR 52.230-2, any procurement contract in excess of the referenced threshold resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR 99), except those contracts which are exempt as specified in 48 CFR 9903.201-1. Any proposer submitting a proposal which, if accepted, will result in a CAS compliant contract, must submit representations and a Disclosure Statement as required by 48 CFR 9903.202 detailed in FAR 52.230-2. The disclosure forms may be found at http://www.whitehouse.gov/omb/procurement_casb.

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

Controlled Unclassified Information (CUI) refers to unclassified information that does not meet the standards for National Security Classification but is pertinent to the national interests of the United States or to the important interests of entities outside the Federal Government and under law or policy requires protection from unauthorized disclosure, special handling safeguards, or prescribed limits on exchange or dissemination. All non-DoD entities doing business with DARPA are expected to adhere to the following procedural safeguards, in addition to any other relevant Federal or DoD specific procedures, for submission of any proposals to DARPA and any potential business with DARPA:

- Do not process DARPA CUI on publicly available computers or post DARPA CUI to publicly available webpages or websites that have access limited only by domain or Internet protocol restriction.
- Ensure that all DARPA CUI is protected by a physical or electronic barrier when not under direct individual control of an authorized user and limit the transfer of DARPA CUI to subawardees or teaming partners with a need to know and commitment to this level of protection.
- Ensure that DARPA CUI on mobile computing devices is identified and encrypted and all communications on mobile devices or through wireless connections are protected and encrypted.
- Overwrite media that has been used to process DARPA CUI before external release or disposal.

6.2.14. Safeguarding of Covered Defense Information and Cyber Incident Reporting

Per DFARS 204.7304, DFARS 252.204-7012, "Safeguarding of Covered Defense Information and Cyber Incident Reporting," applies to this solicitation and all FAR-based awards resulting from this solicitation.

6.2.15. Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements

(a) In accordance with section 101(a) of the Continuing Appropriations Act, 2016 (Pub. L. 114-53) and any subsequent FY 2016 appropriations act that extends to FY 2016 funds the same restrictions as are contained in section 743 of division E, title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235), none of the funds appropriated (or otherwise made available) by this or any other Act may be used for a contract with an entity that requires employees or subcontractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contactors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(b) The prohibition in paragraph (a) of this provision does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(c) *Representation*. By submission of its offer, the Offeror represents that it does not require employees or subcontractors of such entity seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contactors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

6.3. REPORTING

The number and types of reports will be specified in the award document, but will include as a minimum quarterly financial 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. Representations and Certifications

In accordance with FAR 4.1201, prospective proposers shall complete electronic annual representations and certifications at https://www.sam.gov/portal/SAM/.

6.4.2. Wide Area Work Flow (WAWF)

Unless using another approved electronic invoicing system, performers will be required to submit invoices for payment directly via the Internet/WAWF at http://wawf.eb.mil. Registration to WAWF will be required prior to any award under this BAA.

6.4.3. i-EDISON

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

7. Agency Contacts

Administrative, technical or contractual questions should be sent via e-mail to DARPA-BAA-16-35@darpa.mil All requests must include the name, email address, and phone number of a point of contact.

Points of Contact
The BAA Coordinator for this effort may be reached at:
DARPA-BAA-16-35@darpa.mil
DARPA/BTO
ATTN: DARPA-BAA-16-35
675 North Randolph Street
Arlington, VA 22203-2114

8. Other Information

8.1. INTELLECTUAL PROPERTY

8.1.1. Procurement Contract Proposers

8.1.1.1 Noncommercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS, shall identify all noncommercial technical data, and noncommercial computer software that it plans to generate, develop, and/or deliver under any proposed award instrument in which the Government will acquire less than unlimited rights, and to assert specific restrictions on those deliverables. Proposers shall follow the format under DFARS 252.227-7017 for this stated purpose. In the event that proposers do not submit the list, the Government will assume that it automatically has "unlimited rights" to all noncommercial technical data and noncommercial computer software generated, developed, and/or delivered under any award instrument. If mixed funding is anticipated in the development of noncommercial technical data, and noncommercial computer software generated, developed, and/or delivered under any award instrument, then proposers should identify the data and software in question, as subject to

Government Purpose Rights (GPR). In accordance with DFARS 252.227-7013 Rights in Technical Data - Noncommercial Items, and DFARS 252.227-7014 Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation, the Government will automatically assume that any such GPR restriction is limited to a period of five (5) years in accordance with the applicable DFARS clauses, at which time the Government will acquire "unlimited rights" unless the parties agree otherwise. Proposers are advised that the Government will use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE." It is noted an assertion of "NONE" indicates that the Government has "unlimited rights" to all noncommercial technical data and noncommercial computer software delivered under the award instrument, in accordance with the DFARS provisions cited above. Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

A sample list for complying with this request is as follows:

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

8.1.1.2 Commercial Items (Technical Data and Computer Software)
Proposers responding to this BAA requesting a procurement contract to be issued under the FAR/DFARS, shall identify all commercial technical data, and commercial computer software that may be embedded in any noncommercial deliverables contemplated under the research effort, along with any applicable restrictions on the Government's use of such commercial technical data and/or commercial computer software. In the event that proposers do not submit the list, the Government will assume that there are no restrictions on the Government's use of such commercial items. The Government may use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE." Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

A sample list for complying with this request is as follows:

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

(LIST)	(NARRATIVE)	(LIST)	(LIST)	(LIST)

8.1.2. Non-Procurement Contract Proposers - Noncommercial and Commercial Items (Technical Data and Computer Software)

Proposers responding to this BAA requesting a Grant, Cooperative Agreement or Other Transaction for Prototype shall follow the applicable rules and regulations governing that instrument, but in all cases should appropriately identify any potential restrictions on the Government's use of any Intellectual Property contemplated under that award instrument. This includes both Noncommercial Items and Commercial Items. Although not required, proposers may use a format similar to that described in Paragraphs 1.a and 1.b above. The Government may use the list during the source selection evaluation process to evaluate the impact of any identified restrictions, and may request additional information from the proposer, as may be necessary, to evaluate the proposer's assertions. If no restrictions are intended, then the proposer should state "NONE." Failure to provide full information may result in a determination that the proposal is not compliant with the BAA – resulting in nonselectability of the proposal.

8.1.3. All Proposers – Patents

Include documentation proving your ownership of or possession of appropriate licensing rights to all patented inventions (or inventions for which a patent application has been filed) that will be utilized under your proposal for the DARPA program. If a patent application has been filed for an invention that your proposal utilizes, but the application has not yet been made publicly available and contains proprietary information, you may provide only the patent number, inventor name(s), assignee names (if any), filing date, filing date of any related provisional application, and a summary of the patent title, together with either: 1) a representation that you own the invention, or 2) proof of possession of appropriate licensing rights in the invention.

8.1.4. All Proposers-Intellectual Property Representations

Provide a good faith representation that you either own or possess appropriate licensing rights to all other intellectual property that will be utilized under your proposal for the DARPA program. Additionally, proposers shall provide a short summary for each item asserted with less than unlimited rights that describes the nature of the restriction and the intended use of the intellectual property in the conduct of the proposed research.

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 4.3.2 beginning on Page 32 of DARPA-BAA-16-35. This worksheet must be included with the coversheet of the Cost Proposal.

1. Are all items from Section 4.3.8.2 (Volume II, Cost Proposal) of DARPA-BAA-16-35 included on your Cost Proposal cover sheet?
   ○ **YES** ○ **NO** **Appears on Page(s)** [Type text]
   If reply is "No", please explain:

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

   If reply is "No", please explain:

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

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

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

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

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

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

   If reply is "No", please explain:

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

If reply is "No", please explain:

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

   If reply is "No", please explain:

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

   If reply is "No", please explain:

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

   If reply is "No", please explain:

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

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

   If reply is "No", please explain:

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

    If reply is "No", please explain:

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

    If reply is "No", please explain:

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

    If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

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

If reply is "No", please explain:

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

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

If reply is "No", please explain: