NATIONAL INSTITUTE OF ALLERGY & INFECTIOUS DISEASES (NIAID)

2021 DMID Omnibus Broad Agency Announcement (BAA):

No. HHS-NIH-NIAID-BAA2021-1

Solicitation Issue Date: February 23, 2021

Participating NIAID Divisions: Division of Microbiology & Infectious Diseases (DMID)

Issuing Office: Office of Acquisitions, DEA, NIAID, NIH
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This solicitation contains opportunities to submit a proposal under the following distinct Research Areas, which are identified below:

RESEARCH AREA	NIAID DIVISION	TITLE	PAGE NO.	PROPOSALS DUE
001	DMID	Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases	6	05/24/2021
002	DMID	Development of Therapeutic Products for Biodefense, Anti-Microbial Resistant (AMR) Infections and Emerging Infectious Diseases	9	05/24/2021
003	DMID	Advanced Development of Sequencing- Based Diagnostics for Biothreats and Emerging Infectious Diseases	13	05/24/2021

* Proposals must be received before **3:00 PM Eastern Time** on the date specified herein. Please see the Proposal Submission Instructions for more information.

Offers will be valid for 240 days unless a different period is specified by the Offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.

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SECTION 1. - BROAD AGENCY ANNOUNCEMENT INFORMATION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA). The BAA is governed by Federal Acquisition Regulation (FAR) 6.102 and FAR 35.016, as well as the National Institutes of Health (NIH) Policy Manual, Chapter 6035, Broad Agency Announcements. A BAA may be used as a solicitation mechanism for basic and applied research directed toward advancing the state-of-the-art or increasing knowledge or understanding and that part of development not related to the development of a specific system or hardware procurement. BAAs are general in nature, identifying areas of research interest, and shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated.

This solicitation contains multiple distinct Research Areas. Offerors may submit a proposal in response to one, or more, of the Research Areas contained herein. **Offers submitted in response to this BAA must present separate detailed technical and business proposals designed to meet the Technical Objectives described for each Research Area proposed.** The Statement of Work (SOW), including the specific technical requirements and performance specifications, shall be developed and proposed by the Offeror, not the Government.

Proposals are NOT evaluated against each other since they are not submitted in accordance with a common SOW issued by the Government. Instead, Research and Technical Objectives are provided in the BAA that describe individual Research Areas in which the Government is interested. Proposals received in response to the BAA are evaluated in accordance with the Evaluation Factors for Award specified in this announcement. The Government reserves the right to conduct discussions with all, some, one, or none of the proposals received in response to this BAA. If discussions are conducted, NIAID reserves the right to suggest modifying, adding or deleting milestones, decision points, research plans, processes, schedules, budget or product. The Government also reserves the right to make awards without discussions. Additionally, the Government reserves the right to accept proposals in their entirety or to select only portions of proposals for award. Multiple awards are anticipated. The selection for award under this BAA will be based upon the evaluation factors, importance to the agency programs, and the availability of funds.

SECTION 2. - CONTRACTING OFFICER POINTS OF CONTACT

This BAA contains Research Areas issued by the Division of Microbiology and Infectious Diseases (DMID) within the NIAID. The Contracting Officer (CO) point of contact for questions related to the specific DMID Research Areas is identified below:

Research Area 001: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases

Research Area 002: Development of Therapeutic Products for Biodefense, Anti-Microbial Resistant (AMR) Infections and Emerging Infectious Diseases

Research Area 003: Advanced Development of Sequencing-Based Diagnostics for Biothreats and Emerging Infectious Diseases

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SECTION 3. - RESEARCH AREAS AND TECHNICAL OBJECTIVES

3.1 - DIVISION OF MICROBIOLOGY AND INFECTIOUS DISEASES (DMID) BACKGROUND

Research supported by NIAID, NIH, and the Department of Health and Human Services (DHHS), strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. NIAID also has a key role in the development of new medical countermeasures (MCMs) against potential agents of bioterrorism, drug-resistant pathogens, and emerging and re-emerging infectious diseases. Through a variety of research grants and contracts, NIAID's DMID supports basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics targeting multiple pathogens, including NIAID Category A, B, and C priority pathogens (https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens).

NIAID/DMID intends to use this BAA to help address goals articulated in a number of strategic plans. The National Biodefense Strategy (https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf) articulates the need to enhance preparedness through medical countermeasures, including vaccines, therapeutics and diagnostics. The World Health Organization (WHO) has prioritized diseases with epidemic potential and for which there are no or insufficient countermeasures (https://www.who.int/blueprint/priority-diseases/en/), as well as bacteria for which new antibiotics are urgently needed (https://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed). Similarly, the Centers for Disease Control and Prevention (CDC) has highlighted threats for which antimicrobial resistance is concerning, serious or urgent https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

The goal of DMID Omnibus BAA is to advance vaccines, therapeutics and diagnostics which could be deployed against biodefense and/or emerging pathogens to protect human health and well-being. In particular, supporting these vaccines, therapeutics and diagnostics through early clinical development and manufacturing reduces risk and enables transition to other funding to support advanced clinical development and large-scale manufacturing. Through this solicitation, NIAID aims to advance research and development of promising new therapeutics, vaccines and diagnostics addressing infections caused by the pathogens specified in each of the three (3) Research Areas described below.

3.2 - RESEARCH AREAS

3.2.1- *Research Area 001 - Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases*

3.2.1.1 - *Budget and Award Information*

NIAID estimates that three (3) or more awards may be issued across Research Areas 001 and 002. The total cost and duration for each award may vary depending upon the scope of the project and the technical objectives of the award(s). NIAID estimates a total FY22 budget of up to $11 million for the non-severable base work (direct and indirect costs combined) across all contracts in Research Areas 001 and 002, depending on the number of technically meritorious proposals, importance to agency programs, and availability of funds.

The total duration of a proposed contract should be consistent with the nature and complexity of the offeror's proposed research. The total performance period comprised of the base and any options proposed by an Offeror shall not exceed five (5) years. Clinical trial activities are encouraged to start as soon as possible and be completed within the 5-year period.

Awards are anticipated to be made in or around May 2022; at the discretion of the government, awards may be streamlined to meet agency needs.

3.2.1.2 - *Technical Objectives*

Research Area 001 seeks to advance vaccine technologies and platforms that have sufficient proof of concept data and/or clinical data to support vaccine development through manufacturing, toxicology testing, and testing in phase 1 or 2 clinical trials. The goal of Research Area 001 is to advance vaccine technologies and platforms which could be deployed against agents important for biodefense and/or emerging pathogens to protect human health and well-being. The development of these platforms and technologies to rapidly progress into Phase 1 clinical trials will provide critical data to reduce the risk for future development of these technologies into approved therapies and vaccines.

Vaccines for Anti-Microbial Resistant (AMR) Organisms

One objective of Research Area 001 is to develop vaccines to address anti-microbial resistant (AMR) organisms including biodefense, Gram negative, Gram positive and fungal pathogens. Pathogens of particular interest are described below:

Vaccines focused on biodefense pathogens, such as but not limited to, *Burkholderia spp*, *Francisella tularensis and Yersinia pestis.* **NIAID will exclude, specifically for this BAA, vaccines for *Bacillus anthracis***.

Vaccines focused on antimicrobial resistant Gram-negative organisms, such as but not limited to, *Pseudomonas aeruginosa* and *Escherichia coli*.

Vaccines focused on multi drug resistant Gram-positive bacteria, such as but not limited to, *Staphylococcus aureus*.

Vaccines focused on fungal pathogens, such as but not limited to*, Candida auris* and other *Candida* species.

Vaccines for Pandemic Preparedness and Emerging Infectious Diseases

A second objective is to support development of vaccines for emerging viruses and pandemic preparedness. Pathogens of particular interest are described below:

Vaccines that target coronaviruses with pandemic potential. Specifically, NIAID seeks to support the development of pan-coronavirus (pan-CoV) vaccine candidates that provide broad and durable protective immunity to multiple CoV strains. Preference will be given to approaches that utilize novel immunogen design, as opposed to the development and 'mixing' of individual monovalent vaccines. **NIAID will exclude, specifically for this BAA, vaccine candidates that only protect against SARS-CoV-2 alone.**

Vaccines that target other emerging viruses to include Eastern equine encephalitis virus (EEEV), tick borne viruses, and non-Zaire Ebolaviruses/filoviruses (such as SUDV, MARV). **NIAID will exclude specifically for this BAA vaccines targeting the following pathogens: Ebola Zaire, Lassa, Chikungunya, Zika and Nipah.**

The candidate product(s) may also include adjuvant(s) that enhances the immune responses. Preference will be given to novel adjuvants that have not previously been in clinical trials or have demonstrated enhanced immunogenicity appropriate for the associated antigen and disease. Additionally, where feasible, vaccines providing protection with a single dose with adjuvant are also preferred over multi-dose administrations.

Novel delivery platforms that reduce logistical requirements, are readily scalable and/or provide other benefits such as generation of potent mucosal immunity may be developed as well. Cross-cutting technologies applicable to more than one vaccine component are also of interest.

3.2.1.3 - *Technical Approach*

Offerors may propose a vaccine against a single pathogen or multiple pathogens; NIAID reserves the right to negotiate vaccines for a single indication, multiple indications and/or combined indications, balancing the faster, straightforward development and regulatory path of a single indication with flexibility and preparedness against multiple pathogens.

NIAID will prioritize technically acceptable proposals based on programmatic need, maturity of the candidate product, and risk/benefit assessment.

- Proposals shall provide:

    1. Sufficient background to support development of the vaccine candidate including nonclinical proof of concept data, as well as, any clinical data that may be available.

2. A Target Product Profile and Product Development Plan for the candidate product, including regulatory, clinical, non-clinical, and manufacturing activities to be undertaken.
3. Nonclinical immunogenicity and efficacy studies in a relevant animal model(s) to demonstrate vaccine candidate refinement or optimization.
4. Description of current manufacturing process including product characterization and assay development.
5. Manufacturing and formulation process development.
6. Manufacturing, characterization and release of pilot lot current good manufacturing practice (cGMP) material.
7. Real time and accelerated vaccine stability testing over the duration of the contract.
8. Conduct of non-clinical studies, including all Investigational New Drug (IND)-enabling toxicology studies, combination product approvals and multivalent immunogenicity and interference studies, as needed.
9. Development of all assays and reagents needed to support Phase 1, Phase 1/2 OR Phase 2 clinical trials.
10. Development, submission, and sponsorship of an IND/combination product application, including compliance with all regulatory requirements.
11. Design, conduct, completion, and analysis of a Phase 1 or Phase 1/2 clinical trial of the candidate product in normal healthy volunteers shall be included. Upon completion of protocol development, DMID will determine if the offeror will hold the IND and conduct the clinical trial.
12. The provision of clinical and non-clinical samples from all studies to NIAID and, for clinical trials, obtaining future use consent from volunteers for their samples.
13. Proposed project shall include completion of clinical trial within the 5-year period of award. Clinical trial activities are encouraged to start no later than year three and complete within the 5-year award period.
14. Proof of concept activities to leverage vaccine platform for pandemic preparedness.

- The scope of the product development activities to be undertaken will depend on the status of the individual candidate product, as well as regulatory requirements.

3.2.1.4 - ***Additional Requirements***

I. This Research Area focuses on the development of promising lead vaccine candidates/products and testing these candidates in a clinical trial. Lead candidates shall have the following requirements provided in order of preference:

   a. Lead vaccine candidates identified and optimized
   b. Proof of concept data that includes immunogenicity using the adjuvant to be used in the clinical trial
   c. Efficacy data in a relevant animal model
   d. Development of upstream and downstream manufacturing processes
   e. Lead vaccine candidate characterized by well controlled assays including potency assay(s)

II. Organizations responding to this Research Area, collectively with the proposed subcontractors and consultants where applicable, must have documented expertise in vaccine discovery and development, including demonstrated knowledge of regulatory guidelines and submission processes for candidate products directed against emerging infectious diseases and/or biological threats identified in the Technical Objectives.

3.2.1.5 - *Contracts awarded under this Research Area will NOT support:*

- Basic research and discovery of new series/candidates/products
- Development of devices or diagnostics in the absence of a companion product
- Development of therapeutics
- Vaccines candidates directed against *Bacillus anthracis,* Ebola Zaire, SARS-CoV-2 vaccines based on solely using the spike protein as the antigen, Lassa, Chikungunya, Zika, and Nipah.
- Research involving the use of Human Fetal Tissue.

3.2.2 - Research Area 002 - Development of Therapeutic Products for Biodefense, Antimicrobial Resistant (AMR) Infections and Emerging Infectious Diseases

3.2.2.1 - *Budget and Award Information*

NIAID estimates that three (3) or more awards may be issued across Research Areas 001 and 002. The total cost and duration for each award may vary depending upon the scope of the project and the technical objectives of the award(s). NIAID estimates a total FY22 budget of up to $11 million for the non-severable base work (direct and indirect costs combined) across all contracts in Research Areas 001 and 002, depending on the number of technically meritorious proposals, importance to agency programs, and availability of funds.

The total duration of a proposed contract should be consistent with the nature and complexity of the offeror's proposed research. The total performance period comprised of the base and any options proposed by an Offeror shall not exceed five (5) years. Clinical trial activities are encouraged to start as soon as possible and be completed within the 5-year period.

Awards are anticipated to be made in or around May 2022; at the discretion of the government, awards may be streamlined to meet agency needs.

3.2.2.2 - *Technical Objectives*

The objective of Research Area 002 is the development of promising new therapeutics to address infections caused by NIAID Category A, B, and C priority pathogens and select bacterial and fungal infections identified in the 2019 CDC Antibiotic Resistance Threats Report https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf. For the purposes of this solicitation, therapeutic activity is defined as the cure or mitigation of disease, preferably, once signs and symptoms of infection are evident. For the purposes of this solicitation, a therapeutic candidate refers to an advanced lead series, optimized leads, or product candidate, and is either a small molecule (synthetic or natural product) or a biological product (*e.g.* monoclonal antibodies, recombinant proteins).

Proposals are encouraged for the development of broad-spectrum therapeutics with extended therapeutic activity over more than one pathogen. Therapeutic candidates with a limited spectrum

that target high-priority pathogens for which no standard clinical treatment exists or for which drug resistance poses a significant public health concern are eligible. If needed, for narrow-spectrum candidates at later stages of development (IND enabling/Phase 1/Phase 2), efforts to incorporate investigation of novel diagnostics (useful for clinical development or clinical use) and/or collaborations with diagnostics developers are encouraged.

Proposals on non-traditional therapeutics and anti-toxins are encouraged, provided they have demonstrated therapeutic activity when used alone or in combination with an existing licensed product.

Research Area 002 will support lead optimization, pre-clinical (IND enabling) studies and clinical trials that include Phase 1 and Phase 2 studies or confirmatory trials no greater than 120 subjects. The scope of support differs depending on the stage of the project being proposed, as outlined below.

Details below describe development phases in-scope of Research Area 002:

Lead Optimization

- Synthesize lead compounds from selected lead scaffolds: new analogs with improved potency, reduced off-target activities, and physiochemical/metabolic properties suggestive of reasonable *in vivo* pharmacokinetics.
- Conduct non-GLP *in vivo* toxicity in accordance with the product's intended use.
- Demonstrate *in vivo* activity and potential for efficacy consistent with the product's intended use (i.e. dose, schedule, duration, route of administration).
- Initiate experiments to identify PK/PD relationships and define efficacious exposure targets for further pre-clinical and clinical studies.
- Select lead candidate and initiate IND-enabling studies.

Pre-Clinical (IND Enabling) Studies

- Demonstrate acceptable ADME characteristics and/or immune responses in non-GLP animal studies as necessary for IND filing.
- Conduct GLP non-clinical studies for toxicology, pharmacology, and immunogenicity (as appropriate).
- Continue development of animal models for determining efficacy and defining PK/PD relationships for further pre-clinical and clinical studies.
- Develop a scalable and reproducible manufacturing process amenable to GMP. Manufacture GMP-compliant pilot lots.
- Initiate development of in-process assays and analytical methods for product characterization and release, including assessments of potency, purity, identity, strength, sterility, and quality as appropriate.
- Prepare and submit IND package to FDA.

Phase 1

Phase 1 clinical trial(s) to determine the safety and pharmacokinetics of the clinical test article in healthy volunteers including Phase 2-enabling studies in special populations (i.e. renal-impairment, elderly).

Phase 2

Phase 2 clinical trials(s) to determine safety, pharmacokinetics and efficacy of the clinical test article in patients.

Proposals that initiate with a single therapeutic candidate for evaluation in clinical trials are expected to complete evaluation in a Phase 1 and/or Phase 2 clinical trial within the 5-year proposed period of performance. Phase 1 and 2 clinical trial completion is defined as completion of a Final Clinical Study Report following International Conference on Harmonization (ICH) Guidelines on Structure and Content of Clinical Study Reports E3.

Proposals that initiate with a single therapeutic candidate for support of IND-enabling studies are expected to complete evaluation in a Phase 1 clinical trial within the 5-year proposed period of performance. Phase 1 clinical trial completion is defined as completion of a Final Clinical Study Report following ICH Guidelines on Structure and Content of Clinical Study Reports E3.

Proposals that initiate with more than one lead compound (or lead series) for support of lead optimization are expected to provide clear plans and criteria for selecting a single clinical candidate therapeutic by the end of the second year of funding to enable completion of IND-enabling activities and submission of the IND within a 5-year period of performance.

3.2.2.3 - *Technical Approach*

Proposals are encouraged for the development of broad-spectrum therapeutics with extended therapeutic activity over more than one pathogen; priorities are listed below but broad-spectrum activity does not require activity against this list. Limited spectrum therapeutic candidates that target high-priority pathogens for which no standard clinical treatment exists or for which drug resistance poses a significant public health concern are eligible if they target one of the specific pathogens listed below:

1. Antimicrobial Therapeutics
    a. Active against the effects of one or more of the urgent or serious, and concerning drug-resistant bacterial threats or urgent fungal threats (*Candida auris*) listed in the 2019 CDC Antibiotic Resistance Threats Report (https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf); OR
    b. Display activity against the effects of one of the following bacterial pathogens: *Bacillus anthracis, Francisella tularensis, Yersinia pestis, Burkholderia pseudomallei, and especially Burkholderia mallei*.
2. Antiviral Therapeutics
    a. Active against viruses that are classified as NIAID Category A, B, or C viral threat agents, OR
    b. Display activity against infection caused by one of the following viral families:
        i. Flaviviruses (esp. Zika, Dengue, and Yellow Fever virus)
        ii. Filoviruses (esp. Ebola, Sudan, and Marburg virus)
        iii. Orthopox virus representative of Variola major
        iv. Pathogenic Coronaviruses (e.g. MERS, SARS-CoV and SARS-CoV-2)

- Small molecules, preference will be given for oral delivery
- Monoclonal antibodies, shall be at IND-enabling or Phase 1 stage.

v. Alphaviruses (especially EEEV)
vi. Influenza (e.g., H1N1, H3N2)
vii. Other hemorrhagic fever viruses (e.g. Lassa fever)

3. Anti-toxin Therapeutics

Anti-toxin lead series/lead/product candidate must meet at least one of the following criteria:

a. Displayed activity against Ricin intoxication;
b. Displayed activity against the effects of *Staphylococcus* enterotoxin B;
c. Biological product: displayed broad-spectrum activity against the effects of all the known serotypes of *Clostridium botulinum* neurotoxin (serotype A, B, C, D, E, F, G);
d. Small molecule product: displayed activity against the effects of at least two of the known serotypes of *Clostridium botulinum* neurotoxin;
e. Function as small molecule agents against the effects *Bacillus anthracis* Protective Antigen, Lethal Factor and/or Edema Factor.

For this Research Area, an anti-toxin therapeutic lead series/lead/product candidate is a single product meeting the following criteria/definitions:

a. An agent intended for use in the cure, mitigation or treatment of intoxication;
b. An agent that has demonstrated activity against a specific toxin in an appropriate *in vivo* model of disease.

3.2.2.4 - *Additional Requirements*

I. Regardless of the proposed entry point, therapeutic lead series/lead/product candidate must show demonstrated, phase-appropriate evidence of all the following characteristics:
- Chemical structure and if appropriate, relevant Structure Activity Relationships to support lead optimization strategy
- Synthesis/manufacturing feasibility;
- Appropriate *in vitro* AND *in vivo* efficacy; and
- Appropriate *in vitro* AND *in vivo* pharmacokinetic and toxicology.

These characteristics must be reflected in the draft Target Product Profile (TPP).

II. Organizations responding to this Research Area, collectively with the proposed subcontractors and consultants where applicable, must have documented expertise in drug discovery and development, including demonstrated knowledge of regulatory guidelines, and submission processes for candidate products directed against emerging infectious diseases and/or biological threats.

3.2.2.5 -*Contracts awarded under this Research Area will <u>NOT</u> support:*

- Basic research and discovery of new series
- Hit-to-Lead optimization and studies

- Development of candidates/products or lead series that have not demonstrated therapeutic activity in a relevant animal model of disease OR have not demonstrated stage appropriate pharmacokinetics
- Development of candidates/products or lead series from a known class that don't demonstrate a unique advantage over other members of the class
- Development of licensed products as new formulations or prodrugs
- Development of licensed products for additional clinical indications
- Development of licensed products in combination with other licensed products
- Development of topical sanitation products
- Development of serum-derived products
- Development of devices
- Development of probiotics and other microbiome related products
- Research involving the use of Human Fetal Tissue.

3.2.3 - Research Area 003 - Advanced Development of Sequencing-Based Diagnostics for Biothreats and Emerging Infectious Diseases

3.2.3.1 – *Budget and Award Information*

NIAID estimates that one (1) or more awards may be issued across Research Area 003. The total cost and duration for each award may vary depending upon the scope of the project and the technical objectives of the award(s). NIAID estimates a total FY22 budget of up to $4 million for the non-severable base work (direct and indirect costs combined) across all contracts in Research Areas 003, depending on the number of technically meritorious proposals, importance to agency programs, and availability of funds.

The total duration of a proposed contract should be consistent with the nature and complexity of the offeror's proposed research. The total performance period comprised of the base and any options proposed by an Offeror should not exceed five (5) years. Clinical trial activities are encouraged to start as soon as possible and be completed within the 5-year period.

Awards are anticipated to be made in or around May 2022; at the discretion of the government, awards may be streamlined to meet agency needs.

3.2.3.2 – *Technical Objectives*

NIAID is interested in supporting the development of promising sequencing-based diagnostics for biothreat pathogens as well as pathogens causing emerging and re-emerging infectious diseases.

Specifically, the objective of Research Area 003 is to advance the research and development of nucleic acid and protein sequencing solutions on established commercial platforms for the targeted and agnostic detection of bio-threat and naturally emerging infectious pathogens. It is not required

to complete the development and FDA clearance of the diagnostic during the project period; however, the targeted metrics for the final diagnostic product should include:

- Turnaround time – pathogen ID within 1-2 hours of specimen collection;
- Throughput – minimum of 10 patient samples processed per sequencing run;
- Sensitivity – analytical sensitivity of > 97% for infectious pathogen detection;
- Specificity – limited off- target detection of < 3%;
- Ease of use – automated nucleic acid or protein extraction and sample preparation; simplified transfer to sequencing system; data analyses operated and interpreted with minimal training;
- Regulatory – FDA pre-EUA and/or 510(k) clearance; and
- System utility – other commercially sustainable assays cleared or in development or in planning on same or equivalent system.

Details below describe development activities that are IN SCOPE of Research Area 003:

- Nucleic acid or protein extraction method development;
- Automated nucleic acid or protein preparation method development;
- Sequencing assay development to detect one or more required pathogens;
- Metagenomic sequencing assay development for agnostic detection of untargeted pathogens;
- Internal and external controls development;
- Integration of chemistry processing on automated platforms;
- Software development, including database improvement for faster and/or more comprehensive analysis patient sample data;
- Reagent scale-up for process validation and pilot manufacturing; and
- Establishment of clinical studies to validate performance.

3.2.3.3 – *Technical Approach*

Proposed program must be in early through late-stage development for a sequencing-based diagnostic test that supports biodefense and naturally emerging and re-emerging infectious pathogen preparedness. Diagnostic must detect one of the following agents:

- *Bacillus anthracis,* including genotypic resistance markers
- *Yersinia pestis,* including genotypic resistance markers
- *Francisella tularemia,* including genotypic resistance markers
- *Burkholderia* sp., including genotypic resistance markers
- Botulinum toxin , including identifying and distinguishing relevant serotypes
- ESKAPE pathogens (*Enterococcus faecium, Staph. aureus, Klebsiella pneumonia, Acinetobacter baumanii, Pseudomonas aeruginosa, Enterobacter species)*, including genotypic resistance markers
- Lassa virus
- Nipah virus
- Rift Valley Fever virus
- Enterovirus D68 virus
- Candida auris
- Coccidioides sp.
- Novel coronaviruses

At the end of the performance period, it is expected that the diagnostic or diagnostic prototype shall:

- Detect proposed pathogen analyte reproducibly and with clinical accuracy directly from a relevant clinical matrix (blood, urine, respiratory swab, cerebrospinal fluid, stool, or bronchoalveolar lavage) without a culture step;
- Be designed either for low-throughput use in near-patient settings such as physician's office, community pharmacy, and hospital emergency room, or for high-throughput or rapidly scalable use in hospital laboratories or central reference testing labs;
- Require a maximum of 5 minutes of manual preparation prior to loading the clinical sample for automated extraction, sample prep, and sequencing; and
- Generate actionable diagnostic results within 1-2 hours without additional manual intervention.

The capability to detect and distinguish a required agent from among multiple other agents common to a geographic region or population is strongly encouraged.

3.2.3.4 – ***Additional Requirements***

I. Developers must present proof-of-concept data that the proposed sequencing method can detect the targeted pathogen analyte (see pathogen list above) preferably from a relevant clinical matrix (e.g., blood, urine, respiratory swab, cerebrospinal fluid, stool, or bronchoalveolar lavage) and has the capability for agnostic detection of any relevant infectious pathogen.

II. Organizations responding to this Research Area, collectively with their proposed subcontractors and consultants where applicable, should have documented or proposed access to all reagents, facilities, and capabilities required to perform the proposed research, such as antibodies or other capture reagents, virulent pathogens, clinical samples, and biocontainment facilities. They should also have documented or planned expertise in product development in order to have the capability to advance the development and validation of a candidate diagnostic through FDA clearance and commercial launch.

3.2.3.5 – ***Contracts awarded under this Research Area will NOT support:***

- Development of a diagnostic that does not include one (1) of the above-listed agents.
- Development of diagnostic tests to identify pathogens from culture or isolate (bacterial plate).
- Development of diagnostics that rely solely on the detection of host-response antibodies.
- Basic research and discovery of new host-based diagnostic targets.
- Development of platforms that will require more than 5 minutes of manual steps to process the sample prior to loading it into the diagnostic.
- Development of diagnostics that will require additional manual steps after the clinical sample has been loaded to start the test.
- Development of diagnostics that will only be validated using non-pathogenic or surrogate organisms.

3.3 - RESEARCH AREAS 001 AND 002 - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

The following information supplements Section 4 – Instructions, Conditions, and Notices to Offerors of this solicitation, and should be used for preparing proposals in response to Research Area 001 or 002. Separate and distinct proposals must be submitted for each Research Area to which you are proposing.

3.3.1 - PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Product Development Plan that describes the critical path for the proposed candidate/product to eventual licensure and identifies the decision points/gates for progress of the candidate/product. Offerors should point out areas of significant uncertainty and propose likely alternatives.

The Product Development Plan should detail the specific tasks and stages to be performed with contract funding that can be reasonably completed within the period of performance. The Product Development Plan should include a summary of the following:

a. A description of the intended use/indication of the proposed candidate product and the public health gap the product is intended to fill.

b. A Target Product Profile for the candidate product, including the performance specifications and features the candidate product should have including potential stability, dosing and safety.

c. A description of the candidate product as it is currently configured. Include a description of how the candidate meets the technical objectives.

d. Data to support the characterization and selection of the candidate/product for further development. A summary of the data that demonstrates activity in an appropriate animal model.

e. A synopsis of any discussions and meetings with the U.S. Food and Drug Administration (FDA) for the proposed product. Provide in an appendix any relevant FDA documents such as meeting agendas, presentations, and meeting minutes.

f. A brief description of critical activities and/or issues that are part of the product development strategy through submission of a biologics license application (BLA) or new drug application (NDA).

g. A description of regulatory activity plans to support the proposed work.

h. A description of good laboratory practice (GLP) safety and clinical plans to support the proposed work.

3.3.2 - WORK PLAN

Technical proposals shall include a work plan detailing the specific tasks that the Offeror proposes to perform with contract funding that can reasonably be completed within the period of performance. The technical proposal shall include a SOW that includes base and options,

milestones, and deliverables. An associated Gantt chart shall be included in the technical proposal while the associated task linked budget shall be included in the business proposal.

In addition, the SOW shall provide for updates of the technical approaches in the Work Plan, as applicable, upon a change in any task, that must be approved by the Contracting Officer's Representative (COR) and the CO prior to the initiation of any activities related to its execution.

The Work Plan shall include:

a. Base, options and milestones for key project/task objectives.

b. Deliverables with appropriate specifications or references to assess successful completion of the activities and milestones.

c. A Gantt chart of proposed activities that can be correlated with a task-linked budget at a level that facilitates Government oversight of those activities. The task-linked budget should provide a breakdown of direct costs linked to each activity, task and subtask contained on a detailed chart.

d. A detailed discussion of the proposed technical approach for each activity to be performed to achieve the key project objectives, with sufficient detail to fully explain and justify the scientific/technical rationale for the proposed approach and/or methodologies.

e. The following, as applicable for the project being proposed:

- Approach for manufacturing and Chemistry, Manufacturing, and Controls (CMC) development of candidate product to optimize production, formulation and delivery.
- Description of non-clinical studies for safety, toxicology, pharmacology, immunogenicity and efficacy, as applicable, including all IND-enabling studies.
- Approach for development of assays and reagents needed to support product development activities.
- Development and submission of an IND and performance of clinical trials to demonstrate product safety and/or early immunogenicity.

f. A project management plan identifying project manager, processes, and activities for contractor and subcontractor(s).

g. Plans for quality control over the implementation, coordination and conduct of the activities set forth in the Work Plan, including plans to conduct regulatory audits.

h. A Risk Management and Mitigation Plan.

i. A plan describing which data and resources, reagents, assays and animal models developed with contract funding will be shared with the scientific community.

j. Offerors proposing subcontracts and/or consultants to perform portions of the proposed work should clearly identify the specific tasks for which they plan to utilize subcontractors and/or consultants.

The entire proposal will be subject to negotiations including Product Development Plan, work activities, SOW, timeline and budget.

3.3.3 - CLINICAL TRIAL PROTOCOL DEVELOPMENT AND IMPLEMENTATION

Human subjects research may be carried out under this contract with the approval of DMID. Describe experience in the conduct of human subject research in accordance with DMID, NIAID, and NIH policies and guidelines and provide a statement acknowledging willingness to conduct clinical research according to these policies and in accordance with applicable ICH and FDA regulations and guidance. NIH policy is published at https://grants.nih.gov/policy/clinical-trials.htm; NIAID policy can be found at https://www.niaid.nih.gov/research/niaid-clinical-research-standards; DMID forms and policies are at https://www.niaid.nih.gov/research/dmid-clinical-research-policies. Upon completion of protocol development, DMID will determine if the offeror will hold the IND and conduct the clinical trial, using the form "Request to Sponsor an IND/IDE for a DMID-Funded Clinical Trial." The form will be included as an attachment to the contract award.

Provide a Protocol Synopsis for each proposed clinical trial, including a brief description of the following:

- Study objectives and endpoints
- Human subjects protection
- Provisions for data monitoring and safety reports
- Draft inclusion/exclusion criteria and recruitment, and retention of study participants
- Summary of statistical approach

Document experience of the Offeror and any proposed subcontractor(s) and consultant(s) with designing early phase clinical trials, executing early phase clinical trials and managing early phase clinical trials in compliance with regulatory requirements and good clinical practice (GCP).

Provide a plan that specifies at which points in the SOW it will be critical to engage in communications with the FDA and the means by which NIAID will be kept apprised of such communications.

3.3.4 - REGULATORY COMPLIANCE, QUALITY CONTROL & ASSURANCE, and DATA MANAGEMENT

- Describe the data management and quality control systems/procedures that will be used for all studies and procedures in accordance with 21 CFR 11.
- Describe the statistical design and analysis resources that will be used to support contract activities.
- Provide a plan to develop and maintain quality assurance documentation to support adherence to FDA regulatory standards and guidance.
- Document experience of the Offeror and any proposed subcontractors and consultants experience with performing regulated studies in accordance with FDA regulations and guidance, including GLP, cGMP, and/or GCP guidelines as appropriate to their proposed SOW.
- Provide an audit history and audit plan to determine when audits need to be performed, timely scheduling of audits, performance of audits, and responding to audit reports.

3.3.5- UNIFORM COST ASSUMPTIONS

Offerors should use the following assumptions for the purposes of estimating costs and preparing the technical proposal:

a. Audits: Assume QA audits of critical phases for the duration of the contract period of performance. For example, anticipate a GLP audit of toxicology site, GMP audit of manufacturing site, and GCP audit of clinical site.

b. Purchase of Equipment: Cost will NOT be allowed for the purchase of any equipment, hardware, or software under this contract.

c. Alterations and Renovations: Cost will NOT be allowed for any facility construction, alterations, or renovations under this contract.

d. Programmatic Presentations and Meetings: Assume attendance at the following meetings:

1) Post Award Contract Initiation Meeting

The Contractor shall be responsible for arranging a one-day meeting at 5601 Fishers Lane, Rockville, MD within 60 days after award date. Attendees should include all Key Personnel and Key Subcontractor Personnel.

2) Annual Contract Review Meetings

For each year of performance, the Contractor shall attend an Annual Contract Review meeting. The meetings will be held on an alternating-year basis at the Contractor's facility or a location at 5601 Fishers Lane, Rockville, MD. Each meeting will be one-day in length. Attendees should include all Key Personnel and Key Subcontractor Personnel.

3) Monthly Meetings/Teleconferences

The Contractor' PI and Project Manager shall plan, conduct, and participate in meetings with the COR at a minimum of monthly intervals via teleconference to discuss progress, problems, proposed solutions, and any matter that is relevant to the scientific and financial administration of the project and future activities. The schedule for those meetings will be established by the COR after contract award. The Contractor shall prepare and submit the meeting agenda and distribute the agenda and background materials to all meeting participants at least 2 business days in advance of the meeting. The Contractor shall prepare and provide a summary of all meeting and teleconferences to the COR within the timeframe stated in the delivery schedule and include each summary in the Monthly Technical Progress Reports.

3.3.6 - POST-AWARD REQUIREMENTS

The following post award requirements will apply to all awards made under Research Areas 001 and 002 of this BAA.

Offerors are instructed to address responsibility for complying with these requirements in the proposed SOW for the Technical Proposal. Offerors are NOT required to submit documentation to address these post-award requirements in their technical proposals. Instructions for submitting documentation associated with post-award requirements will be provided during negotiations.

3.3.6.1 - Contractual Commitments

Upon award of a contract, the contractor shall be required to make legal commitments through acceptance of Government contract clauses contract. The outline that follows is illustrative of the types of provisions required by the FAR that shall be included in the contract. This is not a complete list of provisions to be included in contracts, nor does it contain specific wording of these clauses. Copies of complete terms and conditions applicable to your contract will be provided during negotiations.

1) Inspection: Work performed under the contract is subject to Government inspection and evaluation at all times.

2) American-made Equipment and Products: When purchasing equipment or products under a contract award, the contractor shall purchase American-made items whenever possible.

3) Termination for Default: The Government may terminate the contract for default if the contractor fails to perform the work described in the contract and such failure is not the result of excusable delays.

4) Contract Work Hours: The contractor may not require an employee to work more than eight hours a day or forty hours a week unless the employee is compensated accordingly (i.e., overtime pay).

5) Covenant Against Contingent Fees: No person or agency has been employed to solicit or secure the contract upon an understanding for compensation except bona fide employees or commercial agencies maintained by the contractor for the purpose of securing business.

6) Disputes: Any dispute concerning the contract that cannot be resolved by agreement shall be decided by the CO with right of appeal.

7) Equal Opportunity: The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.

8) Gratuities: The Government may terminate the contract if any gratuities have been offered to any representative of the Government to secure the contract.

9) Termination for Convenience: The Government may terminate the contract at any time for convenience if it deems termination to be in its best interest, in which case the contractor will be compensated for work performed and for reasonable termination costs.

10) Patent Infringement: The contractor shall report each notice or claim of patent infringement based on the performance of the contract.

3.4 - RESEARCH AREAS 001 AND 002 – *REPORTING REQUIREMENTS AND DELIVERABLES*

3.4.1 - Reporting Requirements

In addition to reporting requirements and deliverables identified elsewhere in this solicitation, it is expected that awards resulting from Research Areas 001 and 002 will include the following reports and deliverables:

a. ***Monthly Progress Reports***

This report shall include a description of the technical activities and results during the reporting period and the activities planned for the ensuing reporting period and shall include a budget summary for costs incurred during the monthly reporting period for the base period and each option and milestone. The funding level shall be presented in correlation with percent completion of the activities under the base, option and/or milestone. Monthly Progress Reports shall not be required when the Annual Progress Report is due.

b. ***Annual Progress Reports***

This report shall include a summary of the technical activities and results for the entire contract period. This report shall also include a description of the technical activities performed and results obtained during the annual reporting period. A budget summary for costs incurred during the annual reporting period for the base period and each option and milestone shall be presented in correlation with percent completion of the activities under the base, option and/or milestone. An Annual Progress Report shall not be required for the period when the Final Report is due.

c. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001 applies. Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

d. Final Report

This report includes a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. An annual report will not be required for the period when

the Final Report is due. The Contractor shall submit, with the Final Report, a summary of salient results (not to exceed 250 words) achieved during the performance of the contract.

e. Product Development Plan and Work Plan

The Contractor shall update the Product Development Plan and create a Work Plan to incorporate the progress from the effective date of the contract. The Contractor shall submit an updated Product Development Plan for review within thirty (30) calendar days of the effective date of the contract and prior to initiation of product development activities, unless otherwise negotiated with the COR and the CO. This updated Product Development Plan and Work Plan shall include:

1) Clearly defined goals, product development stages and product development activities.

2) A breakdown of activities by fiscal year and non-severable stages, and applicable decision gates.

3) Quantitative and qualitative criteria and associated data elements for assessing the scientific merit and feasibility of moving to the next stage of product development.

4) A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a task-linked budget (a budget linked to each major activity). An updated Gantt chart should be provided to outline the proposed schedule after award of the contract.

5) The Work Plan shall include a description of the studies to be performed within each stage of the project. The Contractor shall also be required to submit a revised Product Development Plan and associated Work Plan when a change to the approved plans is requested by the COR.

6) Risk identification, analysis, and mitigation strategies for accomplishing the objectives of this contract within the period of performance, particularly with respect to adverse experimental or production results, new scientific findings or regulatory guidance from FDA.

NOTE – For purposes of this BAA:

- The Product Development Plan describes the critical path for the proposed candidate/product toward eventual licensure and identifies the decision points/gates for progress of the candidate/product.
- The Work Plan describes the studies to be performed at each stage of the project within the 5-year term of award in order to implement the Product Development Plan and advance the product through Phase 1 clinical testing.

f. Milestone Completion

A Milestone Report shall be submitted when the Contractor has completed a stage of product development as defined in the Work Plan for the Implementation of the Staged Product Development Plan. These reports shall be in sufficient detail to explain comprehensively the

results achieved. The description shall also include pertinent data and/or conclusions resulting from the analysis and scientific evaluation of data accumulated to date under the project. Offerors shall propose the timing of these reports to coincide with the decision points specified in their SOW.

Note: Contract activities shall be divided into manageable time frames with associated deliverables. Funding of subsequent deliverables shall be funded by Options. Each Option shall be fully funded when exercised and shall be dependent on successful completion of critical Milestones, including the United States Government acceptance of associated deliverables, when applicable. The critical predecessor activities should constitute decision-enabling criteria for successor activities. The contract budget shall be aligned with the Base Period, Options and associated tasks identified in the Product Development Plan and associated Gantt chart.

g. Audit Reports

Within thirty (30) calendar days of completion of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP or GCP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

h. Draft and Final Clinical Trial Protocols

NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award), the Contractor shall develop a protocol and all associated documents for each clinical trial and submit drafts for review as well as all final protocols and protocol amendments for approval by DMID. Associated documents include: Informed Consent; Quality Management Plan; Clinical Monitoring Plan; Plan for Management of Subcontractor Activities; Enrollment Plan; Data Management Plan; Pharmacy Manual; Laboratory Manual; Statistical Analysis Plan; Specimen Handling Manual; Safety Monitoring Management Plan; Investigator's Brochure. Prior to FDA submission and enrollment, additional reviews and approval periods may be required for changes in the final protocol. Three (3) weeks should be planned for each review period. It is recommended but not required that protocols be submitted using approved DMID templates; if not using DMID template, ensure all information in the DMID template is included. The DMID templates and other important information regarding performing human subject research are available at https://www.niaid.nih.gov/research/dmid-clinical-research-policies and https://www.niaid.nih.gov/grants-contracts/human-subjects, respectively.

i. Request to Sponsor an IND/IDE for a DMID-Funded Clinical Trial

Upon completion of protocol development, the form, "Request to Sponsor and IND/IDE for a DMID-Funded Clinical Trial" must be filled out and submitted to the Clinical Project Manager and COR. The form will be provided as an attachment to the contract award.

j. Draft and Final Clinical Study Report

For each clinical study performed with contract support, a Draft Clinical Study Report shall be provided upon completion of the analysis of all data generated in the clinical trial. Following review and approval by DMID, final Clinical Study Reports shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_Guideline.pdf).

k. Draft and Final Non-Clinical Study Protocols

Provide electronic copies of draft protocols for all non-clinical studies for review and approval to the COR. Allow at least 10 calendar days for review unless otherwise agreed upon by the COR. The non-clinical study protocols shall undergo at least one round of revision and resubmission for final approval.

l. Draft and Final Non-Clinical Study Reports

For each non-clinical study performed with contract support, a Draft Non-Clinical Study Report should be prepared within thirty (30) calendar days, unless otherwise approved by the COR, of the completion of the analysis of all data and submitted to COR for review. A Final Non-Clinical Study Report shall be submitted to the COR within thirty (30) calendar days of finalization of the report after the draft reports have been reviewed. Allow at least one round of revision and resubmission for final approval unless otherwise agreed upon by the COR. The Non-Clinical Study Reports shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies performed.

m. FDA Correspondence and Meetings

Submit for review and approval planned FDA communications as well as any subsequent correspondence and resulting meeting summaries.

n. Human Subject IRB Annual Report (Form OMB No. 0990-0263)

Within thirty (30) calendar days of each anniversary date of the effective contract award, the Contractor shall submit the Human Subject Annual Report.

o. Clinical Monitoring Plan

For each clinical trial performed with contract support, a Clinical Monitoring Plan should be prepared and submitted forty-five (45) calendar days prior to the intended initiation date of the clinical trial.

p. Clinical Monitoring Reports

A copy of each Clinical Monitoring Report shall be provided within thirty (30) calendar days of the completion of the clinical monitoring visit, unless significant GCP violations were discovered in the clinical monitoring visit. If significant GCP violations were discovered, the Contractor will notify the COR as soon as the Contractor learns about the violation, and the Clinical Monitoring Report shall be provided within fifteen (15) calendar days of the completion of the clinical monitoring visit.

q. QA Reports

Upon request of the COR, the Contractor shall provide a copy of the QA reports within five (5) calendar days from the COR request.

r. Safety Oversight Reports

The Contractor shall provide open (blinded) and closed (unblinded) reports to be reviewed by the safety oversight monitoring board at the intervals specified by the approved clinical protocol. The Contractor shall provide the report at least ten (10) business days prior to each board meeting date in a format mutually agreed upon. The Contractor shall provide shell reports (without any data) at least ten (10) business days prior to the organizational meeting of the safety board.

s. Samples of Products

The Contractor shall submit samples of non-GMP candidate products and reagents as well as GMP products and reagents manufactured with contract funding. The type of material and the amount will be specified in the contract.

t. Technology Transfer

Technology Transfer packages shall include complete protocols and critical, assays or procedures developed and/or improved with contract funding.

u. Institutional Biosafety Approval

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments.

v. Other Technical and Regulatory Records

Copies of other reports and documents for work generated under the BAA may include draft and final reports for Process Development, Assay Qualification, Assay Validation, Assay Technology Transfer, Batch Records, SOPs, Master Production Records, and Certificates of Analysis. The delivery schedule, requirements of other reports and deliverables shall be proposed by the Offerors in their technical proposal. They will be developed further after receipt of proposals as a result of finalization of the SOW and other terms and conditions of any resultant contract during negotiations.

w. Annual Contract Review Meeting

A report of the Post Award Contract Initiation Meeting and Annual Contract Review Meetings shall be prepared by the Contractor and submitted within twenty-one (21) calendar days following the date of the meetings. These reports shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

x. Teleconference and Meeting Minutes

Minutes of regular, as well as ad hoc teleconferences and meetings shall be provided by the Contractor within five (5) business days following the date of the teleconference or meeting. Agendas shall be provided two (2) business days before meeting.

3.4.2 - Deliverables

Delivery of other reports and deliverables will be proposed by the Offerors in their technical proposal. They will be developed further after receipt of proposals as a result of finalization of the SOW and other terms and conditions of any resultant contract during negotiations.

All electronic reports and deliverables shall be submitted through the NIAID Electronic Reports and Deliverables System, available here: https://erds.niaid.nih.gov/

-- END OF RESEARCH AREAS 001 AND 002 –

3.5 - RESEARCH AREA 003 - *ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS*

The following information supplements Section 4 – Instructions, Conditions, and Notices to Offerors of this solicitation, and should be used for preparing proposals.

3.5.1 – PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Product Development Plan that provides detailed information about the current development status of the diagnostic and outlines the Offeror's plans to advance the development of the diagnostic. The Product Development Plan should include the following - AS APPLICABLE – based on the stage of development of the proposed diagnostic:

1. A description of the current status of the diagnostic and plans for the assay development of the diagnostic including, e.g., internal controls, external controls, and software.
2. A description of the assay integration plan on a commercially established automated platform.
3. A description of the developers' roles and responsibilities, organization charts, timelines, and proposed risk analyses.
4. A description of studies to perform initial validation testing of the diagnostic using human clinical samples containing virulent pathogens.
5. A description of plans to manufacture the diagnostic under GMP conditions.
6. A description of plans to conduct clinical studies using prospectively collected samples.

3.5.2 – WORK PLAN (For the implementation of the PRODUCT DEVELOPMENT PLAN)

Technical proposals shall include a work plan detailing specific tasks that the Offeror proposes to perform with contract funding that can reasonably be completed within the period of performance. These completed tasks include milestones and other gating items for Go/No Go decisions with a timeline Gantt chart that can be correlated with a task-linked budget at a level that facilitates government oversight of funded activities.

The Work Plan for the candidate diagnostic product submitted with the Technical Proposal will be subject to negotiations and if an award is made, the SOW, to be developed by the Offeror and provided with the Technical Proposal, shall provide for the updated Work Plan to be approved by the COR and the CO prior to the initiation of any activities related to its execution. In addition, the SOW shall provide for annual updates of the Work Plan--and additional updates upon a change in any task--that must be approved by the COR and the CO prior to the initiation of any activities related to its execution. The Work Plan shall include:

a. Base, Options, and milestones for key project objectives.

b. Threshold decision gates using objective, measurable criteria to enable Go/No-Go decisions for advancement into the next stage of development. For each decision gate proposed, a description of the specific qualitative and quantitative criteria, associated data elements and the process for making decisions to proceed or not proceed (Go/No-Go), for advancement of the candidate diagnostic through the next stage of product development shall be presented.

c. Timelines for: the initiation, conduct and completion of product development activities for each stage; the analysis of outcomes and findings; and, the preparation of detailed reports

summarizing the results of work completed and an analysis of the data as it relates to the qualitative and quantitative criteria established for Go/No-Go decision making.

d. A Gantt chart of proposed activities that are associated with a task-linked budget at a level that facilitates Government oversight, and contractor management of those activities. A Gantt chart of proposed activities that can be correlated with a task-linked budget at a level that facilitates Government oversight of those activities.

   The Gantt chart should be organized by each specific decision gate/stage of product development proposed, as well as the overall product development program. Schedules should be shown in terms of calendar months from the date of authorization to proceed or, where applicable, the date of a stated event. The timeline will identify summary tasks and subtasks, including predecessor and successor logic for all activities covering the initiation, conduct and completion of all product development activities in a base period and in subsequent option periods.

   The task-linked budget should provide a breakdown of direct costs linked to each activity, task and subtask contained on a detailed chart.

e. A detailed discussion of the proposed technical approach for each activity to be performed to achieve the key project objectives, with enough detail to fully explain and justify the scientific/technical rationale for the proposed approach and/or methodologies.

f. The following, AS APPLICABLE for the project being proposed:
   • Approach for manufacturing
   • Description of other studies, including all Investigational Device Exemption (IDE) and/or FDA submission-enabling studies.

g. Plans for quality control over the implementation, coordination and conduct of the activities set forth in the Work Plan, including plans to conduct audits.

h. A risk management and mitigation plan required to address the integration of adverse experimental or production results, new scientific findings and/or guidance from FDA into the proposed goals and timelines.

i. A plan for sharing data and resources, reagents, assays and animal models developed with contract funding with the scientific community.

j. A list and description of all items to be delivered to the Government at each stage in the product development process during the performance of the contract and a timeline for delivery to be determined at time of award.

   NOTE: Depending on the status of the individual candidate product, the Contractor may be required to deliver to the Government an amount of product for any purpose deemed necessary by the Government.

k. A Technical Proposal Cost Summary to include: a list of all subcontracts by activity (for example, GMP manufacture, etc.) including a budget for each stage of product development proposed for funding (direct costs plus indirect costs).

l. Offerors proposing subcontracts and/or consultants to perform portions of the proposed work should clearly identify the specific tasks for which they plan to utilize subcontractors and/or consultants, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors and/or consultants, and the expected advantages of such an approach. Processes for subcontractor and consultant identification, selection, management and evaluation should be described. Expected deliverables associated with consulting services should be clearly delineated.

m. The technical proposal should include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the Offeror's understanding of the project may be evaluated (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf). However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs.

The Product Development Plan will be subject to negotiations, and if an award is made, the resulting contract shall provide for continuing revision of the Product Development Plan following periodic input and approval from the Government.

3.5.3 – CLINICAL STUDY PROTOCOL DEVELOPMENT AND IMPLEMENTATION (AS APPLICABLE)

Human subjects research may be carried out under this contract with the approval of DMID. Describe experience in the conduct of human subjects research in accordance with DMID, NIAID, and NIH policies and guidelines and provide a statement acknowledging willingness to conduct clinical research according to these policies and in accordance with applicable ICH and FDA regulations and guidance.

Provide a Protocol Synopsis for each proposed clinical study and/or clinical trial, including a brief description of all of the following:

• Study objectives and endpoints
• Human subjects protection
• Provisions for data monitoring and safety reports
• Draft inclusion/exclusion criteria and recruitment, and retention of study participants
• Informed consent
• Quality management plan – if applicable
• Clinical monitoring plan – if applicable
• Summary of statistical approach – if applicable
• Plan for management of subcontractor activities

Document experience of the Offeror and any proposed subcontractor(s) and consultant(s) experience with designing clinical studies, executing clinical studies and managing clinical studies in compliance with regulatory requirements and GCP.

Provide a plan that specifies at which points in the SOW it will be critical to engage in communications with the FDA and the means by which NIAID will be kept apprised of such communications.

3.5.4 – REGULATORY COMPLIANCE, QUALITY CONTROL & ASSURANCE AND DATA MANAGEMENT (AS APPLICABLE)

- Describe the data management and quality control systems/procedures that will be used for all studies and procedures for data entry and validation, documentation of data corrections, routine maintenance and backup, transmission of data, data reporting and exporting system, access control and confidentiality, and data retrieval and disaster recovery in accordance with 21 CFR 11.
- Describe the statistical design and analysis resources that will be used to support contract activities.
- Provide a plan to develop and maintain quality assurance documentation to support adherence to FDA regulatory standards and guidance that bear on the conduct of assays under GLP, manufacturing under GMP, and performance of clinical trials under GCP standards, as relevant to the Product Development Plan.
- Document experience of the Offeror and any proposed subcontractors and consultants experience with performing regulated studies in accordance with FDA regulations and guidance, including GLP, cGMP, and/or GCP guidelines as appropriate to their proposed SOW.
- Describe a plan to determine when audits need to be performed, timely scheduling of audits, performance of audits, and responding to audit reports
- Provide an audit history of the facilities proposed for use in carrying out contract activities that will be performed under GLP, cGMP and/or GCP.
- Provide letters signed by the appropriate authority allowing for pre-award site visits to the Offeror's facility and proposed subcontractors' facilities. Site visits may include GLP, cGMP, or GCP audits (as appropriate) performed by independent auditors contracted by the NIAID.

3.5.5 – UNIFORM COST ASSUMPTIONS

Offerors should use the following assumptions for the purposes of estimating costs and preparing the technical proposal:

a. Purchase of Equipment: Cost will NOT be allowed for the purchase of any equipment, hardware, or software under this contract.

b. Alterations and Renovations: Cost will NOT be allowed for any facility construction, alterations, or renovations under this contract.

c. Programmatic Presentations and Meetings: Assume attendance at the following meetings:

1) Post Award Contract Initiation Meeting

The Contractor shall be responsible for arranging a one-day meeting at 5601 Fishers Lane, Rockville, MD within 60 days after award date. Attendees should include all Key Personnel and Key Subcontractor Personnel.

2) Annual Contract Review Meetings

For each year of performance, the Contractor shall attend an Annual Contract Review meeting. The meetings will be held at the Contractor's facility, and a location at or near

5601 Fishers Lane, Rockville, MD.., on an alternating-year basis. Each meeting will be one-day in length. Attendees should include all Key Personnel and Key Subcontractor personnel.

3) Monthly Meetings/Teleconferences

Plan and conduct meetings of the Contractor's PI and Project Manager with the COR at a minimum of monthly intervals via teleconference, to discuss progress, problems, proposed solutions and any matter that is relevant to the scientific and financial administration of the project and future activities. The schedule for those meetings will be established by the COR after the contract award. The Contractor shall prepare and submit the meeting agenda and distribute the agenda and background materials to all meeting participants at least 2 calendar days in advance of the meeting, prepare and provide a summary of all meetings and teleconferences to the COR within the timeframe stated in the delivery schedule and include each summary in the Monthly Technical Progress Reports.

3.5.6– POST-AWARD REQUIREMENTS

The following POST-AWARD requirements will apply to all awards made under Research Areas 003 of this BAA.

Offerors are instructed to address responsibility for complying with these requirements in the proposed SOW for the Technical Proposal. Offerors are NOT required to submit documentation to address these post-award requirements in their technical proposals. Instructions for submitting documentation associated with post-award requirements will be provided during negotiations.

3.5.6.1 – Contractual Commitments

Upon award of a contract, the contractor shall be required to make legal commitments through acceptance of Government contract clauses contract. The outline that follows is illustrative of the types of provisions required by the Federal Acquisition Regulations that shall be included in the contract. This is not a complete list of provisions to be included in contracts, nor does it contain specific wording of these clauses. Copies of complete terms and conditions applicable to your contract will be provided during negotiations.

1) Inspection: Work performed under the contract is subject to Government inspection and evaluation at all times.

2) American-made Equipment and Products: When purchasing equipment or products under a contract award, the contractor shall purchase American-made items whenever possible.

3) Termination for Default: The Government may terminate the contract for default if the contractor fails to perform the work described in the contract and such failure is not the result of excusable delays.

4) Contract Work Hours: The contractor may not require an employee to work more than eight hours a day or forty hours a week unless the employee is compensated accordingly (i.e., overtime pay).

5) Covenant Against Contingent Fees: No person or agency has been employed to solicit or secure the contract upon an understanding for compensation except bona fide employees or commercial agencies maintained by the contractor for the purpose of securing business.

6) Disputes: Any dispute concerning the contract that cannot be resolved by agreement shall be decided by the CO with right of appeal.

7) Equal Opportunity: The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.

8) Gratuities: The Government may terminate the contract if any gratuities have been offered to any representative of the Government to secure the contract.

9) Termination for Convenience: The Government may terminate the contract at any time for convenience if it deems termination to be in its best interest, in which case the contractor will be compensated for work performed and for reasonable termination costs.

10) Patent Infringement: The contractor shall report each notice or claim of patent infringement based on the performance of the contract.

3.6 – RESEARCH AREA 003 – *REPORTING REQUIREMENTS AND DELIVERABLES*

3.6.1 – Reporting Requirements

In addition to reporting requirements and deliverables identified elsewhere in this solicitation, it is expected that awards resulting from Research Areas 003 will include the following reports and deliverables:

a. Monthly Progress Reports

This report shall include a description of the technical activities and results during the reporting period and the activities planned for the ensuing reporting period and shall include a budget summary for costs incurred during the monthly reporting period for the base period and each option and milestone. The funding level shall be presented in correlation with percent completion of the activities under the base, option and/or milestone. Monthly Progress Reports shall not be required when the Annual Progress Report is due.

b. Annual Progress Reports

This report shall include a summation of the technical activities and results for the entire contract period covered and shall include a description of the technical activities and results during the reporting period, a budget summary for costs incurred during the annual reporting period for the base period and each option and milestone. The funding level shall be presented in correlation with percent completion of the activities under the base, option and/or milestone. An Annual Progress Report shall not be required for the period when the Final Report is due.

c. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001.

d. Final and Draft Reports

This report includes a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. An annual report will not be required for the period when the Final Report is due. The Contractor shall submit, with the Final Report, a summary of salient results (not to exceed 250 words) achieved during the performance of the contract. The draft report will be due 30 days prior to the end of the contract.

e. Product Development Plan and Work Plan

The Contractor shall update the Product Development Plan and create a Work Plan to incorporate the progress from the effective date of the contract. The Contractor shall submit an updated Product Development Plan for review within thirty (30) calendar days of the effective date of the contract and prior to initiation of product development activities, unless otherwise

negotiated with the COR and the CO. This updated Product Development Plan and Work Plan shall include:

1) Clearly defined goals, product development stages and product development activities.

2) A breakdown of activities by fiscal year and non-severable stages, and applicable decision gates.

3) Quantitative and qualitative criteria and associated data elements for assessing the scientific merit and feasibility of moving to the next stage of product development.

4) A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a task-linked budget (a budget linked to each major activity). A Gantt chart should be provided to outline the proposed activities.

5) A description of the studies to be performed within each stage of the project. The Contractor shall also be required to submit a revised Product Development Plan and associated Work Plan when a change to the approved plans is requested by the COR.

6) Risk identification, analysis, and mitigation strategies for accomplishing the objectives of this contract within the period of performance, particularly with respect to adverse experimental or production results, new scientific findings or regulatory guidance from FDA.

NOTE – For purposes of this BAA:

• The Product Development Plan describes the critical path for the proposed candidate/product toward eventual licensure and identifies the decision points/gates for progress of the candidate/product.

• The Work Plan describes the studies to be performed at each stage of the project within the 5-year term of award in order to implement the Product Development Plan and advance the product through mid-stage development.

f. Decision Gate Report

A Decision Gate Report shall be submitted when the Contractor has completed a stage of product development and has reached a decision point, as defined in the Work Plan for the Implementation of the Staged Product Development Plan. These reports shall be in sufficient detail to explain comprehensively the milestones and other gating items achieved. The description shall also include pertinent data and/or conclusions resulting from the analysis and scientific evaluation of data accumulated to date under the project. Offerors shall propose the timing of these reports to coincide with the decision points specified in their SOW.

Note: Contract activities shall be divided into manageable time frames with associated deliverables. Initial funding shall be for the Base Period only. Funding of subsequent deliverables shall be funded by Options. Each Option shall be fully funded when exercised and

shall be dependent on successful completion of critical gating items, including the United States Government acceptance of associated deliverables, when applicable. The critical predecessor activities should constitute decision-enabling criteria for successor activities. The contract budget shall be aligned with the Base Period, Options and associated tasks identified in the Product Development Plan and associated Gantt chart.

g. Audit Reports

Within thirty (30) calendar days of completion of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP or GCP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

h. Draft and Final Clinical Study and/or Clinical Trial Protocols

NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in the NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award), the Contractor shall develop a protocol and all associated documents for each clinical study and/or clinical trial and submit drafts for review as well as all final protocols and protocol amendments for approval by DMID. Prior to FDA submission and/or enrollment, additional reviews and approval periods may be required for changes in the final protocol. Three (3) weeks should be planned for each review period. It is recommended that protocols be submitted using approved DMID templates.

The DMID templates and other important information regarding performing human subject research are available at https://www.niaid.nih.gov/grants-contracts/human-subjects.

i. Draft and Final Clinical Study Report

For each clinical study performed with contract support, a Draft Clinical Study Report shall be provided upon completion of the analysis of all data generated in the clinical study. If a clinical trial is performed final Clinical Trial Reports shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3.

j. FDA Correspondence and Meetings

Submit for review and approval planned FDA communications as well as any subsequent correspondence and resulting meeting summaries.

k. Human Subject IRB Annual Report (Form OMB No. 0990-0263)

Within thirty (30) calendar days of each anniversary date of the effective contract award, the Contractor shall submit the Human Subject Annual Report.

l. Clinical Monitoring Plan - As applicable

For each clinical trial performed with contract support, a Clinical Monitoring Plan should be prepared and submitted forty-five (45) calendar days prior to the intended initiation date of the clinical trial.

m. Clinical Monitoring Reports - As applicable

A copy of each Clinical Monitoring Report shall be provided within thirty (30) calendar days of the completion of the clinical monitoring visit, unless significant GCP violations were discovered in the clinical monitoring visit. If significant GCP violations were discovered, the Contractor will notify the COR as soon as the Contractor learns about the violation, and the Clinical Monitoring Report shall be provided within fifteen (15) calendar days of the completion of the clinical monitoring visit.

n. QA Reports – As applicable

Upon request of the COR, the Contractor shall provide a copy of the QA reports within five (5) calendar days from the COR request.

o. Safety Oversight Reports – As applicable

The Contractor shall provide open (blinded) and closed (unblinded) reports to be reviewed by the safety oversight monitoring board at the intervals specified by the approved clinical protocol. The Contractor shall provide the report at least ten (10) business days prior to each board meeting date in a format mutually agreed upon. The Contractor shall provide shell reports (without any data) at least ten (10) business days prior to the organizational meeting of the safety board.

p. Samples of Products

The Contractor shall submit samples of GMP material manufactured with contract funding. The type of material and the amount will be specified in the contract.

q. Technology Transfer

Technology Transfer packages shall include complete protocols and critical, assays or procedures developed and/or improved with contract funding.

r. Institutional Biosafety Approval

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments.

Note: Copies of other reports and documents for work generated under the BAA may include draft and final reports for Process Development, Assay Qualification, Assay Validation, Assay Technology Transfer, Batch Records, SOPs, Master Production Records, and Certificates of Analysis. The delivery schedule, requirements of other reports and deliverables shall be proposed by the Offerors in their technical proposal. They will be developed further after

receipt of proposals as a result of finalization of the SOW and other terms and conditions of any resultant contract during negotiations.

s. Annual Contract Review Meeting

A report of the Post Award Contract Initiation Meeting and Annual Contract Review Meetings shall be prepared by the Contractor and submitted within twenty-one (21) calendar days following the date of the meetings. These reports shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

t. Teleconference and Meeting Minutes

Minutes of regular, as well as ad hoc teleconferences and meetings shall be provided by the Contractor within two (2) business days following the date of the teleconference or meeting. Agendas shall be provided two (2) business days before such meetings.

3.6.2 - Deliverables

Delivery of other reports and deliverables will be proposed by the Offerors in their technical proposal. They will be developed further after receipt of proposals as a result of finalization of the SOW and other terms and conditions of any resultant contract during negotiations.

All electronic reports and deliverables shall be submitted through the NIAID Electronic Reports and Deliverables System, available here: https://erds.niaid.nih.gov/

-- END OF RESEARCH AREA 003 –

SECTION 4. - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

4.1 - GENERAL INSTRUCTIONS TO OFFERORS

4.1.1 - Submission, modification, revision, and withdrawal of proposals.

4.1.1.1 - The first page of the proposal must show--

i. The solicitation number;
ii. The name, address, telephone number and electronic address;
iii. Names, titles, telephone number, and electronic addresses of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
iv. Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

4.1.1.2 - Submission, modification, revision, and withdrawal of proposals.

i. Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation.

ii. (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the CO determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

iii. Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

iv. If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the

solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

v. Proposals may be withdrawn by written notice received at any time before award. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

4.1.1.3 - Offerors shall submit proposals in response to this solicitation in English, and in U.S. dollars.

4.1.1.4 - Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

4.1.1.5 - Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

4.1.1.6 - Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the CO.

4.1.2 - Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

4.1.3 - Restriction on disclosure and use of data.

4.1.3.1 - The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)."

4.1.3.2 - In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

4.1.3.3 - Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

4.1.4 - Contract award

4.1.4.1 - The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

4.1.4.2 - The Government may reject any or all proposals if such action is in the Government's interest.

4.1.4.3 - The Government may waive informalities and minor irregularities in proposals received.

4.1.4.4 - The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be among the most highly rated proposals. An offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

4.1.4.5 - The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

4.1.4.6 - The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

4.1.4.7 - Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

4.1.4.8 - The Government may determine that a proposal is unacceptable if the prices proposed are

materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

4.1.4.9 - Cost realism analysis will be performed and may be considered by the source selection authority in evaluating performance or schedule risk.

4.1.4.10 - A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

4.1.4.11 - If a debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of significant elements in the proposal.

(ii) A summary of the rationale for not selecting the proposal for award.

(iii) reasonable responses to relevant questions about whether award procedures contained in the BAA, applicable regulations, and other applicable authorities were followed in the process of not selecting the proposal for award.

(End of Provision)

4.2 - GENERAL INFORMATION

4.2.1 - Representations, Certifications, and Other Statements of Offerors

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

a) Go to the System for Award Management (SAM) and complete the Representations and Certifications. The SAM website may be accessed at: http://www.sam.gov; and

b) Complete, and INCLUDE, the Representations and Certifications as part of your BUSINESS PROPOSAL.

4.2.2 – Representation Regarding Certain Telecommunications and Video Surveillance Services or Requirement

FAR Clause **52.204-24, Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment** (Aug 2020) is incorporated into this BAA solicitation.

Offerors submitting a proposal in response to this solicitation are required to provide a representation regarding use of covered telecommunications equipment or services when submitting an offer as part of your BUSINESS PROPOSAL. Please refer to paragraph (d) of FAR Clause 52.204-24.

Effective August 13, 2020, the Government is prohibited from contracting with any entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system unless an exception applies or a waiver has been granted.

4.2.3 - NAICS Code and Size Standard

Note: The following information is to be used by the Offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541715.

2. The small business size standard is 1,000 employees.

THIS REQUIREMENT IS NOT SET ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the NAICS Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

4.2.4 – Contract Type and Number of Awards

4.2.4.1 - It is contemplated that multiple cost-reimbursement completion type contracts will be awarded. Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

4.2.4.2 - FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section 4.3.3 - Business Proposal Instructions, in this solicitation for additional information about this certification.

4.2.5 - Commitment of Public Funds

The CO is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

4.2.6 - Promoting Efficient Spending

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35 , entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 3, 2012, the Department of Health and Human Services (DHHS)

issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing, and Publications" (See https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/.)

In support of these directives, the NIH issued a January 30, 2012, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See http://oamp.od.nih.gov/)

Any contract awarded as a result of this solicitation will

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and
- Limit the procurement of meeting space, promotional items, printing and publications.

4.2.7 - Communications Prior to Contract Award

Offerors shall direct all communications to the attention of the Contract Specialist or CO cited at the beginning of this announcement. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

4.2.8 - Release of Information

Contract selection and award information will be disclosed to Offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful Offerors as they are eliminated from the competition, and to all Offerors following award.

4.2.9 - Preparation Costs

This BAA does not commit the Government to pay for the preparation and submission of a proposal.

4.2.10 - Service of Protest (September 2006) - FAR 52.233-2

Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the CO (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Alexandra Buck
Contracting Officer
Office of Acquisitions
National Institute of Allergy and
Infectious Diseases
DEA, Office of Acquisitions
5601 Fishers Lane, Room 3D39, MSC 9821
Rockville, Maryland 20892-9821

The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

4.3 - INSTRUCTIONS TO OFFERORS

4.3.1 - General Information

4.3.1.1 - Authorized Official

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this BAA. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in Section 4.3.2.1 - PROPOSAL SUBMISSION INSTRUCTIONS. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

I. COVER PAGE

Include BAA title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in Section 4.3.2 - TECHNICAL PROPOSAL INSTRUCTIONS.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in Section 4.3.3 – BUSINESS PROPOSAL INSTRUCTIONS.

4.3.1.2 - Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated. However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

4.3.1.3 - Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations.

4.3.1.4 - Evaluation of Proposals

The Government will evaluate proposals in accordance with the factors set forth in SECTION 6 this BAA.

4.3.1.5 - Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the CO determines that the initial prices are fair and reasonable and that discussions are not necessary.

4.3.1.6 - Use of The Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

4.3.1.7 - Privacy Act - Treatment Of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this SOLICITATION pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:
- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

4.3.1.8 - Selection of Offerors

a. The acceptability of the technical portion of each proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the BAA, utilizing point scores and written critiques. The committee may suggest that the CO request clarifying information from an offeror.

b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis.

c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal or to resolve minor or clerical errors.

d. If the Government intends to conduct discussions prior to awarding a contract, oral or written discussions will be conducted with selected offerors to address identified weaknesses, questions, and areas for clarification, as well as to refine the proposed SOW and deliverables.

4.3.1.9 - Institutional Responsibility Regarding Conflicting Interests of Investigators

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

4.3.1.10 - ROTC Access And Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2)

a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

4.3.1.11 - Certification of Filing and Payment of Taxes

None of the funds appropriated or otherwise made available by the Consolidated Appropriations Act of FY 2014, may be used to enter into a contract in an amount greater than $5,000,000 unless the prospective contractor certifies in writing to the agency awarding the contract that, to the best of its knowledge and belief, the contractor has filed all Federal tax returns required during the 3 years preceding the certification, has not been convicted of a criminal offense under the Internal Revenue Code of 1986, and has not, more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding.

4.3.1.12 - 52.203-98 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements--Representation (DEVIATION)

a. In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Resolution Appropriations Act, 2015 (Pub. L. 113-235), Government agencies are not permitted to use funds appropriated (or otherwise made available) under that or any other Act for contracts 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 subcontractors 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.

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 internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors 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.

(End of provision)

4.3.1.13 - Prohibition on Contractor Involvement with Terrorist Activities

For awards funded with appropriated bio-defense funds, the Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

4.3.1.14 - Electronic and Information Technology Accessibility Notice, HHSAR 352.239-73 (December 2015)

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/the-board/laws/rehabilitation-act-of-1973.

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508 . In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION 7 - List of Attachments, of this solicitation.

4.3.1.15 - Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (FEBRUARY 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. System for Award Management, FAR Provision 52.204-7 (October 2016). **Alternate I** (July 2013) is not applicable to this solicitation.
b. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991)
c. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991)
d. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003)
e. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009)
f. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999)
g. Certification Regarding Trafficking in Persons Compliance Plan, FAR Provision 52.222-56 (March 2015)

4.3.2 - TECHNICAL PROPOSAL INSTRUCTIONS

It is strongly recommended that offerors use the following template as the format for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These Technical Proposal Instructions reflect the requirements of the BAA and provide specific instructions and formatting for the Technical Proposal. These Technical Proposal Instructions are applicable to all proposals submitted in response to this BAA and should be used as a Table of Contents for your Technical Proposal. Offerors should also refer to the Technical Proposal Instructions in Section 3, for specific requirements applicable to the Research Area for which you are proposing.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference materials and attachments, the Technical Evaluation Criteria in Section 6, and the BAA as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts and/or consultants to perform portions of the proposed SOW should clearly identify the specific tasks for which they plan to utilize subcontractors and/or consultants, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors and/or consultants, and the expected advantages of such an approach.

Offerors must refer to Section 4.3.2.1.3 – Formatting and Page Limitations, which details strict guidelines, including page limitations, formatting and layout of proposals, and prohibits the offerors use of links to internet web site addresses (URLs) to direct readers to alternate sources of information.

4.3.2.1 - PROPOSAL SUBMISSION INSTRUCTIONS

4.3.2.1.1 - Receipt Date

This BAA includes three distinct Research Areas, each with a specified closing date and time, identified below. An Offeror must submit a separate and distinct proposal for each Research Area to which it wishes to propose.

RESEARCH AREA	NIAID DIVISION	TITLE	RECEIPT DATE AND TIME
001	DMID	Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases	3:00PM Eastern Time, 05/24/2021
002	DMID	Development of Therapeutic Products for Biodefense, Anti-Microbial Resistant (AMR) Infections and Emerging Infectious Diseases	3:00PM Eastern Time, 05/24/2021
003	DMID	Advanced Development of Sequencing-Based Diagnostics for Biothreats and Emerging Infectious Diseases	3:00PM Eastern Time, 05/24/2021

4.3.2.1.2 - Online Submission of Electronic Proposals

a. For this solicitation, NIAID requires proposals to be submitted Online via the electronic Contract Proposal Submission (eCPS) website: https://ecps.nih.gov. Submission of proposals by any other method is not permitted.

b. For directions on using eCPS, go to the website https://ecps.nih.gov and then click on "How to Submit."

c. All Offerors must complete: "PHS Human Subjects and Clinical Trials Information Form", available in Section 7. Attachments. This form must be submitted as a separate document in eCPS for all proposal submissions in addition to the Technical and Business proposals.

4.3.2.1.3 - Formatting and Page Limitations

a. The Technical Proposal shall not exceed 150 pages, inclusive of CV's. Although no page limit has been placed on the Business Proposal, Offerors are encouraged to limit its content to only those documents required by this solicitation, and necessary to provide adequate support for the proposed costs.

b. Total page count does not include: Title and Back Page; Table of Contents; and Section Dividers that do not contain information other than the title of the Section.

c. Pages in excess of this limitation will be removed from the proposal and will not be considered.

d. Proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information.

e. Font size must be 10 to 12 points.

f. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.

g. Margins must be at least one-inch on all sides.

Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in its entirety.

4.3.2.2 - TECHNICAL PROPOSAL – TABLE OF CONTENTS

*The Technical Proposal is limited to 150 pages, inclusive of CV's.

SECTION 1:

1) PROPOSAL TITLE PAGE

Include BAA title and number, name of organization, DUNS number, and identify if the proposal is an original or a copy. Offerors that include data in their proposals that they do not want disclosed to the public for any purpose, or used by the Government except for

evaluation purposes, shall also include the legend regarding Restriction on Disclosure and Use of Data prescribed by FAR 52.215-1 (e)]

2) TABLE OF CONTENTS

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide a brief description of the proposed project, including:

1) 1-2 sentence summary describing the concept the offeror is proposing.

2) A summary describing the scope of the activities proposed.

3) A brief description of the activities proposed by the offeror and all proposed subcontractors, including identification of all proposed subcontractors and a list of key personnel for the offeror and the proposed subcontractors with degrees, titles and role in the project.

4) By area of expertise, provide the proposed total number and hours or effort of personnel: the number currently employed to be assigned to this contract; all proposed subcontractors; and total number of additional staff to be hired and trained.

5) A brief description of the facilities and other resources to be made available by the proposed prime contractor (offeror) and any proposed subcontractors.

SECTION 3: STATEMENT OF WORK FORMAT

Offeror(s) are required to provide a SOW in their proposal. The SOW shall be developed by each offeror based on the information in Section 3 of this solicitation, entitled "Research Areas and Technical Objectives", and shall consist of two parts: (1) Scope, and (2) Technical Requirements. Provided below is an outline of the SOW format that should be used by all offeror(s) in the preparation of their Technical Proposals. The headers and subheaders may be adjusted to match the requirements as proposed in each offeror's individual technical proposal.

Contracts awarded as a result of this BAA will include the SOW proposed by the offeror. Offeror(s) will be required to perform the activities and provide the resources appropriate to the scope of their specific negotiated SOW.

The opening paragraph under the Technical Requirements section of the SOW shall be followed by a description of all activities that the Contractor shall perform after the award of the contract. The Technical Requirements shall include all activities required to effectively implement the project and shall include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and other deliverables, along with a timetable for their delivery.

NOTE TO OFFEROR: Each offeror shall provide detailed specifications of the requirement utilizing the following sample outline of tasks and subtasks. Any tasks or subtasks that are not applicable to your proposed effort should be deleted. Any tasks or subtasks specific to your proposed effort not addressed below shall be added.

SAMPLE STATEMENT OF WORK FOR RESEARCH AREAS 001 and 002

1. SCOPE

Instruction to offerors: Provide a brief description (one to two paragraphs) of the overall project and objectives in broad terms that indicates the size and magnitude of the proposed effort.

2. TECHNICAL REQUIREMENTS

[NOTE TO OFFEROR: The Technical Requirements shall begin with the following introductory paragraph.]

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below. Specifically, the Contractor shall:

A. Product Development Plan, including as applicable:
   1. **Efficacy Studies (Including Model Development)**
   2. **Animal Safety Studies**
   3. **Non-Clinical Research and Development**
      a. Efficacy Studies (including model and assay development)
      b. Animal Safety Studies (including pharmacology/toxicology)
   4. **Manufacturing and CMC Development**
   5. **Clinical Trial Protocol Development and Implementation**
   6. **Other IND/IUO-Enabling Studies**
   7. **Process Development**
   8. **cGMP Manufacturing**

B. Work Plan
C. Regulatory Compliance, Quality Control, Assurance and Data Management
D. Project Management
E. Communication and Contract Review Meetings
F. Reports and Deliverables

SAMPLE STATEMENT OF WORK FOR RESEARCH AREA 003

1. SCOPE

Instruction to offerors: Provide a brief description (one to two paragraphs) of the overall project and objectives in broad terms that indicates the size and magnitude of the proposed effort.

2. TECHNICAL REQUIREMENTS

[NOTE TO OFFEROR: The Technical Requirements shall begin with the following introductory paragraph.]

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below. Specifically, the Contractor shall:

A. Product Development Plan, including as applicable:
1. Diagnostic Development
2. Integration and Optimization of Diagnostic
3. Initial Diagnostic Testing Using Human Clinical Samples Containing Virulent Pathogens – pre-existing human clinical samples or human samples spiked with virulent pathogens
4. Diagnostic Manufacturing
5. Clinical Feasibility Testing Using Prospectively Collected Samples

B. Work Plan
C. Regulatory Interactions, Quality Control, Assurance and Data Management
D. Project Management
E. Communications and Contract Review Meetings
F. Reports and Deliverables

SECTION 4: TECHNICAL DISCUSSIONS

In addition to the guidance provided in the Technical Proposal Instructions of the BAA, this section of your technical proposal should include documentation to demonstrate how you will accomplish the work detailed in your proposed SOW. It is recommended that your proposal be organized in accordance with the order of your SOW and the technical evaluation criteria provided in Section 6.

SECTION 5: SCIENTIFIC AND TECHNICAL PERSONNEL

Provide information relevant to document individual training, experience, qualifications and expertise necessary for the successful completion of the proposed SOW. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the contract.

1) Principal Investigator (PI): Describe the experience, training, expertise, and qualifications, and level of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under the proposed SOW.

2) Other Key Scientific and Technical Personnel: Describe the experience, training, expertise and qualifications for all proposed key scientific and technical personnel.

Note - Offerors should assure that the principal investigator, and all other personnel proposed, shall not be committed on federal grants and contracts for more than a total of 100% of their time. If the situation arises where it is determined that a proposed employee is committed for more than 100% of his or her time, the government will require action on the part of the offeror to correct the time commitment.

SECTION 6: PROJECT MANAGEMENT

1) Provide a Project Management Plan for the overall organization that addresses the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the proposed SOW. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s).

2) Provide a Staffing Plan that describes roles, responsibilities, and level of effort for all personnel, including all proposed subcontractors and consultants. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. Include a chart of the proposed organizational/management structure for the project.

3) Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.

4) Outline how the PI (or Project Manager) will communicate with the COR and CO and how the PI (or Project Manager) will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

SECTION 7: FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Technical Proposal should document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the proposed SOW, including:

1) Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

2) Identification and description of ALL support resources (including Information Technology systems) that will be required to effectively complete the proposed SOW.

SECTION 8: OTHER CONSIDERATIONS

This section of the Technical Proposal should document other resources not covered in Sections 1 through 7 above, necessary to carry out the proposed SOW.

4.3.2.3 - HUMAN SUBJECTS

Important Note to Offerors: As applicable to the offeror's proposed approach, the following subparagraphs should be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

4.3.2.3.1 - Notice to Offerors of Requirements, Protection of Human Subjects, HHSAR 352.270-4(a) (December 2015)

a. The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) Web site at: http://www.hhs.gov/ohrp/index.html .These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

b. The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

c. Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.101(b)(1)-(6) are exempt from complying with 45 CFR part 46. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

d. Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

e. In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; seehttp://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. 46.111 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at http://www.hhs.gov/ohrp/assurances/index.html).

f. Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the CO may offer information concerning a solicitation.

g. The offeror shall document in its proposal the approved FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research. If the offeror does not have an approved FWA from OHRP, the offeror must obtain an FWA before the deadline for proposal submission. When possible, the offeror shall also certify the IRB's review and approval of the research. If the offeror cannot obtain this certification by the time of proposal

submission they must include an explanation in their proposal. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision)

4.3.2.3.2 - Instructions to Offerors Regarding Protection of Human Subjects

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

a. Risks to the subjects
   - Human Subjects Involvement, Characteristics, and Design:
     - Briefly describe the overall study design in response to the solicitation.
     - Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.
     - List any collaborating sites where human subjects research will be performed and describe the role of those sites and collaborating investigators in performing the proposed research.

   - Study Procedures, Materials, and Potential Risks
     - Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.
     - For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
     - Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
     - Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.

b. Adequacy of Protection Against Risks
   - Recruitment and Informed Consent:
     - Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to

consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

- For research involving children: If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.
- If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

- Protection Against Risk:
  - Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
  - Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
  - In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

- **Vulnerable Subjects, if relevant to your study** - Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).
  - Pregnant Women, Fetuses, and Neonates or Children - If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.
    - HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
    - HHS' Subpart D - Additional Protections for Children
    - OHRP Guidance on Subpart D Special Protections for Children as Research Subjects and the HHS 407 Review Process

c. Potential Benefits of the Proposed Research to the Subjects and Others
- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

Note: Financial compensation of subjects should not be presented as a benefit of participation in research.

d. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note : If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the FDA and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

4.3.2.3.3 - Required Education in the Protection of Human Research Participants

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research on-line tutorial , entitled “Protecting Human Research Participants” at: http://phrp.nihtraining.com . This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: http://pphi.nihtraining.com. You may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual, entitled, "Protecting Study Volunteers in Research," can be obtained through Centerwatch, Inc. at: http://store.centerwatch.com/c-29-training-guides.aspx .

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the CO with the title of the education program and a one sentence description of the program that the replacement has completed.

4.3.2.3.4 - Inclusion of Women and Minorities in Research Involving Human Subjects

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended November 2017," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research."

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the SOW, national and local demography, knowledge of the

racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" (see Section J, Attachments)

NOTE 1 : *For all proposals, use the ethnic and racial categories and complete the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" in accordance with the Office of Management and Budget (OMB) Directive No. 15.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials *** require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm , Definitions - Significant Difference).
*The definition of an " **NIH-Defined Phase III clinical trial** " can also be found at this website.) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups,

OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section 7 – Attachments of this BAA)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Cumulative Inclusion Enrollment Report," for reporting in the resultant contract.

4.3.2.3.5 - Inclusion of Children in Research Involving Human Subjects

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are clear and compelling reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 18 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.grants.nih.gov/grants/guide/notice-files/NOT-98-024.html

Offerors also may obtain copies from the contact person listed in the BAA.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
  1) There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
  2) The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
  3) A separate, age-specific study in children is warranted and preferable. Examples include:
     - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
     - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
     - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
     - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
     - Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
     - Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 18 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

4.3.2.3.6 - Research Involving Prisoners as Subjects

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://www.hhs.gov/ohrp/policy/prisoner.html .

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
    a. to describe the prevalence or incidence of a disease by identifying all cases, or
    b. to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
    c. the research presents no more than minimal risk, and
    d. no more than inconvenience to the prisoner subjects, and
    e. prisoners are not a particular focus of the research.

    For more information about this Waiver see http://www.gpo.gov/fdsys/pkg/FR-2003-06-20/html/03-15580.htm

4.3.2.3.7 - Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (see http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). All NIH-funded projects conducted abroad that involve research with recombinant or synthetic nucleic acid molecules must also comply with the NIH Guidelines. In addition to biosafety and containment requirements, the *NIH Guidelines* delineate points to consider in the development and conduct of human gene transfer clinical trials, including ethical principles and safety reporting requirements (see Appendix M of the *NIH Guidelines*).

Prior to beginning any clinical trial involving the transfer of recombinant or synthetic nucleic acid molecules into humans, the trial must be registered with the NIH Office of Science Policy (OSP) and, if applicable, reviewed by the NIH Recombinant DNA Advisory Committee (RAC). If this contract involves a human gene transfer trial raising unique and/or novel issues, the trial may be discussed by the RAC in a public forum (see Appendix M-I-B of the *NIH Guidelines* for the specific criteria for the selection of protocols for RAC review and discussion). Approval of an Institutional Biosafety Committee (IBC) and the Institutional Review Board (IRB) are necessary before the COR and CO may approve the protocol prior to the start of the research. IBC approval may not occur until the protocol registration process with NIH is complete. If the trial is reviewed by the RAC, IBC approval may not occur before the RAC has concluded its review of the protocol and the protocol registration process with NIH is complete.

For human gene transfer research, Appendix M-I-C-4 of the NIH Guidelines requires any serious adverse events (SAEs) that are both unexpected and possibly associated with the human gene transfer product to be reported to NIH OSP and an IBC within 15 days, or within 7 days if the event was life-threatening or resulted in a death. A copy of the report must also be filed with the COR and CO. SAE reports must also be submitted within their mandated time frames to the IRB, FDA, and, if applicable, the Health and Human Services (HHS) Office for Human Research Protections (OHRP). In addition, annual reports must be submitted to NIH OSP covering certain information about human gene transfer protocols. Further information about the content of these reports can be found in Appendix M-I-C-3 of the *NIH Guidelines*. Additional information on the requirements that pertain to human gene transfer can be found in a series of Frequently Asked Questions at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/faq .

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the CO to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an IBC registered with NIH OSP that complies with the requirements of the *NIH Guidelines*. Further information about compliance with the *NIH Guidelines* can be found on the NIH OSP web site: at: http://osp.od.nih.gov.

4.3.2.3.8 - Human Stem Cell Research

On March 9, 2009, the President issued Executive Order (EO) 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The NIH has published Guidelines on Human Stem Cell Research at: http://stemcells.nih.gov/policy/pages/2009guidelines.aspx . The Guidelines implement EO 13505 with regard to extramural NIH-funded human stem cell research, establish policy and procedure under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that are currently eligible for use in NIH-funded research. This registry is available at: http://grants.nih.gov/stem_cells/registry/current.htm . Proposed human embryonic stem cell line(s) must be on the NIH Registry at the time of proposal submission. Any possible changes to the proposed cell line must be discussed in the proposal. Offerors wishing to have Human Embryonic Stem Cell Lines added to the NIH Human Embryonic Stem Cell Registry must submit the request on Form NIH 2890 through the following website: http://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm .

4.3.2.3.9 - Data and Safety Monitoring in Clinical Trials

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the COR.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description

of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:

    - PD/PI: While the PD/PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
    - Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
    - Independent Monitoring Committee or Safety Monitoring Committee: a small group of independent experts.
    - Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

The NIH Policy for Data and Safety Monitoring at: http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

4.3.2.3.10 - Registration of and Results Reporting for Applicable Clinical Trials in ClinicalTrials.gov

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-

bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf ,Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov (http://www.clinicaltrials.gov/) and imposes new requirements that apply to all applicable clinical trials, including those supported in whole or in part by NIH funds. This Policy, along with FDAAA, requires:

1) The registration of all "applicable clinical trials" in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and

2) The reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

The resultant contract will support one or more applicable clinical trial subject to FDAAA.

The "responsible party" is the entity responsible for registering and reporting trial results in ClinicalTrials.gov.

1) Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."
2) Where there is no IND/IDE holder or where the Government is the IND/IDE holder, the Government will generally be considered the "Sponsor" and may designate the contractor's PI as the "Responsible Party."
3) For Multi-Center trials where there is no IND/IDE holder or where the Government is the IND/IDE holder, the "Responsible Party" will be designated at one site (generally the lead clinical site) and all other sites will be responsible for providing necessary data to the "Responsible Party" for reporting in the database.

Additional information is available at http://prsinfo.clinicaltrials.gov

4.3.2.3.11 - Plan for the Dissemination of Information of NIH-Funded Clinical Trial

Offerors are required to submit a plan for the dissemination of NIH-funded clinical trial information in the proposal. At a minimum, the plan must contain sufficient information to assure that:

1. The Contractor shall register and submit results information to ClinicalTrials.gov as outlined in the NIH policy on the Dissemination of NIH-Funded Clinical Trial Information and according to the specific timelines stated in the policy (this can be a brief statement);
2. Informed consent documents for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and
3. The Contractor has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with NIH policy on the Dissemination of NIH-Funded Clinical Trial Information requirements.

If the Offerors plan does not meet these minimum standards or is otherwise not acceptable as determined by the CO, the contract award cannot be issued until an approved plan has been submitted.

4.3.2.3.12 - Plan for Single Institutional Review Board (sIRB)

Offerors are required to submit a plan for the sIRB information in the technical proposal for each protocol involving more than one domestic site. At a minimum, the plan shall:

1. Participating sites will adhere to the sIRB Policy;
2. Sites and the sIRB will adhere to the communication plan described in the authorization/reliance agreement; and
3. If, in the case of restricted-award, a sIRB has not yet been identified, include a statement that the offeror will follow the sIRB Policy and communicate plans to select a registered IRB of record. This information must be provided to the CO prior to initiating recruitment for a multi-site study.

The Offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, in accordance with the Federal Acquisition Regulation (FAR) 31.202, Direct Costs and FAR 31.203, Indirect Costs.

4.3.2.3.13 - Exceptions to The Single Institutional Review Board (sIRB) Policy

In the technical proposal, Offerors may request an exception to the sIRB policy for one or more studies.

1. For sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions):

    a. The Offeror shall identify any site that meets the requirements for the Single IRB policy but is required to have local IRB review because of a federal, state, or tribal law, regulation or policy; and

    b. The Offeror shall provide specific citation for policy-based exceptions.

2. Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy. The Offeror shall provide the parent contract number to request an exception.

3. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification:

    a. Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
    b. Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).

c. Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).

- For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.

- Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception*. The Offerors should not assume that an *other exception* will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their CO. For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions*, the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an *Other Exception* to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO.

Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals with which the Government holds discussions. All requests for *other exceptions* must be reviewed by the NIH ERC. The decision of NIH ERC is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.

The award budget may need to be adjusted if an exception is granted.

4.3.2.3.14 - PHS Human Subjects and Clinical Trials Information Form

Offerors shall submit the "PHS Human Subjects and Clinical Trials Information Form" with each technical proposal for work involving human subjects.

FORM SUBMISSION INSTRUCTIONS

1. The PHS Human Subjects and Clinical Trials Information Form must be submitted with your technical proposal.
2. Offerors must use the form and follow the associated instructions posted on the website at: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files.

4.3.2.3.15 - Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The **NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects** applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The proposal for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Offeror must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the Offeror must provide acceptable justification for the exclusion in the proposal.

The Contractor must submit cumulative data as prescribed in the **Age Enrollment Report template** on participant age at enrollment in monthly progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided in progress reports.

4.3.2.3.16 - Posting Clinical Trial Informed Consent Forms to ClinicalTrials.gov

The **Revised Common Rule** sections 46.102(b) and 46.116(h) requires Contractors with to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database **ClinicalTrials.gov** . Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to **Regulations.gov** .

1. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database **ClinicalTrials.gov** .
2. The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit.
3. The CO and/or COR may permit or require redactions as appropriate.
4. Informed Consent Forms for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

5. Informed Consent Forms must be compliant with the HHS Policy for the Protection of Human Research Subjects (45 CFR 46).

4.3.2.4 - Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-5(a) (December 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the CO. Prior to award, the CO will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The CO will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (Email: olaw@od.nih.gov; Phone: 301-496-7163).

(End of provision)

The PHS Policy is available on the internet at: http://www.grants.nih.gov/grants/olaw/olaw.htm.

4.3.2.5 - Research Involving Live Vertebrate Animals

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

The following criteria must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

i. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) SOW. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

ii. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

iii. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

iv. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

A concise (no more than 1-2 pages), complete description addressing these criteria must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the VAS, see NIH Guide Notice NOT-OD-16-006 at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html .

The Contract Proposal VAS Worksheet is provided as an Attachment in SECTION 7 of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: http://grants.nih.gov/grants/olaw/VAScontracts.pdf

4.3.2.6 - Possession, Use and Transfer of Select Biological Agents or Toxins

Notice to Offerors of Requirements of Select Agents Regulations - October 16, 2008 (http://www.selectagents.gov/Regulations.html): 42 CFR Part 73, Possession , Use, and Transfer of Select Agents and Toxins (relating to public health and safety): 7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) (and, 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002. They are designed to improve the ability of the United States Government to prevent, prepare for, and respond to bioterrorism and other public health emergencies. These regulations establish requirements regarding registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

Listings of HHS and USDA Select Agents and Toxins, and overlap Select Agents or Toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.selectagents.gov/ and http://www.selectagents.gov/SelectAgentsandToxinsList.html

For foreign institutions, see the NIAID Select Agent Award information (https://www.niaid.nih.gov/grants-contracts/select-agents).

If the proposed contract will not involve the possession, use or transfer Select Agents or Toxins, the offeror must include a statement in its technical proposal that the work does not now nor will it in the future (i.e. throughout the life of the award) involve the possession, use or transfer Select Agents or Toxins.

Domestic Institutions
For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

- Include details about the Select Agent in their technical proposal, including the quantity proposed to be used during contract performance.
- Describe the proposed use of the Select Agent or Toxin, including any restricted experiments.

- Comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: http://www.selectagents.gov/Regulations.html, as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

- Include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- Describe the proposed use of the Select Agent or Toxin, including any restricted experiments.
- When requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.selectagents.gov/Regulations.html for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes an assessment of the foreign laboratory facility by an NIAID representative. During this assessment, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. Laboratory assessments are conducted every three years for the life of the contract.

A NIAID chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC , Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the site visit , the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.selectagents.gov/Regulations.html. The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the CO. The CO will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving a Select Agent or Toxin at a foreign institution until NIAID grants this approval.

4.3.2.7 - Enhancing Reproducibility Through Rigor and Transparency

The offeror shall demonstrate compliance with the NIH Policy on enhancing Reproducibility through Rigor and Transparency as described in NIH Guide Notice NOT- OD-15-103 . Specifically, the offeror shall describe in its technical proposal the information described below:

A. Compliance Factors

1. Describe the scientific premise for the Technical Proposal. The scientific premise is the research that is used to form the basis for the proposed research. Offerors should describe the general strengths and weaknesses of the prior research being cited by the offeror as

crucial to support the proposal. It is expected that this consideration of general strengths and weaknesses could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.

2. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

3. Explain how relevant biological variables, including sex, [if deemed necessary by the IC, additional variables may be included here] are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for proposals proposing to study only one sex. If your proposal involves human subjects, the sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion and justify the proposed proportions of individuals (such as males and females) in the sample. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

4. If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposal. Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

   Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals. If the Technical Proposal does not propose the use of key biological and/or chemical resources, a plan for authentication is not required, and the offeror should so state in its proposal.

4.3.2.8 - Dual Use Research of Concern

The offeror shall demonstrate compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or "DURC" policy. The offeror shall provide in its technical proposal each of the following items:

a. Identification of the agents or toxins subject to the DURC policy.
b. A description of the categories of experiments in which the identified agents or toxins produces or aims to produce or can be reasonably anticipated to produce one or more of the effects identified in Section 6 of the DURC policy.
c. For projects involving any of the agents listed in the DURC policy and that involve or are anticipated to involve any of the categories of experiments listed in the DURC policy, an indication of whether or not the project meets the definition of "dual use research of concern" in Section 4C of the policy.
d. For projects meeting the definition of "dual use research of concern," a draft risk mitigation plan.

e. Certification that the offeror is or will be in compliance with all aspects of the DURC policy prior to use of pertinent agents or toxins.

The Government shall not award a contract to an offeror who fails to certify compliance or whose draft risk mitigation plan is unsatisfactory to the Government. If selected for award, an approved risk mitigation plan shall be incorporated into the contract.

4.3.2.9 - Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Policy," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website:

http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf

4.3.2.9.1 - Sharing Research Data

[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing

will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

4.3.2.9.2 - Sharing of Model Organisms for Biomedical Research

The NIH Research Tools Policy (http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html), the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at: http://www.ott.nih.gov/hhs-manual-toc ; for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) ((https://autm.net/surveys-and-tools/agreements/material-transfer-agreements/mta-toolkit/uniform-biological-material-transfer-agreement)
- How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

4.3.2.9.3 - Data Sharing Policy for Large-Scale Human Genomic Data

1. Pursuant to the NIH Genomic Data Sharing Policy located at: https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf, all offerors proposing NIH-funded research that generates large-scale human genomic data shall provide:

   a. A plan for submission of genomic data to the NIH-designated data repository, and
   b. An Institutional Certification.

   As an alternative, Contractors may provide an appropriate justification on why submission to the repository is not possible with the proposal submission to the CO for approval.

2. Pursuant to the NIH Genomic Data Sharing Policy located at: https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf, Contractors who request access to controlled-access genomic data in the NIH repository for proposed research will be reviewed by the NIH Data Access Committees (DACs). NIH DACs will accept requests for proposed research uses beginning one month prior to the anticipated data release date. The access period for all controlled-access data is one year; at the end of each approved period, data users can request an additional year of access or close out the project. Additionally, Contractors requesting access to the data shall abide by the database of Genotypes and Phenotypes (dbGaP) Approved User Code of Conduct (https://dbgap.ncbi.nlm.nih.gov/aa/GWAS_Code_of_Conduct.html). Large-scale data include genome-wide association studies, single nucleotide polymorphisms arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism.

4.3.2.9.4 - Sharing HeLa Cell Whole Genome Sequence Data and Family Acknowledgement

1. Offerors proposing to generate HeLa Cell Whole Genome Sequence Data shall include a plan for submission of this data with the proposal pursuant to the HeLa Whole Genome Sequence Data guidance in NIH Guide Notice NOTOD-13-099, available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-099.html.

2. Offerors shall also submit with the proposal an acknowledgement that the offeror has read and shall agree to the provisions of the HeLa Genome Data Use Agreement available at: **https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?view_pdf&stacc=phs000640.v1.p1** .

3. The following acknowledgment, or a variation of it that has been reviewed by the HeLa Genome Data Access Working Group, shall be made in any dissemination of research findings: "The genome sequence described/used in this research was derived from a HeLa cell line (URL to dbGaP). Henrietta Lacks, and the HeLa cell line that was established from her tumor cells without her knowledge or consent in 1951, have made significant contributions to scientific progress and advances in human health. We are grateful to Henrietta Lacks, now deceased, and to her surviving family members for their contributions to biomedical research. This study was reviewed by the NIH HeLa Genome Data Access Working Group."
   Contact helagenome@nih.gov for acknowledgement variation requests.

4.3.3 - BUSINESS PROPOSAL INSTRUCTIONS

Offerors should propose a budget that is aligned with the SOW proposed. As such, Business Proposals must provide a detailed task-linked budget that consists of a breakdown of total costs (direct costs, indirect costs, and fees) to the Base and each Option proposed, accompanied with a detailed Gantt chart. Proposed budgets should also include an annual breakdown where annual budgets will be based on the total amount for all activities starting in that fiscal year.

A summary budget reflecting the total costs over the period of performance of the proposed contract shall be provided in the same "Breakdown of Proposed Estimated Costs (plus fee) and Labor Hours" format (see http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx).

The Gantt timeline will consist of summary tasks, tasks and subtasks, including predecessor and successor logic for all activities covering the initiation, and conduct and completion of all product development activities. Product development activities will be planned and structured such that the Base and each individual Option will be performed within the entire performance period of the contract. The lowest level of tasks or subtasks for each activity for which budget is assigned will be determined by the Offeror. However, the budget plan, based on the task-linked budget must provide for feasible execution, management and oversight. Budget linked to activities at the lowest level will include budget for all subordinate activities.

4.3.3.1 - General Instructions

4.3.3.1.1 - Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

4.3.3.1.2 - Business Proposal – Table of Contents

SECTION 1 – PROPOSAL COVER SHEET (use form NIH 2043)

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403 5(b)(1) and Table 15 2. By submitting this proposal, we grant the CO and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting

information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;.

8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
9. Date of submission; and
10. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

SECTION 2 – COST OR PRICE SUPPORT

Section 4 of the BAA specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in a clearly marked section of the proposal.

SECTION 3 – UNIFORM COST ASSUMPTIONS

Offerors should refer to Section 3, Research Areas and Technical Objectives, for Uniform Cost Assumptions applicable to the specific Research Area under which you are proposing.

SECTION 4 – OPTIONS

Each Option must be budgeted separately within the Business Proposal. All uniform cost assumptions associated with Options are to be delineated here.

4.3.3.1.3 - Certified Cost or Pricing Data

1) General Instructions

A. In submitting your proposal, you must include an index, appropriately referenced, of all the certified cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

B. As part of the specific information required, you must submit, with your proposal, certified cost or pricing data (as defined at FAR 2.101). You must clearly identify on your cover sheet that certified cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including:

1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and

2. The nature and amount of any contingencies included in the proposed price.

C. You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

D. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

E. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

F. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

G. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

2) Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. Materials and services. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when certified cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own certified cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor certified cost or pricing data as part of your own certified cost or pricing data as required in paragraph A.2. below. These requirements also apply to all subcontractors if required to submit certified cost or pricing data.

1. *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).

2. *All Other*. Obtain certified cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of certified cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $12.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. Also submit any information reasonably required to explain your estimating process (including the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data, and the nature and amount of any contingencies included in the price). The CO may require you to submit certified cost or pricing data in support of proposals in lower amounts. Subcontractor certified cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the certified cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's certified cost or pricing data is required as described in this paragraph, it must be included, along with your own certified cost or pricing data submission, as part of your own certified cost or pricing data. You must also submit any other certified cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. Direct Labor. Provide a time phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. Indirect Costs. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. Other Costs. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. Royalties. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

1. Name and address of licensor.
2. Date of license agreement.
3. Patent numbers.
4. Patent application serial numbers, or other basis on which the royalty is payable.
5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
6. Percentage or dollar rate of royalty per unit.
7. Unit price of contract item.

8. Number of units.
9. Total dollar amount of royalties.
10. If specifically requested by the CO, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.202 and 31.205-37).

F. Facilities Capital Cost of Money. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

3) Formats for Submission of Line Item Summaries

The detailed breakdown shall be in the format as shown on the form Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours. For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the BAA cites specific line items, by number, a cost breakdown for each line item must be furnished.

See: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx

4) General Information

A. There is a clear distinction between submitting certified cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of certified cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the CO or an authorized representative. As later information comes into your possession, it should be submitted promptly to the CO in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of certified cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

B. By submitting your proposal, you grant the CO or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

4.3.3.1.4 - Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (October 2010)

A. Exceptions from certified cost or pricing data.

1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The CO may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

a. Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

b. Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

i. For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

ii. For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

iii. For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

2) The offeror grants the CO or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

B. Requirements for certified cost or pricing data. If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the CO and the Contractor agree to a different format and change this clause to use Alternate I.

2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

4.3.3.1.5 - Salary Rate Limitation

Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The Executive Schedule, Level II* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants.

LINK TO EXECUTIVE SCHEDULE RATES OF PAY: http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/
(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

***Note to Offerors**: The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

4.3.3.1.6 - Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $700,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c. The offeror understands that:
    1. No contract will be awarded unless and until an acceptable plan is negotiated with the CO which plan will be incorporated into the contract, as a material part thereof.
    2. An acceptable plan must, in the determination of the CO, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-

Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

3. If a subcontracting plan acceptable to the CO is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The CO shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the CO in determining the responsibility of the offeror for award of the contract.
5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
6. The offeror will submit, as required by the CO, subcontracting reports in accordance with the instructions thereon, and as further directed by the CO. Subcontractors will also submit these reports to the Government's CO or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $700,000 adopt a plan similar to the plan agreed upon by the offeror.
10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.
11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. **The anticipated minimum goals for this RFP are as follows:**

33% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

4.3.3.1.7 - Mentor-Protégé Program, HHSAR 352.219-70 (December) 2015

a. Large business prime contractors serving as mentors in the HHS Mentor-Protégé Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protégé agreements as part of their offers. The amount of credit provided by the CO to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at www.esrs.gov . The mentor firm and protégé firm shall submit to the CO a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protégé firm and provision of $5,000 of developmental assistance as $15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of—

1. Mentor firms--large businesses that:

(i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
(ii) Have a Mentor-Protégé agreement approved by HHS' OSDBU;

2. Protégé firms--firms that:

(i) Seek developmental assistance;
(ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
(iii) Have a Mentor-Protégé agreement approved by HHS' OSDBU; and

3. Mentor-Protégé agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

4.3.3.1.8 - HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone .

4.3.3.1.9 - Total Compensation Plan

a. **Instructions**

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. **Evaluation**

1. **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to

obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. **Cost (Professional Compensation)**

   Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. **Other (Labor Relations)**

   An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. **Federal Acquisition Regulation Clauses incorporated by Reference**

   FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

4.3.3.1.10 - Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the CO. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

   a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

   b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

   The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the CO having cognizance of the property);

b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

NOTE: The CO will consider any potentially unfair competitive advantage that may result from an offeror or contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.

3. Government-Furnished Property

   No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "Appendix Q, HHS Contracting Guide for Contract of Government Property," which can be found at: https://web.archive.org/web/20111015044731/http:/www.hhs.gov/hhsmanuals/ .

4.3.3.1.11 - Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (JULY 2013)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than System for Award Management.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9

digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of Provision)

4.3.3.1.12 - Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

4.3.3.1.13 - Adequate Accounting System

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section 4, Instructions, Conditions, and Notices to Offerors, of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.
To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
  - Proper segregation of direct costs from indirect costs.
  - Identification and accumulation of direct costs by contract.
  - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
  - Accumulation of costs under general ledger control.
  - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
  - A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
  - Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
  - Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
  - Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
  - Segregation of preproduction costs from production costs, if applicable.
- Accounting system provides financial information:
  - Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
  - Required to support requests for progress payments.
- Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.
- Accounting system is currently in full operation.

The CO reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror's accounting system is compliant as certified above.

4.3.3.1.14 - Facilities Capital Cost of Money , FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] Fac Cap Cost of Money (Has) The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] **Fac Cap Cost of Money (Has Not)** The prospective Contractor **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

4.3.3.1.15 - Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this BAA, Performance History and Pertinent Contracts."

a. **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. **Organizational Experience Related to the BAA**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this BAA. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the SOW in this BAA.

c. **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost**

schedules on efforts, either past or on-going, which is comparable or related to the effort required by this BAA.

d. **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this BAA; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this BAA. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important BAA requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

4.3.3.1.16 - Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a. Willingness to perform as a subcontractor for specific duties (list duties).
b. What priority the work will be given and how it will relate to other work.
c. The amount of time and facilities available to this project.
d. Information on their cognizant field audit offices.
e. How rights to publications and patents are to be handled.
f. A complete cost proposal in the same format as the offeror's cost proposal.

4.3.3.1.17 - Proposer’s Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

4.3.3.1.18 - Travel Costs/Travel Policy

a. Travel Costs - Commercial

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall

be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b. Travel Policy

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

4.3.3.1.19 - Certification of Visas for Non-U.S. Citizens

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

4.3.3.1.20 - Intellectual Property

The awardee is solely responsible for the timely acquisition of all appropriate property rights, including intellectual property rights, and all materials needed for the awardee to perform the project. Before, during, and subsequent to the award, the U.S. Government is not required to obtain for the awardee any property rights, including intellectual property rights, or any materials needed by the awardee to perform the project.

The awardee is required to report to the U.S. Government all inventions made in the performance of the project, as specified by 35 U.S.C. Sect. 202 (Bayh-Dole Act).

4.3.3.1.21 - Cost Sharing

Cost sharing is permitted for proposals under this solicitation.

SECTION 5 - SPECIAL CONTRACT REQUIREMENTS

This section identifies special contract requirements that may be applicable to an offeror's proposed project. Any resultant contract shall include provisions applicable to the selected offeror's organization and the specific scope of activities awarded, as required by Public Law, Executive Order, Regulation, or Policy in effect at the time of execution of the proposed contract. Offeror's should review these items carefully to ensure required information is included in the proposal.

5.1 - PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).

d. If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the CO may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The CO may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the CO's written notice of suspension, the CO may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause)

5.2 - HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by NIAID, written notice of such approval has been provided by the CO, and the Contractor has provided to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of

Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

5.3 - REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html .

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the CO: the title of the education program and a one sentence description of the program that has been completed by the replacement.

5.4 - DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.
Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Board and/or Plan shall be established and approved prior to beginning the conduct of the clinical trial.

5.5 - GOOD CLINICAL PRACTICE TRAINING FOR NIH AWARDEES INVOLVED IN NIH-FUNDED CLINICAL TRIALS

All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the ICH E6 (R2). GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. GCP training should be refreshed at least every three years to remain current with regulations, standards and guidelines. The Contractor shall provide completion of training documentation to the COR.

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical Trial Staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

5.6 - CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION

The Contractor conducting clinical trials, funded wholly or partially through the NIH extramural and intramural programs, shall ensure that its NIH-funded clinical trials are registered at, and summary results information is submitted to, www.clinicaltrials.gov for public posting. See NIH Guide Notice NOT-OD-16-149 dated September 16, 2016.

All NIH-funded clinical trials shall be registered and results information submitted to www.clinicaltrials.gov regardless of study phase, type of intervention, or whether they are subject to the regulation 42 CFR Part 11. Clinical trials subject to the regulation are called "applicable clinical trials."

The Contractor must submit a plan with its proposal to meet the regulatory requirements of the dissemination of information of NIH-funded Clinical Trials. The Contractor and investigators are required to comply with all terms and conditions of award, including following their acceptable plan for the dissemination of NIH-funded clinical trial information.

The Contractor must register all NIH-funded clinical trials in www.clinicaltrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought. The Contractor shall include the trial registration number (NCT number) in the Technical Progress Report covering the period in which registration occurred, and as a standalone notification to the CO within ten (10) calendar days of the registration. Each NIH-funded clinical trial must have only one entry in ClinicalTrials.gov that contains its registration and results information
The Contractor shall include a specific statement in all informed consent documents relating to posting of clinical trials information to www.clinicaltrials.gov . The responsibilities of the Contractor will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the Contractor is the responsible party, the Contractor will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the Contractor is not the responsible party, the Contractor will coordinate with the responsible party to ensure that all regulatory requirements are met.
3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the Contractor will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Failure to comply with the terms and conditions of the award may provide a basis for enforcement actions. Identifying clinical trial record as non-compliant in ClinicalTrials.gov may lead to termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

The CO may take one or more of the following enforcement actions, if the Contractor fails to provide evidence of compliance within 30 days.

- Temporary withhold payments pending correction of the deficiency;
- Disallow all or part of the cost of the activity or action not in compliance;
- Wholly or partly suspend or terminate the contract award;
- Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding regulations at 2 CFR part 376;
- Withhold further awards for the project and program;
- Take other remedies that may be legally available.

5.7 - CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION PLAN

The special terms and conditions in the Contract Award that include a clinical trial:

1. The clinical trial(s) supported by this award is subject to the plan dated [DATE] submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan must state that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant. The plan also must state that primary summary results shall be reported in ClinicalTrials.gov, including adverse event information, not later than one year after the primary completion date of the trial. The reporting of summary results is required by this term of award.
2. This award is subject to reporting requirements with each submission of the annual report. Contractor shall agree to the following annual certification. By affirming this annual certification:

The Contractor hereby certifies that all investigators conducting NIH-funded clinical trials under the NIH contract number __ are in compliance with the Contractor's plan addressing compliance with the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded wholly or partially under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Primary summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the primary completion date of the trial.

5.8 - CERTIFICATE OF CONFIDENTIALITY

Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions governing the authority of the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act.
Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of the NIH Policy for Issuing Certificate of Confidentiality (CoC) NOT-OD-17-109, the Contractor shall protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act as a term and condition of the contract. The certificate will not be issued as a separate document.
NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research (except for human subjects' research that is determined to be exempt from all or some of the requirements of 45 CFR 46) if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

The Contractor shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

The Contractor is permitted to disclose only in below circumstances. The Contractor shall notify the CO minimum ten (10) calendar days prior to disclosure.

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

In accordance with 45 CFR Part 75.303(a), the contractor shall maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

The recipient of CoCs shall ensure that any company/institution/individual not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate is subject to the requirements of subsection 301(d) of the Public Health Service Act. The Contractor shall ensure that Subcontractors who receive funds to carry out part of the Federal award are subject to subsection 301(d) of the Public Health Service Act and the NIH Policy for Issuing CoC.

5.9 - SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For Institutional Review Board (IRB), the Contractor shall use the single Institutional Review Board (sIRB) of record for multi-site research. All domestic sites participating in multi-site studies involving a non-exempt human subjects research funded wholly or partially by the National Institutes of Health (NIH) shall use a sIRB to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46 and the NIH Policy on the Use of Single Institutional Review Board for Multi-Site Research . Any IRB serving as the sIRB of record for NIH funded research shall be registered with the HHS Office for Human Research Protections (OHRP) and shall have membership sufficient to adequately review the proposed study.

The Contractor shall provide to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 certifying IRB review and approval of the research that encompasses all sites of performance.

This paragraph applies only if the Government provided a sIRB through a separate entity as stated in section- C . When the Government provided sIRB through a separate entity, the Contractor agrees to use of the sIRB. The Contractor shall provide to the CO sIRB information and data in a timely manner as necessary to meet the policy and/or regulatory requirements of the Protection of Human Subjects at 45 CFR Part 46.

5.9.1 - Exceptions to the NIH Single IRB Policy

The Contractor may request an exception in the following instances:

1. Sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions);
2. *Other exceptions* , to be determined by NIH if there is a compelling justification; and
3. Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy.

Policy-based exceptions and time limited exceptions are automatically granted when identified in the sIRB Plan.

Other exceptions must be reviewed by NIH sIRB Exceptions Review Committee (ERC) and are expected to be granted rarely. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification-

a. Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
b. Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).
c. Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).
   - For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.
d. Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception.* The Offerors should not assume that an *other exception* will be granted when considering what sIRB costs to include in the budget.

5.9.2 - Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their CO. For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions*, the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an Other Exception to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO. For time limited exceptions, Contractor shall provide the parent contract number to the CO.

5.9.3 - Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals with which the Government holds discussions. The decision of NIH ERC is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.

The award budget may need to be adjusted if an exception is granted.

5.10 - PLAN FOR SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For this multi-site study, the _____ (contractor/each contractor) agrees to adhere to the NIH sIRB policy, and the _____ (IRB Name) IRB shall serve as the single IRB of record. All participating sites have agreed to rely on the _____ (IRB Name) IRB, and a written authorization/reliance agreement shall be developed. Any additional sites added after contract award shall also agree to rely on this study's single IRB of record. Communication plans for interactions between the sIRB and participating sites shall be described in the authorization/reliance agreement. All participating sites shall, prior to initiating the study, sign the authorization/reliance agreement that shall clarify the roles and responsibilities of the sIRB and participating sites. The _____ (Contractor Name/Name of the Coordinating Center or Contract Research Organization (CRO)/Names of Contractor's Lead Person and Alternate Person) shall maintain records of the authorization/reliance agreements, including the communication plans. The approved sIRB plan will be incorporated as a term and condition of the award. Any updates/changes to the plan shall be provided to the COR with a copy submitted to the CO within 30 calendar days.

5.10.1 - Exceptions to the Single IRB Plan

The Contractor may request an exception to the sIRB plan under the following instances:

- Sites for which federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions)
  *Review by a single IRB of record will not be possible for (**sites)** because of federal/state/tribal law, regulation, or policy (**provide specific citation(s))***
- *Other exceptions* , to be determined by NIH if there is a compelling justification
  *Review by a single IRB of record will not be possible for (**this contractor)** because of (**provide compelling justification and rationale why local IRB is uniquely qualified to be the reviewing IRB for the specific site(s**)).*
- Time Limited Exceptions: New multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy.
  *Review by a single IRB of record will not be possible for (**sites)** because of ongoing multi-site parent study (**provide parent contract number)**.*

5.11 - INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended

November 2017," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm .

The Contractor must submit the results of valid analyses by sex/gender and race/ethnicity to Clinicaltrials.gov for all NIH-conducted or supported applicable NIH-defined Phase III clinical trials. This requirement does not apply to NIH-defined Phase III trials not considered to applicable clinical trials under 42 CFR Part 11. The Contractor must report applicable NIH-defined Phase III clinical trials involving research subjects of all ages, including foreign awards and domestic awards with a foreign component. The Contractor must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

Note: Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information, including the results of the valid analyses by sex/gender and race/ethnicity, from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of new use is being sought.

5.12 – INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The Contractor must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Contractor must provide a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the contractor must provide acceptable justification for the exclusion.

The Contractor must submit cumulative data as prescribed in the Age Enrollment Report template on participant age at enrollment in monthly progress reports. Investigators planning to conduct research

involving human subjects should design their studies in such a way that de-identified individual level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided in progress reports.

5.13 – POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database ClinicalTrials.gov . Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to Regulations.gov . The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit. The CO and/or COR may permit or require redactions as appropriate.

5.14 - REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf , Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the COR, with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

The [Contractor is the Sponsor, therefore/Government is the Sponsor and delegates the Contractor's Principal Investigator as/Government is the Sponsor, therefore] the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).

Additional information is available at: http://prsinfo.clinicaltrials.gov .

5.15 - HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

5.16 - HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the CO of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

5.17 - RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) available at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the *NIH Guidelines* .

The *NIH Guidelines* stipulate biosafety and containment measures for recombinant or synthetic nucleic acid research, which is defined in the *NIH Guidelines* as research with (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines* .

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the CO to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with the NIH Office of Science Policy that complies with the requirements of the *NIH Guidelines* . Further information about compliance with the *NIH Guidelines* can be found on the NIH Office of Science Policy website available at: http://osp.od.nih.gov /.

5.18 - HUMAN STEM CELL RESEARCH

All research conducted under this contract shall be in accordance with NIH Guidelines on Human Stem Cell Research (http://stemcells.nih.gov/policy/pages/2009guidelines.aspx), and shall involve the use of approved human embryonic stem cells (hESCs) or derivatives that are listed on the NIH Human Embryonic Stem Cell Registry (http://grants.nih.gov/stem_cells/registry/current.htm).

- Sections II and III of the National Institutes of Health Guidelines for Research Using Human Stem Cells (http://stemcells.nih.gov/policy/pages/2009guidelines.aspx) apply specifically to human embryonic stem cells (hESCs).
  - Section II details the eligibility criteria used by NIH to determine if specific hESC lines are eligible for use in NIH-funded research.
  - Section III explains the responsibility of NIH-funding recipients to assure that hESCs used in NIH-funded research are approved by NIH.
- Section IV sets limits on certain animal studies using all types of human pluripotent stem cells, including, but not limited to, those developed by methods such as the expression of genes involved in establishing pluripotency (e.g. the "Yamanaka factors") and the culturing of embryonic germ cells from primordial germ cells. Prohibited experiments include those in which the cells are introduced into non-human primate blastocysts and the breeding of animals in which the cells may contribute to the germ line.
- Section V details other types of research not eligible for NIH funding: the derivation of stem cells from human embryos and research using hESCs derived from sources other than human embryos created using in vitro fertilization for reproductive purposes.

  Research involving the use of human embryonic stem cells, or derivatives, that are not listed on the NIH Registry may not be conducted with Federal funding. Derivatives include, but are not limited to, subclones of hESC lines, modified hESC lines (such as a line expressing green fluorescent protein), differentiated cells developed from hESC lines (such as muscle progenitor cells), and cellular materials (such as DNA, RNA, and proteins). Thus, no federal funds may be used for the generation of new data from unapproved hESC lines or derivatives. However publicly accessible data from unapproved lines or derivatives are not considered "derivative" and therefore not subject to this prohibition. Such publicly accessible data can be used and analyzed with federal funds.

5.19- NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the SOW and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103 , "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102 , "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research , whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm , including FAQs and a General Policy Overview.

5.20 - DATA SHARING IN LARGE-SCALE HUMAN OR NON-HUMAN GENOMIC DATA

The Contractor shall comply with the NIH "Genomic Data Sharing Policy" located at: https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf. The contractor shall submit and certify data obtained in the genomic data study to the data repository in accordance with the policy. The contractor shall also submit the data to the CO and COR.
Large-scale data include genome-wide association studies, single nucleotide polymorphisms arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism.

5.21 - SHARING HeLa CELL WHOLE GENOME SEQUENCE DATA AND FAMILY ACKNOWLEDGEMENT

All research using HeLa Cell Whole Genome Sequence data shall be conducted in accordance with NIH notice NOT-OD-13-099, entitled, "Notice of NIH Guidance on the Family Acknowledgement and Use of HeLa Cell Whole Genome Sequence Data" located at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-099.html. The Contractor shall submit HeLa Whole Genome Sequence Data generated under this contract to the database of Genotypes and Phenotypes (dbGaP) available at: http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000640.v1.p1, in accordance with the HeLa Genome Data Use Agreement available at:
https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?view_pdf&stacc=phs000640.v1.p1.

The following acknowledgment, or a variation of it that has been reviewed by the HeLa Genome Data Access Working Group, shall be made in any dissemination of research findings:

"The genome sequence described/used in this research was derived from a HeLa cell line (URL to dbGaP). Henrietta Lacks, and the HeLa cell line that was established from her tumor cells without her knowledge or consent in 1951, have made significant contributions to scientific progress and advances in human health. We are grateful to Henrietta Lacks, now deceased, and to her surviving family members for their contributions to biomedical research. This study was reviewed by the NIH HeLa Genome Data Access Working Group."

Contact helagenome@nih.gov for acknowledgement variation requests.

5.22 - NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov .

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov .

5.23 - DUAL USE RESEARCH OF CONCERN

The contractor shall comply with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or "DURC policy". The responsibilities of the contractor include but are not limited to:

1. Establishing internal policies and practices that provide for the identification and effective oversight of DURC;
2. Establishing an institutional review entity (IRE);
3. Ensuring that laboratory personnel conducting research have received education and training;
4. Maintaining records of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract, for the term of the contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation;
5. Promptly providing records upon request by the U.S. Government, of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract;
6. Obtaining pre-approval from the COR for all communications with third-parties, involving DURC funded by this contract; and
7. Obtaining pre-approval from the CO for subcontracts, subgrants, consultant agreements, or any other subaward involving research subject to the DURC policy and funded by this contract. The contractor shall ensure that the substantive requirements of this article are included in any such agreements.

Non-compliance with the DURC policy or with this article may result in suspension, debarment or termination for default.

5.24 - NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015)

The Contractor shall not use any funds obligated under this contract to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
(End of clause)

5.25 - ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

5.26 - CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

a. The Contractor shall not use any funds obligated under this contract for any abortion.
b. The Contractor shall not use any funds obligated under this contract for the following:
    1. The creation of a human embryo or embryos for research purposes; or
    2. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on

fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

c. The term ``human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
d. The Contractor shall not use any Federal funds for the cloning of human beings.

(End of clause)

5.27 - LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

5.28 - DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

5.29 - CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the CO.
b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.
c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.
d. If at any time during performance of this contract, the CO determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c)above, the CO may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the CO's written notice of suspension, the CO may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed

from the list of those contractors with Animal Welfare Assurances.

Note : The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov ; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

(End of clause)

5.30 - ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated _____ , which is incorporated by reference.

5.31 - INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, NIAID environment (NIH) directly, or through collaborative research or holding facilities under contract to ___ except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, NIAID environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

5.32 - PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: http://oma.od1.nih.gov/manualchapters/intramural/3044-2/

5.33 - OMB CLEARANCE

In accordance with HHSAR 352.211-3, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the COR and the CO has issued written approval to proceed.

5.34 - RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

5.35- GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

5.36 - OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the SOW as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the SOW and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least ___ days prior to the expiration date of this contract, and estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE] Article in SECTION B of this contract.

5.37 - SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov .

1. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

   April 30th
   October 30th
   Expiration Date of Contract

2. Summary Subcontract Report (SSR)

   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

5.38 - ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY NOTICE HHSAR 352.239-73 (December 2015)

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.
b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and standards/communications-and-it/about-the-section-508-standards .
c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508 . In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.
d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

- The "HHS Section 508 Product Assessment Template" is included in SECTION 7 - Attachments, of this solicitation.

5.39 - INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal

Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: : http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;
    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
    3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

    Significant financial interests do not include the following:

    1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
    2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.

d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period

of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the CO pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the CO of the corrective action taken or to be taken. The CO will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.

The CO and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The CO may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the CO may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the CO may be necessary until the matter is resolved.

If the CO determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

5.40 - PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the _____ , National Institutes of Health, Department of Health and Human Services, under Contract No. _____ "

5.40.1 - Advanced Copies of Press Releases

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the COR has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

5.41 - REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

5.42 - OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.
Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

a. Sharing of Model Organisms for Biomedical Research

[The plan for sharing model organisms submitted by the Contractor is acceptable/The Contractor's plan for sharing model organisms, dated _____ , is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the CO for any changes in its plan.

5.43 - SHARING RESEARCH DATA

[The data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated _____ is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the CO for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

5.44 - POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The work being conducted under this contract may involve the possession, use, or transfer of a select agent or toxin. The contractor shall not conduct work involving a Select Agent or Toxin under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer a Select Agent or Toxin under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.selectagents.gov/Regulations.html) as required, before using NIH funds for work involving a *Select Agent or Toxin* . **No NIH funds can be used for research involving a *Select Agent or Toxin* at a domestic institution without a valid registration certificate.**

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin* , before using NIH funds for any work directly involving a *Select Agent or Toxin* , the foreign institution must provide information satisfactory to the NIAID that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes a site visit to the foreign laboratory facility by an NIAID representative. During this visit, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agent or Toxin and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents or Toxins under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select

agents. Site visits to foreign laboratories are conducted every three years after the initial review. **No NIH funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the CO.**

Prior to conducting a restricted experiment with a Select Agent or Toxin under this contract or any associated subcontract, the contractor must discuss the experiment with the COR and request and obtain written approval from the CO. **Domestic institutions** must submit to the CO written approval from the CDC to perform the proposed restricted experiment. **Foreign institutions** require review by a NIAID representative. The prime contractor must contact the COR and the NIAID Office of International Extramural Activities (OIEA) at mailto:niaidforeignawards@niaid.nih.gov for guidance on the process used by NIAID to review proposed restricted experiments. The NIAID website provides an overview of the review process at https://www.niaid.nih.gov/grants-contracts/select-agents. The CO will notify the prime contractor when the process is complete. **No NIH funds can be used for a restricted experiment with a Select Agent or Toxin at either a domestic or foreign institution without written approval from the CO.**

Listings of HHS and USDA select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.selectagents.gov/ and http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html .

For foreign institutions, see the NIAID Select Agent Award information: (https://www.niaid.nih.gov/grants-contracts/select-agents).

5.45 - HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a *Highly Pathogenic Agent (HPA).* The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(http://www.cdc.gov/biosafety/publications/index.htm under "Publications);
2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or
3. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

5.46 - PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

5.47 – CONSTITUTION DAY

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

5.48 - CONTRACT CLAUSES

THE FOLLOWING GENERAL CLAUSE LISTING WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS BAA. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS BAA:

The complete listing of these clauses may be accessed at:
https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors

5.48.1 - General Clauses for a Cost-Reimbursement Research and Development Contract

5.48.2 - Authorized Substitutions of Clauses

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

SECTION 6 - EVALUATION FACTORS FOR AWARD

6.1 - GENERAL

Proposals will be evaluated against the following evaluation factors in the order of importance: technical and cost. Although technical factors are of paramount consideration in the award of the contract, cost/price is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The estimated cost of an offer must be reasonable for the tasks to be performed and will be subject to analysis by the Government.

The merit of each technical proposal will be evaluated by a peer review group. The Government reserves the right to convene multiple peer review groups to evaluate proposals. Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the proposed research. The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the BAA. Each proposal must demonstrate the feasibility of its approach and its relevance to the Research and Technical Objectives of the BAA. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria.

Each proposal will be reviewed by a peer review group selected for their competence in relevant scientific and technical fields. Each review group will be responsible for evaluating proposals for scientific and technical merit.

A contract may be awarded only if the proposal has been recommended as technically acceptable by the peer review group. *Funding for any/all technically acceptable proposals is not guaranteed.* ***Proposals that are found to be technically unacceptable by the peer review group will not be considered further for award.***

Following the proposal evaluation, the Government will conduct negotiations with selected offerors to address identified weaknesses, questions, and areas for clarification, as well as to refine the proposed SOW and deliverables. The selection of proposals for award is based upon the evaluation factors, importance to the agency programs, and fund availability.

6.2 - PRE-AWARD SITE VISIT OR SITE AUDIT

Offerors selected for negotiations may be subject to a pre-award site visit or auditing of their facilities and Quality Assurance and Quality Control (QA/QC) capabilities. The decision to conduct a pre-award site visit or to audit specific facilities will be made by the COR. Offerors, including proposed subcontractors, will be requested to make specified (by the government) non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by the NIAID or its designee. Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are requested to make available key staff or other staff determined by the Government as essential for this site visit.

6.3 - TECHNICAL EVALUATION CRITERIA:

The evaluation criteria are used by the peer review group when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are listed in order of equal importance.

CRITERIA	WEIGHT
CRITERION 1: SCIENTIFIC AND TECHNICAL MERIT	**50**

A. Relevance and merit of the proposed scientific approach to the research and technical objectives of the BAA.
B. Soundness of the supporting research used to justify the proposed work.
C. Documented ability of the offeror to successfully complete the proposed activities as demonstrated through the technical approach.
D. The potential of the research to: increase knowledge or understanding; the degree of innovation; and/or potential to advance the state-of-the-art.
E. Sufficiency of the proposed strategy to ensure a robust and unbiased approach, as appropriate for the work proposed. Adequacy of the proposed plan to address relevant biological variables, including sex, as applicable, for studies in vertebrate animals and/or human subjects.

CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL	**20**

Appropriateness and adequacy of the qualifications of the proposed Principal Investigator and scientific and technical personnel, including any proposed subcontractors and consultants, to perform the proposed SOW.

CRITERION 3: PROJECT MANAGEMENT	**15**

Appropriateness and adequacy of the proposed Project Management Plan, Staffing Plan, project management systems, and timelines.

CRITERION 4: ORGANIZATIONAL FACILITIES, EQUIPMENT, AND OTHER RESOURCES	**15**

Availability and adequacy of the necessary facilities, equipment, and other resources to safely and successfully implement the proposed research.

TOTAL POSSIBLE WEIGHT:	**100**

6.4 - COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal.

6.5 - HUMAN SUBJECT EVALUATION

In the event an Offeror’s research project involves human subjects, NIH Policy requires:

6.5.1 - Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Sections 4 and 5 for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with your organization, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position through proposal revision. Once discussions are closed, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

6.5.2 - Women and Minorities

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm , Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

  OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),

  OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Sections 4 and 5 of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is

because:

- the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
- overriding factors dictate selection of subjects); or
- gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Sections 4 and 5 of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with your organization, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position through proposal revision. Once discussions are closed, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

6.5.3 - Children

Children (i.e. individuals under the age of 18) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the

investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Sections 4 and 5 of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with your organization, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position through proposal revision. Once discussions are closed, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

6.5.4 Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

Individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

Your proposal must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the Offeror must provide acceptable justification for the exclusion in the proposal. Also, see Sections 4 and 5 of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for individuals across the lifespan; or concerns are identified as to the offeror's response regarding the inclusion of individuals across the lifespan; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with your organization, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position through proposal revision. Once discussions are closed, if your proposed plan for the inclusion of individuals across the lifespan is still found to be unacceptable, then your proposal may not be considered further for award.

6.5.5 - Data and Safety Monitoring

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the SOW and Sections 4 and 5 in the solicitation, as well as any further technical evaluation factors in this Section 6, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

6.6 - LIVE VERTEBRATE ANIMALS EVALUATION

If applicable, the offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following criteria. (See NIH Guide Notice NOT-OD-16-006 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html):

A. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the proposed SOW. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
B. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
C. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

D. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all criteria will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the criteria, or no discussion can be found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government holds discussions with your organization, you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position through proposal revision. Once discussions are closed, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

6.7 - EVALUATION OF OPTIONS

It is anticipated that any contracts awarded from this solicitation may contain option provisions.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

6.8 - EVALUATION OF AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

If the offeror has proposed the use of key biological and/or chemical resources, the offeror’s plan for authentication will be reviewed for adequacy.

Any concerns associated with key biological and/or chemical resource authentication raised during the review process will need to be resolved prior to award.

6.9 - EVALUATION OF DATA SHARING PLAN

The offeror’s plan for the sharing of final research data, or, if data sharing is not possible, the offeror’s documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

6.10 - EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH

If applicable, the offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Sections 4 and 5 should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government holds discussions with your organization, you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and through proposal revision. If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award.

6.11 - EVALUATION OF PLAN FOR SUBMISSION OF GENOME-WIDE ASSOCIATION STUDY (GWAS) DATA

If applicable, the Offeror's plan for the submission of genome-wide association study (GWAS) data to the NIH-designated GWAS data repository will be assessed for appropriateness and adequacy. Proposals submitted for GWAS in which the data submission expectation cannot be met will be considered for award on a case-by-case basis.

6.12 - EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government elects to negotiate with you, you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Negotiated Proposal. If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

SECTION 7. - ATTACHMENTS

The following documents are incorporated into this solicitation:

Attachment 1 - Proposal Intent Response Form: http://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files

Attachment 2 - Technical Proposal Cost Summary: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf

Attachment 3 - Summary of Related Activities: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf

Attachment 4 - Contract Proposal Vertebrate Animal Section (VAS) Worksheet: http://grants.nih.gov/grants/olaw/VAScontracts.pdf

Attachment 5 - Planned Enrollment Report, PHS-398/2590 - http://grants.nih.gov/grants/funding/phs398/PlannedEnrollmentReport.pdf

Attachment 6 - Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310): http://www.hhs.gov/ohrp/sites/default/files/ohrp/assurances/forms/optional310form.rtf

Attachment 7 - Proposal Summary and Data Record (NIH 2043): http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf

Attachment 8 - Small Business Subcontracting Plan: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files

Attachment 9 - Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet: https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrctprpslsprdsht08-2014_508.xlsx

Attachment 10 - Offeror's Points of Contact: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf

Attachment 11 - Certificate of Current Cost or Pricing Data: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/cert-current-cost.pdf

Attachment 12 - Disclosure of Lobbying Activities, OMB Form SF-LLL: http://www.gsa.gov/portal/forms/download/116430

Attachment 13 - HHS Section 508 Product Assessment Template: http://www.hhs.gov/web/508/contracting/technology/vendors.html

Attachment 14 - PHS Human Subjects and Clinical Trials Information Form:
https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files

Attachment 15 - Cumulative Inclusion Enrollment Report:
https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/humansubjectstudy-v1.0.pdf