SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE 1 OF PAGES 159

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
N/A	**RFP-16-100-SOL-00008**	☐ SEALED BID (IFB) ☒ NEGOTIATED(RFP)	**05/06/2016**	N/A

7. ISSUED BY CODE	8. ADDRESS OFFER TO *(If other than Item 7)*
HHS/OS/ASPR/AMCG 330 Independence Ave, SW, RM G-640 Washington, DC 20201	

NOTE: In sealed bid solicitations "offer" and "Offeror" mean "bid" and "bidder."

SOLICITATION

9. Sealed offers in original and **1** copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in See Section L for Instructions until **12:00 PM** *(Hour)* local time 06/20/16 *(Date)*

CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1.
All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	a. TELEPHONE *(NO COLLECT CALLS)*	b. E-MAIL ADDRESS
	Elizabeth Steiner	(202) 205-8926	**Elizabeth.Steiner@hhs.gov**

11. TABLE OF CONTENTS

((x)	SEC.	DESCRIPTION	PAGE(S)	(x)	SEC.	DESCRIPTION	PAGE(S)
PART I – THE SCHEDULE				PART II – CONTRACT CLAUSES			
X	A	SOLICITATION/CONTRACT FORM	01	X	I	CONTRACT CLAUSES	46
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	03	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	07	X	J	LIST OF ATTACHMENTS	58
X	D	PACKAGING AND MARKING	17	PART IV – REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	18	X	K	REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS	59
X	F	DELIVERIES OR PERFORMANCE	19				
X	G	CONTRACT ADMINISTRATION DATA	29	X	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	72
X	H	SPECIAL CONTRACT REQUIREMENTS	34	X	M	EVALUATION FACTORS FOR AWARD	88

OFFER *(Must be fully completed by Offeror)*

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within 150 calendar days *(60 calendar days unless a different period is inserted by the Offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52-232-8)*	10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	CALENDAR DAYS

14. ACKNOWLEDGMENT OF AMENDMENTS *(The Offeror acknowledges receipt of amendments to the SOLICITATION for Offerors and related documents numbered and dated:*	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER *(Type or Print)*

15B. TELEPHONE NO. AREA CODE NUMBER EXT.	☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: ☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)*	ITEM

24. ADMINISTERED BY *(If other than Item 7)* CODE	25. PAYMENT WILL BE MADE BY CODE

26. NAME OF CONTRACTING OFFICER *(Type or print)*	27. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	28. AWARD DATE

IMPORTANT -- Award will be made on this form, or on Standard Form 26, or by other authorized official written notice.

NOTE TO OFFERORS

The information in SECTION A - Solicitation/Contract Form contains important information for any Offeror interested in responding to this solicitation. Any contract resulting from this solicitation will include in its SECTION A - Solicitation/ Contract Form, accounting, appropriation and general information applicable to the contract award.

The contract schedule, set forth in SECTIONS B through H, contains contractual information pertinent to this solicitation. It is not an exact representation of the contract document that will be awarded as a result of this solicitation. The contract cost or price and other contractual provisions unique to the Offeror's proposal may be included in the resultant contract.

The contract schedule is intended to provide the Offeror with information to aid in understanding the likely terms and conditions of any resultant contract.

PART I – THE SCHEDULE
SECTION B – SUPPLIES OR SERVICE AND PRICE / COST

BARDA Biological Nonclinical Studies Network (NSN)

B.1. Brief Description of Supplies and Services

This Request for Proposal (RFP) solicits proposals for an indefinite delivery, indefinite quantity (IDIQ) contract for the acquisition of biological nonclinical services for animal model studies, analytical services, and toxicology services. It is anticipated that fixed-price and cost reimbursement type task orders under the IDIQ contract will be issued to support the development of biological countermeasures in the BARDA portfolio.

The Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), seeks to maintain a network of Good Laboratory Practices (GLP) laboratories that will provide capability for animal model development studies, analytical services, and toxicology services in support of the BARDA portfolio. In the animal models, the challenge dose generally should be the same as that which produces the human disease or condition and the pathophysiological mechanism of its toxicity should be reasonably well-understood and mimic the human disease/condition as closely as possible. When these models are used to test the efficacy of potential medical countermeasures (MCMs) against biological threats, the mechanism of action of the countermeasure will need to establish the utility of the animal model as a surrogate for humans. BARDA anticipates that contracts awarded from this RFP will serve to facilitate nonclinical studies in support of development of medical countermeasures and/or supportive reagents and assays for regulatory acceptance in the U.S.

The Pandemic and All Hazards Preparedness Act (PAHPA) of 2006 established the Biomedical Advanced Research and Development Authority (BARDA) to support development and acquisition of MCMs to prevent or treat the medical consequences of chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza (PI), and emerging infectious diseases (EID). These MCMs include vaccines, therapeutics, diagnostics, and medical devices. Additionally, BARDA is entrusted to foster innovation of technologies that enable better manufacturing, testing, and utilization of these medical countermeasures.

The Nonclinical Studies Network (NSN) is a key element in the successful development of medical countermeasures for biological threats, particularly since efficacy of products directed against most of these threats cannot be verified using clinical studies. The United States Government (USG) therefore seeks appropriate GLP facilities that are adequate and available to support establishing new or existing nonclinical tests and/or models for the development of Biological MCMs against biological threats, influenza and emerging infectious diseases.

B.3. Prices / Costs

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror. It is anticipated that the final contract will contain a base period of five years (60 months).

B.3.1. Base Period

Base Period of Performance: _____ through _____.

Item	Supplies/Services	Minimum Ordering Amount	Maximum Ordering Amount
0001	Nonclinical Studies Network & Technical Reports	$50,000	$45,000,000

B.3.2. Option Periods

The final contract will not contain Option CLINs.

B.4. ADVANCE UNDERSTANDINGS

The final contract may contain additional advance understandings between the Government and the Offeror.

B.4.1. Minimum Ordering Amount – $50,000

The minimum ordering amount for any task order awarded under this IDIQ is $50,000.

B.4.2. Maximum Ordering Amount – $45,000,000

The Contractor(s) shall not receive payment from the Government in an amount greater than $45,000,000.00 for successful performance under this contract. This contract ceiling is the Government's most optimistic scenario with respect to the Government's needs and level of funding.

B.4.3. Minimum Order Guarantee

The total minimum guarantee under this IDIQ contract is $50,000. This one-time amount will be issued upon award on the base contract. This amount can only be claimed at the end of the 60 month period of performance if no task orders are received and if the Contractor takes advantages of fair opportunity, as described in FAR 16.505, by proposing on at least one task order.

B.4.4. Pricing of Task Orders

The Government will issue Requests for Task Order Responses (RTORs) and contractors will compete for task orders for nonclinical research services based on the work described in SECTION C of this contract. Upon delivery and acceptance of the services described in

each task order, the Government shall pay to the Contractor the price, costs or fee set forth in the task order.

Individual task orders will be issued as requirements occur, and will specify work to be performed. The Contractor shall perform all services in accordance with each task order's work statement/specifications. The terms and conditions under the base IDIQ contract are incorporated into all task orders issued pursuant to this contract.

See SECTION G.4. for further ordering information and procedures.

B.4.5. Funding

Funds consisting of the total value of the minimum guarantee will be obligated on the base contract. Funds for the services provided will be obligated, at the task order level, as they become available, unilaterally by the Government.

B.4.6. Cost Unallowable Unless Authorized by the Contracting Officer

This section prohibits or restricts the use of contract funds for the following, unless otherwise approved in advance by the Contracting Officer:

a) Acquisition, by purchase or lease, of any interest in real property;
b) Rearrangement or alteration of facilities;
c) Purchase of lease of any item of general purpose office furniture or office equipment regardless of dollar value;
d) Accountable Government Property;
e) Overtime
f) Travel to attend general scientific meetings/conferences;
g) Foreign Travel Costs;
h) Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
i) Costs to be paid for the performance of a fixed-price subcontract that exceeds $150,000.00;
j) Refreshments and Meal Expenditures.

B.4.7. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget

For contract work performed on a cost reimbursement basis, the Contractor agrees to provide a detailed breakdown on invoices of the below cost categories as applicable. A sample invoice form is provided as Attachment #8.

1. Direct Labor - Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when unit price is over $1,000.

5. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
6. Consultant Fees - Identify individuals and amounts.
7. Subcontracts - Attach subcontractor invoice(s).
8. Equipment - Cite authorization and amount.
9. G&A - Cite rate and amount.
10. Total Cost
11. Fixed Fee
12. Total Cost Plus Fixed Fee (Total CPFF)

For contract work performed on a cost reimbursement basis, monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government. Also note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31. Invoice submission information is provided in SECTION G.6.

SECTION C: STATEMENT OF OBJECTIVES (SOO)

Introduction and Background

Within the Federal government, the Department of Health and Human Services is tasked with protecting the civilian population by providing leadership in research, development, acquisition, deployment, and use of effective medical countermeasures for the adverse health effects resulting from exposure to pandemics and emerging infectious disease threats. Response and recovery were identified as key elements of national defense in the National Strategy to Combat Weapons of Mass Destruction (http://www.whitehouse.gov/new/releases/2002/12/WMDStrategy.pdf). The lead role of HHS in these endeavors was emphasized in Biodefense for the 21st Century (http://www.whitehouse.gov/homeland/20040430.html) and in the National Strategy for Medical Countermeasures against Weapons of Mass Destruction (http://www.whitehouse.gov/news/releases/2007/02/20070207-2.html). These three documents represent the foundation for addressing the Nation's CBRN medical countermeasure needs. Additionally, on February 3, 2015, the former BARDA Director, Dr. Robin Robinson, informed Congress that , "HHS has made significant progress improving vaccines and manufacturing technologies. Specifically, BARDA has worked with and engaged with industry to achieve the following: Establishment of a national infrastructure to rapidly develop, manufacture, and test new influenza vaccines and medical countermeasures for emerging infectious diseases, such as Ebola." This effort includes the, "Nonclinical Studies Network, which is able to perform animal testing."

HHS, through the interagency Public Health Emergency and Medical Countermeasure Enterprise (PHEMCE) is responsible for the integration of requirements for the advanced development and procurement of medical countermeasures for CBRN threats specified by DHS as material threats. The *HHS PHEMCE Strategy for Chemical, Biological, Radiological, and Nuclear Threats* (*HHS PHEMCE Strategy*), published in the Federal Register on March 20, 2007 describes the strategic policy goals and objectives for identifying requirements and establishes the priorities for the development of the medical countermeasures. The *HHS PHEMCE Implementation Plan for Chemical, Biological, Radiological, and Nuclear Threats (HHS PHEMCE Implementation Plan), published in the Federal Register on April 2007 and updated December 2012,* delineates HHS medical countermeasure priorities for research, development and acquisition to address the highest priority CBRN threats.

The Technical Capabilities required to meet the SOO objectives are the following:

1. Technical Plan and Approach
2. Facilities
3. Scientific and Technical Personnel
4. Quality Systems
5. Program and Risk Management

Please note: Response **must** be provided for **each** of the above listed Technical Capabilities (1-5) to be considered for evaluation. Please ensure that your proposal clearly addresses each of the above five technical capabilities in your SOO submission.

A proposal may be submitted for only one, two or all three of the subject areas listed in this RFP. Each proposal must be a standalone submission.

Analytical Services (AS)

BARDA has a requirement for selective, sensitive, qualified, and validated analytical methods for the quantitative evaluation of vaccines, drugs, metabolites (analytes) and biomarkers. These analytical methods are critical for the successful conduct of nonclinical, biopharmaceutics and clinical studies. Successful offerors will be required to perform analytical services such as: assay development, assay validation, and quantitative determinations of biological, chemical, and physical parameters in samples.

C.1.AS Technical Plan & Approach for Analytical Services (AS)

C.1.AS.1. The USG seeks appropriate GLP facilities that are adequate and available to provide analytical services to support development of new or existing MCMs.

C.1.AS.2. The USG seeks GLP analytical support (this includes small molecule analysis, large molecules- proteins, biomarkers, and other analytical signals) required by animal studies (toxicology, efficacy, safety) and clinical studies). These laboratories must have the capability to develop assays, validate assays, and provide high through-put analysis of clinical and non-clinical studies.

C.1.AS.3. The USG seeks facilities with the ability to develop methods for quantitative determination of vaccine components, viruses, bacteria, drug and/or metabolites, and biomarkers that are required to support the development of the potential therapeutic or device in accordance with applicable FDA and ICH guidance, and following pharmaceutical/medical device industry best practices.

C.1.AS.4. The USG seeks facilities that can perform for the quantitative determination of drugs and/or metabolites, and proteins in biological matrices, including procedures such as gas chromatograph (GC), high-pressure liquid chromatography (HPLC), combined GC and LC mass spectrometric (MS) procedures, such as LC-MS, LC-MS-MS, GC-MS and GC-MS-MS; ligand binding assays (LBAs), and immunological and microbiological BA procedures.

C.1.AS.5. The USG seeks a description of services such as method development, feasibility, transfer and validation; pharmacokinetic and toxico-kinetic analyses, protein binding determination, antibody drug conjugate and/or other macromolecule analysis, biomarker method development and validation, and/or derivatization assays.

C.1.AS.6. The USG seeks facilities for development or utilization of assays for determination of immune responses in animals and humans for the measurement of T cell responses, ASC, innate immune responses, mucosal immunity among others.

C.1.AS.7. The USG seeks facilities for the development and utilization of virological assays for the qualification or quantification of viruses including, if necessary, those pertaining to select agents with high containment requirements.

C.1.AS.8. The USG seeks a description of the biological matrices in which the offeror has previously conducted method development and validation.

C.1.AS.9 The USG seeks a description of the Offeror's ability to provide support for the selection and/or synthesis of appropriate internal standards.

C.1.AS.10 The USG seeks a description/listing of analytical methods for both small molecules and therapeutic proteins for which the methods were successfully validated and utilized to support the analysis of study sample in accordance with Good Laboratory Procedures (GLP).

C.1.AS.11 The USG seeks a description of the Offeror's experience with the use of surrogate matrices.

C.1.AS.12 The USG seeks a description of the Offeror's sample management procedures from receipt through sample disposal, including how an audit trail of the location and conditions of samples are maintained.

C.1AS.13 The USG seeks a description of the offeror's approach for reanalysis of samples and reporting of samples which have been reanalyzed.

C.1.AS.14 The USG seeks a brief description of the offeror's procedure for Incurred Sample Reanalysis, particularly in regard to multi-analyte methods. The USG seeks a description of the software used to collect, analyze, and report bioanalytical study sample data.

C.2.AS <u>Facilities</u> for Analytical Services (AS)

C.2.AS.1 The USG seeks facilities that comply with USG biocontainment and biosecurity policies and standards, as well as resources that are appropriate for the management of the biological samples associated with the development or conduct of the analytical assay. If necessary, due to the nature of the biological sample or the assay, this facility shall have permits and associated qualifications to enable access to biological high priority threats (e.g. Select agents), as identified in the 2015 PHEMCE Strategy and Implementation Plan where current approved Federal, State and/or local licenses/certifications for animal work and where applicable, ensure that regulations through CDC and/or USDA are followed (42 CFR Part 73, 7 CFR Part 331, and/or 9 CFR Part 121). Conduct work in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations.

C.2.AS.2 The USG seeks laboratories that can provide analytical support to assess samples from the progression of the disease in animal models and demonstrate prospective correlates of protection (i.e., clinical laboratory capabilities and adoption of novel biomarker testing).

C.3.AS Scientific and Technical Personnel for Analytical Services (AS)

C.3.AS.1. The offeror(s) shall provide personnel who possess the necessary education, training, and experience to successfully provide analytical services in support of animal model and medical countermeasure development.

C.3.AS.2. A suitable plan for training, certification and recertification of scientific and technical personnel should be provided.

C.4.AS Quality Systems for Analytical Services (AS)

C.4.AS.1. The USG seeks laboratories that can develop a quality control (QC)/quality assurance (QA) monitoring plan that shall ensure appropriate storage conditions of select/test biological agent(s) to be tested as well as the appropriate storage conditions and documentation regarding the handling and security for the candidate products (drugs/biologics) being tested for efficacy.

C.4.AS.2. The USG seeks laboratories that can submit evidence of an effective Regulatory and Quality Management System (QMS) (21 CFR Part 58). Offeror(s) shall ensure that the details in the submitted proposal incorporate: 1) QMS in all aspects of the proposal to provide analytical services; 2) a copy of a Quality Plan; 3) a quality reporting structure; 4) an FDA inspection history that provides all observations listed on the FDA Form-483 and associated corrective actions; 5) a regulatory platform that can comply with the evolving regulatory environment regarding requirements for animal research and the FDA regulatory guideline for animal studies in support of approval/ or licensure, such as, 21 CFR Part 58, “Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies,” and 21 CFR Parts 314 and 601 and subparts, “New Drug and Biological Drug Products: Evidence Needed to Demonstrate Effectiveness of medical countermeasures under New Drugs when Human Efficacy Studies Are Not Ethical or Feasible. (i.e., the Animal Rule).

C.5.AS Program & Risk Management for Analytical Services (AS)

C.5.AS.1. The USG seeks laboratories that can provide and implement plans for the overall management, integration and coordination of all contract activities, timelines, and task-linked budgets including the management and coordination of activities carried out under subcontracts. The offeror(s) shall develop a risk mitigation plan highlighting potential problems and/or issues that may arise while providing analytical support, the impact on cost, performance and timelines, and appropriate remediation plans.

C.5.AS.2. The offeror(s) shall propose an integrated management plan for analytical support, including key subcontractors. Management of personnel should include, but is not limited to, providing a list of key individuals and their qualifications to carry out the work detailed in the SOO.

Animal Model Testing (AMT)

BARDA intends to retain and expand its capability to develop animal model and MCM testing. This will insure sufficiently characterized reagents and appropriate studies enable BARDA's development of therapeutics, either through planned Clinical Studies, or through the FDA Animal Rule. Although not every study conducted under this contract will be GLP, offeror(s) should have previous experience conducting GLP studies in small and large animal models at their facilities

C.1.AMT. Technical Plan & Approach for Animal Model Testing (AMT)

C.1.AMT.1. The USG seeks organizations capable of developing animal models to determine the efficacy of potential MCMs (e.g. strain screening) according to FDA Guidelines for the Development of Animal Models.

C.1.AMT.2 The USG seeks organizations capable of carrying-out animal model studies where the challenge dose is similar to that which produces the human disease or condition, and the pathophysiological mechanism of its toxicity should be reasonably well-understood and mimic the human disease/condition as closely as possible.

C.1.AMT.3 The USG seeks laboratories with experience conducting nonclinical safety evaluations following exposure of a drug through multiple routes of administration.

C.2.AMT Facilities for Animal Model Testing (AMT)

C.2.AMT.1. The USG seeks safe facilities and resources that can access Select Agents, influenza strains and/or emerging infectious disease pathogens to address biological high priority threats as identified in the 2015 PHEMCE Strategy and Implementation Plan where current approved Federal, State and/or local licenses/ certifications for animal work and where applicable, ensure that regulations through CDC and/or USDA are followed (42 CFR Part 73, 7 CFR Part 331, and/or 9 CFR Part 121). Conduct work in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations.

C.2.AMT.2. The USG seeks laboratories that have established protocols for routine care and health surveillance for laboratory animals, including on-call veterinary coverage 24 hours per day.

C.2.AMT.3. The USG seeks laboratories that can conduct studies to establish the pathophysiology/natural history of selected biological threat agents or infectious pathogens in appropriate animal species at different ages in response to government needs.

C.2.AMT.4. The USG seeks laboratories that can design a protocol and perform efficacy evaluations in various species on candidate compounds (i.e., drugs and biologics) as specified in task order Statement of Work to permit further product development including but not limited to the assessment and optimization of the

formulation, route of administration, effective dose levels, dose schedule, therapeutic index (i.e. the ratio of the drug/biologic's adverse event plasma concentration over the plasma concentration sufficient for efficacy), and timing of administration (pre-exposure, post-exposure, delayed administration, as well as the determination of the effective dose levels and the therapeutic index (i.e., the ratio of the highest plasma concentration not associated with adverse effects over the lowest plasma concentration associated with the demonstration of efficacy).

C.2.AMT.5. The USG seeks laboratories that can provide analytical support to monitor the progression of the disease in animal models and demonstrate prospective correlates of protection; (i.e., clinical laboratory capabilities and adoption of novel biomarker testing).

C.2.AMT.6. The USG seeks laboratories that can provide microbiological support for the pathogens(s) specified in the task order Statement of Work, including quality-controlled master and working banks; SOPs for production and characterization challenge material under standardized media and growth conditions, and master and working banks for cell lines where applicable. USG seeks laboratories that can develop and/or provide acceptance criteria for the use of challenge material in animal model studies.

C.2.AMT.7. The USG seeks laboratories that have adequate statistical and pharmacokinetics support to analyze and predict experimental hypotheses for models, including pharmacokinetic modeling (both individual animal and population approaches using compartmental and non-compartmental methods).

C.2.AMT.8. The USG seeks laboratories with the capability of controlled exposure of various animal species to biological, influenza, or emerging infectious disease pathogens in order to develop models to evaluate the efficacy of potential.

C.2.AMT.9. In all cases described above, the USG seeks laboratories with the capability to perform these procedures and studies in animal models of human at-risk and special populations (e.g., juvenile, pediatric, geriatric, pregnancy, etc).

C.2.AMT.10. The USG seeks laboratories capable of submitting study data to BARDA in SEND format.

C.3.AMT <u>Scientific and Technical Personnel</u> for Animal Model Testing (AMT)

C.3.AMT.1. The offeror(s) shall provide personnel who possess the necessary education, training, and experience to work with a wide range of animal species and agents identified on the CDC Biothreat and Emerging Infectious Disease list.

C.3.AMT.2. A suitable plan for training, certification and recertification of scientific and technical personnel should be provided. Specifically, BARDA is interested in the train of technical staff for handling agents in containment, GLP training and the handling of animal in accordance with animal welfare guideline.

C.4.AMT <u>Quality Systems</u> for Animal Model Testing (AMT)

C.4.AMT.1. The USG seeks laboratories that can develop a quality control (QC)/quality assurance (QA) monitoring plan that shall ensure appropriate storage conditions of select/test biological agent(s) to be tested as well as the appropriate storage conditions and documentation regarding the handling and security for the candidate products (drugs/biologics) being tested for efficacy. Specifically BARDA is looking for organization with a proactive quality program. This can be simple data trending to the more complex effort associated with real time quality monitoring.

C.4.AMT.2. The USG seeks laboratories that can submit evidence of an effective Regulatory and Quality Management System (QMS) (21 CFR Part 58). Offeror(s) shall ensure that the details in the submitted proposal incorporate: 1) QMS in all aspects of the proposal to fulfill the proposal objectives; 2) a copy of a Quality Plan; 3) a quality reporting structure; 4) an FDA inspection history that provides all observations listed on the FDA Form-483 and associated corrective actions; 5) a regulatory platform that can comply with the evolving regulatory environment regarding requirements for animal research and the FDA regulatory guideline for animal studies in support of approval/ or licensure, such as, 21 CFR Part 58, "Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies," and 21 CFR Parts 314 and 601 and subparts, "New Drug and Biological Drug Products: Evidence Needed to Demonstrate Effectiveness of medical countermeasures under New Drugs when Human Efficacy Studies Are Not Ethical or Feasible. (i.e., the Animal Rule). Offerors must possess the ability to look at the overall BARDA mission which is the licensure of medical countermeasures.

C.5.AMT <u>Program & Risk Management</u> for Animal Model Testing (AMT)

C.5.AMT.1. The USG seeks laboratories that can provide and implement plans for the overall management, integration and coordination of all contract activities, timelines, and task-linked budgets including the management and coordination of activities carried out under subcontracts. The offeror(s) shall develop a risk mitigation plan highlighting potential problems and/or issues that may arise during animal model development studies, the impact on cost, performance and timelines, and appropriate remediation plans. The USG is interested in how the offerors build team to address the technical efforts (the science), the budget and the coordination of limited facilities.

C.5.AMT.2. The offeror(s) shall propose an integrated management including key subcontractors. Management of personnel should include, but is not limited to, providing a list of key individuals and their qualifications to carry out the work detailed in the SOO. The USG does not expect every offeror to have all of the personnel, equipment and facilities to support all of BARDA's future task orders. However, the offeror should have a plan to identify other organization with specialized skills to support the BARDA mission.

Toxicology Services (TS)

BARDA has a requirement to evaluate the nonclinical safety and pharmacokinetic/toxicokinetic profile of medical countermeasures under development. These toxicology services are critical for the successful conduct of nonclinical, biopharmaceutics and clinical studies. A successful offeror will be required to carry out necessary toxicology, pharmacokinetics, safety pharmacology, nonclinical absorption, distribution, metabolism and elimination (ADME) studies in accordance with applicable health authority requirements, including, but not limited to the Food and Drug Administration (FDA) and the International Conference on Harmonization the Office of Economic (ICH).

C.1.TS Technical Plan & Approach for Toxicology Services (TS)

C.1.TS.1. The USG seeks organizations capable of providing capability and expertise to execute the nonclinical safety and/or ADME regulatory studies that are required to support the development of potential therapeutics. These studies should be conducted in accordance with the applicable FDA and ICH guidance and follow standard pharmaceutical/medical device industry practices.

C.1.TS.2. The USG seeks organizations capable of conducting Toxicology studies to support the safety of individual phases of clinical development. Studies in at least two animal species (one being a non-rodent) should be used to assess acute, subchronic and chronic toxicity at the proposed site of exposure.

C.1.TS.3. The USG seeks organizations capable of conducting Pharmacokinetic/Toxicokinetic Studies. During the conduct of subchronic and chronic toxicity studies, concurrent pharmacokinetic/toxicokinetic analyses should be performed to evaluate the drug's ADME (absorption, disposition, metabolism and excretion) profile and to determine if the drug is systemically absorbed. Appropriate analytical methodology should be established as early as possible to provide for precise, consistent and reliable pharmacokinetic data.

C.1.TS.4. The USG seeks organizations capable of conducting a standard battery of tests to evaluate all new molecular entities for the potential to induce genotoxic effects. A drug should be evaluated for potential genetic toxicity prior to the submission of the IND.

C.1.TS.5. The USG seeks organizations capable of conducting reproductive toxicology studies, which should be carried out to explore the possible effects of the drug on fertility and reproductive performance. Additional studies should be performed to examine whether the drug is teratogenic or has an effect on perinatal/postnatal development

C.1.TS.6. The USG seeks laboratories with experience conducting nonclinical safety evaluations following exposure of a drug through multiple routes of administration.

C.1.TS.7. The USG seeks laboratories with the ability to carry-out histopathology studies, including slide preparation and evaluation of tissues.

C.1.TS.8. The USG seeks organizations with historical pathology databases that include descriptions regarding route and species.

C.1.TS.9. The USG seeks organizations with the capacity to prepare samples and conduct histological assessment of tissues.

C.1.TS.10. The United States Government (USG) seeks appropriate Good Laboratory Practices (GLP) facilities that are adequate and available to provide nonclinical animal services to support development of new or existing MCMs.

C.2.TS <u>Facilities</u> for Toxicology Services (TS)

C.2.TS.1. The USG seeks laboratories that have established protocols for routine care and health surveillance for laboratory animals, including on-call veterinary coverage 24 hours per day.

C.2.TS.2. The USG seeks laboratories that can provide analytical support to monitor the progression of the disease in animal models and demonstrate prospective correlates of protection; (i.e., clinical laboratory capabilities and adoption of novel biomarker testing).

C.2.TS.3. The USG seeks laboratories that have adequate statistical and pharmacokinetics support to analyze and predict experimental hypotheses for models, including pharmacokinetic modeling (both individual animal and population approaches using compartmental and non-compartmental methods).

C.2.TS.4. In all cases described above, the USG seeks laboratories with the capability to perform these procedures and studies in animal models of human at-risk and special populations (e.g., pediatric, geriatric, pregnancy, etc.).

C.2.TS.5. The USG seeks laboratories capable of submitting study data to BARDA in SEND format.

C.3.TS <u>Scientific and Technical Personnel</u> for Toxicology Services (TS)

C.3.TS.1. The offeror(s) shall provide personnel who possess the necessary education, training, and experience to conduct nonclinical safety studies involving common species used in toxicology and safety pharmacology studies. This includes rodents, rabbits, swine, dogs, nonhuman primates and other commonly used species. This training and education should include experience in conducting toxicology, safety pharmacology, and pharmacokinetic studies with pharmaceutical agents and/or devices. The Offeror's key personnel should also be able to identify and interpret non-clinical safety findings as they relate to clinical drug safety, including special populations such as pediatrics and pregnant women.

C.3.TS.2. A suitable plan for training, certification and recertification of scientific and technical personnel should be provided. Specifically, BARDA is interested in staff trained to lead and conduct multisite studies in accordance with GLPs, OECD, current international drug development regulatory guidance and guidelines, as well as standard pharmaceutical industry practices. Personnel should also be trained and certified to support all aspects of a toxicology study, including formulation preparation and analysis, drug supply, bioanalytical analysis, and toxicokinetic evaluation.

C.4.TS Quality Systems for Toxicology Services (TS)

C.4.TS.1. The USG seeks laboratories that can develop a quality control (QC)/quality assurance (QA) monitoring plan that shall ensure appropriate security, handling, and storage conditions of test articles, biological specimens, study records and final reports in accordance with GLP regulations.

C.4.TS.2. The USG seeks laboratories that can submit evidence of an effective Regulatory and Quality Management System (QMS) (21 CFR Part 58). Offeror(s) shall ensure that the details in the submitted proposal incorporate: 1) QMS in all aspects of the proposal to fulfill the proposal objectives; 2) a copy of a Quality Plan; 3) a quality reporting structure; 4) an FDA inspection history that provides all observations listed on the FDA Form-483 and associated corrective actions; 5) a regulatory platform that can comply with the evolving regulatory environment regarding requirements for animal research and the FDA regulatory guideline for animal studies in support of approval/ or licensure, such as, 21 CFR Part 58, “Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies,” OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, No. 13, and all applicable FDA Pharm/Tox and ICH Safety guidance.

C.5.TS Program & Risk Management for Toxicology Services (TS)

C.5.TS.1. The USG seeks laboratories that can provide and implement plans for the overall management, integration and coordination of all contract activities, timelines, and fixed-price budgets including the coordination of activities carried out by subcontractors as part of an OECD- compliant multidose study. The offeror(s) shall develop a risk mitigation plan highlighting potential problems and/or issues that may arise during each task order, their impact on cost, performance and timelines, and appropriate remediation plans

C.5.TS.2. The offeror(s) shall maintain a historical control database of clinical pathology, anatomical pathology and reproductive toxicity in all toxicology species used for the conduct of nonclinical GLP toxicology and safety pharmacology studies.

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email as described in SECTION F.3.1.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Technical inspection and acceptance will be take place at:

Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
330 Independence Avenue, S.W.
Room G640
Washington, D.C. 20201

E.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR 52.246-4, Inspection of Services - Fixed Price (August 1996)

FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)

FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)

FAR 52.246-16, Responsibility for Supplies (April 1984)

SECTION F – DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The base period of performance under this contract will be for sixty (60) months from date of award. There are no options.

F.2. DELIVERIES

Successful performance of the final contract shall be deemed to occur upon performance of the work described in SECTION C of this contract and upon delivery and acceptance of the items described in SECTION F.3 by the Contracting Officer or their duly authorized representative.

Deliverables will be further defined upon the issuance of specific task orders.

F.3. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.3.1. Submission of Contract Deliverables

Documents will be delivered electronically (via email to the Contracting Officer) and in original hard copy to the Contracting Officer and the Contracting Officer's Representative. Unless otherwise specified by the Contracting Officer all hard copy deliverables and reports furnished to the Government under the resultant contract (including invoices) shall be addressed as follows:

UPS/FedEx/Courier	USPS Mail Packages
Contracting Officer HHS/ASPR/AMCG 200 C St. SW Washington, DC 20024 Email: Elizabeth.Steiner@hhs.gov	Contracting Officer HHS/ASPR/AMCG 330 Independence Ave. SW, Room G640 Washington, DC 20201

UPS/FedEx/Courier	USPS Mail Packages
Contracting Officer Representative HHS/ASPR/BARDA 200 C St. SW Washington, DC 20024 Email: Elizabeth.Steiner@hhs.gov	Contracting Officer Representative HHS/ASPR/BARDA 330 Independence Ave. SW, Room G640 Washington, DC 20201

In addition to those reports required by other terms of this contract, the Contractor(s) shall submit to the CO and the COR technical progress reports as identified in the TO. These reports shall be subject to the technical inspection and requests for clarification by the COR. These reports shall be brief and factual and prepared in accordance with the formats described in the following section.

F.3.2 Description and Format of Reports

1) Monthly Technical Progress Reports

During periods in which work is being performed under a TO, Monthly Technical Progress Reports are due on the fifteenth (15th) calendar day of each month for the previous calendar month. The Contractor shall submit a report to the COR and the CO. The Contractor shall submit a separate Monthly Technical Progress Report for each TO under which work is being performed. Monthly Technical Progress Reports are not required for periods with no active task orders.

The format and type of Monthly Technical Progress Report and Executive Summary will be provided by the COR within fifteen (15) calendar days of contract award. Monthly Technical Progress Reports will include project timelines, milestones and summaries. A Monthly Technical Progress Report will not be required for the period when a Quarterly Technical Report or Final Technical Report is due. The Contractor shall submit one copy of the Monthly Technical Progress Report electronically via e-mail to the COR and the CO.

The report shall be submitted in Microsoft Word, Microsoft Excel, Microsoft PowerPoint, Microsoft Project or compatible, editable formats. Technical Progress reports shall, at a minimum, include the following information:

Title Page: The Technical Progress Report title page shall include the contract number and title, the period of performance or milestone being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission.

Distribution List: A list of persons receiving the Technical Progress report.

Introduction/ Background: An introduction covering the purpose and scope of the report.

Summary: A table organized by task order summarizing ongoing activities

Progress: The report shall detail, document and summarize, organized by task order, the results of work performed, test results and milestones achieved during the period covered. Progress should be represented as % of total project plan completed, as well as % completed for the month based on forecasted for the month. Information supporting the summary shall also be provided.

A summary of work planned for the next reporting period shall be included.

Issues: Issues resolved, new issues and outstanding issues shall be enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines shall be provided.

Invoices: Summary of any invoices submitted during the reporting period.

Action Items: Summary table of activities or tasks to be accomplished by a certain date and by whom.

Attachments: Each report will include an attachment with an up to date contract history including invoice submission/acceptance dates, and modifications. Results on the project are provided as attachments where appropriate.

2) Quarterly Technical Progress Reports

The format and type of the Quarterly Technical Progress Report and Executive Summary will be provided by the COR within fifteen (15) calendar days of contract award. Quarterly Technical Progress Reports will include project summaries as well as performance metrics for the prime contractor. A Quarterly Technical Progress Report will not be required for the period when the Final Technical Report is due. The Contractor shall submit one copy of the Quarterly Technical Progress Report electronically via e-mail to the COR and CO. The report shall be submitted in Microsoft Word, Microsoft Excel, Microsoft PowerPoint, Microsoft Project or compatible, editable formats.
Quarterly Technical Progress Reports are not required for periods with no active task orders. Quarterly Technical Progress reports shall, at a minimum, include the following information:

Title Page: The Quarterly Technical Progress Report title page shall include the contract number and title, the period of performance being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission.

Distribution List: A list of persons receiving the Technical Progress report.

Introduction/ Background: An introduction covering the purpose and scope of the report.

Summary: A table organized by task order summarizing ongoing activities.

Progress: The report shall summarize, organized by Task Order, the results of work performed. Progress should be represented as % of total project plan completed, as well as % completed for the quarter based on forecasted for the quarter. Information supporting the summary shall also be provided. A summary of work and travel planned for the next reporting period shall also be provided.

Issues: Issues resolved, new issues and outstanding issues shall be enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines shall be provided.

Invoices: Summary of any invoices submitted during the reporting period.

Action Items: Summary table of activities or tasks to be accomplished by a certain date and by whom.

Attachments: Each report will include an attachment with an up to date contract history including invoice submission/acceptance dates, and modifications. Results on the project are provided as attachments where appropriate.

3) Executive Summary

The Executive Summary shall accompany each Technical Progress Report, be formatted as a Microsoft PowerPoint presentation, and include the following:

Title page: Executive Title, the contract number and title, the period of performance or milestone being reported, the contractor's name and the date of submission.

Project Progress: Presented as milestone events, test results, tasks and other activities achieved during the reporting period as talking point bullets.

Project Issues: Presented headings and each item as a talking point bullet.

4) Final Technical Report

For each TO, a Final Technical closeout report will be compiled. The Final Technical Closeout Report will include the following:

Title page: containing Executive Title, the contract number and title, TO Title and period of performance reported, the contractor's name and the date of submission.

Project Progress: presented as milestone target and accomplishment, test results, tasks and other activities achieved during the reporting period as talking point bullets.

Project Issues and Resolutions: presented headings and each item as a talking point bullet.

5) Final Closeout Report

The Contractor shall submit a comprehensive Final Report that details, documents, and summarizes the results of the entire contract work. The report shall explain comprehensively the results achieved. It shall also contain a summary of all task orders issued under the contract and a determination that everything under the contract has been completed and accepted. A draft Final Report shall be submitted to the CO and COR for review and comment at least 45 days prior to contract expiration date. Upon final acceptance by the CO, an electronic copy shall be submitted to the CO not later than 30 days following the expiration date of the contract.

F.4. DELIVERABLE SCHEDULE

Deliverable	Description	Due Date
1.0 Kickoff Meeting/Status Update Meetings/Annual Meeting/Periodic Site Visits/Security and Quality Systems Audits	The contractor shall complete a Kickoff meeting after contract award and/or within a month of task/delivery order award to be held at a location determined by the COR. The purpose of the Task/Delivery Order initiation meeting will be to orient the contractor to HHS/BARDA task/delivery order procedures, review contract requirements, and to plan implementation of initial task/delivery order activities. Status Update Meetings: Plan and conduct meetings of the contractor's Program Director, Program Team, Contracting Officer's Representative and Contracting Officer. This will include other BARDA personnel deemed appropriate by the Contracting Officer's Representative, at a minimum of monthly intervals, either in person or via teleconference, to review protocols, the status of approved work assignments, discuss any matters relevant to the scientific and financial administration of the contract and future activities. The contractor shall prepare and distribute the agenda as well as meeting/teleconference materials to all participants, provide a summary of all meetings, and teleconferences. Annual Meetings: The contractor shall arrange and may conduct annual site visits for AMCG contract and BARDA program staffs to review and discuss the following items: project progress; problems, obstacles, and approaches to overcoming identified problems and obstacles; recommendations for modifications in project timelines, objectives, and research approaches/methodologies based on outcomes to date; and future plans. These site visits shall be attended by the Principal Investigator, the contractor's business representative, and all key personnel. The contractor shall be responsible for the following activities: 1.Planning and submitting the agenda to the Contracting Officer's Representative for approval 2.Developing written and oral presentation materials of all task/delivery orders 3.Presenting summaries of all active task/delivery orders 4.Discussing timelines related to active and future task/delivery orders 5.Discuss methodologies and approaches	Within a month of contract award a Kickoff meeting will be held. Program Review Meetings shall occur at least annually during contract period of performance. The schedule for Status Update Meetings will be established by the Contracting Officer's Representative and Contracting Officer after contract award. Annual Meetings should occur once a year within 30 days of the anniversary of the contract award date. Periodic Site Visits will occur on an adhoc basis. Security and Quality Systems Audits/QA audits may be conducted pre-award and on an ad hoc basis. A summary of these audits will be provided within 25 business days to the contractor.

	Periodic Site Visits will include, if applicable, subcontractor facilities. Security and Quality Systems Audits/QA audits The contractor shall take the necessary corrective action within a timely manner.	
2.0 Biweekly Teleconference	A conference call between the Contracting Officer's Representative and designees and the Contractor's Project Leader/delegate and designees shall occur bi-weekly or as otherwise determined by the Contracting Officer. The contractor shall participate in biweekly teleconferences with BARDA to discuss the performance of the contract. The contractor shall record, maintain and provide draft meeting minutes to the Contracting Officer's Representative for approval within three days after teleconference. The Contracting Officer's Representative will approve the draft version. The contractor shall distribute the final approved version duly marked as final within 3 business days after receipt of BARDA approval.	Biweekly or as determined by the Contracting Officer.
3.0 Monthly/Quarterly/Annual, Task Order/Milestone Technical Progress Reports (Described in F.3.2)	The Monthly/Quarterly/Annual Task/Order Technical Progress reports shall address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS) in the Gantt chart. 1. An Executive Summary in MS PowerPoint format, highlighting the progress, issues, and relevant activities. The Executive Summary should be limited to a few slides, and also highlight only critical issues for that reporting period and resolution approach. 2. Progress in meeting contract milestones - broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned progress and actual progress during the period covered, explaining occurrences of any differences between the two, and the corrective steps and actions are planned, if behind schedule. 3. The reports shall also include a three month rolling forecast of key planned activities, referencing the WBS. 4. A tracking log of progress on regulatory submissions with the FDA submission number, description of submission, date of submission, status of submission, and next steps. 5. Estimated and Actual Expenses This report shall also contain a narrative statement as to whether	Reports shall be submitted in an electronic format on the 15th day of each month for the previous calendar month with an Annual Report submitted on the 15th day of the final month of each contract year for the previous twelve calendar months. These reports are subject to the technical inspection and requests for clarification by the Contracting Officer's Representative. Progress reports are not required for the periods when the Annual Report(s) and Final Report are due.

	there is any discrepancy at this time between the % of work completed and the cumulative costs incurred to date. This section of the report shall also contain estimates for the subcontractors' expenses from the previous month if the subcontractor did not submit a bill in the previous month. These expenses shall be listed for each subcontractor. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors. Milestones will be identified for each Task/Delivery Order and progress toward each Milestone will be reported as part of the Technical Progress Report. Separate Milestone reporting is not required.	
4.0 Invention Reporting Requirement	All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Contracting Officer. If no invention is disclosed, or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer.	In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.
5.0 Technical Documents	The contractor shall provide complete technical documents for COR review and approval. All documents shall be duly marked as either 'Draft' or 'Final'. These technical documents shall include, but shall not be limited to, the following: 1. Non-clinical study overview with flowchart (demonstration of relationship between studies should include clinical study) 2. Draft SOWs to be sent to subcontractors for concept approval, including number of animals 3. Draft protocols and critical reagents 4. Draft and Final Reports	Draft documents shall be submitted to COR for review and comment. COR will provide feedback within 10 business days. Contractor shall submit all final technical documents within 10 business days of completion or as mutually agreed to during the program execution with the Contracting Officer's Representative
6.0 Draft Final Task Order Report	A Draft Final Task Order Report containing a summation of the work performed and the results obtained for the entire contract period of performance. The draft report shall be duly marked as 'Draft'.	Due 90 days prior to the completion date of the contract.

6.1 Final Task Order Report	The Final Task Order Report incorporating the feedback received from COR/CO and containing a summation of the work performed and the results obtained for the entire contract period of performance. The final report shall be duly marked as 'Final'. The contractor shall submit one (1) copy of a comprehensive final report to the Contracting Officer and two (2) copies (one electronically on a CD) to the Contracting Officer's Representative. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved under all milestones. Additional elements to be included in the Annual Report will be discussed, and approved by the Contracting Officer.	Due on/before the completion of the contract
7.0 Standard Operating Procedures	The contractor shall make internal and subcontractor Standard Operating Procedures (SOPs) available for review electronically.	Upon request from the Contracting Officer's Representative and Contracting Officer
8.0 FDA Correspondence and Mtgs Summaries	The contractor shall forward initial CBER/CDER-issued draft minutes and final minutes of any meeting with the FDA to COR. All documents shall be duly marked as either 'Draft' or 'Final'.	Within 5 business days of each meeting for contractor's minutes and upon receipt of minutes from CBER/CDER
8.1 FDA Meetings	The contractor shall forward the dates and times of any meeting with the FDA to COR and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (Contracting Officer's Representative, Contracting Officer, and up to 2 subject matter experts).	This is to be scheduled during the contract period of performance
8.2 FDA Submissions	The contractor shall provide COR the opportunity to review and comment; upon all draft regulatory documents before submission to the FDA. The contractor shall provide COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either 'Draft' or 'Final'.	BARDA shall provide comment within 5 business days after receipt. BARDA reserves the right to request more than 5 business days for review of any regulatory submission that is more than 50 pages. The contractor shall inform COR of the anticipated submission length so COR can make a determination if more than 10 business days will be needed to complete its review of the document. Final FDA submissions shall be submitted to COR concurrently or no later than 1 calendar day of its submission to CBER/CDER.

8.3 FDA Audits	The contractor shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of all FDA's arrival to conduct site visits/audits by any regulatory agency. In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract. The contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483, and the Establishment Inspection Report (EIR). The contractor shall provide the Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. The contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The contractor shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.	The contractor shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of receipt from the CBER/CDER or subcontractor.
8.4 Other Regulatory Agencies	The contractor shall provide BARDA with an electronic copy of all state, local and federal agency (e.g. CDC, OLAW, USDA) inspection reports related to the contractor's ability to perform under this contract. Upon BARDA request, the Contractor shall provide subsequent contractor responses and corrective action plans submitted in response to these inspection reports.	The contractor shall provide inspection reports within 10 business days of receipt. Responses and corrective action plans shall be provided within 5 business days of submission to federal agencies.
9.0 Contractor Audit/Site Visits	The contractor shall inform the Contracting Officer's Representative and Contracting Officer in advance of upcoming audits/site visits of subcontractors as part of the bi-weekly communications, including goals and agenda. Upon completion of the audit/site visit the contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, details and concerns for addressing areas of non-conformance to FDA regulations for GLP guidelines, as identified in the audit report, must be provided to COR. The contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution	Reports and responses relating to contractor audits/site visits are due to COR within 5 business days of report completion.

10.0 Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission	Within 30 calendar days for manuscripts and 15 calendar days for abstracts. Included in the annual report, the contractor shall provide a list of all publications and presentations resulting from task order awards.
11.0 Press Releases	The contractor agrees to accurately and factually represent the work conducted under this contract in all press releases	The contractor shall ensure that the Contracting Officer has received, and approved an advanced copy of any press release to this contract; not less than 5 business days prior to the issuance of the press release
12.0 Security Plan	The contractor shall provide an updated security plan annually.	Updated Security Plan due annually within 30 calendar days of contract anniversary date.
12.1 Security Reporting/Plan	The contractor shall report to the government any activity; or incident that is in violation of established security standards; or indicates the loss or theft of government products	The contractor shall report within 24 hours after occurrence of activity or incident.
13.0 Risk Mitigation Plan	The contractor shall provide a Risk Mitigation Plan Matrix and shall describe a comprehensive plan outlining program and risk management.	The contractor shall provide a finalized plan 90 days after contract award.
14.0 AAALAC Accreditation and OLAW Assurance (AMT and TS only)	The contractor shall provide current documentation to support AAALAC accreditation and OLAW Assurance annually	Documentation due within 30 calendar days of contract anniversary date
15.0 Select Agent Registration (AMT only)	The contractor shall provide documentation to support Select Agent registration annually	Documentation due within 30 calendar days of contract anniversary date

F.5. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FAR 52.242-15, Stop Work Order (August 1989)
FAR 52.242-15, Stop Work Order (August 1989), Alternate I (April 1984)

SECTION G – CONTRACT ADMINISTRATION

G.1. CONTRACTING OFFICER (CO)

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract. Any other commitment, either explicit or implied, is invalid.

The CO is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) obligate or de-obligate funds into the contract; or (6) otherwise change any terms and conditions of this contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The Government's Contracting Officer's Representative (COR) is:

To be identified at the time of award of contract

As delegated by the CO, the COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) assisting the CO in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

G.3. CONTRACTOR'S POINTS OF CONTACT

The Contractor shall provide primary and secondary points of contact (POC) that will be available 24 hours per day, 7 days per week, to be notified in case of a public health emergency.

G.4. ORDERING PROCEDURES

G.4.1. Ordering Official

The Contracting Officer is the only designated Ordering Official for the contract. The Contracting Officer will sign all orders (including written confirmation of oral/telephonic orders) involving requests for supplies and/or services under this contract.

G.4.2. Multiple Award Ordering

Fair opportunity will be provided to all prime contractors for each task order unless one of the circumstances described in FAR 16.505(b)(2)(i) applies to the order or a statute expressly authorizes or requires that the purchase be made from a specified source. Task order competitions will utilize best value with “trade-off” analysis. The Government reserves the right to make multiple awards.

G.4.3. Method of Ordering

Each RTOR issued by HHS will include a statement of work, evaluation factors for award, specific reporting requirements, deliverables, required components of the offer to be submitted, format for submission, and delivery schedule, the relevant importance of technical and cost factors, any special instructions, and any other issues pertinent to the proposed task order, including information on whether it is anticipated that the task order will be awarded with or without discussions. Time allowed for proposal preparation and submission will vary depending on the task and will be designated in each RTOR.

Contractors shall be required to respond with intent to propose for each RTORs. Those contractors that are not capable of performing the services described in the RTOR must notify the Contracting Officer in writing within the notification time established in the RTOR for notification of intent to propose or, if a notification date is not provided, prior to the close date of the RTOR.

In providing services under this contract, the following procedures shall apply to the award of task orders. All work required under this contract shall be authorized through execution of an agreement “task order” signed by the Contractor and Contracting Officer. The task order may be awarded at any time within the period of performance.

When the Government elects to fill a requirement under this contract, the Contracting Officer shall provide a RTOR to the contractors that receive contracts for the particular subject for which responses are being solicited (Animal Model Testing, Analytical Services, and Toxicology Services).

The Government may, at its discretion, award task orders with optional work packages or periods of performance. The Contractor performing the task order may be required to perform the optional work packages or periods of performance at the sole discretion of the Government

If necessary, the Contracting Officer will arrange a teleconference between contractors and the Contracting Officer to discuss the proposed task order prior to submitting task order proposals (technical and business). Business proposals shall include appropriate support of all costs proposed as necessary for performing the services identified in the task order.

Contractors shall submit their proposals in response to a RTOR, which shall include, but not necessarily be limited to the following information:

1. Statement that the Contractor has a clear understanding of the task requirement.

2. Statement of technical and managerial resources and expertise the Contractor can provide to satisfy the requirement;
3. A schedule of performance, identify major milestones, deliverables and delivery date, and task completion; and
4. A cost schedule necessary to complete the work.

The Government will evaluate proposals and conduct negotiations as necessary. Task orders will be awarded to the contractor(s) whose proposal is determined to be the most advantageous to the Government based on the technical and cost factors specified in the RTOR. The Government reserves the right to make an award on the most favorable initial proposal without discussions.

The contracting officer is the only individual authorized to issue a task order under this contract. Unless specifically authorized by the contracting officer, the Contractor shall not commence work on a requirement until a fully executed task order has been awarded.

G.4.4. Minimum and Maximum Amount

Minimum and maximum ordering amounts are discussed in SECTION B.4.

G.5. PAYMENT BY ELECTRONIC FUNDS TRANSFER (JUL 2013)

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–Central Contractor Registration, in SECTION I, requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments (Attachment #12).

G.6. INVOICE SUBMISSION

(a) The Contractor shall submit invoices to the Contracting Officer at the address provided in SECTION F.3. Unless otherwise specified by the Contracting Officer, one (1) hard copy of the invoice shall be delivered by first class mail to the CO with a courtesy copy to be sent by electronic mail. The invoice shall be deemed as 'received' upon receipt of the hard copy of the invoice at the address provided. Invoice composition instructions are provided in B.4.7 and in Attachment #6 (Cost-Reimbursement Type Contracts) and Attachment #7 (Fixed-Price Type Contracts). A sample invoice form is provided as Attachment #8.
(b) The Contractor agrees to include (as a minimum) the following information on each invoice:

(1) Contractor's Name & Address
(2) Contractor's Tax Identification Number (TIN)
(3) Contract Number
(4) Invoice Number
(5) Invoice Date
(6) Contract Line Item Number
(7) Quantity
(8) Unit Price & Extended Amount for each line item
(9) Total Amount of Invoice

(10) Name, title and telephone number of person to be notified in the event of a defective invoice
(11) Payment Address, if different from the information in (b) (1).

(c) The invoice shall be signed by a person authorized to bind the contractor.

(d) The Contractor shall not submit an invoice prior to delivery of goods or services.

(e) Invoice numbering should include for the base and each TO should be formatted year_month #.

(f) The Contractor shall include the following certification at the bottom of the payment request: "I hereby certify that the salaries billed in this payment request are in compliance with the current HHS Salary Rate Limitation Provisions in Section I of the contract."

G.7. CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

G.8. EVALUATION OF CONTRACTOR PERFORMANCE

(a) *Purpose:* In accordance with FAR 42.1502, the contractor's performance will be periodically evaluated by the government in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

(b) *Performance Evaluation Period*: The contractor's performance will be evaluated at least annually.

(c) *Evaluators*: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

(d) *Performance Evaluation Factors*: The contractor's performance will be evaluated in accordance with SECTION M, Attachment #9, Contract Performance Evaluation Report.

(e) *Contractor Review*: A copy of the evaluation will be provided to the contractor as soon as practicable after completion of the evaluation. The contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 30 calendar days after receipt of the evaluation.

(f) *Resolving Disagreements between the Government and the Contractor*: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, contractor's response, and review comments, if any, will be retained as part of the evaluation.

(g) *Release of Contractor Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the contractor whose performance is being evaluated. Disclosure of such information

could cause harm both to the commercial interest of the Government and to the competitive position of the contractor being evaluated, as well as impede the efficiency of Government operations.

(h) *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(i) *Retention Period*: The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1. LABORATORY LICENSE REQUIREMENTS

The contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended). This requirement shall also be included in any subcontract for services under the contract.

H.2. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Department of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. The USDA office contact information is available at http://www.aphis.usda.gov. The USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http://www.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH), http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. PHS.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http://www.nal.usda.gov/awic/legislat/usdaleg1.htm issued by the USDA under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the *Guide* as its primary evaluation tool. It also uses the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*. It is published by the Federated of Animal Science Societies http://www.fass.org.

H.3. REQUIREMENTS FOR ADEQUATE ASSURANCE OF PROTECTION OF VERTEBRATE ANIMAL SUBJECTS

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the OLAW, establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines “animal” as “any live, vertebrate animal used, or

intended for use, in research, research training, experimentation, biological testing or for related purposes." This Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or Local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.

No PHS-supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval but should provide information satisfactory to the Government assuring the humane care and use of such animal.

H.4. CARE OF LABORATORY ANIMALS

(a) Notice to Offerors of Requirement for Compliance With the Public Health Service Policy on Humane Care and Use of Laboratory Animals (January 2006)

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 award may be made to an applicant organization, 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, applicant organizations must establish an Institutional Animal Care & Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. Applicant organizations are required to provide verification of IACUC approval prior to release of 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 Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Assurance and verification of IACUC approval are required. The Contracting Officer 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 (E-mail: *olaw@od.nih.gov* ; Phone: 301–496–7163).

H.5. CARE OF LIVE VERTEBRATE ANIMALS

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by 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 sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(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 Sections 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 of 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 Contracting Officer 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 Contracting Officer 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 Contracting Officer's written notice of suspension, the Contracting Officer 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 approved 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 (E-mail: ace@aphis.usda.gov; Website: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

H.6. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Contractors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance with the

PHS. Contractors are encouraged to visit the OLAW website at http://grants.nih.gov/grants/olaw/references/phspol.htm for additional information. OLAW may be contacted at the NIH at (301) 594-2289.

Under governing regulations, federal funds that are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities that do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28.

H.7. 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 Government funds for work involving a Select Agent or Toxin. No U.S. Government 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 BARDA funds for any work directly involving a Select Agent or Toxin , the foreign institution must provide information satisfactory to BARDA 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 site by a BARDA 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. Visits to foreign sites are conducted every three years after the initial review. No U.S. Government funds can be

used for work involving a Select Agent or Toxin at a foreign institution without written approval from the Contracting Officer.

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 Contracting Officer. Domestic institutions must submit to the Contracting Officer written approval from the CDC to perform the proposed restricted experiment.

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. The foreign institution must also, when requested during negotiations, provide information satisfactory to BARDA that include 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.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract.

No BARDA 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 Contracting Officer.

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 .

H.8. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

H.9. 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 defined in SECTION F.3.

H.10. CONFLICT OF INTEREST

(a) The Contractor warrants that to the best of its knowledge and belief except as otherwise disclosed, no actual or apparent organizational or employee conflict of interest exists as defined below:

(i) a situation in which the nature of work under a Government contract and a Contractor's organization and any of its affiliate organizations or their successors in interest (hereinafter collectively referred to as the "Contractor"), financial, contractual or other interests are such that the appearance of the Contractor's objectivity in performing the contract work may be impaired, may otherwise result in a biased work product, or may result in the contractor being given an unfair competitive advantage; or

(ii) a financial interest or relationship, professional or otherwise, of an employee, subcontractor employee, or consultant (hereinafter referred to as "employee") with an entity that may actually impair or have the appearance of impairing the objectivity of the employee in performing the contract work, or

(iii) an employee has had, currently has, or is reasonably expected to have, official responsibilities with an outside organization, or some other financial interest or business affiliation, such that a reasonable person with knowledge of the relevant facts might question the employee's objectivity/impartiality in performing the contract.

(iv) For purposes of paragraphs a(i) - (a)(iii), the financial interests and business affiliations of the employee's spouse, minor children, and business partners are imputed to the employee.

(b). The Contractor agrees that if changes in their organization or employees have occurred that give rise to the appearance of a conflict of interest since submission of their final proposal revision (FPR) and contract award or occur during the performance of this contract, it shall make an immediate and full disclosure to the Contracting Officer and COR in writing. Such disclosure should include a description of the circumstances, and a description of any action which the contractor has taken or proposes to take to avoid, neutralize, or mitigate any actual or apparent conflict of interest.

(c). The Contractor has an ongoing responsibility to notify the Government Contracting Officer and COR in writing if any actual or apparent conflict of interest arises during the period of performance of the contract. The written notification must provide details of the conflict of interest and any planned mitigation.

(d). The Contractor agrees to immediately notify the Contracting Officer and the COR of (1) any actual or apparent personal conflict of interest with regard to any of its employees working on, having published, or having access to information regarding this contract, or (2) any such information regarding this contract, when such conflicts have been reported to the Contractor.

(e). The Contractor agrees to notify the Contracting Officer and COR prior to incurring costs for that employee's work when an employee may have a conflict of interest. In the event that the conflict of interest does not become known until after performance on the contract begins, the Contractor shall immediately notify the Contracting Officer and COR of the conflict of interest. The employee shall recuse himself/herself from work on this contract when an actual or apparent conflict has been identified until such time as it is determined that the conflict does not exist or it is resolved. The Contractor shall continue performance of this contract until notified by the Contracting Officer of the appropriate action to be taken.

(f). The provisions of this clause shall be included in all subcontracts and consulting agreements to avoid, neutralize, or mitigate actual or apparent conflicts of interest.

H.11. 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 BARDA 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?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

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 BARDA-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer 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 BARDA-funded research project.

The Contracting Officer 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 Contracting Officer 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 Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA-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 Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded 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 managed or reported by the Institution, the 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.

H.12. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

In accordance with FAR 16.505(b)(6), the following individual has been designated as the HHS/ASPR Ombudsman for task order and delivery order contracts:

Cassandra Freeman
HHS/ASPR/AMCG
330 Independence Ave., S.W.
Room G640
Washington, D.C. 20201
Cassandra.Freeman@hhs.gov

H.13. SHARING RESEARCH DATA

The Contractor's data sharing plan, dated [TBD at contract award] is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA 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 Health Information Privacy at http://www.hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA-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.

H.14. CONFIDENTIALITY OF INFORMATION

Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.15. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance, all data generated, all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Offeror shall provide the Government with an electronic copy of all correspondence with the FDA within 24 hours of receipt. The Government shall acquire unlimited rights to all data funded under a contract awarded in response to this RFP in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.16. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (HHS). HHS reserves the right to review any other data determined by HHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.17. DISSEMINATION OF INFORMATION

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.18. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.19. PUBLICATION AND PUBLICITY

The Contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority 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 Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No._____"

H.20. 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.

H.21. REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR-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 e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

H.22. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (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 or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 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 or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

H.23. 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.

H.24. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES

The contractor is hereby notified of the restrictions on the use of HHS funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions: the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 – Limitations on the Payment of Funds to Influence Federal Transactions and FAR Clause 52.203-12 (Oct 2010).

In addition, the current HHS Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes; for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress; or any State or Local legislative body itself.

The current HHS Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

H.25. 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.

H.26. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-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, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR 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 ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at
http://www.phe.gov/Preparedness/planning/science/Pages/AccessPlan.aspx

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

I.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

Full text of the FAR clauses may be accessed electronically at:
https://www.acquisition.gov/far/index.html

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-7	Jul 2013	System for Award Management
FAR	52.204-10	Jul 2013	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-12	Dec 2012	Data Universal Numbering System Number Maintenance
FAR	52.204-13	Jul 2013	System for Award Management Maintenance
FAR	52.204-15	Jan 2014	Service Contract Reporting Requirements for Indefinite-Delivery Contracts
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data—Modifications
FAR	52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-17	Oct 1997	Waiver of Facilities Capital Cost of Money
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
FAR	52.216-7	Jun 2013	Allowable Cost and Payment
FAR	52.216-7	Aug 2012	Allowable Cost and Payment, Alternate II

FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.216-27	Oct 1995	Single or Multiple Awards
FAR	52.219-8	Oct 2014	Utilization of Small Business Concerns
FAR	52.219-9	Oct 2015	Small Business Subcontracting Plan
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	Jul 2013	Post-Award Small Business Program Rerepresentation
FAR	52.222-3	Jun2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-26	Apr 2015	Equal Opportunity
FAR	52.222-29	Apr 2015	Notification of Visa Denial.
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-41	May 2014	Service Contract Labor Standards
FAR	52.222-43	May 2014	Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts)
FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-14	May 2014	Rights in Data -- General
FAR	52.227-14	May 2014	Rights in Data – General, Alternate II (Dec 2007)
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.229-3	Feb 2013	Federal, State and Local Taxes
FAR	52.230-2	Oct 2015	Cost Accounting Standards
FAR	52.232-1	Apr 1984	Payments
FAR	52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
FAR	52.232-8	Feb 2002	Discounts for Prompt Payment
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-11	Apr 1984	Extras
FAR	52.232-17	May 2014	Interest
FAR	52.232-18	Apr 1984	Availability of Funds
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jul 2013	Prompt Payment
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes - Fixed-Price Alternate V (Apr 1984)
FAR	52.243-2	Aug 1987	Changes—Cost-Reimbursement Alternate V (Apr 1984)
FAR	52.243-6	Apr 1984	Change Order Accounting
FAR	52.243-7	Apr 1984	Notification of Changes
FAR	52.244-2	Oct 2010	Subcontracts, Alternate I (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting

FAR	52.244-6	Feb 2016	Subcontracts for Commercial Items
FAR	52.245-1	Apr 2012	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
FAR	52.249-5	Sept 1996	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

I.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR Chapter 3) CLAUSES

Full text of the HHSAR clauses can be found at
http://www.hhs.gov/oamp/policies/index.html

HHSAR	352.203-70	December 18, 2015	Anti-Lobbying
HHSAR	352.215-70	December 18, 2015	Late Proposals and Revisions
HHSAR	352.216-70	December 18, 2015	Additional Cost Principles
HHSAR	352.222-70	December 18, 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	December 18, 2015	Safety and Health
HHSAR	352.224-70	December 18, 2015	Privacy Act
HHSAR	352.227-70	December 18, 2015	Publications and Publicity
HHSAR	352.233-71	December 18, 2015	Litigation and Claims
HHSAR	352-239.73	December 18, 2015	Electronic Information and Technology Accessibility Notice
HHSAR	352.270-5a	December 18, 2015	Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
HHSAR	352.270-5b	December 18, 2015	Care of Live Vertebrate Animals

I.3. ADDITIONAL CONTRACT CLAUSES

I.3.1. Additional HHS Acquisition Regulation (HHSAR) Clauses – In Full Text

352.231-70 Salary Rate Limitation (December 18, 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.
(b) For purposes of the salary rate limitation, the terms “direct salary,” “salary,” and “institutional base salary,” have the same meaning and are collectively referred to as “direct salary,” in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and

administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.
(c) The salary rate limitation also applies to individuals under subcontracts.
(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.
(e) See the salaries and wages pay tables on the Office of Personnel Management website for Federal Executive Schedule salary levels.
(End of clause)

I.3.2. Additional Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses – In Full Text

52.216-18 Ordering (Oct 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from the date of contract award to the end of applicable ordering period.
(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.
(End of clause)

52.216-19 Order Limitations (Oct 1995)

(a) Minimum order. When the Government requires supplies or services covered by this contract in an amount of less than **$50,000**, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.
(b) Maximum order. The Contractor is not obligated to honor—

(1) Any order for a single item in excess of **$7,500,000**;
(2) Any order for a combination of items in excess of **$45,000,000**; or
(3) A series of orders from the same ordering office within **7 days** that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.
(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office **within 2 days** after Contractor receives the order, with written notice stating the Contractor's intent not to ship the item (or items) called for

and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.
(End of clause)

52.216-22 Indefinite Quantity (Oct 1995)

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.
(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the “maximum.” The Government shall order at least the quantity of supplies or services designated in the Schedule as the “minimum.”
(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.
(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor’s and Government’s rights and obligations with respect to that order to the same extent as if the order were completed during the contract’s effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after the effective date of the contract.
(End of clause)

52.222-2 Payment for Overtime Premiums (Jul 1990)

(a) The use of overtime is authorized under this contract if the overtime premium does not exceed $0 or the overtime premium is paid for work -

> (1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;
> (2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;
> (3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or
> (4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall -

> (1) Identify the work unit; e.g., department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected

unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;
(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;
(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and
(4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.
(End of clause)

52.222-35 Equal Opportunity for Veterans (Oct 2015)
(a) Definitions. As used in this clause--"Active duty wartime or campaign badge veteran," "Armed Forces service medal veteran," "disabled veteran," "protected veteran," "qualified disabled veteran,' and "recently separated veteran" have the meanings given at FAR 22.1301.
(b) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans, and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.
(c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts of $150,000 or more unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate of identify properly the parties and their undertakings.
(End of clause)

52.222-36 – Equal Opportunity for Workers With Disabilities (Jul 2014)

(a) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60.741.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities.
(b) Subcontracts. The Contractor shall include the terms of this clause in every subcontract or purchase order in excess of $15,000 unless exempted by rules, regulations, or orders of the Secretary, so that such provisions will be binding upon each subcontractor or vendor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs of the U.S. Department of Labor, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.
(End of Clause)

52.222-49 Service Contract Labor Standards—Place of Performance Unknown (May2014)

(a) This contract is subject to the Service Contract Labor Standards statute , and the place of performance was unknown when the solicitation was issued. In addition to places or areas identified in wage determinations, if any, attached to the solicitation, wage determinations have also been requested for the following which will be determined under TO. The Contracting Officer will request wage determinations for additional places or areas of performance if asked to do so in writing which will be determined under TO.

(b) Offerors who intend to perform in a place or area of performance for which a wage determination has not been attached or requested may nevertheless submit bids or proposals. However, a wage determination shall be requested and incorporated in the resultant contract retroactive to the date of contract award, and there shall be no adjustment in the contract price.

(End of clause)

52.227-11 Patent Rights--Ownership by the Contractor (May 2014)

(a) As used in this clause--

"Invention" means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

"Made" means—

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or

(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

"Nonprofit organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

"Practical application" means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

"Subject invention" means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor's rights.

(1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License.

(i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor

fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor's license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(ii) The Contractor's license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(c) Contractor's obligations.

(1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within 2 years of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 days prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within 1 year after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within 10 months of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either 10 months of the first filed patent application (whether provisional or nonprovisional) or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights—

(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention—

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within 60 days after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government’s interest.

(1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to—

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, “This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention.”

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor’s permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall—

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications. [Complete according to agency instructions.]

(k) Subcontracts.

(1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes statute in connection with proceedings under paragraph (h) of this clause.

(End of Clause)

52.227-14 Rights in Data—General.

Alternate II (Dec 2007). As prescribed in 27.409(b)(3), insert the following paragraph (g)(3) in the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (Dec 2007)

(a) These data are submitted with limited rights under Government Contract No. _____ (and subcontract _____, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure: [Agencies may list additional purposes as set forth in 27.404-2(c)(1) or if none, so state.]

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of Clause)

PART III – ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following Attachments are provided with this Solicitation:

1. Sample Request for Task Order Response - Analytical Services (AS)
2. Sample Request for Task Order Response - Animal Model Testing (AMT)
3. Sample Request for Task Order Response - Toxicology Services (TS)
4. Capabilities Matrix (AS, AMT, TS)
5. Offeror's Points of Contact
6. Invoice Instructions for Cost Reimbursement Contracts
7. Invoice Instructions for Fixed-Price Contracts
8. Sample Invoice Form
9. Contract Performance Evaluation Report
10. Past Performance Questionnaire
11. Summary of Related Activities
12. ACH Vendor/ Miscellaneous Payment Enrollment Form
13. SF-LLL, Disclosure of Lobbying Activities, with Instructions:
    http://www.whitehouse.gov/omb/grants/sfllin.pdf
14. Small Business Subcontracting Plan:
15. Risk Mitigation Plan/Matrix Template
16. Security Plan Template with Instructions

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K – REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

NOTE: IF YOU INTEND TO SUBMIT A PROPOSAL, YOU SHALL:

1. Complete the Online Representations and Certifications Application (ORCA) at website https://www.sam.gov

2. Complete this section and include it as part of your BUSINESS PROPOSAL.

If you are unable to access any documents electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

K.1 FAR 52.203-2 -- Certificate of Independent Price Determination (Apr 1985)

(a) The offeror certifies that --

(1) The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to --

(i) Those prices;

(ii) The intention to submit an offer; or

(iii) The methods or factors used to calculate the prices offered.

(2) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award (in the case of a negotiated solicitation) unless otherwise required by law; and

(3) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory --

(1) Is the person in the offeror's organization responsible for determining the prices being offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) of this provision; or

(2)

(i) Has been authorized, in writing, to act as agent for the following principals in certifying that those principals have not participated, and will not participate in any action contrary to

subparagraphs (a)(1) through (a)(3) of this provision _____ [insert full name of person(s) in the offeror's organization responsible for determining the prices offered in this bid or proposal, and the title of his or her position in the offeror's organization];

(ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) of this provision have not participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) of this provision; and

(iii) As an agent, has not personally participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) of this provision.

(c) If the offeror deletes or modifies subparagraph (a)(2) of this provision, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure. FAR 52.203-11 Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (Sep 2007)

(End Provision)

K.2 FAR 52.204-5 -- Women-Owned Business (Other Than Small Business) (Oct 2014)

K.3 FAR 52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (Apr 2016)

(a) (1) The North American Industry classification System (NAICS) code for this acquisition is 541 -- Professional, Scientific, and Technical Services/541711 -- Research and Development in Biotechnology.

(2) The small business size standard is 500.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) (1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.

(2) If the provision at 52.204-7 is not included in this solicitation, and the offeror is currently registered in the System for Award Management (SAM), and has completed the Representations and Certifications section of SAM electronically, the offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certification in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

[x] (i) Paragraph (d) applies.

[_] (ii) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c) (1) The following representations or certifications in SAM are applicable to this solicitation as indicated:

(c)(1) The following representations or certifications in SAM are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—

(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.

(iv) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(v) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation.

(vi) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(vii) 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law. This provision applies to all solicitations.

(viii) 52.214-14, Place of Performance—Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(ix) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(x) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(xi) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(xii) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xiii) 52.222-25, Affirmative Action Compliance.This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xiv) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xv) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA–designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xvi) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA–designated items.

(xvii) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xviii) 52.225-4, Buy American—Free Trade Agreements—Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225-3.

(A) If the acquisition value is less than $25,000, the basic provision applies.

(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.

(C) If the acquisition value is $50,000 or more but is less than $77,533, the provision with its Alternate II applies.

(D) If the acquisition value is $77,533 or more but is less than $100,000, the provision with its Alternate III applies.

(xix) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xx) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan—Certification. This provision applies to all solicitations.

(xxi) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran-Representation and Certifications. This provision applies to all solicitations.

(xxii) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.

(2) The following representations or certifications are applicable as indicated by the Contracting Officer:

[Contracting Officer check as appropriate.]

__ (i) 52.204-17, Ownership or Control of Offeror.

__ (ii) 52.204-20, Predecessor of Offeror.

__ (iii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

__ (iv) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment- Certification.

__ (v) 52.222-52, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Certification.

__ (vi) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA–Designated Products (Alternate I only).

__ (vii) 52.227-6, Royalty Information.

__ (A) Basic.

__(B) Alternate I.

__ (viii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically via the SAM website accessed through https://www.acquisition.gov. After reviewing the SAM database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this

solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM
(End of provision)

K.4 FAR 52.209-5 -- Certification Regarding Responsibility Matters (Oct 2015)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that --

(i) The Offeror and/or any of its Principals --

(A) Are [_] are not [_] presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have [_] have not [_], within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property (if offeror checks “have”, the offeror shall also see 52.209-7, if included in this solicitation); and

(C) Are [_] are not [_] presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision; and

(D) Have [_], have not [_], within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds $3,500 for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) Examples.

(i) The taxpayer has received a statutory notice of deficiency, under I.R.C. §6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. §6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. §6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has [[_] has not [_], within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) “Principal,” for the purposes of this certification, means an officer; director; owner; partner; or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

(End of Provision)

K.5 FAR 52.209-7 -- Information Regarding Responsibility Matters (Jul 2013)

(a) Definitions. As used in this provision—

"Administrative proceeding" means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceeding at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

"Federal contracts and grants with total value greater than $10,000,000" means—

(1) The total value of all current, active contracts and grants, including all priced options; and

(2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

"Principal" means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror [_] has [_] does not have current active Federal contracts and grants with total value greater than $10,000,000.

(c) If the offeror checked "has" in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

(1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:

(i) In a criminal proceeding, a conviction.

(ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more.

(iii) In an administrative proceeding, a finding of fault and liability that results in—

(A) The payment of a monetary fine or penalty of $5,000 or more; or

(B) The payment of a reimbursement, restitution, or damages in excess of $100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

(2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.

(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management database via https://www.acquisition.gov (see 52.204-7).
(End of provision)

K.6 FAR 52.219-1 -- Small Business Program Representations (Oct 2014)

(a) Definitions. As used in this provision--

“Economically disadvantaged women-owned small business (EDWOSB) concern” means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

“Service-disabled veteran-owned small business concern”--

(1) Means a small business concern--

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) “Service-disabled veteran” means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

“Small business concern” means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (b) of this provision.

“Small disadvantaged business concern, consistent with 13 CFR 124.1002,” means a small business concern under the size standard applicable to the acquisition, that--

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by--

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States, and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

“Veteran-owned small business concern” means a small business concern--

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

“Women-owned small business concern” means a small business concern--

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

“Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127),” means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

(b) (1) The North American Industry Classification System (NAICS) code for this acquisition is _____ _____ [insert NAICS code].

(2) The small business size standard is _____ [insert size standard].

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(c) Representations.

(1) The offeror represents as part of its offer that it [_] is, [_] is not a small business concern.

(2) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it [_] is, [_] is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it [_] is, [_] is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the offeror represented itself as a women-owned small business concern in paragraph (c)(3) of this provision.] The offeror represents as part of its offer that—

(i) It [_] is, [_] is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It [_] is, [_] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(4)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (c)(4) of this provision.] The offeror represents as part of its offer that--

(i) It [_] is, [_] is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It [_] is, [_] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(5)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [The offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it [_] is, [_] is not a veteran-owned small business concern.

(7) [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(6) of this provision.] The offeror represents as part of its offer that is [_] is, [_] is not a service-disabled veteran-owned small business concern.

(8) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents, as part of its offer, that –

(i) It [_] is, [_] is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR part 126; and

(ii) It [_] is, [_] is not a HUBZone joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (c)(8)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm’s status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall --

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

(End of Provision)

K.7 FAR 52.222-25 Affirmative Action Compliance (Apr 1984)

The offeror represents that --

(a) It * has developed and has on file, * has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2); or

(b) It * has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(End of Provision)

K.8 FAR 52.222-38 Compliance with Veterans' Employment Reporting Requirements (Feb 2016)

By submission of its offer, the offeror represents that, if it is subject to the reporting requirements of 38 U.S.C. 4212(d) (i.e., if it has any contract containing Federal Acquisition Regulation clause 52.222-37, Employment Reports on Veterans), it has filed the most recent VETS-4212A Report required by that clause.

(End of provision)

K.9 FAR 52.225-25 Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications (Oct 2015)

(a) Definitions. As used in this provision—

"Person"—

(1) Means—

(i) A natural person;

(ii) A corporation, business association, partnership, society, trust, financial institution, insurer, underwriter, guarantor, and any other business organization, any other nongovernmental entity, organization, or group, and any governmental entity operating as a business enterprise; and

(iii) Any successor to any entity described in paragraph (1)(ii) of this definition; and

(2) Does not include a government or governmental entity that is not operating as a business enterprise.

"Sensitive technology"—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

(b) The offeror shall e-mail questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

(c) Except as provided in paragraph (d) of this provision or if a waiver has been granted in accordance with 25.703-4, by submission of its offer, the offeror—

(1) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran;

(2) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act. These sanctioned activities are in the areas of development of the petroleum resources of Iran, production of

refined petroleum products in Iran, sale and provision of refined petroleum products to Iran, and contributing to Iran's ability to acquire or develop certain weapons or technologies; and

(3) Certifies that the offeror, and any person owned or controlled by the offeror, does not knowingly engage in any transaction that exceeds $3,500 with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) (see OFAC's Specially Designated Nationals and Blocked Persons List at http://www.treasury.gov/ofac/downloads/t11sdn.pdf).

(d) Exception for trade agreements. The representation requirement of paragraph (c)(1) and the certification requirements of paragraphs (c)(2) and (c)(3) of this provision do not apply if—

(1) This solicitation includes a trade agreements notice or certification (e.g., 52.225-4, 52.225-6, 52.225-12, 52.225-24, or comparable agency provision); and

(2) The offeror has certified that all the offered products to be supplied are designated country end products or designated country construction material.

(End of provision)

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.1. CONTRACT TYPE

This RFP is being solicited as Full and Open Competition, indefinite-delivery, indefinite quantity type contract. It is anticipated that one or more awards will be made from this solicitation.

During the period of performance of the contract, the government may order, and the Contractor shall provide, services as identified in future task orders. At the discretion of the government, task orders issued under this contract may be Firm-Fixed Price (FFP) or Cost Reimbursement (CR).

L.2. DELIVERY AND PACKAGING OF PROPOSAL:

Offerors are invited to submit a proposal in response to this solicitation. All proposals received will become part of the official file.

Offerors may respond to subject area(s) Analytical Services (AS), Animal Model Testing (AMT), or Toxicology Services (TS) **or** Offerors may respond to any combination of the three including responding to all three. If responding to more than one subject area, each response submission must be a separate standalone complete proposal (with all required appendices and parts). **Each response must be submitted separately.**

The following instructions establish the acceptable minimum requirements for the format and content of proposals.

The proposal must be prepared in three parts, “Mandatory Criteria”, 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 the other. Submissions should be single-spaced, paginated (consecutively starting with page 1), and readable in all required copies.

L.2.2 DELIVERY OF PROPOSAL: Proposals must be submitted in both hard copy and electronic formats. Electronic submissions should be sent via e-mail and must be received no later than June 20, 2016 – 12 PM ET. Mailed and hand delivered submissions should be delivered on or before June 20, 2016 – 12 PM ET. No files should be password protected. Facsimile submissions are not authorized.

Mail Submission

- One original signed full proposal (stamped “original”)
- One copy of the original full proposal

Submit the hard-copy documents in three-ring binders with tabbed divider pages separating each section. The original and one hardcopy of the full proposal including appendices should be delivered no later than the date and time specified above to the applicable address as shown below:

UPS/FedEx/Courier/Hand Delivery	USPS Mail Packages
Contracting Officer Elizabeth Steiner	Contracting Officer Elizabeth Steiner

ASPR-AMCG-202-205-8926 200 C St. SW Washington, DC 20024	ASPR – AMCG 330 Independence Ave. SW, Room G640 Washington, DC 20201

NOTE: Because 200 C Street is a secure building, respondents that send proposals by UPS, FedEx, or other couriers should allow extra time for the proposal to be delivered to the contracting office. Failure to use the specified address or arrange for pick up in sufficient time could result in your proposal being delivered late.

Electronic Submission

Electronic submissions should be sent via e-mail to Elizabeth.Steiner@hhs.gov prior to the date and time specified above.

Electronic submissions should be in Adobe PDF, MS Word, Microsoft Excel, and Microsoft Project 2007 (as appropriate) via e-mail to Elizabeth.Steiner@hhs.gov.

The subject line should read: PROPOSAL, offeror's name, submission area (AS or AMT or TS).

L.2.3 PACKAGING OF PROPOSAL: To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

1. COVER PAGE
Include RFP title, RFP number, proposal title, name of organization, DUNS No., CAGE number, POC, identification of the proposal part, and indicate whether the proposal is an original or a copy. All proposal parts (Mandatory Criteria, Technical Proposal and Business Proposal) must begin with a Cover Page.

2. MANDATORY CRITERIA
The Offeror shall provide a dedicated section that addresses the mandatory criteria for eligibility. Please clearly crosswalk the mandatory criteria elements as described in SECTION M.2 to the documentation provided to support criteria compliance. **There is no page limit on mandatory criteria.**

3. TECHNICAL PROPOSAL
It is recommended that the technical proposal consist of a cover page, a table of contents, responses to the technical evaluation criteria and the information requested in the SOO in the form of a Statement of Work (SOW) (maximum 50 pages total). Appendices may be provided with the technical proposal, with the appropriate tabs (maximum 100 pages total).

4. BUSINESS PROPOSAL
It is recommended that the business proposal consist of a cover page, a table of contents, labor categories/rates, the information requested in the Sample Request for Task Order Response, required business forms, past performance, and a small business subcontracting plan (as applicable).

The Offeror shall also provide a copy of its most current negotiated indirect cost rate agreement. If the Offeror does not have a negotiated rate agreement, the rates proposed will need to be justified and may need to be negotiated. Provide a breakout of all possible labor with individual names of staff and corresponding labor rates, summary of related activities, disclosure of lobbying activities, representations and certifications, past performance, a small business subcontracting plan (as applicable), and other

administrative data as described herein as well as the business portion of the corresponding sample RTOR response. **There is no page limit on the business proposal.**

L.3 MANDATORY CRITERIA

The mandatory criteria for eligibility as described in SECTION M.2 must be met at the time of proposal submission. Offerors must show completion of all of the mandatory criteria by providing current documentation to support the listed criteria. Offeror proposals submitted that do not meet the mandatory criteria for eligibility will not be eligible for further evaluation.

L.4. TECHNICAL PROPOSAL

L.4.1. Technical Proposal Instructions

Offerors shall prepare their technical proposal submissions to address evaluation factors listed in M.3 Technical Evaluation Criteria while responding to the requirements listed in SECTION C.

The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on capabilities of the Offeror and a Statement of Work to respond to the Government's requirements as defined in the Statement of Objectives. At minimum, Offerors should address how the project is to be organized, staffed, and managed. Information should be provided with sufficient detail to demonstrate your ability to understand and manage important events and tasks. The Offeror must submit a detailed explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

Proposals will be evaluated (as prescribed in FAR 15) by a technical review panel in accordance with the evaluation criteria merit rating as described in SECTION M. This evaluation produces color code ratings which are based upon the information contained in the Offeror's proposal.

As part of the technical proposal, the Offeror will be required to submit a cross reference between the RFP and technical proposal to assist the government in their review.

It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the technical proposal should be presented in the order specified below.

L.4.1.1. Technical Proposal – Components

(1) Section 1: Cover Page
- RFP title, RFP number, proposal title, name of organization, DUNS No., CAGE number, POC, identification of the proposal part, and indicate whether the proposal is an original or a copy.
- Table of Contents / Cross reference to RFP

(2) Section 2: Technical Proposal Overview
Provide a brief overview of the Technical Proposal, including the following:

A. A brief description of activities to be performed by the Offeror and all proposed subcontractors to expand capabilities (example: path support, surgical implants, behavior SMEs), including identification of all proposed subcontractors and a list of key personnel for the Offeror and the proposed subcontractors with degrees, titles and role within the project.

B. Offerors should describe the activities to be subcontracted, the method and level of integration between the prime and any proposed subcontractor(s), and the expected advantages of such an approach. A summary of staff expertise including the total number trained number available to be assigned to this contract for the Offeror and all proposed subcontractors, and the total number of additional staff to be hired and trained.

(3) Section 3: Technical Criteria

The Statement of Objectives, included as SECTION C, provides the Government's overall objectives, and the Offeror's required support to achieve those objectives. The response should provide a detailed plan indicating how each aspect of the SOO shall be accomplished. This plan should be in as much detail as considered necessary to fully explain the proposed technical approach or method. The proposal should reflect a clear understanding of the nature of the work being undertaken. The proposal must include information on how the project is to be organized, staffed, and managed. This information should demonstrate your understanding of important events or tasks and their management. You must explain how the management and coordination of consultant and/or subcontractor efforts will be accomplished. The Offeror shall use the SOO, together with other applicable portions of the RFP as a basis for preparing a proposed statement of work (SOW). The SOW shall be submitted as part of the technical proposal and will be incorporated into the contract at award.

1) Technical Capabilities

Animal Model Testing (AMT)

1. Scientific and technical merit of the approach for animal studies. Describe the facilities and equipment available to successfully support the Statement of Objectives.
2. Document the capability to deliver biological agents (aerosol, IM, IV, etc.)
3. Experience in virology and bacteriology methods
4. Plan to share animal model procedures and data.
5. Computer-based information technology and data management system (example SEND format).

Analytical Services (AS)

1. Scientific and technical merit of the approach for assay development.
2. Regulatory documentation and compliance with GLP.
3. Experience in virology and bacteriology method development.
4. Knowledgeable concerning the impact of the biological matrices in assay development.
5. Describe your approach in reporting results and sample reanalysis.
6. Define your capability to develop assays for both small molecules and therapeutic proteins.

Toxicology Services (TS)

1. Describe you capability and expertise in the performance of nonclinical safety and ADME regulatory studies.

2. What type of nonclinical safety studies have been performed in your laboratory?

3. Provide a listing of available animal models for toxicology studies.

4. Define your approach to support safety studies for special population (Juvenal, pregnant and geriatric).

5. How provides histopathology support?

6. Regulatory documentation and compliance with GLP.

2) Facilities

Animal Model Testing (AMT)

1. The technical proposal must contain a discussion of present facilities and equipment that will be used in the performance of the contract.

2. Capacity for animal holding for both small and large animals

3. Containment space ASBL 3 and 4 and BSL 3 and 4 wet lab space.

4. A plan to share analytical procedures and data.

Analytical Services (AS)

1. Describe the facilities and equipment available to qualify and validated analytical methods for the quantitative evaluation of vaccines, drugs, metabolites and biomarkers.

2. Brief description of laboratory containment to support BARDA's select agent program.

3. A plan to share analytical procedures and data.

Toxicology Services (TS)

1. Provide a description of facility space and any containment space

2. Provide accreditation documentation

3. A plan to share analytical procedures and data.

3) Scientific and Technical Personnel

Animal Model Testing (AMT)

1. Describe expertise in working with a wide range of animal species and agents identified on CDC Biothreat and Emerging Infectious Disease list.

2. Provide an overview of relevant experience and competency to complete the work identified in the technical proposal, organizational chart, and ability to manage select agents. The technical proposal must list the names and proposed duties of the professional personnel, consultants, and key subcontractor employees assigned to the project. Their CV should be included, as appendices listed in L.4.2 item #2, and be limited to 3 pages for each individual.

3. Provide a list of the numbers of technicians. This list should identify the number of years of relevant experience, certification(s)/degrees, special technical training.

4. Identify key personnel for this contract. Key personnel should be limited number of staff. Any change in key personnel requires a modification to the contract.

Analytical Services (AS)

1. Describe expertise in assay development and developing methods for quantitative evaluation of vaccines, drugs, metabolites and biomarkers.

2. Provide an overview of relevant experience and competency to complete the work identified in the technical proposal, organizational chart. Provide a list of the numbers of technicians. This list should identify the number of years of relevant experience, certification(s)/degrees, special technical training.

3. Identify key personnel for this contract. Key personnel should be limited number of staff. Any change in key personnel requires a modification to the contract

Toxicology Services (TS)

1. Describe expertise in the performance of nonclinical safety and ADME regulatory studies.

2. Describe expertise in conducting nonclinical safety studies involving common species used in toxicology and safety pharmacology studies

3. Provide a list of the numbers of technicians. This list should identify the number of years of relevant experience, certification(s)/degrees, special technical training.

4. Identify key personnel for this contract. Key personnel should be limited number of staff. Any change in key personnel requires a modification to the contract.

4) Quality Systems

Animal Model Testing (AMT)

1. Demonstrate the quality system to be employed to accomplish the technical requirements of the SOO.
2. Provide the Quality plan for monitoring storage conditions of select/test biological agent(s) to be tested as well as the appropriate storage conditions and documentation regarding the handling and security for the candidate products (drugs/biologics) being tested for efficacy.
3. Regulatory Documentation and compliance with GLP

Analytical Services (AS)

1. Describe QA/QC program to be employed to accomplish the technical requirements of the SOO.
2. Regulatory Documentation and compliance with GLP

Toxicology Services (TS)

1. Provide quality plan (QA/QC) for monitoring security, handling, and storage conditions of test articles, biological specimens, study records and final reports in accordance with GLP regulations.
2. Provide evidence of Quality Management Systems, regulatory documentation and compliance with GLP, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, No. 13, and all applicable FDA Pharm/Tox and ICH Safety guidances.

5) Program and Risk Management

Animal Model Testing (AMT)

Describe in sufficient detail a comprehensive plan outlining the Offeror's approach to program and risk management including management of subcontractors. A Risk Mitigation Plan shall be provided that will address potential problems that may arise during animal model studies and remediation plans to circumvent major time disruption to the projects under this IDIQ contract (Attachment #14). The risk mitigation will be finalized 90 days after contract award.

Analytical Services (AS)

Describe in sufficient detail a comprehensive plan outlining the Offeror's approach to program and risk management including management of subcontractors. A Risk Mitigation Plan shall be provided that will address potential problems that may arise and remediation plans to circumvent major time disruption to the projects under this IDIQ contract (Attachment #14). The risk mitigation will be finalized 90 days after contract award.

Toxicology Services (TS)

Describe in sufficient detail a comprehensive plan outlining the Offeror's approach to program and risk management. A Risk Mitigation Plan shall be provided that will address potential problems that may arise and remediation plans to circumvent major time disruption to the projects under this IDIQ contract (Attachment #14). The risk mitigation will be finalized 90 days after contract award.

6) Sample Request for Task Order Response

Cross-reference to the main volume of the technical proposal is encouraged to limit the amount of redundant information. The sample task order response for AS, TS, or AMT must address the criteria defined in Section M.3.

The business portion of the Offeror's response to Sample RTOR must be included in the Offeror's Business Proposal.

L.4.2. Appendices to Technical Proposal

Items below can be revised during negotiations with the successful Offeror(s) and will be incorporated into the contract.

1) The Offeror shall describe their **Security Plan**, which covers physical, personnel, transport mechanisms and staffing, and Information Technology (IT) infrastructure security. (Attachment #16)

2) **Curriculum vitae** of key personnel. There should be enough detail to ensure the USG that key individuals will be able to perform the work described in the Technical Proposal (maximum of five pages). The resumes should contain information on education, background, recent experience, and specific or technical accomplishments, as they pertain to their ability to support the objectives of this project. The approximate percentage of time each individual will be available for this project must be stated. The proposed staff hours of each individual should be allocated against each project task or subtask. This appendix will also support Technical Evaluation Factor 3 Scientific and Technical Personnel.

3) **Animal Welfare Plan**

L.5. BUSINESS PROPOSAL

L.5.1 Business Proposal Instructions

The business proposal does not have a page limitation. The proposal must be signed by an official authorized to bind the Offeror(s) organization and must stipulate that it is predicated upon all the terms and conditions of this RFP.

(1) Communications Prior to Contract Award
Offerors shall direct all communications to the attention of the Contracting Officer cited on the face page of this RFP. Communication with any other Government official regarding this RFP is strictly prohibited, and may disqualify your proposal from further consideration.

L.5.2. Business Proposal - Components

(1) Section 1: Cover Page
- RFP title, RFP number, proposal title, name of organization, DUNS No., CAGE number, POC, identification of the proposal part, and indicate whether the proposal is an original or a copy.
- Table of Contents / Cross reference to RFP

(2) Section 2: All Labor Categories and Labor Rates (Unburdened)
The Offeror shall provide a list of all employees, labor categories and all actual salary labor rates for all positions with any possible work under the prospective contract. The hourly rates proposed for each labor category shall be listed as unburdened. If labor pools are used then please provide the unburdened labor rates as a range.

Employee Name *(example)*	**Labor Category** *(example)*	**Standard Hourly Base Labor Rate (provide unburdened hourly rate)** *(example)*
Jane Doe	*Sr. Director (individual)*	*$ 65.80*
John Smith	*Technician II (labor pool)*	*$28.20*
		$

If necessary, documentation to support the actual individual unburdened labor rate as associated with each employee and labor category will be requested in a future negotiation correspondence. Requested supporting documentation may include but not be limited to HR screen shots of individual positions/salaries and/or a descriptive list of labor categories/positions.

The name, labor category, and fully unburdened hourly rates list will be incorporated into any resultant contract award and must be used for budgeting task orders and reimbursement of labor costs. Unburdened individual hourly rates by employee will be broken out and submitted to the USG in task order responses. The current and approved rates at the time of task order response will be used for burdening. Only rates established as provisional or approved (by your cognizant audit agency or HHS) will be acceptable to be applied. Fee cannot be included in labor burdening.

(3) Section 3: Sample RTOR Response

The business proposal shall include the business portion of the Offeror's response to Sample Request for Task Order response. For Sample Request for Task Order Response for Animal Model Testing please cross walk pricing from the WBS. The sample ROTR business proposals shall not exceed 15 pages each.

(4) Section 4: Required Business Forms

All forms must be executed as necessary in the indicated places by an official authorized to bind the Offeror. The following forms shall be duly completed and submitted as a part of the Business Proposal:

1) Offeror's Points of Contact (Attachment #5)
2) Summary of Related Activities (Attachment #11)
3) Completed Disclosure of Lobbying Activities (Attachment #13)
4) A completed Representations and Certifications contained in Part IV, SECTION K, of this solicitation

(5) Section 5: Past Performance

Offerors shall submit the following information as part of their business proposal for both the Offeror and proposed major subcontractors.

The Offeror shall provide a list of the last five (5) contracts completed during the past three years and all contracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial customers. Any previous activities with BARDA must all be included in the submitted past performance list. Offeror's that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

(a) Name of Contracting Organization
(b) Contract Number
(c) Total Contract Value
(d) Description of Requirement
(e) Contracting Officer's name, email and telephone number
(f) Program Manager's name, email and telephone number
(g) Statement from Offeror as to why this contract is relevant to this project.

In addition to the above requested information, the Offeror shall submit a completed questionnaire (Attachment #10) for each of the contracts listed. The Government reserves the right to consider past performance information from any source. It is the responsibility of the Offerors to ensure submission of these questionnaires to be delivered directly from their references to the Government. All questionnaires shall be submitted to:

Elizabeth Steiner
Contract Specialist
330 Independence Ave. SW Rm G640
Washington, DC 20201
Email: Elizabeth.Steiner@hhs.gov

All questionnaires shall be submitted via mail or email no later than the closing date and time that is referenced in this solicitation. The Government reserves the right not to consider any past performance questionnaires that are received after the due date.

Each Offeror will be evaluated on their performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations, and as an evaluation factor against which the Offeror's relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates quality of performance, relative to the size and complexity of the acquisition under consideration.

(6) Section 6: Small Business Subcontracting Plan

1) See Attachment #14 - Small Business Subcontracting Plan Template

Subcontracting Plan: All Offerors, other than those certifying themselves as a small business under the authorized NAICS industry subsector, shall provide a completed "Small Business Subcontracting Plan" in accordance with the instructions provided in FAR Clause 52.219-9 "Small Business Subcontracting Plan - Alternate II". The basis of the plan should be the maximum ordering amount of the IDIQ (section B.4.2).

Shown below are the FY2016 subcontracting goals for HHS. These subcontracting goals are based on the total subcontracting dollars of the contract. (This means total value of all subcontracts awarded under all TOs against this ID/IQ contract).

The anticipated minimum subcontracting goals for this solicitation are as follows:

- 33% for Small Business
- 5% for Small Disadvantaged Business
- 5% for Women-Owned Small Business
- 3% for HUBZone Small Business
- 3% for Veteran-Owned Small Business
- 3% for Service-Disabled Veteran-owned Small Business

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 (Attachment #13) in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in this Request for Proposals:

(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 Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, 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 Contracting Officer 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 Contracting Officer shall notify the Offeror in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Offeror 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 Contracting Officer 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 Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer 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 (SF 294 and SF 295) 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.

A Subcontracting Plan must be submitted with the original proposal and will be subject to negotiations if your proposal is determined to be in the competitive range. Small Business Subcontracting Plan Format (must be submitted with your original Business Proposal) http://www.hhs.gov/osdbu/forms.html

Assistance with Obtaining Small Business Sources: If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (http://www.hhs.gov/about/smallbusiness/osdbustaff.html) or you may contact the OSDBU headquarters at (202) 690-7300.

2) Extent of Small Disadvantaged Business Participation

(Note: This paragraph on small disadvantaged business participation applies to all Offerors, including Offerors who are small business concerns even though they are exempt from the requirement for a Subcontracting Plan under FAR 52.219.)

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $700,000 ($1,500,000 for construction) subject to certain limitations (see FAR 19.201 and 19.1202). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.
The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is: http://www.arnet.gov/References/sdbadjustments.htm

*Note: Public Law 103-355, which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, Offerors must provide information that describes their plans for meeting the targets set forth in their proposal. This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.

If the evaluation factor in this solicitation includes an SDB evaluation factor or Subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation is not in any way intended to be a substitute for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE
Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value
Total Contract Value- $1,000,000	5%
SDB Participation by Prime (Includes joint venture partners and team arrangements)*	2%
SDB Participation by subcontractors	3%

*Note: FAR Subpart 9.6 defines “contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime Contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

L.6. Other Administrative Data

(1) The proposal must stipulate that it is predicated upon all the terms and conditions of this RFP. In addition, it must contain a statement to the effect that it is firm for a period of at least 150 days from the date of receipt by the Government.

(2) The proposal must list any current commitments with the Government relating to nonclinical work or services being performed under any government funding vehicle and indicate whether these commitments will or will not interfere with the completion of work and services as contemplated under this proposal.

(3) The Offeror must demonstrate that it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source.

(4) It is HHS policy that Offeror's provide all equipment and facilities necessary for performance of contracts; however, in some instances, an exception may be granted to provide Government furnished property or to authorize purchase with contract funds. If additional equipment must be acquired, you must include in your proposal a description and the estimated cost of each item, and state whether you propose to furnish the item with your own funds. The Offeror must identify all Government-owned property in its possession that it proposes to use in performing the prospective contract.

(5) An adequate accounting system is a preliminary requirement for all Offeror's. Demonstration of an established system to provide cost accounting and financial data that are adequate for government contract costing purposes will be required during pre-award. To be considered adequate, an accounting system consistent with generally accepted accounting principles (GAAP) and any other contractual requirements must be established. In addition to establishing a system that meets GAAP requirements for financial reporting, government contractors must establish a system that records the incurrence of contract costs in accordance with government laws and regulations, particularly the cost accounting standards (CAS) and the federal acquisition Regulations (FAR) cost principles. While the use and design of specific accounting records may vary, the record keeping systems for all government contractors must include a general ledger, a job cost ledger, labor distribution records, time records, subsidiary journals, a chart of accounts, and financial statements.
The accounting system must accomplish the following:

1. Identifies and segregates direct and indirect costs by cost element
2. Identifies varying levels of indirect costs (e.g. fringe benefits, labor related overhead, and G&A costs)
3. Provides actual cost data at interim periods to allow for contract re-pricing or negotiating revised contract targets
4. Accumulates costs on both a current and cumulative basis (e.g. year to date, and project to date).
5. A timekeeping system that identifies employees' labor costs to appropriate cost objectives to facilitate accurate recording of employee labor costs.
6. Establishes the accounting period and perform reconciliations of time sheets to labor costs included in job cost ledgers and of basic cost records to the general books of account.
7. Excludes from costs charged to government contracts, amounts which are not allowable per terms of FAR Part 31, contract Cost Principles and Procedures, and augmented by CAS 405.

L.7. INQUIRIES

Inquiries concerning the solicitation document should be submitted in writing. Any additions, deletions, or changes to the solicitation will be made by an amendment.

Offerors are instructed specifically to contact only the solicitation contracting officer (listed above) in connection with any aspect of this requirement prior to contract award. Proposals and all correspondence relating to the solicitation document shall be submitted to the contracting officer through email address Elizabeth.Steiner@hhs.gov.

Inquiries should be received at the Contracting Office no later than FIFTEEN (15) business days prior to the proposal due date.

L.8. INCURRING COSTS

The costs of preparing responses to this solicitation are not considered an allowable direct charge on any resultant award. Proposal preparation costs will not be considered.

L.9. NAICS CODE AND SIZE STANDARD

The following information is to be used by the Offeror in preparing its Representations and Certifications (See SECTION K of this RFP), specifically in completing the FAR provision 52.219-1, Small Business Program Representation.

(1) The NAICS Code is 541711.
(2) The small business size standard is 500 employees.

L.10. THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS

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 North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

L.11. USE OF THE METRIC SYSTEM OF MEASUREMENT

Please use only the metric system of measurement.

L.12. POTENTIAL AWARD WITHOUT DISCUSSIONS

The Government reserves the right to award a contract under this solicitation without discussions.

L.13. SOLICITATION PROVISIONS INCORPORATED BY REFERENCE

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address: http://farsite.hill.af.mil/

The following provisions are incorporated by reference in this solicitation, FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998).

FAR 52.204-6 Data Universal Numbering System (DUNS) Number, (Jul 2013).
FAR 52.204-7 System for Award Management, (Jul 2013).
FAR 52.204-18 Commercial and Government Entity Code Maintenance (Jul 2015)
FAR 52.215-1 Instructions to Offerors -- Competitive Acquisition (Jan 2004) -- Alternate I (Oct 1997)
FAR 52.215-16 Facilities Capital Cost of Money, (Jun 2003).
FAR 52.222-24 Preaward On-Site Equal Opportunity Compliance Evaluation (Feb 1999)
FAR 52.232-38 Submission of Electronic Funds Transfer Information with Offer, (July 2013)
HHSAR 352.215-70 Late Proposals and Revisions, (December 18, 2015)

SOLICITATION PROVISIONS IN FULL TEXT:

FAR 52.216-1 -- Type of Contract (Apr 1984)

The Government contemplates award of an indefinite-delivery, indefinite quantity type contract resulting from this solicitation.

FAR 52.233-2, Service of Protest (Sep 2006)

(a) 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 General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Department of Health & Human Services
Assistant Secretary for Preparedness & Response
Office of Acquisition Management, Contracts and Grants
330 Independence Avenue, S.W. Room G640
Washington, DC 20201

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

L.14. PRE-PROPOSAL TELECONFERENCE

A pre-proposal teleconference may be held approximately three weeks after the RFP is released.

An amendment to the RFP will be posted on FedBizOpps to announce the date, address and room number of the pre-proposal conference if/when it is scheduled.

If a teleconference will be held, Offeror's will need to submit to the Contracting Officer any questions they would like addressed at the pre-proposal conference no later than 7 business days after the RFP is released.

SECTION M – EVALUATION FACTORS FOR AWARD

M.1. Basis of Award

Selection of an Offeror for contract award will be based on an evaluation of proposals against the factors identified in this section. The non-cost factors in order of importance are: Mandatory Criteria, Technical Evaluation Criteria, and Past Performance. In the evaluation process, all evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The tradeoff process described in FAR 15.101-1 will be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award(s) to other than the lowest priced or highest technically rated Contractor. In any case, the Government reserves the right to make an award(s) to the offerors(s) whose proposal provides the best overall value to the Government.

In addition, prior to award, the Offeror's proposal must be considered acceptable for use of animal welfare, and security and the use of biological agents. Also, for an (other than a small business concern) to be selected for award, the Small Business Subcontracting Plan required by FAR 52.219-9 must be acceptable.

The technical evaluation will be based on the demonstrated capabilities of the offerors to translate the Statement of Objectives into a functional and executable technical proposal and response to the sample task order request(s). The proposal must document the offeror's implementation plan to perform the work thereby meeting the Statement of Objectives. Offerors must submit information sufficient to evaluate their proposals for technical completeness to carry out or perform criteria being evaluated.
The Government reserves the right to not conduct discussions if it is determined to be in the best interest of the Government. Therefore, Offerors are encouraged to ensure that initial proposals contain the Offeror's most favorable terms and reflect its best possible performance potential.

Pre-Award Survey and/or Site-Inspections.

The Government reserves the right to conduct announced pre-award survey and/or site inspection of the Contractor's facilities, production capabilities, financial capabilities, accounting system, management systems, safety program, and quality assurance systems. Findings from any pre-award survey will be considered in determining the Contractor's responsibility in accordance with FAR Subpart 9.1. The purpose of the pre-award survey and/or site-inspection will be to supplement the Government's evaluation of the Contractor's proposal. The results will be incorporated in the overall evaluation of the Contractor's proposal for use in the source selection decision. By submission of a proposal, a Contractor authorizes such pre-award survey and/or site-inspection deemed appropriate by the Government.

M.2. MANDATORY CRITERIA FOR ELGIBILITY

The following mandatory criteria for eligibility must be met at the time of proposal submission. Proposals that do not meet the mandatory criteria for eligibility will be considered non-responsive and will not be considered for further evaluation. All proposals that satisfy the mandatory eligibility criteria will be considered for a second phase (technical evaluation) where it will be evaluated based on the technical criteria under M.3. Similarly, all foreign Offeror's and foreign facilities will be evaluated on a case by case basis for licensing equivalent to match the licenses listed in the mandatory criteria (if United States standardized licenses are not available).

Mandatory Criteria for AS

1. GLP Capabilities: To demonstrate compliance with the mandatory requirement to have existing GLP capabilities, the Offeror should have at least one completed GLP study. Please provide a list of all GLP studies conducted in the past three years.

Mandatory Criteria for AMT

1) GLP Capabilities: To demonstrate compliance with the mandatory requirement to have existing GLP capabilities, the Offeror should have at least one completed GLP study. Please provide a list of all GLP studies conducted in the past three years.
2) Documentation to support Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation or equivalent.
3) Documentation to support U.S. Department of Agriculture (USDA) - licensed animal research facility, or equivalent (OLAW Assurance).
4) Documentation of CDC/USDA Select Agent registration.

Mandatory Criteria for TS

1. GLP Capabilities: To demonstrate compliance with the mandatory requirement to have existing GLP capabilities, the Offeror should have at least one completed GLP study. Please provide a list of all GLP studies conducted in the past three years.
2. Documentation to support Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) accreditation or equivalent.
3. Documentation to support U.S. Department of Agriculture (USDA) - licensed animal research facility, or equivalent (OLAW Assurance).

M.3. TECHNICAL EVALUATION CRITERIA

Proposals meeting the mandatory criteria for eligibility shall be evaluated against the following evaluation factors for each subject area.

Separate technical evaluations will be done for each subject area.

For all subject area submissions (AS, AMT and TS) technical proposals will be evaluated with respect to the below six (6) factors for determination of the competitive range. Technical factors are listed in descending order of importance as shown below:

1) **Technical Plan and Approach**
2) **Facilities**
3) **Scientific and Technical Personnel**
4) **Quality Systems**
5) **Program and Risk Management**
6) **Sample Request for Task Order Response**

Note: The Sample Request for Task Order Response is for evaluation purposes only. No task order award will result from Offerors' Sample ROTRs.

ANALYTICAL SERVICES

M.3.1.AS Evaluation Factors

1) Technical Plan & Approach

The respondent must demonstrate the capability to conduct a scientifically and regulatory acceptable analytical method validation, and have the ability to perform the quantitative evaluation of vaccines, drugs, metabolites (analytes) and biomarkers, as well as quantitative determination of viruses, drugs and/or metabolites, and proteins in biological matrices, in biological matrices from nonclinical and clinical studies.

The technical approach response shall contain sufficient quantitative details (without reference to cost or price) to permit a complete and accurate evaluation of the approach from strictly a technical (regulatory and scientific) viewpoint. The Offeror's proposal should demonstrate:

1. Demonstrate thorough understanding through prior experience for developing, utilizing, validating, scale-up (high throughput), and technology transfer an analytical method/procedure, and the ability to perform the quantitative evaluation of vaccines, drugs, metabolites (analytes) and biomarkers, as well as quantitative determination of drugs and/or metabolites, and proteins in biological matrices, in biological matrices from nonclinical and clinical studies.

2. The soundness, feasibility, and validity of the proposed plans, methods, techniques, and procedures described in the technical proposal

2) Facilities

The Offeror must demonstrate that it possesses, or can obtain the necessary space and qualified facilities and equipment to successfully perform the Statement of Objectives. The following facilities and characteristics must be identified:

1. Availability of adequate accredited facilities, that comply with USG biocontainment and biosecurity policies and standards, with appropriate containment/disposal of bioactive agents;

2. Availability and appropriateness of equipment and other resources necessary for the proposed nonclinical studies including IT systems (with back-up plan), data management (with back-up plan), and capabilities for receipt, storage, shipping and inventory of products, pathogens, and specimens.

3. Adequacy of the plan to share analytical procedures and data:

    a. Evaluation of Data Sharing Plan - The Offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

    b. Evaluation of the plan to provide nonclinical dataset files (aka 'SEND' datasets) to BARDA.

3) Scientific and Technical Personnel

1. The Offerors shall provide an outline of an organization chart indicating clear lines of authority and responsibility for the project's management.

   Offeror should also identify the number of personnel available to support this contract (technicians, QA, QC, administrative support), the following are examples of Key Personnel that should be identified:

   i. Chief Scientific Officer
   ii. Program Director (PD)/Study Directors
   iii. Head of Quality Assurance (QA)/Quality Control (QC)
   iv. Program Manager
   v. Statistician

2. The Offeror shall provide availability, experience, and capabilities of proposed professional staff, subcontractors and other professional and technical staff, as well as letters of commitment for personnel not currently employed by the Offeror.

4) Quality Systems

Offeror should describe the quality system to be employed to accomplish the technical requirements of the SOO. The response must include:

1. Capability to comply with Good Laboratory Practices (21 CFR Part 58). Limitation and/or exceptions to GLP compliance relative to required technical capabilities of this solicitation should be stated.

2. Documentation of regulatory agencies' facility audits and inspections for the last three year.

3. Description of quality systems employed for non-GLP studies.

4. Role of quality assurance in non-GLP studies.

5. Quality control plan for GLP and non-GLP studies.

6. Quality management of subcontractors.

7. Quality monitoring plan including quality metrics tracked and trended, corrective and preventative action, and change management.

5) Program and Risk Management

Offeror should demonstrate the following:

a. Project management controls to keep multidisciplinary and multiple project tasks on time and on budget, quality control measures, monitoring and tracking, methods and resources to be used and identification of problems likely to occur with plans addressing them.

b. Project Management Plan to ensure efficient planning, initiation, implementation, conduct, completion of activities, and communication with the Government COR and Contracting Officer.

c. Plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.

d. Plan to identify and remediate problems in subcontractor performance.

e. Plans to ensure the secure storage, transmission and verification of data that addresses areas of privacy and confidentiality.

f. Risk mitigation and management plan.

6) Sample Request for Task Order Response for Analytical Services

Technical Approach. The Offeror must demonstrate the capability to conduct a scientifically and regulatory acceptable BA method validation, and have the ability to perform the quantitative determination of drugs, metabolites, and therapeutic proteins in biological matrices from nonclinical and clinical studies.
The technical approach response shall contain sufficient quantitative details to permit a complete and accurate evaluation of the approach from strictly a technical (regulatory and scientific) viewpoint. The Offeror's Sample Task Order Response should demonstrate:

a. An understanding of the current state of knowledge about the regulatory and scientific considerations for developing and validating a bioanalytical procedure, and the ability to perform the quantitative determination of drugs, metabolites, and therapeutic proteins in biological matrices from nonclinical and clinical studies.

b. An understanding of the attributes of the molecule and the challenges that may be encountered due to those attributes.

c. The soundness, feasibility, and validity of the proposed plans, methods, techniques, and procedures described in the technical proposal.

ANIMAL MODEL TESTING

M.3.1.AMT Evaluation Factors

1) Technical Plan & Approach

Scientific and technical merit of the approach for nonclinical studies, to include as applicable provision of animals and animal models, new animal model development, protocol development, conduct of product efficacy studies, and support measurements (immunological, pharmacological, clinical, pathological, etc.).

2) Facilities

The Offeror must demonstrate that it possesses, or can obtain the necessary space and qualified facilities and equipment to successfully perform the Statement of Objectives. The following facilities and characteristics must be identified:

1. Availability of adequate accredited animal facilities, with appropriate containment/disposal of bioactive agents;

2. Availability and appropriateness of equipment and other resources necessary for the proposed nonclinical studies including IT systems (with back-up plan), data management (with back-up plan), and capabilities for receipt, storage, shipping and inventory of products, pathogens, and specimens.

3. Adequacy of the plan to share analytical procedures and data:

    c. Evaluation of Data Sharing Plan - The Offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

    d. Evaluation of the plan to provide nonclinical dataset files (aka ‘SEND’ datasets) to BARDA.

3) Scientific and Technical Personnel

1. The Offerors shall provide an outline of an organization chart indicating clear lines of authority and responsibility for the project’s management.

   Offeror should also identify the number of personnel available to support this contract (technicians, QA, QC, administrative support) At a minimum testing), the following are examples of Key Personnel that should be identified:

   i. Chief Scientific Officer
   ii. Program Director (PD)/Study Directors
   iii. Head of Quality Assurance (QA)
   iv. Head of Regulatory Affairs
   v. Program Manager
   vi. Statistician

2. The Offeror shall provide availability, experience, and capabilities of proposed professional staff, subcontractors and other professional and technical staff as well as letters of commitment for personnel not currently employed by the Offeror.

4) Quality Systems

Offeror should describe the quality system to be employed to accomplish the technical requirements of the SOO. The response must include:

1. Capability to comply with Good Laboratory Practices (21 CFR Part 58). Limitation and/or exceptions to GLP compliance relative to required technical capabilities of this solicitation should be stated.
2. Documentation of regulatory agencies' facility audits and inspections for the last three year.
3. Description of quality systems employed for non-GLP studies.
4. Role of quality assurance in non-GLP studies.
5. Quality control plan for GLP and non-GLP studies.
6. Quality management of subcontractors.
7. Quality monitoring plan including quality metrics tracked and trended, corrective and preventative action, and change management.

5) Program and Risk Management

Offeror should demonstrate the following:

1. Project management controls to keep multidisciplinary and multiple project tasks on time and on budget, quality control measures, monitoring and tracking, methods and resources to be used and identification of problems likely to occur with plans addressing them.
2. Project Management Plan to ensure efficient planning, initiation, implementation, conduct, completion of activities, and communication with the Government COR and Contracting Officer.
3. Plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.
4. Plan to identify and remediate problems in subcontractor performance.
5. Plans to ensure the secure storage, transmission and verification of data that addresses areas of privacy and confidentiality.
6. Risk mitigation and management plan.

6) Sample Request for Task Order Response

<u>Technical Approach</u>

1. <u>Technical Approach Factor:</u> The respondent must demonstrate the capability to provide a technical approach. The technical approach response shall contain sufficient quantitative details (without reference to cost or price) to permit a complete and accurate evaluation of the approach from strictly a technical viewpoint. The focus of the sample task order response evaluation will be based on the Offerors plan for developing an animal model according to FDA guidelines. The Offeror's response should demonstrate:

    1. An understanding of the complexity of Biothreat Virus X-01 and laboratory disease models as outlined in the FDA Guidelines for the Development of Animal Models

    2. An understanding of the current state of clinical knowledge about Biothreat Virus X-01 (what information would the offeror collect and why)

    3. The soundness, feasibility, and validity of the proposed plans, methods, techniques, and procedures described in the technical proposal

4. A viable, efficient, and innovative approach to obtaining viral strains and assuring their later availability to other research groups

TOXICOLOGY SERVICES

M.3.1.TS Evaluation Factors

1) Technical Plan & Approach

The technical approach response shall contain sufficient quantitative details without reference to cost or price and should demonstrate:

1. An understanding of the current state of knowledge about the regulatory and scientific considerations in the conduct of a nonclinical safety pharmacology, toxicology, PK or nonclinical ADME study for the development of MCMs.

2. An understanding of small and large molecules, and challenges that may be encountered due to those attributes. For example, therapeutics that may have poor solubility, poor bioavailability, high volatility,

3. The soundness, feasibility, and validity of the proposed plans, methods, techniques, and procedures described in the technical proposal

2) Facilities

The Offeror must demonstrate that it possesses, or can obtain the necessary space and qualified facilities and equipment to successfully perform the Statement of Objectives. The following facilities and characteristics must be identified:

1. Availability of adequate accredited animal facilities, with appropriate containment/disposal of bioactive agents;

2. Availability and appropriateness of equipment and other resources necessary for the proposed nonclinical studies including IT systems (with back-up plan), data management (with back-up plan), and capabilities for receipt, storage, shipping and inventory of products, pathogens, and specimens.

3. Adequacy of the plan to share analytical procedures and data:

    a. Evaluation of Data Sharing Plan - The Offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

    b. Evaluation of the plan to provide nonclinical dataset files (aka ‘SEND’ datasets) to BARDA.

3) Scientific and Technical Personnel

1. The Offerors shall provide an outline of an organization chart indicating clear lines of authority and responsibility for the project’s management.

Offeror should also identify the number of personnel available to support this contract (technicians, QA, QC, administrative support) At a minimum testing), the following are examples of Key Personnel that should be identified:

i. Chief Scientific Officer

ii. Program Director (PD)/Study Directors
iii. Head of Quality Assurance (QA)
iv. Head of Regulatory Affairs
v. Head of Toxicology
vi. Program Manager
vii. Statistician

2. The Offeror shall provide availability, experience, and capabilities of proposed professional staff, subcontractors and other professional and technical staff as well as letters of commitment for personnel not currently employed by the Offeror.

4) Quality Systems

Offeror should describe the quality system to be employed to accomplish the technical requirements of the SOO. The response must include:

1. Capability to comply with Good Laboratory Practices (21 CFR Part 58). Limitation and/or exceptions to GLP compliance relative to required technical capabilities of this solicitation should be stated.

2. Documentation of regulatory agencies' facility audits and inspections for the last three year.

3. Description of quality systems employed for non-GLP studies.

4. Role of quality assurance in non-GLP studies.

5. Quality control plan for GLP and non-GLP studies.

6. Quality management of subcontractors.

7. Quality monitoring plan including quality metrics tracked and trended, corrective and preventative action, and change management.

5) Program and Risk Management

Offeror should demonstrate the following:

1. Project management controls to keep multidisciplinary and multiple project tasks on time and on budget, quality control measures, monitoring and tracking, methods and resources to be used and identification of problems likely to occur with plans addressing them.

2. Project Management Plan to ensure efficient planning, initiation, implementation, conduct, completion of activities, and communication with the Government COR and Contracting Officer.

3. Plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.

4. Plan to identify and remediate problems in subcontractor performance.

5. Plans to ensure the secure storage, transmission and verification of data that addresses areas of privacy and confidentiality.

6. Risk mitigation and management plan.

6) Sample Request for Task Order Response

Technical Approach

The response to Sample Task Order request (Toxicology Services) shall contain sufficient quantitative details (without reference to cost or price) to permit a complete and accurate evaluation of the approach from strictly a technical (regulatory and scientific) viewpoint.

1. An understanding and clearly defined regulatory and scientific approach needed to successfully complete the sample request for task order response.

2. An understanding of the attributes of the defined molecule in the RTOR and the challenges that may be encountered due to those attributes. For example, therapeutics that may have poor solubility, poor bioavailability, high volatility.

3. The soundness, feasibility, and validity of the proposed RTOR, methods, techniques, and procedures described in the technical proposal.

M.3.3 MERIT RATINGS (AS, AMT and TS)

The following color-coded ratings will be used for each factor and as an overall rating:

Color	Definition
Blue	Exceeds specified minimum performance or capability requirements in a way beneficial to the USG. Proposal must have one or more strengths and no weaknesses or deficiencies.
Green	Meets specified minimum performance or capability requirements necessary for acceptable contract performance. There may be minor but correctable weaknesses and no deficiencies.
Yellow	Meets specified minimum performance or capability requirements necessary for acceptable contract performance. There are apparent or moderate weaknesses that are correctable and no deficiencies.
Red	Fails to meet specified minimum performance or capability requirements. There are unacceptable weaknesses and/or deficiencies. An overall merit rating of red is not eligible for award.

M.4. SECURITY PLAN

The Offeror shall provide a written security plan that includes a complete description of the relevant specific security measures that will be used to reduce vulnerabilities (Attachment #16). The Security Plan alone will be evaluated by a team from the ASPR Program Protection Office.

Submitted plans will be rated “acceptable” or “unacceptable.”

Acceptable: Meets the minimum performance or capability requirements. There may be minor but correctable weaknesses.

Unacceptable: Fails to meet the performance or capability requirements. There are unacceptable weaknesses.

M. 5. ANIMAL WELFARE PLAN

Offeror shall provide documentation demonstrating compliance with the requirements of the Office of Laboratory Animal Welfare (OLAW) including the Offeror's OLAW Assurance number (http://grants.nih.gov/grants/olaw/olaw.htm).

The Offeror must submit a plan that describes how the Offeror will comply with the PHS Policy and addresses the three points listed below:

1. Provide information on the veterinary care of the animals involved.

2. Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic and tranquilizing drugs or restraining devices where appropriate to minimize distress, pain and injury.

3. Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association https://www.avma.org.
   If not, present a justification for not following the recommendations.

Submitted plans will be rated "acceptable" or "unacceptable."

Acceptable: Meets the minimum performance or capability requirements. There may be minor but correctable weaknesses.

Unacceptable: Fails to meet the performance or capability requirements. There are unacceptable weaknesses.

M.6. BUSINESS PROPOSAL EVALUATION

Business proposals will be evaluated to determine responsible and responsive Offeror's who provide the best value to the Government.

The Offeror's business proposal shall be evaluated separately from the technical proposal and then the overall analysis of the business and technical proposals will be evaluated to reach the best overall value to the Government.

The business portion of the Offeror's response to Sample RTOR (Attachments 1, 2, and 3) must be included in the Offeror's Business Proposal. Cost analysis will be used for evaluation of the sample task orders responses.

M.6.1 Sample Request for Task Order Response Price Factors

The Offeror's price submission will be evaluated considering the response to the sample task order request. For Animal Model Testing (AMT), the sample RTOR is for a cost-reimbursable effort. For the Analytical Services (AS) and Toxicology Services (TS) the sample RTOR is a fixed-price effort.

. The proposed cost/prices will be evaluated to determine cost realism (cost reimbursable RTOR) and reasonableness (fixed price RTOR). The basis of evaluation may include the use of various cost/ price realism analysis techniques to ensure a fair and reasonable price such as, but not limited to:

- Comparing the Offeror's total cost/price proposed to an Independent Government Estimate (IGE)
- Comparison of proposed prices received in response to the solicitation.
- Comparison of proposed prices with resources proposed.
- Obtaining information/reports from Government agencies, and the Independent Government Cost Estimate.

Review and analysis of cost and pricing data as well as other cost and pricing data submitted

The Offeror's price submission shall represent the Offeror's best efforts to respond to the Sample RTOR. Any inconsistency between promised performance and price shall be explained in the submission. The Offeror's price must be determined to be reasonable. Additional cost and price analysis techniques described in FAR Part 15.404 may be used to assess cost and price reasonableness.

M.7. Past Performance

An evaluation of Offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any Offeror whose proposal is deemed technically unacceptable. The evaluation will be based on information obtained from references provided by the Offeror, other relevant past performance information obtained from other sources known to the USG, and any information supplied by the Offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each Offeror. Performance risks are those associated with an Offeror's likelihood of success in performing the acquisition requirements as indicated by that Offeror's record of past performance. The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an Offeror's performance on a list of contracts but rather the product of subjective judgment by the USG after it considers relevant information.

When assessing performance risks, the USG will focus on the past performance of the Offeror as it relates to all acquisition requirements, such as the Offeror's record of performing according to specifications, including standards of good workmanship; the Offeror's record of controlling and forecasting costs; the Offeror's adherence to contract schedules, including the administrative aspects of performance; the Offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the Offeror's business-like concern for the interest of the customer.

The USG will consider the currency and relevance of the information, source of the information, context of the data and general trends in the Offeror's performance. The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror. In this case, past performance will be noted as "No relevant past performance history identifiable."

The following rating method shall be used in the evaluation of past performance information:

- Acceptable – Based on the Offeror's performance records little to no doubt exists that the Offeror will successfully perform the required effort. Sources of information indicate that the Offeror's performance is at least average or that unfavorable reports are offset by favorable reports.

- Unacceptable – Based on the Offeror's performance record some minor to serious doubt exists that the Offeror will successfully perform the required effort. Sources of information make unfavorable to unsatisfactory reports about the Offeror's performance and they express concern about doing business with the Offeror again or would not do business with the Offeror again.

- Neutral – The lack of relevant performance record, or the unavailability of past performance information, may result in an undetermined past performance assessment, which will neither be used to the advantage nor disadvantage of the Offeror.

M.8. SMALL BUSINESS SUBCONTRACTING PLAN

A Small Business Subcontracting Plan must be submitted with the original proposal and will be subject to negotiations if the proposal is determined to be in the competitive range.

The Subcontracting Plan will be evaluated on an acceptable/not acceptable basis. An acceptable plan will meet or exceed the established minimum HHS FY2016 subcontracting goals and criteria explained in section L.5.2(6).

Failure to submit and negotiate an acceptable subcontracting plan prior to conclusion of negotiations shall make the Offeror ineligible for award of a contract. This does not apply to small businesses under the selected NAICS code.

Small Business Subcontracting Plan Format (must be submitted with your original Business Proposal). Evaluation of SDB participation will be considered based on the information presented in the Offeror's proposal. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform. The plan will be included in and made a part of any resultant contract.

ATTACHMENT #1

Sample Request for Task Order Response - Analytical Services (AS)

DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR THE QUANTITATIVE ANALYSIS OF DRUGS AND/OR METABOLITES, THERAPEUTIC PROTEINS, AND BIOMARKERS IN BIOLOGICAL MATRICES

The Objective of this sample request for task order response (RTOR) is for the Offeror to demonstrate an understanding of BARDA's requirements for the development and validation of analytical methods used for the analysis of clinical and nonclinical samples of drugs and their metabolites (analytes) and biomarkers in biological matrices. The tasks to be conducted will support regulatory requirements for the investigation and use of human therapeutics.

This sample task order response will be used only for evaluation purposes. This is part of the total IDIQ proposal evaluation package.

Task Order Title

Development and Validation of Analytical Methods for the Quantitative Analysis of Drugs and/or Metabolites, Therapeutic Proteins, and Biomarkers in Biological Matrices Obtained from Clinical and Nonclinical Studies in Support of the Registration and Marketing Authorization of Therapeutic Medical Countermeasures.

1. Background

BARDA Requirement

BARDA develops and procures needed MCMs, including vaccines, therapeutics, diagnostics, countermeasures, against a broad array of public health threats, whether natural, accidental, or intentional in origin. To successfully develop such medical countermeasures (MCMs), a complete drug development program is needed.

For the purposes of this proposal, BARDA in interested in the offeror's ability to develop analytical methods/procedures that are performed for the quantitative determination of drugs, metabolites, and therapeutic proteins in biological matrices such as blood, serum, plasma, or urine tissue, following regulated analytical principles. This would include, but not be limited to, guidance documents from the Food and Drug Administration (FDA) and the International Conference on Harmonization (ICH).

2. Objectives

Scenario for Sample Request for Task Order Response: For the purposes of the evaluating the offeror's technical approach, the respondent should prepare a sample task order response and take into consideration the following in developing a selective and reproducible analytical method:

- An analytical method is needed for the quantitative determination of filgrastim-sndz in blood with a lower limit of quantification of.5.0 ng/mL.
- The selection of the most appropriate method should include an assessment of published methods for analysis, and provide a rationale for selection of an

established assay or the development of a new or modified method.

- Describe the format for which a specific, detailed description of the analytical method will be provided.
- For each step of the proposed analytical method, discuss the extent to which environmental matrix, material, or procedural variables can affect the estimation of analyte in the matrix from the time of collection of the material up to and including the time of analysis.
- The rationale for selection of the proposed concentration range for which the analyte(s) will be determined.
- How the accuracy, precision, reproducibility, response function, and selectivity of the method for endogenous substances, metabolites, and know degradation product would be established for the biological matrix.
- The technical approach should address some of the potential challenges in developing an analytical method.
- A description of the how the methodology will be applied to routine drug analysis and the documentation that will be generated to support the quality and integrity of the results of study sample analysis.

3. **Technical Approach**

At a minimum the technical approach should have the following sections:

a. Brief description of the regulatory requirements (i.e. FDA, ICH), and a detailed study outline/plan for the validation of analytical methods and the quantitative analysis of clinical and nonclinical samples of the analyte of interest in biological matrices. These study outlines/plans should demonstrate scientifically and regulatory acceptable principles based on the molecule and its proposed therapeutic use(s).

b. Technical approach including an Offeror-defined Statement of Work (SOW)

c. Contract Work Breakdown Structure (WBS)

d. Project Schedule/Gantt chart

4. Cost estimates Business Proposal Submission

The price submission should be clearly marked "**Volume II, Price Submission, and Sample Task Order Response Analytical Services".**

The response shall include the fixed-price for each of the studies the offeror proposes to conduct under the Sample RTOR. In Table 1 the respondent shall provide the cost for the activities they propose to conduct for BARDA. Each WBS title must track back to specific tasks in the technical proposal. The specific tasks in the proposal should address:

1. Method development for chemical and/or ligand binding assay (LBA)
2. Full or complete method validation for chemical and/or LBA
3. Analysis of multiple analytes in chemical and/or LBA
4. Method development and validation in specialized tissues for chemical and/ or LBA
5. Analysis of study samples for chemical and/ or LBA

Table 1. Price Factors

Task	Cost
Method Development[1], Chemical Assay	
Single Analyte	
Multiple Analytes	
Non-routine Matrix	
Method Development, Ligand Binding Assay	
Single Analyte	
Multiple Analytes	
Non-routine Matrix	
Method Validation, Chemical Assay	
Single Analyte	
Multiple Analytes	
Non-routine Matrix	
Method Validation, Ligand Binding Assay	
Single Analyte	
Multiple Analytes	
Non-routine Matrix	
Study Sample Analysis[2], Chemical Assay	
Single Analyte	
Multiple Analytes	
Non-routine Matrix	
Study Sample Analysis[2], Ligand-Binding Assay	

Single Analyte	
Multiple Analytes	
Non-routine Matrix	

[1]Method Development and Validation can be rolled into a single cost

[2]Cost per sample

Contract Line Item Description	Base Period			
	Quantity	Unit	Unit Price	Total Price
Line Item Subtotal				
Fringe Benefits				
Subtotal Line Item & Fringe				
Overhead				
Subtotal Line Items, Fringe and Overhead				
ODC's				
Travel				
Subcontracts				
Consultants				
Materials				
CDs				
Subtotal ODCs				
Subtotal - All Costs				
G&A				
Total Cost				

Fee/Profit				
Total Estimated Yearly Values				

ATTACHMENT #2

Sample Request for Task Order Response - Animal Model Testing (AMT)

The Objective of this sample request for task order response is for the Offeror to demonstrate an understanding of BARDA's requirements for the development of an animal model. This sample RTOR will be used only for evaluation purposes.

Task Order Title

Development of a Small Animal Model for the Evaluation of Medical Countermeasures Against Biothreat Virus X-01.

1. Background

BARDA Requirement

The threat of exposure to weaponized Biothreat Virus X-01 and resultant human cases is within BARDA's mandate for the development of Medical Countermeasures (MCMs) to treat patients exposed to Biothreat Virus X-01. To successfully develop such MCMs, improved understanding of Biothreat Virus X-01 disease and suitable animal models of the human disease are required.

Pathogen Strains

While there are several isolates of Biothreat Virus X-01 commonly used for experimentation, appropriate comparative data essential to establish an animal model does not exist. The impact of strain variation on the route of infection, virulence, disease presentation, and mortality is not understood. Moreover, laboratory passage of individual strains can affect virulence. Therefore a better understanding of the underlying cause of this variation is needed.

Biothreat Virus X-01 Information (all of the following information is hypothetical for this exercise only)

- Transmitted to human by infected mosquitoes
- RNA virus that belongs to the alphavirus genus
- Disease symptoms include muscle pain, headache, nausea, fatigue and rash
- Causes disease in approximately 25% of infected individuals
- Isolates are available from researchers in the endemic area, an academic institution in US, a researcher at a public institution in Europe
- There are no known lethal animal models
- No known MCM
- It is considered to be a BSL-3 agent
- Biothreat Virus X-01 grows in Vero E6 cells
- No available diagnostic assays available

2. Objectives

The offeror shall provide a technical approach for the development of a small animal model using Biothreat Virus X-01 as the challenge agent. This model could be used in future experiments to evaluate either a vaccine or therapeutic medical countermeasure. The technical approach should address the key elements defined by the FDA in the "Guidance for Industry – Product Development Under the Animal Rule."

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM399217.pdf

Specifically the offerors are directed to Section V. Essential elements of an Animal Model. It is the offerors responsibility to provide a technical approach that supports the proposed animal model.

3. Technical Approach Volume 1

At a minimum the technical approach should have the following sections:

a. Description of the requirements and narrative of the technical approach addressing the requirements

b. Technical approach including an Offeror-defined Statement of Work (SOW)

c. Contract Work Breakdown Structure (WBS)

d. Project Schedule/Gantt chart

4. Cost Estimates Business Proposal Submission

1. The price submission should be clearly marked "**Volume II, Price Submission, and Sample Task Order Response Animal Model Testing (AMT)."**

2. The response shall include the labor/pricing matrix(ces) for the base period using the format included in Table 2 below. In Table 2 respondent shall list all labor categories proposed for each major Section of the SOW by WBS number and title. The WBS title must track back to Specific Tasks of the technical proposal. The labor/pricing matrix(ces) should include labor categories, the number of full time equivalents (FTEs), the number of total hours per labor category, and the total dollar value.

Table 1 – Labor/Price Matrix to be completed for each subsection in section 2.0

WBS 1.0 – (*subsection Title and number)* Labor/Price Matrix				
Labor Category	Estimated Hours	Standard Hourly Rate	OH(%) or any other cost associated with total labor	Total Price
		$		$
		$		$
		$		$
		$		$
Labor Subtotal				$
Materials Cost				$
Other Direct Costs				$
Fee ($/%)			%	$
Grand Total				$

Table 2- Cost Centers

Cost Center	Unit	Price per Unit	Total Units	Total Cost
E.g. Pathology Slides	Slide	$1/slide	1000	$1000

Table 3- Material(s) Matrix

Materials Base Year	Base Year Cost	Materials Option Period 1	Estimated Option Period 1 Cost
Grand Totals			

ATTACHMENT #3

Sample Request for Task Order Response - Toxicology Services (TS)

The Objective of this sample task order (TO) response is for the Offeror to demonstrate an understanding of BARDA's requirements for the conduct of nonclinical safety studies that support regulatory requirements for the investigation and use of human therapeutics. This sample RTOR will be used only for evaluation purposes. This is part of the total IDIQ proposal evaluation package.

Task Order Title

Conduct of Toxicology, Safety Pharmacology, Pharmacokinetics, Absorption, Distribution, Metabolism and Elimination (ADME) Studies on Medical Countermeasures (Therapeutics and Medical Devices) in Support of Human Clinical Trials and Marketing Authorization

1. Background

BARDA Requirement

BARDA develops and procures needed MCMs, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, whether natural, accidental, or intentional in origin. To successfully develop such MCMs, a complete drug development program is needed, including an appropriate nonclinical safety program [toxicology, pharmacokinetics, safety pharmacology, nonclinical absorption, distribution, metabolism and elimination (ADME)] conducted in accordance with applicable health authority requirements, including, but not limited to the Food and Drug Administration (FDA) and the International Conference on Harmonization the Office of Economic (ICH).

2. Objectives

Scenario for Sample RTOR: The technical approach should consider the following scenario.

1. The required study design is a juvenile toxicity study of a molecule that will be used for 14 days in adults and children from 6 months to 17 years of age.
2. In patients, the molecule will be administered by intravenous infusion (iv) at doses of 400-800 mg twice daily.
3. The compound is a small molecule, new molecular entity (NME) that has been shown in previous studies to cause reversible testicular toxicity, immunotoxicity, and potential effects on the cardiovascular and respiratory systems.

3. Technical Approach

At a minimum the technical approach should have the following sections:

1. Brief description of the regulatory requirements (i.e. FDA, ICH, OECD), and a detailed protocol study outline for each of the nonclinical safety studies that the Offeror would conduct. These protocols should demonstrate scientifically and regulatory acceptable principles based on the molecule and its therapeutic use.

2. Technical approach including an Offeror-defined Statement of Work (SOW)
3. Contract Work Breakdown Structure (WBS)
4. Project Schedule/Gantt chart

4. Cost estimates -Business Proposal Submission

The price submission should be clearly marked "**Volume II, Price Submission, and Sample Task Order Response Toxicology Services".**

The response shall include the fixed-price for the study the Offer proposes to conduct under the Sample RTOR.

- The in-life phase, including standard pre- and post-termination procedures and preparation of the integrated study report.
- Specialized pre and/or post-termination procedures or evaluations
- Analysis of dosing formulations
- Bioanalytical analysis of study samples
- Toxicokinetic/Pharmacokinetic data analysis

Contract Line Item Description	**Base Period**			
	Quantity	**Unit**	**Unit Price**	**Total Price**
Line Item Subtotal				
Fringe Benefits				
Subtotal Line Item & Fringe				

Overhead				
Subtotal Line Items, Fringe and Overhead				
ODC's				
Travel				
Subcontracts				
Consultants				
Materials				
CDs				
Subtotal ODCs				
Subtotal - All Costs				
G&A				
Total Cost				
Fee/Profit				
Total Estimated Yearly Values				

STUDY OUTLINE

REGULATORY COMPLIANCE

REGULATORY GUIDELINES

ROUTE

TEST SYSTEM

- SPECIES, BREEDER
- AGE OF RECEIPT
- MEANS OF IDENTIFICATION

DOSING REGIMEN

TEST ARTICLE PREPARATION

ANALYSIS OF DOSING FORMULATIONS

- INCLUDE TYPE OF SAMPLES AND INTERVAL(S) EVALUATED

ACTIVITIES AND OBSERVATIONS

- TOXICOLOGY ENDPOINTS

SUBSETS AND DEVELOPMENTAL EVALUATIONS

- INCLUDE TYPE OF EVALUATION AND TIMING

TOXICOKINETICS

- INCLUDE COLLECTION METHOD, AND NUMBER OF TIMEPOINTS COLLECTED/ANIMAL
- ASSUME A VOLUME OF 0.5 ML WHOLE BLOOD NEEDED FOR ANALYSIS

VETERINARY CARE AND TREATMENT (PALLIATIVE AND PROPHYLACTIC MEASURES)

- TREATMENT GUIDELINES
- REMOVAL ANIMAL FROM STUDY
- EUTHANASIA
- APPROVE TREATMENT OF CONTRAINDICATIONS

TERMINAL PROCEDURES

ATTACHMENT #4

CAPABILITIES MATRIX (AS, AMT, TS)

Analytical Services (AS) Capability Matrix

Immuno-assays	
Hemagglutination Inhibition	
Micronucleus	
Neuraminidase enzyme-linked lectin assay	
Ig-Isotype (IgA, IgG1, IgG2, IgM) by ELISA or ELISPOT	
Anti-stalk ELISA	
ADCC assay	
Phagocytosis assay	
Upper respiratory mucosal immune response	
Influenza specific T- Lymphocytes: cytokine profile by ELISPOT or by Intracellular cytokine staining (ICS)- FLOW (Please indicate which)	
Plasmablasts (PB) by ELISPOT or Flow (Please indicate which)	
Influenza specific Memory B cells (MBC) by ELISPOT	

Animal Model Testing (AMT) Capability Matrix

Biological Agent (Viral or Bacterial) Experience.

Table 1: Biological Agent (Viral or Bacterial) Exposures1 NIAID Category A & B Priority Pathogens	Host Species/Strains (i.e., Guinea pigs, NHP, Rabbits, etc)	Pathogen, Strain	Challenge Route	Stage of Model		
				Agent Characterization	LD50/ ID50	Natural History
Bacillus anthracis (anthrax)						
Clostridium botulinum toxin (botulism)						
Yersinia pestis (plague)						
Variola major						

(smallpox) and other related pox viruses						
Francisella tularensis (tularemia)						
Arenaviruses (provide subspecies)						
Bunyaviruses (provide subspecies)						
Flaviruses (provide subspecies)						
Filoviruses (provide subspecies)						
Burkholderia pseudomallei						
Influenza (provide subtypes)						
Coxiella burnetii (Q fever)						
Brucella species (brucellosis)						
Burkholderia mallei (glanders)						
Chlamydia psittaci (Psittacosis)						
Ricin toxin (from Ricinus communis)						
Epsilon toxin of Clostridium perfringens						
Staphylococcus enterotoxin B						
Rickettsia prowazekii (Typhus fever)						

Other						

1. The agent listing should be the NIAID Category A & B priority pathogens.

Animal Species Experience

Species	Number of Cages	Maximum Census	Animal Supplier

Please include a second table supplying current and average animal species lab booking ad maximum animal-room capacity.

Location of facility	Animal #1	Animal #2	Animal #3	Animal #4

Toxicology Services (TS) Capability Matrix

Toxicology Services	
General toxicity	
Genotoxicity	
Developmental/reproductive toxicity	
Immunotoxicity	
Neurotoxicity	
Phototoxicity	
Carcinogenicity	
Juvenile	
Safety pharmacology (including hERG)	
License, training and staff to handle radiolabel isotopes	
GLP/ISO 10993 medical device compliant studies	

Animal Species	
Mice	
Rats	
Guinea Pigs	
Rabbits	
Dogs	
Swine	
NHPs	

Animal Surgery		
	Small animal	Large Animal
Ovarectomy		
Device and pump implantation		
Electrocardiograph telemetry transponders		
Vascular catheterizations		
Non-vascular catheterizations		

Examinations					
	Rats	Rabbits	Dogs	Swine	NHPs
Ophthalmology exams					
Telemetrized cardiovascular exams					

Routes of Administration						
	Mice	Rats	Rabbits	Dogs	Swine	NHPs
Oral (including nasogastric)						
Intravenous (tethered infusion)						
Intravenous (non-tethered infusion)						
Intramuscular						
Subcutaneous						
Intraperitoneal						
Dermal						
Inhalation						
Intraocular						
Intranasal						
Intrathecal						
Intracerebroventricular						

ATTACHMENT #5
OFFEROR'S POINTS OF CONTACT

Complete the following and return with the BUSINESS PROPOSAL.

Name, Title and Address* of Business Representative with whom daily contact is required

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

Name, Institutional Title and Address of Proposed Principal

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

These exact addresses are necessary to ensure that contact can be made with the proper individual(s) in the most expeditious manner.

*****Please use actual street address, not P.O. Box.

ATTACHMENT #6
INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.
Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.
Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.
Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by pre-contract cost provisions.
Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.
Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.
Currency: All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.
Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.
Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.
(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.
(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.
(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer,

to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request. Include numbering in format of year_month #.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost see the HHS *Contractor's Guide for Control of Government Property (http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&cad=rja&uact=8&ved=0CB4QFjAA&url=http%3A%2F%2Fncioa.cancer.gov%2Foa-internet%2Freference%2FAppendix_Q_HHS_Contracting_Guide-508.pdf&ei=NRraVO6WGsqAygTz7oL4Cw&usg=AFQjCNG-0KqILRbM1IgEntH08pUZhXTV4A&sig2=XUvZkNK95EJ7uvFs0A83ig*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and
- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in SECTION I.3.1. of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the HHS Salary Rate Limitation Provisions in Section I of the contract."

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

ATTACHMENT #7
INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED-PRICE TYPE CONTRACTS

General The Offeror shall submit vouchers or invoices as prescribed herein.
Format Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.
Number of Copies: As indicated in the contract.
Frequency Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.
Preparation and Itemization of the Invoice The invoice shall be prepared as follows:
(a) Designated Billing Office and address:

HHS/ASPR/BARDA
330 Independence Ave, Room G640
Washington DC 20201
ATTN: Contracting Officer

(b) Invoice Number
(c) Date of Invoice
(d) Contract number and date
(e) Payee's name and address. Show the Offeror's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Offeror, or a different payee has been designated, then insert the name and address of the payee instead of the Offeror.
(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.
(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)
(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency: Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Offeror. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

ATTACHMENT #8
SAMPLE INVOICE FORM

Company Name

Designated Billing Office Name and Address: DHHS/OS/ASPR/AMCG Attn: Contracting Officer 330 Independence Avenue., S.W. Room G640 Washington, D.C. 20201	**Invoice/Finance Number:** **Date Invoice Prepared:** **Contract No.** **Effective Date:**
Contractor's Address and Contact Information: POC: Name of accountant or COO or signatory authority for invoice Title: Phone: E-Mail: **TIN:** **DUNS #:**	**Total Estimated Cost of Order:** **Office of Acquisitions:** Contracting Officer (insert name here) Office of Acquisitions Management, Contracts, and Grants (AMCG) **Central Point of Distribution:**

This invoice represents reimbursable costs for the period from

Expenditure Category	Amount Billed		
	Current	Cumulative	Contract Value
Direct Costs:			
Direct Labor			
Fringe Benefits **0.00%**			
Total Labor Costs:			
Overhead **0.00%**			
Travel			
Subcontracts			
Consultant Fees			
Materials and Supplies			
Other			
Total Direct Costs			
G&A Rate **0.00%**			
Subtotal:			
Fixed Fee **0.0%**			
Total Amount Claimed			
Adjustments			
Grand Total	**$ -**		

I certify that all payments requested are for appropriate purposes and in accordance with the contract.

Name/signature of signatory authority for invoicing

ATTACHMENT #9
CONTRACT PERFORMANCE EVALUATION REPORT

Evaluation Type: Interim __ Final __ (*check one*)		
Evaluating Organization:	**Reporting Period: From to**	
Contracting Office:	**Contract Number:**	**Order Number:**

Contractor Name:	**Contractor Address:**	
DUNS:	**City:**	**State:**
Additional or Alternate Contractor Name:	**Zip/Postal Code:**	**Country:**

TIN:	**Industrial Code (NAICS):**	**Commodity Code:**	**Contract Type:**

Contract Award Date:	**Contract Expiration Date:**	**Contract Value:**

Requirement Description:

Ratings

Summarize contractor performance and check the number which corresponds to the rating for each rating category (*See attached Rating Guidelines).*

Quality of Product or Service

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Quality of Product or Service (2000 characters maximum):

Cost Control (*Rating and Comments for Cost Control are not required if contract type is Fixed-Price)*

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Cost Control (2000 characters maximum):

Timeliness of Performance

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Timeliness of Performance (2000 characters maximum):

Business Relations

_0=Unsatisfactory _1=Poor _2=Fair _3=Good _4=Excellent _5=Outstanding

Government Comments for Business Relations (2000 characters maximum):

Additional Info

Subcontracts

Are subcontracts involved? __Yes __No (*Check one)*
Government Comment on subcontracts (2000 characters maximum):

Contractor Key Personnel

Contractor Manager/Principal Investigator (*name):*
Government Comment on Contractor Manager/Principal Investigator (2000 characters maximum):

Contractor Key Person (*name):*
Government Comment on Contractor Key Person (2000 characters maximum):

Contractor Key Person (*name):*
Government Comment on Contractor Key Person (2000 characters maximum):

Small Business Subcontracting Plan

Did the contractor make a good faith effort to comply with its subcontracting plan consistent with the goals and objectives, reporting and other aspects of the plan? _Yes _No _N/A (*Check one)*

If this is a bundled contract, did the contractor meet the goals and objectives for small business participation?
_Yes _No _N/A (*Check one)*

Government Comments on Small Business Subcontracting Plan (2000 characters maximum):

Small Disadvantaged Business Goals

Did the contractor make a good faith effort to comply with its subcontracting plan consistent with the goals and objectives, for small disadvantaged business (SDB) participation, monetary targets for SDB participation, and required notifications? _Yes _No _N/A (*Check one)*

Government Comments on Small Disadvantaged Business Goals (2000 characters maximum):

Customer Satisfaction

Is/was the contractor committed to customer satisfaction? _Yes _No (*Check one)*

Would you recommend the selection of this firm again? _Yes _No (*Check one)* – *FINAL REPORT ONLY*

Government Comments on Customer Satisfaction (2000 characters maximum):

Admin Info

Project Officer/COR
Name:
Phone:
Fax:
E-mail Address:

Contractor Representative
Name:
Phone:
Fax:
E-mail Address:

Alternate Contractor Representative (*Required to insure that at least one person is notified of evaluation)*
Name:
Phone:
Fax:
E-mail Address:

Contracting Officer:
Name:
Phone:
Fax:
E-mail Address:

Contractor Comments

Quality of Product of Service

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Cost Control

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Timeliness of Performance

___Contractor has elected not to comment

Contractor Comments for Timeliness of Performance (2000 characters maximum):

Business Relations

___Contractor has elected not to comment

Contractor Comments for Business Relations (2000 characters maximum):

Overall Comment

___Contractor has elected not to comment

Contractor Comments for Quality of Product of Service (2000 characters maximum):

Rating Guidelines

Quality of Product or Service

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Non-conformances are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards containing similar requirements.
Poor	Overall compliance requires significant Agency resources to ensure achievement of contract requirements.
Fair	Overall compliance requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, quality problems, and the Contractor has met the contract requirements.
Excellent	There are no quality issues, and the Contractor has substantially exceeded the contract performance requirements without commensurate additional costs to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that was significantly in excess of anticipated achievements and is commendable as an example for others, so that it justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Cost Control

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Ability to manage cost issues is jeopardizing performance of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, this level of ability to manage cost issues constitutes a significant impediment in consideration for future awards.
Poor	Ability to manage cost issues requires significant Agency resources to ensure achievement of contract requirements.
Fair	Ability to control cost issues requires minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or very minimal, cost management issues and the Contractor has met the contract requirements.
Excellent	There are no cost management issues and the Contractor has exceeded the contract requirements, achieving cost savings to the Government.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where the contractor achieved cost savings and performance clearly exceeds the performance levels described as "Excellent".

Timeliness of Performance

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Delays are jeopardizing the achievement of contract requirements, despite use of Agency resources. Recovery is not likely. If performance cannot be substantially corrected, it constitutes a significant impediment in consideration for future awards.
Poor	Delays require significant Agency resources to ensure achievement of contract requirements.
Fair	Delays require minor Agency resources to ensure achievement of contract requirements.
Good	There are no, or minimal, delays that impact achievement of contract requirements.
Excellent	There are no delays and the contractor has exceeded the agreed upon time schedule.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

Business Relations

0 = Unsatisfactory 1 = Poor 2 = Fair 3 = Good 4 = Excellent 5 = Outstanding

Unsatisfactory	Response to inquiries and/or technical, service, administrative issues is not effective. If not substantially mitigated or corrected it should constitute a significant impediment in considerations for future awards.
Poor	Response to inquiries and/or technical, service, administrative issues is marginally effective.
Fair	Response to inquiries and/or technical, service, administrative issues is somewhat effective.
Good	Response to inquiries and/or technical, service, administrative issues is consistently effective.
Excellent	Response to inquiries and/or technical, service, administrative issues exceeds Government expectation.
Outstanding	The contractor has demonstrated an outstanding performance level that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances where contractor performance clearly exceeds the performance levels described as "Excellent".

ATTACHMENT #10
PAST PERFORMANCE QUESTIONNAIRE

PAST PERFORMANCE QUESTIONNAIRE – APPLY TO PRIME OFFEROR:

Your assistance is requested in support of a source selection. Request a representative of the contracting organization and a technical representative, the Program Manager (PM), and the Contracting Officer's Representative (COR), complete this questionnaire and e-mail to:

HHS/OS/ASPR/BARDA
Attn: Elizabeth Steiner, Contracting Officer
elizabeth.steiner@hhs.gov

When complete, the information on this form is **SOURCE SELECTION SENSITIVE INFORMATION (41 U.S.C. 423)** and shall be protected accordingly.

BLOCKS 1 THROUGH 8 TO BE COMPLETED BY THE OFFEROR

1. CONTRACTOR NAME & ADDRESS:	2. CONTRACT NO.:
	3. CONTRACT AWARD DATE:
	4. PERIOD OF PERFORMANCE/COMPLETION DATE:
	5. Approximate percentage of work being performed (or completed) by subcontractor(s): %
	6. Information on subcontractor(s) (*where more than % of work was completed by the subcontractor*).
	7. CONTRACT VALUE (WITH OPTIONS): $
	8. TYPE OF CONTRACT:

9. TITLE OF CONTRACT AND DESCRIPTION OF CONTRACT REQUIREMENTS:

BLOCKS 9 THROUGH 10F TO BE COMPLETED BY EVALUATION ORGANIZATION REPRESENTATIVE

10. EVALUATION:

a. EVALUATOR'S NAME	POSITION (PCO/PM/COR/OTHER)	ORGANIZATION	PHONE NUMBER/E-MAIL

b. MONTHS CONTRACTOR PERFORMANCE MONITORED BY EVALUATOR:	

c. RATINGS - Please check the block beside the response code that best reflects your evaluation of the contractor's performance.

Please answer each of the following questions with a rating that is based on objective measurable performance indicators to the maximum extent possible. Commentary to support rating may be noted at the end of the questionnaire under 'additional comments'.

Assign each area a rating of 0 (Unsatisfactory), 1 (Poor), 2 (Fair), 3 (Good), 4 (Excellent) or 5 (Outstanding). Use the attached Rating Guidelines as guidance in making these evaluations. Circle the appropriate rating. If you do not have enough personal knowledge or feedback from internal customers who directly received products and services from the contractor to make a determination on any of the performance criteria below, please circle "N/A" (not applicable /no opinion).

A. Quality of Product or Service							
A-1. Compliance with contract requirements	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
A-2. Accuracy of reports	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
A-3. Effectiveness of personnel	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
A-4. Technical excellence	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
B. Cost Control							
B-1. Record of forecasting and controlling target costs	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
B-2. Current accurate and complete billings	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
B-3. Best value (balance of performance vs. cost).	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
B-4. Relationship of negotiated costs to actuals	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
B-5. Cost efficiencies	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
C. Timeliness of Performance							
C-1. Met interim milestones	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
C-2. Reliability	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
C-3. Responsive to technical direction	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
C-4. Completed on time including wrap-up and contract administration	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
C-5. Met delivery schedules	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D. Business Relations							
D-1. Effective management, including subcontracts	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D-2. Reasonable/cooperative behavior	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D-3. Responsive contract requirements	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D-4. Notification of problems	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D-5. Flexibility	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D-6. Pro-active vs. reactive	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D-7. Effective small/small disadvantaged business subcontracting program	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E. Security							
E-1. Understanding of physical security compliance.	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E-2. Compliance with communication and information security.	☐N/A	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
F. Customer Satisfaction							
F-1. The contractor is committed to customer satisfaction	☐ Yes	☐ No					
F-2. Would you recommend selection of this firm again?	☐ Yes	☐ No					

RATING GUIDELINES

RATING GUIDELINES QUALITY OF PRODUCT OR	COST CONTROL	TIMELINESS OF PERFORMANCE	BUSINESS RELATIONS	SECURITY
0 – Unsatisfactory	Contractor is not in compliance and is jeopardizing achievement of contract objectives	Contractor is unable to manage costs effectively	Contractor delays are jeopardizing performance of contract objectives	Response to inquiries, technical/service/ administrative issues is not effective
1 – Poor	Major problems have been encountered	Contractor is having major difficulty in managing costs effectively	Contractor is having major difficulty meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is marginally effective
2 – Fair	Some problems have been encountered	Contractor is having some problems in managing costs effectively	Contractor is having some problems meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is somewhat effective
3 – Good	Minor inefficiencies/errors have been identified	Contractor is usually effective in managing costs	Contractor is usually effective in meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is usually effective
4 – Excellent	Contractor is in compliance with contract requirements and/or delivers quality products/services	Contractor is effective in managing costs and submits current, accurate and complete	Contractor is effective in meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is effective
5 – Outstanding: The Contractor has demonstrated an outstanding performance level in any of the above four categories that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when Contractor				

ATTACHMENT #11
SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the Offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals***** in this proposal.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*****If an individual has no obligation(s), so state.

b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*****.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*****If no commitment of effort is intended, so state.

c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

Name	Title/Position	Total Proposed Effort
1.		
2.		
3.		
4.		

ATTACHMENT #12
ACH VENDOR / MISCELLANEOUS PAYMENT ENROLLMENT FORM

Payment Information Form
The information requested on this form concerns your financial institution, your account at that institution, and personal information which needs to verified and completed.

Privacy Act Statement
The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 USC 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to your financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

Check one of the following:

☐ Federal Employee: ☐ Contractor: ☐ Vendor:

Name: _____

Business Address: _____

_____

Remit To
(If same as above, leave blank. Must match address on invoice for internal control purposes.)
Address: _____

_____

Taxpayer Identification # (TIN): ___ ___ ___ ___ ___ ___ ___ ___ ___
(If you are an individual, this may be your Social Security number)

1. Payee's Telephone Number: (_____) _____

2. Name of Financial Institution: _____

3. Address of Financial Institution:

_____

_____

_____

4. Financial Institution's 9-digit ABA Routing Number for

Transfer of Funds: ___ ___ ___ ___ ___ ___ ___ ___ ___

5. Depositor Account Title: _____

6. Depositor Account Number:														

7. Type of Account: ☐ Checking ☐ Savings

8. Signature and Title of Authorized Official of Financial Institution:

_____

Telephone Number: (_____) _____ Date: _____

********** The following must be signed by the payee**********

I have verified the information on this form.

_____ _____

Signature Date

ATTACHMENT #13
DISCLOSURE OF LOBBYING ACTIVITIES, WITH INSTRUCTIONS

Please complete form available here:
http://www.whitehouse.gov/omb/grants/sfllllin.pdf

ATTACHMENT #14
SMALL BUSINESS SUBCONTRACTING PLAN

If applicable, please complete Small Business Subcontracting Plan.

OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION
SMALL BUSINESS SUBCONTRACTING PLAN

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by the Federal Acquisition Regulations (FAR) Subpart 19.7. The U.S. Department of Health and Human Services (HHS), Office of Small and Disadvantaged Business Utilization (OSDBU) recommend offerors use the following format to submit proposed Individual Subcontracting Plans, including modifications. It is not intended to replace any existing Corporate/Commercial Plan that is more extensive. A subcontracting Plan is required if the estimated cost of the contract ***may exceed $700,000 ($1,500,000 for construction)*** *Small businesses are excluded. Questions should be forwarded to the Contracting Officer or Operating Division (OPDIV) Small Business Specialist.*

HHS Operating Division (OPDIV): _____

SOLICITATION OR CONTRACT NUMBER: _____

DATE OF PLAN: _____

CONTRACTOR: _____

ADDRESS: _____

STATE/ZIP CODE_____

DUNN & BRADSTREET NUMBER: _____

ITEM/SERVICE (Description): _____

_____

_____

_____

_____

_____

NEW / INITIAL CONTRACT

PERIOD OF CONTRACT PERFORMANCE (MM/DD/YYYY – MM/DD/YYYY):_____
_____

Base (if options apply) $_____ Performance Period/Quantity
_____

Option 1: $_____ Performance Period/Quantity
_____

Option 2: $_____ Performance Period/Quantity
_____

Option 3: $_____ Performance Period/Quantity
_____

Option 4: $_____ Performance Period/Quantity
_____

$_____ Total Contract Cost

CONTRACT MODIFICATION (if applicable)

NEW PERIOD OF CONTRACT PERFORMANCE (MM/DD/YYYY – MM/DD/YYYY):_____

Original/Base $_____ Performance Period/Quantity _____

Modification $_____ Performance Period/Quantity _____

Task Order $_____ Performance Period/Quantity _____

$_____ Modified Total Contract Cost

Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor requesting supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (http://www.hhs.gov/about/smallbusiness/osdbustaff.html) or you may contact the OSDBU headquarters at (202) 690-7300.

HHS current subcontracting goal is **33.0%** for Small Business (hereafter referred to as SB), **5.00%** for Small Disadvantaged Business, including 8(a) Program Participants, Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), **5.00%** for Women-Owned Small Business and Economically Disadvantaged Women-Owned Small Business (hereafter referred to as WOSB), **3.00%** HubZone business (hereafter referred to as HUBZone), 3.00% Veteran Owned Small Business (hereafter referred to as VOSB) and **3.00%** Service Disabled Veteran-Owned Small Business (hereafter referred to as SDVOSB) concerns for **Fiscal Year (FY) 2016**. For this procurement, HHS expects all proposed subcontracting plans to contain at a minimum the aforementioned percentages.
These percentages shall be expressed as percentages of the total estimated subcontracting dollars.

1. Type of Plan (check one)

_____ ***Individual plan*** (all elements developed specifically for this contract and applicable for the full term of this contract).

_____ ***Master plan*** (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

_____ ***Commercial products/service plan*** (goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts) this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non-government purposes. The plan is effective during the offeror's fiscal year (attach a copy). ***The Summary Subcontracting Report (SSR) must include a breakout of subcontracting prorated for HHS and other Federal agencies.***

2. Goals

Below indicate the dollar and percentage goals for Small Business (SB), Small Disadvantaged (SDB) including Alaska Native Corporations and Indian Tribes, Women-owned and Economically Disadvantaged Women-Owned (WOSB), Historically Underutilized Business Zone (HUBZone), Veteran Owned Small Business (VOSB), Service-Disabled Veteran-Owned (SDVOSB) Small Businesses and "Other than Small Business" (Other) as subcontractors. Indicate the base year and each option year, as specified in FAR 19.704 or project annual subcontracting base and goals under commercial plans. If any contract has more four options, please attach

additional sheets which illustrate dollar amounts and percentages. **PLEASE NOTE: Zero dollars is not an acceptable goal for the SB, SDB, WOSB, HUBZone, VOSB or SDVOSB categories since this does not demonstrate a good faith effort throughout the period of performance of the contract.** Formula for below: 2.b. + 2.h. = 2.a.

a. **Total estimated dollar value of ALL planned subcontracting**, i.e., with ALL types of concerns under this contract is _____ (Base Period - if options apply).

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

b. **Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES** (including SDB, WOSB, HUBZone, VOSB and SDVOSB): (% of "a")
$ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

c. Total estimated dollar value and percent of planned subcontracting with **SMALL DISADVANTAGED BUSINESSES**: (% of "a") $ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

d. Total estimated dollar value and percent of planned subcontracting with **WOMEN-OWNED SMALL BUSINESSES**: (% of "a") $ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

e. Total estimated dollar and percent of planned subcontracting with **HUBZone** SMALL BUSINESSES:
(% of "a") $ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

f. Total estimated dollar and percent of planned subcontracting with **VETERAN-OWNED SMALL BUSINESSES**: (% of "a") $ _____and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

g. Total estimated dollar and percent of planned subcontracting with **SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESSES**: (% of "a") $ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

h. Total estimated dollar and percent of planned subcontracting with **"OTHER THAN SMALL BUSINESSES"** *(As defined by the Small Business Administration as "any entity that is not classified as a small business. This includes large businesses, state and local governments, non-profit organizations, public utilities, educational institutions and foreign-owned firms.)* (% of "a") $ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

i. Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply):

Products and/or Services	Other	Small Business	SDB	WOSB	Hubz	VOSB	SDVOSB
1							
2							
3							
4							
5							
6							
7							
8							
9							

10							

j. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone and SDVOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, WOSB, HUBZone, VOSB and SDVOSB concerns were determined, how the capabilities of these concerns were considered contract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

_____

_____

k. Indirect costs have ____ have not ____ been included in the dollar and percentage subcontracting goals above (check one).

l. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns:

_____

_____

_____

3. Program Administrator:

NAME: _____

TITLE: _____

ADDRESS: _____

_____

TELEPHONE: _____

E-MAIL: _____

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? (If NO is checked, please who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing; __yes __ no

b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns from all possible sources; __yes __ no

c. Ensuring periodic rotation of potential subcontractors on bidder's lists; __ yes __ no

d. Assuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing. __ yes __ no

e. Ensuring that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns. __ yes __ no

f. Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, HUBZone, VOSB and SDVOSB small business participation. __ yes __ no

g. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns to include the System for Award Management (http://sam.gov), local small business and minority associations, local chambers of commerce and Federal agencies' Small Business Offices; ___ yes ___ no

h. Establishing and maintaining contract and subcontract award records; __ yes __ no

i. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; __ yes __ no

j. Ensuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; __ yes __ no

k. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; __ yes __ no

l. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals; ___yes ___ no

m. Preparing and submitting timely, required subcontract reports; ___ yes ___ no

n. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures; __ yes __ no

o. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and __ yes __ no

p. Other duties:

_____

_____

_____

4. Equitable Opportunity

Describe efforts the offeror will undertake to ensure that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

1. Contact minority and small business trade associations; 2) contact business development organizations and local chambers of commerce; 3) attend SB, SDB, WOSB, HUBZone, VOSB and SDVOSB procurement conferences and trade fairs; 4) review sources from the System for Award Management (http://www.sam.gov); 5) review sources from the Small Business Administration (SBA), Dynamic Small Business Search database

(DSBS) http://dsbs.sba.gov/); 6) Consider using other sources such as the National Institutes of Health (NIH) e-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/). The NIH e-PIC is not a mandatory source; however, it may be used at the offeror's discretion; and 7) Utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conduct workshops, seminars and training programs;

2. Establish, maintain, and utilize SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides, and other data for soliciting subcontractors; and

3. Monitor activities to evaluate compliance with the subcontracting plan.

Additional Efforts:

_____

_____

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $700,000 ($1,500,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." Note: In accordance with FAR 52.212-5(e) and 52.244-6(c) the contractor is not required to include flow-down clause FAR 52.219.-9 if it is subcontracting commercial items.

6. Reporting and Cooperation

The contractor gives assurance of 1) cooperation in any studies or surveys that may be required; 2) submission of periodic reports which illustrate compliance with the subcontracting plan; 3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and 4) subcontractors submission of ISRs and SSRs. **ISRs and SSRs shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website https://esrs.symplicity.com/index?_tab=signin&cck=1**

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	ISR	4/30
Apr 1 - Sept 30	ISR	10/30
Oct 1 - Sept 30	SSR	10/30
Contract Completion	Year End SDB Report	30 days after completion

Please refer to FAR Part 19.7 for instruction concerning the submission of a Commercial Plan: SSR is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit ISR (bi-annually) for the awarding Contracting Officer's review and acceptance via the eSRS website.

b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website. (***Note**:* Log onto the OSDBU website to view the HHS Agency Coordinator contact information http://www.hhs.gov/grants/small-business-programs/index.html

Note: ***The Request for Proposal (RFP) will indicate whether a subcontracting plan is required. Due to the nature and complexity of many HHS contracts, particularly the Centers for Medicare and Medicaid (CMS), the contractor may not be required to submit its subcontracting reports through the eSRS. The Contracting Officer will confirm reporting requirements prior to the issuance of an award. For more information, contact Agency Coordinator-eSRS on 202-690-7300.***

7. Record keeping

FAR 19.704(a) (11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

c. SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides and other data identifying such vendors;

d. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, VOSB and SDVOSB sources;

e. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation (1) whether SB, SDB,

WOSB, HUBZone, VOSB and/or SDVOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards;

f. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;

g. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and

h. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This is not required on a contract–by–contract basis for commercial plans.)

i. Other records to support your compliance with the subcontracting plan: (Please describe)

_____

_____

_____

8. Timely Payments to Subcontractors

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with SB concerns, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns.

Your company has established and used such procedures:

_____ yes _____ no

9. Description of Good Faith Effort

Maximum practicable utilization of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits**. When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d) (4) (F) directs that liquidated damages shall be paid by the contractor.** In order to demonstrate your compliance with a good faith effort to achieve the SB, SDB, WOSB, HUBZone, VOSB and SDVOSB small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting official prior to approval of the plan.

_____
_____
_____

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: _____

Typed/Print Name: _____

Title: _____

Date: _____

This plan was reviewed by:

Signature: _____

Typed/Print Name: _____

Title: Contracting Officer Date: _____

This plan was reviewed by:

Signature: _____

Typed/Print Name: _____

Title: HHS Small Business Specialist Date: _____

This plan was reviewed by:

Signature: _____

Typed/Print Name: _____

Title: Small Business Administration Procurement Center Representative

Date: _____

This plan was approved by:

Signature: _____

Typed/Print Name: _____

Title: Contracting Officer Date: _____

ATTACHMENT #15
RISK MITIGATION PLAN/MATRIX TEMPLATE

Offeror's Name Risk Mitigation Matrix Risks Identified from XXXX (Contract # or Specific Document) Date											
Prior to Risk Mitigations Strategy						Post Risk Mitigations					
Risks	Probability of Occurrence	Risk to project (Severity)	Risk to Cost	Risk to Schedule	Risk to Tech Performance	Risk Mitigation effort	Probability of Occurrence	Risk to project (Severity)	Risk to Cost	Risk to Schedule	Risk to Tech Performance

ATTACHMENT #16

SECURITY PLAN TEMPLATE WITH INSTRUCTIONS

COMPANY SECURITY PLAN TEMPLATE

Prepared by:
Program Protection Office

Office of Biomedical Advanced Research and Development Authority

Preface

Intent; The intent of this document is to provide possible practices and procedures that entities may use to assist them in developing and implementing the written security plan required by the Office of Biomedical Advanced Research and Development Authority (BARDA). The ideas and suggestions provided in this document do not constitute or establish minimum standards but are provided as general guidance. Each security program will be assessed in its totality. This document was prepared as a reference guide and template to assist entities in the development of a site-specific security plan. Additionally, a BARDA Audit Checklist is provided at Appendix B.

A good security plan model could be to organize into the following sections: Physical Security, Personnel Security, Information Security, Security Awareness Training, Information Technology Security, and Transportation Security (shipping). For each section, we recommend that you provide a complete description of the relevant specific security measures you will use to reduce your vulnerabilities. You should also discuss personnel roles and responsibilities for implementing each measure. There is set formula for what an acceptable security plan looks like. Sometimes very simple changes in procedures can achieve the same result as a much more costly equipment-based solution.

A layered approach to security is recommended when designing an overall security strategy. Security protective measures developed in unison are more cost effective and successful. Each layer alone may be capable of stopping an incident but in combination, their security value is multiplied, creating a much stronger, formidable system. A potential terrorist, criminal, or unauthorized person who has to overcome multiple security layers in order to carry out an attack is more likely to be pre-empted, deterred, or to fail during the attempt. The below illustration depicts the concept of layered security.

General Outline of Security Plan Topics

I. Organization and Responsibilities
II. Site- Specific Risk Assessment
    a. Statement of Threats
        i. Industrial Espionage
        ii. Criminal
        iii. Terrorism
        iv. Natural Disasters
    b. Vulnerability + Consequence of Loss=Risk
III. Threat Levels
    a. Low – Protective Measures
    b. Medium – Protective Measures
    c. High – Protective Measures
IV. Physical Security
    a. General Description
    b. Access Control
        i. Perimeter
        ii. Internal
        iii. Badge Policy
            1. Permanent employees
            2. Visitors
            3. Others
    c. Parking Areas
    d. Security Lighting
    e. Other Building Features
    f. Signage
    g. Designation of Restricted Areas
        i. Entry Points
        ii. Electronic Access Control
        iii. Electronic Intrusion Detection
        iv. Closed Circuit Television
        v. Other Control Measures
V. Personnel Security Program
    a. General Description
    b. Recruitment of New Employees
        i. Interview process
        ii. Background Checks
        iii. Suitability / Adjudication Guidelines
        iv. Non-Disclosure Agreements
        v. Rules of Behavior
        vi. Access Determination/Badge System
    c. Temporary Employees
        i. Interview
        ii. Background Checks
        iii. Non-Disclosure Agreements
        iv. Access Determination/Badge System
    d. Contractor Support
    e. Termination
        i. Denial of Access

ii. Post Employee Interview
iii. Non-Disclosure Agreements

VI. Information Security
a. General Description
b. Identification of Sensitive Information
c. Physical Document Control
i. Marking
ii. Secure Storage
iii. Destruction Policy
d. Information Technology Security
i. General Description
ii. Media Control
1. Media Protection
2. Sanitization and Disposal of Information
3. Input/Output Controls
iii. Equipment
1. Workstations
2. Laptops and Other Portable Computing Devices
iv. Personally Owned Equipment and Software
v. IT Disaster Recovery
1. Backup Data.
2. Store Backup Data

VII. Security Awareness Training and Reporting Requirements
a. Training
i. New Employees
ii. Annual
b. Security Reporting
i. Reporting of Compromise
ii. Reporting of Incidents

VIII. Transportation Security

I. Organization and Responsibilities – Provide an overview of key company personnel with security responsibilities. Include an organization chart, key personnel, contact numbers, and areas of expertise.

II. Site Specific Risk Assessment - Provide an assessment of the threat environment and discuss potential hazards that could undermine or hinder completion of the contract. Threats, such as terrorism, industrial espionage/sabotage, may appear to pose a minimal risk to company operations but the possibility of their occurrence and its impact on operations can not be ignored. Additionally, an all-hazards approach should be considered when developing a security strategy. Loss of power, severe weather, and other natural or manmade disasters can be mitigated by thoughtful security and contingency planning. With limited security dollars, each company will design the countermeasures to vulnerabilities to meet its primary security objectives while addressing identified risks.

III. Threat Levels – Institute a graduated Threat Advisory System to advise employees of potential increased threats and to implement a set of corresponding protective measures which would further reduce vulnerability and increase response capability during periods of heightened alert. Threat levels can be as simple as: Low; Medium; High; or something that corresponds with local, state, or federal government procedures. During periods of heightened alert, entities should consider the following no cost / low cost measures:

- Increase the visible security personnel presence wherever possible.
- Rearrange exterior vehicle barriers (if available) to alter traffic patterns near facilities.
- Institute a vehicle inspection program.
- Institute/increase vehicle, foot, and roving security patrols.
- Implement random security guard shift changes.
- Arrange for law enforcement vehicles to be parked randomly near entrances and exits.
- Approach all illegally parked vehicles in and around facilities, question drivers and direct them to move immediately, if owner cannot be identified, have vehicle towed by law enforcement.
- Report any suspicious activity immediately to law enforcement.
- Limit the number of access points and strictly enforce access control procedures.
- Implement stringent identification procedures to include conducting 100% "hands on" checks of security badges for all personnel, if badges are required.
- Remind personnel to properly display badges, if applicable, and enforce visibility.
- Require two forms of photo identification for all visitors.
- X-ray packages and inspect handbags and briefcases at entry if possible.
- Validate vendor lists for all routine deliveries and repair services.

IV. Personnel Security – Provide a detailed description of your Personnel Security Program that includes hiring practices, determination of suitability for employment, termination for cause processes, and individual training goals. Personnel Security focuses on verifying the identity and credentials of a candidate and assessing their trustworthiness based on past behavior. Examples of Personnel Security measures include:

- Conduct national and local criminal history check;
- Confirm past employment (five years);
- Verify education;
- Perform reference checks;
- Perform credit check;

- Confirm Citizenship and Social Security number;
- Conduct drug and alcohol testing;
- Sign non-disclosures agreements.

Entities should also provide a description of methods and practices used to determine suitability for employment. Suitability refers to identifiable character traits and conduct sufficient to decide whether an individual is likely or not likely to be able to carry out the duties of a job with appropriate integrity, efficiency, and effectiveness. When adjudicating suitability, the process should carefully weigh reliable information about the person, past and present, favorable and unfavorable, before reaching a final determination. Consideration should also be given to the following when evaluating a potential employee's suitability:

- Nature, extent and seriousness of the conduct
- Circumstances surrounding the conduct, to include knowledgeable participation
- Frequency of the conduct
- Individual's age and maturity at the time of the conduct
- Extent to which participation was voluntary
- Presence or absence of rehabilitation and other permanent behavioral changes
- Motivation for the conduct
- Potential for pressure, coercion, exploitation, or duress
- Likelihood of continuation or recurrence.

V. Physical Security – Provide a detailed description of your Physical Security Program designed to prevent or deter attackers from accessing a facility, resource, or information. Physical Security program uses a coordinated approach using obstacles, barriers, equipment, and policies to limit access to company property to only those with a need.

a. Obstacles and barriers provide the ability to prevent, discourage, or delay entry into the protected space at its outer boundaries. Some examples of physical security techniques (in escalating order) include:

- Install a fence around the site;
- Fenced sites should have a "clear zone" inside and outside the fence for unobstructed observation;
- Fenced-in sites should have the capability to have locked, secure gates;
- Installation of a security alarm system;
- Sufficient lighting in and around the site;
- Random checks of lighting and fencing in and around the site;
- Increase testing the security alarm systems;
- Increase testing the site alarm system with local law enforcement; and
- Locking hardware for gates should be case-hardened chain and high-security padlocks;
- Employ additional portable lighting in and around the site for critical assets, and
- Employ obstacles or barriers in addition to standard fencing. Examples would be using concertina or razor wire to provide a double fence, or placing Jersey barriers to restrict vehicular traffic. While the concertina wire or Jersey barriers would have to already be on site, they can be put in place very quickly.

b. Badge System - An access badge system is an effective method to control entry to the company facilities, offices, and restricted areas other places that have access controlled

entry points. Entry points may be doors, turnstiles, parking gates or other controlled entry points. Access badges use various technologies to identify the holder of the badge to the access control system. The most common technologies are magnetic stripe, proximity, barcode, smart cards and various biometric devices. The access badge contains information in digital form that is decoded by a card reader. The information is transmitted to the access control system. The access control system is a computer running access control software that makes access control decisions based on information about the holder of the access badge. If the credential has the proper privilege the access control system unlocks the controlled access point. Simultaneously, information about the transaction is stored in the access control system for later retrieval. Reports can be generated that will reveal who entered what portal at what time. Considerations for a badge system include:

- Establish a control and custody process for the identification badge program;
- Enforce display of badge for employees while at work and for visitors;
- Require photo identification badges for permanent employees and long term visitors;
- Limit site access to one entrance and exit for visitors;

c. Intrusion Detection - Use of alarms, lightning, and locks provide enhanced security for protected space and improve the reliability of traditional physical security tactics, such as employee training, guards, and fencing. Each improvement is designed to restrict access to authorized personnel. Additional security measures that directly enhance the physical protection of property include:

- Training for employees to recognize unauthorized people inside the facility;
- Institute periodic roving patrols of the facility perimeter by guard force;
- Install a property alarm system;
- Integrate alarm systems with security force and regularly exercise and check for reliability;
- Tie site alarm system into local law-enforcement department;
- Have a video camera monitor areas not under direct observation;
- Employ explosive detection devices; and
- Use metal detectors/x-ray machines to screen personnel, visitors, and bags.

d. Personnel Protection – Unfortunately, the threat of violence in the workplace is a variable which you may choose to address as part of your security plan. The first step in protecting the work force from physical threats is educating the individual to recognize threatening situations. This must also be supported by systems and infrastructure that provide the capability for a proper response. Robust communications, particularly the ability to communicate as well as function under duress, are an essential consideration. The response capability should be described in terms of timing, capability, and quantity. Any response that can disrupt or otherwise degrade a potential attack scenario, without placing additional people at risk or otherwise raising the potential target value, may be considered as a security measure. For example:

- Determine if the organization has personnel deemed as critical and more likely to be targeted, if so, establish procedures for the protection of personnel deemed critical;
- Identify and assess potential safe havens within buildings to use in emergencies (safe havens are areas that are more survivable than other areas in buildings-basements, hallways, inner rooms, or stairwells-and that generally offer a significant barrier to an intruder);

- Inform employees about buildings that contain safe havens;
- Have an emergency evacuation plan;
- Ensure the emergency evacuation plan has escape routes, emergency lighting, and exits; and
- Establish emergency lockdown/shelter-in-place procedures, then;
    - Conduct drills moving employees to designated safe havens; and
    - Periodically run drills to test the emergency evacuation plan;
    - Establish procedures for retaining essential employees on site.

VI. Information Security – Provide a detailed description of your Information Security Program designed to protect information systems against unauthorized access to or modification of information, whether in storage, processing or transit, and against the denial of service to authorized users or the provision of service to unauthorized users, including those measures necessary to detect, document, and counter such threats. This program should address physical and electronic media.

a. Identifying physically marking and then protecting sensitive program information are the lynchpins of an effective information security program. BARDA contracts are unclassified but information within the program can be designated as proprietary, company confidential, Critical Infrastructure Program information, sensitive but unclassified, and other handling designations. By identifying sensitive information and using appropriate markings warns and informs the recipient of the degree of protection required. Examples of information security for the protection of physical media include:

- Identify information that should be considered sensitive (proposed listing at Appendix A)
- Institute security training program on the marking, handling, dissemination, and destruction of physical and electronic media containing sensitive information.
- Develop a destruction policy using approved methods (burning or shredding)
- Establish destruction or turn-in policies for computer equipment.

b. The use of systems can enhance security and allows for the rapid dissemination of information. However, these systems must be secure or protected to prevent intrusion. Once again, some security measures are listed below. Develop one or more primary objectives and then use the measures below, or others you think of, to satisfy each primary objective. Examples of IT Systems security techniques include:

- Install a computer-intrusion-detection system;
- Monitor Internet activity in your organization;
- Periodically test back-up power for communication systems;
- Hire consultants to attempt to penetrate your system and/or assess your vulnerability to outside hackers;
- Do not disseminate sensitive program information over the unsecured internet connection;
- Develop policies limiting downloading capabilities from company computer systems; and
- Identify specific sanitized laptops for use by company personnel on travel.

VII. Security Awareness Program – Describe in detail your Security Awareness Program which educates your personnel of company security policies and the need to protect the physical and,

especially, information assets of your company. An effective Security Awareness Program gains the trust of its personnel and continually re-enforces practical security responsibilities throughout the service of each employee. Examples of security awareness programs include include:

- Security education training as part of new employee indoctrination;
- Post reminders in the work place that includes Security points of contact for questions and to report violations;
- Annual security education training, highlighting the need for continued vigilance and improvements made in the company security strategies and policies;
- Host outside guest speakers to discuss the importance of security, threats, and personal protection;
- Conduct after hour inspections to ensure compliance with company policies;
- Provide incentives for recognized excellence in security awareness.

VIII. Transportation Security - Describe in detail your Transportation Security Program which protects materials while in transit from theft, destruction, manipulation, or damage.

a. A vehicle or shipment in transit represents not just a moving target, but a critical space in constant exposure to an uncontrolled environment harboring a diversity of threats. When defining primary objectives, it is important to remember that the cargo is the prime source of consequential damage. Security measures that do not, in some way, link directly to the covered materials, but just the vehicle, may be of limited value. Examples of transportation security considerations include:

- Plan for primary (phone/cell phone), secondary (radio), and tertiary (satellite tracking) means of communications;
- Install by-pass and shutdown mechanisms;
- Install panic-button option in vehicles;
- Install theft-protection devices to disable fuel, hydraulics, and/or electrical systems;
- Seal trailers/containers;
- Driver should always have a communication device readily available
- Institute a two-person rule
- Inspect cargo manifest and match with cargo;
- See that all tractor/trailer access panels/doors are locked and seals remain intact/undamaged;
- Implement a search plan for tractors and trailers on the site;
- Routinely check truck transits to ensure routing plan is on file prior to departure
- Coordinate routes with law enforcement authorities
- Devise an Incident Management Plan
- Arrange with consignee to notify shipper and carrier if the cargo does not reach its destination, and
- Purchase all other necessary technology devices to be installed.

b. Tracking Systems - satellite systems and other technologies are excellent examples of graduated security capabilities. The frequency of location and status checks can be varied with alert levels and tailored to specific materials, reflecting the threat environment and potential consequences.

c. Cargo Status and Seals - Cargo seals, tamper-proof locks, and other technology may be utilized. Some cargo seals are designed to show signs of physical tampering, while others are electronic and can provide wireless notification if breached by an unauthorized individual. However, a basic locking system may be all that is necessary to deter theft. Of course, seals are not appropriate in all circumstances. For example, it would be counterproductive to use seals for bulk shipments which require multiple pickups or drops (unloading). Check paperwork to ensure it is complete and accurate.