

9/21/2015 SOLICITATION, OFFER AND		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1 75
2. CONTRACT NO.		3. SOLICITATION NO. 15-100-SOL-00015		4. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input type="checkbox"/> NEGOTIATED (RFP)	5. DATE ISSUED 06/19/2015
7. ISSUED BY Department of Health and Human Services OS/ASPR/BARDA 330 Independence Ave. SW, Room G644 Washington, DC 20201			CODE	8. ADDRESS OFFER TO (If other than Item 7) SEE ARTICLE L. 3.	

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

SOLICITATION

9. Sealed offers in original and See L.3. 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 N/A until **12:00PM** local time **09/21/2015**
(Hour) (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 Dorothy McMillan	B. TELEPHONE (NO COLLECT CALLS) AREA CODE NUMBER: EXT: (202) 260-8541	C. E-MAIL ADDRESS Dorothy.McMillan@hhs.gov
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OFFER (Must be fully completed by Contractor)

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 _____ calendar days (60 calendar days unless a different period is inserted by the Contractor) 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 <small>(See Section I, Clause No. 52-232-8)</small>	10 CALENDAR DAYS	20 CALENDAR DAYS	30 CALENDAR DAYS	CALENDAR DAYS
	%	%	%	%
14. ACKNOWLEDGMENT OF AMENDMENTS <small>(The Contractor acknowledges receipt of amendments to the SOLICITATION for Contractors)</small>	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF CONTRACTOR	CODE	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER <small>(Type or Print)</small>	
15B. TELEPHONE NO. AREA CODE NUMBER EXT.	<input type="checkbox"/>	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: <input type="checkbox"/> 10 U.S.C. 2304(c)() <input type="checkbox"/> 41 U.S.C. 253(c)()		23. SUBMIT INVOICES TO ADDRESS SHOWN IN <small>(4 copies unless otherwise specified)</small>	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 <small>(Signature of Contracting Officer)</small>	28. AWARD DATE

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

AUTHORIZED FOR LOCAL REPRODUCTION / PREVIOUS EDITION IS UNUSABLE STANDARD FORM 33 (REV. 9-97) / Prescribed by GSA / FAR (48 CFR) 53.214(c)

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PART I – THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM** , HEREIN 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** , HEREIN, 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 PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B--SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Department of Health and Human Services (HHS) through the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR), supports the advanced development of new monoclonal antibodies with novel mechanisms of action that exhibit broad-spectrum neutralizing activity across Influenza A subtypes, and treat infected individuals with a focus on the severely ill, hospitalized population with the goal of U.S.-licensure and a plan for U.S. supply of these monoclonal antibodies during a pandemic. Supported activities may include Phase 2 and 3 clinical studies, process development, manufacturing of clinical and registration lots, assay development and validation, non-clinical testing and regulatory activities.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. ESTIMATED COST -OPTION

- (a) The estimated cost of the Base Period of this contract is \$ _____ .
- (b) The fixed fee for the Base Period of this contract is \$ _____ . The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.
- (c) The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is _____ .
- (d) If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

A. BASE PERIOD (30 Months)

BASE PERIOD - Year 1 (12 Months)				
CLIN	Deliverable	Estimated Cost	Fixed Fee	Extended CPFF
0001	Milestone 1. Product Development Plan			
0002	Milestone 2. Clinical Development and Regulatory Plan			
0003	Milestone 3. Feasibility Plan to manufacture, test, and release product containing the monoclonal antibody candidate			
0004	Milestone 4. Base Period (Year 1) Contractor Defined Milestones. Contractor shall include a plan with initial proposal and if acceptable to the Government perform milestones in accordance with the plan.			
0005	Technical Progress Reports with Executive Summary	NSP	NSP	NSP
0006	Earned Value Management (EVM) Data			
0007	Draft Security Plan	NSP	NSP	NSP
0008	Final Security Plan	NSP	NSP	NSP
BASE PERIOD – Year 2 (12 Months)				
0009	Milestone 5. Base Period (Year 2) Contractor Defined Milestones. Contractor shall include a plan with initial proposal and if acceptable to the Government perform milestones in accordance with the plan.			
0010	Technical Progress Reports with Executive Summary	NSP	NSP	NSP
0011	Earned Value Management (EVM) Data			
BASE PERIOD – Year 3 (6 Months)				
0012	Milestone 6. Base Period (Year 3) Contractor Defined Milestones. Contractor shall include a plan with initial proposal and if acceptable to the Government perform milestones in accordance with the plan.			
0013	Technical Progress Reports with Executive Summary	NSP	NSP	NSP
0014	Earned Value Management (EVM) Data			
0015	Draft Final Report	NSP	NSP	NSP
0016	Final Report & Summary of Salient Results	NSP	NSP	NSP

B. OPTION PERIOD (30 Months)

OPTION PERIOD – Year 3 (6 Months)				
CLIN	Deliverable	Estimated Cost	Fixed Fee	Extended CPFF
1001	Milestone 7. Option Period (Year 3) Contractor Defined Milestones. Contractor shall include a plan with initial proposal and if acceptable to the Government perform milestones in accordance with the plan.			
1002	Technical Progress Reports with Executive Summary	NSP	NSP	NSP
1003	Earned Value Management (EVM) Data			
OPTION PERIOD – Year 4 (12 Months)				
1004	Milestone 8. Option Period (Year 4) Contractor Defined Milestones. Contractor shall include a plan with initial proposal and if acceptable to the Government perform milestones in accordance with the plan.			
1005	Technical Progress Reports with Executive Summary	NSP	NSP	NSP
1006	Earned Value Management (EVM) Data			
OPTION PERIOD –Year 5 (12 Months)				
1007	Milestone 9. Option Period (Year 5) Contractor Defined Milestones. Contractor shall include a plan with initial proposal and if acceptable to the Government perform milestones in accordance with the plan.			
1008	Technical Progress Reports with Executive Summary	NSP	NSP	NSP
1009	Earned Value Management (EVM) Data			
1010	Draft Final Report	NSP	NSP	NSP
1011	Final Report & Summary of Salient Results	NSP	NSP	NSP

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

- a. This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Travel to attend general scientific meetings; 9) Consultant Costs; 10) Subcontract Costs; 11) Patient Care Costs; 12) Accountable Government Property-(defined as non-expendable personal property with an acquisition cost of \$1,000 or more and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value; 13) Printing costs-(as defined in the Government Printing and Binding Regulations; and 14) Research Funding.
- b. Travel Costs
- (1) Travel
- (a) Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred by the Prime Contractor in direct performance of this contract shall not exceed \$0.00 without the prior written approval of the Contracting Officer.
- (b) Subject to the annual dollar limitation specified under B.4.b.1.a. above, the Contractor shall invoice and be Reimbursed for all travel costs in accordance with Federal Acquisition Regulation (FAR) 31.2., Contracts With Commercial Organizations, Subsection 31.205-46 Travel Costs.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

(a) Termination of Contract

If the Contractor fails to meet the milestones, within the specified time periods as stated in the statement of work, the Government has the right to terminate the contract for default, in accordance with FAR 52.249-6, Termination (Cost-Reimbursement) (May 2004).

(b) Subcontracts and Consultants

Award of any FFP subcontract or FFP consulting agreement in excess of \$150,000 or any flexibly priced subcontract or consulting agreement shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract or consulting agreement shall be provided to the Contracting Officer within ten (10) days.

(c) Earned Value Management System (EVMS) Implementation Requirements

The Contractor and the Government agree that the EVMS implementation requirements that are contained in this contract are limited to the implementation requirements outlined by the 7 Principles of Earned Value Management Tier 2 System Implementation Intent Guide contained as an Attachment to the contract. The total amount of this contract reflects the use of the 7 Principles of EVMS Implementation. Any EVMS implementation requirements that are beyond the intent of the 7 Principles of EVMS Implementation shall not proceed until the Contracting Officer sends a written request for a proposal to the Contractor and a bilateral modification is issued to the contract for the purposes of incorporating the additional costs for the performance of these requirements into the contract.

(d) Overtime Compensation

No overtime (premium) compensation is authorized under the subject contract,

(e) Establishment of Indirect Cost Rate

The Contractor has six (6) months after contract award to provide a Government approved Indirect Cost Rate Agreement. Until such time, the Contractor may bill indirect costs at temporary billing rates in the following table. If the approved indirect cost rate agreement is not submitted within the time specified, the Contractor will be considered in breach of contract.

RATE	TYPE	BASE	PERIOD

(f) Contract Number Designation

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated 6/10/2015, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).
- b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Contracting Officer's Representative (COR).

ARTICLE C.2. REPORTING REQUIREMENTS

In addition to those reports required by other terms of this contract, the Contractor(s) shall submit to the Contracting Officer and the Project Officer/COR technical progress reports covering the work accomplished during each reporting period on a basis as established by the Project Officer/COR. These reports are subject to the technical inspection and requests for clarification by the Project Officer/COR. These reports shall be brief and factual and prepared in accordance with the following format:

1. TECHNICAL REPORTS

I. **Monthly Technical Progress Reports:** On the fifteenth (15th) of each month for the previous calendar month or within fifteen (15) days past the achievement of prescribed project milestones, the Contractor shall submit a report to the Project Officer/COR and Contracting Officer. The frequency of Technical Progress Reporting will be determined by the Project Officer/COR and the Contracting Officer. The format and type of Technical Progress Report and Executive Summary will be provided by the Project Officer/COR within fifteen (15) calendar days of contract award. Technical Progress Reports will include project timelines, milestones and summaries of validation, product manufacturing, product testing, clinical evaluation, and other regulatory aspects. A Technical Progress Report will not be required for the period when a Final Report is due. The Contractor shall submit one copy of the Technical Progress Report electronically via e-mail and two (2) paper copies. Any attachments to the e-mail report shall be submitted in Microsoft Word, Microsoft Excel, Microsoft PowerPoint, Microsoft Project, AutoCad [.dwg] and/or Adobe Acrobat [.pdf] files. Such reports shall, at a minimum, include the following information:

- A. Title page containing Technical Progress Report, 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;
- B. Introduction/Background - An introduction covering the purpose and scope of the contract effort;
- C. Progress - The report shall detail, document and summarize the results of work performed, test results and milestones achieved during the period covered. Also to be included is a summary of work planned for the next reporting period;
- D. 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;
- E. A summary of the meetings, conference calls, workshops that have taken place during the reporting period, especially all correspondence with the FDA;
- F. Invoices – Summary of any invoices submitted during the reporting period including personnel and material charges in keeping with the Work Breakdown Structure for the respective tasks in the overall Work Plan;
- G. Action Items – Summary table of activities or tasks to be accomplished by a certain date and by whom;
- H. Distribution List – A list of persons receiving the Technical Progress report;
- I. Attachments –
 - i. Clinical Trial data sheets using the BARDA provided documentation process
 - ii. Regulatory communications and correspondence
 - iii. Results on the project are provided as attachments where appropriate.

II. **The Executive Summary:** which shall accompany each Technical Progress Report, will be formatted in a Microsoft PowerPoint presentation and include the following:

- A. Title page containing Executive Title, the contract number and title, the period of performance or milestone being reported, the Contractor's name and the date of submission;
- B. Project Progress presented as milestone events, test results, tasks and other activities achieved during the reporting period as talking point bullet;
- C. Project Issues presented headings and each item as a talking point bullet.

III. **Draft Final Report:** The Contractor is required to submit the Draft Final Technical Report to the Contracting Officer and Contracting Officer Representative. The CO and the COR will review the draft and provide the Contractor with comments in accordance with the dates set forth in ARTICLE F.2. of this contract.

IV. **Final Technical Report:** The Contractor shall submit a Final Report to the Project Officer/COR and Contracting Officer within 30 calendar days prior to the expiration date of the contract. The Contractor shall document and summarize the results of the entire contract. This report shall be in sufficient detail to explain comprehensively the results achieved in performance of the contract statement of work as stated herein. A summary listing of the items and quantities delivered to the Government under this contract shall be included in this report.

V. **Summary of Salient Results**

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

VI. **Annual Technical Progress Report for Clinical Research Study Populations**

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations (when appropriate) for each study being performed under this contract. The Contractor also shall state that it is a final report, for

reporting purposes in the final report. If the clinical study(s) involves US and non-US sites, the US sites and non-US sites should be reported on separate report titled Cumulative Inclusion Enrollment Reports.

VII. Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents

For work involving the possession, use, or transfer of a *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*, the following information shall also be included in each Quarterly Progress Report:

1. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.
2. If work with a new or additional *Select Agent or Toxin* and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:
 - a. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;
 - b. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (<http://www.selectagents.gov/Regulations.html>) or listed on the U.S. National Select Agents Registry restricted experiments website (<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Restricted%20Experiments.html>);
 - c. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the bio-containment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.
 - d. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior BARDA approval is required.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each Quarterly Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each Quarterly Progress Report.

3. OTHER REPORTS/DELIVERABLES

- a. Reporting of Financial Conflict of Interest (FCOI)

All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in electronic and hardcopy format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94.

45 CFR Part 94 is available at: <http://www.ecfr.gov/cgi-bin/text-idx?=&ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>. See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

ALL REPORTS SHALL BE SUBMITTED IN ACCORDANCE WITH INSTRUCTIONS DESCRIBED IN SECTION D OF THE CONTRACT.

ARTICLE C.3. DRAFT AND FINAL SECURITY PLAN

The work to be performed under this contract will involve access to sensitive Biomedical Advanced Research and Development Authority [BARDA] program information. Upon contract award, the Program Protection Officer (PPO) will review the Draft

Security Plan in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and if changes are required, submit a Final Security Plan to the U.S. Government within thirty (30) calendar days after receipt of the Program Protection Officer's (PPO) comments. The Final Security plan shall include a timeline for compliance of all the required security measures. Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer and Contracting Officer's Representative a letter certifying compliance to the elements outlined in the Final Security Plan. The execution of the work under this contract shall be in accordance with the approved Final Security Plan. As outlined above, the content of the Final Security Plan shall be a continuation of the Draft Security Plan submitted when requested by BARDA after contract award. The Contractor shall ensure that the storage, generation, transmission or exchanging of BARDA sensitive information has the appropriate security controls in place. As a minimum, the Final Security Plan shall address the following items:

Personnel Security Policies and Procedures including, but not limited to: Recruitment of new employees; Interview process; Personnel background checks; Suitability/adjudication policy; Access determination; Rules of behavior/conduct; Termination procedures; Non-disclosure agreements.

Physical Security Policies and Procedures including but not limited to: Internal/external access control; Identification/badge Requirements; Facility visitor access; Parking areas and access; Barrier/perimeter fencing;

Shipping, receiving and transport (on and off-site); Security lighting; Restricted areas; Signage; Intrusion detection systems; Closed circuit television; Other control measures.

Information Security Policies and Procedures including but not limited to: Identification of sensitive information; Access control/determination; Secured storage infrastructure; Document control; Retention/destruction requirements.

Information Technology Security Policies and Procedures including but not limited to: Intrusion detection and prevention systems; firewalls, Encryption systems; Identification of sensitive information/media; Passwords; Removable media; Laptop policy; Media access control/determinations; Secure storage; System document control; System backup; System disaster recovery.

The following instruction/intent shall be incorporated:

Security Reporting Requirement – Violations of established security protocols shall be reported to the Contracting Officer (CO) and Contracting Officer's Representative (COR) upon discovery within 24 hours of its receipt of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system have been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The Contracting Officer in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the Contracting Officer.

ARTICLE C.4. 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 Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). 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.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The first annual utilization report shall be due on or before _____. Thereafter, reports shall be due on or before the ____ [Calendar/Working] day following the reporting period.] The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
HHS/ASPR/AMCG
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201

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 at the address listed above.

SECTION D – PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

I. Method of Delivery

Unless otherwise specified by the Contracting Officer or the Project Officer/COR, delivery of items, to be furnished to the Government under this contract (including invoices), shall be made by first class mail. All deliverables shall be marked with the contract number and Contractor name.

II. Addressees – For all contract deliverables.

Project Officer/COR HHS/OS/ASPR/BARDA 330 Independence Avenue, SW Room G644 Washington, D.C. 20201	Contracting Officer HHS/OS/ASPR/AMCG 330 Independence Avenue, SW Room G644 Washington, D.C. 20201
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SECTION E – INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative (who for the purposes of resultant contract will be the Project Officer/COR) will perform inspection and acceptance of materials and services to be provided under the contract.
- b. For the purpose of this SECTION, the BARDA Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer (CO). The COR will assist in resolving technical issues that arise during performance. The COR is not authorized to change any contract items or authorize any changes in the Statement of Work, modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.
- c. Inspection and acceptance will be performed at:

Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority
Office of Acquisition Management, Contracts & Grants
330 Independence Avenue,
S.W. Room 644G
Washington, D.C. 20201

- d. 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 CO will make its full text available.

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

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from the date of contract award to thirty (30) months after contract award.
- b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
Option 1 (Year 3)	6 Months
Option 1 (Year 4)	12 Months
Option 1 (Year 5)	12 Months

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract, will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984) and in accordance with and by the date(s) specified below and any shipping specifications stated in SECTION D of this contract:

ITEM	Deliverable	Quantity	Due Date
	<i>Milestone 1(BASE Year 1)</i>		
0001	Comprehensive milestone-driven Product Development Plan	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	1 st Report due on/before ____; thereafter, due on/before the 15 th of the month and within 15 days of achieving a milestone following each reporting period. Not due when Final is due.
	<i>Milestone 2(BASE Year 1)</i>		
0002	Integrated Clinical Development and Regulatory Plan	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within six (6) months after contract award
	<i>Milestone 3(BASE Year 1)</i>		
0003	Feasibility Plan to manufacture, test, and release product containing the monoclonal antibody candidate	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within twelve (12) months after contract award
	<i>Milestone 4(BASE Year 1)</i>		
0004	Contractor Defined Milestones	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within fifteen (15) days after contract award
	<i>Progress Reporting</i>		
0005	Monthly Technical Progress Reports with Executive Summary	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	1 st Report due on/before ____; thereafter, due on/before the 15 th of the month and within 15 days of achieving a milestone following each reporting period. Not due when Final is due.

0006	Earned Value Management (EVM) Data	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	1 st Report due on/before____; thereafter, due on/before the 15 th of the month and within 15 days of achieving a milestone following each reporting period. Not due when Final is due.
0007	Draft Security Plan	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within thirty (30) days after contract award
0008	Final Security Plan	Original – C.O. 3 Copies – P.O. 1 Electronic Copy – P.O.	Within thirty (30) days after USG’s final comments
0009	Annual Utilization Report	Original – C.O.	1 st Report due twelve months after contract execution; thereafter due annually on or before the 15 th day following the reporting period.
0010	Final Invention Statement	Original – C.O.	Due on the expiration date of the contract.
N/A	Contract Financial Report	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due on a quarterly basis on/before the 15 th of the month. Not due when Final Report is due. See ARTICLE G.5.
0011	Draft Final Report	Original – C.O. 3 Copies – P.O. 1 Electronic Copy – P.O.	Due thirty (30) days prior to the expiration date of the contract
0012	Final Report & Summary of Salient Results	Original – C.O. 3 Copies – P.O. 1 Electronic Copy – P.O.	Due on/before the expiration date of the contract
	<i>Milestones 5 (Base Year 2)</i>		
0013	Contractor Defined Milestones	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within fifteen (15) days after contract award
	<i>Milestone 6 (Base Year 3)</i>		
0014	Contractor Defined Milestones	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within fifteen (15) days after contract award
	<i>Milestone 7 (Option Year 3)</i>		
0015	Contractor Defined Milestones	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within fifteen (15) days after contract award
	<i>Milestone 8 (Option Year 4)</i>		
0016	Contractor Defined Milestones	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within fifteen (15) days after contract award
	<i>Milestone 9 (Option Year 5)</i>		
0017	Contractor Defined Milestones	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within fifteen (15) days after contract award

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov//far>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUG 1989) with Alternate I (APR 1984)

SECTION G – CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

- 1) 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.
- 2) The Contracting Officer 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 any costs incurred during the performance of this contract; (5) obligate funds into or de-obligate funds from the contract; or (6) otherwise change any terms and conditions of this contract.
- 3) 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 this contract.

ARTICLE G.2. CONTRACTING OFFICER’S REPRESENTATIVE (COR)

The following Contracting Officer’s Representative (COR) [To be specified prior to award] will represent the Government for the purpose of this contract:

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) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and(5) assisting in the resolution of technical problems encountered during performance.

The alternate COR is responsible for carrying out the duties of the COR only in the event that the COR can no longer perform his/her duties as assigned.

The Contracting Officer 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) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

The Government may unilaterally change its COR designation.

ARTICLE G.3. KEY PERSONNEL, HHSAR 352.270 (JANUARY 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for

example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individual(s) are considered to be essential to the work being performed hereunder:

[To be specified prior to award]

NAME	TITLE
	Principal Investigator
	Program Manager
(OTHERS ADDED AS NECESSARY)	

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

Invoice/Financing Request instructions are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures to meet the requirements of a “proper invoice” pursuant to FAR Subpart 32.9, Prompt Payment. All invoices shall include the appropriate documentation to support the amounts claimed/billed. All costs/prices shall be identified by CLIN. The Contractor shall submit an original and two copies of each invoice to the address shown below:

HHS/OS/ASPR/AMCG
 330 Independence Avenue, SW, Room G644
 Washington, DC 20201
 Attn: Contracting Officer
 Contract No. _____

ARTICLE G.5. CONTRACT FINANCIAL REPORT

- a. Financial reports on the attached form, Financial Report of Individual Project/Contract (Attachment 12), shall be submitted by the Contractor in accordance with the instructions, which accompany the form, no later than the 15th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing. Financial reports shall be submitted by the Contractor to the Contracting Officer whom is approving official, at the address specified in Block 7 on the face page of the contract.
- b. Unless otherwise stated in that part of the instructions entitled, “Preparation Instructions”, all columns A through J shall be completed for each report submitted.
- c. The first financial report shall cover the period consisting of the FIRST FULL THREE CALENDAR MONTHS following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.
- d. The Contractor shall submit an electronic copy of the payment request to the approving official. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MS Word, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor’s name, contract number, and unique invoice number.

[Note: The original payment request must still be submitted in hard copy and mailed to the approving official to meet the requirements of a “proper invoice”]

The Contracting Officer may require the Contractor to submit additional detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

- e. The listing of expenditure categories to be reported is incorporated within Attachment 12 entitled, "Financial Report of Individual Project/Contract", located in SECTION J and made a part of this contract.
- f. The Government may unilaterally revise the expenditure categories to reflect the allotment of additional funds.
- h. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:
 1. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 2. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number].* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 3. Invoice Matching Option. This contract requires a three-way match.
 4. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
 5. Inquiries regarding payment of invoices shall be directed to the Contracting Officer.

ARTICLE G.6. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

- a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
- b. The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.
- c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

ARTICLE G.7. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d) (2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
 Office of Acquisition Management and Policy
 National Institutes of Health
 6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663
 BETHESDA, MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.8. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the pre-award negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "**Contractor's Guide for Control of Government Property**", which can be found at:

ARTICLE G.9. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually at CO discretion.

Interim and final evaluations will be submitted to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted 30 days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses and review comments, if any, will be retained as part of the contract file and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

<http://www.cpars.gov>

SECTION H – SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

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

ARTICLE H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

- a.) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.
- b.) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this

contract and will discharge its obligations, duties and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

- c) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OHRP, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) 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. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Health and Human Subject Assurances.

ARTICLE H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.4. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.5. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.6. 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.

ARTICLE H.7. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.8. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) creation of 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.

ARTICLE H.9. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.10. OMB CLEARANCE

In accordance with HHSAR 352.201-70, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

ARTICLE H.11. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.12. PRIVACY ACT, HHSAR 352.224-70 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html .

The Privacy Act System of Records applicable to this project is Number _____. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm>

ARTICLE H.13. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.14. CERTIFICATION OF FILING AND PAYMENT OF TAXES

The Contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

ARTICLE H.15. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in SECTION I. of this contract, the Government may by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

NOTE: The Government will notify the Contractor of its intent to conduct an Internal Process Review (IPR) prior to the exercise of the option.

ARTICLE H.16. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

- (1) The Small Business Subcontracting Plan, dated (to be completed at contract award) 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/Contract Specialist/title of alternate designee] shall be included as a contact for notification purposes at the following email address:

To be determined at contract award

ARTICLE H.17. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in

36 CFR part 1194. Information about Section 508 Final provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards>.

- b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding \$100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.
- c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, Or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found on the HHS Web site (<http://www.hhs.gov/web/508/contracting/technology/vendors.html>).
[(End of HHSAR 352.239-73(b))]
- d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

[End of HHSAR 352.239-73(c)]

ARTICLE H.18. 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 HHS contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site:

: <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

As required by 45 CFR Part 94, the Institution shall, at a minimum:

- a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - 1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Included are payments and equity interests;
 - 2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
 2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
 - c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.
 - d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.
 - e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.
 - f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

ARTICLE H.19. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of The Officer of the 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, Department of Health and Human Services, under Contract No. [Insert Contract No.]"

Any manuscript or scientific meeting abstract containing data generated under this contract must be provided to BARDA prior to submission.

Contracting Officer's Representative review will have no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

ARTICLE H.20. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in HHS funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The website to file a complaint on-line is: <http://oig.hhs.gov/fraud/hotline/> and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.21. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a *Highly Pathogenic Agent (HPA)*. The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(<http://www.cdc.gov/biosafety/publications/index.htm>) under "Publications);
2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or
3. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

ARTICLE H.22. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: <http://apps.usfa.fema.gov/hotel/>.

ARTICLE 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.

ARTICLE H.24. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

ARTICLE H.25. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes

provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

ARTICLE H.26. DATA AND SAFETY MONITORING REQUIREMENTS

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary.

The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible BARDA COR regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

1. **Independent Safety Monitor (ISM)** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.
2. **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.
3. **Data and Safety Monitoring Board (DSMB)** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

ARTICLE H.27. CONFIDENTIALITY OF INFORMATION

- a. 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.
- b. 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.
- c. 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.
- d. 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.

- e. 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.
- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.28. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (October 2009)

- 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 ; Web site: (http://www.aphis.usda.gov/animal_welfare).

ARTICLE H.29. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at:

<http://grants1.nih.gov/grants/olaw/references/phspol.htm>

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated _____, which is incorporated by reference.

ARTICLE H.30. NOTICE PRIOR TO PUBLICATION

The Contractor shall not release any reports, manuscripts, press releases or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.270-6.

ARTICLE H.31. 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.

ARTICLE H.32. CLINICAL RESEARCH

These Clinical Terms apply to all grants and contracts that involve clinical research.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by the Government under this contract, as defined in Rights in Data Clause in FAR 52.227-14. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form, to ensure the Government ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary.

ARTICLE H.33. SAFETY AND MONITORING ISSUES

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval

Before award and then with the annual progress report, the Contractor must submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

1. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
2. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
3. Termination or temporary suspension of patient accrual.
4. Termination or temporary suspension of the protocol.
5. Any change in IRB approval.
6. Any other problems or issues that could affect the participants in the studies.

Contractors must notify BARDA through the Contracting Officer's Representative (COR) or Contracting Officer (CO) of any of the above changes by email within 72 hours for items 3 – 6 and 7 days items 1 – 2, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an Institutional Bio-safety Committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ARTICLE H.34. BARDA PROTOCOL REVIEW PROCESS BEFORE PATIENT ENROLLMENT BEGINS

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review and approval by the Government:

1. IRB or IEC approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
2. Documentation of IRB or IEC approval, including OHRP FWA number, IRB or IEC registration number, and IRB or IEC name.
3. IRB or IEC approved informed consent document, identified by version number, date, or both and date it is valid.
4. Plans for the management of side effects.
5. Procedures for assessing and reporting adverse events.
6. Plans for data and safety monitoring, and monitoring of the clinical study site, pharmacy, and laboratory.
7. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within two weeks (10 business days) of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the BARDA COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written Contract Officer Authorization (COA) Letter will be provided to the Contractor. This COA provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

ARTICLE H.35. REQUIRED TIME SENSITIVE NOTIFICATION

Under the contract, the Contractor must submit to the Contracting Officer's Representative (COR) as follows:

1. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted within 24 hours of the occurrence of the event.
2. *Expedited safety reports of serious and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the BARDA Contracting Officer's Representative within 48 hours of the occurrence of the event.
3. *IDE reports of unanticipated adverse device effect* – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the BARDA Contracting Officer's Representative within 24 hours of the occurrence of the event.
4. *Expedited safety reports* – should be sent to the BARDA COR concurrently with the report to FDA.
5. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the BARDA COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

In a future task order where BARDA is not the IND sponsor, the reporting requirements would be defined accordingly.

Safety reporting for research not performed under an IND or IDE

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed Upon by the BARDA Contracting Officer's Representative and the Contractor.

ARTICLE H.36. BARDA CLINICAL TRIAL DATABASE INFORMATION REPORTING

The contractor must be prepared to provide initial information on each clinical study conducted under this contract to BARDA. Study specific information is required at study start-up and regular updates on site by site enrollment will be required. Study specific information may include phase of study, ages of subjects being study, number of subjects planned, estimated start and completion dates, subcontractor information and role on study, clinical site information. Clinical site information may include site Principal Investigator, location, FWA number and expiration date, certification of site human subjects training as required by OHRP.

Updated information on enrollment will include site by site enrollment including the number of subjects screened, enrolled (dosed), withdrew, and completed. Enrollment information will be provided on a regular basis as determined by BARDA prior to study start.

It is expected to have an electronic transfer of study-specific data sets from the Contractor's automated information management systems or other data sources and files directly to a secure data capture system known as the BARDA Tracking Tool. Standard Data Submissions refers to the electronic transfer of study-specific, de-identified data sets from the contractor's automated information management systems or other data sources directly to another automated information management system. BARDA's information management system is automated. Submission of data to BARDA's system will be done through secure file transfer protocol (sFTP). Data submission can be done manually or automatically, depending on the contractor's preference and capability. Similarly, in most cases data will be able to be automatically generated from a contractor's system. The BARDA Tracking Tool will go through a testing phase to ensure appropriate handover of data from contractors. BARDA's secure data capture system is known as the BARDA Tracking Tool or BTT.

ARTICLE H.37. cGMP MANUFACTURING

When manufacturing material for use in human clinical trials, all product must be manufactured according to cGMP guidelines. Any manufacturing deviations that could result in loss of drug product for use in clinical trials must be reported to the CO via use of a deviation summary report.

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

THE FOLLOWING GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL CONTRACTOR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

CONTRACTORS ARE ENCOURAGED TO REVIEW THESE CLAUSES AND TO DISCUSS ANY QUESTIONS THEY MAY HAVE ABOUT THEM DURING NEGOTIATIONS. THE FULL TEXT OF THESE CLAUSES MAY BE ACCESSED ELECTRONICALLY AT THE FOLLOWING ADDRESSES:

<http://www.acquisition.gov/far/>

HHSAR Clauses at: <http://www.hhs.gov/policies/hhsar/subpart352.html>.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.202-1	Nov 2013	Definitions
52.203-3	Apr 1984	Gratuities
52.203-5	May 2014	Covenant Against Contingent Fees
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
52.203-7	May 2014	Anti-Kickback Procedures
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
52.204-4	May 2011	Printed or Copied Double-Sided on Recycled Paper
52.204-7	Jul 2013	System for Award Management
52.204-10	Jul 2013	Reporting Executive Compensation and First-Tier Subcontract Awards
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Aug 2013	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data
52.215-14	Oct 2010	Integrity of Unit Prices
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.217-8	Nov 1999	Option to Extend Services

52.219-8	Oct 2014	Utilization of Small Business Concerns
52.219-9	Oct 2014	Small Business Subcontracting Plan
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
52.219-28	Jul 2013	Post-Award Small Business Program Representation
52.222-2	Jul 1990	Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Apr 2015	Equal Opportunity
52.222-35	Jul 2014	Equal Opportunity for Veterans
52.222-36	Jul 2014	Affirmative Action for Workers with Disabilities
52.222-37	Jul 2014	Employment Reports on Veterans
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Aug 2013	Employment Eligibility Verification (Over \$100,000)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	May 2014	Rights in Data – General, Alternate II (Dec 2007): Insert in para. (g)(3)(b)(i) “Use (except for manufacture) by support service contractors.”
52.227-16	Jun 1987	Additional Data Requirements
52.228-7	Mar 1996	Insurance – Liability to Third Persons
52.230-2	May 2014	Cost Accounting Standards
52.230-6	Jun 2010	Administration of Cost Accounting Standards
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer—System for Award Management
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.243-6	Apr 1984	Change Order Accounting
52.244-2	Oct 2010	Subcontracts, Alternate I (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting
52.244-6	Apr 2015	Subcontracts for Commercial Items
52.245-1	Apr 2012	Government Property
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

<u>HHSAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2006)
352.203-70	Mar 2012	Anti-Lobbying
352.216-70	Jan 2006	Additional Cost Principles
352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Jan 2006	Publications and Publicity
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.233-71	Jan 2006	Litigation and Claims
352.242-70	Jan 2006	Key Personnel
352.242-73	Jan 2006	Withholding of Contract Payments
352.242-74	Apr 1984	Final Decisions on Audit Findings

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. FAR Clause **52.215-23, Limitations on Pass-Through Charges** (October 2009), is added.
- b. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (October 2014) is added.
- c. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefore. *[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]*

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), 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.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

- (1) FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).
- (2) FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).
 “.....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/report-fraud/OIG_Hotline_Poster.pdf

- (3) FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (December 2014).

- (4) FAR Clause **52.210-1, Market Research** (April 2011).
- (5) FAR Clause **52.217-8, Option to Extend Services** (November 1999).
 "..The Contracting Officer may exercise the option by written notice to the Contractor within _____ [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION]
- (6) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (Oct 2014).
 "(c) Waiver of evaluation preference.....
 [] Offeror elects to waive the evaluation preference."
- (7) FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013)
- (8) FAR Clause **52.224-1, Privacy Act Notification** (April 1984).
- (9) FAR Clause **52.224-2, Privacy Act** (April 1984).
- (10) FAR Clause **52.230-2, Cost Accounting Standards** (May 2014)
- (11) FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).
- (12) FAR Clause **52.237-3, Continuity of Services** (January 1991).
- (13) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).
- (14) FAR Clause **52.251-1, Government Supply Sources** (April 2012).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

- (1) HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).
- (2) HHSAR Clause **352.223-70, Safety and Health** (January 2006).
- (3) HHSAR Clause **352.231-70, Salary Rate Limitation** (August 2012).

Note: The Salary Rate Limitation is at the Executive Level II Rate.

See the following website for Executive Schedule rates of pay: <http://www.opm.gov/oca/> .

(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

- (4) HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

- (1) FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (July 2013)

As prescribed in 32.706-1(b), insert the following clause:

- a. *The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management (SAM) database at <http://www.acquisition.gov>.*
- b. *As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIS consists of two segments--*
 1. *The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--*
 - i. *Government personnel and authorized users performing business on behalf of the Government; or*
 - ii. *The Contractor, when viewing data on itself; and*
 2. *The publicly-available segment, to which all data in the non-public segment of FAPIS is automatically transferred after a waiting period of 14 calendar days, except for--*
 - i. *Past performance reviews required by subpart 42.15;*
 - ii. *Information that was entered prior to April 15, 2011; or*
 - iii. *Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.*
- c. *The Contractor will receive notification when the Government posts new information to the Contractor's record.*
 1. *If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIS.*
 2. *The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.*
 3. *As required by section 3010 of Pub. L. 111-212, all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available.*
- d. *Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.*

- (2) FAR Clause **52.217-8, Option to Extend Services** (November 1999).

"..The Contracting Officer may exercise the option by written notice to the Contractor within _____ [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION].

- (3) FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

- a. The Government may extend the term of this contract by written notice to the Contractor within _____ [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION]; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least _____ days [60 days unless a different number of days is inserted] before the contract expires. The preliminary notice does not commit the Government to an extension.
- b. If the Government exercises this option, the extended contract shall be considered to include this option clause.
- c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed _____ [MONTHS/YEARS].

- (4) FAR **52.222-55 Minimum Wages Under Executive Order 13658** (December 2014).

- (5) FAR Clause **52.237-3, Continuity of Services** (January 1991).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

- (1) HHSAR Clause **352.237-73, Non-Discrimination in Service Delivery** (March 2012).

It is the policy of the Department of Health and Human Services that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). By acceptance of this contract, the contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract. The contractor shall include this clause in all sub-contracts awarded under this contract for supporting or performing the specified program and services. Accordingly, the contractor shall ensure that each of its employees, and any sub-contractor staff, is made aware of, understands, and complies with this policy.

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 2:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 3:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable and submitted with the Technical Proposal.)

Attachment 4:	Technical Proposal Cost Summary	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf
Attachment 5:	Summary of Related Activities	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf
Attachment 6:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable and submitted with the Business Proposal.)

Attachment 7:	Proposal Summary and Data Record	http://www.oamp.oc.nih.gov/sites/default/files/DGS/contracting/forms/NIH2043.pdf
Attachment 8:	Summary of Proposed Estimated Costs (Template)	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/buscost.html http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx
Attachment 9:	Offeror's Points of Contact	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf
Attachment 10:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.gsa.gov/portal/forms/download/116430
Attachment 11:	Small Business Subcontracting Plan	http://www.hhs.gov/asfr/ogapa/osbdu/Small%20Business/subcontractplan.html

INFORMATIONAL ATTACHMENTS: (The following attachments and reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment 12:	Financial Report of Individual Project/Contract and Instructions	See Attachment Section at the end of this RFP
Attachment 13:	Invoice/Financing Request Instructions— Cost-Reimbursement	See Attachment Section at the end of this RFP
Attachment 14:	Past Performance Questionnaire	See Attachment Section at the end of this RFP
Attachment 15:	Contract Performance Reports (EVM)	Format 1: Work Breakdown Structure http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-1.pdf Format 2: Organizational Categories http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-2.pdf Format 3: Baseline http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-3.pdf Format 4: Staffing http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-4.pdf Format 5: Explanations and Problem Analyses http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-5.pdf
Attachment 16:	7 Principles of Earned Value Management Tier 2 System Implementation Intent Guide 01 October 2011	See Attachment Section at the end of this RFP
Attachment 17:	Privacy Act System of Records	http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.html
Attachment 18:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	http://grants.nih.gov/grants/olaw/VAScontracts.pdf
Attachment 19:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	http://www.hhs.gov/ohrp/assurances/forms/of310.pdf

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K – REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: <http://www.sam.gov> ; and
2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**

SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

3. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.
(End of Clause)

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

ARTICLE L.1. PROPOSAL REQUIREMENTS

The proposal must include a Contractor Work Plan (CWP) that describes the activities to be performed in response to the RFP requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget. The level of detail contained in the CWP and the corresponding Gantt chart will be sufficient to facilitate management and execution of the contract by the successful Offeror. (If the CWP exceeds 10 pages, also include a Summary of the CWP that is no more than 10 pages.)

ARTICLE L.2. GENERAL INFORMATION

A. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2006)]

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

"*Discussions*" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the Offeror being allowed to revise its proposal.

"*In writing*", "*writing*", or "*written*" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the Offeror. Offerors using commercial carriers shall ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the Offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the Offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.*

- (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 3:00 PM EST, for the designated Government office on the date that proposal or revision is due.
 - (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--
 - (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
 - (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
 - (3) It is the only proposal received.
 - (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.
 - (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
 - (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
 - (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an Offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the Offeror may propose to provide any item or combination of items.
 - (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
 - (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
 - (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
 - (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the Offeror).
 - (e) *Restriction on disclosure and use of data.*
 - (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the

Offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the Offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

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

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

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

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

2) In addition, the Offeror must mark each page of data it wishes to restrict with the following statement:

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

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

(f) *Contract award.*

- (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible Offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
- (2) The Government may reject any or all proposals if such action is in the Government's interest.
- (3) The Government may waive informalities and minor irregularities in proposals received.
- (4) The Government intends to evaluate proposals and award a contract without discussions with Offerors (except clarifications as described in FAR 15.306(a)). Therefore, the Offeror's initial proposal shall contain the Offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the Offeror specifies otherwise in the proposal.

- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so. In the event that more than one award is made, the U.S. Government reserves the right to use contract clauses, including 52.249-6, Termination (Cost-Reimbursement) to down-select at any time.
- (7) Exchanges with Offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful Offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) If a post-award debriefing is given to requesting Offerors, the Government shall disclose the following information, if applicable:
 - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed Offeror's offer.
 - (ii) The overall evaluated cost or price and technical rating of the successful and debriefed Contractor and past performance information on the debriefed Offeror.
 - (iii) The overall ranking of all Offerors, when any ranking was developed by the agency during source selection;
 - (iv) A summary of the rationale for award.
 - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful Offeror.
 - (vi) Reasonable responses to relevant questions posed by the debriefed Offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

B. NAICS CODE AND SIZE STANDARD

Note: 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 provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The North American Industry Classification System (NAICS) code for this acquisition is **541711**.
- (2) The small business size standard is **500 employees**.

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

C. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that multiple awards will be made from this solicitation and that the award(s) will be made on/about **FEB 2016**.

It is anticipated that the award(s) from this solicitation will be a multi-year, cost-reimbursement type contract with a period of performance of thirty (30) months.

FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to

certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

D. PRE-PROPOSAL CONFERENCE

A pre-proposal conference (**To Be Determined**) may be held with prospective offerors at TBD on TBD. The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements which may be helpful in the preparation of proposals and for answering any questions which you have regarding this solicitation.

The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by offerors. Therefore, you are requested to mail written questions concerning any areas of uncertainty which, in your opinion, require clarification or correction, in sufficient time to be received on or before TBD at the address specified in Block 7 of SECTION A - Solicitation/Contract Form of this solicitation.

Your questions should be submitted to the contract specialist, Sherica Teshome and the envelope should be marked, "Pre-proposal conference, RFP No. 15-100-SOL-00015." A set of all questions and answers will be furnished simultaneously to all prospective offerors whether or not they are in attendance.

Because of space limitations, each prospective offeror shall be limited to a total of 2 representatives.

Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

E. COMMITMENT OF PUBLIC FUNDS

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

F. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this SOLICITATION. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

G. RELEASE OF INFORMATION

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

H. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

I. PREPARATION COSTS

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

J. SERVICE OF PROTEST (SEPTEMBER 2006) – FAR 52.233-2

(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 Government Accountability 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 Acquisitions 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.

K. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70 (JANUARY 2006)

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it appears to offer the best value to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

ARTICLE L.3. INSTRUCTIONS TO OFFERORS

A. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) Contract Type and General Clauses

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

(2) Authorized Official and Submission of Proposal

A.) The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

B.) HAND DELIVERY OF PROPOSALS:

ALL OFFERORS MUST CONTACT THE CONTRACT SPECIALIST AT LEAST TWO WEEKS BEFORE PROPOSAL DUE DATE FOR SPECIFIC INSTRUCTIONS ON MAKING HAND-DELIVERIES.

OFFERORS MUST CONTACT THE CONTRACT SPECIALIST VIA EMAIL AT SHERICA.TESHOME@HHS.GOV

(3) Proposal Summary and Data Record

The Offeror must complete this form, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

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

(5) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) Evaluation of Proposals

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

(7) Potential Award without Discussions

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

(8) Use of the Metric System of Measurement

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

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

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

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

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

(9) Privacy Act – Treatment of Proposal Information

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

The HHS is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract. Failure to provide any or all of the requested information may result in a less than adequate review.

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

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

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(10) Selection of Offerors

- a) The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an Offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If awards are made without conducting discussions, Offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an Offeror's past performance information and adverse past performance information to which the Offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-
 - (1) Communications will be held with Offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which a has not had a prior opportunity to respond. Also, communications may be held with any other Offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all Offerors in the competitive range.

While it is HHS' policy to conduct discussions with all Offerors in the competitive range, HHS reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each Offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price Offeror or other than the highest technically rated Offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable), the cost analysis and other evaluation factors listed in Section M.
- f) The HHS reserves the right to make a single award, multiple awards or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet HHS requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

(11) Institutional Responsibility Regarding Conflicting Interests of Investigators

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at:

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=9f130b6d2d48bb73803ca91ce943be3a;rgn=div5;view=text;node=45%3A1.0.1.1.53;idno=45;cc=ecfr>

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a.) Facilities Capital Cost of Money, FAR Clause 52.215-16 (June 2003).
- b.) Limitations on Pass-Through Charges—Identification of Subcontract Effort, FAR Provision 52.215-22 (Oct 2009)

(13) Certification of Filing and Payment of Taxes

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

(14) Past Performance Information

a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 5 contracts completed during the past Four years and ALL CONTRACTS AWARDED currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(15) 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.

(16) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. Central Contractor Registration, FAR Provision 52.204-7 (July 2013).

Alternate I (July 2013) [is/is not] applicable to this solicitation.

b. Data Universal Numbering System Number, FAR Provision 52.204-6 (July 2013).

c. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).

d. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

e. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22,

(October 2009).

- f. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

(17) Pre-Award Site Visits

Possible pre-award site visits will be conducted with Offerors in the competitive range in conjunction with discussions/negotiations, if timing permits. The purpose of these visits is to verify information provided within the proposal and determine current resource (personnel, facility, etc.) support. Site visits will include written verification of a viable continuity of operations plan (COOP) and stockpiles of raw materials, parts/components or contingency plans to assure the Offerors' ability to provide finished products during a pandemic influenza outbreak. Site visits will be required to inspect the Offeror's manufacturing facilities and may extend to include subcomponent contractors/suppliers/vendors and their ability to comply with COOP and stockpiling requirements.

B. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how the objectives are to be accomplished. The Offeror's technical approach should be in as much detail as necessary to fully explain the proposed technical approach. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate the ability to understand and manage key deliverables and tasks.

THE TECHNICAL PROPOSAL SHALL NOT EXCEED **100 PAGES** IN LENGTH AND THE APPENDIX SHALL NOT EXCEED **500 PAGES** IN LENGTH.

(1) Technical Discussions

The technical discussion included in the technical proposal shall respond to the items set forth below:

(a) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This shall support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the Offeror's

best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

(b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel and the approximate percentage of the total time each will be available for this program.

OFFERORS SHALL ASSURE THAT THE PRINCIPAL INVESTIGATOR AND ALL OTHER PERSONNEL PROPOSED SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Single Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment or on a subcontract or consultant basis. The technical areas, character and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the Offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments and a listing of relevant publications.

(2) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the Offeror's proposed schedules.

(3) Technical Evaluation

Proposals will be technically evaluated in accordance with the factors and weights as described in SECTION M Evaluation Factors for Award of this solicitation.

(4) Additional Technical Proposal Information

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The Offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the Offeror's proposal only.
- c) A detailed summary of process development, scale-up and clinical manufacturing results including in process and final product yields, shall be incorporated as an appendix in the preliminary results section of the technical proposal.
- d) A detailed summary of pre-clinical studies including records of consultation with the Center For Drug Evaluation and Research (CDER) at FDA shall be incorporated as an appendix in the preliminary results section of the technical proposal.
- e) The completed Milestone I study report and a detailed summary of any additional stages of product development that have been completed shall be incorporated as an appendix in the preliminary results section of the technical proposal.
- f) Many of the technical proposal requirements can be satisfied by inclusion, in whole or part, of the Offeror's Investigational New Drug, if applicable, and relevant supplements.

(5) Human Subjects

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, HHSAR 352.270-8(a) (January 2006)

- (a) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by HHS.
- (b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the

individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

- (c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.
- (d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OPDIV will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301-496-7014), is recommended.
- (e) In accordance with 45 CFR Part 46, prospective Offerors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site:
<http://www.hhs.gov/ohrp/>
- (f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(6) Instructions to Offerors Regarding Protection of Human Subjects

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

- a. Risks to the subjects
 - o Human Subjects Involvement and Characteristics:
 - Describe the proposed involvement of human subjects in response to the solicitation.
 - Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
 - Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.
 - o Sources of Materials:
 - Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
 - o Potential Risks:
 - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
 - Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

- b. Adequacy of Protection Against Risks
 - o Recruitment and Informed Consent:
 - Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.
 - o Protection Against Risk:
 - Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
 - Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
 - In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.
- c. Potential Benefits of the Proposed Research to the Subjects and Others
 - o Discuss the potential benefits of the research to the subjects and others.
 - o Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
 - o Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.
- d. Importance of the Knowledge to be Gained
 - o Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
 - o Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

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

Collaborating Site(s)

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

(7) Research Involving Prisoners as Subjects

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

f. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

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

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

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

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

(8) **Data and Safety Monitoring in Clinical Trials**

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary.

The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible BARDA COR regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

1. **Independent Safety Monitor (ISM)** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.
2. **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.
3. **Data and Safety Monitoring Board (DSMB)** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

(9) **Care of Live Vertebrate Animals**

- a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-9(a) (January 2006)

The PHS Policy on Human Care and Use of Laboratory Animals 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 which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless OLAW approves the Animal Welfare Assurance. Prior to award, the Contracting Officer will notify Offeror(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OLAW negotiate an acceptable Animal Welfare Assurance with those Offeror(s). For further information contact OLAW, at NIH, Bethesda, Maryland 20892 (301-496-7163).

The following specific address for OLAW is provided for ease of contact:

Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1 – Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982 (For Hand-delivered/express mail use Zip code 20817)

FAX copies of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm> .

- b. The following information must be included in the Offeror's technical proposal:
- identification of the species and approximate number of animals to be used;
 - rationale for involving animals and for the appropriateness of the species and numbers used;
 - a complete description of the proposed use of the animals;
 - a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
 - a description of any euthanasia method to be used.
- c. If an Animal Assurance is already in place, the Offeror's proposal shall include:
- The Animal Welfare Assurance number.
 - The date last certified by OLAW. (i.e. assurance letter from OLAW)
 - Evidence of recent AAALAC Accreditation, if required by the SOW contained in this solicitation.

C. BUSINESS PROPOSAL INSTRUCTIONS

(1) **Basic Cost/Price Information**

- a. The following instructions must be observed for preparing your pricing proposal where cost or pricing data are required.

Note 1: There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met

when all accurate cost or pricing data reasonably available to the Contractor have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the Contractor's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

Note 2: By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

General Instructions:

A. You must provide the following information on the first page of your pricing proposal:

- (1) Solicitation, contract, and/or modification number;
- (2) Name and address of Contractor;
- (3) Name and telephone number of point of contact;
- (4) Name of contract administration office (if available);
- (5) The contractor's representative responsible for handling contract administration upon award (reference section G-5), if different from item (4) above;
- (6) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
- (7) Proposed cost; profit or fee; and total;
- (8) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
- (9) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS (other than a noncompliance that the cognizant Federal agency official has determined to have an immaterial cost impact), and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
- (10) The following statement:

This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
- (11) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP (please include this information on the front page of your business proposal); and
- (12) Date of submission.

- B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
- C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 2.101). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including --
 - (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
 - (2) The nature and amount of any contingencies included in the proposed price.
- D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the “Formats for Submission of Line Item Summaries” section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
- E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

Cost Elements:

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

- A. *Materials and services.* Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR [15.403-4](#). Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph IIA(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.
 - (1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR [15.403-4](#) priced on the basis of adequate price competition. For inter-organizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR [31.205-26\(e\)](#)).
 - (2) *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR [15.403-4](#) and not otherwise exempt, in accordance with FAR [15.403-1\(b\)](#) (*i.e.*, adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$11.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor’s proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor’s Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor’s data. For standard commercial items fabricated by the Contractor that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost.

For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

- B. *Direct Labor.* Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. *Indirect Costs.* Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. *Other Costs.* List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. *Royalties.* If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
 - (1) Name and address of licensor.
 - (2) Date of license agreement.
 - (3) Patent numbers.
 - (4) Patent application serial numbers, or other basis on which the royalty is payable.
 - (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
 - (6) Percentage or dollar rate of royalty per unit.
 - (7) Unit price of contract item.
 - (8) Number of units.
 - (9) Total dollar amount of royalties.
 - (10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR [27.202](#) and [31.205-37](#)).
- F. *Facilities Capital Cost of Money.* When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR [31.205-10](#)).

Format for Submission of Line Item Summaries:

Cost Elements (1)	Proposed Contract Estimated – Total Cost (2)	Proposed Contract Estimate – Unit Cost (3)	Reference (4)

Column and Instruction

- (1) Enter appropriate cost elements.
- (2) Enter those necessary and reasonable costs that, in your judgment, will properly be incurred in efficient contract performance. When preproduction or startup costs are significant, or when specifically requested to do so by the Contracting Officer, provide a full identification and explanation of them.
- (3) Optional, unless required by the Contracting Officer.

Identify the attachment in which the information supporting the specific cost element may be found. (Attach separate pages as necessary.)

(5) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of \$650,000 for the entire period of performance, the Offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J – LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a) **THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.**
- b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c) The Offeror understands that:
- (1) No contract will be awarded unless and until an acceptable plan is negotiated with the 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 \$550,000 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.

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

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

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

(6) **HUBZone Small Business Concerns**

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

(7) **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 \$550,000 (\$1,000,000 for construction) subject to certain limitations (see

FAR 19.1202-1 and 19.1202-2(b). 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 shall 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	SDB Dollars
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime (Includes joint venture partners and team arrangements)*	10%	\$100,000
SDB Participation by subcontractors	15%	\$150,000

*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.

(8) Notice of Earned Value Management System - Pre-Award IBR, HHSAR 352.234-1 (October 2008)

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Business Proposal entitled, "Earned Value Management System."

- e. The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of solicitation).
- f. If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines.
 - 1. The plan shall:
 - iv. Describe the EVMS the offeror intends to use in performance of the contract;
 - v. Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;
 - vi. Describe the management system and its application in terms of the EVMS guidelines;
 - vii. Describe the proposed procedure for application of the EVMS requirements to subcontractors;
 - viii. Provide documentation describing the process and results, including Government participation if applicable, of any third-party evaluation or self-evaluation of the system's compliance with the EVMS guidelines;
 - ix. Provide a schedule of events leading up to formal validation and Government acceptance of the offeror's EVMS, if the value of the offeror's proposal, including options, is \$25 million or more.
 - 2. The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.
 - 3. The Contracting Officer will review the offeror's EVMS implementation plan prior to contract award.
 - 4. The offeror's EVMS plan must provide milestones indicating when the offeror anticipates that the EVMS will be compliant with the ANSVEIS Standard-748 guidelines.
- g. The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractors, or subcontracted effort, subject to the EVMS requirement.

(9) Other Administrative Data

a) Property

- (1) It is HHS policy that Offerors will provide all property necessary for performance of contracts. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the Offeror requests that Government property be provided, other than that specified under "Government Furnished Property", below, the proposal must include comprehensive justification addressing the following items:
 - (a) State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
 - (b) Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.
- (2) Government Property

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

- (a) A list or description of all Government property that the Offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- (b) The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- (c) The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- (d) The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Offeror possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

(10) Government-Furnished Property – No Government Furnished Property is offered for this acquisition.

- a) The management and control of any Government property shall be in accordance with the HHS Publication entitled, Contractors Guide for Control of Government Property, which can be found at:

http://www.hhs.gov/oamp/policies/Contractors_guide_for_control_of_gov_property.pdf

(11) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (July 2013)

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

- (1) The solicitation number (or other procurement identification number).
- (2) The Offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the Offeror's official authorized to provide this information.
- (4) The name, address, and 9-digit Routing Transit Number of the Offeror's financial agent.
- (5) The Offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the Offeror's financial agent.
- (7) If applicable, the Offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the Offeror's financial agent is not directly on-line to the Fedwire and therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

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

(12) **Adequate Accounting System**

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be

Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

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

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

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

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

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

- (a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

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

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

(13) **Qualifications of the Offeror**

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

a) **General Experience**

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

b) **Organizational Experience Related to the RFP**

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

(c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

(d) **Pertinent Contracts**

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

(e) **Pertinent Grants**

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

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

(14) **Subcontractors**

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

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

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP shall refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

(15) **Proposer's Annual Financial Report**

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

(16) **Representations and Certifications – SECTION K**

One copy of [SECTION K](#) (which includes FAR Clause 52.204-8, Annual Representations and Certifications) shall be completed and signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor.

(17) **Travel Cost/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by Offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

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

(18) **Past Performance Information**

a) Offerors shall submit the following information as part of their **business** proposal.

A list of the last three (3) contracts completed during the past three years and all contracts currently being performed that are similar in nature to the solicitation work scope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as a subcontract that exceeds \$500,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The Offeror may provide information on problems encountered on the identified contracts and the Offeror's corrective actions.

- b) The Government is not required to contact all references provided by the Offeror. Also, references other than those identified by the Offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the Offeror's past performance.
- c) A Past Performance Questionnaire must be sent by the Offeror to the references for their response. It is the Offeror's responsibility to ensure that the questionnaires are completed and returned to the Government by their references in accordance with the instructions provided in [Article M.5](#) of this RFP.

SECTION M – EVALUATION FACTORS FOR AWARD

ARTICLE M.1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against seven factors. The non-cost factors are: technical, past performance, Small Disadvantaged Business (SDB) participation, and Evaluation of Options. In addition, prior to award, the Offeror's proposal must be considered acceptable for use of human subjects and animal welfare. Offeror's are advised that in the evaluation process, all evaluation factors other than cost or price, when combined, are significantly more important than cost or price. Technical activities must connect directly to costs in the business proposal. The trade off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the USG to consider award(s) to other than the lowest priced or highest technically rated Offeror. In any case, the Government reserves the right to make an award(s) to that Offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Offerors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Contract(s) will be awarded to the Offeror(s) whose proposal is considered to be the most advantageous to the Government, cost and other factors considered. Each Offeror must submit a proposal that separately addresses evaluation criteria specified below as they relate to the statement of work and delivery requirements.

ARTICLE M.2. MANDATORY CRITERIA FOR ELIGIBILITY

Listed below is the mandatory qualification criteria. The MANDATORY QUALIFICATION CRITERIA establishes conditions that must be met at the time of proposal submission. As a threshold matter, Offerors mandatory criteria will be evaluated as either "acceptable" or "unacceptable". In order to be considered further, Offerors must be evaluated as "acceptable" under each criteria.

The term 'Offeror' is defined as follows: 1) a single, fully integrated and independent pharmaceutical company; 2) partnership of a prime Contractor with legitimate subsidiary or corporate partner that performs monoclonal antibody manufacturing and/or clinical studies; 3) a teaming arrangement with the Offeror as the prime Contractor partnered with subcontractors such as contract manufacturing organizations (CMOs) and/or contract research organizations (CROs) as members that perform biopharmaceutical product development, manufacturing, and/or clinical trials.

The offeror shall include all information which documents and/or supports the qualification criteria and provide an index within its technical proposal which directs the reviewer(s) to the specific area(s) of the technical proposal. The minimum mandatory eligibility criteria are as follows:

- *In vitro* studies demonstrating broad-spectrum neutralizing activity across multiple subtypes of influenza A viruses including but not limited to modern strains of H1N1, H3N2, H5N1 and H7N9.
- An extensive package of pre-clinical animal studies demonstrating efficacy against multiple strains of influenza. The studies should demonstrate the utility of initiating treatment later in infection (48-96 hours after infection with a preference for 72-96 hours after infection) and in combination with other influenza antiviral drugs. Additionally, dose-ranging animal studies should provide a basis for choosing doses for Phase 2 studies based on PK/PD modeling.
- A package of pre-clinical safety studies enabling an IND filing.
- An active US Investigational New Drug (IND) application for the proposed broad-spectrum influenza monoclonal antibody(s)

- A completed clinical study report documenting Phase 1 dose-escalation evaluation of the proposed broad-spectrum influenza monoclonal antibody(s)

ARTICLE M.3. TECHNICAL EVALUATION CRITERIA

The Offeror shall discuss in detail a work plan that indicates how each aspect of the Statement of Work is to be accomplished. The Offeror shall demonstrate their full understanding of the key elements essential to complete the requirement, including how the project will be organized, staffed and managed. The completeness and quality of the Offeror’s proposal and supporting data will be evaluated in terms of relative risk and the likelihood of successful completion of the project. All proposals will be evaluated in accordance with the technical factors and points set forth below. Failure by the Offeror to provide any of the information requested below will result in a lower assessment that will impact the Offeror’s ability to be scored within the competitive range.

Number	Evaluation Criteria	Points
I	Target Product Profile	40
II	Technical Methodology and Approach	20
III	Development Plan	20
IV	Facilities	5
V	Quality Systems	5
VI	Personnel/Management Plan	5
VII	Organizational Experience	5
	Total	100

Technical Evaluation Sub-factors – There are seven sub-factors for technical evaluation criteria.

Failure by the Offeror to provide any of the information requested below will result in a lower assessment that will impact the Offeror’s ability to be scored within the competitive range.

1. Target Product Profile – 40 Points

- A. The proposal should describe the target product profile of the broad-spectrum influenza monoclonal antibody candidate with data supporting the proposed profile.
- B. The proposal should provide a detailed description of the studies planned to be performed during the development process to confirm the proposed target product profile.
- C. The proposal should describe how the target product profile aligns with the Key Attributes for a broad-spectrum influenza monoclonal antibody candidate listed below.
 - a. An indication for the treatment of seriously ill, hospitalized patients 6 months and older who are infected with influenza.
 - b. Broad-spectrum neutralizing activity across multiple subtypes of influenza A viruses including but not limited to contemporary strains of H1N1, H3N2, H5N1 and H7N9 (EC₅₀ values < 5 µg/ml using standard micro-neutralization assays preferred).
 - c. Single dose treatment regimen consisting of a formulation that contains no more than three monoclonal antibodies (one preferred).
 - d. Effective when treatment is initiated within 48-96 hours of influenza symptom onset (72-96 hours preferred).
 - e. Suitable for use in combination with other approved influenza antivirals.

2. Technical Methodology and Approach – 20 Points

- A. The proposal should describe the production system used to produce the broad-spectrum influenza monoclonal antibody candidate. Include a description of the proposed monoclonal antibody production system used, its origin, stability, results of

all investigations to assess tumorigenicity, oncogenicity or contamination with adventitious agents if applicable, results of prior regulatory evaluation or review by FDA or other regulatory agencies, and any other factors pertaining to its regulatory status or that may affect FDA licensure of a monoclonal antibody produced using the proposed production system.

- B. The proposal should include a detailed summary of process development, analytical development, product stability, scale-up and clinical manufacturing plans and available results.
- C. The proposal should include a detailed summary of toxicology and pre-clinical studies (including records of consultation with Center for Drug Evaluation and Research (CDER) at FDA as an appendix).
- D. The technical proposal should detail results of all clinical testing that has been completed in the U.S. or internationally including protocol synopsis, therapeutic description and end points.
- E. The technical proposal should detail any plans to identify and explain the mechanism(s) of action

3. Development Plan – 20 Points

- A. The technical proposal should provide a Contractor's Work Plan (CWP) that describes the activities to be performed in response to the RFP requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget specifying activities to be supported by the government. The level of detail contained in the CWP and the corresponding Gantt chart should be sufficient to facilitate management and execution of the contract by the successful Offeror(s).
- B. The technical proposal should describe, in detail, the Offeror's work plan to complete all activities identified in the contractor's defined statement of work. Discuss phasing and integration of research and development activities and, as possible, including experimental design, including sample size and analytic strategy. Indicate anticipated difficulties in carrying out the research plan and potential approaches to overcome them. Decision trees for the critical pathway for product development should be provided for manufacturing, process development, product assay development, clinical evaluation, clinical assay development, and regulatory licensure plan.
- C. The technical proposal should describe the extent to which the Offeror has unencumbered access to intellectual property necessary to fulfill its obligations under the contract. The U.S. Government expects and intends to require that the Offeror will take all steps necessary to secure access to all intellectual property, know-how and tangible materials. Accordingly, the U.S. Government requires written evidence that the Offeror has secured access to such intellectual property, know-how and tangible materials to the proposed broad-spectrum influenza monoclonal antibody technology unencumbered by legal or patent constraints.

4. Facilities – 5 Points

- A. The technical proposal should describe the Offeror's corporate strategy for supplying the broad-spectrum influenza monoclonal antibody candidate to the USG during a pandemic.
- B. The technical proposal should include information concerning 1) site selection criteria; 2) manufacturing processes and 3) a description of the facility quality and regulatory program. Identify potential barriers to implementation of the facility strategy and approaches to overcome those barriers.
- C. The technical proposal should describe any facilities to be used for development and manufacture of investigational lots of the broad-spectrum influenza monoclonal antibody suitable for clinical evaluation under an IND as specified in the proposal, including documentation of compliance with cGMP.

5. Quality Systems – 5 Points

The proposal should include descriptions of the corporate quality systems in place to ensure both internal and subcontractor development activities meet GxP standards.

6. Organizational Experience – 5 Points

The proposal should describe previous programs for monoclonal antibody (particularly antiviral) development, evaluation, licensure, and production to document organizational capabilities to complete proposed activities, achieve regulatory approvals, and successfully produce a broad-spectrum influenza monoclonal antibody therapeutic.

7. Personnel/Management Plan – 5 Points

- A. The technical proposal should provide the name of the Principal Investigator (PI)/Project Director responsible for the overall implementation of the contract, co-investigators and key participants for technical aspects of the project. Describe the qualifications, experience, and accomplishments of the PI, co-investigators, and key participants. Include, in an attachment, *curricula vitae* of supervisors and key technical personnel, and the approximate percentage of time each will be available for this program.
- B. The technical proposal should describe the experience and qualifications of other personnel who will be assigned to work on this program. Using organizational charts show the composition of task or work groups by project area. Document the general qualifications of work groups and recent experience with similar programs.
- C. The technical proposal should list names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment or on a subcontract or consultant basis. Indicate the technical areas, character, and extent of subcontract or consultant activities and anticipated sources. For all proposed personnel who are not currently members of Offeror's staff, provide a letter of commitment or other evidence of availability. The letter of commitment must at a minimum include (1) the specific items or expertise they will provide; (2) their availability to the project and the amount of time anticipated; (3) their willingness to act as a consultant and (4) how rights to publication and patents will be handled.

ARTICLE M.4. COST

The Government's evaluation of the Offeror's cost and fee (if proposed) will include an analysis of cost realism in addition to the total cost and fee. The cost realism analysis will be used to determine what the Government shall realistically expect to pay for the proposed effort, the Offeror's understanding of the work and the Offeror's ability to perform the contract.

ARTICLE M.5. PAST PERFORMANCE FACTOR

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.

Each Offeror will be evaluated on their performance under three (3) existing and/or prior contracts for similar services. Contracts/awards may include those entered with the Federal Government, state and local governments and commercial concerns. Past performance will be evaluated using a set of questions that address the quality of service, cost control, timelines of performance, business relations and the overall customer satisfaction for projects of similar nature. The questionnaires must be sent by the Offeror to previous or existing customers, who in turn shall complete and submit the surveys to the contracts office as instructed on the questionnaire provided in this RFP, SEE SECTION J LIST OF ATTACHMENTS.

Each past performance question shall be worth a maximum of 5 points. Questions seeking a "yes" or "no" answer will be scored as follows: "yes" = 5 and "no" = 0. The total score of each questionnaire received will be determined by calculating the average of the ratings provided in the questionnaire. Therefore, the maximum number of points for each questionnaire is 5. If specific questions are not answered or are answered with "N/A", then the question will not be included in the calculation of the average. The overall total score for the past performance rating for an Offeror will be determined by calculating the average of the total scores of the questionnaires received for that Offeror. The overall total score will be rounded to the nearest whole number.

The Government 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, or the unavailability of past performance information will result in the factor not being scored or rated so not to prejudice the Offeror. 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:

Sherica Teshome
Contract Specialist
HHS/ASPR/AMCG
Email: Sherica.Teshome@hhs.gov
Fax: 202/205-5919

All questionnaires must be submitted via email or fax by the proposal due date referenced on the face page (Block 9) of this solicitation. The Government reserves the right not to consider any past performance questionnaires that are received after the due date or by means other than facsimile.

ARTICLE M.6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored but the Government's conclusions about overall commitment and realism of the Offeror's SDB Participation targets will be used in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of 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.

Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Extent of commitment to use SDB concerns
- (c) Complexity and variety of the work SDB concerns are to perform
- (d) Realism of the proposal
- (e) Past performance of Offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- (f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

If the offerors response to the above subfactors are acceptable to the CO and the Small Disadvantaged Business Utilization Specialist the plan will be considered acceptable; if not it will be considered unacceptable.

ARTICLE M.7. HUMAN SUBJECT EVALUATION

This research project involves human subjects. HHS policy requires:

a) **Protection of Human Subjects from Research Risks**

The Offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by HHS that a designated exemption is appropriate.

If you claim that this research shall be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal shall address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals) or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to

address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

b) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plan to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, or
- Plan to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), or
- Plan to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the Offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
 - the purpose of the research constrains the Offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
 - overriding factors dictate selection of subjects); or
 - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
 - inclusion of those groups would be inappropriate with respect to their health; or
 - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

Based on the evaluation of the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or “acceptable.” See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

c) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers’ evaluation of the Offeror’s response, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the Offeror’s response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or “acceptable.” If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

ARTICLE M.8. ANIMAL WELFARE

The Government will evaluate the Offeror’s plan on how they will comply with all requirements concerning the use of animals for experimentation and any requirements of the Office of Laboratory Animal Welfare <http://grants.nih.gov/grants/olaw/olaw.htm>

If the Offeror has an Animal Welfare Assurance on file with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), provide the Assurance number with the proposal. If the Offeror proposes animal studies, the Offeror must submit a plan that describes how the Offeror will comply with the PHS Policy and addresses the five points listed below:

1. Provide a detailed description of the proposed use of the animals in the work outlined in the experimental design and methods section. Identify the species, strains, ages, sex and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species and the numbers used. If animals are in short supply, costly or to be used in large numbers, provide an additional rationale for their selection and their numbers.
3. Provide information on the veterinary care of the animals involved.
4. 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 comfortable restraining devices where appropriate to minimize comfort, distress, pain and injury.
5. 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 <http://www.avma.org/resources/euthanasia.pdf>. If not, present a justification for not following the recommendations.

Your plan may be rated “unacceptable or acceptable.” If your proposal is rated “unacceptable” and the Government includes your proposal in the competitive range, you will be afforded an opportunity to further discuss or clarify your position during such discussions and in any proposal revisions. If, after discussions, any area of animal care is still found to be unacceptable, your proposal may not be considered further for award.

ARTICLE M.9. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s)

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments