UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

Current Report

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 27, 2012**

CYTORI THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-34375**	**33-0827593**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

3020 Callan Road, San Diego, California 92121
(Address of principal executive offices, with zip code)

(858) 458-0900
(Registrant's telephone number, including area code)

n/a
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry Into a Material Definitive Agreement.

On September 27, 2012, Cytori Therapeutics, Inc., a Delaware corporation (the "Company"), entered into a contract with the U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority (BARDA) for the evaluation and development of Company's cell therapy for the treatment of thermal burns combined with radiation injury.

The contract consists of a guaranteed base period and three optional segments that can be initiated solely at the discretion of BARDA. The Guaranteed Base Period evaluation study is designed to demonstrate proof of concept for use of the Company's Celution System as a countermeasure for a combined injury involving thermal burn and radiation exposure. The base period study will last for two years for a cost plus fixed fee amount of approximately $4.7 million. The three contract options will extend the contract term to up to five years if all options are exercised. The options cover: (i) research and development, regulatory, clinical, and other tasks required for completion of a pilot clinical trial of the Celution System, for a cost plus fixed fee amount of up to $32.6 million; (ii) research and development, regulatory, and clinical activities necessary to achieve regulatory clearances to optimize a treatment for combined injury involving thermal burn and radiation exposure, at a cost plus fixed fee amount of up to $23.4 million and (iii) a pivotal clinical trial for FDA approval of the use of the Celution System for thermal burn injury, at a cost plus fixed fee amount of up to $45.5 million.

The total contract funding amount would be up to $106.2 million if all of the above options are exercised by the BARDA. The Company does not currently have any relationship with BARDA aside from this contract.

The foregoing is only a brief description of the material terms of the contract and does not purport to be a complete description of the rights and obligations of the parties there under. The foregoing description is qualified in its entirety by reference to Contract HHSO100201200008C dated September 27, 2012, which is filed as Exhibit 10.90 to this Current Report and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.90	Contract HHSO100201200008C dated September 27, 2012, by and between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (portions of the exhibit have been omitted pursuant to a request for confidential treatment).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CYTORI THERAPEUTICS, INC.

Date: October 3, 2012

By: /s/ Mark E. Saad
Mark E. Saad
Chief Financial Officer

NSN 7540-01-152-8069 | 26-107 | STANDARD FORM 26 (REV. 4-85)
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AWARD/CONTRACT	1.THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING N/A	PAGE OF PAGES 1 55

2. CONTRACT *(Proc. Inst. Indent.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
HHSO100201200008C	**See Block 20C.**	OS99307

5. ISSUED BY CODE	6. ADMINISTERED BY *(If other than Item 6)* CODE
Office of Acquisitions Management, Contracts, and Grants (AMCG) **330 Independence Ave., S.W. Room G640** **Washington, D.C. 20201**	**See Block 5.**

7. NAME AND ADDRESS OF CONTRACTOR *(No. street, county, state and ZIP Code)*	8. DELIVERY **See Schedule.**
Cytori Therapeutics, Inc. **3020 Callan Road** **San Diego, CA 92121**	9/ DISCOUNT FOR PROMPT PAYMENT N/A.
CAGE: 4AW88 TIN: 330827593	10. SUBMIT INVOICES ADDRESS SHOWN IN: ITEM See Section G.
CODE DUNS No. 111029179 FACILITY CODE	

11. SHIP TO/MARK FOR CODE N/A	12. PAYMENT WILL BE MADE BY CODE N/A
See Block 5.	See Block 5.

13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION: **N/A**
10 U.S.C. 2304(c)( ) 41 U.S.C. 253(c)( )

14. ACCOUNTING AND APPROPRIATION DATA
Appropriation Year: 2012; Object Class: 25106; CAN# 1992002

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. UNIT PRICE	15D. AMOUNT	15E. UNIT PRICE	15F. AMOUNT
See Section B.					
			15G. TOTAL AMOUNT OF CONTRACT		**$4,683,680.00**

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. X CONTRACTOR'S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return 2 copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. o AWARD (*Contractor is not required to sign this document.)* Your offer on Solicitation Number _ _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER ***	
Mark Saad, Chief Financial Officer		
19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
	9/27/12		9/27/12
/s/ Mark Saad *(Signature of person authorized to sign)*		BY /s/ *** *(Signature of Contracting Officer)*	

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

CONTRACT TABLE OF CONTENTS

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This purpose of this contract is develop a product that will combine the wound healing properties of the Celution ® System, which has been developed by the Contractor *** as a medical countermeasure for use in the context of combined injury and radiation exposure, and to obtain FDA licensure of the Celution ® System with indications for use that explicitly include thermal burn.

The Research and Development (R&D) effort will progress in specific stages that cover the base performance segment and nine (9) option segments as specified in this contract. The period of performance for the base period is 24 months. Work performed during the base segment and during the option segments is considered to constitute a non-severable discrete work segment that is necessary for the R&D effort.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The total estimated cost of ***the base performance segment*** is **$4,356,912.00**.
b. The total fixed fee for ***the base performance segment*** is **$326,768.00**. The fixed fee shall be paid subject to Allowable Cost and Payment and Fixed Fee Clauses.
c. The total amount of ***the base performance segment***, CLIN 0001, represented by the sum of the total estimated cost plus fixed fee is **$4,683,680.00.**
d. The total amount for the base segment shall not exceed $4,683,680.00. The total amount obligated by the Government for the base segment of the contract shall not exceed $4,683,680.00 and the Government will not be responsible for any Contractor incurred costs that exceed this amount unless a modification to the contract is signed by the Contracting Officer which expressly increases this amount.
e. It is estimated that the amount currently allotted will cover performance of the contract through **27 September 2014 (2 years from start date)**.
f. The Contractor shall maintain records of all contract costs and such records shall be subject to the Audit and Records-Negotiation and Final Decisions on Audit Findings clauses of the General Clauses.

CLIN	Estimated Period of Performance	Supplies/Services	Total Estimated Cost	Fixed Fee	Total Est. Cost Plus Fixed Fee
0001	28 September 2012 through 27 September 2014	Studies needed to demonstrate proof-of-concept for use of the Celution System as a medical countermeasure for combined injury involving thermal burn and radiation exposure Reports and Other Data Deliverables.	$ ***	$ ***	$ 4,683,680.00

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

ARTICLE B. 3. OPTION PRICES

a. Unless the government exercises its option pursuant to the option clause contained in ARTICLE I.2, the contract consists only of the Base Work segment specified in the Statement of Work as defined in SECTONS C and F, for the price set forth in ARTICLE B.2 of the contract.

b. Pursuant to FAR Clause 52.217-9 (Option to Extend the Term of the Contract), the Government may, by unilateral contract modification, require the Contractor to perform the Option Work Segments specified in the Statement of Work as defined in SECTIONS C and F of this contract. If the Government exercises the/these option(s), written notice must be given to the Contractor within 30 days after the Government has completed its analysis of the deliverables associated with the applicable GO/NO GO Decision gate*;* and the Government must give the Contractor a preliminary written notice of its intent to exercise the option at least 30 days before the contract expires. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION G of this contract. The estimated cost of the contract will be increased as set forth below:

CLIN/ Option	Estimated Period of Performance	Supplies/Services	Total Estimated Cost	Fixed Fee	Total Estimated Cost Plus Fixed Fee
0002/1	28 September 2013 through 27 September 2016	Research and development, regulatory, clinical, and other tasks required for completion of a Pilot Clinical Trial of the Celution System in thermal burn injury Reports and Other Data Deliverables	$ ***	$ ***	$ 32,641,997.00
0003/2	28 September 2015 through 27 September 2017	Clinical, regulatory, and other tasks required for completion of a Pivotal Clinical Trial leading to FDA licensure for use of the Celution System in thermal burn injury. Reports and Other Data Deliverables	$ ***	$ ***	$ 45,501,320.00
0004/3	28 September 2013 through 27 September 2017	Research and development, clinical, regulatory and other tasks required to develop and obtain FDA clearance for a *** that has ease of use and other characteristics suitable for use in thermal burn injury following a mass casualty event. Reports and Other Data Deliverables	$ ***	$ ***	$ 23,420,322.00

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

ARTICLE B. 4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses, unless authorized in writing by the Contracting Officer, the cost of the following items or activities shall be unallowable as direct costs:

1) Acquisition, by purchase or lease, of any interest in real property;

2) Special rearrangement or alteration of facilities;

3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value;

4) Accountable Government Property (*see* the Contractor's Guide for Control for Government Property incorporated by ARTICLE G.10. of this contract);

5) Travel to attend general scientific meetings;

6) Unapproved foreign travel – Subject to the procedure specified under subparagraph b.2 below;

7) Patient care costs (*see* Attachment 6);

8) Printing Costs (as defined in the Government Printing and Binding Regulations);

9) Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meeting, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

10) No overtime (premium) compensation is authorized under the subject contract. Billing of actual hours should be limited to total productive hours in a month (8 hours/day).

b. Travel Costs

a. Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract during the base segment or any option segment(s) shall not exceed amount negotiated in the final proposed budget without the prior written approval of the Contracting Officer. Cost must be consistent with Federal Acquisition Regulations (FAR) 52.247-66 – Preference for U.S. Air Flag carriers.

b. Subject to the annual dollar limitation specified under B.4.b.1.a. above, the Contactor shall invoice and be reimbursed for all travel costs in accordance with FAR 31.2 – Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

a. Man-in-Plant

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility The man-in-plant shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility.

b. Subcontracts and Consultants

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

- Is of the cost reimbursement type;
- Is Fixed-Price and exceeds $150,000 or 5% of the total estimated cost of the contract;

Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Article.

c. Reference FAR 52.244-2 (e) Subcontracts.

FAR 52.244-2 (e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (d) of this clause, including the following information:

(i). A description of the supplies or services to be subcontracted.

(ii). Identification of the type of subcontract to be used.

(iii). Identification of the proposed subcontractor.

(iv). The proposed subcontract price.

(v). The subcontractor's current, complete, and accurate cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi). The subcontractor's Disclosure Statement or Certificate relating to Cost Accounting standards when such data are required by other provisions of this contract.

(vii). A negotiation memorandum reflecting-

(A). The principal elements of the subcontract price negotiations;

(B). The most significant considerations controlling establishment of initial or revised prices;

(C). The reason cost or pricing data were or were not required;

(D). The extent, if any, to which the Contractor did not rely on the subcontractor's cost or pricing data in determining the price objective an in negotiating the final price;

(E). The extent to which it was recognized in the negotiation that the subcontractor's cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F). The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G). A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

The Contractor shall obtain the Contracting Officer's written consent (COA) prior to placing any consultant awards.

d. **Consultants**

Consultant fees to be paid to the following individuals: ***

e. **Site Visits and Inspections**

At the discretion of the USG and independent of activities conducted by the Contractor, with 48 hours notice to the contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis, including collection of product samples and intermediates held by the contractor, or subcontractor. In case of subcontractor visits and inspections that are independent of activities conducted by the Contractor, the USG shall demonstrate cause for such visit and/or inspection. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowed costs. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, and cGMP/GLP/GCP compliance.

If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA for review and acceptance.

- If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to BARDA.

QA AUDIT:
BARDA reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA for review and acceptance. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications
- Contractor shall notify the COR and CO within 5 business days of report completion.

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

f. **Invoices - Cost and Personnel Reporting and Variances from the Negotiated Budget**

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

b. Fringe Benefits - Cite rate and amount

c. Overhead - Cite rate and amount

d. Materials & Supplies - Include detailed breakdown when total amount is greater than $1,000.

e. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately domestic travel, general scientific meeting travel, and foreign travel.

f. Consultant Fees - Identify individuals and amounts.

g. Subcontracts - Attach Subcontractor invoice(s). Cite applicable COA or notification.

h. Equipment - Cite authorization and amount.

i. Other Direct Costs - Include detailed breakdown when total amount is greater than $1,000.

j. G&A - Cite rate and amount.

k. Total Cost

l. Fixed Fee

m. Total CPFF

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government. In order to verify allowability, further breakdown of costs may be requested at the Government's discretion.

g. **Confidential Treatment of Sensitive Information**

The Contractor shall guarantee strict confidentiality of any information/data of a sensitive nature that is provided to the Contractor by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of information/data that is sensitive in nature, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer. (See also HHSAR clause 352.224-70).

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the Contractor shall first have given notice to the Government and give the Government a reasonable opportunity to quash such order and to obtain a protective order requiring that the information/data of a sensitive nature that is the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the information/data disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order; (b) otherwise required by law, in the opinion of legal counsel to the Contractor as expressed in an opinion letter in form and substance reasonably satisfactory to the Government, which shall be provided to the Government at least two (2) business days prior to the Contractor's disclosure of the information/data; or (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/data.

h. **Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables with USG entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio's Portfolio Advisory Committee (PAC) Charter, Technology Transfer Agreements (TTA) between BARDA and the Defense Threat Reduction Agency and the National Institute of Allergies and Infectious Diseases (NIAID), BARDA may share technical deliverables set forth in Article F.2 with colleagues within the Integrated Portfolio. This advance understanding does not authorize BARDA to share financial information outside HHS. The Contractor is advised to review the terms of FAR Clause 52.227-14 regarding the Government's rights to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall 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 **28 September 2012** as set forth in SECTION J-List of Attachments, attached hereto and made a part of the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

Refer to ARTICLE F.2. for specific instructions regarding Reporting Requirements.

ARTICLE C.3. PROJECT MEETING CONFERENCE CALLS

A teleconference call between the Contracting Officer's Technical Representative and the Contractor's Program Manager shall occur bi-weekly (every two weeks), or at the discretion of the U.S. Government. During this call, the Program Manager will discuss the activities during the reporting period, any problems that have arisen, and the activities planned for the ensuing reporting period. The Contractor's Program Manager may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative.

Contractor will be responsible for preparing an agenda for the conference call and providing to BARDA no later than 2 business days prior to the scheduled conference call.

ARTICLE C.4. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor confidential or proprietary data) and USG personnel as required by the Contracting Officer's Representative in order to facilitate review of contract activities.

ARTICLE C.5 SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, including, but not limited to: the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed 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. See also FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor).

Reports and documentation submitted to the Contracting Officer shall be sent to the Contracting Officer to the address set forth in SECTION G – CONTRACT ADMINISTRATION DATA.

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.

Unless otherwise specified by the Contracting Officer, delivery of reports to be furnished to the Government under this contract (including invoices), shall be delivered to BARDA electronically along with a concurrent email notification to the Contracting Officer, Contract Specialist, and COR summarizing the electronic delivery.

Delivery of physical reports to be furnished shall be addressed to the COR, CO, and CS (as defined in SECTION G – CONTRACT ADMINISTRATION DATA).

SECTION E – INSPECTION AND ACCEPTANCE

The Contracting Officer (CO) or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this contract.

For the purpose of this SECTON, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

Inspection and acceptance will be performed at:

Biomedical Advanced Research and Development Authority/Office of Acquisition Management, Contracts, and Grants (AMCG)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 Independence Avenue, S.W., Room G644
Washington, D.C. 20201

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. ESTIMATED PERIOD OF PERFORMANCE

Under CLIN 0001, the estimated period of performance for the base performance segment of this contract shall be consistent with the dates set forth in ARTICLE B.2. If the Government exercises its option(s) pursuant to the Option Clauses in Article G.11 and Article I.2 of the contract, the period of performance will be increased as shown in the table in Article B.3.

ARTICLE F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work dated **28 September 2012** set forth in SECTION J-List of Attachments of this contract and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract and the Statement of Work dated 23 October 2011 set forth in SECTION J-List of Attachments will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-34, F.O.B. DESTINATION, (NOVEMBER 1991), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

CYTORI DELIVERABLES SCHEDULE

General Deliverables

Deliverable	Due Date(s)
BARDA Audit Reports	If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit COR and CO will review the report and provide a response to the Contractor with 10 business days Once corrective action is completed, the Contractor will provide a final report to BARDA
QA Audit	Notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications Notify the COR and CO within 5 business days of report completion
Bi-weekly conference call agenda	No later than 2 business days prior to the scheduled conference call
Meeting/Teleconference Minutes	No later than 2 business days following the meeting/teleconference
Data/Data Analysis	Within 10 business days of request by COR or CO
Monthly Progress Report	On the 15th calendar day following the month being reported upon
Annual Progress Report	On or before the 15th calendar day of the month following each 12 months of the performance period
Draft Final Technical Report	60 calendar days prior to the end of the contract and all options. BARDA shall provide comments within 30 calendar days
Final Technical Report	On or before the end date of the contract and all options

Draft and Final Reports for Non-Clinical Studies and Clinical Studies	Draft report to BARDA at least 30 business days following the end of the study BARDA will provide feedback to Contractor within 15 business days of receipt Final report, incorporating or addressing BARDA feedback, to BARDA within 15 business days of receipt of feedback
Final Invention Report	On or before the end date of the contract and all options
	FDA Related Deliverables
FDA Meeting Notices	Notification to BARDA within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings
FDA Meeting Minutes	Initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA within 3 business days of receipt
FDA Submissions	Draft FDA submissions to BARDA at least 15 business days prior to FDA submission. BARDA will provide feedback to Contractor within 10 business days of receipt. Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of it submission to CDER.
FDA Audits	Notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice. Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 3 business days of receiving correspondence from the FDA or third party. Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

Manufacturing Campaign Reports	Submit at least 15 business days prior to FDA submission. Final FDA submission shall be submitted to BARDA concurrently or no later than 1 business day after submission to the FDA.
Other FDA Correspondence	Within 3 business days of correspondence
Copies of FDA Correspondence and Meeting Summaries	For any formal meeting with the FDA, the contractor shall forward initial draft minutes and subsequently final meeting minutes appropriately formatted within thirty (30) calendar days of the FDA meeting to the BARDA COR. The contractor shall forward the final draft minutes of any informal meeting with the FDA to BARDA. The contractor shall forward the dates and times of any meeting with the FDA to BARDA at least 30 days prior to the meeting. Contractor shall provide BARDA with five (5) business days in which to review and provide comments upon any document back to the contractor.
Incident Report (As needed)	Contractor shall communicate and document all critical programmatic concerns, risks, or potential risks with BARDA. Due within 48 hours of activity or incident or within 24 hours for a security activity or incident. Email or telephone with written follow-up to COR and CO. Additional updates due to COR and CO within 48 hours of additional developments. Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues. If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days.

Base Period		9/28/12 to 9/27/14		
Name	WBS Number	Start Date	Finish/Due Date	Deliverable
Technical and Project Management	1.1.1.4	9/28/2012	10/22/2012	Updated Task/Deliverables List
Hiring: Base Period	1.1.1.5	10/2/2012	1/22/2013	Include in the applicable monthly report
Subcontractor Management	1.1.2	10/16/2012	1/7/2013	Subcontractor Management Plan
Risk Management	1.1.3.3	10/16/2012	3/11/2013	Risk Management Plan
EVMS: Implementation Plan	1.1.4.2	10/15/2012	3/24/2013	EVMS Systems Plan
EVMS: Implementation	1.1.4.4	3/24/2013	7/24/2013	EVMS Systems Report
Preclinical Studies: Multiple Final Reports	1.3.1.3.16	10/2/2012	5/5/2014	Final report submitted to and accepted by BARDA CO/COR
Human Preclinical Studies Report	1.3.2.1	9/28/2012	2/24/2014	Final report submitted to and accepted by BARDA CO/COR
Pilot Clinical Trial Clinical Protocol Draft Development Plan	1.4.1.3	9/5/2013	10/18/2013	Draft or Outline Clinical Protocol submitted to BARDA CO/COR approval
***	1.5.1.2	12/9/2013	12/9/2013	Meeting minutes
***	1.6.1	10/30/2012	8/19/2013	Final report submitted to and accepted by BARDA CO/COR
***	1.6.2	11/27/2012	8/5/2013	Final report submitted to and accepted by BARDA CO/COR

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

Option 1: Pilot Clinical Study		9/28/2013 to 9/27/16		
Name		**Start Date**	**Finish Date**	**Deliverable**
Clinical Hiring	1.1.1.6.1	3/19/2014	7/8/2014	Include in the applicable bi-monthly report
Development Hiring	1.1.1.6.2	3/19/2014	5/20/2014	Include in the applicable bi-monthly report
*** Feasability Final Report	1.3.1.4.1	3/19/2014	1/21/2015	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.3.1.4.2	3/19/2014	10/22/2014	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.3.1.4.3	5/1/2014	7/29/2015	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.3.2.3.1	3/19/2014	9/18/2014	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.3.2.3.2	3/19/2014	9/8/2014	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.3.2.4	3/19/2014	7/14/2014	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.3.2.5	4/4/2014	11/19/2014	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.4.1.4	3/19/2014	12/11/2015	Final report submitted to and accepted by BARDA CO/COR
*** Protocol Development Submission	1.4.2.1	3/23/2015	4/10/2015	Protocol submitted to and accepted by BARDA CO/COR
***	1.5.1.6	10/27/2014	10/27/2014	***
*** Report	1.6.3.1	3/9/2014	4/22/2014	Interim Report
*** Report	1.6.3.2	3/9/2014	8/5/2014	Interim Report
*** Final Report	1.6.3.3	8/6/2014	9/17/2014	Final report submitted to and accepted by BARDA CO/COR

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

Option 2: Pivotal Clinical Trial		9/28/14 to 9/27/17		
Name		**Start Date**	**Finish Date**	**Deliverable**
Clinical Hiring	1.1.1.7	6/2/2015	8/10/2015	Include in the applicable bi-monthly report
*** Interim Report	1.4.2.4	2/12/2016	2/12/2016	***
Study Complete Final Report	1.4.2.10	6/1/2017	6/1/2017	Final report submitted to and accepted by BARDA CO/COR
***	1.5.3.2	6/1/2017	6/1/2017	***
***	1.5.3.3	9/21/2017	9/21/2017	***

Option 3: Comb. Inj. Treatment Optimization		9/28/13 to 9/27/17		
Name		**Start Date**	**Finish Date**	**Deliverable**
Clinical Hiring	1.1.1.8	6/3/2016	7/14/2016	Include in the applicable bi-monthly report
Research and Development Hiring	1.1.1.9	3/19/2014	5/27/2014	Include in the applicable bi-monthly report
*** Studies Final Report	1.3.1.5	3/19/2014	1/25/2017	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.3.2.2	3/9/2014	8/19/2014	Final report submitted to and accepted by BARDA CO/COR
*** Final Report	1.4.3	1/13/2016	5/10/2017	Final report submitted to and accepted by BARDA CO/COR
***	1.5.4	4/27/2017	8/30/2017	***
*** Final Report	1.6.4	9/16/2015	5/22/2017	Final report submitted to and accepted by BARDA CO/COR

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

2. **Detailed Description of Select Contract Deliverables**

Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract and in SECTION J-List of Attachments, attached hereto and made a part of the contract.

A. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The format should include:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission; The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).

  Estimated and Actual Expenses

  This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level as far as possible. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to the Integrated Master Schedule, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to the Integrated Master Schedule for the next reporting period and preprints/reprints of papers and abstracts.

  In accordance with FAR 52.215-2, Audit and Records-Negotiation, BARDA may request on an ad hoc basis that the Contractor provide raw data. BARDA may request additional data at a reporting level or at lower levels, as BARDA deems necessary.

A monthly Progress Report will not be required in the same month that the Annual Technical Progress Report is submitted.

B. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due.

The first Annual Progress Report shall be submitted in accordance with the date set forth in ARTICLE F.2 of this contract. Each Annual Progress Report shall include:

A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission; The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance; regulatory compliance audits, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates described in the Integrated Master Schedule. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Integrated Master Schedule.
- SECTION III Part A: In accordance with FAR 52.215-2, Audit and Records-Negotiation, BARDA may request on an ad hoc basis that the Contractor provide raw data. BARDA may request additional data at a reporting level or at lower levels, as BARDA deems necessary.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and

2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

An annual Progress Report will not be required in the same month that the Final Technical Progress Report is submitted.

C. Draft Final Technical Progress Report and Final Technical Progress Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. The Draft Final Technical Progress Report and the Final Technical Progress Report shall be submitted in accordance with the dates set forth in ARTICLE F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.

1. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

2. SECTION II: RESULTS - A detailed description of the work performed related to the Integrated Master Schedule, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

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

Final Technical Progress Report: The Contractor will deliver the final version of the Final Technical Progress Report on or before the completion date of the contract. The final version shall include or address the Contracting Officer’s Representative comments and Contracting Officer comments on the draft report. Final Technical Progress Report shall be submitted on or before the completion date of the contract.

D. Summary of Salient Results

The Contractor shall submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

E. Other Technical Progress Reports

1. Draft Reports and Final Reports for Non-Clinical Studies and Clinical Studies

- The non-clinical study and Clinical study reports shall follow the format of International Conference on Harmonization document ICH E3 “Guidelines on Structure and Content of Clinical Study Reports” (http://www.pharmacontract.ch/support/su_ich_liste.htm)
- Draft and Final Reports for Non-Clinical Studies and Clinical Studies funded by this contract will be submitted to the Contracting Officer’s Representative and Contracting Officer (CO) for review and comment within the time frames set forth by ARTICLE F.2.of this contract.
- Subcontractor prepared reports received by the Prime Contractor shall be submitted to the Contracting Officer’s Representative and Contracting Officer (CO) for review and comment as set forth by ARTICLE F.2. of this contract.
- The Government shall provide written comments to the Draft Final Report for Non-Clinical Studies and Clinical Studies in accordance with the dates set forth in ARTICLE F.2.of this contract.
- The comprehensive Final Report for Non-Clinical Studies and Clinical Studies will be submitted to the Contracting Officer and the Contracting Officer’s Representative as set forth by ARTICLE F.2. of this contract.. The final version shall include or address the Contracting Officer’s Representative comments and Contracting Officer comments on the draft report.
- See section ARTICLE F.2. REPORTING REQUIREMENTS AND DELIVERABLES for additional clarification and deliverable requirements.

2. Audit Reports

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

3. Other Technical Documents:

- Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Standard Operating Procedures, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports.
- The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the USG.

- **Data:** The Contractor shall provide raw data or specific analysis of data generated with contract funding at the request of the BARDA COR. *See* FAR 52.227-14. Data/data analysis will be delivered to the Government pursuant to the terms set forth in ARTICLE F.2 of this contract.

- Contractor shall provide the requested document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA

F. Deliverables Arising from FDA Correspondence

a. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.

- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 3 business days of receipt. All documents shall be duly marked as either “Draft” or “Final”.

b. FDA Submissions

The Contractor shall provide BARDA the opportunity to review and comment upon all draft documents before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either “Draft” or “Final”.

- Contractor shall submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission

- BARDA will provide feedback to Contractor within 10 business days of receipt

- If corrective action is recommended, the Contractor must address, in writing, its consideration of all concerns raised by BARDA

- The Contractor shall consider revising their documents to address BARDA’s concerns and/or recommendations prior to FDA submission

- Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of it submission to CDER.

c. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.

- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 3 business days of receiving correspondence from the FDA or third party.

- Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

d. Manufacturing Campaign Reports

Contractor shall provide Manufacturing Campaign Reports to BARDA for review and comment prior to submission to FDA.

The COR and CO reserve the right to request within the PoP a non-proprietary Manufacturing Campaign Report for distribution within the USG.

- Contractor will submit Manufacturing Campaign Reports at least 15 business days prior to FDA submission.
- If corrective action is recommended, Contractor must address, in writing, all concerns raised by BARDA.
- Contractor shall consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission.
- Final FDA submission shall be submitted to BARDA concurrently or no later than 1 business day after submission to the FDA.

e. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA. All documents shall be duly marked as either "Draft" or "Final."

- Contractor shall provide written summary of any FDA correspondence within 3 business days of correspondence.

G. Other Reports/Deliverables

1. Meeting Minutes

The Contractor shall provide an electronic copy of meeting minutes for all conference calls and face-to-face meetings including the Government and Contractor. Minutes will be submitted directly to the BARDA COR for review and official approval pursuant to the terms set forth in ARTICLE F.2 of this contract. After contract award a Kickoff meeting will be held. The contractor shall prepare and submit a report of this Kickoff meeting based on the minutes to the meeting.

2. Copies of FDA Correspondence and Meeting Summaries

1. For any formal meeting with the FDA, the contractor shall forward initial draft minutes and subsequently final meeting minutes appropriately formatted within thirty (30) calendar days of the FDA meeting to the BARDA Contracting Officer's Technical Representative. All documents shall be duly marked as either "Draft" or "Final".

2. The contractor shall forward the final draft minutes of any informal meeting with the FDA to BARDA.

3. The contractor shall forward the dates and times of any meeting with the FDA to BARDA at least 30 days prior to the meeting and make arrangements for appropriate BARDA staff to attend FDA meetings. BARDA staff shall include up to a maximum of four people (COTR, CO and up to two Subject Matter Experts (SMEs)).

4. The contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA. The contractor shall provide BARDA with five (5) business days in which to review and provide comments back to the contractor.

H. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed 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. See also FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor).

Reports and documentation submitted to the Contracting Officer shall be sent to the Contracting Officer to the address set forth in SECTION G – CONTRACT ADMINISTRATION DATA.

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 G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

*** Contracting Officer
DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W.
***
Washington, D.C. 20201
E-mail: ***

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

1) The Contracting Officer (CO) 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 the 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 reimburse to the Contractor of any costs incurred during the performance of this contract; (5) 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 US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.

4) The Government may unilaterally change its CO designation.

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

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

***
Contracting Officer's Representative (COR)
Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (DHHS)

Mailing Address:
330 Independence Avenue, S.W.
***
Washington, D.C. 20201
Office: ***
Email: ***

The COR is responsible for:

1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;

2) Assisting the Contracting Officer in 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 Government may unilaterally change its COR designation.

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

ARTICLE G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:
***

The key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) business days prior to diverting any of the specified individuals to other programs or contracts, including, where practicable, an instance when an individual must be replaced 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.

ARTICLE G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Financial Report of Individual Project/Contract (see Attachments 2 and 3) shall be submitted by the Contractor in accordance with the instructions for completing this form, which accompany the form, in an electronic copy, not later than the 30th business 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.

b. Unless otherwise stated in that part of the instructions for completing this form, entitled "PREPARATION INSTRUCTIONS," (see Attachment 4) 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 Contracting Officer may require the Contractor to submit 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 the Attachment 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 “Financial Report of Individual Project/Contract” to reflect the allotment of additional funds.

ARTICLE G.5. INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING

1) The billing address that should be shown on the invoice is the same as defined in ARTICLE G.2. of this contract.

*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.

2) The Contractor shall submit an electronic copy of contract monthly invoices/financial reports to the Contracting Officer and Contract Specialist as defined above, in ARTICLE G of this contract.

3) Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting made a part of the contract in Section J (See also ARTICLE B.5. and Attachment 2) .

4) Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

5) The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base segment or any option segment(s) (See estimated costs under Articles B.2. and B.3., of the contract) and the reasons for the variance. Also refer to the requirements of the Limitation of Cost FAR 52.232-20 clause in the contract.

6) All invoice submissions shall be in accordance with FAR Clause 52.232-25 (c) in Section I of this contract.

ARTICLE G.6. REIMBURSEMENT OF COST

1) The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with the clause entitled Allowable Cost and Payment in Section I, Contract Clauses, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

   a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.

   b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

   c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

   d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

      (i) Air travel shall be by the most direct route using “air coach” or “air tourist” (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

      (ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

      (iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

(iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

ARTICLE G.7. INDIRECT COST RATES

The following rates will be utilized for billing purposes during both the base and option periods: Fringe benefits at 24%, and a general and administrative expense rate (G&A) of 50% for FY2012 and 51% for FY2013 through FY2016. The billing rates for the option period will be based on the incurred cost submission for the previous calendar year, subject to Government audit adjustments. Final rate proposals must be sent to the Contracting Officer, within 6 months subsequent to the fiscal year end. (See also FAR Clause 52.216-7 incorporated herein)

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted September 27, 2013.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty 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.

2. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://www.cpars.csd.disa.mil/cparsmain.htm

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

ARTICLE G.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

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

ARTICLE G.10. GOVERNMENT PROPERTY

1. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/hhsmanuals/ (HHS Logistics Management Manual)

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

2. Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated in this contract in paragraph 1. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

3. Title will vest in the Government for equipment purchased as a direct cost.

ARTICLE G.11. EXERCISE OF OPTIONS

Unless the Government exercises its option pursuant to the Option Clause set forth in Section I, Article I.2, the contract will consist only of **CLIN 0001** of the Statement of Work, Deliverables and Requirements as defined in Sections C, F and J 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, under Article I.2, the Government may, by unilateral contract modification, require the Contractor to perform **the additional CLINs listed in Section B, Article B.3.,** and as also defined in Sections C, F and J of this contract. If the Government exercises an option, written notice must be given to the Contractor within 30 days after the Government has completed its analysis of the deliverables associated with the applicable GO/NO-GO Decision gates*;* and the Government must give the Contractor a preliminary written notice of its intent to exercise the option at least 30 days before the contract expires. The amount of the contract may then be increased as set forth in Section B, Article B.3 provided that funds are available.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. CLINICAL AND NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial *and* non-clinical study funded under this contract and submit all such protocols and protocol amendments to the BARDA Contracting Officer's Representative (COR) for evaluation and comment. Approval is required before work under a protocol may begin. BARDA COR comments will be forwarded to the Contractor within ten (10) business days. The Contractor must address, in writing, all concerns (*e.g.* study design, safety, regulatory, ethical, and conflict of interest) raised by the BARDA COR.

If the draft protocols are to be submitted to the FDA, BARDA review shall occur before submission, pursuant to the terms set forth by ARTICLE F.2 of this contract. The Contractor shall consider revising their protocols to address BARDA's concerns and recommendations prior to FDA submission. The Contractor must provide BARDA with a copy of FDA submissions, within the time frame set forth by ARTICLE F.2 of this contract.

Execution of clinical and non-clinical studies requires written authorization from BARDA. The Government will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol.

BARDA shall have rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in PART II of this contract and defined in the FAR. BARDA reserves the right to request that the Awardee provide any contract deliverable in a non-proprietary form to ensure BARDA has the ability to review and distribute the deliverables as BARDA deems necessary.

Important information regarding performing human subject research is available at http://www3.niaid.nih.gov/healthscience/clinicalstudies/.

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Technical Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

1. Non-Clinical Terms of Award

These Non-Clinical Terms of Award detail an agreement between the Biomedical Advanced Research and Development Authority (BARDA) and the Contractor; they apply to all grants and contracts that involve non-clinical research.

a. Safety and Monitoring Issues

i. PHS Policy on Humane Care and use of Laboratory Animals

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current Institutional Animal Care and Use Committees (IACUC) documentation of continuing review and approval and the Office of Laboratory Animal Welfare (OLAW) federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter trial or study), each institution's IACUC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval and federal wide assurance number.

The Contractor must ensure that the application, as well as all protocols, are reviewed by the performing institution's IACUC.

To help ensure the safety of animals used in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
- All material changes in IACUC policies and procedures, identified by version number, date, and all required signatories (if applicable).

- Termination or temporary suspension of the study(ies) for regulatory issues.

- Termination or temporary suspension of the protocol.

- Any change that is made in the specific IACUC approval for the indicated study(ies).

- Any other problems or issues that could affect the scientific integrity of the study(ies), i.e., fraud, misrepresentation, misappropriation of funds, etc.

Contractor must notify BARDA of any of the above changes within five (5) working days from the time the Contractor becomes aware of such changes by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IACUC and a copy of any responses from the IACUC.

If a non-clinical protocol has been reviewed by an institutional biosafety 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.

ii. Non-Clinical Data and Safety Monitoring Requirements

BARDA strongly recommends continued safety monitoring for all non-clinical studies of investigational drugs, devices, or biologics. FDA expects non-clinical studies to include safety in addition to efficacy. Awardee should consider evaluation of clinical relevant safety markers in the pivotal and non-pivotal, non-clinical studies. In preparation for clinical trials of licensed or not yet licensed products, it is imperative that BARDA-sponsored studies of any type measure the risk and safety parameters that are elicited and proved a safety profile from the studies for future human risk assessment.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy subject for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102(i)).

BARDA will work with the Contractor on decisions regarding the type and extent of safety data accrual to be employed before the start of efficacy or safety studies.

The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRP facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CRO’s as BARDA deems necessary.

b. BARDA Review Process before Non-Clinical study Execution Begins

BARDA is under the same policy-driven assurances as NIH in that it has a responsibility to ensure that mechanisms and procedures are in place to protect the safety and welfare of animals used in BARDA-funded non-clinical trials. Therefore, before study execution, the Contractor must provide the following (as applicable) for review and comment by BARDA:

- IACUC approved (signed) non-clinical research protocol identified by version number, date, or both, including details of study design, euthanasia criteria, proposed interventions, and exclusion criteria.
- For non-pivotal mouse studies, the Contractor will provide an annual animal care and use protocol.
- Documentation of IACUC approval, including OLAW federal wide number, IACUC registration number, and IACUC name.
- Contractor should reduce the number of animals required for a study using power of statistics.
- Plans for the management of side effects, rules for interventions and euthanasia criteria.
- Procedures for assessing and collecting safety data were appropriate.
- If a study is contracted through Contract Research Organizations (CROs), work orders and service agreements the Contractor shall assure an integrated safety documentation plan is in place for the study site, pharmacy service records on the dosing material to be used and excipients, and laboratory services (including histopathology).
- Documentation that the Contractor and all required staff responsible for the conduct of the research have received training in the protection and handling of animals, or that the CRO has the required documentation.
- Purchasing of animals and/or other supplies for non-clinical studies funded in part or in whole by BARDA requires written approval by the Contracting Officer in accordance with the contract. The Contractor must have the ability to return/re-sell animals, at purchase price, to distributor or a third part, in the event that the Contracting Officer Authorization is not granted.
- Provide justification for whether studies require good laboratory practice (GLP) conditions.
- Provide justification for whether studies will be classified as non-pivotal or pivotal studies.

Documentation of each of the above items shall be submitted to the BARDA for evaluation and comment in conjunction with the protocol. Execution of non-clinical studies requires written authorization from BARDA in accordance with this section of the contract.

c. References

Public Health Service Policy on Humane Care and Use of Laboratory Animals:

http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf

USDA Animal Welfare Act:

http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=3&tax_subject=182&topic_id=1118&level3_id=6735&level4_id=0&level5_id=0&placement_default=0

2. Clinical Terms of Award

These Clinical Terms of Award detail an agreement between the Biomedical Advanced Research and Development Authority (BARDA) and the Contractor; they apply to all grants and contracts that involve clinical research.

i. Safety and Monitoring Issues

a. Institutional Review Board or Independent Ethics Committee Approval

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance 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 BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols is reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the statues of ongoing protocols, including the following:

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

The Contractor must notify BARDA through the Project Officer (PO) or Contracting Officer (CO) of any of the above changes within five (5) working days by email or fax, 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 biosafety 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.

b. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial 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 be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research and not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood form a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102I).

Final decisions regarding the type of monitoring to be used must be made jointly by BARDA and the Contractor before enrollment starts. Discussions with the responsible BARDA Project Officer 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.

- **Independent Safety Monitor** – 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.

- **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.

- **Data and Safety Monitoring Board** – 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

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 BARDA before enrollment starts. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with BARDA.

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

ii. 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 trial. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place prior to patient accrual or enrollment at each participating institution.

- 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.

- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.

- IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid.

- Plans for the management side effects.

- Procedures for assessing and reporting adverse events.

- Plans for data and safety monitoring (see B above) and monitoring of the clinical study site, pharmacy, and laboratory.

- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to the BARDA) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from BARDA in accordance with this section of this contract.

iii. Investigational New drug or Investigational Device Exemption Requirements

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from GDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted.

The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

iv. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA representative or the Contracting Officer's technical representative (COR) as follows:

- 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 (7) days after the IND sponsor's receipt of the information, must be submitted to the BARDA representative or the contraction officer's technical representative within 24 hours of FDA notification.

- 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 day after the IND sponsor's receipt of the information, must be submitted to the BARDA representatives or the Contracting Officer's Technical Representative within 24 hours of FDA notification.

- 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 representative or the Contracting Officer's Technical Representative within 24 hours of FDA notification.

- Expedited safety reports – should be sent to the BARDA representative or the Contracting Officer's Technical Representative concurrently with the report to FDA.

- 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 representative or the Contracting Officer's Technical Representative will contract the Contractor within ten (10) working days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Leader, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

- Safety reporting for research not performed under an IND or IDE.

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the BARDA Project Officer or the Contracting Officer's Technical Representative and the Contractor.

ARTICLE H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4 (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 the performance of this contract, the Contracting Officer determines, in consultation with 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 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 Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

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

Provision by the Contractor to the 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. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

ARTICLE H.5. NEEDLE EXCHANGE

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. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5 (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.7. 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. This policy may be accessed at:

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

ARTICLE H.8. PUBLICATION AND PUBLICITY

No information related to data obtained under this contract shall be released or publicized without the prior written consent of BARDA.

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, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state: (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and; (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication." Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201200008C "

ARTICLE H.9. REVIEW OF PRESS RELEASES

Contractor agrees to accurately and factually represent the work conducted under the contract in all press releases.

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than six (6) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201200008C"

ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

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

ARTICLE H.11. 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.12. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days.

The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions, which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

ARTICLE H.13. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (Jan 2006)

The Contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

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

In addition, as set forth in HHSAR 352.203-70 “Anti-Lobbying” (January 2006), the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

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

ARTICLE H.14. PRIVACY ACT APPLICABILITY

1) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at http://www.gpoaccess.gov/cfr/index.html

2) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

ARTICLE H.15. LABORATORY LICENSE REQUIREMENTS

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

ARTICLE H.16. DISSEMINATION OF INFORMATION (May 1998)

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer.

ARTICLE H.17. 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 (DHHS). DHHS reserves the right to review any other data determined by DHHS to have been generated under 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.

Contractor shall provide data or data analysis to Contracting Officer and Contracting Officer Representative within 20 business days of request.

ARTICLE H.18. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

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

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

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

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

ARTICLE H.19. REQUIREMENTS FOR ADEQUATE ASSURANCE OF PROTECTION OF VERTEBRATE ANIMAL SUBJECTS

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines "animal" as "any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes." This Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.

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

ARTICLE H.20. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.21. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

ARTICLE H.22. EXPORT CONTROL NOTIFICATION

Offerors are responsible for ensuring compliance with all export control laws and regulations that maybe applicable to the export of and foreign access to their proposed technologies. Offerors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

ARTICLE H.23. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor 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 principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. For the purposes of this part relating to financial interests, "Investigator" includes the Investigator's spouse and dependent children. 45 CFR Part 94 is available at the following Web site: 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

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

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each

investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.24. QA AUDIT REPORTS

BARDA reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications
- Contractor shall notify the COR and CO within 5 business days of report completion.

ARTICLE H.25. BARDA AUDITS

Contractor shall accommodate periodic or ad hoc site visits by BARDA. If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA.

- If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to BARDA.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: https://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:

FARCLAUSE NO.	DATE	TITLE
52.202-1	*Jan 2012*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*Apr 1984*	*Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)*
52.203-6	*Sep 2006*	*Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)*
52.203-7	*Oct 2010*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*Jan 1997*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*Jan 1997*	*Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-12	*Oct 2010*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)*
52.204-7	*Feb 2012*	*Central Contractor Registration*
52.204-10	*Feb 2012*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)*
52.209-6	*Dec 2010*	*Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)*
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*

FAR CLAUSE NO.	DATE	TITLE
52.215-10	*Aug 2011*	*Price Reduction for Defective Certified Cost or Pricing Data (Over $700,000)*
52.215-12	*Oct 2010*	*Subcontractor Cost or Pricing Data (Over $700,000)*
52.215-14	*Oct 2010*	*Integrity of Unit Prices (Over the Simplified Acquisition Threshold)*
52.215-15	*Oct 2010*	*Pension Adjustments and Asset Reversions (Over $700,000)*
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 Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications*
52.215-22	*Oct 2009*	*Limitations on Pass-Through Charges – Identification of Subcontract Effort*
52.215-23	*Oct 2009*	*Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)*
52.216-7	*Jun 2011*	*Allowable Cost and Payment*
52.216-8	*Jun 2011*	*Fixed Fee*
52.219-8	*Jan 2011*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-9	*Jan 2011*	*Small Business Subcontracting Plan (Over $650,000, $1.5 million for Construction)*
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan (Over $650,000, $1.5 million for Construction)*
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*
52.222-19	*Mar 2012*	*Child Labor – Cooperation with Authorities and Remedies*
52.222-21	*Feb 1999*	*Prohibition of Segregated Facilities*
52.222-26	*Mar 2007*	*Equal Opportunity*
52.222-35	*Sep 2010*	*Equal Opportunity for Veterans ($100,000 or more)*
52.222-36	*Oct 2010*	*Affirmative Action for Workers with Disabilities*
52.222-37	*Sep 2010*	*Employment Reports on Veterans ($100,000 or more)*
52.222-40	*Dec 2010*	*Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)*
52.222-50	*Feb 2009*	*Combating Trafficking in Persons*

FAR CLAUSE NO.	DATE	TITLE
52.222-54	*Jan 2009*	*Employment Eligibility Verification (Over the Simplified Acquisition Threshold)*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-18	*Aug 2011*	*Encouraging Contractor Policies to Ban Text Messaging While Driving*
52.225-1	*Feb 2009*	*Buy American Act - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.225-25	*Nov 2011*	*Prohibition on Contracting with Entities Engaging in Sanctioned Activities Related to Iran – Representation and Certification*
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	*Dec 2007*	*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	*Dec 2007*	*Rights in Data — General*
52.227-16	*Jun 1987*	*Additional Data Requirements*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*Oct 2010*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*Jan 1986*	*Assignment of Claims*
52.232-25	*Oct 2008*	*Prompt Payment, Alternate I (Feb 2002)*
52.232-33	*Oct 2003*	*Payment by Electronic Funds Transfer—Central Contractor Registration*
52.233-1	*Jul 2002*	*Disputes*
52.233-2	*Sep 2006*	*Service of Protest*
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 2001*	*Penalties for Unallowable Costs (Over $700,000)*
52.242-4	*Jan 1997*	*Certification of Final Indirect Costs*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.242-15	*Aug 1989*	*Stop Work Order*
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate V (Apr 1984)*
52.244-2	*Oct 2010*	*Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over the Simplified Acquisition Threshold)*
52.244-6	*Dec 2010*	*Subcontracts for Commercial Items*
52.245-1	*Apr 2012*	*Government Property*
52.245-9	*Apr 2012*	*Use and Charges*
52.246-9	*Apr 1984*	*Inspection of Research and Development (Short Form)*
52.246-23	*Feb 1997*	*Limitation of Liability (Over the Simplified Acquisition Threshold)*
52.247-34	*Nov 1991*	*FOB Destination*
52.247-63	*Jun 2003*	*Preference for US Flag Air Carriers*
52.249-6	*May 2004*	*Termination (Cost-Reimbursement)*
52.249-14	*Apr 1984*	*Excusable Delays*
52.251-1	*Apr 2012*	*Government Supply Sources*
52.253-1	*Jan 1991*	*Computer Generated Forms*

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

HHSARCLAUSE NO.	DATE	TITLE
352.201-70	*Jan 2006*	*Paperwork Reduction Act*
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*
352.223-70	*Jan 2006*	*Safety and Health*
352.224-70	*Jan 2006*	*Privacy Act*
352.227-70	*Jan 2006*	*Publications and Publicity*
352.228-7	*Dec 1991*	*Insurance – Liability to Third Persons*
352.231-71	*Jan 2001*	*Pricing of Adjustments*
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*
352.270-4	*Jan 2006*	*Protection of Human Subjects*
352.270-6	*Jan 2006*	*Restrictions on Use of Human Subjects*

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 05/2012].

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

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

a. FAR Clause 52.217-9, Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days after the Government has completed its analysis of the deliverables associated with the applicable GO/NO GO Decision gate*;* provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days 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 5 years.

b. FAR Clause 51.219-1 Small Business Program Representations (Apr 2012)

(a) (1) The North American Industry Classification System (NAICS) code for this acquisition is 325411.

(2) The small business size standard is 750 employees.

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

(b) *Representations*.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Means a small business concern—

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

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

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

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

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

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

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

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

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

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

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

(d) *Notice*.

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

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

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

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

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

(End of 52.219-1)

c. FAR Clause 52.219-28, Post-Award Small Business Program Representation (April 2009).

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

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, which is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall represent its size status in accordance with the size standard in effect at the time of this representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/contractingopportunities/officials/size/index.html .

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it [X] is, [ ] is not a small business concern under NAICS Code assigned to contract number.

b. FAR 52.232-99 Providing Accelerated Payment to Small Business Subcontractors (DEVIATION) (AUG 2012)

This clause implements the temporary policy provided by OMB Policy Memorandum M-12-16, Providing Prompt Payment to Small Business Subcontractors, dated July 11, 2012.

(a) Upon receipt of accelerated payments from the Government, the contractor is required to make accelerated payments to small business subcontractors to the maximum extent practicable after receipt of a proper invoice and all proper documentation from the small business subcontractor.
(b) Include the substance of this clause, including this paragraph (b), in all subcontracts, with small business concerns.
(c) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated 28 September 2012.

2. Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Reimbursement Type Contracts,

Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Reimbursement Type Contracts, 5 pages.

3. Financial Report of Individual Project/Contract, 1 page

4. Instructions for Completing Financial Report of Individual Project/Contract, 3 pages

5. Inclusion Enrollment Report

Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.

6. Research Patient Care Costs

Research Patient Care Costs, 1 page.

7. Report of Government Owned, Contractor Held Property

Report of Government Owned, Contractor Held Property, 1 page. Located at: http://rcb.cancer.gov/rcb-internet/forms/Govt-Owned-Prop.pdf **(Not Attached)**

8. Contractor Performance Metrics Reporting

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

1) Annual Representations and Certifications completed on the System for Award Management (SAM) website.

2) Human Subjects Assurance Identification Numbers:

Cytori Therapeutics, Inc.: FWA00007108

3) Animal Welfare Assurance Numbers (OLAW/PHS):

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*** Material has been omitted pursuant to a request for confidential treatment, and the omitted contents were filed separately with the Securities and Exchange Commission.