EX-10.7 4 s105258_ex10-7.htm EXHIBIT 10-7

Exhibit 10.7

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

Phase I: To advance commercialization efforts for IPdR (5-iodo-2-pyrimidinone-2'-deoxyribose), a prodrug of the radiosensitizer IUdR (5-iodo-2'-deoxyuridine). The Phase I will determine the scientific merit, feasibility and potential for commercialization of oral IPdR as a radiation sensitizer for use in cancer treatment. Administrative tasks will be completed to enable an IND for the Contractor; formulation of GMP manufactured IPdR into 250 mg capsules; submission of a letter of intent (LOI) to CTEP; protocol preparation and IRB approval for the proposed Phase I clinical trial and establishment of companion diagnostics for analyzing clinical specimens from Phase I patients.
Phase II: To perform the first-in-human therapeutic trial assessing safety and pharmacokinetics of 5-iodo-2- pyrimidinone-2'-deoxyribose (IPdR), as a radiosensitizer for cancer treatment. The Phase I clinical trial and PK study will be performed as the first step in the plan to commercialize IPdR.

ARTICLE B.2. PRICES

a. The total fixed price of this contract is $191,971.

b. Upon delivery and acceptance of the item specified in the DELIVERY Article in SECTION F and described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit prices set forth below:

PAYMENT SCHEDULE

Description	Invoice #	Period Covered	Amount
PDF Kick-Off Presentation	HHSN261201400013C - 01	Month 1	$ 47,993
Quarterly Report 1	HHSN261201400013C - 02	Month 2-3	$ 47,993
Quarterly Report 2	HHSN261201400013C - 03	Month 4-6	$ 47,993
Draft Commercialization Plan, Draft Final Report	HHSN261201400013C - 04	Start date of contract through one month prior to contract completion date	$ 23,996
PDF of Final Presentation, Final Report, Summary of Salient Results, Final Commercialization Plan	HHSN261201400013C - 05	Entire Contract Period of Performance	$ 23,996
TOTAL FIXED PRICE			$ 191,971

ARTICLE B.3. OPTION FOR PHASE II

a. The fixed price of the Base Period (Phase I) of this contract is $191,971.

b. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)	Fixed Fee ($)	Estimated Cost Plus Fixed Fee ($)
Base Period 9/19/2014 - 6/18/2015	$ 181,105	$ 10,866	$ 191,971
Option Period: 6/19/2015 - 6/18/2017	$ 1,347,280	$ 80,837	$ 1,428,117
Total [Base Period and Option]	$ 1,528,385	$ 91,703	$ 1,620,088

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. **Indirect Costs**

1. In no event shall the final amount reimbursable for indirect costs exceed ceiling rates of 15% of Direct Labor for Fringe Benefits, 30% of Direct Labor for Overhead, and 12% of Direct Labor for G&A.

2. The Government is not obligated to pay any additional amount should the final indirect cost rates exceed these negotiated ceiling rates. In the event that the final indirect cost rates are less than these negotiated ceiling rates, the Government's obligation shall be reduced to conform to the lower rate.

   Any costs over and above this cost ceiling shall not be reimbursed under this contract or any other Government contract, grant, or cooperative agreement.

3. The Contractor shall complete all work in accordance with the Statement of Work, terms and conditions of this contract.

b. **Subcontract**

To negotiate a fixed price type subcontract with with Rhode Island Hospital for Phase I for an amount not to exceed $65.549 for the period 9/19/2014-6/18/2015 . Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

If the Government exercises its option for Phase II pursuant to the Option Provision Article in Section H of this contract, the total estimated Subcontract amount will be increased as follows:

Option 6/19/2015-6/18/2017 - $623,269

Consultant

c. **Consultants** Consultant fee(s) to be paid to the following individual(s): Phase II only

Name	Rate Per Hour	Number of Hours	Total Cost Including Travel Not to Exceed
Carl Schmidt, Commercialization Consultant, Phase II	$ 200	100	$ 20,000

d. **Scientific Meetings**

a. Travel to general scientific meetings shall be unallowable without the prior written approval of the Contracting Officer. No retroactive approvals will be issued, and no travel costs incurred without prior Contracting Officer approval will be paid.

b. All travel requests shall be sent to both the Contracting Officer and the Contracting Officer's Representative (COR) 90 calendar days prior to the planned start date of the travel. If it is determined that the travel is allowable, then the Contracting Officer will issue written approval.

e. **Contract Number Designation**

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. HHSN261201400013C
NCI Control No. N01CO-2014-00013 .

f. **SBIR Funding Agreement Certification**

The SBIR Funding Agreement Certification form, located in SECTION J, must be completed at the time of award prior to the performance of work under this contract, in accordance with the SBIR Policy Directive issued by SBA (October 18, 2012).

For additional information, see NIH Policy Notice NOT-OD-13-116, entitled, "New Program Certifications Required for SBIR and STTR Awards," located at: http://grants.nih.gov/grants/guide/notice-files/NOT- OD-13-116.html .

g. **SBIR Fast Track Recertification Requirement**

Phase I and Phase II SBIR awards are considered separate funding agreements under the Fast-Track Initiative. Therefore, Phase I Fast-Track awardees must recertify that they meet all of the eligibility criteria for an SBIR or STTR award prior to issuance of the Phase II award.

h. **Software Purchases**

All software purchases must first be approved in writing by the Contracting Officer.

ARTICLE B.5. PROVISONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

1. Conferences and Meetings
2. Food for Meals, Light Refreshments, and Beverages
3. Promotional Items *[includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees.]*
4. Acquisition, by purchase or lease, of any interest in real property;
5. Special rearrangement or alteration of facilities;
6. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
7. Travel to attend general scientific meetings;
8. Foreign travel;
9. Consultant costs;
10. Subcontracts;
11. Patient care costs;
12. Accountable Government Property (defined as non-expendable personal property with an acquisition cost of $1,000 or more and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to person use), regardless of acquisition value.
13. Printing Costs (as defined in the Government Printing and Binding Regulations).

b. **Travel Costs**

1. Domestic Travel

   Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $9,600 in Phase II without the prior written approval of the Contracting Officer.

2. The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.2 - Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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

Document Title	Date
Statement of Work - Phase I	August 25, 2014
Statement of Work - Phase II	August 25, 2014

b. Privacy Act System of Records Number 09-25-0200 is applicable to this contract and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Contracting Officer's Representative (COR).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in an electronic format via email as attachments to the following designated NCI Branch Distribution Mailbox.: Ncibranchbinvoices@mail.nih.gov

Each email submission shall contain only one deliverable, if the attached file for the deliverable exceeds 50 MB, the Contractor shall divide the deliverable into files of 50 MB each. All deliverables shall be limited to five file attachments or less.

The subject line of the email shall read as follows:

Deliverable_Contract Number_Vendor's Name_Deliverable Description_Due Date

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

a. **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:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

1. **Kick-off Presentation**

The Contractor shall prepare and submit a kick-off presentation. Presentation of the slides will occur either in-person, through Webinar, or teleconference. The presentation shall cover the following:

a. Discussion of the Contractor's organization/project status, particularly changes that occurred since the proposal submission.

b. The Contractor's recent achievements (patents, publications, sales, regulatory approvals, partnerships, awards, etc.).

c. Status of the field.

d. Status of commercial and academic competitors.

e. Where is the proposed project positioned against the state of the art.

f. Intellectual property landscape.

g. Refresher on the proposed technology/ R&D.

h. Detailed plan for the first budget period of the contract.

i. Milestones (technical and commercial) to be achieved by the end of the first budget period of the contract.

j. Discussion of anticipated technical risks and alternative approaches.

k. Questions to the NCI

2. Quarterly Report

Phase I

The Contractor shall submit two (2) Quarterly Reports which shall include:

a. Summary of technical objectives with status of each objective clearly marked (e.g. previously complete, complete during the reporting period, not started, etc.).

b. Clear description of activities accomplished in the quarter.

c. Analysis of experimental data and presentation of selected data.

d. Comments regarding the timeliness of performance.

e. Brief explanation of objectives/activities to be pursued in the next reporting period.

The report shall generally be no longer than five (5) pages excluding tables presenting the data, figures, images, and graphs.

Phase II

The Contractor shall submit Quarterly Reports which shall include the same information as required for the Phase I Quarterly Reports. The first reporting period in Phase II consists of the first full three (3) months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three (3) full calendar months.

The first Phase II Quarterly Report shall be due 15 calendar days after the first complete reporting period. Thereafter, report shall be due on or before the 15th calendar day following each reporting period.

3. Draft Updated Commercialization Plan

The Contractor shall submit an updated commercialization plan which shall include:

a. Value of the SBIR Project. Expected Outcomes, and Impact

Describe, in layperson's terms, the proposed project and its key technology objectives. State the product, process, or service to be developed in Phase III. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR contract integrates with the overall business plan of the company.

b. Organization

Give a brief description of the Contractor's organization including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the Contractor's organization. Indicate the Contractor's vision for the future, how the Contractor will grow/maintain a sustainable business entity, and how the Contractor will meet critical management functions as the Contractor's organization evolves from a small technology R&D business to a successful commercial entity.

c. Market, Customer, and Competition

Describe the market and/or market segments being targeted and provide a brief profile of the potential customer. Tell what significant advantages the Contractor's innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles the Contractor will have to overcome in order to gain market/customer acceptance of the Contractor's innovation. Describe any strategic alliances, partnerships, or licensing agreements the Contractor has in place to get FDA approval (if required) and to market and sell the Contractor's product. Briefly describe the Contractor's marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years.

d. Intellectual Property (IP) Protection

Describe how the Contractor is going to protect the IP that results from the Contractor's innovation. Also note other actions the Contractor may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to the Contractor's.

e. Finance Plan

Describe the necessary financing the Contractor will require to commercialize the product, process, or service, and when it will be required. Describe the Contractor's plans to raise the requisite financing to launch the Contractor's innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

- Letter of commitment of funding.
- Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.
- Letter of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation.
- Specific steps the Contractor is going to take to secure Phase III funding.

f. Production and Marketing Plan

Describe how the production of the Contractor's product/process/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps the Contractor will take to market and sell the Contractor's product/process/service. For example, explain plans for licensing, Internet sales, etc.

g. Revenue Stream

Explain how the Contractor plans to generate a revenue stream for the Contractor's organization should this project be a success. Examples of revenue stream generation include, but are not limited to; manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how the Contractor's staffing will change to meet the Contractor's revenue expectations.

The Draft Updated Commercialization Plan shall be submitted one (1) month before the the Phase I completion date. The Contracting Officer's Representative (COR) will provide comments regarding the Draft Updated Commercialization Plan within two (2) weeks from the receipt date of the document.

4. Draft Final Report and Draft Summary of Salient Results

Phase I

The Draft Final Report for Phase I shall consist of the work performed and results obtained for the entire contract period of performance of Phase I as stated in SECTION F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved.

The Draft Summary of Salient Results for Phase I shall be consist of a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

Both the Draft Final Report and Draft Summary of Salient Results for Phase I shall be submitted one (1) month before the the Phase I completion date. A Quarterly Report shall not be required for the period when the Phase I Final Report is due. The COR will provide comments regarding the Draft Final Report and Draft Summary of Salient Results for Phase I within two (2) weeks from the receipt date of the document.

Phase II

The Draft Final Report for Phase II shall consist of the work performed and results obtained for the entire contract period of performance of Phase II as stated in SECTION F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved.

The Draft Summary of Salient Results for Phase II shall consist of a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

Both the Draft Final Report and Draft Summary of Salient Results for Phase II shall be submitted one (1) month before the Phase II contract completion date. A Quarterly Report shall not be required for the period when the Phase II Final Report is due. The COR will provide comments regarding the Draft Final Report and Draft Summary of Salient Results for Phase II within two (2) weeks from the receipt date of the document.

5. Final Commercialization Plan

The Contractor shall provide the Final Commercialization Plan by the completion date of the Phase I portion of the contract. This document shall include the changes required in the Draft Updated Commercialization Plan as well as the comments provided by the COR.

6. Final Report

Phase I

The Contractor shall provide the Phase I Final Report by the completion date of the Phase I portion of the contract. This document shall include the changes required in the Phase I Draft Final Report as well as the comments provided by the COR.

Phase II

The Contractor shall provide the Phase II Final Report by the completion date of the Phase II portion of the contract. This document shall include the changes required in the Phase II Draft Final Report as well as the comments provided by the COR.

7. Final Presentation

Phase I

The Contractor shall prepare and submit a final presentation which shall be due on or before the completion date of Phase I portion of the contract. Presentation of the slides shall occur either in-person, through Webinar, or teleconference. The presentation shall cover the following:

a. Discussion of the Contractor's organization/project status.

b. The Contractor's achievements during the Phase I performance period (patents, publications, sales, regulatory approvals, partnerships, awards, etc.)

c. Detailed results of the performed research and development.

d. Discussion of proposed milestones and whether they were achieved during the contract performance.

e. Summary of submitted commercialization plan.

f. If the Contractor is interested in pursuing Phase II research, detailed discussion of the anticipated Phase II technical activities with emphasis on how they fit in the commercialization plan. The Phase II research plan and commercialization plan shall be included in the final presentation for Phase I.

g. Questions to the NCI.

Phase II

The Contractor shall prepare and submit a final presentation which shall be due on or before the completion date of Phase II portion of the contract. Presentation of the slides shall occur either in-person, through webinar, or teleconference. The presentation shall cover the following:

a. Discussion of the Contractor's/project status.

b. The Contractor's achievements during the performance period (patents, publications, sales, regulatory approvals, partnerships, awards, etc.).

c. Detailed technical results of the performed research and development.

d. Discussion of proposed milestones and whether they were achieved during the contract performance.

e. Summary of progress towards commercialization.

f. Questions to the NCI.

8. Final Summary of Salient Results

Phase I

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

Phase II

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

9. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Cumulative Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

b. **Other Reports/Deliverables**

1. **Reporting of Financial Conflict of Interest (FCOI) - Phase II**

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

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

(Reference subparagraph g. of the INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST Article in SECTION H of this contract.)

2. **Section 508 Annual Report**

The Contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: http://www.hhs.aov/web/508/contracting/technologv/vendors.html under "Vendor information and Documents."

3. **NIH Small Business Innovation Research (SBIR) Program Life Cycle Certification**

In accordance with the SBIR/STTR Reauthorization Act of 2011, the Contractor shall complete and submit the NIH Small Business Innovation Research (SBIR) Life Cycle Certification form, located in SECTION J of the contract, to the Contracting Officer. This certification is required to ensure the Contractor is meeting the program's requirements during the life cycle of the contract.

The Life Cycle Certification form shall be submitted as follows:

- Phase I SBIR Contractors shall submit the Certification at the time of receiving final payment or disbursement.
- Phase II SBIR Contractors shall submit the Certification prior to receiving more than 50% of the total contract amount**AND** prior to final payment or disbursement.

The Contracting Officer, may, at any time after award request further clarifications and supporting documentation in order to assist in the verification of any information provided by the Contractor.

For additional information, see NIH Policy Notice NOT-OD-13-116, entitled, "New Program Certifications Required for SBIR and STTR Awards," located at: http://grants.nih.gov/grants/guide/ notice-files/NOT-OD-13-116.html.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the completion date of the contract.

All reports shall be submitted in accordance with the DELIVERIES Article in SECTION F

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 email address specified in SECTION F.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

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.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
National Cancer Institute
9609 Medical Center Drive, Room 1W542, MSC 9706 Bethesda, MD 20892-9706

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from 09/19/2014 through 06/18/2015.

b. If the Government exercises its option pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
Option for Phase II	June 19, 2015 - June 18, 2017

ARTICLE F.2. DELIVERIES

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

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below:

Item No.	Description	Delivery Schedule
1.	SBIR Funding Agreement Certification	At time of award, prior to the performance of any work under this contract.
2.	Kick Off Presentation	Due at the conclusion of the Kick- Off presentation which shall be completed within 30 calendar days of contract award.
3.	Quarterly Report One - Phase 1	Due within 15 calendar days of completion of month 3 of performance.
4.	Quarterly Report Two - Phase 1	Due within 15 calendar days of completion of month 6 of performance.
5.	Draft Updated Commercialization Plan, Draft Summary of Salient Results, and Draft Final Report and Draft Final Report - Phase 1	Due one (1) month before the Phase I completion date.
6.	Final Presentation, Final Summary of Salient Results, Final Report and Final Presentation - Phase 1	Due on or before Phase I completion date.
7.	Quarterly Reports - Phase II	Within 15 calendar days after each reporting period.
8.	Draft Summary of Salient Results, and Draft Final Report and Draft Final Report - Phase II	One month prior to the Phase II completion date.
9.	Final Summary of Salient Results, Final Report and Final Presentation - Phase II	Due on or before the Phase II completion date.
10.	Final Presentation- Phase II	Due on or before the completion of Phase II.

Item No.	Description	Delivery Schedule
11.	Annual Technical Progress Report for Clinical Research Study Population (Cumulative Inclusion Enrollment Report) - **Phase II**	Due one year after the start of Phase II.
12.	Protection of Human Subjects Assurance Identification/I RB Certification/Declaration of Exemption", Form OMB No. 0990-0263	Prior to starting any work involving human subjects.
13.	Annual Utilization Report	Due one year after the start of Phase II.
14.	Final Invention Statement	Due on or before contract completion date.
15.	Invention Disclosure Report	Due on or before contract completion date.
16.	Section 508 Annual Report	Due one year after the start of Phase II.
17.	Section 508 Conformance Certification	Due on or before Phase I completion date.
18.	New or Revised Financial Conflict of Interest (FCOI) Report and Mitigation Report	Due as FCOI arises.
19.	SBIR Program Life Cycle Certification - **Phase 1**	Due on or before Phase I completion date.
20.	SBIR Program Life Cycle Certification - **Phase II - Report 1**	Due prior to receiving 50% of the total contract amount.
21.	SBIR Program Life Cycle Certification - **Phase II - Report 2**	Due on or before Phase II completion date.

b. The above items shall be addressed and emailed to ncibranchbinvoices@mail.nih.gov. The following addresses are provided for general correspondence and other deliveries:

Addressee	Deliverable Item No	Quantity
Andrea Giuliano, Contract Specialist National Cancer Institute Office of Acquisitions, Room 1E148 9609 Medical Center Drive, MSC 9705 Bethesda, MD 20892-9705	1-14, 16-21	Electronically
Deepa Narayanan, COR National Cancer Institute NCI SBIR & STTR Programs, Room 1W542 9609 Medical Center Drive, MSC 9705 Bethesda, MD 20892-9705	2-12	Electronically
OPERA, OEH, NIH 6705 Rockledge Drive Suite 310, MSC 7980 Bethesda, Maryland 20892-7980	13-15	1 Hard Copy

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, **Stop Work Order** (August 1989) (Applicable to Phase I)

52.242-15, Stop WorkOrder, Alternate I (April 1984) is applicable to Phase II of this contract.

52.242-17, Government Delay of Work (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

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

Deepa Narayanan, Ph.D.

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

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual is considered to be essential to the work being performed hereunder:

Name	Title
Theodore L. Phillips, M.D.	Principal Investigator

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice Instructions for **NIH Fixed-Price Type Contracts, NIH(RC)-2 (Phase I)** and Invoice/Financing Request Instructions and Contract Financial Reporting for **NIH Cost-Reimbursement Type Contracts NIH(RC)-4 (Phase II),** are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

a. The original invoice shall be submitted to the following designated billing office:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

b. One courtesy copy of the original invoice shall be submitted electronically as follows:

1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.

2. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Contractor Name_Invoice 123456") [Note: Please do not use special characters such as (#, $, %,*, &,!) when saving your attachment. Only the underscore symbol (_) is permitted.]

3. **Transmit** the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch B - ncibranchbinvoices@mail.nih.gov . Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

(e.g, HHSN261201400013C_Clinical Development of IPdR for Radiosensitizafion_Shuttle Pharmaceuticals, LLS_Invoice 12345) **[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.]**

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute.

   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [*Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   d. Invoice Matching Option. This contract requires a two-way match.

   e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

   f. The contract period of performance is: 9/19/2014 - 6/18/2015

   g. The Contract Title is:

      Clinical Development of IPdR for Radiosensitization

   h. Contract Line Items as follows:

Line Item #	**Line Item Description**
1	Clinical Development of IPdR for Radiosensitization

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

ARTICLE G.5. GOVERNMENT PROPERTY

a. 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, "HHS Contracting Guide for Contract of Government Property," which is incorporated into this contract by reference. This document can be accessed at:
http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf
Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Requests for information regarding property under this contract should be directed to the following office:

Division of Logistics Services, NIH
Property Management Branch
6011 Building, Suite 639
6011 EXECUTIVE BLVD MSC 7670
BETHESDA MD 20892-7670
nihcontractproperty@nih.gov

b. Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated in this contract in paragraph a. 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.

c. Contractor-Acquired Government Property - Schedule l-B

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor will be authorized to acquire the property listed in the attached Schedule l-B for use in direct performance of the contract, following receipt of the Contracting Officer’s written approval, based on contractor-furnished prices and evidence of competition. Schedule l-B is included as an attachment in SECTION J of this contract.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluations will be prepared Annually as determined by the Contracting Officer.

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.

b. Electronic Access to Contractor Performance Evaluations

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

http://www.cpars.gov

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

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

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. If at any time during 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.

(End of clause)

ARTICLE H.2. HUMAN SUBJECTS

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

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

ARTICLE H.3. RESTRICTION ON USE OF HUMAN SUBJECTS, HHSAR 352.270-6 (January 2006)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) designated under the Contractor's Federal-wide assurance of compliance. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

Prisoners shall not be enrolled in any HHS research activities until all requirements of HHS Regulations at 45 CFR PART 46, Subpart C have been met. If a Research Subject becomes a prisoner during the period of this contract, 45 CFR PART 46, Subpart C will apply to research involving that individual.

ARTICLE H.4. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

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

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

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

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

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

ARTICLE H.5. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

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

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

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

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

ARTICLE H.6. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/g,etdoc.cgi?dbname=110_cong_public_Iaws&docid=f:publ085.110.pdf, Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and

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

In addition, the Contractor shall notify the Contracting Officer's Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

The Contractor is the Sponsor, therefore the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).

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

ARTICLE H.7. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html.

ARTICLE H.8. NEEDLE DISTRIBUTION

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

ARTICLE H.9. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar *amount of* Federal funds for the project *or* program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.10. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.11. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

ARTICLE H.12. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.13. PRIVACY ACT, HHSAR 352.224-70 (January 2006)

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

(End of clause)

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

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: http:// oma.od.nih.gov/public/MS/privacy/PAfiles/read02svstems.htm.

ARTICLE H. 14. OMB CLEARANCE

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

ARTICLE H. 15. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

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

ARTICLE H. 16. GUN CONTROL

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

ARTICLE H. 17. CERTIFICATION OF FILING AND PAYMENT OF TAXES

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

ARTICLE H. 18. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 30 calendar days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the OPTION FOR PHASE II Article in SECTION B of this contract.

ARTICLE H. 19. LIMITATIONS ON SUBCONTRACTING - SBIR

Phase I - The Contractor shall perform a minimum of two-thirds of the research and/or analytical effort (total contract price less profit/fee) conducted under this contract. Any deviation from this requirement must be approved in writing by the Contracting Officer.

Phase II - The Contractor shall perform a minimum of one-half of the research and/or analytical effort (total contract price less profit/fee) conducted under this contract. Any deviation from this requirement must be approved in writing by the Contracting Officer.

ARTICLE H.20. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at http://www.section508.gov/. The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/guidelines-and-standards.

b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding $100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found on the HHS Web site (http://www.hhs.gov/ web/508/contracting/technology/vendors.html).

[(End of HHSAR 352.239-73(b)]

d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report: Annually
[End of HHSAR 352.239-73(c)]

ARTICLE H.21. CONFIDENTIALITY OF INFORMATION

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

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

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

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

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

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

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

The following information is covered by this article:

All data on participants in the clinical trial(s) performed under this contract.

ARTICLE H.22. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST - PHASE II

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site:: http://www.ecfr.gov/cgi-bin/text-idx? c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51 &idno=45 As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

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

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.

d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH- funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests.. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.23. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause**352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN261201400013C"

ARTICLE H.24. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.25. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. **Service Involving the Use of Information Technology**
   YEAR 2000 COMPLIANCE–SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

   The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

ARTICLE H.26. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE I 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: http://www. acquisition, gov/far/. HHSAR Clauses at: http:// www.hhs.gov/policies/hhsar/subpart352.html.

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

FAR CLAUSE NO.	***DATE***	***TITLE***
52.202-1	*Nov 2013*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-12	*Oct 2010*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*
52.203-17	*Apr 2014*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.204-10	*Jul 2013*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)*
52.204-13	*Jul 2013*	*System for Award Management Maintenance*
52.209-6	*Aug 2013*	*Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)*
52.215-8	*Oct 1997*	*Order of Precedence - Uniform Contract Format*
52.219-6	*Jul 1996*	*Notice of Total Small Business Set-Aside*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Feb 1999*	*Prohibition of Segregated Facilities*
52.222-26	*Mar 2007*	*Equal Opportunity*
52.222-35	*Jul 2014*	*Equal Opportunity for Veterans ($100,000 or more)*
52.222-36	*Jul 2014*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*Jul 2014*	*Employment Reports on Veterans ($100,000 or more)*
52.222-50	*Feb 2009*	*Combating Trafficking in Persons*
52.222-54	*Aug 2013*	*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	*May 2014*	*Buy American - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*Dec 2007*	*Authorization and Consent, Alternate I (Apr 1984)*
52.227-2	*Dec 2007*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.227-11	*May 2014*	*Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.*

FAR CLAUSE NO.	*DATE*	*TITLE*
52.227-20	*May 2014*	*Rights in Data - SBIR Program*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-23	*May 2014*	*Assignment of Claims*
52.232-25	*Jul 2013*	*Prompt Payment*
52.232-33	*Jul 2013*	*Payment by Electronic Funds Transfer-System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*May 2014*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.243-1	*Aug 1987*	*Changes - Fixed Price, Alternate V (Apr 1984)*
52.244-6	*Jul 2014*	*Subcontracts for Commercial Items*
52.249-1	*Apr 1984*	*Termination for the Convenience of the Government (Fixed-Price) (Short Form)*
52.249-9	*Apr 1984*	*Default (Fixed-Price Research and Development) (Over the Simplified Acquisition Threshold)*
52.253-1	*Jan 1991*	*Computer Generated Forms*

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

HHSAR CLAUSE NO.	*DATE*	*TITLE*
352.202-1	*Jan 2006*	*Definitions*
352.203-70	*Mar 2012*	*Anti-Lobbying*
352.222-70	*Jan 2010*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Jan 2006*	*Publications and Publicity*
352.231-71	*Jan 2001*	*Pricing of Adjustments*
352.242-70	*Jan 2006*	*Key Personnel*
352.242-73	*Jan 2006*	*Withholding of Contract Payments*

[End of GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE I CONTRACT- Rev. 08/2014].

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SBIR PHASE II 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: http://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs. gov/policies/hhsar/subpart352.html.

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

FAR CLAUSE NO.	***DATE***	***TITLE***
52.202-1	*Nov 2013*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*May 2014*	*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	*May 2014*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*May 2014*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*May 2014*	*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)*
52.203-17	*Apr 2014*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper (Over the Simplified Acquisition Threshold)*
52.204-10	*Jul 2013*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)*
52.204-13	*Jul 2013*	*System for Award Management Maintenance*
52.209-6	*Aug 2013*	*Protecting the Government's Interest 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*
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*

FAR CLAUSE NO.	*DATE*	*TITLE*
52.215-21	*Oct 2010*	*Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications*
52.215-23	*Oct 2009*	*Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)*
52.216-7	*Jun 2013*	*Allowable Cost and Payment*
52.216-8	*Jun 2011*	*Fixed Fee*
52.219-6	*Jul 1996*	*Notice of Total Small Business Set-Aside*
52.219-8	*May 2014*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-14	*Dec 1996*	*Limitations on Subcontracting*
52.222-2	*Jul 1990*	*Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Feb 1999*	*Prohibition of Segregated Facilities*
52.222-26	*Mar 2007*	*Equal Opportunity*
52.222-35	*Jul 2014*	*Equal Opportunity for Veterans ($100,000 or more)*
52.222-36	*Jul 2014*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*Jul 2014*	*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*
52.222-54	*Aug 2013*	*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	*May 2014*	*Buy American - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*Dec 2007*	*Authorization and Consent, Alternate I (Apr 1984)*
52.227-2	*Dec 2007*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.227-11	*May 2014*	*Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.*
52.227-20	*May 2014*	*Rights in Data - SBIR Program*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*May 2014*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*May 2014*	*Assignment of Claims*
52.232-25	*Jul 2013*	*Prompt Payment, Alternate I (Feb 2002)*
52.232-33	*Jul 2013*	*Payment by Electronic Funds Transfer–System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*May 2014*	*Disputes*

FAR CLAUSE NO.	*DATE*	*TITLE*
52.233-3	*Aug 1996*	*Protest After Award, Alternate I (Jun 1985)*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-1	*Apr 1984*	*Notice of Intent to Disallow Costs*
52.242-3	*May 2014*	*Penalties for Unallowable Costs (Over $700,000)*
52.242-4	*Jan 1997*	*Certification of Final Indirect Costs*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate V (Apr 1984)*
52.244-2	*Oct 2010*	*Subcontracts (Over the Simplified Acquisition Threshold), Alternate 1 (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over the Simplified Acquisition Threshold)*
52.244-6	*Jul 2014*	*Subcontracts for Commercial Items*
52.245-1	*Apr 2012*	*Government Property*
52.245-9	*Apr 2012*	*Use and Charges*
52.249-6	*May 2004*	*Termination (Cost-Reimbursement)*
52.249-14	*Apr 1984*	*Excusable Delays*
52.253-1	*Jan 1991*	*Computer Generated Forms*

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

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

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT SBIR PHASE II CONTRACT- Rev. 08/2014].

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

a. **Alternate I** (October 1997) of FAR Clause **52.215-14, Integrity of Unit Prices** (October 2010) is added.

b. The following clauses are added to this contract (Phase I only):

- FAR Clause **52.203-3, Gratuities** (April 1984)
- FAR Clause **52.203-5, Covenant Against Contingent Fees** (May 2014)
- FAR Clause **52.203-6, Restrictions on Subcontractor Sales to the Government** (September 2006)
- FAR Clause **52.203-7, Anti-Kickback Procedures** (May 2014)
- FAR Clause **52.203-8, Cancellation, Recission, and Recovery of Funds for Illegal or Improper Activity** (May 2014)
- FAR Clause **52.203-10, Price or Fee Adjustment for Illegal or Improper Activity** (May 2014)
- FAR Clause **52.204-4, Printed or copied Double-Sided on Postconsumer Fiber Content Paper** (May 2011)
- FAR Clause **52.215-2, Audit and Records Negotiation** (October 2010)
- FAR Clause **52.215-14, Integrity of Unit Prices** (October 2010)
- FAR Clause **52.219-8, Utilization of Small Business Concerns** (May 2014)
- FAR Clause **52.219-14, Limitations on Subcontracting** (December 1996)
- FAR Clause **52.222-40, Notification of Employee Rights Under the National Labor Relations Act** (December 2010)
- FAR Clause **52.229-3, Federal, State and Local Taxes** (February 2013)
- FAR Clause **52.232-2, Payments under Fixed-Price Research and Development Contracts** (April 1984)
- FAR Clause **52.232-17, Interest** (May 2014)
- FAR Clause **52.242-13, Bankruptcy** (July 1995)
- FAR Clause **52.244-5, Competition in Subcontracting** (December 2010)

The following clause(s) is substituted as follows:

- FAR Clause **52.249-1, Termination for the Convenience of the Government (Fixed-Price)(Short Form)** (April 1984) is deleted in its entirety and **FAR Clause 52.249-2, Termination for the Convenience of the Government (Fixed Price)** (April 2012) is substituted therefor.

c. **Alternate I** (February 2002), of FAR Clause **52.232-25, Prompt Payment** (July 2013) is deleted.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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.

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

1. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

2. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

3. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

4. FAR Clause **52.224-2, Privacy Act** (April 1984).

5. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

6. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

7. FAR Clause **52.244-5, Competition in Subcontracting** (December 1996).

8. **Alternate I** (April 2012), FAR Clause **52.245-1, Government Property** (April 2012).

9. FAR Clause **52.246-23, Limitation of Liability** (February 1997).

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

1. HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).

2. HHSAR Clause **352.231-70, Salary Rate Limitation** (August 2012).

Note: P.L. 113-76 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective January 17, 2014.

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

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

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

1. **NIH(RC)-11, Research Patient Care Costs** (4/1/84)

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

This contract incorporates the following clauses in full text.

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

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

a. The Government may extend the term of this contract by written notice to the Contractor within 15 calendar days before the contract expires; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 calendar 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 five (5) years.

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

THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

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 - Phase I, dated 08/25/2014, 2 pages.

Statement of Work - Phase II, dated 08/25/2014, 3 pages.

2. Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2

Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2, (8/12), 3 pages.

3. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost- Reimbursement Type Contracts, NIH(RC)-4

Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, (8/12), 6 pages.

4. Cumulative Inclusion Enrollment Report

Cumulative Inclusion Enrollment Report, PHS 398/2590, (Rev. 08/12), 1 page. Located at:

http://grants.nih.gov/grants/funding/phs398/CumulativelnclusionEnrollmentReport.pdf

5. Privacy Act System of Records, Number

Privacy Act System of Records, Number 09-25-0200,10 pages.

6. Research Patient Care Costs

Research Patient Care Costs, NIH(RC)-11, 4/1/84,1 page.

7. Disclosure of Lobbying Activities, SF-LLL

Disclosure of Lobbying Activities, SF-LLL, dated 7/97, 2 pages.

8. Government Property - Schedule IB

Government Property - Schedule IB, dated September 19, 2014, 1 page.

9. Report of Government Owned, Contractor Held Property

Report of Government Owned, Contractor Held Property, dated 3/2008,1 page. Located at:http://oamp.od.nih.gov/ sites/default/files/DGS/contracting-forms/Govt-Owned-Prop.pdf

10. NIH Small Business Innovation Research (SBIR) Program Funding Agreement Certification

NIH Small Business Innovative Research (SBIR) Program Funding Agreement Certification, 3 Pages.

11. NIH Small Business Innovation Research (SBIR) Program Life Cycle Certification

NIH Small Business Innovative Research (SBIR) Program Life Cycle Certification, 3 pages.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Annual Representations and Certifications are completed and located in The System for Award Management (SAM) website (http://www.sam.gov). This includes the changes identified in paragraph (b) of the FAR provision 52.204-8, Annual Representations and Certifications, contained in the Contractor's proposal.

2. NIH Representations & Certifications, dated February 2013

4. Human Subjects Assurance Identification Number FWA00022203.

END of the SCHEDULE

(CONTRACT)

Shuttle Pharmaceuticals, LLC
HHSN261201400013C
August 25, 2014

STATEMENT OF WORK - PHASE I SBIR

I. Background Information and Objectives

A. Background information

The objective of this project is to advance commercialization efforts for IPdR (5 -iodo- 2pyrimidinone-2'-deoxyribose), a prod rug of the radiosensitizer lUdR (5-iodo-2'- deoxyuridine). In Phase I, the Contractor shall determine the scientific merit, feasibility and potential for commercialization of oral IPdR as a radiation sensitizer for use in cancer treatment. Administrative tasks shall be completed to enable an IND for the Contractor; formulation of GMP manufactured IPdR into 300 mg capsules; submission of a letter of intent (LOI) to CTEP; protocol preparation and IRB approval for the proposed Phase I clinical trial and establishment of companion diagnostics for analyzing clinical specimens from Phase I patients. The tasks detailed for the Phase I effort are intended to facilitate an IND for IPdR for the Contractor.

B. Technical Objectives

Objective 1. Activate the IPdR IND to enable the Contractor to provide GMP IPdR to the sub-contractor (BrUOG/RIH) for the Phase I and PK clinical trial.

Task 1.1. The Contractor shall file administrative documents to initially cross-file (IND 70,333) and obtain an IND for IPdR to enable performance of the Phase I and PK study at Brown University (Lifespan/RIH).
Milestone 1.1. The Contractor shall cross-file on the IPdR IND currently held by CTEP to permit performance of the Phase I clinical trial in Phase II of this contract.
Task 1.2. The Contractor shall negotiate an agreement with CTEP to transfer sufficient cGMP clinical product IPdR from the NCI DTP to the Contractor for performance of the clinical trial.
Milestone 1.2. Bulk cGMP drug shall be formulated into clinical product (encapsulated) IPdR, 250 mg capsules, for use in the proposed Phase I and PK clinical trial.
Task 1.3. The Contractor shall formulate and encapsulate cGMP IPdR into capsules **(**250 and 500 mg).
Milestone 1.3. IPdR in capsules of 300 mg shall be available for the Phase I and PK clinical trial.

Objective 2. Obtain approvals for the Phase I and PK clinical protocol from Brown University (Lifespan/Rhode Island Hospital) and CTEP. Develop efficacy protocols satisfying FDA "Orphan Drug" status.

Task 2.1. The Contractor shall submit a Letter of Intent (LOI) to NCI CTEP for approval of the Phase I and PK clinical studies of IPdR.
Milestone 2.1. The Contractor shall obtain a favorable response to an LOI to NCI CTEP for Phase I and PK studies.
Task 2.2. The Contractor shall obtain IRB approval of the complete Phase I and PK study
Milestone 2.2. IRB approved Phase I for safety and feasibility of IPdR + RT.
Task 2.3. The Contractor shall consult with the FDA regarding "Orphan Drug" status for IPdR as a radiosensitizing drug for use in rectal cancer treatment

Milestone 2.3. The Contractor shall obtain FDA guidance on requirements for IPdR approval as an "Orphan Drug" leading to a strategy to accomplish this task.

Objective 3. Establish the in-house (Shuttle Pharmaceuticals, LLC Laboratories) biomarker assays for evaluating clinical specimens to be obtained from patients entering IPdR clinical trials.

Task 3.1. The Contractor shall establish plasma IPdR—>IUdR—>IU PK and %IUdR-DNA cellular incorporation assays in the Contractor's laboratories for use in patient plasma and tissue samples during the IPdR Phase I and PK dose escalation.
Milestone 3.1. The Contractor shall optimize LC/MS/MS PK, HPLC and flow cytometry assays for %IUdR-DNA incorporation in cells.
Task 3.1. The Contractor shall complete the Phase I work plan and report progress and achieved milestones to NIH to allow the project to progress to the Phase II work plan.
Milestone 3.2. The Contractor shall prepare a written report of Phase I progress and achieved milestones submitted and accepted by NIH.

II. Services to be performed

A. General Requirements

1. The Contractor shall independently perform all work and furnish all labor, materials, supplies, equipment and services (except as otherwise specified in the contract)

2. All work shall be monitored by the Government Contracting Officer's Representative.

B. Specific Requirements are summarized in Gantt Chart 1:

Chart 1. Phase I. Milestones, Deliverables, Timeline and Work Distribution between the Contractor and Lifespan/Rhode Island Hospital (L/RIH).

Site	Milestones and Deliverables	Months								
		1	2	3	4	5	6	7	8	9
SP, L/RIH	*Objective 1. Task 1.1.* **Milestone 1.1.** Activation of the IPdR IND									
SP	*Objective 1. Task 1.2.* **Milestone 1.2. I**PdR clinical product is obtained from CTEP suitable for use in the Phase I clinical trial									
SP	*Objective 1. Task 1.3.* **Milestone 1.3.** Sufficient quantity of 300 mg capsules of IPdR are provided to complete the Phase I clinical trial.									
SP, L/RIH	*Objective 2. Task 2.1.* **Milestone 2.1.** NCI CTEP approval of the Phase I and PK LOI.									
SP, L/RIH	*Objective 2. Task 2.2.* **Milestone 5.** The Phase I clinical trial receives IRB approval.									
SP	*Objective 2. Task 2.3.* **Milestone 6.** FDA provided advice for "Orphan Drug" status for IPdR in rectal cancer treatment.									
SP	*Objective 3. Task 3.1.* **Milestone 3.1.** The %IUdR-DNA cellular incorporation assays for Phase II is established in Shuttle Pharmaceuticals laboratories.									
SP	*Objective 3. Task 3.2.* **Milestone 3.2.** Written final report of achieved Phase I SBIR milestones to advance to the Phase II SBIR.work plan.									

Shuttle Pharmaceuticals, LLC
HHSN261201400013C
August 25, 2014

STATEMENT OF WORK - PHASE II SBIR

I. Background Information and Objectives

A. Background information

Although radiosensitization is integral to the treatment of many types of human cancers, the drugs currently available are also cytotoxic, and there is no drug with FDA approval for the indication of radiosensitization. IPdR represents a potential first-in-class non-cytotoxic radiation sensitizer to biologically enhance radiation therapy effects on cancers. In Phase II, the Phase I clinical trial will be performed to determine safety and feasibility. This shall allow the Contractor to advance its proposed commercialization plan and to raise capital for efficacy clinical trials leading to FDA approval.

B. Technical Objectives

Objective 1: Perform the Phase I and PK clinical trial of IPdR-mediated radiosensitization in patients with locally advanced gastrointestinal cancers, presenting for palliative radiation therapy to the abdominal and/or pelvic regions.

The Contractor shall:

Task 1.1. Perform the Phase I clinical trial.
Milestone 1.1. Initiation and performance of the Phase I and PK clinical trial of lUdR with RT.
Milestone 1.3. Collect and transfer clinical samples to the Contractor's laboratories for analysis.

Objective 2: Perform PK analyses to determine optimal dosing schedule of IPdR and perform biomarker assays of %IUdR-DNA cellular incorporation in clinical specimens.

The Contractor shall:

Task 2.1. Determine pharmacokinetics (PK) and %IUdR-DNA for biomarker analysis.
Milestone 2.1. Obtain and analyze clinical specimens for PK & %IUdR-DNA determinations.
Milestone 2.2. Perform PK analyses.
Milestone 2.3. Determine and correlate %IUdR-DNA incorporation with clinical observations.

Objective 3: Use results of the Phase I and PK clinical trial to design the Phase IB/ll clinical trials in patients with rectal cancers.

The Contractor shall:

Task 3.1. Analyze the PK data to determine optimal IPdR dosing.
Milestone 3.1. Establish optimum dosing schedule of IPdR, based on PK data.
Task 3.2. Design and write the Phase IB/ll protocol for efficacy determination.
Milestone 3.2. Write Phase IB/ll clinical protocol for IPdR and RT in rectal cancer.

Objective 4: Advance the business development and commercialization plan for company sustainability

The Contractor shall:

Task 4.1. Advance results of the Phase I clinical trial to raise capital for efficacy clinical trials of IPdR and RT.
Milestone 4.1. Ensure that the written business development and commercialization plan is available for entering capital markets to commercialize IPdR.
Task 4.2. Prepare and submit a final written report to the Government at the conclusion of the Phase II contract.
Milestone 4.1. Submit written final progress report.

II. Services to be performed

A. General Requirements

1. The Contractor shall independently perform all work and furnish all labor, materials, supplies, equipment and services (except as otherwise specified in the contract)

2. All work shall be monitored by the Contracting Officer's Representative.

B. Specific Requirements

The tasks are detailed for the Phase II effort, intended to perform the Phase I clinical trial and PK study for IPdR for Shuttle Pharmaceuticals are summarized in Gantt Chart 2:

Chart 2. Phase II Milestones, Deliverables and Work Distribution between the Contractor and Lifespan/Rhode Island Hospital (L/RIH) for Clinical Development of IPdR as a Radiosensitizer.

		Delivery Schedule (months)											
Site	**Milestones and Deliverables**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**18**	**20**	**22**	**24**
L/RIH	Obiective 1. Task 1.1												
	Milestone 1.1. Initiation and performance of the Phase I and PK clinical trial of lUdR with RT.												
	Milestone 1.2. Safety and MTD parameters for IPdR with RT.												
	Milestone 1.3. Collect and transfer clinical samples to SP Labs.												
L/RIH	Obiective 2. Task 2.1.												
SP	**Milestone 2.1.** Obtain clinical specimens for PK & %IUdR-DNA												
	Milestone 2.2. PK analyses												
	Milestone 2.3. %IUdR-DNA incorporation is determined and correlated with clinical observations.												
SP	Obiective 3: Task 3.1.												
	Milestone 3.1. Dosing schedule of IPdR is established, based on PK												
SP	Obiective 3: Task 3.2.												
	Milestone 3.2. Written Phase IB/ll clinical protocol												
SP	Obiective 4: Task 4.1.												
	Milestone 4.1 Written business and commercialization plan.												
SP,	Obiective 4: Task 4.2.												
L/RIH	**Milestone 4.2.** Final report submitted to NIH.												

INVOICE INSTRUCTIONS FOR NIH FIXED-PRICE CONTRACTS. NIH(RC)-2

Format: Submit payment requests on Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, or the Contractor's self-generated form provided it contains all of the information prescribed herein. DO NOT include a cover letter with the payment request.

Number of Copies: Submit payment requests in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Submit payment requests upon delivery and acceptance of goods or services unless otherwise authorized by the Contracting Officer.

Currency: All NIH contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Preparation and Itemization of the Payment Request: Prepare payment requests as follows:

Note: All information must be legible or the invoice will be considered improper and returned to the Contractor.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract. Any invoice identified as improper will be sent to this address. Also include the name, title, phone number, and e-mail address of the Point of Contact in case of questions. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Data Universal Numbering System (DUNS) or DUNS+4 number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract, and as registered in the System for Acquisition Management (SAM) database.

When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and DUNS number), with the remittance information clearly identified as such.

(c) **Invoice/Voucher Number:** Identify each payment request by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order. Payment requests with duplicate invoice numbers will be considered improper and returned to the contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the contractor chooses to reclaim those costs on a supplemental invoice, the contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised (example: 8675309-05R).

(d) **Date Invoice/Voucher Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (as applicable).

(f) **Contract Title:** Insert the contract title listed on the cover page of the contract and/or Section G of the Contract Schedule.

(g) **Current Contract Period of Performance:** Insert the contract start date/effective date through the current completion date of the contract.

(h) **Total Fixed-Price of Contract/Order:** Insert the total fixed-price of the contract/order.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Identify the Central Point of Distribution, as specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(I) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Description of Supplies or Services:** Provide a description of the supplies or services, by line item (if applicable), quantity, unit price (where appropriate), and total amount. The item description, unit of measure, and unit price **must match** those specified in the contract. For example, if the contract specifies 1 box of hypodermic needles (100/box) with a unit price of $50.00, then the invoice must state 1 box, hypodermic needles (100/box), $50.00, **not** 100 syringes at $0.50 each. Invoices that do not match the line item pricing in the contract will be considered improper and will be returned to the Contractor.

(n) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period, including any adjustments, if applicable. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request.

(o) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed to date, including any adjustments as applicable. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request.

(p) **Freight or Delivery Charges:** Identify all charges for freight or express shipments, other than f.o.b. destination, as a separate line item on the invoice. (If shipped by freight or express, and charges are more than $25, attach prepaid bill.)

(q) **Government Property:** If the contract authorizes the purchase of any item of Government Property (e.g., equipment), the invoice must list each item for which reimbursement is requested. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and
- Contracting Officer Authorization (COA) Number, if the equipment is not covered by the Property Schedule.

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR NIH COST-REIMBURSEMENT CONTRACTS. NIH(RC)-4

Format: Submit payment requests on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Submit payment requests in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: : If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall cite the amount(s) and month(s) in which the costs were incurred.

Contractor's Fiscal Year: Prepare payment requests in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract shall not exceed the United States dollars authorized.

Costs Requiring Advance Approval: Costs requiring advance approval by the Contracting Officer, which are not set forth in the Contract Schedule shall be identified by the Contracting Officer's Authorization (COA) Number as a separate expenditure category on the payment request. In addition, the Contractor shall show any cost limitation or ceiling set forth in the Contract Schedule, i.e. an Advance Understanding, as a separate expenditure category on the payment request.

Invoice/Financing Request Identification: Identify each payment as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** Submit the completion invoice promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and all performance provisions have been completed.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request:

The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.***All information must be legible or the invoice will be considered improper and returned to the Contractor.***

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract. Any invoice identified as improper will be sent to this address. Also include the name, title, phone number, and e-mail address of the Point of Contact in case of questions. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Data Universal Numbering System (DUNS) or DUNS+4 number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract, and as registered in the System for Award Management (SAM) database.

When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and DUNS number), with the remittance information clearly identified as such.

(c) **Invoice/Financing Request Number:** Identify each payment request by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order. Payment requests with duplicate invoice numbers will be considered improper and returned to the contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the contractor chooses to reclaim those costs on a supplemental invoice, the contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised (example: 8675309-05R).

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (as applicable).

(f) **Contract Title:** Insert the contract title exactly as it appears on the cover page of the contract and/or Section G of the Contract Schedule.

(g) **Current Contract Period of Performance:** Insert the contract start date/effective date through the current completion date of the contract.

(h) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fee. If billing under an order, insert the total estimated cost of the order, exclusive of fee. For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment.

(i) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable). For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment (where applicable). **Note:** *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, insert the amount available to be earned as identified in the contract and indicate the type of fee to be billed on the payment request.*

(j) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(I) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(m) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(n) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(p) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract.

For Level of Effort contracts only, the Contractor shall provide the following information on a separate sheet of paper attached to the payment request:

- hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the Contract Schedule) for the current billing period, and

- hours or percentage of effort and cost by labor category from contract inception through the current billing period. (NOTE: The Contracting Officer may require the Contractor to provide additional breakdown for direct labor, such as position title, employee name, and salary or hourly rate.)

2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Cite the rate(s) used to calculate fringe benefit costs, if applicable.

3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Contract of Government Property).* Show permanent research equipment separate from general purpose equipment.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Precede the item with an asterisk (*) if the equipment is below the $1,000 approval level. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and,
- Contracting Officer Authorization (COA) number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

4) Materials and Supplies: Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

5) Premium Pay: List remuneration in excess of the basic hourly rate.

6) Consultant Fee: List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

7) Travel: Include domestic and foreign travel. Foreign travel is travel outside of the United States and its territories and possessions. However, for an organization located outside the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

8) Subcontract Costs: List subcontractor(s) by name and amount billed.

9) Other: List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(q) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(r) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(s) **Fixed-Fee***:* Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract. **Note:** *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, provide the same documentation for the amount claimed.*

(t) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(u) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(v) **Grand Totals**

(w) **Certification:** The Contractor shall include the following certification at the bottom of each payment request:

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

Note*: The contract may require additional certifications (See Invoice Submission Instructions in Section G of the Contract Schedule)*

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim payment requests.

FINANCIAL REPORTING INSTRUCTIONS:

These instructions correspond to the Columns on the Sample Invoice/Financing Request.

Column A - Expenditure Category: Enter the expenditure categories required by the contract.

Column B - Cumulative Percentage of Effort/Hrs. Negotiated: Enter the percentage of effort or number of hours agreed to for each employee or labor category listed in Column A.

Column C - Cumulative Percentage of Effort/Hrs. Actual: Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D - Amount Billed - Current: Enter amounts billed during the current period.

Column E - Amount Billed - Cumulative: Enter the cumulative amounts to date.

Column F - Cost at Completion: Enter data only when the Contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G - Contract Amount: Enter the costs agreed to for all expenditure categories listed in Column A.

Column H - Variance (Over or Under): Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission **shall not** be deemed as notice under the Limitation of Cost Clause in the contract.

Modifications: List all new modification(s) (not previously reported) in the amount negotiated for an item in the appropriate cost category.

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the Contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address:
National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B432, MSC 8500
Bethesda, MD 20892-8500

(b) Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number:
ABC CORPORATION
100 Main Street
Anywhere, U.S.A. Zip+4
Name, Title, Phone Number, and E-mail Address of Contractor's Point of Contact.
DUNS or DUNS+4:_____
TIN:_____

(c) Invoice/Financing Request No.:_____
(d) Date Invoice/Financing Request Prepared:
_____
(e) Contract No. and Order No. (if applicable):
_____
(f) Contract Title:
_____
(g) Current Contract Period of Performance:
_____
(h) Total Estimated Cost of Contract/Order:
_____
(i) Total Fixed Fee (if applicable):_____

(j) Two-Way Match:____
Three-Way Match:_____
(k) Office of Acquisitions:_____
(l) Central Point of Distribution:_____

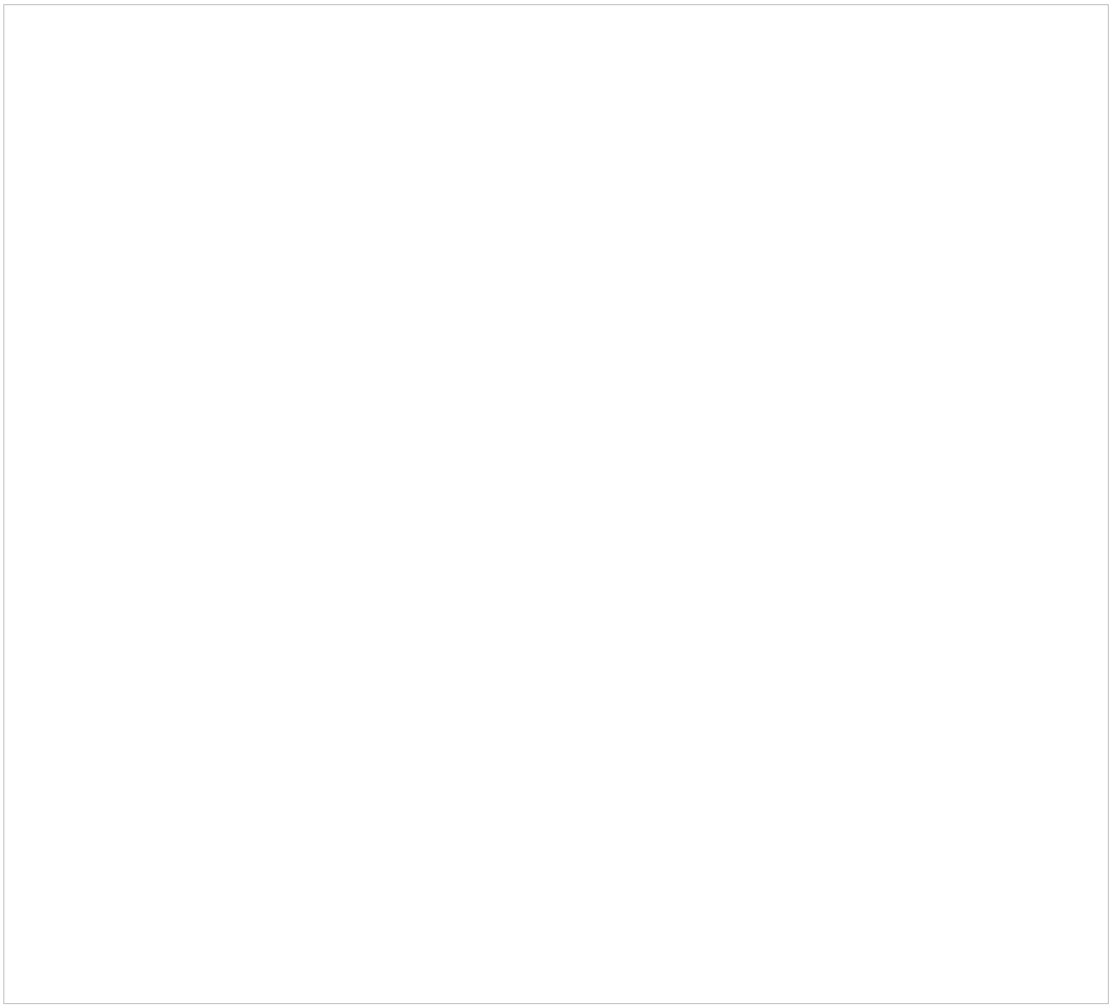
(m) This invoice/financing request represents reimbursable costs for the period from _____ to _____.

Expenditure Category* A	Cumulative % of Effort/Hrs Neg. B	Actual C	Amount Billed (n) Current D	(o) Cum E	Cost at Comp F	Contract Value G	Variance H
(p) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits __%							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(a) Cost of Money __%							
(r) Indirect Costs ___%							
(s) Fixed Fee ___%							
(t) Total Amount Claimed							
(u) Adjustments							
(v) Grand Totals							

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

_____ _____
(Name of Official) (Title)

*Attach details as specified in the contract or requested by the Contracting Officer



09-25-0200 SYSTEMS LISTING

SYSTEM NAME:

Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at NIH and Contractor research facilities which collect or provide research data for this system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored, is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Adults and/or children who are the subjects of clinical, basic, or population-based research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: name, study identification number, address, relevant telephone numbers, social security number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curricula vitae); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Research and Investigation," "Appointment and Authority of the Directors of the National Research Institutes," "National Cancer Institute," "National Eye Institute," "National Heart, Lung and Blood Institute," "National Institute on Aging," "National Institute on Alcohol Abuse and Alcoholism," "National Institute on Allergy and Infectious Diseases," "National Institute of Arthritis and Musculoskeletal and Skin Diseases," "National Institute of Child Health and Human Development," "National Institute on Deafness and Other Communication Disorders," "National Institute of Dental and Craniofacial Research," "National Institute of Diabetes, and Digestive and Kidney Diseases," "National Institute of Drug Abuse," "National Institute of Environmental Health Sciences," "National Institute of Mental Health," "National Institute of Neurological Disorders and Stroke," and the "National Human Genome Research Institute" of the Public Health Service Act. (42 U.S.C. 241,242,248,281, 282,284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 2851, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S):

To document, track, monitor and evaluate NIH clinical, basic, and population-based research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1 .A re cord may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241,42 U.S.C. 290dd-2,42 CFR Part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR Part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of r ecords to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is, therefore, deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social security numbers, date of birth and other identifiers may be disclosed: (1) to the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.
6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in research studies.
7. PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

   PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain disea ses and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.
9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.
10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.
11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEV ABILITY:

During data collection stages and follow-up, retrieval is by personal identifier (e.g., name, social security number, medical record or study identification number, etc.). During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

1. Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.
2. Physical Safeguards: Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.
3. Procedural Safeguards: Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.
4. Implementation Guidelines: These practices are in compliance with the standards of Chapter 45- 13 of the HHS General Administration Manual, “Safeguarding Records Contained in Systems of Records,” supplementary Chapter PHS hf: 45-13, and the HHS Automated Information Systems Security Program Handbook.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix IB “Keeping and Destroying Records” (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions.

SYSTEM MANAGER(S) AND ADDRESS(ES):

See Appendix I for a listing of current System Managers. This system is for use by all NIH Institutes and Centers.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate IC Privacy Act Coordinator listed below. In cases where the requester knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requester must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to designate, in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship.

If the requester does not know which Institute or Center Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address: NIH Privacy Act Officer, Office of Management Assessment, 6011 Executive Blvd., Room 601L, Rockville, MD 20852.

NIH Privacy Act Coordinators

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, Clinical Center (CC), Building 10, Room 1N208, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Center for Complementary and Alternative Medicine (NCCAM), Building 31, Room 2B11, 31 Center Drive, Bethesda, MD 20892-2182.

Privacy Act Coordinator, National Cancer Institute (NCI), Building 31, Room 10A34, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Center on Minority Health and Health Disparities (NCMHD), Democracy Plaza II, Room 800, 6707 Democracy Boulevard, Bethesda, MD 20892-5465.

Privacy Act Coordinator, National Center for Research Resources (NCRR), Rockledge I, Room 5140, 6705 Rockledge Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Eye Institute (NEI), Building 31, Room 6A32, 31 Center Drive, Bethesda, MD 20892-2510.

Privacy Act Coordinator, National Human Genome Research Institute (NHGRI), Building 10, 3C710, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Heart, Lung, and Blood Institute (NHLBI), Building 31, Room 5 A3 3, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute on Aging (NIA), Gateway Building 31, Room 2C234, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 400, 6000 Executive Boulevard, Bethesda, MD 20892-7003.

Privacy Act Coordinator, National Institute of Allergy and Infectious Diseases (NIAID), 6700-B Rockledge Drive, Room 2143, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Natcher Building, Room 5AS49, 45 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Biomedical Imaging and Bioengineering (NIBIB), Building 31, Room 1B37, 31 Center Drive, Bethesda, MD 20892-2077.

Privacy Act Coordinator, National Institute of Child Health and Human Development (NICHD), Building 31, Room 2A11, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, Office of Extramural Affairs, National Institute on Drug Abuse (NIDA), Neuroscience Center, 6001 Executive Boulevard, Room 3158, Bethesda, MD 20892-9547.

Privacy Act Coordinator, National Institute on Deafness and Other Communication Disorders (NIDCD), Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Dental and Craniofacial Research (NIDCR), Natcher Building, Room 4AS25, 45 Center Drive, Bethesda, MD 20892-6401.

Privacy Act Coordinator, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Building 31, Room 9A47, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, Research Triangle Park, NC 27709.

Privacy Act Coordinator, National Institute of General Medical Sciences (NIGMS), Natcher Building, Room 2AN32, 45 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Mental Health (NIMH), Neuroscience Center, 6001 Executive Boulevard, Room 8102, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Neurological Disorders and Stroke (NINDS), Building 31, Room 8A33, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Nursing Research (NINR), Rockledge II, Room 710, 6701 Rockledge Drive, Bethesda, MD 20892.

RECORD ACCESS PROCEDURE:

Same as Notification Procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:

Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I: System Manager(s) and Address(es)

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Computer Systems Analyst, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 344, 6130 Executive Boulevard, Bethesda, MD 20892.

American Burkitt's Lymphoma Registry, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Suite 434, 6130 Executive Boulevard, Bethesda, MD 20892.

Chief, Genetic Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute (NCI), Executive Plaza South, Room 7122, 6120 Executive Boulevard, Bethesda, MD 20892- 7236.

Program Director, Research Resources, Biological Carcinogenesis Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 540, 6130 Executive Boulevard, Bethesda, MD 20892.

Chief, Environmental Epidemiology Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 443,6130 Executive Boulevard, Bethesda, MD 20892.

Associate Director, Surveillance Program, Division of Cancer Prevention, National Cancer Institute (NCI), Executive Plaza North, Room 343K, 6130 Executive Boulevard, Bethesda, MD 20892.

Head, Biostatistics and Data Management Section, Center for Cancer Research, National Cancer Institute (NCI), Building 6116, Room 702, 6116 Executive Boulevard, Bethesda, MD 20892.

Chief, Clinical Research Branch, Center for Cancer Research, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), 501 W. 7th Street, Room 3, Frederick, MD 21702.

Deputy Branch Chief, Navy Hospital, NCI-Naval Medical Oncology Branch, Center for Cancer Research, National Cancer Institute (NCI), Building 8, Room 5101, Bethesda, MD 20814.

Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 804, 6130 Executive Boulevard, Bethesda, MD 20892.

Director, Extramural Clinical Studies, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), Fort Detrick, Frederick, MD 21702.

Clinical Operations Manager, National Eye Institute (NEI), Building 10, Room 10S224, 10 Center Drive, Bethesda, MD 20892.

Director, Division of Biometry and Epidemiology, National Eye Institute (NEI), Building 31, Room 6A52, 31 Center Drive, Bethesda, MD 20892.

Associate Director, Office of Clinical Affairs, National Heart, Lung, and Blood Institute (NHLBI), Building 10, Room 8C104, 10 Center Drive, Bethesda, MD 20892-1754.

Senior Scientific Advisor, Office of the Director, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI), Federal Building, Room 220, 7550 Wisconsin Avenue, Bethesda, MD 20892.

Chief Laboratory of Epidemiology, Demography and Biometry, National Institute on Aging (NIA), Gateway Building, Room 3C309, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Chief, Research Resources Branch, Intramural Research Program, National Institute on Aging (NIA), 5600 Nathan Shock Drive, Baltimore, MD 21224.

Clinical Director, National Institute on Aging (NIA), 5600 Nathan Shock Drive, Baltimore, MD 21224.

Deputy Director, Division of Biometry and Epidemiology, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 514, 6000 Executive Boulevard, Bethesda, MD 20892- 7003.

Deputy Director, Division of Clinical and Prevention Research, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 505, 6000 Executive Boulevard, Bethesda, MD 20892-7003.

Chief, Respiratory Viruses Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), Building 7, Room 106,7 Memorial Drive, Bethesda, MD 20892.

Chief, Hepatitis Virus Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), Building 7, Room 202,7 Memorial Drive, Bethesda, MD 20892.

Chief, Biometry Branch, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), 6700-B Rockledge Drive, Room 3120, Bethesda, MD 20892.

Clinical Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Building 10, Room 9S205,10 Center Drive, Bethesda, MD 20892.

Chief, Contracts Management Branch, National Institute of Child Health and Human Development (NICHD), Executive Plaza North, Room 7A07, 6130 Executive Boulevard, Bethesda, MD 20892.

Director of Intramural Research, National Institute on Deafness and Other Communication Disorders (NIDCD), Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.

Chief, Scientific Programs Branch, National Institute on Deafness and Other Communication Disorders (NIDCD), Executive Plaza South, Room 400C, 6120 Executive Boulevard, Bethesda, MD 20892-7180.

Clinical Director, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room INI 17,10 Center Drive, Bethesda, MD 20892-1191.

Chief, Scientific Review Branch, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room 1N117,10 Center Drive, Bethesda, MD 20892-1191.

Research Psychologist, Gene Therapy and Therapeutics Branch, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room 1N105,10 Center Drive, Bethesda, MD 20892- 1190.

Chief, Clinical Investigations, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Building 10, Room 9N222,10 Center Drive, Bethesda, MD 20892.

Chief, Phoenix Clinical Research Section, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Phoenix Area Indian Hospital, Room 541, 4212 North 16th Street, Phoenix, AZ 85016.

Chief, Diabetes Research Section, Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Natcher Building, Room 5AN18G, 45 Center Drive, Bethesda, MD 20892-6600.

Privacy Act Coordinator, Office of Extramural Affairs, National Institute on Drug Abuse (NIDA), 6001 Executive Boulevard, Room 3158, Bethesda, MD 20892-9547.

Chief, Epidemiology Branch, National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, Research Triangle Park, NC 27709.

Director, Intramural Research Program, National Institute of Mental Health (NIMH), Building 10, Room 4N224,10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Mental Health (NIMH), Neuroscience Center, Room 8102,6001 Executive Boulevard, Bethesda, MD 20982.

Privacy Act Coordinator, National Institute of Neurological Disorders and Stroke (NINDS), Building 31, Room 8A33, 31 Center Drive, Bethesda, MD 20892.

Chief, Epilepsy Branch, National Institute of Neurological Disorders and Stroke (NINDS), Neuroscience Center, 6001 Executive Boulevard, Suite 2110, Bethesda, MD 20892-9523.

Assistant Director, Clinical Neurosciences Program, Division of Intramural Research, National Institute of Neurological Disorders and Stroke (NINDS), Building 10, Room 5N234,10 Center Drive, Bethesda, MD 20892.

Acting Chief, Laboratory of Central Nervous Systems Studies, Intramural Research Program, National Institute of Neurological Disorders and Stroke (NINDS), Building 36, Room 4A21, 36 Convent Drive, Bethesda, MD 20892-4123.

Clinical Director, National Human Genome Research Institute (NHGRI), Building 10, Room 10C101D, 10 Center Drive, Bethesda, MD 20892.

Deputy Director, Division of Extramural Research, National Institute of Neurological Disorders and Stroke (NINDS), Neuroscience Center, Room 3307, 6001 Executive Boulevard, Bethesda, MD 20892.

Director, Office of Clinical and Regulatory Affairs, Division of Extramural Research and Training, Democracy Plaza II, Room 401,6707 Democracy Boulevard, Bethesda, MD 20892-5475.

Privacy Act Coordinator, National Institute of Biomedical Imaging and Bioengineering (NIBIB), Building 31, Room 1B37,31 Center Drive, Bethesda, MD 20892-2077.

Privacy Act Coordinator, National Center on Minority Health and Health Disparities (NCMHD), Democracy Plaza II, Room 800, 6707 Democracy Boulevard, Bethesda, MD 20892-5465.

RESEARCH PATIENT CARE COSTS — NIH(RC)-11

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreementto make payment to any lobbying entity 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 employeeof a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1 st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee,"then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a)Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b)Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (Ml).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is OMB No. 0348-0046. Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, DC 20503.

Schedule l-B

Contractor Acquired Government Property

Biological Specimen Freezer (-80) (For purchase in Phase II)	$	12,000

Attachment 8
September 19, 2014

SBIR Funding Agreement Certification

Contract Number:

Program Director(s)/Principal Investigators) (PD(s)/PI(s)):

All small businesses that are selected for award of an SBIR funding agreement must complete this certification at the time of award and any other time set forth in the contract that is prior to performance of work under this contract. This includes checking all of the boxes and having an authorized officer of the contractor sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on this information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award. A similar certification will be used to ensure continued compliance with specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions references in those authorities.

If the Contracting Officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Contracting Officer believes, after award, that the business is not meeting certain contract requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that(all boxes must be checked):

1. The business concern meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.
   ☒ Yes ☐ No

2. If a corporation, all corporate documents (articles of incorporation and any amendments, articles of conversion, by-laws and amendments, shareholder meeting minutes showing director elections, shareholder meeting minutes showing officer elections, organizational meeting minutes, all issued stock certificates, stock ledger, buy-sell agreements, stock transfer agreements, voting agreements, and documents relating to stock options, including the right to convert non-voting stock or debentures into voting stock) evidence that it meets the ownership and control requirements set forth in 13C.F.R. § 121.702.
   ☒ Yes ☐ No ☐ N/A Explain why N/A:

3. If a partnership, the partnership agreement evidences that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.
   ☒ Yes ☐ No ☐ N/A Explain why N/A: (LLC)

4. If a limited liability company, the articles of organization and any amendments, and operating agreements and amendments, evidence that it meets the ownership and control requirements set forth in 13 C.F.R. §121.702.
   ☒ Yes ☐ No ☐ N/A Explain why N/A:

5. The birth certificates, naturalization papers, or passports show that any individuals it relies upon to meet the eligibility requirements are U.S. citizens or permanent resident aliens in the United States.
   ☒ Yes ☐ No ☐ N/A Explain why N/A:

6. It has no more than 500 employees, including the employees of its affilliates.
☒ Yes ☐ No

7. SBA has not issued a size determination currently in effect finding that this business concern exceeds the 500 employee size standard.
☒ Yes ☐ No

8. During the performance of the award, the principal investigator will spend more than half of his/her time as an employee of die awardee or has requested and received a written deviation from this requirement from the Contracting Officer.
☒ Yes ☐ No Deviation approved in writing by Contracting Officer: %

9. All, essentially equivalent work, or a portion of the work proposed under this project (check the applicable line):
☒ Has not been submitted for funding by another Federal agency.

☐ Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.

☐ A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Contracting Officer.

10. During die performance of award, it will perform die applicable percentage of work unless a deviation from this requirement is approved in writing by the Contracting Officer (check the applicable line and fill in if needed):

☒ SBIR Phase I: at least two-thirds (66 2/3%) of the research

☒ SBIR Phase II: at least half (5 0%) of die research

☐ Deviation approved in writing by the Contracting Officer %

11. During performance of award, the research/research and development will be performed in the United States unless a deviation is approved in writing by the Contracting Officer.
☒ Yes ☐ No

12. During the performance of award, the research/research and development will be performed at my facilities with my employees, except as otherwise indicated in the SBIR proposal and approved in the Notice of Award
☒ Yes ☐ No

13. It has registered itself on SBA's database as majority-owned by venture capital operating companies, hedge funds or private equity firms.
☐ Yes ☒ No ☐ N/A Explain why N/A:

14. It is a Covered Small Business Concern (a small business concern that: (a) was not majority-owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms on die data on which it submitted a proposal in response to an SBIR solicitation; and (b) on the date of the SBIR award, which is made more than 9 months after the closing date of the solicitation, is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms).
☒ Yes ☐ No
It will notify the Federal agency immediately if all or a portion of the work proposed is subsequentiy funded by another Federal agency.
☒ Yes ☐ No

I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern that the information provided in this certification, the proposal, and all other information submitted in connection with this proposal is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §380 1 et seq); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180; and (6) other administrative penalties including termination of SBIR/STTR awards.

Date 9/19/2014

Signature /s/ ANATOLY DRITSCHILO

Printed Name (First, Middle, Last) ANATOLY DRITSCHILO

Title CEO

Organization Name Shuttle Pharmaceuticals, LLC

NIH Small Business Innovation Research Program
Life Cycle Certification

All SBIR Phase I and Phase II Contractors must complete this certification at all times set forth in the funding agreement (see § 8(h) of the SBIR Policy Directive). This includes checking all of the boxes and having an authorized officer of the Contractor sign and date the certification each time it is required.

A certification is required at the following times:

- For SBIR Phase I Contractors: At the time of receiving final payment or disbursement.
- For SBIR Phase II Contractors: prior to receiving more than 50% of the total contract amount and prior to final payment or disbursement.

If the Contractor cannot complete this certification or cannot ensure compliance with the certification process, it should notify the Contracting Officer immediately. If resolution cannot be reached, the Contracting Officer will void or terminate the award, as appropriate.

Contract Number:

Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)):

Please read carefully the following certification statements. The Federal government relies on the information to ensure compliance with specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, the SBIR Policy Directive, and also any statutory and regulatory provisions referenced in those authorities.

If the Contracting Officer believes that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that(all boxes must be checked):

1. The principal investigator spent more than one half of his/her time as an employee of the Contractor or has requested and received a written deviation from this requirement from the Contracting Officer.

   ☐ Yes ☐ No Deviation approved in writing by Contracting Officer:_____%

2. All, essentially equivalent work, or a portion of the work performed under this project (check the applicable line):

   ☐ Has not been submitted for funding by another Federal agency.

☐ Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.

☐ A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Contracting Officer.

3. Upon completion of the contract it will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Contracting Officer (check the applicable line and fill in if needed):

   ☐ SBIR Phase I: at least two-thirds (66 2/3%) of the research

   ☐ SBIR Phase II: at least half (50%) of the research

   ☐ Deviation approved in writing by the Contracting Officer: %

4. The work is completed and it has performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Contracting Officer (check the applicable line and fill in if needed).

   ☐ SBIR Phase I: at least two-thirds (66 2/3%) of the research

   ☐ SBIR Phase II: at least half (50%) of the research

   ☐ Deviation approved in writing by the Contracting Officer: %

   ☐ N/A because work is not completed

5. The research/research and development is performed in the United States unless a deviation is approved in writing by the Contracting Officer.

   ☐ Yes ☐ No Waiver has been granted

6. The research/research and development is performed at my facilities with my employees, except as otherwise indicated in the SBIR proposal and approved in the contract.

   ☐ Yes ☐ No

☐ I will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

☐ I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

☐ I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern that the information provided in this certification, the proposal, and all other information submitted in connection with the award, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

Date

Signature

Printed Name (First, Middle, Last)

Title

Business Name

BEGINNING WITH THE EFFECTIVE DATE OF THIS MODIFICATION, THE GOVERNMENT AND THE CONTRACTOR MUTUALLY AGREE AS FOLLOWS:

ARTICLE B.3. OPTION FOR PHASE II subparagraph d is revised as follows:

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost($)	Fixed Fee($)	Estimated Cost Plus Fixed Fee($)
Base Period **9/19/2014 - 8/03/2015**	$ 181,105	$ 10,866	$ 191,971
Option Period: **8/04/2015 - 8/03/2017**	**$ 1,347,280**	**$ 80,837**	**$ 1,428,117**
Total [Base Period and Option]	$ 1,528,385	$ 91,703	$ 1,620,088

ARTICLE B.4. ADVANCE UNDERSTANDINGS, subparagraph b., is revised as follows:

b. **Subcontract**

A fixed type subcontract with Rhode Island Hospital for Phase I for an amount not to exceed $65,549 for the period for the period 9/19/2014-**8/03/2015**.

If the Government exercises its option for Phase II pursuant to the Option Provision Article in Section H of this contract, the total estimated Subcontract amount will be increased as follows:

Option 8/04/2015-8/03/2017 - $623,269

ARTICLE F.1. PERIOD OF PERFORMANCE- is revised as follows:

a. The period of performance of this contract shall be from 09/19/2014 through**08/03/2017.**

b. If the Government exercises its option pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
Option for Phase II	**August 04, 2015 - August 03, 2017**

ARTICLE F.2. DELIVERIES-subparagraph b is revised as follows:

b. The above items shall be addressed and emailed to ncibranchbinvoices@mail.nih.gov .The following addresses are provided for general correspondence and other deliveries:

Addressee	Deliverable Item No	Quantity
Sandra Addae, Contract Specialist National Cancer Institute Office of Acquisitions, 9609 Medical Center Drive, Room 1E632 MSC 9705 Bethesda, MD 20892-9705	1-14, 16-21	Electronically
Deepa Narayanan, COR National Cancer Institute NCI SBIR & STTR Programs, Room1W5429609 Medical Center Drive, MSC9705Bethesda, MD 20892-9705	2-12	Electronically
OPERA, OEH, NIH6705 Rockledge DriveSuite 310, MSC 7980Bethesda, Maryland 20892-7980	13-15	Electronically

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT -2.f. and 2.h are revised as follows:

2. f. The contract period of performance is: 9/19/2014 - **08/03/2017**

2. h. Contract line items as follows:

Line Item #	Line Item Description
1	**Clinical Development of IPdR for Radiosensitization**
2	**Phase II Clinical Development of IPdR for Radiosensitization**

ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE II CONTRACT-is deleted and replaced in its entirety.

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: http://www.acquisition.gov/far/ . *HHSAR Clauses at:* http://www.hhs.gov/policies/hhsar/subpart352.html

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	*Nov 2013*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*May 2014*	*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	*May 2014*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*May 2014*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*May 2014*	*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)*
52.203-17	*Apr 2014*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.203-99	*Feb 2015*	*Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paperf(Over the Simplified Acquisition Threshold)*
52.204-10	*Jul 2013*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)*
52.204-13	*Jul 2013*	*System for Award Management Maintenance*
52.209-6	*Aug 2013*	*Protecting the Government's Interest 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*
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*
52.219-6	*Jul 1996*	*Notice of Total Small Business Set-Aside*

FAR CLAUSE NO.	DATE	TITLE
52.219-8	*Oct 2014*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-14	*Dec 1996*	*Limitations on Subcontracting*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Apr 2015*	*Prohibition of Segregated Facilities*
52.222-26	*Apr 2015*	*Equal Opportunity*
52.222-35	*Jul 2014*	*Equal Opportunity for Veterans ($100,000 or more)*
52.222-36	*Jul 2014*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*Jul 2014*	*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	*Mar 2015*	*Combating Trafficking in Persons*
52.222-54	*Aug 2013*	*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	*May 2014*	*Buy American - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*Dec 2007*	*Authorization and Consent, Alternate I (Apr 1984)*
52.227-2	*Dec 2007*	*Notice and Assistance Regarding Patent and Copyright Infringement*
52.227-11	*May 2014*	*Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.*
52.227-20	*May 2014*	*Rights in Data - SBIR Program*
52.229-3	*Feb 2013*	*Federal, State and Local Taxes (Over the Simplified Acquisition Threshold)*
52.232-2	*Apr 1984*	*Payments under Fixed-Price Research and Development Contracts*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*May 2014*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-23	*May 2014*	*Assignment of Claims*
52.232-25	*Jul 2013*	*Prompt Payment*
52.232-33	*Jul 2013*	*Payment by Electronic Funds Transfer-System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*May 2014*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.243-1	*Aug 1987*	*Changes - Fixed Price, Alternate V (Apr 1984)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over the Simplified Acquisition Threshold)*
52.244-6	*Apr 2015*	*Subcontracts for Commercial Items*
52.249-2	*Apr 2012*	*Termination for the Convenience of the Government (Fixed-Price)*
52.249-9	*Apr 1984*	*Default (Fixed-Price Research and Development)(Over the Simplified Acquisition Threshold)*

FAR CLAUSE NO.	DATE	TITLE
52.253-1	*Jan 1991*	*Computer Generated Forms*

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	*Jan 2006*	*Definitions*
352.203-70	*Mar 2012*	*Anti-Lobbying*
352.222-70	*Jan 2010*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Jan 2006*	*Publications and Publicity*
352.231-71	*Jan 2001*	*Pricing of Adjustments*
352.242-70	*Jan 2006*	*Key Personnel*
352.242-73	*Jan 2006*	*Withholding of Contract Payments*

[End of GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE II CONTRACT- Rev. 04/2015].

All other terms and conditions of this contract remain unchanged and in full force and effect.