EX-10.9 6 s105258_ex10-9.htm EXHIBIT 10-9

Exhibit 10.9

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

In this Phase I project the objectives are to develop and annotate AA prostate epithelial cancer cell line with donor matched normal prostate epithelial cells and bio-banked reference prostate tissues. Also to support the feasibility of establishing 50 prostate cancer cell lines from AA men in a subsequent Phase II application, prepare written protocols for tissue collection, processing, establishment of conditionally reprogrammed cells and the reagents necessary for performing studies with these cells.

ARTICLE B.2. PRICES

a. The total fixed price of this contract is $224,687.

b. Upon delivery and acceptance of the item(s) and/or service(s) 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	HHSN261201600038C - 01	Month 1	$ 50,000
Quarterly Report 1	HHSN261201600038C - 02	Months 1-3	$ 50,000
Quarterly Report 2	HHSN261201600038C - 03	Months 4-6	$ 50,000
Draft Final Report	HHSN261201600038C - 04	Effective date of contract through one month prior to completion date of contract	$ 37,344
Final Report, Contract Outcomes Report, Final Presentation, and all other contract deliverables	HHSN261201600038C - 05	Entire Period of Performance of contract	$ 37,343
TOTAL FIXED PRICE			$ 224,687

ARTICLE B.3. 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. **Establishment of Indirect Cost Rate**

Fringe Benefits costs are funded at a rate of 15% of Total Direct Labor Costs; Overhead costs are funded at a rate of 39% of Total Direct Labor and Fringe Benefits Costs; G&A is funded at a rate of 12% of Total Direct Labor and Fringe Benefits Costs; however, the Contractor shall not bill or be reimbursed for indirect costs until such time as an indirect cost proposal has been submitted to the cognizant office responsible for negotiating the indirect cost rates, unless a temporary billing rate(s) has been included herein. Unless otherwise specified below, the indirect cost rate proposal shall be submitted no later than three (3) months after the date of contract award.

b. **Subcontract**

To negotiate a fixed price type subcontract with Georgetown University for Cell and Animal-Based Models to Advance Health Disparity Research for an amount not to exceed $70,129 for the period 9/19/2016 through 6/18/2017. 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.

c. **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. HHSN261201600038C .

NCI Control No. N43CO-2016-00038 .

d. **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.

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, dated September 19, 2016, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format via e-mail, as attachments, to the following designated NCI Branch Distribution Mailbox: NCIbrancheinvoices@mail.nih.gov.

Each e-mail 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 e-mail 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: 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. Slides shall be prepared and presentation of the slides shall occur either in-person or through webinar or teleconference. The presentation shall cover the following:

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

b. 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 the proposed project is 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 Reports**

The Contractor shall submit Quarterly Reports, which shall include:

a. Summary of technical objectives with status of each objective clearly marked (*e.g.* previously completed, completed during this 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.

This report shall generally be no longer than five (5) pages, excluding tables, figures, images and graphs used to present data.

3. **Draft Final Report**

The Contractor shall submit a Draft Final Report. The Government Contracting Officer's Representative (COR) will review and provide comments on the Draft Final Report, which the Contractor shall incorporate into a revised Final Report (- see Reporting Requirement Item 4).

The Draft Final Report shall include the following three sections:

Section 1: Summary of Salient Results

The Summary of Salient Results shall summarize in 200 words or less the salient results achieved during performance of the contract.

Section 2: Final Technical Report

The Final Technical Report shall set forth the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved.

Section 3: Draft Commercialization Plan

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 Phases II and 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 Ill 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.

4. **Final Report**

The Contractor shall submit a Final Report. This document shall incorporate revisions in response to the comments provided by the Government COR after review of the Draft Final Report (- see Reporting Requirements Item 3).

5. **Contract Outcomes Report**

The Contractor shall submit a Contract Outcomes Report using a fillable PDF form to be provided by the Government. The Contract Outcomes Report must be provided as a filled-in version of the PDF form provided and not as a printed or scanned copy of this document.

6. **Final Presentation**

The Contractor shall prepare and submit a final presentation. Slides shall be prepared and presentation of the slides shall occur either in-person or through webinar or teleconference. The presentation shall cover the following:

a. Discussion of the Contractor's organization and project status;

b. Contractor's achievements during the 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. Discussion of the anticipated Phase II activities with emphasis on how they fit into the commercialization plan, if Contractor is interested in pursuing Phase II research;

g. Questions to the NCI.

b. **Other Reports/Deliverables**

1. **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.gov/web/508/contracting/technology/vendors.html under "Vendor Information and Documents."

2. **N I H 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 ward 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 or before the completion date of the contract.

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 via e-mail.

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 required 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
   Rockville, MD 20850

   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

The period of performance of this contract shall be from 09/19/2016 through 06/18/2017.

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 date(s) specified below:

Item	Description	Delivery Schedule
(1)	SBIR Funding Agreement Certification	Due at time of award, prior to performance of any work under this contract.
(2)	Kick-Off Presentation	Due on or before 30 calendar days following the effective date of the contract.
(3)	Quarterly Report One	Due on or before 15 calendar days following completion of 3 full months of contract performance.
(4)	Quarterly Report Two	Due on or before 15 calendar days following completion of 6 full months of contract performance.
(5)	Draft Final Report	Due on or before 1 month prior to the contract completion date.
(6)	Final Report	Due on or before the contract completion date.
(7)	Contract Outcomes Report	Due on or before the contract completion date.
(8)	Final Presentation	Due on or before the contract completion date.
(9)	Final Invention Statement	Due on or before the contract completion date.
(10)	Invention Disclosure Report	Due on or before the contract completion date.
(11)	SBIR Program Life Cycle Certification	Due on or before the contract completion date.
(12)	Section 508 Annual Report	Due on or before the contract completion date.

b. The above items shall be addressed and delivered to ncibrancheinvoices@mail.nih.gov, as well as to the following addressees:

Addressee	Deliverables
Kathleen Sears Office of Acquisitions searsky@mail.nih.gov	All deliverables, in electronic format.
Todd Haim NCI SBIR & STTR Programs Haimte@mail.nih.gov	All deliverables, in electronic format.
OPERA, OEH, NIH 6705 Rockledge Drive Suite 310, MSC 7980 Bethesda, MD 20892-7980	Items 9 and 10, in 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)

Alternate I (April 1984) is not applicable to this contract.

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:

Todd Haim

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 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of Clause)

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

Name	Title
Dr. Johng Rhim	Principal Investigator

ARTICLE G.3. INVOICE SUBMISSION

a. Invoice Instructions for NIH Fixed-Price Type Contracts, NIH(RC)-2, 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 "Ash Stevens_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 E - ncibrancheinvoices@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, HHSN2612XXXXXC_Clinical Genetics Support_Ash Stevens_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. 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. 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.

g. The contract title.

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

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. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

A Final evaluation 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.

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

b. Electronic Access to Contractor Performance Evaluations

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

http://www.cpars.gov

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable:
1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103, "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102, "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http:// www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available athttp://grants.nih.gov/reproducibility/index.htm, including FAQs and a General Policy Overview.

ARTICLE H.3. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

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

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http:// publicaccess.nih.gov.

ARTICLE H.4. 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.5. 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.6. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

(End of clause)

ARTICLE H.7. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated 9/19/2016, which is incorporated by reference.

ARTICLE H.8. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

UNDER GOVERNING POLICY, FEDERAL FUNDS ADMINISTERED BY THE PUBLIC HEALTH SERVICE (PHS) SHALL NOT BE EXPENDED FOR RESEARCH INVOLVING LIVE VERTEBRATE ANIMALS WITHOUT PRIOR APPROVAL BY THE OFFICE OF LABORATORY ANIMAL WELFARE (OLAW), OF [**AN ANIMAL WELFARE ASSURANCE THAT COMPLIES WITH THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS AND/OR A VALID INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) APPROVAL**]. THIS RESTRICTION APPLIES TO ALL PERFORMANCE SITES (e.g. COLLABORATING INSTITUTIONS, SUBCONTRACTORS, SUBGRANTEES) WITHOUT OLAW-APPROVED ASSURANCES, WHETHER DOMESTIC OR FOREIGN.

ARTICLE H.9. 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.10. GUN CONTROL

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

ARTICLE H.11. LIMITATIONS ON SUBCONTRACTING - SBIR

The Contractor shall perform a minimum of two-thirds of the research and/or analytical effort conducted under this contract, as measured by total contract dollars. Any deviation from this requirement must be approved in writing by the Contracting Officer.

ARTICLE H.12. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015)

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) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" 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 is available at http://www.hhs.gov/web/508. The complete text of Section 508 Final Provisions can be accessed athttp://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards.

b. The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

c. The Section 508 accessibility standards applicable to this contract are:
None.

d. In the event of a modification(s) to this contract or order,which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

e. If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http:// www.hhs.gov/web/508. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

ARTICLE H.13. 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. HHSN261201600038C."

ARTICLE H.14. 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.15. ADVANCED COPIES OF PRESS RELEASES

Press releases shall be considered to include the public release of information to any medium, excluding peer- reviewed scientific publications. The Contractor shall not publish a press release related to this contract without receiving prior concurrence from the Contracting Officer (CO). The Contractor shall submit an advance copy of the press release to the Contracting Officer and Contracting Officer's Representative (COR). Upon acknowledgement of receipt, the Contracting Officer will have five (5) working days to respond with concurrence or comments. In the event that the Contracting Officer does not communicate concurrence or comments to the Contractor within five (5) working days following acknowledgement of receipt of the press release advance copy, concurrence may be presumed.

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)*
52.203- 99	*Feb 2015*	*Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)*
52.204- 10	*Oct 2015*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)*
52.204- 13	*Jul 2013*	*System for Award Management Maintenance*
52.209-6	*Oct 2015*	*Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)*
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	*Apr 2015*	*Prohibition of Segregated Facilities*
52.222-26	*Apr 2015*	*Equal Opportunity*
52.222-35	*Oct 2015*	*Equal Opportunity for Veterans ($150,000 or more)*
52.222-36	*Jul 2014*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*Feb 2016*	*Employment Reports on Veterans ($150,000 or more)*
52.222-50	*Mar 2015*	*Combating Trafficking in Persons*
52.222-54	*Oct 2015*	*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*

FAR CLAUSE NO.	***DATE***	***TITLE***
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*
52.232-23	*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	*Jun 2016*	*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***
352.203-70	*Dec 2015*	*Anti-Lobbying*
352.222-70	*Dec 2015*	*Contractor Cooperation in Equal Employment Opportunity Investigations*
352.227-70	*Dec 2015*	*Publications and Publicity*
352.237-75	*Dec 2015*	*Key Personnel*

[End of GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE I CONTRACT- Rev. 08/2016].

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

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

a. ***Alternate IV*** *(October 2010) of FAR Clause* ***52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data —Modifications*** *(October 2010) is added.*

b. The following clause(s) are added to this contract:

- 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, Rescission, 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** (October 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.

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 **52.204-18 Commercial and Government Entity Code Maintenance** (July 2016)
2. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).
3. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

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

1. HHSAR Clause **352.208-70, Printing and Duplication** (December 2015)

2. HHSAR Clause **352.223-70, Safety and Health** (December 2015)

3. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015)

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

   See the following website for Executive Schedule rates of pay: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/.

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

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

This contract incorporates the following clauses in full text.

a. **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, dated September 19, 2016, 2 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. Safety and Health

Safety and Health, HHSAR Clause 352.223-70, (12/15), 2 pages.

4. Disclosure of Lobbying Activities, SF-LLL

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

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

NIH Small Business Innovative Research (SBIR) Program Funding Agreement Certification, 3 pages, located at: http://grants.nih.gov/grants/funding/sbir_forms/SBIR%20Funding%20Agreement%20Certification.pdf.

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

NIH Small Business Innovative Research (SBIR) Program Life Cycle Certification, 3 pages, located at: http:// grants.nih.gov/grants/funding/sbir_forms/SBIR%20Life%20Cycle%20Certification.pdf.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

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

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

   (End of clause)

5. Animal Welfare Assurance Number A3282-1.

END of the SCHEDULE

(CONTRACT)

STATEMENT OF WORK (Phase I)

TITLE:	Cell-Based Models for Prostate Cancer Health Disparity Research
PRINCIPAL INVESTIGATOR:	Dr. Johng Rhim
PROJECT DURATION:	9 months
COMPANY:	Shuttle Pharmaceuticals, LLC
SUBCONTRACTORS:	Georgetown University

I. Background Information and Objectives

A. Background Information

Prostate cancer health disparities studies have shown that African-American (AA) men are at higher risk for developing prostate cancer, as well as at higher risk of cancer specific death rates, as compared to Caucasian American (CA) men. The causes of disparities have been attributed to socioeconomic differences, environmental exposures and biological factors. Most disparities studies have been population based, in part, due to the lack of relevant in vitro and in vivo models to support biological studies. In this Phase I proposal, we will develop an annotated AA prostate epithelial cancer cell line with donor matched normal prostate epithelial cells and bio-banked reference prostate tissues. To support the feasibility of establishing 50 prostate cancer cell lines from AA men in a subsequent Phase II application, we will prepare written protocols for tissue collection, processing, establishment of conditionally reprogrammed cells and the reagents necessary for performing studies with these cells. We will determine commercial feasibility for cell distribution and reagent marketing through a private-public partnership.

B. Technical Objectives

The three technical objectives of this proposal focus on determining the feasibility for establishing paired cancer and normal epithelial cell lines from African-American patients presenting with prostate cancers. In the first objective, three previously harvested, de-identified and bio-banked prostate cells from AA patients will be grown and characterized to develop standard operating protocols and optimal media conditions. The second objective will be to optimize growth medium for use with AA cell lines. The third objective is to negotiate intellectual property (license) through Georgetown University to support commercialization of AA cell lines.

Objective 1. Grow paired cancer and normal epithelial cells from AA prostate tumors and normal biopsy specimens bio-banked on IRB protocol # 2012-163.

Task 1.1. Establish malignant and non-malignant cell lines from AA prostatectomy specimens.
Milestone 1.1. Expand and freeze 20 vials for each AA cell line to perform characterizations.

Task 1.2. Characterize and annotate AA cells.
Milestone 1.2. Full characterization of AA cell lines, including: cell origin, cell growth > 30 passages, capacity to form xenograft tumors, karyotypes, expression of prostate tissue and tumor specific markers, STR authentication and Mycoplasma testing

Task 1.3. Expand early passages of CRCs for freezing and banking in the CRC bio-repository.
Milestone 1.3. 50 vials of 1 -2x10^6 cells/vial are banked for each normal/tumor AA cell pair.

Task 1.4. Prepare written protocols and standard operating procedures (SOPs) for establishing AA cell lines.
Milestone 1.4. SOPs for establishing AA cell lines and SOPs for cell growth and annotation.

Objective 2. Determine the optimal growth medium and conditions for growing prostate CRCs with and without irradiated feeder cells.

Task 2.1. Collect and concentrate the conditioned medium from J2-irradiated fibroblasts in sufficient quantity to support AA cell growth in 50 flasks. Test effects of graded concentrations of conditioned medium on AA cells using telomerase and cell growth assays.

Milestone 2.1.1. Documentation of effects of conditioned medium on AA cell growth.
Milestone 2.1.2. Optimal formulation of conditioned medium supplement for AA prostate cell growth.

Task 2.2. Optimize the panel of supplementary growth factors for AA prostate CRC cell growth.
Milestone 2.2. Proprietary formula of growth factors needed to promote AA CRC culture growth.

Task 2.3. Compare cell characteristics under different media and growth conditions.
Milestone 2.3. Determine cell growth over at least 30 passages, capacity to form xenograft tumors, karyotype at early and late passages and expression of prostate specific markers.

Objective 3. Negotiate a licensing agreement for commercialization of AA derived cells, submit a Phase I final report to SBIR administration and prepare a Phase II SBIR application.

Task 3.1. Through the GU Office of Technology Commercialization, negotiate to obtain a licensing agreement to support commercialization of established AA cells.
Milestone 3.1. Executed licensing agreement.

Task 3.2. Submit a written final Phase I report to SBIR administration.
Milestone 3.2. Phase I milestones have been reached and SBIR administration is informed of the technical and commercial feasibility of establishing 50 model AA cell lines supporting a Phase II application in response to an appropriate NIH/SBIR RFA.

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 will be monitored by the Government Project Officer identified in Section G of the contract.

B. Specific Requirements

Phase I Milestones and Timeline

Objectives	Milestone	Months 1-3	Months 4-6	Months 7-9
Objective 1		***	***	***
	Milestone 1.1.Repository of 20 frozen vials of each initial model AA cell line.	X		
	Milestone 1.2. Annotation data completed for initial AA cell lines		X	
	Milestone 1.3. Repository of 50 frozen vials of each AA cell line.			X
	Milestone 1.4. Written protocols, annotation reports and SOP's.		X	X
Objective 2			***	***
	Milestone 2.1. Optimal media formula for growing AA prostate cells.		X	
	Milestone 2.2. Growth media supplements for AA prostate cells.		X	
	Milestone 2.3. Annotation of cell growth, xenograft tumor formation, genetic analysis, marker expression, and cell of origin			X
Objective 3				***
	Milestone 3.1. Executed licensing agreement.			X
	Milestone 3.2. Written final report of achieved Phase I milestones and application for Phase II SBIR funding			X

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.

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

(m) **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.

Safety and Health, HHSAR 352.223-70 (DEC 2015)

a. To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

1. In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:
    I. 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at https://www.osha.gov/.
    II. Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

2. The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:
    I. Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at http://www.cdc.gov/biosafety/publications/index.htm.
    II. Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at http://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-handling-and-disposal-of-chemicals.

b. Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable "Changes" clause set forth in this contract.

c. The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

d. If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

e. The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

DISCLOSURE OF LOBBYING ACTIVITIES
Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

Approved by OMB
0348-0046

1. Type of Federal Action:
☐ a. contract
b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

2. Status of Federal Action:
☐ a. bid/offer/application
b. initial award
c. post-award

3. Report Type:
☐ a. initial filing
b. material change
For Material Change Only:
year _____quarter date_____ of last report_____

4. Name and Address of Reporting Entity:
☐ Prime ☐ Subawardee
Tier_____ , *if known* :

Congressional District, *if known:*

5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:
_____
_____
_____
_____
_____
Congressional District, *if known:*_____

6. Federal Department/Agency:
_____

7. Federal Program Name/Description:
_____

CFDA Number, *if applicable :*_____

8. Federal Action Number, *if known:*
_____

9. Award Amount, *if known:*
$ _____

10. a. Name and Address of Lobbying Registrant
(if individual, last name, first name, MI):
_____
_____
_____
_____
_____

b. Individuals Performing Services *(including address if different from No. 10a)*
(last name, first name, MI):
_____

11 Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____
Print Name: _____
Title: _____
Telephone No.:_____ Date: _____

Federal Use Only:

Authorized for Local Reproduction
Standard Form LLL (Rev. 7-97)

PRINT

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 employee of 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 1st 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 (MI).

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

SBIR Funding Agreement Certification

Grant Contract Number: _____

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

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0001). Do not return the completed form to this address.

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 Notice of Award or Contract Award that is prior to performance of work under this award. This includes checking all of the boxes and having an authorized officer of the awardee 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 Grants Management or 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 Grants Management or Contracting Officer believes, after award, that the business is not meeting certain Notice of Award 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 13 C.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: _____

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 affiliates.

   ☐ 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 the awardee or has requested and received a written deviation from this requirement from the Grants Management or Contracting Officer.

   ☐ Yes ☐ No Deviation approved in writing by Grants Management or 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 proposaland approved in writing by the Grants Management or Contracting Officer.

10. During the performance of award, it will perform the applicable percentage of work unless a deviation from this requirement is approved in writing by the Grants Management or 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 Grants Management or 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 Grants Management or 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 application and approved in the Notice of Award or Contract 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 the data on which it submitted an application 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

15. It will notify the Federal agency immediately if all or a portion of the work proposed is subsequently 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 application, and all other information submitted in connection with this application, 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 _____

Organization Name _____

HHS Small Business Innovation Research Program Life Cycle Certification

All SBIR Phase I and Phase II awardees 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 awardee sign and date the certification each time it is required. Awardees are not required to submit this certification directly to NIH but must instead complete the certification and maintain it on file in accordance with the records and retention policy in Section 8.4.2 of the NIH Grants Policy Statement or as listed in the SBIR contract solicitation or contract award.

A certification is required at the following times:

- For SBIR Phase I Awardees: At the time of receiving final payment or disbursement from the Payment Management System or via contract.
- For SBIR Phase II Awardees: prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System or via contract.

In addition, SBIR awardees indicate compliance with these certification requirements by drawing or requesting funds from the Payment Management System. If the grantee cannot complete this certification or cannot ensure compliance with the certification process, it should notify the funding agreement officer immediately. If resolution cannot be reached, the funding agreement officer will void or terminate the award, as appropriate.

Grant or 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 funding agreement 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 awardee or has requested and received a written deviation from this requirement from the funding agreement officer.

   ☐ Yes ☐ No Deviation approved in writing by funding agreement 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 funding agreement officer.

3. Upon completion of the award it will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the funding agreement 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 funding agreement 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 funding agreement 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 funding agreement 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 funding agreement 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 application and approved in the Notice of Award or Contract Award.

   ☐ 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 application, 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.. § 3729 EC Esq.); (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 _____