Exhibit 10.11

SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

RESEARCH AGREEMENT AND SUBCONTRACT
BETWEEN
GEORGETOWN UNIVERSITY
AND
SHUTTLE PHARMACEUTICALS, LLC.
PURSUANT TO
AWARD NUMBER HHSN261201600027C - NCI CONTROL NUMBER:N43CO-2016-00027

("Predictive biomarkers of prostate cancer patient sensitivity for radiation late effect")

SUBGRANTEE:	**Georgetown University**
ADDRESS:	**37th And O Streets, NW** **Washington, DC 20057**
SUBGRANT PERIOD:	**September 19, 2016 - September 18. 2017**
ESTIMATED COST:	**$100,000**

PREAMBLE

This cost-reimbursable Agreement is between **Shuttle Pharmaceuticals, LLC,** a small business concern organized as a Limited Liability Company under the laws of the state of Maryland and having a principal place of business at One Research Court, Suite 450 Rockville, MD 20850 ("Sponsor") and **GEORGETOWN UNIVERSITY,** a nonprofit institution of higher education organized as a non-stock corporation under federal charter and whose principal place of business is situated at 37th and O Streets, N.W., Washington, D.C., U.S.A. ("Georgetown" or "Subgrantee"). It constitutes a Subgrant for the transfer of substantive programmatic work under **AWARD NO.** HHSN261201600027C - **NCI CONTROL NO: N43CO-2016-00027** (Prime Agreement), which was issued to Sponsor by the**National Institutes of Health** (NIH).

In consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, and intending to be legally bound, the parties expressly agree to the terms and conditions contained in this Agreement.

ARTICLE I. STATEMENT OF WORK

The Subgrantee agrees to undertake activities in accordance with the Statement of Work appended as**ATTACHMENT A.**

ARTICLE II. KEY PERSONNEL

The activities to be performed under this Agreement arc under the direction of **Dr. Amrita K. Cheema.** Should Dr. Cheema be unable to continue during the period of performance of this Agreement, Sponsor reserves the right to approve or disapprove any successor recommended by the Subgrantee.

ARTICLE III. PERIOD OF PERFORMANCE

The effective period of performance of this Agreement shall begin on **September 19, 2016** and shall terminate on **September 18, 2017**.

ARTICLE IV. CONSIDERATION AND ALLOWABLE COSTS

In return for the Subgrantee's performance of the work required by **ARTICLE I** and agreement to abide by the terms contained in this Agreement, the Sponsor will reimburse the Subgrantee for its actual allowable costs up to a ceiling amount of **$100,000.** The Subgrantee agrees not to invoice for an amount in excess of **$100,000** unless additional funds are obligated by formal written modification to this Agreement. Costs shall be incurred in accordance with the Budget, which is appended as **ATTACHMENT B** and is an integral part of this Agreement. The authorized amount will cover direct and indirect costs of the research, as detailed in the budget, **ATTACHMENT B.** The allowability of direct and indirect costs will be in accordance with applicable 2 CFR 200. The Subgrantee is authorized to move funds between line items in the Budget, provided that the total amount of expenditures docs not exceed funds currently obligated by this Agreement and is within the policies stated in the NIH Grants Policy Statement.

Funds obligated are for the defined Period of Performance only, as stated in Article III. Carryover of funds remaining at the end of this period is not automatic and must be asked for in a letter to the Sponsor. Sponsor will seek the approval of NIH. Carryover funds to Subgrantee arc not available until such approval has been received by Sponsor. Such approval will be forwarded to Subgrantee in a Modification to this agreement as detailed in Article XXIII.

ARTICLE V. PAYMENT

A. Payments for performance under this Agreement shall be issued by the Sponsor to the Subgrantee on a cost reimbursable basis within 30 days of receipt of ***proper, approved*** invoice(s) in the Sponsor Office. Invoices should be submitted monthly and no less than quarterly.

B. To be considered ***proper,*** an invoice must contain the Agreement identification number **(HHSN261201600027C),** sufficiently itemize expenses for which the Subgrantee is invoicing, and contain an original dated approval signature of an authorized representative of the Subgrantee. This signature shall certify that the expenses recited in the invoice reflect actual expenditures consistent with the terms of this Agreement.

C. To be considered ***approved,*** an invoice must also bear the dated approval initials or signature of **Scott Grindrod, Ph.D.** or his designee. The Sponsor Accounting Office shall seek to obtain this approval by submitting the invoice to **Peter Dritschilo, President and CFO** after receipt.

D. Invoices shall be sent to:

Shuttle Pharmaceuticals, LLC.
One Research Court, Suite 450
Rockville, MD 20850

Payment shall be made to:

Georgetown University

and shall be sent to:

Sponsored Projects Financial Operation
2121 Wisconsin Ave., NW
4th Floor
Washington, DC 20007
Attention: Chief Accounting Officer

Tax ID: 53-0196603

E. Invoices that exceed cither the period of performance of this Agreement or the obligated amount of this Agreement may be considered improper invoices and may be returned to the Subgrantee unpaid. Acceptance and payment by the Sponsor of any improper invoices shall not be construed as a waiver of the Sponsor's right to return future improper invoices.

F. A final invoice clearly marked "FINAL" must be received within sixty (60) days of the close of the expiration date of the award. Invoices received after this date may be considered improper invoices, and may be returned to the Subgrantee unpaid.

ARTICLE VI. RECORDS AND AUDIT

A Records for this Agreement arc to be retained by the Subgrantee for at least three years after final payment under this Agreement and all pending matters arc closed. If an audit, litigation, or other action involving the records is started before the end of the three year period, the records must be retained until all issues arising out of the action are resolved or until the end of the three year period, whichever is later. The Subgrantee agrees to give the Sponsor, the National Institutes of Health, the Comptroller General of the United States, or any of their authorized representatives access to these records and any other pertinent books, documents, papers or other records, in order to make audits, examinations, excerpts and transcripts.

B. The Subgrantee agrees to comply with the requirements of 2 CFR 200 as appropriate. The Subgrantee further agrees to provide the Sponsor with copies of any independent auditors' reports within 30 days of their receipt by the Subgrantee. Where the report includes instances of non-compliance with federal laws and regulations, the Subgrantee shall provide copies of responses to the report and a plan for corrective action.

ARTICLE VII. PUBLICATIONS

In the event either Party wishes to publish or present any material from work performed under this Agreement, the Subgrantee agrees to submit a manuscript of the publication or an abstract of the presentation to Dr. Scott Grindrod for comment at least thirty (30) days prior to submission for publication or presentation.

The Subgrantee further agrees that when publishing, or submitting for publication, in scientific, peer-reviewed or other scholarly publications, the Subgrantee shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this Subgrant in any media by including an acknowledgement substantially as follows:

"The project described was supported by Award Number **(hhsn261201600027c)** from the Shuttle Pharmaceuticals, LLC. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Shuttle Pharmaceuticals, LLC or the National Institutes of Health."

ARTICLE VIII. PATENTS AND INVENTIONS

Pursuant to the Bayh-Dole Act and Executive Order 12591 (April 10, 1987), all recipients of Federal research funding (i.e., all Federal grantees and contractors and consortium participants and other organizations receiving funds under Federal grants and contracts, whether small businesses, large businesses, or non-profit organizations) are subject to the same invention reporting requirements and regulations. These are included in the regulations issued by the Department of Commerce, found at 37 CFR Part 401.

For purposes of this Subgrant, Sponsor is the grantor. Subgrantee will establish and implement an employee invention reporting policy to identify the parties who perform work under this Subgrant and who may be reasonably expected to make inventions.

The determination of the rights of ownership and disposition of inventions resulting from the performance of the work done under this Subgrant and the administration of such inventions shall be in accordance with NIH policies and the Small Business Innovation Research (SBIR) agreement entered into by and between the Parties dated 10/28/2016, attached hereto as ATTACHMENT C

ARTICLE IX. INDEMNIFICATION

The Subgrantee shall defend, indemnify and hold the Sponsor, its officers, employees, and agents, harmless from any and all liability, loss, expenses (including reasonable attorney's fees), or claims for injury or damages arising out of the performance of this Agreement but only in proportion to and to the extent such liability, loss, expense, attorney's fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of the Subgrantee, its officers, employees, or agents.

The Sponsor shall defend, indemnify and hold the Subgrantee, its officers, employees, and agents, harmless from any and all liability, loss, expenses (including reasonable attorney's fees), or claims for injury or damages arising out of the performance of this Agreement but only in proportion to and to the extent such liability, loss, expense, attorney's fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of die Sponsor, its officers, employees, or agents.

ARTICLE X. CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS - PRIMARY COVERED TRANSACTIONS

A. The Subgrantee certifies to the best of its knowledge and belief, that it and its principals:

1. Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

2. Have not within a three-year period preceding this agreement been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

3. Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (2) of this certification; and

4. Have not within a three year period preceding this agreement had one or more public transactions (Federal, State, or local) terminated for cause or default.

B. Where a prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall provide an explanation.

ARTICLE XL TERMINATION

A. Either Party may terminate this Agreement for cause or convenience by giving the other Party thirty (30) days written notice.

B. In all instances of termination or suspension, the Subgrantee shall be given written notice of the termination or suspension, including a written explanation of the reason(s) for such action. Where appropriate, the Subgrantee shall be given reasonable time to cure any deficiency in its performance. If the deficiency is not corrected within a reasonable time, as defined by the Sponsor in consultation with the Subgrantee, the Agreement may then be immediately terminated or suspended.

C. Upon receipt of a notice of termination or suspension as specified above, the Subgrantee shall take immediate action to minimize all expenditures and obligations financed by this Agreement and shall cancel unliquidated obligations wherever possible. Except as provided below, no further reimbursement shall be made after the effective date of termination or suspension. The Subgrantee shall within 30 calendar days after the effective date of termination or suspension repay to the Sponsor all unexpended funds disbursed by the Sponsor that are not otherwise obligated by a legally binding transaction applicable to this Agreement. Should the funds paid by the Sponsor to the Subgrantee be insufficient to cover the Subgrantee's obligations in the legally binding transaction, the Subgrantee may submit to the Sponsor within 60 calendar days after the effective date of termination or suspension a written claim covering such obligations. The Sponsor Sponsored Accounting Office shall determine the amount(s) to be paid by the Sponsor to the Subgrantee under such claims in accordance with the applicable cost principles.

ARTICLE XII. DISPUTES

A. There is no formal procedure established for resolving disputes between the Sponsor and the Subgrantee. It is Sponsor policy to make every reasonable effort to resolve all issues fairly by negotiation without litigation. Any disputes arising under this Agreement shall be brought to the attention of the Georgetown University Medical Center Office of Sponsored Research. Authority for resolving such disputes on behalf of the Subgrantee shall reside with the Sr. Associate Vice President of the Office of Sponsored Research or her designee.

B. This Article shall not be construed to limit the administrative or legal rights otherwise available to the parties in the event of violations of the terms or conditions of this Agreement.

ARTICLE XIII. NOTICES

Any official notices required under the terms of this Agreement shall be hand delivered or sent by Certified Mail, postage prepaid, return receipt requested, to the appropriate individual and address listed below.

For the Sponsor:

Peter Dritschilo, President and CFO
Shuttle Pharmaceuticals, Inc.
One Research Court, Suite 450
Rockville, MD 20850

Phone: 240-403-4212 (Work)
240-271-0642 (Cell)
Email: peter.dritschllo@shuttlepharma.org

For the Subgrantee:

Marjan Mobini
Sr. Grants & Contracts Officer
Office of Sponsored Research
Georgetown University
3300 Whitehaven Street, NW
Washington, DC 20007
Tel: 202-687-7866
Email: mobinim@georgetown.edu

ARTICLE XIV. IRB APPROVAL

Research involving human subjects shall not be conducted under this subgrant until Subgrantee has provided to Sponsor a properly completed "Protection of Human Subjects Assurance identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Subgrantee's self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310). Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

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

ARTICLE XV. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Subgrantee should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 (Revised August 25, 2000) at the following website:

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

The terms and conditions referencing Human Subjects Assurance and Required Education in the Protection of Human Research Participants are in full force as if written in their entirety and are made a part of this Subgrant.

ARTICLE XVI. HIPAA

Notwithstanding anything to the contrary in this Agreement, all individually identifiable health information shall be treated as confidential by the parties in accordance with all applicable federal, state or local laws and regulations governing the confidentiality and privacy of individually identifiable health information, including without limitation, the HIPAA Privacy Regulation and any regulations and official guidelines promulgated thereunder, and the parties agree to take such additional steps and/or to negotiate such amendments to this Agreement as may be required to ensure that the parties are and remain in compliance with the HIPAA Privacy Regulation and official guidance. Institution hereby certifies that it complies with all applicable HIPAA requirements.

ARTICLE XVII. INCORPORATED TERMS OF THE PRIME AGREEMENT

This Agreement is subject, where applicable, to the following terms and conditions of the Prime Agreement.

1. FAR 52. 252-2
2. Section G
3. Section H
4. Section I

These terms are in full force and effect as if written in this Article in their entirety. Where the terms read or imply "The Government or the National Institutes of Health" they shall be considered to read or imply "The Sponsor". Where they read or imply "The Grantee" they shall be considered to read or imply "The Subgrantee". Where they read or imply a Sponsor official, they shall be considered to read or imply the relevant Sponsor official.

These additional terms supplement the articles of this Agreement. They do not replace or supersede nor are they replaced or superseded by the Articles of this Agreement. In the event of a conflict between the Articles of this Agreement and these additional terms and conditions, a resolution shall be achieved in accordance with **ARTICLE XII**.

ARTICLE XVIII. ATTACHMENTS

The following attachments are an integral part of this Agreement:

ATTACHMENT A.	Statement of Work
ATTACHMENT B.	Budget
ATTACHMENT C.	SBTR Agreement
ATTACHMENT D.	(If applicable IRB Approval or IACUC Approval)

ARTICLE XIX. REPORTING REQUIREMENTS

Subgrantee's Principal Investigator will provide to **Dr. Scott Grindrod** quarterly technical progress reports and a final technical report on all work to be performed under this Agreement as required to fulfill reporting requirements under the Prime Award and to enable with the filing of the continuation application of such award.

ARTICLE XX. INDEPENDENT CONTRACTOR

In performing activities under this Agreement, Subgrantee shall be deemed to be and shall be an independent contractor and, as such, shall not be entitled to any benefits applicable to employees of the Sponsor.

ARTICLE XXI. GOVERNING LAW

This Agreement shall be governed by the laws of the District of Columbia.

ARTICLE XXII. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision, or condition of this Agreement.

ARTICLE XXIII. MODIFICATION OR AMENDMENT

No modification or amendment to this Agreement shall be valid unless in writing, signed by an authorized representative of the Sponsor and an authorized representative of the Subgrantee. Only designated individuals within the Georgetown University Medical Center, Office of Sponsored Research are authorized to modify this Agreement for Georgetown.

ARTICLE XXIV. ENTIRE AGREEMENT

This writing contains the entire agreement of the parties and there are no promises, understandings, or agreements of any kind pertaining to this Agreement other than those written in this Agreement.

ARTICLE XXV. SEVERABILITY

In the event that any term or provision of this Agreement or any application of a term or provision of this Agreement is deemed illegal, or unenforceable, the remainder of this Agreement or the application of such a term or provision shall not be affected, except with regard to those persons or circumstances to which it was specifically held invalid or unenforceable.

ARTICLE XXVI. ANTI-TERRORISM

The Subgrantee is reminded that U.S. Executive Orders 13224 and U.S. Law prohibits transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of die Subgrantee to ensure compliance with these Executive Orders and Laws. This provision must be included in all subcontracts/subawards issued under this subgrant agreement.

ARTICLE XXVII. CAPTIONS OR HEADINGS

Captions or headings contained in this Agreement are inserted only as a matter of convenience and do not in any way define, limit, or extend the scope or intent of this Agreement or any term or provision of this Agreement.

ARTICLE XXVIII. COUNTERPARTS

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

ARTICLE XXIX. CERTIFICATION REGARDING FINANCIAL CONFLICTS OF INTEREST

In this Article, capitalized terms have the meaning given to them in the Public Health Service's regulations on Promoting Objectivity In Research, codified in Title 42, Part 50, Subpart F of the Code of Federal Regulations, as they may from time to time be amended ("PHS Regulations"). The Subgrantee certifies to the Sponsor that [check ONE statement below]:

☒ Subgrantee has adopted Financial Conflicts of Interest policies and procedures that comply with the PHS Regulations. Subgrantee will comply with the requirements of its own Financial Conflicts of Interest policies and procedures with respect to its performance under this Agreement. Within 1 day of receipt of a "just in time" notice from the Sponsor [or: of the execution of this Agreement], and thereafter within 30 days of discovering any new Significant Financial Interests for its Investigators, Subrecipient shall report to the Sponsor any identified Financial Conflicts of Interest for its Investigators.

The report will contain all elements required by the PHS Regulations[, including: (i) Project/Contract number; (ii) principal investigator/project director; (iii) name of the Investigator with the Financial Conflict of Interest; (iv) name of entity in which the Investigator has a Significant Financial Interest that gives rise to a Financial Conflict of Interest; (v) nature of the financial interest; (vi) value of the financial interest, within dollar ranges, or if the value cannot be readily determined through reference to public prices or other reasonable measures, a statement to that effect; (vii) a description of how the financial interest relates to the PHS-funded research and the basis for the Subgrantee's determination that the financial interest conflicts with such research; and (viii) a description of the key elements of the management plan, **including (a) the role and principal duties of the conflicted Investigator in the research project, (b) conditions of the management plan, (c) how the management plan is designed to safeguard objectivity in the research project (d) confirmation of the Investigator's agreement to the management plan. (e)how the management plan will be monitored to ensure Investigator compliance, and (f) other information as needed]**.

☐ Subgrantee has not adopted Financial Conflicts of Interest policies and procedures that comply with the PHS Regulations. In performing its obligations under this Agreement, Subgrantee will follow Sponsor's Financial Conflicts of Interest Policy [http://ora.georgctown.edu/FCOIPolicyRequircments.html]. which will be incorporated into the Subaward Agreement by reference. Subgrantee will require its Investigators to complete the Financial Conflicts of Interest Disclosure forms provided by the Sponsor. Within 1 day of receipt of a "just in time" notice from the Sponsor [or: of the execution of this Agreement], and thereafter within 30 days of discovering any new Significant Financial Interests of its Investigators, Subrecipient shall report to the Sponsor any Significant Financial Interests reported by its Investigators. Subgrantee will ensure that its Investigators provide full information to Sponsor regarding any Significant Financial Interests, in order for the Sponsor to determine if such Significant Financial Interests are related to the research and constitute a Financial Conflict of Interest and to make required reports to the funding agency. If Sponsor determines that any of Subgrantee's Investigators have Financial Conflicts of Interest, Subgrantee will ensure that its Investigators comply with the terms of any conflict management plan(s) issued by the Sponsor with respect to such Financial Conflicts of Interest.

ARTICLE XXX. ACCEPTANCE

This Agreement shall not be considered accepted or effective until signed below by authorized representatives of both of the parties. By signing below, each individual warrants that he or she is authorized to bind his or her organization to this Agreement.

The parties agree that this Agreement may be signed by either party by electronic means. Neither party will challenge the legal effect of cither party's signature or the enforceability of this Agreement solely because the signature is in electronic form.

FOR SHUTTLE PHARMACEUTICALS, LLC.	**FOR GEORGETOWN UNIVERSITY:**
/s/ Peter Dritschilo	**/s/ Trudy Bright**
NAME: Peter Dritschilo,	**NAME: Trudy Bright**
TITLE: President and CFO	**TITLE: Director, Office of Sponsored Research**
Date: 11/21/16	**Date: 11/22/2016**

ATTACHMENT A.
STATEMENT OF WORK

[Blue – To be filled out by NCI STAFF]

STATEMENT OF WORK (Phase I)

TITLE: Predictive biomarkers for prostate cancer patient sensitivity for radiation late effects

PRINCIPAL INVESTIGATOR(S): Scott Grindrod, PhD
PROJECT DURATION: 12 months
COMPANY: Shuttle Pharmaceuticals, Inc.
SUBCONTRACTORS: Georgetown University

I. Background Information and Objectives

A. Background Information

Patients treated for prostate cancer may experience treatment related late effects that adversely affect quality of life and may prove life-threatening. The objective of this Phase I SBIR application is to determine the technical and commercial feasibility of a biomarker panel predictive of radiation mediated late effects in patients treated for prostate cancer. We will develop a metabolite signature of radiation responses in a cohort of patients undergoing stereotactic body radiation therapy (SBRT) for prostate cancer. Analysis of banked plasma samples will be correlated with clinical outcomes to identify markers of urinary and gastrointestinal late effects for validation in a larger clinical population to be proposed in a subsequent Phase II application. The Phase II effort will allow Shuttle Pharmaceuticals to advance its proposed commercialization plan and to raise capital to support validation clinical trials leading to FDA approval.

Patients treated with stereotactic body radiation therapy (SBRT) for prostate cancers on an IRB approved protocol have banked clinical specimens and detailed monitoring of quality of life parameters. Sub-sets of these patients have developed urinary incontinence (Ul), symptomatic urinary flare (USF), obstructed voiding symptoms/retention (UR) and radiation proctitis (RP). We have used high resolution mass spectrometry based metabolomics/lipidomic profiling to analyze this unique cohort of patient samples and propose here, to leverage our established analytical platform to advance product development and validation of a biomarker panel predictive of radiation toxicities. Metabolites in plasma from a cohort of 100 de-identified patients will be analyzed to develop a kit supporting metabolomic analysis to serve as a biomarker panel predictive of patient susceptibility for radiation late effects.

B. Technical Objectives

The three technical objectives of this proposal focus on determining the feasibility for developing a metabolite panel predictive of clinical outcomes in prostate cancer patients treated with radiation therapy (SBRT). In Objective 1, we will use technology in the Waters Center of Excellence at Georgetown University to perform metabolite analysis on de-identified, bio-banked plasma samples from 100 patients. In the first objective, untargeted metabolite profiles will be obtained and analyzed for correlations with clinical outcomes, including cancer recurrence, urinary tract injury and rectal injury. Candidate metabolites will be validated and a metabolite "kit" will be designed and tested in Objective 2. Standard operating procedures (SOPs) will be prepared and purity, stability and storage capacity will be tested. Objective3 is to consolidate the intellectual property (metabolite panels) within Georgetown University policies and obtain a license to develop and commercialize the biomarker panels. Submitting a final report to NIH staff documenting success in achieving the Phase I milestones will allow preparation of a phase II application to clinically validate the biomarker panel and support commercialization efforts.

Objective 1. Develop a metabolite biomarker panel of radiation late effects.

Task 1.1. Perform untargeted metabolomics profiling of plasma specimens using UPLC-ESI-QTOFMS.

Milestone 1.1. Metabolite raw data on clinical samples from 100 patients

Task 1.2. Perform biostatistics analysis of raw data to identify candidate metabolite signatures.

Milestone 1.2. Metabolite signatures for cancer recurrence, urinary tract injury and rectal injury.

Task 1.3. Validate and evaluate biomarker performance using SID-MRM-MS. Identify candidate molecules for biomarker development.

Milestone 1.3. Panels of validated biomarkers that correlate to cancer recurrence, urinary injury and rectal injury (for kit development).

Objective 2. Design and test a metabolite "kit" suitable for GLP clinical application

Task 2.1. Define the operating range of the biomarker assay.

Milestone 2.1. Accuracy and precision of the assay is available for preparing standard operating procedures (SOPs).

Task 2.2. Determine the assay optimization and standardization.

Milestone 2.2. Purity, stability and storage capacity data for selected metabolites will be used in SOPs.

Task 2.3. Determine robustness of the assay.

Milestone 2.3. Assay repeatability available for the SOPs.

Objective 3. Review achieved milestones, evaluate commercialization potential and advance a Phase II SBIR application for clinical trial validation of the biomarker

Task 3.1. Disclose intellectual property to the GU Office of Technology Commercialization.

Milestone 3.1. Provisional patent application submission.

Task 3.2. Prepare and submit the final report of Phase I accomplishments.

Milestone 3.2. Written final report is accepted by NIH staff allowing submission of a Phase II application.

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

		Months 1-3	Months 4-6	Months 7-9	Months 10-12
Objective 1		******	******		
GU	Milestone 1.1. Metabolite raw data on clinical samples from 100 patients	X	X		
SP/GU	Milestone 1.2. Metabolite sianatures for cancer recurrence, urinary tract injury and rectal injury.		X		
SP	Milestone 1.3. Panels of validated biomarkers for assay kit development.		X	X	X
Objective 2			******	******	
SP	Milestone 2.1. Accuracy and precision of the assay for standard operating procedures (SOPs)		X	X	
SP	Milestone 2.2. Puritv. stability and storaae capacity data for selected metabolites for SOPs.		X	X	
SP	Milestone 2.3. Assay repeatability for SOPs.			X	
Objective 3			***	******	******
SP/GU	Milestone 3.1. Provisional patent application submission.		X	X	X
SP	Milestone 3.2. Written final report is accepted by NIH staff; submit a Phase II SBIR application.			X	X

SP = Work will be performed in Shuttle Pharmaceuticals Laboratory/ Administrative Offices

GU = Work will be performed in Georgetown University Shared Resource Facilities

ATTACHMENT B.
BUDGET

ATTACHMENT C.
SBIR AGREEMENT