CLINICAL TRIAL AGREEMENT

BETWEEN

THE RESEARCH FOUNDATION FOR THE STATE UNIVERSITY OF NEW YORK

AND

SPONSOR

This Clinical Trial (ACTA) Agreement ("Agreement") is made as of this {DAY} day of {MONTH}, {YEAR} (the "Effective Date") by and between THE RESEARCH FOUNDATION FOR THE STATE UNIVERSITY OF NEW YORK a nonprofit, educational corporation organized and existing under the laws of the State of New York, with an office located at Office of Sponsored Programs, Stony Brook, NY 11794-3362 at Stony Brook University ("Institution") and {COMPANY NAME}, a corporation having its principal place of business at {COMPANY ADDRESS}("Sponsor"). Sponsor and Institution are herein referred to collectively as "Parties." Individually, each of Sponsor and Institution is a "Party."

WHEREAS, Institution and Sponsor have agreed to be part of the ACTA member institution group, and the Parties agree to the use this standard agreement to accelerate the process of translating laboratory discoveries into treatments for patients, to engage communities in clinical research efforts, and to train a new generation of clinical and translational researchers;

WHEREAS, Sponsor is a for-profit organization that intends to conduct a sponsored multicenter clinical trial, described in 1.1 below, involving the use of certain diagnostic(s), drug(s), device(s), or biologic(s) provided by Sponsor;

WHEREAS, the Institution has appropriate facilities and personnel with the qualification, training, knowledge, and experience necessary to conduct such a clinical trial; and

WHEREAS, the Study contemplated by this Agreement is of mutual interest and benefit to Institution and Sponsor, and will further the instructional and research objectives of Institution in a manner consistent with its status as a nonprofit educational, research and health care institution;

NOW, THEREFORE, in consideration for the mutual promises made in this Agreement and for valid consideration, the Parties agree as follows:

1. Scope of Agreement

1.1. Institution will undertake a sponsored multicenter clinical trial ("Study") described in the protocol entitled, "{PROTOCOL TITLE}" which is attached hereto and incorporated

herein as **Exhibit A** ("Protocol"). Institution will use its reasonable efforts to only recruit subjects in accordance with the Protocol. The Study will be conducted at the Institution under the direction of {PRINCIPAL INVESTIGATOR NAME}, a {IDENTIFY ROLE; e.g., EMPLOYEE, FACULTY} of Institution ("Principal Investigator").

1.2. In the event of any conflict between the terms and conditions of this Agreement and the Protocol or between this Agreement and any of its Exhibits, the terms and conditions of the Protocol shall control with respect to matters of the clinical conduct of the Study, and the terms of this Agreement shall control with respect to all other matters.

1.3. Unless otherwise agreed to by the Parties, Sponsor will provide to Institution on a timely basis, without charge, the required quantities of properly-labeled Sponsor drug(s) ("Study Drug") and/or device(s) ("Study Device") and other materials (e.g., Investigator's Brochure, handling and storage instructions, and, if applicable, placebo) necessary for Institution to conduct the Study in accordance with the Protocol. Unless stated otherwise in writing by Sponsor, all such items are and will remain the sole property of Sponsor until administered or dispensed to Study subjects during the course of the Study. Receipt, storage, and handling of Study Drug or Study Device will be in compliance with all applicable laws and regulations, the Protocol, and Sponsor instructions.

1.4. Sponsor and Institution shall comply with and conduct all aspects of the Study in compliance with all applicable federal, state, and local laws and regulations, including generally accepted standards of good clinical practice as adopted by current FDA regulations and statutes and regulations of the U.S. Government relating to exportation of technical data, computer software, laboratory prototypes, and other commodities as applicable to academic institutions. Institution will only allow individuals who are appropriately trained and qualified to assist in the conduct of the Study.

1.5. Institution shall obtain IRB approval for this Study and proof thereof shall be provided to Sponsor. Initiation of the Protocol and Institution's obligation to conduct the Study shall not begin until IRB approval is obtained. Institution shall obtain from each subject, prior to the subject's participation in the Study, a signed informed consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IRB or a waiver of consent as directed by the IRB and further provided that the informed consent is consistent with Institution's policies.

1.6. Sponsor agrees to provide Institution with any data and safety monitoring reports related to the Study, and Institution agrees they will be submitted to the IRB as required. During the Study and for at least two (2) years following the completion of the Study at all sites, Sponsor shall promptly provide Institution and Principal Investigator with the written report of any findings, including Study results and any routine monitoring findings in site monitoring reports, and data safety monitoring committee reports including, but not limited to, data and safety analyses, and any Study information that may (i) affect the safety and welfare of current or former Study subjects, or (ii) influence the conduct of the Study. Institution and/or Principal Investigator will communicate findings to the IRB and Study subjects, as appropriate.

1.7. Institution shall promptly inform Sponsor of any urgent safety measures as instructed in the Protocol or breaches of the Protocol of which Institution becomes aware.

2. Payments

Sponsor agrees to pay Institution in accordance with the budget attached as **Exhibit B** ("Budget") on a prorated basis, according to the actual work completed and any non-cancelable obligated expenses, for subjects who are enrolled into the Study. The Parties acknowledge that the Budget amounts represent an equitable exchange for the conduct of

the Study in light of the professional time and expenses required for the performance of the Study.
In addition to other necessary routing information detailed in Exhibit B, each payment shall clearly reference the: Study Protocol Number and PI name.
For administrative convenience, various Study contact information may be attached hereto and incorporated by reference as Exhibit C, entitled, "Administrative & Study Points of Contact."
The Institution's tax identification number is: __-_____.

3. Confidentiality

It is anticipated that in the performance of this Agreement, Sponsor may need to disclose to Institution information which is considered confidential. The rights and obligations of the Parties with respect to such information are as follows:
"Confidential Information" refers to information of any kind which is disclosed to the Institution by Sponsor for purposes of conducting the Study or Data (as defined below in Section 4) which:
a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure;

b) if disclosed orally, is identified in a marked writing within thirty (30) days as being confidential; or

c) is of such a nature that a reasonable person familiar with the Study would consider it to be confidential or proprietary from the context or circumstances of disclosure.
Notwithstanding the foregoing, Data and results generated in the course of conducting the Study are not Confidential Information for publishing purposes in accordance with Section 9 of this Agreement.

Institution agrees, for a period of five (5) years following the termination or expiration of this Agreement, to use reasonable efforts, no less than the protection given their own confidential information, to use Confidential Information received from Sponsor in accordance with this Section.
Institution agrees to use Sponsor's Confidential Information solely as allowed by this Agreement, and for the purposes of conducting the Study. Institution agrees to make Sponsor's Confidential Information available only to those of its, or its affiliated hospitals' employees, personnel, agents, consultants, and vendors, and approved subcontractors, as applicable, who require access to it in the performance of this Study, and are subject to similar terms of confidentiality.
3.2. The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:
a) is or becomes public knowledge through no breach of this Agreement by Institution;

b) is disclosed to Institution by a third party entitled to disclose such information without known obligation of confidentiality;

c) is already known or is independently developed by Institution without use of Sponsor's Confidential Information as shown by Institution's contemporaneous written records;

d) is necessary to obtain IRB approval of Study or required to be included in the written information summary provided to Study subject(s) and/or informed consent form;

e) is released with the prior written consent of the Sponsor; or

f) is required to support the medical care of a Study Subject.

3.3. Institution may disclose Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable law, IRB, government agency, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Institution, subject to the requirement, order, or subpoena, promptly notifies Sponsor. Sponsor may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Institution will disclose only the minimum amount of Confidential Information necessary to comply with law or court order as advised by Institution's legal counsel.
3.4. No license or other right is created or granted hereby, except the specific right to conduct the Study as set forth by Protocol and under terms of this Agreement, nor shall any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the Parties duly signed by their authorized representatives.
3.5. Upon Sponsor's written request, Institution agrees to return all Confidential Information supplied to it by Sponsor at Sponsor's expense pursuant to this Agreement except that Institution may retain one (1) copy of any such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement.
3.6 Institution may disclose the existence of this Agreement and any additional information necessary to ensure compliance with applicable Federal, State and Institutional policies, regulations, and laws.

4. Data Use/Ownership

"Data" shall mean all data and information generated by Institution as a result of conducting the Study in accordance with the IRB approved Protocol. Data does not include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in the Institution's ordinary course of business operations, which shall remain the sole and exclusive property of the Institution or medical provider. Sponsor shall own and have the right to use the Data in accordance with the signed informed consent and authorization form, applicable laws, and the terms of this Agreement. Notwithstanding any licenses or other rights granted to Sponsor herein, but in accordance with the confidentiality and publication sections herein, Institution shall retain the right to use the Data and results for its publication, IRB, regulatory, legal, clinical, educational, and internal research purposes.

5. HIPAA/HIPAA Privacy

5.1. Institution shall comply with applicable laws and regulations, as amended from time to time, including without limitation, the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA) with respect to the collection, use, storage, and disclosure of Protected Health Information (PHI) as defined in HIPAA. Sponsor shall collect, use, store, access, and disclose PHI collected from Study subjects only as permitted by the IRB approved informed consent form or HIPAA authorization form obtained from a Study subject. Sponsor will collect, use, store, and disclose any Subject Material, defined in Section 15, it receives only in accordance with the informed consent form and, in any event, will not collect, use, store, or disclose any PHI attached to or contained within the Subject Material in any manner that would violate this Section of the Agreement.
Institution acknowledges that, pursuant to Section 111 of the Medicare, Medicaid, and

SCHIP Extension Act of 2007 ("MMSEA"), Sponsor has an obligation to submit certain reports to the Centers for Medicare & Medicaid Services with respect to Medicare beneficiaries who participate in the Study and experience a research injury for which diagnosis or treatment costs are incurred. Sponsor recognizes that Institution and Sponsor are subject to laws and regulations protecting the confidentiality of research subject information. Accordingly: (1) Institution agrees upon prior written request to provide to Sponsor, or a third-party vendor as designated by Sponsor, certain identifiable patient information required by MMSEA for Study subjects who are Medicare beneficiaries and incur medical costs in association with a research injury and whose costs are reimbursed by Sponsor pursuant to this Agreement; and (2) Institution further agrees to otherwise cooperate with Sponsor (and any third-party vendors as designated by Sponsor) to the extent necessary for Sponsor to meet its MMSEA reporting obligations.
5.2. Sponsor's ability to review the Study subjects' Study-related information contained in the Study subject's medical record shall be subject to reasonable safeguards for the protection of Study subject confidentiality and the Study subjects' informed consent form or HIPAA authorization form.
5.3. Sponsor shall not attempt to identify, or contact, any Study subject unless permitted by the informed consent form.

6. Record Retention

As applicable by law, Institution shall retain and preserve a copy of the Study records for the longer of:
a) two (2) years after a marketing authorization for Study Drug, or Study Device has been approved for the indication for which it was investigated or Sponsor has discontinued research on the Study Drug or Study Device;

b) such longer period as required by federal regulatory requirements; or

c) as requested by Sponsor at Sponsor's reasonable storage expense.

7. Monitoring and Auditing

7.1. Site visits by Sponsor and/or its authorized designee (e.g., Study monitor) will be scheduled in advance for times mutually acceptable to the Parties during normal business hours. Sponsor's and/or authorized designee's access is subject to reasonable safeguards to ensure confidentiality of medical records and systems.
7.2. Upon becoming aware of an audit or investigation by a regulatory agency with jurisdiction over the Study, Institution agrees to provide Sponsor with prompt notice of the auditor investigation. If legally permissible or allowable by the regulatory agency and permissible in accordance with the Institution's policy, Sponsor may be available or request to be present with approval from auditor during such audit, but Sponsor agrees not to alter or interfere with any documentation or practice of Institution. Institution shall be free to respond to any regulatory agency inquiries and will provide Sponsor with a copy of any formal response or documentation to the regulatory agency regarding the Study.

8. Inventions, Discoveries and Patents

8.1. It is recognized and understood that certain existing inventions and technologies, and those arising outside of the research conducted under this Agreement, are the separate property of Sponsor or Institution and are not affected by this Agreement, and neither Party

shall have any claims to or rights in such separate inventions and technologies.
8.2. Any new patentable inventions, developments, or discoveries made during and in the performance of the Study ("Inventions") shall be promptly disclosed to Sponsor. Title to Inventions that necessarily use or necessarily incorporate Sponsor's Study Drug and/or Study Device shall reside with Sponsor ("Sponsor Inventions"). Institution shall assign all Sponsor Inventions to Sponsor in writing. Title to Inventions other than Sponsor Inventions ("Other Inventions") shall reside with Sponsor if Sponsor personnel are the sole inventors, with Institution if Institution personnel are the sole inventors, and shall be held jointly if both Institution and Sponsor personnel are inventors.
8.3. To the extent that Institution owns sole or joint title in any such Other Inventions, Sponsor is hereby granted, without option fee other than consideration of the Study sponsored herein and the reimbursement to Institution for patent expenses incurred prior to or during the option period, an option to acquire an exclusive, worldwide, royalty-bearing license to Institution's rights to any Other Invention, which option shall extend for no more than ninety (90) days after Sponsor's receipt of an Invention disclosure from Institution ("Option Period"). The Parties shall use their reasonable efforts to negotiate, for a period not to exceed ninety (90) days after Sponsor's exercise of such option, a license agreement satisfactory to both Parties ("Negotiation Period"). In the event Sponsor fails to exercise its option within the Option Period, or the Parties fail to reach agreement on the terms of such license within the Negotiation Period, Institution shall have no further obligation to Sponsor under this Agreement with regard to the specific Other Invention.
8.4. Institution shall retain a royalty-free, irrevocable license to use for its own internal noncommercial research, educational and patient care purposes, all Sponsor Inventions or Other Inventions licensed or assigned to Sponsor hereunder.
8.5. Nothing contained in this Agreement shall be deemed to grant either directly by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either Party.
8.6. The Parties agree that the provisions of this Agreement are intended to be interpreted and implemented so as to comply with all applicable federal laws, rules, and regulations, including without limitation the requirements of Rev. Proc. 2007-47; provided, however, if it is determined by the Internal Revenue Service or any other federal agency or instrumentality (the "Government") that the provisions of this Agreement are not in such compliance, then the Parties agree to modify the provisions and the implementation of this Agreement so as to be in compliance with all applicable federal laws, rules, and regulations as determined by the Government.

9. Publication

9.1. Institution shall be free to publish, present, or use any Data and results arising out of its performance of the Protocol (individually, a "Publication"). At least thirty (30) days prior to submission for Publication, Institution shall submit to Sponsor for review and comment any proposed oral or written Publication ("Review Period"). Institution will consider any such comments in good faith but is under no obligation to incorporate Sponsor's suggestions. The Review Period for abstracts or poster presentations shall be thirty (30) days. If during the Review Period, Sponsor notifies Institution in writing that: (i) it desires patent applications to be filed on any inventions disclosed or contained in the disclosures, Institution will defer Publication for a period not to exceed sixty (60) days, to permit Sponsor to file any desired patent applications; and (ii) if the Publication contains Sponsor's Confidential Information as defined in Section 3 and Sponsor requests Institution in writing

to delete such Sponsor's Confidential Information, the Institution agrees to delete such Sponsor's Confidential Information only to the extent such deletion does not preclude the complete and accurate presentation and interpretation of the Study results.
9.2. If this Study is part of a multi-center clinical trial, Institution agrees that the first Publication of the results of the Study shall be made in conjunction with the presentation of a joint multi-center Publication of the Study results with the Principal Investigators from all sites contributing Data, analyses, and comments. However, Institution may publish the Data and Study results individually in accordance with this Section 9 upon first occurrence of one of the following: (i) multi-center Publication is published; (ii) no multi-center publication is submitted within eighteen (18) months after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-center Publication.
9.3. If no multi-center Publication occurs within eighteen (18) months of the completion of the Study at all sites, upon request by Institution, Sponsor agrees to provide such Institution access to the aggregate Data from all Study sites.
9.4. If the Institution, through its Principal Investigator, is identified to participate in the multi-center Publication: (i) Institution will have the opportunity to review the aggregate multi-center Data, upon request; and (ii) consistent with the International Committee of Medical Journal Editors (ICMJE) regulations, Institution will have adequate opportunity to review and provide input on any abstract or manuscript prior to its submission for Publication. Institution also retains the right, on behalf of its Principal Investigator, to decline to be an author on any Publication.

10. Use of Name

10.1. Neither Institution nor Sponsor may use the name, trademark, logo, symbol, or other image or trade name of the other Party or its employees and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies endorsement without the prior written consent of an authorized representative of the Party whose name is being used. Such approval will not be unreasonably withheld.
10.2. The Parties understand that the amount of any payment made hereunder may be disclosed and made public by a Party as required by law or regulation, including the Patient Protection and Affordable Care Act of 2010, provided that the disclosure clearly designates the payment as having been made to Institution for research and not to the physician.
10.3. Institution may acknowledge the Sponsor's support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations. Notwithstanding anything to the contrary in this Agreement, Sponsor agrees to allow publicly registered information about the Study to appear on Institution's clinical trials directory/website. Additionally, notwithstanding anything herein to the contrary, Institution shall have the right to post Sponsor's name, the Study title, and the Study period, and funding amount, on Institution publicly accessible lists of research conducted by the Institution.

11. Indemnification and Limitation of Liability

11.1 Sponsor agrees to defend, indemnify, and hold harmless the Institution and its medical affiliates and affiliated hospitals, and each of their trustees, officers, directors, governing bodies, subsidiaries, affiliates, investigators, employees, IRB members, agents, successors, heirs and assigns (collectively referred to as "Institution's Indemnitees"), from and against any third party claims, loss, damage, cost and expense of claims (including

reasonable attorney's fees) and suits alleged to be caused by or arising from the conduct of the Study or use of the Study Drug or Study Device under this Agreement or from the use of the Study results ("Claims"), regardless of the legal theory asserted.
11.2. Sponsor shall have no obligation to provide such indemnification to the extent that such Claim is solely caused by Institution's Indemnitee(s)': (1) failure to adhere to and comply with all material and substantive specifications and directions set forth in the Protocol (except to the extent such deviation is reasonable to protect the rights, safety and welfare of the Study subjects); (2) failure to comply with all applicable laws and regulations in the performance of the Study, or (3) if such claim is directly caused by the negligent acts or omissions of Institution's Indemnitees(s).
11.3. Subject to the limits and without waiving any immunities provided under applicable law (including constitutional provisions, statutes and case law) regarding the status, powers and authority of the Institution or the Institution's principal(s), Institution shall indemnify, hold harmless and defend Sponsor, its directors, officers, employees and agents, ("Sponsor's Indemnitees") from and against only those third party Claims to the extent directly attributable to Institution's negligence in its conduct of the Study. Notwithstanding the above, Institution shall have no obligation to indemnify Sponsor for any other Claims (including, but not limited to, infringement or product liability Claims).
11.4. The indemnified Party shall give notice to the indemnifying Party promptly upon receipt of written notice of a Claim for which indemnification may be sought under this Agreement, provided, however, that failure to provide such notice shall not relieve indemnifying Party of its indemnification obligations except to the extent that the indemnifying Party's ability to defend such Claim is materially, adversely affected by such failure. Indemnifying Party shall not make any settlement admitting fault or incur any liability on the part of the indemnified Party without indemnified Party's prior written consent, such consent not to be unreasonably withheld or delayed. The indemnified Party shall cooperate with indemnifying Party in all reasonable respects regarding the defense of any such Claim, at indemnifying Party's expense. The indemnified Party shall be entitled to retain counsel of its choice at its own expense. In the event a Claim falls under this indemnification clause, in no event shall the indemnified Party compromise, settle or otherwise admit any liability with respect to any Claim without the prior written consent of the indemnifying Party, and such consent not to be unreasonably withheld or delayed.
11.5. EXCEPT FOR THE PARTIES' OBLIGATIONS TO INDEMNIFY EACH OTHER PURSUANT TO THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME.

12. Subject Injury

If a Study subject suffers an adverse reaction, illness, or injury which, in the reasonable judgment of Institution, was directly caused by a Study Drug or Study Device or any properly performed procedures required by the Protocol, Sponsor shall reimburse for the reasonable and necessary costs of diagnosis and treatment of any Study subject injury, including hospitalization, but only to the extent such expenses are not attributable to (i) Institution's negligence or willful misconduct or (ii) the natural progression of an underlying or pre-existing condition or events, unless exacerbated by participating in the Study.

13. Insurance

13.1. Institution shall, at its sole cost and expense maintain a policy or program of insurance or self-insurance at the level of at least $1,000,000 per occurrence (or per claim) and $3,000,000 annual aggregate to support its obligations assumed in this Agreement. However, if Institution is a public entity entitled to governmental immunity protections under applicable state law, then Institution may provide liability coverage in accordance with any limitations associated with the applicable law.
13.2. Sponsor shall, at its sole cost and expense, procure and maintain commercial general liability insurance, clinical trial insurance and products liability insurance or equivalent self-insurance, unless otherwise indicated in an attached work order, in amounts not less than $3,000,000 per occurrence and $10,000,000 annual aggregate. Such commercial general liability insurance, clinical trial insurance and products liability insurance or equivalent self-insurance shall provide contractual liability coverage for Sponsor's indemnification obligations herein.

13.3. Upon written request, either Party will provide evidence of its insurance or self-insurance acceptable to the other Party. Either Party will provide the other Party with written notice of material change in its coverage which would affect such Party's ability to meet its obligations under this Agreement. A Party's inability to meet its insurance obligation constitutes material breach of this Agreement.

14. Term and Termination

14.1. This term of this Agreement shall commence upon the Effective Date and terminate upon the completion of the Parties' Study-related activities under the Agreement, unless terminated early as further described in this Section.
14.2. Sponsor has the right to terminate the Study upon thirty (30) days prior written notice to the Institution. This Study may be terminated immediately at any time for any reason by the Institution or Sponsor when, in their judgment or that of the Principal Investigator, the Institution's IRB, Scientific Review Committee, if applicable, or the Food and Drug Administration, it is determined to be inappropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' rights, welfare, and safety, or the IRB otherwise disapproves the Study. If for any reason Principal Investigator becomes unavailable to direct the performance of the work under this Agreement, Institution shall notify Sponsor. If the Parties are unable to identify a mutually acceptable successor, this Agreement may be terminated by either Party upon thirty (30) days written notice.
14.3. Notwithstanding the above, any Party may, in addition to any other available remedies:
a) immediately terminate this Agreement upon the other Party's material failure to adhere to the Protocol, except for deviation required to protect the rights, safety, and welfare of Study subjects; and/or

b) terminate this Agreement upon the other Party's material default or breach of this Agreement, provided that the defaulting/breaching Party fails to remedy such material default, breach, or failure to adhere to the Protocol within thirty (30) business days after written notice thereof.

14.4. In the event that this Agreement is terminated prior to completion of the Study, for any reason, Institution shall:
a) notify the IRB that the Study has been terminated;

b) cease enrolling subjects in the Study;

c) cease treating Study subjects under the Protocol as directed by Sponsor to the extent

medically permissible and appropriate;

d) terminate, as soon as practicable, all other Study activities; and

e) furnish to Sponsor any required final report for the Study in the form reasonably acceptable to Sponsor.

Promptly following any such termination, Institution will provide to Sponsor copies of Data collected pursuant to the Study Protocol. Upon Sponsor's written request, Institution shall provide to Sponsor all Sponsor's Confidential Information provided under this Agreement provided, however, that Institution may retain one (1) copy of Confidential Information for record keeping purposes, monitoring its obligations, and exercising its rights hereunder, subject to Institution's ongoing compliance with the confidentiality and non-use obligations set forth in this Agreement.

14.5. If this Study is terminated early by either Party, the Institution shall be reimbursed for all work completed, on a pro rata basis, and reasonable costs of bringing the Study to termination incurred through the date of termination, and for non-cancelable commitments properly incurred through that date. Upon receipt of notice of termination, Institution will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with Sponsor to provide for an orderly wind-down of the Study.

14.6. Subsections 1.4, 1.6, and 14.6, and Sections 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 15, 19 and 23, shall survive any termination or expiration of this Agreement, except that Section 3 shall survive for the period stated in Section 3.1. Any provision of this Agreement that by its nature and intent remains valid after termination will survive termination.

15. Subject Material

15.1. Subject Material means any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Study subjects in accordance with and pursuant to the Protocol ("Subject Material").

15.2. Institution agrees to make the Subject Material available to the Sponsor in accordance with the Protocol for the purposes of the Study. The Subject Material may be used by the Sponsor, central lab, or other contracted party only as allowed by the Study subject's informed consent form or pertinent institutional review board(s). Sponsor agrees that any use of Subject Materials, other than as allowed by the Study subject's informed consent form, will require additional IRB review and approval.

16. Subcontract

Institution has the right to subcontract to other sites to conduct the Study in accordance with the Protocol with terms consistent with this Agreement with written approval of the Sponsor, which approval shall not be unreasonably withheld. If Institution subcontracts any Study related duties, Institution shall contract with such subcontractors incorporating terms substantially similar to the terms herein. Such subcontracts may be provided to the Sponsor upon written request. The Sponsor has the right to subcontract to a third-party CRO or Academic Research Organization (ARO) and assign Study-related duties and rights to any Sponsor affiliate. If Sponsor subcontracts any Study-related duties and rights, Sponsor remains responsible for any of those duties and rights.

17. Notices

Any notice, authorization, approval, consent or other communication will be in writing and deemed given:
a. Upon delivery in person;
b. Upon delivery by courier;
c. Upon delivery date by a nationally-recognized overnight delivery service such as FedEx.

If to Sponsor:
{SPONSOR NAME}
{CONTACT NAME}
{CONTACT TITLE}
{ADDRESS LINE}
{TELEPHONE NUMBER}
{FAX NUMBER}
{E-MAIL ADDRESS}

If to Institution:
The Research Foundation for The SUNY
Office of Sponsored Programs, W5510 Melville Library
Stony Brook, NY 11794-3362
631-632-4402
631-632-6963
Osp_contracts@stonybrook.edu

With a copy to Principal Investigator:
{PRINCIPAL INVESTIGATOR NAME}
{PRINCIPAL INVESTIGATOR TITLE}
{ADDRESS LINE}
{TELEPHONE NUMBER}
{FAX NUMBER }
{E-MAIL ADDRESS}

18. Independent Contractor

It is mutually understood and agreed that the relationship between Parties is that of independent contractors. Neither Party is the agent, employee, partner, joint venturer, or servant of the other. Except as specifically set forth herein, neither Party shall have nor exercise any control or direction over the methods by which the other Party performs work or obligations under this Agreement. Further, nothing in this Agreement is intended to create any partnership, joint ventures, lease, or equity relationship, expressly or by implication, between the Parties.

19. Clinical Trial Registry

Prior to enrollment of the first subject in the Study, Sponsor agrees to ensure that the Study is fully registered on www.clinicaltrials.gov in accordance with the requirements of the International Committee of Medical Journal Editors (ICMJE) and Public Law 110-85. Results of this Study will be reported in compliance with applicable laws.

20. Non-Referral/Anti-Corruption Language

20.1. The Parties agree that it is not their intent under this Agreement to induce or

encourage the unlawful referral of subjects or business between the Parties, and there shall not be any requirement under this Agreement that either Party, its employees or affiliates, including its medical staff, engage in any unlawful referral of subjects to, or order or purchase products or services from, the other Party.

20.2. Each Party shall require that their employees, who are involved in the conduct of the Study, will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and shall not make or cause another to make any offer or payment to any individual or entity for the purpose of influencing a decision for the benefit of the other Party.

21. Force Majeure

If either Party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such Party's direct control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather, or other reason beyond the Party's control (a "Disability") then such Party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Budget shall be adjusted to account for cost increases or decreases resulting from the Disability. The Party affected by the Disability shall notify the other Party of such Disability as provided for herein.

22. Counterparts

This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, and is binding on all Parties notwithstanding that each of the Parties may have signed different counterparts. Facsimiles or scanned copies of signatures or electronic images of signatures shall be considered original signature unless prohibited by applicable law.

23. Debarment

The Institution certifies that to its knowledge neither it, nor any of its employees, agents or other persons performing the Study under its direction, is currently debarred, suspended, or excluded under the Federal Food, Drug and Cosmetic Act, as amended, or disqualified under the provisions of 21 CFR §312.70. In the event that the Principal Investigator or any Study personnel becomes debarred or disqualified during the term of this Agreement or within 1 year after termination of the Study, the Institution agrees to promptly notify Sponsor after learning of such event. Institution certifies that it is not excluded from a federal health care program, including Medicare and Medicaid. In the event an Institution becomes excluded during the term of this Agreement or within 1 year after termination of the Study, the Institution agrees to promptly notify Sponsor after learning of such event.

24. Choice of Law

This ACTA shall be construed and enforced in accordance with the laws of the State of New York.

25. Human Research Protection Program

(a) Sponsor acknowledges that Stony Brook University ("University") has a human research protection program ("HRPP") established in accordance with the principles and standards of the Association for the Accreditation of Human Research Protection Programs that is applicable to all clinical research studies, including the Study, that includes: (i) the University's submittal of clinical studies for prospective and continuing review to the IRB as required by the FDA regulations governing the protection of human research subjects, (ii) obtaining of consent from human research subjects for participation in the clinical studies as required by the FDA regulations governing the protection of human research subjects, and (iii) conducting clinical studies in accordance with ethical standards such as the Belmont Report.

(b) During, and for a period of 2 years after completion of the study, Sponsor shall report to the investigator promptly (and no later than 30 days) any information that could directly affect the health or safety of past or current study subjects or influence the conduct of the Study, including but not limited to the Study results and information in site monitoring reports and data safety monitoring committee reports as required by the Protocol. In each case, the Investigator and/or Stony Brook University will communicate these findings to the IRB of record for a determination of need to notify past or current study subjects.

(c) Where the University receives any such information or Study results from Sponsor that impact participant safety or medical care, the University will, to the extent possible, send Study participants a written communication about the results.

26. Entire Agreement

27.

Section and clause headings are used herein solely for convenience of reference and are not intended as substantive parts of the Parties' agreement. This ACTA incorporates the Exhibits referenced herein. This written ACTA constitutes the entire agreement between the Parties concerning the subject matter, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter. Any changes made to the terms, conditions or amounts cited in this ACTA require the written approval of each Party's authorized representative.

The authorized representatives of the Parties have signed this ACTA as set forth below.

{INSTITUTION}	{SPONSOR}
By: _____	By: _____
{NAME}	{NAME}
Title: _____	Title: _____
Date: _____	Date: _____

READ AND ACKNOWLEDGED

By: ___________________________
{PRINCIPAL INVESTIGATOR}
Title:______________________________

Date: _________________________

Exhibit B

Exhibit C