Accelerated Clinical Trial Agreement

This Accelerated Clinical Trial Agreement ("Agreement") is made as of this {DAY} day of {MONTH}, {YEAR} (the "Effective Date") by and between {INSTITUTION NAME; DESCRIBE INSTITUTION}, a [e.g. non-profit, educational, research, healthcare] institution ("Institution") with an address at {INSTITUTION ADDRESS} 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, 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/educational] and [research/healthcare] objectives of Institution in a manner consistent with its status as a [e.g. 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}", as may be amended from time to time and as approved by the Institutional Review Board ("IRB"), which is incorporated herein by this reference ("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 cost, the required quantities of properly-labeled Sponsor {CHOOSE: drug(s) or biologics ("Study Drug") and/or device(s) ("Study Device")} and/or if applicable, placebo, and other written materials (e.g., Investigator's Brochure, handling and storage instructions) 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 written instructions.

1.4. Sponsor certifies that {CHOOSE: drug(s) or biologics ("Study Drug") and/or device(s) ("Study Device")} being provided has been manufactured or otherwise handled according to Good Manufacturing Practices or other applicable regulations for materials to be administered to human subjects and in accordance with all regulatory requirements for such handling, manufacturing, storage, transfer, distribution and delivery to Institution.

1.5 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 Food and Drug Administration ("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 its employees and staff (as applicable) ("Study Personnel") who are appropriately trained and qualified to assist in the conduct of the Study.

1.6. 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. Prior to a subject's participation in the Study, Institution shall obtain from each subject, a signed informed consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IRB and Sponsor, provided that the informed consent is consistent with Institution's policies. Any changes proposed by the Sponsor to the Protocol must be in writing and sent to the Institution and will not take effect until approved by the IRB. If such Protocol changes affect the contract terms (including the budget or payment terms), the Sponsor agrees to promptly work with the Institution to execute an amendment to this Agreement.

1.7. Sponsor agrees to provide Institution through Principal Investigator or designee with any data and safety monitoring reports related to the Study, and Institution agrees that such reports 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, or in a timely manner, appropriate to the level of risk involved, provide the Principal Investigator, or designee at the Institution, 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.

1.8. Institution shall promptly inform Sponsor of all adverse events or Study-related safety issues, 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 A** ("Budget") for the conduct of the Study in accordance with this Agreement and the Protocol. 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 A, each payment shall clearly reference the Study Protocol Number and PI name.

The Institution's tax identification number is: __-_____

3. Confidentiality

3.1. 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 or on behalf of Sponsor for purposes of conducting the Study and 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 or visually, is identified in a marked writing within thirty (30) days as being confidential; or
c) in the absence of markings, 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 by Institution in the course of conducting the Study are not considered Confidential Information for publishing purposes in accordance with Section 9 of this Agreement.

Institution agrees, for a period of five (5) years following either the early termination of the Study, or the completion of the Study at all sites identified by the locking of the database, that it will use reasonable efforts, no less than the protection given to its own confidential information, to not use or disclose the Confidential Information, except as permitted under this Agreement.

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' Study Personnel, and approved subcontractors, as applicable, who require access to it in the performance of this Study and the Agreement 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 to Sponsor;
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 or other verifiable evidence;
d) is necessary to obtain IRB approval of the Study or is 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, regulation, an order by a government agency, IRB, 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 the Protocol and under the 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 Institution may disclose the existence of this Agreement and any additional information necessary to ensure compliance with applicable federal, state, or local laws, and Institutional policies, regulations, and procedures.

4. Data Use/Ownership

"Data" shall mean all data and information generated by Institution in the performance of the Study and required to be delivered 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 publication, IRB, regulatory, legal, and for its own internal educational, patient care, and noncommercial research purposes, without the payment of royalties or other fees.

5. HIPAA Privacy/Data Security

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 and other personal information 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.

5.2 Sponsor is responsible for the security of the Data and shall ensure that it and any of its contractors adopt, implement and maintain appropriate security controls, including but not limited to encryption in transit, to protect against unauthorized access of any PHI or Personal Identifiable Information ("PII") of the subjects or any Institution employees, agents or customers. Sponsor accepts responsibility and liability for any unauthorized disclosure by it or its contractors and shall notify Institution promptly in the event of any breach of data security or unauthorized release of PHI or PII.

5.3 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.

5.4. 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.

5.5. Sponsor shall not attempt to identify, or contact, any Study subject unless expressly 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 {CHOOSE: Study Drug, or Study Device} has been approved for the indication for which it was investigated or Sponsor has discontinued research on the {CHOOSE: Study Drug or Study Device};
b) such longer period as required by federal regulatory requirements; or
c) as requested in writing by Sponsor at Sponsor's reasonable storage expense.

Institution shall use reasonable efforts to notify Sponsor at least forty-five (45) days before the planned destruction of any Study records. Sponsor must make any request to Institution to retain the Study records for a longer period, in writing, within such forty-five (45) day period, with any continued record retention to be at Sponsor's sole expense. If Sponsor does not respond to Institution's notice within forty-five (45) days of its receipt or refuses to pay for the continued storage of Study records, Institution shall have the right to destroy such Study records, at its discretion.

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 its authorized designee's access is subject to applicable Institution policies and procedures, including, but not limited to, reasonable safeguards to ensure confidentiality of medical records and systems.

7.2. Unless otherwise prohibited by FDA/regulatory authority, upon becoming aware of an audit or investigation by a regulatory agency with jurisdiction, that is related to the Study, Institution agrees to provide Sponsor with prompt notice of the audit or investigation. Sponsor may be available on site for the purposes of making itself available to assist the Institution with any queries from the regulatory authority that may require or benefit from input from the Sponsor. If required by the regulatory agency or otherwise allowed by the regulatory agency, Sponsor may request to be present at such audit or investigation, 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.

7.3 In the event Sponsor, or Sponsor's representatives, affiliates, employees, independent contractors, or subcontractors, will monitor Institution Study subject data ("Monitors"), Sponsor agrees that it, and its Monitors will comply with all of Institution's applicable policies and procedures related to such monitoring, Monitors will be advised of relevant information prior to monitoring activities.

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 inventions, developments, or discoveries, made during and in the performance of the Protocol ("Inventions") shall be promptly disclosed to Sponsor. Title to Inventions which are enhancements, modifications or improvements, of the {CHOOSE: Sponsor's Study Drug and/or Study Device} and that are made during and under this Agreement shall reside with Sponsor ("Sponsor Inventions"). Institution shall assign all Sponsor Inventions to Sponsor. Institution represents and certifies that all Institution personnel, including Principal Investigator, performing the Protocol have assigned to or are obligated to assign to Institution (or appropriate technology transfer office, on behalf of Institution), all their rights in or to Inventions that are necessary to enable Institution to grant Sponsor all rights to Inventions that Institution purports to grant under this Agreement. 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. Institution's obligations under Sections 8.2 and 8.3 hereunder shall be performed by its appropriate office with technology transfer responsibilities, if required by and in accordance with Institution policies.

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 have a right 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 any proposed oral or written Publication for Sponsor's review and comments ("Review Period"). Institution will consider any such comments in good faith but is under no obligation to incorporate Sponsor's suggestions. If during the Review Period, Sponsor notifies Institution in writing that: (i) it desires to file patent applications 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, in writing, requests Institution to delete such Sponsor's Confidential Information, then Institution agrees to do so 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. Notwithstanding the foregoing, Institution may publish the Data and Study results individually in accordance with this Section 9 upon the 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 (including final database lock) at all sites, upon request by Institution, Sponsor agrees to provide Institution access to the aggregate results pursuant to the Protocol 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 ("Disclosure Laws"), provided that the disclosure clearly designates the payment as having been made to Institution for research and not to the physician. Institution acknowledges that, by Sponsor's disclosure of such payments, Sponsor must identify the Institution as the payment recipient, and may also need to identify the Principal Investigator in accordance with Disclosure Laws.

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's 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, Study Personnel, 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 ("Claims") alleged to be caused by or arising from: (a) the conduct of the Study; (b) if applicable, the use of the {CHOOSE: Study Drug or Study Device} provided under this Agreement; or (c) Sponsor's material breach of this Agreement, failure to comply with all applicable laws and regulations, negligence, or from the Sponsor's (d) use of the Data or Study results, 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 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) negligent acts or omissions or willful misconduct.

11.3. Subject to the limits, caps, or prohibitions and without waiving any immunities provided under applicable law (including constitutional provisions, statutes, case law and any applicable interpretations thereof – e.g. the State Attorney General's opinion(s)) regarding the status, powers and authority of the Institution or the Institution's principal(s), Institution, to the extent allowed, shall be responsible for its negligence in its conduct of the Study and 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 and 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 TO THE OTHER PARTY 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, medical illness, or injury which was directly caused by the {CHOOSE: Study Drug or Study Device} and/or any properly performed procedures required by the Protocol, Sponsor shall reimburse for the reasonable and necessary expenses of diagnosis and treatment of any Study subject injury, including hospitalization, but only to the extent such adverse reaction, medical illness or injury are not directly caused by (i) Institution's negligence or willful misconduct; (ii) the natural progression of an underlying or pre-existing condition or events, unless exacerbated by participating in the Study; or (iii) Institution's failure to adhere to and comply with the specifications of the Protocol and all reasonable prior written instructions furnished by Sponsor for the use and administration of the {CHOOSE: Study Drug or Study Device} used in the Study. Deviations from the Protocol and written instructions resulting from an imminent threat to the health or safety of a Study subject will not disqualify Institution from reimbursement under this provision.

13. Insurance

13.1. Institution (or an affiliated entity, if applicable) shall, at its sole cost and expense maintain a policy or program of insurance or self-insurance, at levels sufficient 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 a policy or program of insurance or self-insurance at levels sufficient to support its obligations assumed in this Agreement, including but not limited to commercial general liability insurance, clinical trial insurance and products liability insurance or equivalent self-insurance. 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 reasonably acceptable to the other Party. Each Party shall provide prompt, written notice to the other Party upon cancellation or material change to this insurance coverage. 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 earlier 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 by either the Institution or Sponsor when, in its 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 that termination is necessary 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 Principal Investigator, 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 or breach within thirty (30) business days after written notice thereof.

14.4. In the event that this Agreement is terminated for any reason prior to completion of the Study 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 in accordance with the Protocol; 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 agrees to return all Confidential Information supplied to it by Sponsor, at Sponsor's expense, pursuant to this Agreement except that Institution may retain such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement as well as any Confidential Information retained through Institution's automatic backup systems.

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 reasonably 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, 18, 20, 21 and 24, shall survive any termination or expiration of this Agreement, except that a Section that has a specific period stated shall survive for the period stated therein. 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 as required by 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 and/or research authorization. Sponsor agrees that any use of Subject Materials, other than as allowed by the Study subject's informed consent form and/or research authorization, will require additional Institutional review and approval.

16. Sponsor Equipment (if applicable)

16.1. In the event that Sponsor provides Institution with other materials or Equipment (as defined below) for purposes of carrying out the Study, Sponsor shall ensure that such materials or Equipment comply with all applicable laws and shall inform Institution immediately upon Sponsor becoming aware that any Sponsor provided materials or Equipment are subject to recall or otherwise the subject of regulatory withdrawal.

16.2. Sponsor may provide equipment for the conduct of the Study as specified by the Protocol and described in Exhibit B ("Equipment") (optional). Institution agrees that such Equipment shall be used solely in connection with the Study during the term of this Agreement, unless the Parties have a separate written agreement that states otherwise.

17. Subcontract/Assignment

17.1. 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, such approval not to 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. Institution may not assign this Agreement without Sponsor's prior written approval, such approval not to be unreasonably withheld.

17.2. The Sponsor has the right to subcontract to a third-party Contract Research Organization ("CRO") or Academic Research Organization ("ARO") and assign Study-related duties and rights to any Sponsor affiliate or third-party contractors. If Sponsor subcontracts any Study-related duties and rights, Sponsor remains responsible for any of those duties and rights. Sponsor agrees to provide Institution with prompt, written notice of any assignment and/or subcontracting in accordance with the notice requirements under this Agreement. Institution shall have, in its sole discretion, (i) 30 days to conduct due diligence as to the proposed assignee, and (ii) the right, after written notice to the Sponsor, to terminate the Agreement or Study without penalty.

17.3. No assignment and/or subcontracting shall relieve either Party of the performance of any accrued obligation that such Party may have under this Agreement.

18. Notices

This Notice section is not intended to govern the day-to-day communications between the parties necessary to conduct the Study.

Any notice, authorization, approval, consent or other communication will be in writing and deemed given:

a) Upon confirmation of delivery by email;
b) Upon delivery in person;
c) Upon delivery by courier; or
d) Upon delivery date by a nationally recognized overnight delivery service such as FedEx.

For contractual or legal notices or communications:

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

If to Institution:
{INSTITUTION NAME}
{CONTACT NAME}
{CONTACT TITLE}
{ADDRESS LINE}
{TELEPHONE NUMBER}
{E-MAIL ADDRESS}

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

For scientific or safety related notices or communications:

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

If to Institution:
{PRINCIPAL INVESTIGATOR NAME}
{PRINCIPAL INVESTIGATOR TITLE}
{ADDRESS LINE}
{TELEPHONE NUMBER}
{E-MAIL ADDRESS}

19. 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.

20. 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 42 USC § 282 as amended and any applicable regulations including 42 CFR Part 11. Results of the Study will be reported in compliance with applicable laws.

21. Non-Referral/Anti-Corruption Language

21.1. The Parties to this Agreement specifically intend to comply with all applicable laws, rules, and regulations, including (i) the federal anti-kickback statute (42 U.S.C. 1320a-7(b)) and the related safe harbor regulations; and (ii) the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. 1395 (n)). 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.

21.2. Each Party shall require that its 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.

22. 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.

23. 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. Scanned copies of signatures or electronic images of signatures shall be considered original signature unless prohibited by applicable law.

24. Debarment

The Institution certifies that to its knowledge, after due inquiry, 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 personnel reported on FDA Form 1572 or its equivalent, 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 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.

25. Choice of Law – Intentionally omitted

26. Entire Agreement

Section and clause headings are used herein solely for convenience of reference and are not intended as substantive parts of the Parties' agreement. This Agreement incorporates the Exhibits referenced herein. This written Agreement 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 Agreement require the written approval of each Party's authorized representative, except that either Party may change its general contact information (e.g. mailing address) or payee information by providing written notice (including by email) to the other Party.

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

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

READ AND ACKNOWLEDGED

By: _____
{PRINCIPAL INVESTIGATOR}

Title:_____

Date: _____

EXHIBIT A

Budget

EXHIBIT B

Equipment