PROTOCOL TITLE:
PRODUCT:
INSTITUTION: **University of Connecticut Health Center**
PRINCIPAL INVESTIGATOR:

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT together with all Exhibits and Attachments, constitutes the ("Agreement") that is made as of the ____ day of 2013 (the "Effective Date") by and between (Sponsor Name and Address) "Sponsor"; and the University of Connecticut Health Center, located at 263 Farmington Avenue, Farmington, CT 06030, identified above and on the signature page as ("Institution"). Sponsor and Institution may be collectively referred to as parties or singularly referred to as party.

1. **Background.** Sponsor is engaged in the discovery, development and manufacture and sale of tissue engineering products. Sponsor has filed an Investigational New Drug ("IND") application with The Food and Drug Administration ("FDA") for the test article identified above, including any related accessories, components and instruments (the "Product") and desires to sponsor a clinical trial at Institution with respect to the Product (the "Clinical Trial"). Institution has expertise in conducting clinical trials and is willing to conduct the Clinical Trial, subject to the terms and conditions of this Agreement including the protocol attached to this Agreement as Exhibit A and identified above, as amended from time to time in writing by the parties (the "Protocol"). In the event of a conflict between the terms of the Protocol and the terms of this Agreement, this Agreement shall govern the conduct of the parties.

2. **Ownership, Delivery, Handling and Return of Product.** Institution acknowledges that Sponsor is and shall at all times remain the sole owner of the Product. Sponsor will provide Institution with the required quantities of the Product for each patient, following receipt from the Institution of such patient's cartilage sample in accordance with the Protocol, at no charge, for Institution to conduct the Clinical Trial. Institution will handle, store and dispense the Product and patient cartilage samples in accordance with the Protocol, specific instructions provided by Sponsor and FDA regulations and, upon conclusion of the Clinical Trial, will return to Sponsor or Sponsor's designee, at Sponsor's expense, or dispose of all unused Product in accordance with Sponsor's instructions.

3. **Conduct of the Clinical Trial.**

3.1 Strict Accordance with Protocol. The Clinical Trial will be conducted by Institution in strict accordance with the Protocol, which may be amended from time to time only by written agreement of the parties and with approval of the Institutional Review Board. Institution may not deviate from the Protocol without Sponsor's prior written consent; provided, however, Institution may deviate from the Protocol when necessary to protect the safety, rights or welfare of patients enrolled in the Clinical Trial.

3.2 Investigators. The Clinical Trial will be conducted by and under the direction of the researcher named above (the "Principal Investigator"), who is an employee of Institution.

a. Other Clinical Investigators. Sponsor shall have the right to approve the inclusion of any co-investigator (the "Co-Investigators," and the Principal Investigator and any Co-Investigators may individually be referred to as "Investigator" and collectively as "Investigators") recommended by the Principal Investigator, in accordance with Sponsor's policy in Section 3.7 below. Such Co-Investigators shall work under the supervision of Principal Investigator and agree to be bound by the same terms that bind the Principal Investigator under this Agreement. All Investigators shall provide Sponsor with a

completed form FDA 1572, current copy of a curriculum vitae, a financial disclosure statement and certification as required by 21 C.F.R. Part 54 (with prompt updates of relevant changes during the course of the investigation and for one year following the completion of the Clinical Trial), and shall sign a copy of Appendix B.

b. Replacement. In the event the Principal Investigator is unable or unwilling to carry out his/her duties under the Protocol, Institution shall nominate a replacement for the Principal Investigator. Institution and Sponsor shall diligently and cooperatively attempt to identify a replacement for the Principal Investigator that is acceptable to Sponsor and the Institution. In the event Sponsor and/or Institution do not approve a replacement within thirty (30) days after receipt of notice from Institution, this Agreement will terminate, unless Sponsor and Institution elect to extend the period of time during which Sponsor and Institution attempt to reach agreement on a replacement for the Principal Investigator, as determined by Sponsor.

c. No Simultaneous Enrollment in Competitive Studies. Institution shall ensure that Principal Investigator will not enroll subjects, during the Protocol enrollment period, in any clinical trial which is competitive with the Clinical Trial as defined by a patient population as characterized by the inclusion/exclusion specifications in the Protocol.

d. No Additional Studies on Protocol Subjects. Institution agrees that it will not conduct a simultaneous clinical trial or perform any simultaneous research unrelated to the Protocol on any subjects enrolled in the Clinical Trial without Sponsor's prior written consent.

e. **No Conflict for Investigator**. Institution certifies that (a) no Investigator is nor shall be a party to any other agreement or under any obligation to or restriction by any third party which would prevent any Investigator from entering into this Agreement or which would adversely affect conduct of the Clinical Trial or any of the undertakings set forth in this Agreement in any manner; (b) where an Investigator is a member, affiliated with, or an employee of an institution that requires disclosure of any proposed agreements for services such as the agreement contemplated herein, s/he has made such disclosure in accordance with the policies and procedures of such institution, and has obtained prior written approval of this Agreement by such institution, if required.

3.3 Additional Personnel. Institution will arrange for qualified medical, technical, laboratory, clerical and other personnel necessary and desirable to support Institution's obligations under this Agreement. Institution and the Principal Investigator will ensure that all personnel supporting the Institution's obligations under this Agreement will adhere to the Protocol and this Agreement. Institution shall ensure that all personnel are under no contractual or other obligations or restrictions which are inconsistent with Institution's obligations under this Agreement and do not have a financial or other interest in Sponsor or the outcome of the Clinical Trial which might interfere with their independent judgment. Institution certifies that all of its personnel who participate in the Clinical Trial understand and agree to abide by the applicable terms of this Agreement, including, without limitation, the obligations set forth in sections 9 and 10 of this Agreement.

3.4 Institutional Review Board. Institution will initiate the Clinical Trial only after its Institutional Review Board ("IRB") or the equivalent has approved the Protocol in writing and a copy of this approval has been received by Sponsor. The IRB also will review and approve in writing any amendments made to the Protocol by the parties. The Clinical Trial will be carried out under the supervision of the IRB. The Principal Investigator will keep the IRB fully informed of the progress and safety of the Clinical Trial per IRB and FDA requirements. The Principal Investigator will promptly forward to Sponsor copies of all correspondence to or from the IRB, which concern the Clinical Trial.

3.5 Enrollment. Institution will use its reasonable best efforts to enroll patients in the Clinical Trial. In addition to strictly adhering to the Protocol's patient eligibility criteria, Institution at all times will exercise independent

medical judgment as to the suitability of each prospective patient for enrollment in the Clinical Trial.

3.6 **Subject Withdrawal**. If a subject does not report for a scheduled follow-up visit, Principal Investigator shall contact the subject within ten (10) days after the date of the scheduled visit regarding the failure to keep the appointment. If a subject withdraws from the Clinical Trial, Principal Investigator shall follow up with the subject in person or by telephone (if possible), otherwise by certified mail, to determine the reason for the discontinuance and complete the termination form.

3.7 **Patient Consent.** Prior to enrollment in the Clinical Trial and prior to execution of any Protocol specific procedure, Institution will obtain from each patient (a) a signed Informed Consent document in a format that has been previously approved by both Sponsor and the IRB; and (b) a signed HIPAA Authorization in a form reasonably acceptable to Sponsor, which shall, among other things, provide that Sponsor shall be permitted to use and disclose the Clinical Trial patient's health information as permitted in the Informed Consent document. The term "HIPAA Authorization" refers to the requirements for obtaining prior written authorization to use and disclose health information for research in accordance with the health information privacy standards promulgated under federal, state and local privacy laws, including without limitation the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 CFR Parts 160 and 164), as amended from time to time ("HIPAA").

3.8 **Compliance with Regulations.** Institution and the Principal Investigator will adhere to all applicable government laws and regulations and the good clinical practice requirements of the FDA. It is the policy of Sponsor to use only investigators qualified by training and experience. Any investigator who is currently disqualified by the FDA from receiving investigational supplies will not be considered a qualified investigator. In addition, Sponsor reserves the right to exclude an investigator if there is information available to Sponsor indicating that an investigator has repeatedly or deliberately failed to comply with FDA requirements or has submitted false information to Sponsor, another sponsor, or the FDA.

3.9 Sponsor shall promptly notify Investigator of any findings of (1) new and unexpected serious adverse safety events arising from Sponsor's monitoring of the overall Clinical Trial that could affect the safety of Subjects, and (2) trends or patterns of non-serious or expected adverse events that occur at a specificity or severity that is inconsistent with prior observations, all in accordance with its obligations under 21 C.F.R. 312.32(c) and 21 C.F.R. 312.55(b) and FDA Guidance on adverse Event Reporting. In addition, after the Clinical Trial has ended, if the results of the Clinical Trial reveal issues that directly affect the safety of the Subjects, Sponsor shall notify Investigator and/or Institution.

Sponsor will provide copies of the DSMB recommendation letters to the Investigator for submission to the Institutional Review Board.

3.10 **Debarment**. Institution represents that neither the Institution nor any of its Clinical Trial personnel: (a) have been debarred, and to the best of its knowledge, none of such employees are under consideration to be debarred, by the Food and Drug Administration from working in or providing services to any pharmaceutical or biotechnology company; (b) have been found by the FDA, U.S. Department of Health and Human Services ("HHS"), or other international, federal or state regulatory or governmental officials (each an "Agency" and collectively the "Agencies") to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations; (c) have received an Agency warning or other regulatory letter, or if it has, then all outstanding issues have been resolved to the satisfaction of the applicable Agency; (d) have been or are presently excluded from participation in any government healthcare program, debarred from or under any other federal program, convicted of any offense defined in 42 U.S.C. Section 1320a-7, or otherwise deemed ineligible for participation in healthcare programs, nor is aware of any pending or potential actions that would give rise to any such ineligibility; (e) are the subject of a disqualification proceeding or has been disqualified as a clinical investigator by any Agency; (f) have been terminated from any investigation or research project by the FDA or

IRB; or (g) are currently or have been the subject of a proceeding by any Board of Medical Examiners or similar agency that has resulted in the imposition of any limitation, condition, or suspension on such Clinical Trial personnel's right to practice medicine. Institution additionally represents that (1) Institution and Clinical Trial personnel have, and shall maintain throughout the term of the Clinical Trial, all necessary licenses, permits and authorizations to conduct the study; (2) Institution and Institution's IRB have not been disqualified by the FDA; and (3) each Investigator has not been and is not currently a party to any litigation, arbitration or mediation involving the practice of medicine.

3.11 **Part 11 and Electronic Health Records**. Institution represents that to the extent Institution and/or Clinical Trial personnel are using electronic health records, Institution has conducted an assessment regarding the applicability of the Part 11 Requirements (defined below), and either (a) Institution hereby warrants and covenants that all Electronic Records (as that term is defined in 21 CFR Part 11), associated systems, equipment and information, and electronic signatures created, validated, modified, maintained, archived, retrieved, accessed, or transmitted (collectively, "Processed") under any records requirements set forth in FDA regulations shall be Processed by Institution, by Clinical Trial personnel and by all third party licensors and services providers in accordance with 21 CFR Part 11 and with the FDA "Guidance for Industry: Computerized Systems Used in Clinical Trials" (collectively, "Part 11 Requirements"); or (b) Institution has determined and hereby warrants and covenants that Institution and Clinical Trial personnel are not subject to the Part 11 Requirements with respect to the Clinical Trial and the activities conducted pursuant to this Agreement, and Institution has provided Sponsor with sufficient evidence supporting such determination.

4. Records.

4.1 Complete and Accurate Records. Institution will keep complete and accurate records of the status and progress of the Clinical Trial as required by the Protocol and, in any event, with sufficient detail for use in reports to regulatory agencies.

4.2 Clinical Regulatory Binder. Institution will maintain a Regulatory Binder with all documents required by Sponsor.

4.3 Product Disposition. Institution will maintain records on the receipt and disposition of all Products, including dates, quantity and use by patients. If requested by Sponsor, all Product kits will be retained and returned to Sponsor at Sponsor's expense.

4.4 Retention. Institution will retain organized original patient, laboratory and test article inventory records relating to the Clinical Trial for not less then five (5) years following notification by Sponsor that (a) all Product investigations have been discontinued or that (b) the FDA has approved the Biological License Application for the Product. Thereafter, Institution will not destroy such records without providing Sponsor with at least ninety (90) days prior written notice thereof and the opportunity to further store such records, at Sponsor's cost and expense, and at a location or locations selected by Sponsor.

5. Reports.

5.1 Periodic Telephone Reports and Meetings. Institution will keep Sponsor advised of the status of the Clinical Trial through regular telephone conversations and meetings between the Principal Investigator and Sponsor.

5.2 Case Report Forms and Source Documentation. Institution and Principal Investigator promptly will complete, provide, and allow Sponsor access to case report forms ("CRFs") and source documentation for all patients who provide informed consent in the Clinical Trial. Notwithstanding any longer time period set forth in the Protocol, all CRFs must be completed and submitted within two (2) weeks of any patient's visit, with the exception of the baseline visit which must be submitted as soon as possible after the visit to ensure patient

eligibility, and in any event within four (4) business days after such visit.

5.3 Immediate Notice. Institution will immediately notify Sponsor (a) of any deviations from the Protocol necessary to protect the safety, rights or welfare of patients enrolled in the Clinical Trial; (b) upon discovery by it or any of its personnel of a serious or unexpected adverse patient reactions in the course of the Clinical Trial; or (c) of any communication with a regulatory agency concerning (i) the Clinical Trial, including any requests to inspect, examine, copy or remove records of the Clinical Trial, (ii) subject to Institution's confidentiality obligations, of another clinical trial which might have an impact on the Clinical Trial, or (iii) the qualification of the Principal Investigator or other Institution personnel to perform this or any other research.

5.4 Annual IRB Report. Institution will submit an annual report to the IRB regarding the Clinical Trial, with copies filed in the Clinical Regulatory Binder and sent to Sponsor.

5.5 Final Report. Institution will complete a final report on the Clinical Trial within one (1) month of completion of the Clinical Trial. If the Clinical Trial is suspended or terminated prior to completion, Institution will provide Sponsor with a final report of the results of the Clinical Trial through the date of suspension or termination.

5.6 Title and Number. All reports and notices will include the Protocol Title and Sponsor Protocol Number printed above.

5.7 Ownership. Institution acknowledges that Sponsor is and shall at all times remain the sole owner of the CRFs, the final report prepared by Institution, and all other records, reports and data required to be delivered to Sponsor under the Protocol ("Study Reports"); however, Institution may retain one copy of such Study Reports to the extent required by law. The parties acknowledge and agree that individual patient medical records and files, physician clinical notes, source documents and other information which Institution maintains for regulatory, research and patient care purposes ("Source Documents") shall remain the property of Institution and shall not be considered part of Study Reports.

6. Verification

a. SPONSOR. Sponsor's ability to independently verify Institution and Investigators' compliance with the Protocol and the completeness and accuracy of information recorded by Institution and Principal Investigator on the Study Reports is critical to the success of the Clinical Trial. During the Clinical Trial on a regular basis, and thereafter if necessary, with prior notice, Institution and Principal Investigator will permit Sponsor and its representatives, during normal business hours and at mutually agreeable times, to access Institution's facilities and to inspect all records kept or made by Institution or Principal Investigator as part of the Clinical Trial, including original study-related Source Documents, Study Reports, patient records, and test reports for the purpose of monitoring and auditing the Clinical Trial and its compliance with applicable regulations, including for adverse event information and reporting, and as otherwise permitted in the Informed Consent. Institution and Principal Investigator will cooperate with Sponsor in its review of Clinical Trial-related records and its verification of the information contained in the Study Reports. Institution will not be required to disclose information in the Study Reports, which would permit identification of a patient enrolled in, or a candidate for, the Clinical Trial. To the extent reasonably required for compliance by Sponsor with applicable law or regulations or as otherwise permitted by the Informed Consent, Sponsor or Sponsor's representatives may make and/or remove copies of the Protected Health Information (as such term is defined under HIPAA), or similar information governed by applicable federal, state or local laws (if any) relating to the protection of health and/or medical information, if applicable, contained in the Study Reports and Source Documentation for such purposes.

b. Regulatory Authorities. Institution and Principal Investigator shall notify Sponsor immediately by telephone and facsimile (with a follow-up by mail) upon, but not later than twenty-four (24) hours after, learning that an Agency

inspection is scheduled to take place, or, if there is no prior notice by an Agency, that an inspection has commenced, relating to the Clinical Trial. Institution and Principal Investigator shall make all reasonable efforts to coordinate any scheduling of Agency inspections to permit Sponsor and its representatives to attend such inspections. Institution and Principal Investigator shall provide Sponsor with copies of all materials, correspondence and documents which such party receives, obtains, or generates pursuant to any such inspection or audit or in connection with any inquiries, communications or correspondence from any Agency. Institution and Principal Investigator each shall make, and shall ensure that Clinical Trial personnel make reasonable efforts to segregate, and not disclose, any Developments (defined in Section 9.1), Source Documents and other materials, correspondence and documents that are not required to be disclosed during such an inspection, including financial data and pricing information. If FDA issues Form FDA-483 Notice of Observations relating to the Clinical Trial or another Agency issues a similar document, Institution or Investigator, as applicable, shall send a copy of such document promptly to Sponsor, and obtain Sponsor's approval of the draft response to such document before it is sent to the applicable Agency.

7. **Institution to Correct Study Reports.** At Sponsor's request, Institution and Principal Investigator shall promptly correct any errors and/or omissions to the Study Reports and will make available to Sponsor or Sponsor's representative the corrected Study Reports for further verification.

8. **Compensation.**

a. **General**. Sponsor agrees to pay Institution for the Clinical Trial activities conducted by Institution, Investigators and their respective personnel, in the amounts as set forth in Appendix C and in accordance with the payment schedule set forth therein, which payment shall be contingent upon such activities having been conducted in accordance with this Agreement, including the terms and conditions in Appendix C, the Protocol and all applicable laws.

b. Submission Limits. Institution and Investigators shall not (and shall ensure that each Clinical Trial personnel shall not) (a) submit claims for or retain payment by any patient, third-party payor or any other person or entity for any item, procedure or service that has been paid for or provided without charge by Sponsor; or (b) seek or retain payment from Sponsor for any item, procedure or service that is reimbursed by any patient, third-party payor or any other person or entity.

c. Financial Reporting and Disclosure by Sponsor. Sponsor will have the right in its discretion (a) to disclose, as may be required under federal or state law, or as is otherwise desired by Sponsor (i) information relating to the services performed pursuant to this Agreement, including without limitation any and all payments, reimbursement for expenses, or other transfer of value made in other than dollar form relating to this Agreement; (ii) identifying information concerning Institution and Investigators; and (iii) any other information relating to this Agreement or to the Clinical Trial; (b) to display such information, including but not limited to, on Sponsor's websites; and (c) to disclose such information to employers and affiliated institutions of Institution and Investigators, to any other individuals or entities involved in the Clinical Trial, and to regulatory agencies. Notwithstanding the foregoing provisions, Sponsor shall not use the Institution's name or trademark for any such advertising or media dissemination without prior approval from the Institution, except to the extent required by applicable law or regulation.

d. Financial Reporting and Disclosure by Institution. To comply with applicable laws, regulations, journal guidelines and best industry practices, Institution and each Investigator agrees to ensure meaningful disclosure, including without limitation to medical journals or other publications, to hospitals and affiliated institutions, and to individuals and entities involved in the Clinical Trial, to patients in any presentations when discussing Sponsor or any Sponsor products, and to any government agencies or authorities which require such disclosure, as applicable, in connection with the conduct of the Clinical Trial or permitted publication of the research results of (a) the Sponsor's funding and support of the Clinical Trial; and (b) any significant financial or other relationship between Sponsor and Institution, and/or between Sponsor and any Investigator, as applicable (e.g. employee, consultant, owner of equity interest in Sponsor or Sponsor's products, etc.). This obligation is in addition to each Investigator's obligation to

provide a financial disclosure statement as required by Section 3.2(a).

9. Developments.

9.1 Definition. "Developments" include, without limitation, ideas, concepts, discoveries, inventions, developments, know-how, patent rights, trade secrets, techniques, methodologies, modifications, innovations, improvements, writings, documentation, data and other rights (whether or not protectable under state, federal, or foreign patent, trademark, copyright or similar laws), excluding copyright ownership of publications of results of the Clinical Trial, relating to the Product or its use or otherwise related to Sponsor's Confidential Information, which are conceived, discovered, invented, developed, created, made or reduced to practice by Institution, Investigator or their personnel, alone or jointly with Sponsor or others, in performance of the Clinical Trial, subject to section 11.4 with respect to copyrights.

9.2 Ownership. Sponsor shall own all rights, title and interest in and to the Developments and Study Reports. Institution and Principal Investigator shall, and shall cause their respective personnel to, promptly and fully disclose all Developments to Sponsor in writing. Institution and Principal Investigator each, on behalf of itself and its respective personnel, hereby assign and shall assign (a) all of their respective right, title and interest in and to the Developments and Study Reports to Sponsor, including all patents, copyrights and other intellectual property and proprietary rights; and (b) all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Institution represents that it has agreements with all personnel and/or institutional policies in place that effectively vest in Institution any rights which such personnel might otherwise have in the results of their work and are adequate to permit Institution to convey, transfer and assign those rights to Sponsor pursuant to this Section. Institution and Principal Investigator shall cooperate and assist Sponsor to execute and shall cause all personnel to execute all documents reasonably necessary for Sponsor to secure, perfect, effectuate and preserve Sponsor's ownership rights in the Developments and Study Reports.

9.3 Use of Developments. Subject to other provisions of this Agreement, Institution shall have the right to use such Developments for internal research, publication in accordance with section 11 of this Agreement, and teaching purposes only.

10. Confidentiality.

10.1 Definition of Sponsor Confidential Information. "Sponsor's Confidential Information" means, all scientific, technical, trade, business, or any other information, whether written or oral, that is provided to Institution or Principal Investigator by Sponsor in connection with, as part of or in furtherance of the Clinical Trial and any other aspect of this Clinical Trial Agreement or as otherwise provided by Sponsor to Institution or Principal Investigator, including all Developments, Study Reports, the Protocol, Investigator's brochure, Clinical Trial enrollment data, information about the status of the Clinical Trial, communications to and from any Agency, information relating to the Product's regulatory status, and correspondence to or from any clinical events committee or data safety monitoring board, results of the Clinical Trial, and the terms and conditions of this Agreement, all of which is treated by Sponsor as confidential and proprietary, regardless of whether any such information is labeled as "Confidential". "Sponsor's Confidential Information" does not include information which (a) was known to Institution or Principal Investigator at the time it, was disclosed, other than by previous disclosure by Sponsor, as evidenced by written records at the time of disclosure; (b) is at the time of disclosure or later becomes publicly known under circumstances involving no breach of this Agreement; or (c) is lawfully and in good faith made available to Institution or Principal Investigator by a third party who did not derive it directly or indirectly from Sponsor; or (d) independently developed by Institution, Principal Investigator or their personnel not associated with this Agreement prior to Sponsor's disclosure. Notwithstanding the foregoing, the Institution may publish the results of the Clinical Trial in accordance with Section 11 of this Agreement.

10.2 Institution Acknowledgment Regarding Confidentiality and Ownership. Sponsor has developed and will develop Sponsor's Confidential Information over a substantial period of time at substantial expense, and Sponsor's Confidential Information is of great importance to Sponsor's business. During the Clinical Trial, Institution may develop, become aware of or have access to Sponsor's Confidential Information. Institution acknowledges Sponsor is and shall at all times remain the sole owner of such Sponsor's Confidential Information, including without limitation all Confidential Information relating to the Product and all Developments that include any of Sponsor's Confidential Information.

10.3 Nondisclosure of Sponsor's Confidential Information. Neither the Institution nor the Principal Investigator shall directly or indirectly publish, disseminate or otherwise disclose, deliver or make available to any third party any of Sponsor's Confidential Information, except as permitted in this Agreement. Institution or Principal Investigator may disclose Sponsor's Confidential Information to a governmental authority or by order of a court of competent jurisdiction, provided that such reasonable advance notice, if possible, is given to Sponsor, and the disclosure is subject to all applicable governmental or judicial protection available for like material.

10.4 Use of Sponsor's Confidential Information. Institution will, and will require Investigator and all personnel to use Sponsor's Confidential Information solely for the purpose of conducting the Clinical Trial.

10.5 Physical Protection of Sponsor's Confidential Information. Institution and Principal Investigator shall exercise reasonable precautions to physically protect the integrity and confidentiality of Sponsor's Confidential Information. Upon termination or expiration of this Agreement, Institution and Principal Investigator shall promptly return all Sponsor's Confidential Information to Sponsor as directed in writing, but Institution may retain one copy for purposes of monitoring its confidentiality obligations and exercising its rights under this Agreement, for legal and/or archival purposes, which copy shall be afforded the same confidential protection afforded to Institution's own confidential information.

11. Publication.

11.1 Right to Publish; Review by Sponsor. Notwithstanding Institution's confidentiality obligations under Section 10 above, Institution and Principal Investigator shall have the right to publish and disclose the results of the Clinical Trial in accordance with the remainder of this Section 11. In order to balance this right with Sponsor's proprietary interests, Institution or Principal Investigator, as applicable, will submit for Sponsor's review manuscripts intended for publication or other public disclosure at least forty-five (45) days prior to the date of submission for publication or of public disclosure. Sponsor will complete its review within such forty-five (45) day period. Sponsor may require that Institution or Principal Investigator, as applicable, delete from its manuscripts any Sponsor's Confidential Information other than the results of the Clinical Trial. At the end of this forty-five (45) day period, Institution will have the right to publish the manuscript, subject to Sponsor's rights under Sections 11.2 and 11.3 below.

11.2 Opportunity to File Patent Applications. If, during its forty-five (45) day review period, Sponsor notifies Institution that it desires patent applications to be filed on any Developments disclosed or contained in the manuscripts, Institution will defer publication or other disclosure for an additional period, not to exceed seventy-five (75) days, sufficient to permit Sponsor to file any desired patent applications.

11.3 Multi-Center Publication. Institution and Principal Investigator agree that they shall not, without Sponsor's prior written consent, independently publish any results of the Clinical Trial or information pertaining to Institution's and Principal Investigator's activities conducted under this Agreement until the earlier of: (a) the release of the multi-center publication and (b) twelve months after the completion of the clinical trial of the Product at all clinical trial sites (including the receipt by Sponsor of all data sets and the resolution of all queries related thereto)..

11.4 Copyright. Except for publications permitted under this Section 11, (a) copyrights, or copyrightable material, first produced or composed in the performance of the Clinical Trial shall to the extent legally permissible constitute works made for hire, (b) title to and the right to determine the disposition of any such copyrights or copyrightable material shall be held by Institution, and (c) Institution hereby assigns to Sponsor all of its right, title and interest, if any, in and to any such copyrights, or copyrightable materials and agrees to execute such further instruments of transfer, conveyance or assignment with respect to any such copyright or copyrightable materials as may be requested from time to time by Sponsor. With respect to publications permitted under this Section 11, (x) Institution and/or Principal Investigator hereby grants, and shall grant, to Sponsor an irrevocable, royalty-free license to make and distribute copies of such publication under any copyright privileges that the Institution and Principal Investigator may have and (y) the Institution and Principal Investigator shall, in any agreement with a journal or other publisher to publish study results, use reasonable efforts to reserve expressly all copyright rights necessary to grant Sponsor such license and rights.

11.5

Media Contacts. Institution and Principal Investigator shall not, and shall ensure that their respective personnel do not, engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Clinical Trial, the Products, Developments or Study Reports without Sponsor's prior written consent. This provision does not prohibit publication of Study Reports in accordance with this Section 11.

12. Publicity; Advertising. Neither party will use the other party's name nor the name of any member of that party's personnel in publicity relating to this Agreement without the prior written approval of the other party, which approval shall not be unreasonably withheld or delayed. Neither party will use the other party's name or the name of any member of that party's personnel in any advertising, packaging or other promotional material in connection with the Product without the prior written approval of the other party, except as may be required by law.

Notwithstanding the preceding restrictions, (a) the Institution may recognize Sponsor support in academic publications prepared in accordance with Section 11 (including in the Institution's "Annual Report of Research and Scholarly Activity") and (b) Sponosr may use the name of Investigators and Institution in scientific, medical, and other published articles relating to the Clinical Trial.

13. Indemnification.

13.1 By Sponsor. Sponsor will defend, indemnify, save and hold harmless Principal Investigator, Institution and its personnel (together, the "Institution Indemnitees") from and against any claims, demands, suits, actions, causes of action, losses, damages, fines and liabilities, including court costs and reasonable attorneys' fees ("Losses") to the extent arising out of third party claims, actions or proceedings relating to bodily injury or death of any patient enrolled in the Clinical Trial, which injury or death is directly caused by the Product provided by Sponsor and used in accordance with this Agreement, solely to the extent that such losses do not arise out of or in connection with (a) any Institution Indemnitees' (i) failure to follow all applicable federal, state or local laws, regulations, and guidelines, or to conform to reasonable and prudent clinical practices, including GCPs as applicable to clinical studies for the Product; (ii) wrongful or negligent acts or omissions, or willful malfeasance or misuse of the Product; (iii) failure to follow the Protocol or other written recommendations or instructions provided to the Institution Indemnitees by Sponsor; or (b) prior treatment giving rise to the condition for which the Product is used in connection with the Clinical Trial.

13.2 By Institution. Notwithstanding the foregoing provisions, the sole and exclusive means for the presentation of any claim against the Institution, as a party of the State of Connecticut, shall be in accordance with Chapter 53 of the Connecticut General Statutes (Claims Against the State) and such legal proceedings may not be

initiated except as authorized by that Chapter in any state or federal court in addition to, or in lieu of, said Chapter 53 proceedings.

13.3 Additional Conditions. Subject to Sections 13.1 and 13.2, the party making a claim pursuant to this Section 13 shall provide the other party prompt notice (in all events within thirty (30) days) of any such claim, including a description of the alleged basis therefor. With respect to a claim for which indemnification or defense is sought under Section 13.1, Sponsor shall have the right to exercise sole control over the defense and settlement of any such claim, including the sole right to select defense counsel, and to direct the defense or settlement of any such claim or suit; provided that Sponsor shall not enter into any non-monetary settlement or admit fault or liability on Institution's behalf without the prior written consent of institution, which consent shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, if the institution withholds consent to such a proposed settlement, the institution shall bear all costs associated with the difference between the amount of such proposed settlement and any higher amount arising from either any later settlement or any damages award. In the event a claim or action is or may be asserted, the institution shall have the right to select and to obtain representation by separate legal counsel. If institution exercises such right, all costs and expenses incurred by the institution for such separate legal counsel shall be borne by the institution, unless Sponsor fails to assert control of the defense and Sponsor is adjudicated liable by a court of competent jurisdiction, in which case Sponsor shall be responsible for Institution's separate legal counsel's costs and expenses.

13.4 Patient Injury. Sponsor may reimburse Institution at 150% of the Medicare rate for reasonable and necessary medical expenses incurred by patients participating in the Clinical Trial for medical care, including hospitalization, in the diagnosis and treatment of adverse reactions arising directly from or contributed to by the Product or the performance of any test or procedure that is required by the Protocol to which the patient would not have been exposed but for his/her participation in the Clinical Trial . following administration or use thereof in accordance with the Protocol, provided that any such medical expenses are not incurred as a direct or indirect result, in whole or in part, from Institution's, Investigator's or their personnel's (a) failure to follow all applicable federal, state or local laws, regulations, and guidelines, or to conform to reasonable and prudent clinical practices, including GCPs as applicable to clinical studies for the Product; (b) wrongful or negligent acts or omissions, or willful malfeasance or misuse of the Product; (c) failure to follow the Protocol or other written recommendations or instructions provided to the Institution Indemnitees by Sponsor; or (d) prior treatment giving rise to the condition for which the Product is used in connection with the Clinical Trial. The term "adverse reactions" does not mean the natural progression of an underlying or pre-existing condition or events that would have been expected from a standard treatment using currently approved therapies for the patient's condition. Sponsor will not provide compensation for lost wages or for any other damages, expenses or losses, or for medical expenses that have been covered by a patient's medical or other insurance. Sponsor (a) does not intend to seek payment or reimbursement from Medicare, Medicaid, or any other similar government program with respect to such medical expenses and (b) understands and agrees that neither the Institution nor the patient shall be expected to seek payment or reimbursement from any such government programs with respect to such medical expenses. Sponsor's agreement to reimburse Institution under this Section is being provided as reasonable consideration to study subjects willing to participate in the Clinical Trial and does not constitute an admission of liability for any injury, which ultimately could be determined only through an adjudication process, or as a settlement or compromise of any potential future liability claim.

14. Insurance.

Institution is a constituent unit of the University of Connecticut. As such, it is an agency of the State of Connecticut and is self-insured in an amount limited only by the ability of the State of Connecticut to satisfy any judgment arising from the operations of the Institution. Upon request, the Institution will provide a letter issued by the Connecticut Assistant Attorney General, of the State of Connecticut's self-insurance.

15. Limitation of Liability.

EXCEPT FOR LIABILITY ARISING UNDER SECTION 10, IN NO EVENT SHALL ANY PARTY BE LIABLE TO ANY OTHER PARTY FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING FROM OR IN RELATION TO THIS AGREEMENT, THE PROTOCOL OR THE PRODUCT (WHETHER IN CONTRACT, TORT, NEGLIGENCE STRICT LIABILITY, BY STATUTE OR OTHERWISE). THIS LIMITATION SHALL APPLY EVEN IF SUCH PARTY HAS BEEN ADVISED OR IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT FOR LIABILITY ARISING UNDER SECTION 10 AND SECTION 13 (THE "**SECTION 13 EXCEPTION**"), EACH PARTY'S MAXIMUM AGGREGATE LIABILITY TO ALL PARTIES FOR ANY CLAIM RELATED TO, OR IN CONNECTION WITH THIS AGREEMENT, THE PROTOCOL OR THE PRODUCT (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, BY STATUTE OR OTHERWISE) SHALL BE LIMITED TO AN AMOUNT EQUAL TO THE TOTAL PAYMENTS BY SPONSOR TO INSTITUTION UNDER THIS AGREEMENT, PROVIDED, HOWEVER, THAT THE MAXIMUM AGGREGATE LIABILITY OF A PARTY FOR ALL CLAIMS UNDER THE SECTION 13 EXCEPTION SHALL BE LIMITED TO AN AMOUNT EQUAL TO TEN MILLION DOLLARS ($10,000,000).

16. Term and Termination.

16.1 Term. This Agreement will commence on the Effective Date and will continue until completion of the obligations established in this Agreement and the Protocol.

16.2 Termination by Sponsor. Sponsor and Institution may terminate this Agreement or suspend performance, with or without cause at any time, effective immediately upon the expiration of thirty (30) days advance written notice to the other party.

Sponsor reserves the right to terminate the Clinical Trial without advance notice under the following circumstances: (i) noncompliance by the Principal Investigator or the Institution with the Protocol (other than pursuant to Section 3.1) or applicable laws, regulations, FDA policies or GCP Guidelines; (ii) if the Clinical Trial is suspended or terminated at other sites; (iii) to protect the health, safety and welfare of subjects, including if an interim analysis of the Clinical Trial shows it is unlikely to reach its primary endpoint; or (iv) the authorization and approval to conduct the Clinical Trial in the United States is withdrawn by the FDA.

16.3 Termination by Either Party. Either party may terminate this Agreement at any time for Cause, as hereinafter defined. "Cause" means material breach by either party where such breach, if curable, is not remedied to the nonbreaching party's reasonable satisfaction within thirty (30) days after the delivery of written notice thereof by the nonbreaching party to the breaching party.

16.4 Effect of Termination. Upon termination, neither party will have any further obligations under this Agreement, except that Institution and Principal Investigator (a) shall continue conducting procedures in connection with the Clinical Trial to the extent medically advisable on patients already participating in the Clinical Trial; and (b) shall continue to perform the follow-up testing in accordance with the Protocol and provide the data (including without limitation the accurate completion of all CRFs) required under the Clinical Trial for those patients who were enrolled in the Clinical Trial prior to receipt of the termination notice, unless Sponsor instructs otherwise. The terms of this Agreement shall continue to apply with respect to all such follow-up testing and data, and each party shall remain responsible for its liabilities accrued through the date of termination. Sponsor shall pay for all costs of all such continuing procedures and follow-up testing as set forth on Appendix C of this Agreement.

16.5 Non-Cancelable Commitments. In the event of termination of this Agreement prior to completion of the Clinical Trial, Institution and Principal Investigator shall take all reasonable efforts to minimize further costs. Sponsor agrees to pay for any reasonable non-cancelable commitments that are properly incurred by the Institution during the course of enrolling the requisite number of patients unless this Agreement is terminated by Sponsor for Cause as provided above. Sponsor shall not be responsible for any lost profits or lost opportunities.

16.6 Survival. In addition to any obligations which by their nature survive expiration or termination of this Agreement, the following provisions shall survive any expiration or termination of this Agreement for any reason: confidentiality, record keeping, regulatory compliance, intellectual property, notice, termination, publicity, indemnification (including patient injury), insurance, and miscellaneous.

17. Miscellaneous.

17.1 Assignment. This Agreement, and the rights and obligations hereunder, may not be assigned or transferred by either party without the prior written consent of the other party, except that Sponsor may assign this Agreement to an affiliated company or in connection with the merger, consolidation or sale of all or substantially all of its assets. Permitted assignees will assume the terms and conditions of this Agreement.

17.2 Independent Contractor. The relationship between the parties is that of independent contractors and not of partners, joint venturers, employers, employees or any other kind of relationship. This Agreement creates no agency in Institution or the Principal Investigator. Institution does not have nor will it represent that it has any power, right of authority whatsoever to bind Sponsor in any transaction with third parties, or to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, Sponsor. Institution will be solely responsible for its expenses and those of its employees.

17.3 Notice. All notices, statements, demands, requests, consents, communications and certificates from either party hereto to the other shall be made in writing unless specified to the contrary herein and sent by certified mail, return receipt requested, hand delivered or by federal express or similar overnight delivery service for which a receipt is made to the parties, addressed as follows:

(a) If intended for Sponsor:
(Sponsor name and address)

With a copy to:

(b) If intended for Institution:

Name: _____

Title: _____

Address: _____

City, State, Zip _____

With a copy to: Principal Investigator

Name: _____

Title: _____

Address: _____

City, State, Zip _____

or such other addresses as either party hereto may from time to time direct by service of notice to the other party as provided above. Any such notices, statements, demands, requests, consents, communications or certificates shall be deemed given on the date mailed if sent in accordance with this Section 17.3.

17.4 Entire Agreement. The parties understand that this Agreement constitutes the entire agreement of the parties with regard to its subject matter, is the only agreement between Sponsor and Institution and supersedes, terminates, and cancels any prior statements, representations, understandings, or agreements between parties, and is being executed by the parties hereto without reliance upon any representation, warranty, or other statement of any kind whatsoever, whether oral or written, which is not expressly set forth herein.

17.5 No Modification. This Agreement may be changed only by a writing signed by the parties.

17.6 Severability. In the event that any one or more of the provisions contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, that invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect. If any of the provisions of this Agreement are held to be excessively broad, it will be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law.

17.7 Applicable Law. This Agreement will in all events and for all purposes be governed by, and construed in accordance with, the law of The State of Connecticut, exclusive of its choice of law rules.

17.8 Force Majeure. Neither party will be liable for any failure to perform under this Agreement due to fire, flood, storm, earthquake, epidemic, war, national emergency, national disaster, interruption of transportation, or other causes beyond its reasonable control. In the case of a force majeure event, the affected party will promptly notify the other party of the event and how long any non-performance is expected to last.

17.9 Certain Definitions. The words "include," "includes," and "including" are deemed to be followed by "without limitation" whether or not they are in fact followed by such words or words of similar import.

SIGNATURES ON NEXT PAGE

SPONSOR		**INSTITUTION**	
Print:	_____	Print:	_____
Signature:	_____	Signature:	_____
Title:	_____	Title:	_____
Date:	_____	Date:	_____

Read, Understood and Agreed to by Principal Investigator:

Print: _____

Signature: _____

Title: _____

Date: _____