CLINICAL STUDY AGREEMENT

This CLINICAL STUDY AGREEMENT (**"Agreement"**) is made effective as of the **[**number**]** day of **[**month**]**, **[**year**]** (the **"Effective Date"**), and is by and among

(1) ASTRAZENECA **[**PHARMACEUTICALS**]** LP, a Delaware limited partnership with offices at 1800 Concord Pike, Wilmington, Delaware 19803 (**"AstraZeneca"**), and

(2) The University of Texas _____, a State of Texas institution (the **"Institution"**) and a component of The University of Texas System (the **"System"**), located at _____.

Recitals

(A) WHEREAS, AstraZeneca intends to conduct a multi-center clinical study (as defined below) of _____ (**"Study Drug"**).

(B) WHEREAS, the Institution has appropriate facilities and personnel and the Principal Investigator (as defined below) has the qualification, training, knowledge and experience necessary to conduct such a clinical study.

Agreement

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

1 Scope of Work.

1.1 Conduct of the Study. As part of a multi-center clinical study entitled **[**_____**]** ("**Multi-Center Study**"), the Institution, and the Principal Investigator shall conduct the clinical study entitled **[**_____**]** (the **"Study"**) in accordance with this Agreement, Protocol Number **[**__**]** incorporated by reference herein (the **"Protocol"**) and the investigator's brochure for the Protocol (the **"Investigator's Brochure"**), as each may be amended, and all applicable laws, rules, regulations and guidelines relating to the conduct of clinical investigations, including 21 C.F.R. Parts 50, 54, 56 and 312, and good clinical and medical practice (collectively, **"Applicable Laws"**). For purposes of this Agreement, the term "Institution" shall include all employees, executives, officers, directors, faculty, staff and other authorized agents of the Institution.

1.2 Contract Research Organizations. AstraZeneca may retain one or more contract research organizations (**"CRO[s]"**) to assist AstraZeneca in managing and monitoring the Study. The Institution and the Principal Investigator acknowledge AstraZeneca's right to assign or transfer, in whole or in part, without the consent of the Institution or the Principal Investigator, any of its rights or obligations under this Agreement to any such CRO(s). The Institution and Principal

Investigator shall permit such CRO(s) to perform any or all of AstraZeneca's obligations, or to exercise any or all of AstraZeneca's rights, under this Agreement. AstraZeneca shall advise its CRO(s) to use this Agreement when negotiating with Institution.

2 **The Principal Investigator**. For sake of clarity, the Principal Investigator is an employee of Institution and will be named in Exhibit A. The Principal Investigator represents and certifies that he or she has read and understands the Investigator's Brochure. The Principal Investigator is not a party but must sign off read and acknowledged to the entire agreement. Prior to the commencement of the Study, the Principal Investigator shall deliver to AstraZeneca true, complete and correct copies of the Principal Investigator's investigator statement on U.S. Food and Drug Administration (**"FDA"**) Form 1572 and curriculum vitae, each of which shall be signed by the Principal Investigator. During the Study, the Institution shall immediately notify AstraZeneca in writing at such time as it becomes aware that the Principal Investigator plans to leave the Institution or shall be unable to complete the Study. If the Institution and AstraZeneca are unable to agree on an acceptable substitute investigator within fifteen (15) business days following such notice, AstraZeneca may terminate this Agreement pursuant to Section 24.

3 **Representations and Covenants**. The Institution and (to the extent that such representations and covenants relate to the Principal Investigator) the Principal Investigator each represents, certifies and covenants to AstraZeneca, as follows:

3.1 the Principal Investigator is, and at all times during the course of the Study shall be, qualified by training and experience with appropriate expertise to conduct the Study;

3.2 the Institution and the Principal Investigator have, and at all times during the course of the Study shall have, the appropriate licenses, approvals and certifications necessary to safely, adequately and lawfully perform the Study;

3.3 none of the Institution, the Principal Investigator, or any other person who assists in performing the Study is subject to any conflicting obligations or has any financial or other interest in the outcome of the Study or has entered into any contract with respect to the Study that might interfere with the performance of the Study or that might impair the acceptance of the resulting data by the FDA or that might create a conflict of interest;

3.4 the Institution is not currently using, and shall not use the services of any person who assists in performing the Study, including the Principal Investigator, who is debarred or proposed for debarment under the Federal Food, Drug, and Cosmetic Act, as amended, or otherwise disqualified or suspended from performing a clinical research study or otherwise subject to any restrictions or sanctions by the FDA or any other governmental or regulatory authority or professional body with respect to the performance of scientific or clinical investigations. The Institution will promptly notify AstraZeneca if any person who assists in performing the Study becomes so debarred; and

3.5 the Institution and the Principal Investigator have been selected to conduct the Study because of their experience, expertise and resources and not, in any way, as an inducement to, or in return for, past, present or future prescribing, purchasing, recommending, using, dispensing or granting preferential formulary status for any AstraZeneca product.

4 **Facilities**. The Institution and the Principal Investigator shall conduct the Study at the facility first identified above, or such other facilities as AstraZeneca and the Institution may agree in writing, and as shall be listed on FDA Form 1572 (the **"Facility"**). The Institution shall make available all personnel, facilities and resources necessary to efficiently and expeditiously accomplish its responsibilities under this Agreement.

5 Subject Enrollment and Informed Consent.

5.1 Subject Enrollment. The Principal Investigator shall enroll subjects into the Study in accordance with Exhibit A and Exhibit B, as described below, (each, a **"Subject"**). The Principal Investigator shall use all reasonable efforts to complete enrollment by any Subject Enrollment Closing Date set forth in Exhibit A or otherwise notified in writing to the Principal Investigator by AstraZeneca. The Study period may be extended or shortened and the number of Subjects the Institution may enroll in the Study may be changed at AstraZeneca's sole discretion. The Institution acknowledges that the Study is part of the Multi-Center Study, and agrees that when the enrollment goal for the Multi-Center Study as a whole is reached, enrollment will be closed at all sites, including the Institution, regardless of whether the Institution or any other site has reached its individual enrollment goal.

5.2 Informed Consent. The Principal Investigator shall obtain the informed consent of each Subject prior to any screening or participation in the Study using the Informed Consent Materials (as defined in Section 10.3) and in accordance with Applicable Laws. Each Subject shall complete an informed consent form that has been reviewed and approved in advance by AstraZeneca and by an institutional review board approved by the Institution that complies with the requirements of 21 C.F.R. Part 56 (**"IRB"**).

5.3 Adverse Events. The Institution and Principal Investigator shall notify AstraZeneca of any information concerning any serious or unexpected event, injury, toxicity or sensitivity reaction, and the severity thereof, associated with the Study or the Study Drug in accordance with such AstraZeneca guidelines with respect to the reporting of adverse Subject experiences as AstraZeneca may supply in writing to the Institution from time to time.

6 **Compensation**. For the services to be rendered hereunder, AstraZeneca shall pay the Institution in accordance with the budget, payment schedule and procedures set forth in Exhibit A. The parties acknowledge that the amounts to be paid by AstraZeneca under this Agreement are reasonable compensation for the work performed and that neither the Institution nor the Principal Investigator has received any other compensation or other inducement in connection with this Agreement or its participation in the Study. Any amounts paid by AstraZeneca to the Institution for services that have not been performed, or expenses that have not been incurred, under this Agreement shall be promptly refunded to AstraZeneca upon the expiration or termination of this Agreement, or earlier at the written request of AstraZeneca. Except with respect to those expenses reimbursable under Sections 19 and 24.4, the Institution acknowledges and agrees that the payments made by AstraZeneca under this Section 6 represent AstraZeneca's total obligations under this Agreement, and fully cover the costs of conducting the Study. Accordingly, the Institution shall not submit claims to, or otherwise seek reimbursement from, Medicare, Medicaid or any other third party payor, whether public or private, for any costs covered by payments made or goods or services provided by AstraZeneca under this Agreement or otherwise incurred for conducting the Study.

7 **Financial Disclosure Information**. At AstraZeneca's request, the Principal Investigator shall promptly provide to AstraZeneca financial disclosure statements in compliance with 21 C.F.R. Part 54, in the form required by AstraZeneca and executed by the Principal Investigator and any sub-investigators and such other financial information as AstraZeneca may reasonably request. During the term of the Study and for a period of one (1) year thereafter, the Principal Investigator and any sub-investigators shall promptly notify AstraZeneca of any changes to such financial information.

8 **Ownership and Control of Study Drug**. All Study Drug supplied to the Institution shall remain the exclusive property of AstraZeneca until administered or dispensed to Subjects during the course of the Study. The Study Drug shall only be used as described in the Protocol and in compliance with Applicable Laws. Upon termination or completion of the Study, the Institution shall, at AstraZeneca's direction and expense, either return to AstraZeneca or dispose of any quantities of unused Study Drug, in accordance with AstraZeneca's written instructions. The Institution shall maintain complete and accurate records relating to the disposition of the Study Drug supplied to the Institution as set forth in Section 10.1.

9 **Disclaimer**. Without limiting AstraZeneca's obligations under Section 19, ASTRAZENECA DOES HEREBY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, WITH RESPECT TO THE STUDY DRUG, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OR THAT THE USE OF THE STUDY DRUG FOR PURPOSES OTHER THAN SPECIFIED IN THIS AGREEMENT WILL NOT INFRINGE THE RIGHTS, PATENT OR OTHERWISE, OF ANY THIRD PARTY.

10 **Records; Reports; and Regulatory Assistance**.

10.1 Study Documentation. The Institution and the Principal Investigator shall prepare, maintain and retain complete, current, accurate, organized and legible Study Documentation (as defined below) in a manner acceptable for the collection of data for submission to, or review by, the FDA and other regulatory or governmental authorities, and in full compliance with the Protocol and all Applicable Laws. **[On a case-by-case basis, AstraZeneca may at its sole expense request, in writing, longer periods of retention times for Study Documentation.]** For purposes of this Agreement, "Study Documentation" includes all records (related to the Study Drug or Protocol), accounts, notes, reports and data, collected, generated or used in connection with the Study, whether in written, electronic, video or other tangible form, including all recorded original observations and notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the Study. The Principal Investigator and/or Institution will conduct data entry activities, which shall include entry of Subject data after Subject visit and response to queries, within the timelines provided by AstraZeneca. For studies using web based data capture technology ("**WBDC**"), data will be entered in the WBDC system at the Study site. Trained Study personnel will be responsible for entering data on the observations, tests and assessments specified in the Protocol into the WBDC system and according to the CRF instructions as defined in Section 10.2. The CRF instructions will also provide the Study site with data entry instructions. Data entered in the WBDC system will be automatically saved to a central database and changes tracked to provide an audit trail. When data have been entered, reviewed, edited, and Source Data Verification ("**SDV**") performed, the Principal Investigator will be notified to sign the CRF

electronically as per the agreed project process and data will be locked to prevent further editing. A copy of the CRF will be archived at the Study site. When an electronic invalidated system that allows retrospective entry or correction of medical records data is issued, Principal Investigator shall print, sign, date and file a copy of the relevant medical record each time a Subject attends the clinic. The Principal Investigator's electronic signature shall be the legally binding equivalent to a handwritten signature. If medical records of Study Subjects are held in a computerized medical system, such system must be in full compliance with 21 C.F.R. Part 11, the FDA rules on electronic records and signatures.

10.2 Provisions of Data and Reports. The Institution shall provide to AstraZeneca original case report forms (either in paper or electronic if the Protocol calls for WBDC system) (collectively, **"CRFs")** for each Subject participating in the Study and such other reports as and when required by the Protocol or Applicable Laws. The Institution shall provide the final CRFs required by the Study as set forth in Exhibit A or such later date as AstraZeneca may require.

10.3 Institutional Review Board. The Institution shall provide to AstraZeneca documentation verifying review and approval by the IRB of the information to be provided to potential Subjects of the Study to secure their informed consent, including information about any compensation being provided to Subjects for participation in the Study (**"Informed Consent Materials"**), the Protocol, the Investigator's Brochure and amendments to any of the foregoing. The Institution shall ensure that the IRB continues to monitor the Study during the term of this Agreement in accordance with Applicable Laws and in any event at least once per year and shall provide to AstraZeneca documentation of the IRB's continuing review contemporaneously therewith.

10.4 Regulatory Assistance. At the request and expense of AstraZeneca, the Institution and the Principal Investigator shall: (a) assist AstraZeneca in the preparation and submission of investigational new drug applications, new drug applications, any other premarket or marketing applications relating to the Study or the Study Drug, and any amendments or supplements to the foregoing; (b) attend meetings with the FDA and other regulatory or governmental authorities regarding such applications and the associated approvals; and (c) provide such other reasonable assistance as AstraZeneca may request in connection with regulatory matters relating to the Study or the Study Drug.

11 **Audit and Review**. AstraZeneca or its authorized representatives shall have the right, upon advance written notice, at AstraZeneca's expense, and during regular business hours, to: (a) audit all Facilities used in performance of the Study; (b) monitor the conduct of the Study; (c) review, copy and audit all Study Documentation, any other books, records, data and Work Product (as defined below) relating to the Study or the IRB, and all required licenses, certificates and accreditation; and (d) interview the Principal Investigator and other persons who assisted in performing the Study. Subject's medical records are for review purposes only.

12 **Changes to the Protocol**. No change in the Protocol shall be made by the Institution or the Principal Investigator, subject to any Applicable Laws relating to the safety of Subjects that require a deviation from the Protocol, in which case the Institution shall promptly notify AstraZeneca and the IRB of the nature of the deviation and the facts necessitating such deviation as soon as the facts are known to the Institution. AstraZeneca may at any time make changes in the Protocol upon five (5) days' advance written notice to the Institution; provided,

however, that, unless the changes are required by Applicable Laws, do not materially increase the cost of performance of the Study by the Institution or are otherwise agreed to by the Institution, the Institution may terminate this Agreement pursuant to Section 24.

13 **Regulatory Inspections**. If any governmental or regulatory authority (a) contacts the Institution or the Principal Investigator with respect to the Study, (b) conducts, or gives notice of its intent to conduct, an inspection at any Facility or (c) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of the Institution, the IRB or the Principal Investigator that could reasonably be expected to impact any data or clinical activity under the Study, then the Institution shall promptly notify AstraZeneca of such contact or notice. AstraZeneca shall have the right to be present at and to participate in any such inspection or regulatory action with respect to the Study. The Institution shall provide AstraZeneca with copies of all pertinent information and documentation issued by any governmental or regulatory authority and any proposed response. AstraZeneca shall have the right in advance to review and comment on any responses that pertain to the Study. No such response shall contain any false or misleading information with respect to the Study, the Study Drug or AstraZeneca.

14 **Ownership of Materials, Intellectual Property and Work Product.**

14.1 Materials. AstraZeneca shall own all right, title and interest (collectively, **"Rights"**) in and to any equipment, materials, methods, documents, data, software and information supplied by or on behalf of, or purchased at the expense of, AstraZeneca (collectively, **"Materials"**) in connection with the Study, unless specifically agreed to by AstraZeneca in writing. To the extent AstraZeneca supplies computers, Institution agrees that no software may by installed unless there is agreement in writing that such software is required to conduct the Study. The Institution shall make all reasonable UCC or other filings necessary to secure and evidence AstraZeneca's ownership of the Materials as and when requested in writing and reasonably reimbursed by AstraZeneca. The Institution shall: (a) use the Materials only for the purposes described in the Protocol or such other purposes as AstraZeneca may approve in writing, (b) restrict access to and use of the Materials to the Principal Investigator and other personnel for whom such access and use is required to conduct the Study and (c) deliver the Materials to AstraZeneca or its designee at AstraZeneca's reasonable expense on the earlier of the completion of the Study, the termination or expiration of this Agreement, or as otherwise requested in writing by AstraZeneca. For purposes of this Section 14, "AstraZeneca" shall include any designee of AstraZeneca, including any direct or indirect affiliate of AstraZeneca PLC.

14.2 Retained Rights. Each party shall retain all Rights in any patent, patent application, trade secret, know-how and other intellectual property that was owned by such party prior to the Effective Date of this Agreement and no license grant or assignment, express or implied, by estoppel or otherwise, with regard thereto is intended by, or shall be inferred from, this Agreement.

14.3 Inventions. AstraZeneca shall own all Rights in and to each invention, discovery, know-how, trade-secret and other intellectual property, including improvements, whether patentable or not, that is conceived, reduced to practice or otherwise made by the Institution, the Principal Investigator or any other person (other than AstraZeneca) who assists in performing the Study (whether solely or jointly with others) (each, an **"Inventor"**) as a result of or in connection

with the Study or the performance of obligations under this Agreement in accordance with the Protocol, including any patent, trade secret, trademark, or other proprietary right with respect thereto (collectively, the **"Inventions"**). The Institution shall promptly cause each Inventor to take any actions necessary to assign and transfer all Rights in each Invention to AstraZeneca, at AstraZeneca's reasonable expense, including disclosing to AstraZeneca in writing the conception, reduction to practice or making of such Invention, and, without additional consideration and at AstraZeneca's reasonable expense, assigning and transferring to AstraZeneca all Rights to patents, patent applications and Rights to file for patent protection for such Invention throughout the world.

14.4 Work Product. The Institution shall fully disclose to AstraZeneca all work, reports, writings, designs, methods, computer software and data recorded in any form, including but not limited to Study Documentation, that are created, developed, written, conceived or made by the Institution, the Principal Investigator or any other person (whether solely or jointly with others) as a result of or in connection with the Study or the performance of their obligations under this Agreement in accordance with the Protocol (collectively, **"Work Product"**). The Institution and the Principal Investigator each agrees that all Work Product (other than a Subject's primary medical records and any articles or presentations that are published or made in accordance with Section 17) that is copyrightable subject matter shall be considered "work made for hire" within the meaning of the copyright laws of the United States and that AstraZeneca is and shall be the sole author of such Work Product and the sole owner of all Rights therein. In the event that any such Work Product is deemed for any reason not to be a "work made for hire", the Institution will irrevocably assign, and the Institution shall cause the Principal Investigator and each Inventor to irrevocably assign, to AstraZeneca, at AstraZeneca's expense, all of their respective Rights worldwide in and to such Work Product. Such assignments shall include the right to all causes of action for copyright infringement of any such Work Product, including the right to institute, process, defend and settle any suit or other legal or administrative proceeding, to enjoin infringement or misappropriation of such Work Product, together with the sole right to any resulting recovery of damages, royalties, profits, legal fees and costs.

14.5 Assistance. The Institution shall, and shall cause the Principal Investigator and any Inventor to, where applicable and consistent with the requirements of this Agreement: (a) execute all documents and perform all acts deemed necessary by AstraZeneca to evidence AstraZeneca's ownership of any Invention and Work Product (including the making of any biological deposits) and (b) assist AstraZeneca in preparing, prosecuting, obtaining, registering, maintaining, defending and enforcing, at AstraZeneca's sole expense (for actual costs incurred), discretion and exclusive control, all United States patents (including any divisions, continuations, continuations-in-part, reissues, renewals, extensions or the like of any such patent) and any foreign patents or equivalents thereof (including certificates of invention), copyrights, trade secret rights and other proprietary Rights in and to the Inventions and the Work Product in any and all countries as may be determined by AstraZeneca.

14.6 Attorney-In-Fact. The Institution and the Principal Investigator each hereby irrevocably appoints AstraZeneca, and the Institution shall cause each Inventor or any other person, where applicable, irrevocably to appoint AstraZeneca, as attorney-in-fact for the purpose of executing such documents in their respective names as may be necessary or desirable to carry out the purposes of Sections 14.1 through 14.5.

14.7 Government-Funded Activities. The parties hereto agree that all activities under this Agreement (**"Agreement Activities"**) shall fall outside the planned and committed activities of any government-funded project undertaken by the Principal Investigator (**"Government-funded Activities"**) and shall not diminish or distract from the performance of such Government-funded Activities within the meaning of 37 C.F.R. § 401.1(a)(1), and, therefore, that any Invention made hereunder shall not be subject to the conditions of 37 C.F.R. Parts 401 and 404. In the event that Agreement Activities shall be found to be Government-funded Activities, the Institution, Principal Investigator and any other Inventor shall take all actions necessary to retain title to any Invention made under this Agreement, including those required by 37 C.F.R. §§ 401.14(c)(1), (2) and (3). In the event that any Inventions or Work Product conceived or reduced to practice, made or developed by any Inventor hereunder are controlled by federal law in accordance with 37 C.F.R. §§ 501.1 - 501.11 or any other Applicable Laws that would preclude AstraZeneca from obtaining the Rights to such Inventions or Work Product under Sections 14.1 through 14.6, the Institution and the Principal Investigator shall and do hereby, and the Institution shall cause each other Inventor to: (a) secure such waivers and releases available or permitted under Applicable Laws to enable AstraZeneca to obtain such Rights; and (b) if such waivers and releases are not available or permitted, grant to AstraZeneca (or its designee) irrevocable, worldwide, exclusive, fully-paid, royalty-free right and license, with right to sublicense, (or such other similar Rights to the maximum extent permitted by Applicable Laws) to exploit such Invention or Work Product, subject to the right of the U.S. Government to retain an irrevocable, royalty-free right to use such Invention or Work Product throughout the U.S. Government.

15 **Confidential Information.**

15.1 Definition. For purposes of this Agreement, **"Confidential Information"** means any information of AstraZeneca, whether of a technical, business or other nature, including information that relates to AstraZeneca's trade secrets, products, Study Drug, chemical structure, promotional material, developments, proprietary rights or business affairs, together with any Inventions, Work Product and all other written information, data and results collected, prepared, developed or generated by the Institution, the Principal Investigator and any other person pursuant to or in contemplation of this Agreement, including, subject to the Texas Public Information Act and other applicable laws and regulations, this Agreement. This Section 15 is subject to the Institution and the Principal Investigator's publication rights as set forth in Section 17. Confidential Information does not include any information that:

15.1.1 the Institution or the Principal Investigator can prove was known prior to the date of this Agreement and was not subject to any confidentiality restrictions;

15.1.2 the Institution or the Principal Investigator can prove was lawfully obtained from a third party without breach of any obligation of confidentiality;

15.1.3 is or becomes part of the public domain through no act or violation of any obligation of the Institution or the Principal Investigator; or

(For the avoidance of doubt, when AstraZeneca lists or discloses any non-confidential information relating to the Study Drug or the Study in a clinical trial registry or clinical results database, any aspects or details of Confidential Information concerning the Study

Drug or the Study that are not listed or disclosed in such registry or database shall not be deemed to be or become part of the public domain.)

15.1.4 is independently developed by the Institution or the Principal Investigator.

15.2 Non-Disclosure. Subject only to Section 15.4, for a period of five (5) years after the expiration or termination of this Agreement, the Institution and the Principal Investigator shall not, without AstraZeneca's prior written consent or as may be permitted by this Agreement, disclose to any third party any Confidential Information, and shall use such Confidential Information solely for purposes of performing its obligations under this Agreement. The Institution shall restrict the dissemination of Confidential Information to only those persons within the Institution who have a need to know, and shall ensure that they are aware of the obligation of confidentiality required by this Agreement. The Institution and the Principal Investigator shall use at least the same care and discretion in maintaining the confidentiality of the Confidential Information as each uses with its most sensitive confidential information. The Institution or the Principal Investigator, as applicable, shall notify AstraZeneca promptly upon the Institution or the Principal Investigator's discovery of any loss or compromise of the Confidential Information. Upon the termination or expiration of this Agreement or upon AstraZeneca's earlier written request, the Institution or the Principal Investigator shall promptly return to AstraZeneca all Confidential Information at AstraZeneca's reasonable expense, provided that the Institution shall have the right to retain, subject to the other provisions of this Section 15.2, the original copies of each Subject's primary medical records.

15.3 External Discussions. THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR AGREE THAT, BY ENTERING INTO THIS AGREEMENT, THEY HAVE ASSUMED A RELATIONSHIP OF TRUST AND CONFIDENCE WITH ASTRAZENECA PURSUANT TO WHICH THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR WILL HAVE ACCESS TO CONFIDENTIAL INFORMATION. ACCORDINGLY, THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR AGREE THAT, EXCEPT AS EXPRESSLY PERMITTED UNDER THIS SECTION 15, THEY SHALL NOT DISCUSS THE STUDY OR THE STUDY DRUG WITH ANY PERSON NOT PERFORMING SERVICES UNDER THIS STUDY FOR ANY REASON AND SHALL NOT EXPRESS ANY OPINION THAT IS INFORMED, IN WHOLE OR IN PART, WHETHER DIRECTLY OR INDIRECTLY, BY ACCESS TO THE CONFIDENTIAL INFORMATION. FOR THE AVOIDANCE OF DOUBT, NEITHER THE INSTITUTION NOR THE PRINCIPAL INVESTIGATOR SHALL DISCUSS THE STUDY OR THE STUDY DRUG WITH ANY FINANCIAL, SECURITIES OR INDUSTRY ANALYST OR WITH THE MEDIA.

15.4 Exceptions to Non-Disclosure. Notwithstanding Sections 15.2 and 15.3, if the Institution or the Principal Investigator are legally required to disclose Confidential Information or results of the Study, the Institution or the Principal Investigator, as applicable, shall promptly notify AstraZeneca in writing, but no less than three (3) business days, prior to making the required disclosure. If such disclosure is required pursuant to a lawful judicial or government order, the Institution and the Principal Investigator shall permit AstraZeneca to defend against any such order of disclosure and the Institution shall assist, at AstraZeneca's expense, in such defense to the extent permitted by Applicable Laws. If the Institution or the Principal Investigator is thereafter or otherwise required to disclose any Confidential Information, the Institution or the Principal Investigator, as applicable, shall craft such disclosure as reasonably requested by AstraZeneca so that such disclosure shall contain only such Confidential

Information as is required by Applicable Laws. Nothing contained herein shall prohibit the Institution or the Principal Investigator from immediately disclosing results of the Study to the extent necessary to prevent or mitigate a serious health hazard; provided, however, that the Institution or the Principal Investigator, as applicable, shall notify AstraZeneca prior to making such a disclosure and promptly after it has made such a disclosure.

16 **Privacy and HIPAA.**

16.1 Covered Entities. The Institution and the Principal Investigator each represents, certifies and covenants that it is a "Covered Entities" under the provisions of the Health Insurance Portability and Accountability Act of 1996 and any regulations and official guidance promulgated thereunder (**"HIPAA"**). The Institution and the Principal Investigator shall handle all Study Documentation (including Subjects' medical records) in accordance with HIPAA requirements and all other Applicable Laws and shall ensure that they obtain from each Subject a valid authorization that complies with HIPAA and is, in form and substance, acceptable to AstraZeneca, in order for the Institution and the Principal Investigator to provide AstraZeneca with the Study Documentation and to satisfy their other obligations under this Agreement with respect to the Study Documentation.

16.2 AstraZeneca Not Covered By HIPAA. AstraZeneca represents, warrants and covenants, and the Institution and the Principal Investigator acknowledge and agree, that no component of AstraZeneca or any of its affiliates that will be performing any of AstraZeneca's obligations under this Agreement: (a) is a "Covered Entity", (b) will become a "Business Associate" of a Covered Entity by performing its obligations under this Agreement or (c) is otherwise governed by HIPAA.

17 **Publication and Use of Study Results**.

17.1 Study Data. The Institution and the Principal Investigator acknowledge and agree that the Study is being conducted as part of the Multi-Center Study and that data from all sites will be pooled and analyzed, and agree that premature disclosures of data from a single site may be misleading for a Multi-Center Publication (as defined below). After the completion, or earlier termination, of the Multi-Center Study at all participating sites, AstraZeneca shall conduct, or cause to be conducted, such analyses of the data resulting from each site participating in the Multi-Center Study (**"Multi-Center Study Analyses"**) and, if requested, deliver the results of such analyses (**"Multi-Center Study Results"**) to the Principal Investigator together with the underlying data relating only to Subjects enrolled in the Study at the Institution (**"Site Data"**), but not any other data and databases that are supplied, prepared, collected, developed or generated as a result of, in the performance of, or in connection with the Multi-Center Study (**"Multi-Center Study Data"**); provided, however, that AstraZeneca shall have the right to delay the delivery of the Multi-Center Study Results and the Site Data for up to 18 months for regulatory or intellectual property purposes. AstraZeneca shall make the Multi-Center Study Data available to an independent statistician retained by the Principal Investigator, and reasonably acceptable to AstraZeneca, pursuant to a separate confidentiality agreement, solely for purposes of verifying the Multi-Center Study Results, provided that AstraZeneca shall not be required to deliver or otherwise make available the Multi-Center Study Data outside its premises and the statistician shall not have the right to copy or retain any Multi-Center Study Data, and provided further that AstraZeneca shall not be required to make available the Multi-Center Study Data to an independent statistician if it has provided the Principal Investigator

with the report of an independent statistician retained by another investigator conducting the Multi-Center Study, provided that such report is reasonably acceptable to the Principal Investigator. The Institution shall be solely responsible for the fees and expenses of such independent statistician retained by the Principal Investigator and shall provide AstraZeneca and such other investigators who are conducting the Multi-Center Study as AstraZeneca may from time to time designate with certified copies of the report of the independent statistician. Further, AstraZeneca, or its designee, shall have the right to coordinate one or more publications of the Multi-Center Study Results (each, a **"Multi-Center Publication"**).

17.2 Publication and Use of Study Data. The Principal Investigator may use the Multi-Center Study Results and the Site Data for the limited purpose of his or her own research and academic analysis, provided that, subject to Section 17.3, neither the Institution nor the Principal Investigator shall make any publication or presentation with respect to the Multi-Center Study or the Study or the respective results until the earlier of the publication of the first Multi-Center Publication and 18 months after the completion, or earlier termination, of the Multi-Center Study at all participating sites. In no event shall the Institution or the Principal Investigator publish, cause to be published or make any presentation disclosing the raw Site Data or any other Multi-Center Study Data (as distinguished from results of analyses of the Site Data and the Multi-Center Study Results) or make any publication or presentation that is false or misleading or that AstraZeneca determines: (a) is not in accordance with this Section 17, (b) is not consistent with academic standards or (c) is for commercial purposes. Except as provided in this Section 17.2 with respect to the Principal Investigator, the Institution shall not make any publication or presentation with respect to the Study or the Multi-Center Study. In no event will the Institution or the Principal Investigator be so restricted after 18 months have elapsed since the completion of the Study at all centers.

17.3 AstraZeneca Review. The Institution and the Principal Investigator shall submit a copy of any proposed manuscript, abstract, presentation or other document with respect to the Multi-Center Study or the Study, including any Multi-Center Publication of which the Principal Investigator is an author, to AstraZeneca for review and comment at least 60 days prior to its submission for publication or presentation. No publication or presentation with respect to the Multi-Center Study or the Study shall be made unless and until all of AstraZeneca's comments on the proposed publication or presentation have been considered by the Principal Investigator and any Confidential Information has been removed; provided that any Multi-Center Study Analyses or analyses performed by the Principal Investigator using any Multi-Center Study Analyses (or the Site Data) or that have been disclosed in a publication or presentation authorized pursuant to this Section 17 or pursuant to another clinical study agreement under the Multi-Center Study (but not the underlying Multi-Center Study Data (including Site Data), shall not be deemed Confidential Information for purposes of this Section 17. If requested in writing by AstraZeneca, the Institution and the Principal Investigator shall withhold material from submission for publication or presentation for an additional ninety (90) days to allow for the filing of a patent application or the taking of other measures to establish and preserve AstraZeneca's proprietary rights. To the extent that any provision of this Section 17 may be inconsistent in any respect with any statements about publication policy set forth in the Protocol, the provisions of this Section 17 shall control.

17.4 Authorship and Final Contents. Subject to the foregoing, the authorship and final contents, including scientific conclusions and professional judgments, of any paper submitted about the

Multi-Center Study or the Study by the Principal Investigator shall be determined by the Principal Investigator.

17.5 License to AstraZeneca. The Institution and the Principal Investigator agree that, if either publishes the results of the Multi-Center Study or the Study, AstraZeneca is hereby granted an irrevocable, royalty-free license to make and distribute copies of such publication under any copyright privileges that the Institution and the Principal Investigator may have. AstraZeneca also shall have the right to publish independently the results of the Multi-Center Study and the Study. The Institution and the Principal Investigator shall, in any agreement with a journal or other publisher to publish the results of the Multi-Center Study or the Study, use reasonable efforts to reserve expressly all copyright rights necessary to grant AstraZeneca the license and rights contained herein.

17.6 Clinical Trial Registries and Clinical Results Databases. Without limitation to any other right of AstraZeneca hereunder, the Institution and the Principal Investigator acknowledge and agree that AstraZeneca shall have the right to list the Multi-Center Study or the Study on one or more clinical trial registries and to publish the results of Multi-Center Study or the Study in one or more clinical results databases.

18 **Use of Name; Advertising.**

18.1 Use of Name. Subject to Applicable Laws, none of the Institution, the Principal Investigator or AstraZeneca shall mention or otherwise use the name, trademark, trade name or logo of any other party in any publication, press release or promotional material with respect to the Study without the prior written approval of such other party; provided, however, that for non-commercial, internal purposes, AstraZeneca shall have the right to identify the Institution as the site at which the Study was conducted and to identify those individuals responsible for conducting the Study. The Institution may use the name of AstraZeneca and the title of the Study for internal purposes, including, but not limited to, acknowledging the Principal Investigator's work.

18.2 Advertising. Neither the Institution nor the Principal Investigator shall issue to the public any information or statement through the press or any other media, including advertisements for the enrollment of Study Subjects, without the prior written permission of AstraZeneca and the review and approval of the IRB.

19 **Indemnification by AstraZeneca.**

19.1 Indemnification. Except as set forth below, AstraZeneca shall defend, indemnify and hold harmless the Institution, System, their Regents, officers, agents, and employees, including the Principal Investigator and the Institution's other employees and any physician, nurse, nurse's aide, study coordinator or other healthcare personnel providing services to the Institution in connection with its conduct of the Study (collectively, the **"Institutional Indemnified Parties"**) from and against any and all liability, claim, loss, damages and expense (including lawyers' fees and costs of suit) (collectively, **"Losses"**) incurred by them in connection with any and all suits, investigations, claims or demands by or on behalf of Subjects taking part in the Study (or their dependents) against any Institutional Indemnified Party for personal injury (including death) to Subjects to the extent arising out of or relating to: (a) the administration of the Study Drug or of any placebo in accordance with this Agreement, the Protocol and any

other written instructions of AstraZeneca or (b) the performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study, or the use by AstraZeneca of the results of the Study, provided that, in each case (a) or (b), the Institution and the Principal Investigator have (i) used reasonable medical judgment in the conduct of the Study (including the enrollment of Subjects for which participation in the Study is medically appropriate) and (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice.

19.2 Reimbursement of Medical Expenses. Notwithstanding Section 19.1, AstraZeneca shall reimburse the Institution for the direct, reasonable and necessary medical expenses incurred by the Institution for the treatment of any personal injury that is a direct result of (a) the administration of the Study Drug or of any placebo in accordance with this Agreement, the Protocol and any other written instructions of AstraZeneca or (b) any performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study if (i) the Institutional Indemnified Parties have complied with this Agreement, the Protocol and any written instructions of AstraZeneca concerning the Study and (ii) all the requirements of informed consent have been complied with in accordance with Section 5.2. AstraZeneca 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 Subject's medical or other insurance, provided, however, AstraZeneca understands and agrees that Subject is not required to file an insurance claim.

19.3 Exceptions. Sections 19.1 and 19.2 shall not apply to any Loss:

19.3.1 arising out of or relating to the negligence, willful malfeasance or wrongful acts or omissions of any Institutional Indemnified Party, or by the negligent failure of any Institutional Indemnified Party to comply with the provisions of this Agreement, the Protocol or any written instructions of AstraZeneca concerning the Study;

19.3.2 to the extent that such Loss arises out of or relates to the Principal Investigator's or the Institution's negligent failure to promptly report to AstraZeneca any significant or alarming developments that may occur during the Study, including any Subject adverse experiences or Serious Adverse Events (as both such terms are defined in the Protocol); or

19.3.3 that any Institutional Indemnified Party has made any admission in respect of such claim or proceeding or has taken any action relating to such claim or proceeding prejudicial to the defense of it without the prior written consent of AstraZeneca, such consent not to be unreasonably withheld, provided that this condition shall not be treated as breached by any statement required to be made by any Institutional Indemnified Party in connection with the operation of the Institution's internal complaint procedures, accident reporting procedures or disciplinary procedures or by law.

19.4 Effect of Termination or Expiration. Termination or expiration of this Agreement or the Study shall not affect AstraZeneca's obligations to the Institutional Indemnified Parties with respect to any Loss or expense resulting from the conduct of the Study prior to the Institution's or the Principal Investigator's first receipt of notice of termination, to the extent that such Loss or expense would otherwise be covered by this Section 19, but AstraZeneca shall have no obligation under this Section 19 with respect to any activities performed by or on behalf of the Institution or the Principal Investigator after the receipt of such notice.

20 **Indemnification by the Institution**. To the extent authorized by the Constitution and laws of the State of Texas, the Institution shall defend, indemnify and hold harmless AstraZeneca, its Affiliates and their respective officers, directors, partners, employees and agents (collectively, the **"AstraZeneca Indemnified Parties"**) from and against any and all Losses incurred by them in connection with any and all third party suits, investigations, claims or demands to the extent caused by or arising out of the negligent acts or omissions of an Institutional Indemnified Party, including the negligence or willful misconduct of the Institution, the Principal Investigator or any other person who assists in conducting the Study, in performing their obligations under this Agreement, or negligent failure of the Institution, the Principal Investigator or any other person who assists in conducting the Study, to comply with the provisions of this Agreement, the Protocol or any written instructions of AstraZeneca concerning the Study, provided, however, that Institution shall not hold AstraZeneca harmless from Losses arising out of the negligence or willful malfeasance of AstraZeneca Indemnified Parties, or any other person or entity not subject to Institution's supervision or control. Notwithstanding the foregoing, the Institution shall have no obligation pursuant to this Agreement to defend, indemnify or hold harmless an AstraZeneca Indemnified Party from any Losses to the extent caused by a breach of this Agreement by an AstraZeneca Indemnified Party or by such party's negligence or willful misconduct.

21 **Indemnification Procedures.**

21.1 Notice and Assumption of Defense. The party desiring indemnification under Section 19.1 or 20 (the **"Indemnified Party"**) shall promptly provide the other party (the **"Indemnifying Party"**) with written notice of the possibility of a Loss upon learning of any events that could give rise to such Loss or the receipt of any claim, suit, demand or notice with respect thereto, whichever is earlier. The Indemnifying Party shall not be responsible for any Loss, or any increase in any Loss, resulting from any delay by the Indemnified Party in providing such notice. Subject to the statutory duties of the Texas Attorney General, the Indemnified Party shall allow the Indemnifying Party to assume the defense of any such Loss, including the right to select counsel of its choosing and the right to compromise or settle any Loss, provided that the Indemnifying Party shall not make any settlement admitting fault or incur any liability on the part of an Indemnified Party without its written consent, such consent not to be unreasonably withheld. Subject to the statutory duties of the Texas Attorney General, if the Indemnifying Party is required to defend any Loss, the Indemnified Party shall, and shall cause its employees and agents to, cooperate fully in the defense thereof and furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested by the Indemnifying Party in connection therewith. In no event shall the Indemnified Party compromise, settle or otherwise admit any liability with respect to any Loss subject to indemnification under this Agreement without the prior written consent of the Indemnifying Party (such consent not to be unreasonably withheld or delayed).

21.2 No Acknowledgement of Liability. The assumption of the defense of a Loss by the Indemnifying Party shall not be construed as an acknowledgment that such party is liable to indemnify any Indemnified Party in respect of the Loss, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. If it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Loss, the

Indemnified Party shall reimburse the Indemnifying Party for any and all costs and expenses or other Losses incurred by the Indemnifying Party in its defense of the Loss with respect to such Indemnified Party.

22 **Insurance**.

22.1 Insurance Coverage. Institution, as a component of System, is an agency of the State of Texas and is self-insured pursuant to The University of Texas System Professional Medical Malpractice Self-Insurance Plan, under the authority of Section 59.01, Texas Education Code. Institution has and will maintain in force during the term of this Agreement adequate insurance to cover its indemnification obligations hereunder. Additionally, all employees of Institution are covered under Workers Compensation Coverage.

22.2 Primary Insurance. The above policy of insurance shall be primary to any liability insurance carried by AstraZeneca, which insurance(s) shall be excess and non-contributory for claims and losses arising out of the performance of this Agreement.

22.3 Certification. The Institution shall, at AstraZeneca's written request, have its insurance carrier or carriers, or with respect to a self-insurance program have an appropriate officer of the Institution, furnish to AstraZeneca certificates that all insurance required under this Agreement is in force, such certificate to indicate any deductible and any self-insured retention. The Institution shall promptly provide AstraZeneca with written notice of any cancellation, non-renewal, expiration or material modification of any required insurance or self-insurance.

23 **Term**. This Agreement shall be effective as of the Effective Date and shall continue until the earlier of (i) the date that the final Study Documentation has been provided to AstraZeneca following completion of the Study and (ii) the date that this Agreement is terminated in accordance with Section 24.

24 **Termination**.

24.1 Right to Terminate or Suspend Study. The Study may be terminated or suspended by AstraZeneca or the Institution immediately upon written notice to the other for safety concerns or as otherwise required by Applicable Laws. Further, AstraZeneca may terminate or suspend the Study if the Multi-Center Study is terminated or suspended.

24.2 Right to Terminate Agreement. AstraZeneca may terminate this Agreement, in its sole discretion, on ten (10) business days' advance written notice to the Institution. AstraZeneca or the Institution may terminate this Agreement in the event of material breach by the other of this Agreement, provided that the other is given written notice of the nature of the default and an opportunity to cure such default within a period of 15 business days after the giving of notice. AstraZeneca may terminate this Agreement, on written notice to the Institution, immediately upon suspension or termination of the Study. The Institution may terminate this Agreement, on written notice to AstraZeneca, if the Study is suspended or terminated and not recommenced within ninety (90) days. Further, the Institution may terminate this Agreement if AstraZeneca makes changes to the Study that are not required by Applicable Laws and not agreed to by the Institution or approved by the IRB and such changes materially increase the cost of performance of the Study by the Institution.

24.3 Transition Upon Termination. Upon notice of termination of the Study or this Agreement, the Institution shall immediately cease enrollment of Subjects into the Study and, at the election of AstraZeneca, shall: (a) terminate the Study with respect to the enrolled Subjects in an orderly and prompt manner, to the extent medically permissible, and pursuant to consultation with AstraZeneca's clinical monitor, including, without limitation, any required follow-up treatment with previously enrolled Subjects or (b) transfer the enrolled Subjects to another clinical site in accordance with AstraZeneca's instructions. AstraZeneca or its designee shall have the right to assume full control of the terminated Study and the Institution shall turn over all Study Documentation and materials in its possession associated with the Study, including all Work Product, Inventions and Materials, as expeditiously as possible, shall handle the Study Drug in accordance with Section 8 and shall provide such other assistance as is necessary to ensure a smooth and orderly transition of the Study that will not involve any disruption of the Protocol. Upon notice of suspension of the Study, the Institution shall immediately cease enrollment of Subjects into the Study. AstraZeneca shall reimburse Institution for all expenses incurred from such transition except for such transitions required due to an uncured breach of this Agreement by Institution.

24.4 Payment Owed. Except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by the Institution, upon termination of the Study or this Agreement, AstraZeneca shall, upon receipt of applicable invoices and other supporting documentation satisfactory to AstraZeneca: (a) reimburse the Institution for its reasonable and verifiable Study costs and reasonable un-cancelable Study costs or expenses incurred in connection with transfer of Subjects pursuant to Section 24.3 and (b) with respect to Subjects who have not completed the Study at the date of the termination, make payments to the Institution in accordance with Exhibit A for work already performed in accordance with the Study.

24.5 Final Accounting. Within thirty (30) days after the termination of this Agreement, the Institution shall deliver to AstraZeneca a final accounting of all Subjects participating in the Study and the visits completed in accordance with the Study during the term of this Agreement, and all reasonable direct costs incurred in connection with any transfer of the Study. Within thirty (30) days of delivery or receipt of the final accounting, either the Institution shall refund to AstraZeneca any excess amounts paid by AstraZeneca or AstraZeneca shall pay any additional amounts owed to the Institution, as the case may be. AstraZeneca or its designee shall have the right for a period of two (2) years after the payment of any transfer costs to audit the Institution's books and records with respect to such accounting.

25 **Independent Contractor**. In undertaking to perform the respective services hereunder, the Institution and the Principal Investigator are doing so as independent contractors, and not as employees or agents of AstraZeneca. No party shall represent itself as an agent of any other party.

26 **Assignment**. Subject to Section 1.2, no party shall assign this Agreement or any rights or obligations hereunder without the prior written consent of the other parties, except that AstraZeneca, without the consent of any other party hereto, may assign this Agreement and its rights and obligations hereunder (a) to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates, (b) in connection with the transfer, whether by license or otherwise, or sale

of all or substantially all of its rights to the Study Drug or (c) to any direct or indirect affiliate of AstraZeneca PLC.

27 **Severability**. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, to the fullest extent permitted by applicable law and if the rights or obligations of any party will not be materially and adversely affected: (a) such provision will be given no effect by the parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect and (c) the parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the parties. To the fullest extent permitted by applicable law, the parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

28 **Governing Law**. THIS SECTION HAS BEEN INTENTIONALLY OMITTED.

29 **Notices**. Any notice, request or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if hand delivered or sent by an internationally recognized overnight delivery service, costs prepaid, or by facsimile (with transmission confirmed), addressed to the parties at:

If to AstraZeneca, to:		If to the Institution or the Principal Investigator, to:
Address:	1800 Concord Pike FOC CE2 Wilmington, DE 19850	Address:
Facsimile:	302-886-2730 or 302-885-0020	Facsimile:
Attention:		Attention:

With a copy to:

Address:	1800 Concord Pike Wilmington, DE 19850-5438	Address:
Facsimile:	302-886-1578	Facsimile:
Attention:	General Counsel	Attention:

or to such other address as the party to whom notice is to be given may have provided to the other parties in accordance with this Section 29. Such notice, shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed), or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service, whichever is the earlier. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 29 is not intended to govern the day-to-day business communications necessary between the parties in performing their obligations under the terms of this Agreement.

30 **Business Communications**. The Institution and the Principal Investigator consent to receive communications sent by or on behalf of AstraZeneca via mail, e-mail and/or fax at the Principal

Investigator and the Institution's mailing address, e-mail address and fax number set forth below.

If to Institution, to:	If to the Principal Investigator, to:
Address: _____	Address: _____
E-mail address: _____	E-mail address: _____
Facsimile: _____	Facsimile: _____

31 **Survival**. The respective rights and obligations of the parties set forth in Sections 6 (other than the first sentence), 7-11, 13, 14, 16-22, 24, 29 and this Section 31 shall indefinitely survive the expiration or termination of this Agreement to the extent necessary to preserve such rights and obligations.

32 **Entire Agreement**. This Agreement, together with the Exhibits hereto and that certain Confidentiality Agreement by and between the Principal Investigator and the Institution and AstraZeneca in relation to the Study (the "**Confidentiality Agreement**") constitute[s] the entire agreement among the parties hereto with respect to the subject matter of this Agreement. This Agreement, together with the Confidentiality Agreement if applicable, supersede all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each party confirms that it is not relying on any representations, warranties or covenants of any other party except as specifically set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud.

33 **Amendment**. Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each party.

34 **Waiver**. A party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing.

35 **Inconsistency**. In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects (including Section 17), the terms of this Agreement shall prevail.

36 **Construction**. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders, the word "or" has the inclusive meaning represented by the phrase "and/or" and the term "including" or "includes" means including, without limiting the generality of any description preceding such term. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. A reference in this Agreement to a Section or Exhibit is to the referenced Section or Exhibit of this

Agreement. The wording of this Agreement shall be deemed to be the wording mutually chosen by the parties and no rule of strict construction shall be applied

37 <u>Counterparts</u>. This Agreement may be executed in two or more counterpart copies, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument.

THIS AGREEMENT IS EXECUTED by the authorized representatives of AstraZeneca and the Institution as of the date first written above.

ASTRAZENECA **[**PHARMACEUTICALS**]** LP	**[**NAME OF INSTITUTION**]**
Signature :	Signature : .....
Name :	Name : .....
Title :	Title : .....

PRINCIPAL INVESTIGATOR

READ AND ACKNOWLEDGE

Signature : .....

Name : .....

Title : .....

EXHIBIT A

BUDGET

PROTOCOL NO: _____
INSTITUTION: _____
PRINCIPAL INVESTIGATOR: _____
SUBJECT ENROLLMENT OPENING DATE:
SUBJECT ENROLLMENT CLOSING DATE:
DATA COMPLETION DATE:

EXHIBIT B

PROTOCOL