

MASTER CLINICAL TRIAL AGREEMENT

BY AND BETWEEN

AND

MASTER CLINICAL TRIAL AGREEMENT

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MASTER CLINICAL TRIAL AGREEMENT

This Master Clinical Trial Agreement (this "Agreement") is entered into as of May 25, 2005, (the "Effective Date"), by and among (i) [REDACTED], located at [REDACTED] (the "Institution"), and (ii) [REDACTED], [REDACTED], with its principal office and place of business at [REDACTED] ("Sponsor").

WITNESSETH:

WHEREAS, Sponsor desires to conduct one or more clinical trials (each a "Study"), with each Study governed by an applicable protocol (a "Protocol"); and

WHEREAS, the Institution wishes to participate in at least one Study under the Protocol; and

WHEREAS, the Institution represents that it has the experience, capability and resources, including but not limited to sufficient personnel and equipment, to efficiently and expeditiously perform each Study hereunder in a professional and competent manner, and in strict adherence to the applicable Protocol attached hereto and incorporated by reference herein, and Institution further represents that it will utilize its best efforts at all times to devote the necessary personnel and equipment to perform each Study hereunder in such a manner.

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions and any sums to be paid hereunder, the parties hereto agree as follows:

1. Individual Studies.

(a) With respect to each Study in which the Institution participates, the Institution, the Principal Investigator (as defined in Section 2 hereof) and Sponsor will enter into an agreement generally in the form of Exhibit A attached hereto (a "Study Agreement") that will include the following information: (i) a complete copy of the applicable Protocol; (ii) the name and address of the Principal Investigator for the Study, as well as any co-investigators; (iii) the scope of work for the Study; (iv) the budget for the Study, including payment terms; and (v) any other information or terms specific to the Study that are not addressed in this Agreement.

(b) The Institution agrees to perform the research activities and tests and to comply with all of the terms and requirements of the applicable Protocol for each Study in which it participates. The Institution shall be responsible for obtaining any necessary authorizations to perform the Study, including Institutional Review Board approval. The Institution shall not charge any patient enrolled in any Study for any of the procedures required by the applicable Protocol.

(c) The terms and conditions of this Agreement, as supplemented by the applicable Study Agreement, shall govern each Study conducted by the parties hereto. In the event of a conflict between the terms of this Agreement and any Study Agreement, the terms of this Agreement shall govern unless and to the extent that such Study Agreement explicitly states in bold type that it is amending provisions of this Agreement and specifies, in each instance, the

provisions of such Study Agreement that amend this Agreement. Any such amending exhibit shall apply only to the Study pertaining to such Study Agreement and shall not act as an amendment of this Agreement as this Agreement relates to any prior or subsequent Study Agreement.

2. Principal Investigator

Each Study will be conducted by a principal investigator named in the applicable Study Agreement (the "Principal Investigator"). The Principal Investigator shall be responsible for performing the Study and for the direct supervision of any individual performing portions of the Study. In the event the Principal Investigator becomes unable to perform any of the activities in the Study or to complete the Study for any reason, Sponsor and the Institution may mutually agree on a substitute Principal Investigator. The Institution shall use its best efforts to identify and obtain a substitute Principal Investigator acceptable to Sponsor. If Sponsor and the Institution cannot agree on a substitute Principal Investigator within a reasonable period of time, not to exceed 14 days, Sponsor may immediately terminate the applicable Study Agreement.

3. Confidentiality

(a) During the term of this Agreement, the Institution and each Principal Investigator may obtain certain Confidential Information (as defined in Section 3(b) hereof).

(b) "Confidential Information" shall mean (i) any and all information, data or know how, whether written or oral, technical or non-technical, as well as tangible materials, including without limitation samples, compounds, procedures, protocols or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor; and (ii) case report forms and any other data or information resulting from a Study.

(c) The Institution and each Principal Investigator agree (i) to use the Confidential Information only in connection with their performance of this Agreement; (ii) to receive and hold the Confidential Information in strict confidence and take all steps as are necessary to prevent the disclosure of Confidential Information to any third party without the prior written consent of Sponsor, which Sponsor may withhold at its sole discretion; and (iii) to disclose Confidential Information only on a need-to-know basis to its employees and consultants who have entered into written agreements which impose, or are otherwise bound by, restrictions upon the Confidential Information that are at least equivalent to those imposed hereunder.

(d) The Institution and each Principal Investigator shall be relieved of their respective obligations under this Section 3 regarding Confidential Information which: (i) was known to the Institution or the Principal Investigator prior to receipt hereunder as set forth in written records; (ii) at the time of disclosure to the Institution or the Principal Investigator was generally available to the public, or which after disclosure hereunder, becomes generally available to the public, through no fault of the Institution or the Principal Investigator; (iii) is hereafter made available to the Institution or the Principal Investigator from any third party having a right to do so and which was not acquired from Sponsor; (iv) is needed by a third party for purposes of treating a patient who participated in the Study; or (v) is required by law, regulation, subpoena or governmental or judicial order to be disclosed, provided that Institution shall notify Sponsor prior to any such disclosure in order to permit Sponsor to oppose or limit such disclosure by appropriate legal action.

(e) At any time upon request by Sponsor (i) the Confidential Information, including any copies, and (ii) all documents, drawings, sketches, models, designs, data, memoranda, tapes, records and any other material whatsoever developed by Institution that relate to the Confidential Information, including all copies and/or any other form of reproduction and/or description thereof made by the Institution and/or any Principal Investigator, shall, at Sponsor's option, either be returned to Sponsor or destroyed, in which event the Institution shall deliver to Sponsor a written statement certifying that all such information has been appropriately destroyed. The return and/or destruction of such Confidential Information as provided above shall not relieve the Institution of its other obligations under this Agreement.

4. Results and Other Documentation

(a) All documents, protocols, data, know-how, methods, operations, formulas, Confidential Information and materials of any kind provided to the Institution or any Principal Investigator pursuant to this Agreement are and shall remain the property of Sponsor.

(b) Case report forms, safety information, and other data reports developed during a Study shall be the sole and exclusive property of Sponsor, except that individual patient records, the Principal Investigators' research records, and other information which the Institution must maintain for regulatory and patient care purposes shall remain the property of the Institution, *provided, however*, that Sponsor shall be permitted reasonable access thereto, consistent with generally acceptable good clinical practices. Upon request, the Institution shall provide Sponsor copies of data derived from or relating to the Study.

(c) In accordance with the terms of the applicable Study Agreement, upon completion or termination of the Study, (i) all original case report forms shall be submitted to Sponsor and (ii) Sponsor or its agent or the Institution will prepare a complete summary of the results of the Study (the "Final Report"). During the course of the Study and following the completion or termination thereof, the Institution will promptly reply to any questions regarding the summary of results, case report forms, or any other matter relating to the Study.

(d) The Institution and/or the Principal Investigator shall furnish Sponsor with a copy of a manuscript of the paper, abstract or other materials regarding or otherwise referencing any Study data or results for any proposed publication or presentation no later than ninety (90) days prior to the submission of such proposed publication or presentation to a journal, editor, or other third party for the purpose of review and comment. Sponsor, at its option, may be cited as the sponsor on any publication or presentation resulting from the Study. Sponsor shall have the right to request modifications of any proposed publication or presentation if such proposed publication or presentation would jeopardize a patent application, patent, trade secret, or other proprietary right or information relating to this Agreement. If Sponsor believes that any proposed publication contains any information relating to patentable items, the disclosure of such proposed publication to any third party may be delayed by Sponsor for up to six (6) months to permit the filing of appropriate patent applications. Notwithstanding the foregoing, neither the Institution nor the Principal Investigator shall include Confidential Information, as defined in Section 3(b)(i), in any publication or presentation.

(e) Notwithstanding anything herein to the contrary, the Institution and the Principal Investigator acknowledge and agree that for multicenter studies the Study data and results will be pooled and analyzed as stipulated in the Protocol and no presentations or publications of Study data or results will be done individually by the Institution or the Principal Investigator; *provided, however,* that if a multicenter publication is not submitted for publication within twenty-four (24) months after conclusion (at all sites) of any Study, the Institution and/or the Principal Investigator may publish the individual results of such Study from the Institution's site after review by Sponsor in accordance with Section 4(d) hereof.

5. Publicity and Promotional Activities

(a) Notwithstanding anything herein to the contrary, neither the Institution nor the Principal Investigator shall issue a press release or other public statement that references any Study or its results, or that uses Sponsor's names or trademarks, without the express written consent of Sponsor.

(b) No party hereto shall use any other party's or its affiliate's names or trademarks for publicity or advertising purposes, except with the prior written consent of such other party or parties, as the case may be; *provided, however,* that Sponsor may (i) identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study and (ii) use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of Institution consistent with U.S. copyright laws, provided such use does not constitute an endorsement of any commercial product or service by the Institution.

6. Materials Transfer

During the course of a Study, Sponsor may transfer to the Institution compounds, drugs, samples, reagents, devices, and related materials (collectively, "Materials"). Such transfer will be subject to the following conditions:

(i) The Materials and any patient diagnostic tests, bodily fluids, tissue biopsies, data and/or other materials collected in any Study shall be used by the Institution and the Principal Investigator solely for purposes of such Study and only as specified in the applicable Protocol and this Agreement.

(ii) The Institution will not chemically modify the Materials.

(iii) The Institution accepts the Materials with the understanding that their hazardous and toxicological properties have not been completely investigated and therefore are not fully understood. The Institution will handle the Materials accordingly and will inform Sponsor in writing of any life threatening or adverse reactions or effects experienced by persons administered or handling the Materials. In addition, the Institution will promptly inform Sponsor of any test or Study results which suggest: (1) a significant risk for humans, (2) mutagenicity, (3) teratogenicity or (4) carcinogenicity.

(iv) In handling the Materials, the Institution will comply with all applicable national and local laws and regulations including those governing disposal of hazardous substances.

7. Patent Rights

(a) The Institution shall promptly disclose only to Sponsor a full written description of any new invention or discovery resulting from the performance of this Agreement. "New invention or discovery" shall mean any invention or discovery conceived or reduced to practice during and as a part of any Study by the Principal Investigator or any faculty, staff, employees, students or agents of the Institution or the Principal Investigator, or jointly by such an individual or individuals with one or more employees or consultants of Sponsor.

(b) New inventions or discoveries made solely by the Principal Investigator or any faculty, staff, employees, or students of the Institution or the Principal Investigator shall be the sole property of the Institution. New inventions or discoveries made jointly by the Principal Investigator or any faculty, staff, employees, students of the Institution or the Principal Investigator with one or more employees or consultants of Sponsor shall be owned jointly by the Institution and Sponsor. New inventions or discoveries made solely by employees or consultants of Sponsor shall be the sole property of Sponsor. The Institution hereby grants to Sponsor a non-exclusive, royalty-free license to practice any such new invention or discovery and under any patents or patent applications which Institution may file for any such invention.

(c) The Institution or its designated patent agent, consistent with the Institution's patent policy, will offer Sponsor the first opportunity to enter into an exclusive worldwide (or such lesser territory as Sponsor shall request) royalty-bearing license agreement to practice any such new invention or discovery, by exercise of the option provided for below. All remaining terms of the license, including payment to the Institution of a reasonable royalty, shall be established in good faith negotiation by the parties. Sponsor shall have ninety (90) days after actual receipt of the disclosure referenced in Section 7(a) hereof to exercise the option to obtain the license identified above with respect to the identified new invention or discovery by written notification to the Institution. Failure by Sponsor to timely notify the Institution shall be deemed a waiver of Sponsor's option but only with respect to the identified new invention or discovery and not to other new inventions or discoveries subject to this Agreement.

8. Term and Termination

(a) This Agreement shall become effective as of the Effective Date and, unless earlier terminated in accordance with this Section, shall continue in force for a period of sixty (60) months from the Effective Date.

(b) Any Study Agreement may be terminated on prior written notice if any of the following conditions occur:

(i) by either party, if authorization and approval to perform the Study in the United States is withdrawn by the U.S. Food and Drug Administration (the "FDA"); or

(ii) by Sponsor, if animal, human and/or toxicological test results, in the opinion of Sponsor, support termination of the Study; or

(iii) by Sponsor, if the emergence of any adverse reaction or side effect with the Study drug administered in the Study is of such magnitude or incidence, in the opinion of Sponsor, to support termination; or

(iv) by Sponsor, if during the course of this Agreement, the Institution or any employee, agent or representative of the Institution performing services hereunder is debarred or receives notice of any action or threat with respect to its debarment under the provisions of the Act; or

(v) by Sponsor, if during the course of this Agreement the Sponsor determines in its opinion that the Study is not worth pursuing in view of Sponsor's corporate objectives; or

(vi) by either party upon a default in performance of the other party, which default has not been cured within fifteen (15) days from receipt of notice of such default from such party.

(c) Either party may terminate this Agreement at any time upon ninety (90) days prior written notice to the other. If Institution should decide to terminate any ongoing Study (or this Agreement during the course of any Study prior to its completion) for any reason other than legitimate concern for the immediate health and safety of the Study participants, payments received by Institution hereunder with respect to such Study(ies) will be refunded to Sponsor, except for direct pass-through costs and costs for visits and procedures that have already been performed to the time that notice is given

(d) Upon receipt of notice of termination from Sponsor, the Institution and the Principal Investigator shall immediately cease enrolling patients in the applicable Study(ies) and, to the extent medically permissible, cease administering the Study drugs and conducting procedures on patients already enrolled in the Study(ies). The Institution and the Principal Investigator shall use all reasonable efforts upon the request of Sponsor, to prepare case report forms for all patients who have been enrolled in any terminated Study.

(e) In the event of a termination of this Agreement or of any Study Agreement prior to the completion thereof, the Institution hereby covenants and agrees, at Sponsor's request, to promptly assign to Sponsor (or its designee) any subcontracts or other arrangements which the Institution may have entered into in connection with the Institution's performance of services hereunder and to cooperate with Sponsor in good faith to facilitate the transition of such subcontracts or arrangements, and the services to be performed thereunder, to Sponsor (or its designee). In addition, the Institution hereby covenants that it will use commercially reasonable efforts to include appropriate provision in any such subcontract or arrangement permitting the Institution to make such an assignment without obtaining the consent of the other party or parties thereto.

(f) Upon termination of any Study Agreement and/or this Agreement, Sponsor's sole obligation shall be to pay the Institution a pro-rated amount for actual work performed pursuant to each Study up to such date of termination, unless a default in the performance of work is the reason for termination of this Agreement or the applicable Study Agreement. The Institution shall refund to Sponsor, within thirty (30) days after termination of any Study Agreement and/or this Agreement, any funds already paid by Sponsor to the Institution which amounts are in excess of amounts due to the Institution under this Section and the applicable costs associated with study procedures approved by Sponsor, under this Study Agreement

g) Termination of any Study Agreement and/or this Agreement shall not affect any rights or remedies of any party hereto at law or in equity.

9. Scientific Communications

All medical and scientific communications directed to the Institution whether or not containing Confidential Information, shall be addressed to the Principal Investigator for each Study at the address set forth in the Study Agreement. All medical and scientific communications directed to Sponsor shall be addressed to such parties at the addresses set forth in this Agreement and to the individual designated in the Study Agreement.

10. Indemnification

(a) Sponsor shall defend, indemnify and hold harmless the Institution, each Principal Investigator, the Institutional Review Board for the Institution and their respective directors, employees and agents (collectively, unless otherwise specified herein, the "Indemnitees") from and against all losses, damages, costs, claims, suits and expenses, (including reasonable attorneys' fees) for bodily injury or death that are directly attributable to the Institution's testing of the Study drugs pursuant to the terms of the applicable Study, provided that the Indemnitees have complied with (i) all the terms of this Agreement, the applicable Study Agreement and the applicable Protocol; (ii) all dosage and other specifications, directions and recommendations furnished in the applicable Protocol and elsewhere in writing by Sponsor for the use and administration of the Study drugs; and (iii) all laws, rules and regulations applicable to the Study. The indemnity set forth in this Section 10(a) shall not apply to the extent the damages or claims arise out of any negligence, malpractice or other wrongful acts on the part of any Indemnitee or any third party.

(b) The indemnity set forth in Section 10(a) above is expressly conditioned on the appropriate Indemnitees: (i) promptly notifying Sponsor of any such claim or suit; (ii) having maintained records relating to the testing of the Study drugs as required by this Agreement and by applicable law; (iii) making such records available to Sponsor; (iv) cooperating fully with Sponsor in investigating and defending such claim or suit; and (v) in the event of suit, attending hearings and trials and assisting in securing and giving evidence, and obtaining the attendance of necessary and proper witnesses in accordance with the requests of Sponsor. Sponsor shall reimburse the Indemnitees for all reasonable expenses incurred by such Indemnitees at Sponsor's request in connection with Section 10(b)(v) above. Sponsor may, at its sole discretion, and at its own expense, carry out the sole management, defense and settlement of such claims or suits, and shall provide attorneys of its sole choosing to defend against any such claims or suits.

(c) The Institution shall defend, indemnify and hold harmless Sponsor and its directors, employees and agents from and against all losses, damages, costs, claims, suits and expenses (including reasonable attorneys' fees), for bodily injury or death that are attributable to any negligence, malpractice or other wrongful acts on the part of any Indemnitee.

(d) The parties understand and agree that the indemnification provided herein is not intended as, nor is it a substitute for, full and complete malpractice and other forms of liability insurance. The Institution shall maintain appropriate insurance coverage for conducting clinical and investigational studies such as those contemplated by this Agreement with coverage amounts of at least \$1,000,000 per incident and \$2,000,000 in the aggregate, and shall forward to Sponsor

a certificate evidencing such insurance coverage within ten (10) days after execution of this Agreement.

11. Debarment Certification

(a) The Institution hereby certifies that it has not been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a(a) and (b). In the event that during the term of this Agreement, the Institution (i) becomes debarred, or (ii) receives notice of an action or threat of an action with respect to its debarment, the Institution shall notify Sponsor immediately.

(b) In the event that the Institution becomes debarred, this Agreement shall automatically terminate, without any further action or notice by any party hereto. In the event that Sponsor receives notice from the Institution or otherwise becomes aware that a debarment action has been brought against the Institution or that the Institution is threatened with a debarment action as set forth in Section 11(a)(ii) hereof, then Sponsor shall have the right to terminate this Agreement immediately.

(c) The Institution hereby certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership or association which has been debarred under 21 U.S.C. § 335a(a) or (b). In the event that the Institution becomes aware of the debarment or threatened debarment of any individual, corporation, partnership or association providing services to the Institution which directly or indirectly relate to activities under this Agreement the Institution shall notify Sponsor immediately. Upon the receipt of such notice by Sponsor or if Sponsor otherwise becomes aware of such debarment or threatened debarment Sponsor shall have the right to terminate this Agreement immediately.

12. Representations

The Institution represents that it is not now under any agreement to provide services which could conflict with its obligations hereunder, and the Institution agrees not to enter into any conflicting agreements during the term of this Agreement. The Institution represents that it has disclosed to Sponsor any and all direct and indirect financial interests held by the Institution or any of its principals, parents or subsidiaries in any subcontractors to be utilized by the Institution in the performance and execution of this Agreement.

13. Inspections and Record Retention

(a) Authorized representatives of Sponsor shall have the right during the term of this Agreement to inspect at reasonable times the progress of the Study, all sites and facilities at which the Study is being performed and all information and results derived from or relating to it. Sponsor will notify the Institution of the date and time prior to any such inspection. The Institution will promptly notify Sponsor by telephone and subsequently in written form, of any material changes that occur at any time during the Study, including but not limited to changes in personnel involved in the Study.

(b) All documentation from each Study (including case report forms, source documents and clinical information generated as a result of the Study) will be promptly and fully disclosed to Sponsor by the Institution upon request as set forth in the applicable Protocol, and also shall be made available at the Institution's site upon request for inspection, copying, review

and audit at reasonable times by representatives of Sponsor and the FDA or other regulatory agencies. The Institution will promptly notify Sponsor of any proposed regulatory inspection relating to the Study, permit representatives of Sponsor to be present during the inspection and promptly provide Sponsor with a copy of any report issued after the inspection. The Institution agrees to take any reasonable steps requested by Sponsor as a result of a regulatory audit to cure any deficiencies in the case report forms or other documentation from the Study. Documentation from each Study, as further delineated in this Section 12 and in the applicable Protocol, shall be retained by the Institution in accordance with applicable laws and regulations relating to clinical trial records.

14. Compliance with Laws

The Institution and the Principal Investigator shall conduct each Study in accordance with good clinical practices and all other rules and regulations promulgated by the FDA, and all other applicable federal, state and local laws, rules and regulations.

15. Assignment

This Agreement shall inure to the benefit of and be binding upon the successors and assigns of the parties hereto. Notwithstanding the foregoing, neither this Agreement nor any Study Agreement nor any right or obligation hereunder shall be assignable by the Institution without the prior written consent of Sponsor, and any purported assignment without such consent shall be void.

16. Independent Contractors

For purposes of this Agreement, the Institution, the Principal Investigator, their employees and other individuals assigned by them to perform services hereunder ("Staff Members") shall not be deemed agents, servants, partners, joint venturers or employees of Sponsor. Thus, they do not have the authority to take action on Sponsor's behalf or to bind Sponsor without its prior written consent. The Institution, the Principal Investigator and Staff Members are acting in the capacity of independent contractors of Sponsor. Sponsor shall not be responsible for withholding, and shall not withhold, FICA or taxes of any kind from any payments it owes to the Institution. The Institution and/or the Principal Investigator are responsible to provide any and all compensation, benefits and/or insurance to Staff Members. It is also understood and expressly acknowledged that the Institution, the Principal Investigator and Staff Members are not eligible to participate in, nor are they eligible for coverage under, any benefit plans' programs' employment policies, procedures or workers' compensation insurance provided by Sponsor. The Institution agrees to defend, indemnify and hold Sponsor harmless from any and all claims made by any entity on account of an alleged failure by the Institution to satisfy any such tax or withholding or similar statutory or contractual obligations.

17. No Waiver

Any party's failure to require any other party to comply with any provision of this Agreement or any Study Agreement shall not be deemed a waiver of such provision or of any other provision of this Agreement or any Study Agreement.

18. Notices

All notices required or permitted under this Agreement or any Study Agreement shall be in writing and shall be either (i) delivered personally; (ii) given by prepaid telegram or mailed, certified mail return receipt requested; or (iii) sent by a nationally-recognized overnight courier service guaranteeing next-day delivery, to such party's address as set forth below. Notices given hereunder shall be deemed effective upon receipt thereof.

If to the Institution:

If to the Principal Investigator:

To the address set forth in each Study Agreement

If to Sponsor:

By Mail:

With a copy to:

With a copy to

19. Entire Agreement

This Agreement, together with each Study Agreement and any other exhibit hereto represent the entire understanding of the parties with respect to the subject matter hereof. Any modification, amendment or supplement to this Agreement or any Study Agreement shall be in a writing signed by an authorized representative of each party hereto or thereto. In the event that any purchase orders (or any acknowledgment forms, invoices or any other related forms) are issued during the course of this Agreement to document any deliverables, expenses, services, or other items, such forms shall be governed by the terms of this Agreement and none of the terms or conditions of such forms shall be applicable, except those specifying quantity, delivery locations and delivery schedule and invoice information.

20. Survival of Provisions

Sections 3, 4, 5, 6, 7, 8, 10, and 13 hereof shall survive performance, termination or expiration of this Agreement or any Study Agreement for any reason, except for services performed or remaining unperformed at the time of termination.

21. Severability

In case any one of the provisions of this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby.

22. Governing Law; Attorneys' Fees

This Agreement shall be governed by and construed under the laws of the State of California without regard to conflicts of laws provisions. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorneys' fees, costs and necessary disbursements, in addition to any other relief to which the party may be entitled.

23. Headings

Any headings and captions contained in this Agreement are inserted for convenience only and shall not constitute a part thereof.

24. Counterparts

This Agreement and each Study Agreement, and any amendment or supplement hereto or thereto, may be executed in any number of counterparts and any party may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original. The execution of any such amendment or supplement by any party will not become effective until counterparts have been executed by all the parties hereto or thereto.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

SPONSOR:

[REDACTED]

Institution :

[Signature Page to Master Clinical Trial Agreement]

Exhibit A

STUDY AGREEMENT

No. _____

This Study Agreement (this "Study Agreement") is entered into as of _____, 20__ (the "Effective Date"), by and among (i) _____, located at _____ (the "Institution"), and (ii) _____, principal office and place of business at _____ ("Sponsor"). This Study Agreement sets forth the terms and conditions upon which the Institution will participate in a clinical trial (the "Study") being conducted pursuant to the protocol entitled "_____" (the "Protocol").

This Study Agreement is an exhibit to, and incorporates herein by reference all the terms and conditions of, the Master Clinical Trial Agreement by and among the parties hereto dated as of _____, _____ (the "Master Agreement"). Capitalized terms used but not defined herein shall have the meanings ascribed to them in the Master Agreement.

The Principal Investigator, Dr. _____, has agreed to execute the certification attached hereto as Appendix A and incorporated by reference herein. True copies of the Protocol and the Study Budget are attached hereto as Appendix B and Appendix C, respectively, and each is incorporated by reference herein

NOW THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions and any sums to be paid hereunder, the parties hereto agree as follows:

1. **Principal Investigator.** The name, address and contact information for the Principal Investigator and any co-investigator(s) for the Study are as follows:

Contact: _____
Direct Dial: _____
Telecopy: _____

[Address]

The Principal Investigator shall execute the Principal Investigator's Certification attached hereto as Appendix A and deliver it to a representative of Sponsor upon execution of this Study Agreement.

2. **Sponsor Contacts.** All medical and scientific communications directed to Sponsor in connection with the Study shall be addressed to the individuals designated below for Sponsor:

Contact: _____
Direct Dial: _____
Telecopy: _____

By Mail:

3. **Enrollment and Payment**

(a) It is anticipated that the Study will commence on or about _____ and that the Study will be completed on or about _____.

(b) This Study Agreement shall become effective as of the Effective Date and, unless earlier terminated in accordance with the terms of the Master Agreement, shall continue in force until each Final Report required pursuant to this Study Agreement is delivered to and accepted in writing by Sponsor.

(c) It is agreed that the Study will involve the enrollment of a maximum of _____ (#) "Evaluable Subjects" (as defined below) unless Sponsor shall request, in writing, that (i) additional Evaluable Subjects (the "Additional Subjects" and, together with the Evaluable Subjects, the "Subjects") be enrolled in the Study and/or (ii) the maximum number of Evaluable Subjects be reduced (to a number which is not less than the Subjects enrolled by the Institution in an ongoing Study at the time of such request). For purposes of this Study Agreement, an "Evaluable Subject" means a properly enrolled subject who completes the Study as prescribed in the Protocol and, as a result of adherence to the Protocol and the completeness and accuracy of the data collected on the subject's case report form, can be included in the cases from which the safety and efficacy of the Study Drug will be assessed. In no event shall Gilead Sciences, Inc. be obligated to pay any sums for tests performed on Subjects who do not meet all Protocol eligibility criteria or for Additional Subjects who are enrolled in the Study without Gilead Sciences, Inc.'s prior written approval.

(d) During the term of the Study, Sponsor agrees to pay Institution an amount in accordance with the budget attached as Appendix C. Payments will be made by Sponsor to the Institution as set forth in Appendix C.

(e) Payments will be made by check payable to the Institution, and sent with reference to the Study Protocol and number in care of:

Attn: _____
Tax I.D. No: _____

(f) Payment as set forth in this Section 3 shall constitute full and complete payment for participation in the Study by the Institution and the Principal Investigator, including but not limited to overhead and out-of-pocket expenses. Sponsor shall have no other payment obligations hereunder.

4. Miscellaneous

All of the terms and conditions contained in the Master Agreement remain in effect and shall apply to the work conducted pursuant to this Study Agreement. Please indicate your agreement by executing and dating below. This Study Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original and all of which shall constitute the same instrument.

IN WITNESS WHEREOF, the parties have caused this Study Agreement to be executed by their duly authorized representatives as of the Effective Date.

SPONSOR:

By: _____

Date: _____

INSTITUTION:

By: _____

Name: _____

Title: _____

Date: _____

APPENDIX A

PRINCIPAL INVESTIGATOR'S CERTIFICATION

I acknowledge that I have read the Study Agreement to which this certification is attached, and I agree to and will comply with all its terms as an employee of the Institution.

I represent that my entering into this Study Agreement shall not conflict with or be a breach of any other agreement to which I am a party or am bound.

I certify that I have not been delisted by the United States Food and Drug Administration or otherwise disqualified from serving as a Principal Investigator.

I certify that I have not been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335a(a) and (b). In the event that I (i) become debarred, or (ii) receive notice of an action or threat of an action with respect to my debarment during the term of this Study Agreement, I agree to notify Sponsor and the Institution immediately. I also agree that in the event that I become debarred, I shall immediately cease all activities relating to this Study Agreement.

I understand that in the event Sponsor receives notice or otherwise become aware that (i) I have been debarred or delisted, (ii) a debarment or delisting action has been brought against me, or (iii) I have been threatened with a debarment or delisting action, Sponsor shall have the right, at its sole discretion, to terminate this Study Agreement immediately or agree with the Institution to a substitute Principal Investigator who will assume full responsibility and perform all the remaining activities under this Study Agreement.

I understand that the U.S. Food & Drug Administration has adopted regulations requiring disclosure of the personal financial interests of each clinical investigator (including subinvestigators) that might affect the outcome of a clinical study. I understand that if, at any time during a clinical study and for one year following its completion, I, my immediate family or any subinvestigator (i) receives significant compensation 'of other sorts' from the study sponsor (totaling more than US\$25,000), or (ii) enters into a financial arrangement which is contingent on the outcome of the study, or (iii) has a proprietary interest in the study drug(s), or (iv) owns a significant equity interest in the study sponsor (greater than US\$50,000 in value), the FDA may reject data from the study or undertake a formal audit of the study results. I therefore covenant and agree that:

- I will complete the *Clinical Investigator Financial Disclosure Form*, in the form attached hereto as Schedule I and return it to Sponsor; and
- I will use my best efforts to obtain from each subinvestigator who is directly involved in the treatment or evaluation of study subjects at any time during any Sponsor-sponsored study, a completed *Clinical Investigator Financial Disclosure Form*, in the form attached hereto, and return it to Sponsor; and
- I will use my best efforts to assist Sponsor during and after the term of each Sponsor-sponsored study to obtain the financial information required to be disclosed to the FDA pursuant to 21 CFR part 54.

I understand that, as an investigator for a Sponsor-sponsored study, I will have access to confidential information of Sponsor and I am aware that it is a violation of the U.S. securities laws for a person who has material non-public information about a company to purchase or sell securities of such company.

PRINCIPAL INVESTIGATOR

Print Name: _____

Date: _____

APPENDIX B

PROTOCOL

APPENDIX C

STUDY BUDGET