CLINICAL TRIAL RESEARCH AGREEMENT

This Agreement is entered into by and between: The Trustees of the University of Pennsylvania with an address at Office of Research Services, P-221 Franklin Building, 3451 Walnut Street, Philadelphia, PA 19104-6205, hereinafter called "Institution," through its Department of _____, and _____ a corporation with its principal office and place of business at_____, hereinafter called "Sponsor."

BACKGROUND

The research program contemplated by this Agreement is of mutual interest and benefit to the Institution and to the Sponsor, and will further the Institution's instructional and research objectives in a manner consistent with its status as a non-profit, tax-exempt, educational institution.

TERMS

1. SCOPE OF WORK

The Institution shall exercise its best efforts to carry out the research ("Study") set forth in the Protocol dated _____ and entitled _____[name of protocol], and attached hereto as Exhibit A ("Protocol"), in accordance with this Agreement. The Protocol is incorporated into this Agreement by reference. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. Changes in the Protocol may be made only through prior written agreement between the Sponsor and the Institution. Nothing in this Agreement shall be construed as limiting the freedom of the Institution or Principal Investigator from engaging in similar research made under other grants, contracts or agreements with parties other than Sponsor. However, during the period of this Agreement, Institution shall use reasonable efforts not to undertake any obligations that would prevent it from conducting the Study.

2. PRINCIPAL INVESTIGATOR

Institution's Principal Investigator is _____ (Name), hereinafter called “Principal Investigator”, who will be responsible for the direction of the Study in accordance with the Protocol, applicable Institution policies, generally accepted standards of good clinical practice, all applicable local, state and federal laws and regulations governing the performance of clinical investigations. If for any reason, the above named individual is unwilling or unable to continue to serve as Principal Investigator and a successor, acceptable to both the Institution and the Sponsor is not available, this Agreement may be terminated as provided in Article 14.

3. PERFORMANCE PERIOD

The effective period of this Agreement will be from the date of execution of this Agreement and will continue until completion of the obligations established in this Agreement and the Protocol unless otherwise terminated in accordance with Article 14. The effective period may be extended by the mutual written consent of the parties hereto, as provided in Article 16. The Study may not begin until approval is received from the Institution’s Institutional Review Board (“IRB”) and this Agreement is fully executed.

4. RECORDKEEPING

A. The Institution and the Principal Investigator shall prepare and maintain records, reports and data as provided in the Protocol, IRB requirements, and in accordance with all applicable local, state and federal laws and regulations.

B. Institution shall cooperate with any regulatory authority with appropriate jurisdiction and allow them reasonable access to relevant study records and data.

C. Institution shall cooperate with Sponsor in making records, reports and data developed under this Agreement available to the Sponsor upon reasonable notice during Institution's normal business hours. Research results and associated data contained in CRFs and research reports generated pursuant to the Protocol shall be the property of the Sponsor, provided that Institution will be free to use the research results and associated data generated for any reasonable purpose, including non-commercial research, educational purposes and patient care purposes. Institution will be free to publish, present and disclose the research results and associated data generated in the Study in accordance with Article 7. Sponsor may utilize all data and results for any reasonable purpose, including regulatory submissions.

D. Sponsor shall promptly report to Institution any findings from monitoring or safety reporting of this Study or studies using the same or similar Study Drug / Device or treatment regimen that could (i) affect the safety of Study subjects, (ii) affect Study subjects' willingness to continue participation in the Study, (iii) influence the conduct of the research, or (iv) alter the IRB's approval to continue the Study. Sponsor acknowledges and agrees that Institution may communicate any of the afore-mentioned findings to both current and former Study subjects, as well as any participants in studies using the same or similar Study Drug / Device or treatment regimen.

E. For each research subject participating in the Study, Principal Investigator shall prepare and submit to Sponsor all original case report forms as required by the Protocol. Such case report forms shall be the property of Sponsor.

5. COST AND PAYMENT

A. As consideration for performance under the terms of this Agreement, Sponsor shall pay the Institution a total in accordance with the attached budget (Exhibit A). Invoices shall be sent to:

[Sponsor address for invoicing]

All costs outlined on the budget shall remain firm for the duration of the Study, unless otherwise agreed in writing by the Institution and Sponsor. If not budgeted, a one-time clinical trial IRB review fee will be invoiced.

B. Checks will be made payable to: "The Trustees of the University of Pennsylvania." Checks or accompanying letter will reference this Agreement and the Principal Investigator's name and will be sent to:

Office of Research Services
University of Pennsylvania
P-221 Franklin Building
3451 Walnut Street
Philadelphia, PA 19104-6205
ATTENTION: EXECUTIVE DIRECTOR

23-1352685
Institution Tax Identification Number

6. CONFIDENTIAL INFORMATION

A. Sponsor shall not disclose confidential information to the Institution unless it is necessary to the Study. Any confidential information will be in writing and clearly marked by Sponsor as "Confidential" or if disclosed orally, written notice will be provided within thirty (30) days of

disclosure ("Confidential Information"). Institution shall protect Sponsor's Confidential Information with the same degree of care as Institution's own confidential information.

B. Confidential Information may be provided by Sponsor to the Principal Investigator orally and will be included in the definition of Confidential Information. In such cases, the Principal Investigator will assume all obligations for maintaining the confidentiality of such information. Institution shall bear no liability or obligation for Confidential Information disclosed orally to the Principal Investigator. If such information must be transmitted to the Institution in the conduct of its business or to meet the terms of this Agreement, it must be done in writing and marked "Confidential."

C. The Institution's and the Principal Investigator's obligations of confidentiality will exist during the performance of this Agreement and for five (5) years following termination or expiration of this Agreement, unless disclosure is required by law or regulation.

Exceptions are:

(i) if Confidential Information is known by the Institution or Principal Investigator without restriction prior to disclosure under this Agreement;
(ii) if Confidential Information is disclosed to the Institution or Principal Investigator by a third party without an obligation of confidentiality;
(iii) if Confidential Information is available to the public through no fault of the Institution;
(iv) if Confidential Information is independently developed by Institution or Principal Investigator without knowledge or use of Confidential Information disclosed by Sponsor under this Agreement;
(v) or if Confidential Information is published or disclosed in accordance with the terms of this Agreement.

D. Research results and associated data generated by this Study conducted under this Agreement will be considered confidential until the first publication or presentation thereof of data according to the terms of this Agreement or one (1) year after conclusion, abandonment or termination of the Study at all sites.

E. In the event the Sponsor comes into contact or otherwise has access to Study subject's medical records, the Sponsor shall hold in confidence the identity of the subject and shall comply with all applicable law(s) regarding the confidentiality of such records. Sponsor will review and approve of the informed consent document and any HIPAA authorization document. Sponsor agrees that, should Sponsor gain access to any protected health information of Study subjects, Sponsor will treat such protected health information in accordance with the informed consent document, any HIPAA authorization document, and all applicable laws and regulations. If Sponsor gains access to any protected health information that is not covered by an informed consent or HIPAA authorization, Sponsor shall hold such information in the strictest confidence, shall not remove records containing such information from the Institution and, if inadvertently removed, shall immediately return any records containing such information to the Institution.

7. PUBLICATIONS

A. The Principal Investigator and Institution shall be free to publish and present the results and data from the Study with certain provisions.

i. The manuscript or abstract proposed to be published or presented shall be submitted to Sponsor for review and comment at least forty-five (45) days prior to submission for publication or presentation to allow Sponsor to protect its rights to any patentable

inventions disclosed in such publication or presentation and to permit Sponsor to request removal of any Confidential Information provided by Sponsor.

ii. Any such publication or presentation shall acknowledge, as appropriate, the contribution of Sponsor, its employees, agents and representatives.

B. If this Study is part of a multicenter study, the Institution and the Principal Investigator for such Study agree that the first publication or presentation of the results and data of such Study shall be made in conjunction with the presentation of a joint, multicenter publication of the Study results and data with the investigators and the institutions from all appropriate sites contributing data, analyses and comments. Notwithstanding the foregoing, the Institution and/or Principal Investigator may publish or present the results and data from the Institution's site individually (i) twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or (ii) after Sponsor confirms there will be no multicenter Study publication, whichever occurs first.

C. As part of the Institution's compliance with guidelines to facilitate publication of reports resulting from the Study (for example, the International Committee of Medical Journal Editors or World Health Organization guidelines), Institution shall have the right to register the Study, and make publicly available the information registered about the Study, and such information shall not be deemed Confidential Information.

8. PATENTS AND INVENTIONS

A. The entire right, title and interest in and to any invention or discovery that is confirmed through performance of the Study that relates to an indication, use, formulation or dosage of the Study Drug / Device shall be the property of Sponsor ("Sponsor Inventions"). Other than for Sponsor Inventions, it is recognized and understood that the existing inventions and technologies of Sponsor and Institution are their separate property, respectively, and are not affected by this Agreement and neither party shall have any claims to or rights in such existing inventions and technologies of the other party.

B. Title to any inventions or discoveries arising from this Study and conceived and reduced to practice solely by Sponsor employees shall be owned by Sponsor. Title to any inventions or discoveries arising from this Study and conceived and reduced to practice solely by Institution employees, that are not Sponsor Inventions, shall be owned by Institution. Title to any inventions or discoveries arising from this Study and conceived and reduced to practice jointly by Institution employees and Sponsor employees, that are not Sponsor Inventions, shall be jointly owned.

C. Institution will offer Sponsor the first opportunity to enter into a royalty-bearing or royalty-free license, as appropriate, for Institution's rights in any invention or discovery covered by Section 8.B. Any license or assignment granted to Sponsor pursuant to this Agreement shall be subject to Institution's rights to use inventions for internal, noncommercial research.

9. USE OF THE INSTITUTION'S OR SPONSOR'S NAME (ADVERTISING)

The Institution and the Sponsor will obtain prior written permission from each other before using the name, symbols and/or marks of the other in any form of publicity in connection with the Study. This shall not include legally required disclosure by the Institution or Sponsor that identifies the existence of the Agreement. Further, Sponsor's use of the name, symbols and/or marks of Institution, or names of Institution's employees, shall be limited to identification of Institution as the Study site and the Study staff as participants in the Study. Notwithstanding any provision in this Agreement to the contrary, Institution reserves the right to register the Study on its own registry in a manner consistent with the requirements of the International Committee of Medical Journal Editors (*see, inter alia*, "ClinicalTrials.gov Scope Expanded," NLM Technical Bulletin, No. 345, July-August 2005; "Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors," Annals of Internal Medicine, Vol. 141, No. 6, September 21, 2004).

10. NOTICE

Any notice shall be sent to the following addresses, with a copy also sent to the designated facsimile number. Notice shall be effective on the date of receipt.

INSTITUTION:

University of Pennsylvania
Office of Research Services
P-221 Franklin Building
3451 Walnut Street
Philadelphia, PA 19104-6205
Attention: Executive Director
Phone: 215-898-7293
FAX: 215-573-8416

INVESTIGATOR:

SPONSOR:

11. INDEMNIFICATION

A. Sponsor agrees to indemnify, defend and hold harmless the Institution, its trustees, officers, agents, representatives and employees, including Principal Investigator and any co- or sub-investigators, from any and all losses, injuries, harm, liabilities, claims, actions, suits, costs and expenses, including, without limitation, reasonable attorney's fees, for personal injury (including death) or economic loss arising out of or connected with performance of the Study, including the use by Sponsor of Study results.

B. The obligation of indemnification under this section shall not apply to the extent that liabilities are caused by (i) a failure of the Institution and/or Principal Investigator to use the Study Drug / Device in accordance with the Protocol or other written instructions of Sponsor or (ii) the negligence or willful misconduct of the Principal Investigator or any other employee of Institution.

C. Institution must promptly notify Sponsor of any claim or suit against any party to be indemnified hereunder, must allow Sponsor to have full control of any disposition or settlement of such claim or suit, and must fully cooperate with Sponsor regarding such disposition or settlement.

D. Sponsor shall not dispose or settle any claim admitting liability on the part of the Institution without Institution's prior consent.

12. INSURANCE

Sponsor will maintain during the performance of this Agreement a policy or policies of comprehensive general liability insurance at levels sufficient to support the indemnification obligations in this Agreement. This includes broad form and contractual liability and product liability, in a minimum amount of $3,000,000 combined single limit per occurrence and in the aggregate with respect to personal injury, bodily injury and property damage. Sponsor will provide Institution with a certificate of insurance evidencing such coverage at the request of Institution.

13. SUBJECT INJURY

Sponsor shall reimburse Institution for the cost of providing necessary medical treatment to a Study subject for any injuries directly resulting from a Study subject's participation in the Study, unless Institution's negligence or misconduct caused the injury.

14. TERMINATION

A. This Agreement may be terminated by either party for any reason upon thirty (30) days prior written notice.

B. Upon the effective date of expiration or termination, there shall be an accounting conducted by the Institution. Within thirty (30) days after receipt of the final accounting for a Study, Sponsor will make payment to the Institution for:

i. All services rendered and monies expended by the Institution until the date of termination not yet paid for; and

ii. Non-cancelable obligations, including any costs associated with termination, incurred for the Study by the Institution prior to the effective date of termination.

C. Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination. The rights and duties under Articles 5 (Cost and Payment), 6 (Confidential Information), 7 (Publications), 8 (Patents and Inventions), 9 (Use of Name), 10 (Notice), 11 (Indemnification), 12 (Insurance) and 13 (Subject Injury) survive the termination or expiration of this Agreement.

15. APPLICABLE LAW

This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to its principles of conflict of law. The parties agree that the provisions of this Agreement are intended to be interpreted and implemented so as to comply with all federal, state and local laws, rules and regulations applicable to the Institution, including, without limitation, Internal Revenue Service requirements regarding the avoidance of unrelated business income and the appropriate use of the proceeds of tax exempt bonds. If it is determined by the Internal Revenue Service or any other federal, state or local agency, department or instrumentality that the provisions of this Agreement are not in compliance with laws, rules and regulations applicable to Institution or that performance by Institution under this Agreement would not be in compliance with such, then the parties agree to modify the provisions and the implementation of this Agreement so as to be in compliance with all applicable federal, state and local laws, rules and regulations as determined by such governmental body.

16. AMENDMENT

This Agreement and the Protocol may only be extended, renewed or otherwise amended by the mutual written consent of the parties hereto. This Agreement including the Exhibits represents the entire understanding of the parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and either an agreement between Principal Investigator and Sponsor or the Protocol, the terms of this Agreement shall govern. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof. Neither this Agreement nor the rights or obligations hereunder shall be assignable or otherwise transferred or subcontracted without the other party's prior written consent.

17. SUBCONTRACTOR

In the performances of all services hereunder, the Institution shall be deemed to be and shall be an independent contractor and, as such, shall not be entitled to any benefits applicable to employees of the Sponsor.

18. FORCE MAJEURE

Neither party shall be liable for any failure to perform as required by this Agreement to the extent such failure to perform is due to circumstances reasonably beyond such party's control, including, without limitation, labor disturbances or labor disputes of any kind, accident, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrence.

19. DEBARMENT

Institution will not use in any capacity, in connection with the Study, the services of any individual, corporation, partnership or association which:

(1) is debarred under 21 U.S.C. 335a

(2) is disqualified as a clinical investigator under the provision of 21 C.F.R. 312.70.

In the event that Institution becomes aware of the debarment or disqualification of any such individual, corporation, partnership or association providing services under this Agreement, Institution shall notify Sponsor.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate by proper persons thereunto duly authorized.

SPONSOR:	INSTITUTION:
_____	The Trustees of the University of Pennsylvania
By: _____ (Signature)	By: _____ (Signature)
Print: _____	Print: _____
Title: _____	Title: _____
Date: _____	Date: _____

PRINCIPAL INVESTIGATOR:

I understand that I may be under strict obligations of confidentiality under the terms and conditions of this Clinical Trial Research Agreement and related Confidentiality Agreements. I will abide by such terms and conditions along with all other terms and conditions that apply to me. I understand that I may be personally responsible for breaches of confidentiality for information provided to me under this Clinical Trial Research Agreement and the related Confidentiality Agreements, if any.

ACKNOWLEDGED AND AGREED TO BY PRINCIPAL INVESTIGATOR

By: _____
(Signature)

Print: _____

Date: _____

EXHIBIT A

PROTOCOL AND BUDGET

THIS PAGE SHOULD INCLUDE A COPY OF THE PROTOCOL AND THE BUDGET, INCLUDING PAYMENT SCHEDULE.