

**7/1/2002**

**CLINICAL TRIAL RESEARCH AGREEMENT**

**Between**



**And**

**The Trustees of the University of Pennsylvania**

# CLINICAL TRIAL RESEARCH AGREEMENT

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## EXHIBIT A:

Copy of Protocol

Budget

## CLINICAL TRIAL RESEARCH AGREEMENT

This Agreement is entered into by and between: THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation, owner and operator of the University of Pennsylvania Health System, through its Department of \_\_\_\_\_ hereinafter called "Institution," 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

The parties hereto, intending to be legally bound, agree as follows:

1. SCOPE OF WORK

The Institution shall exercise its best efforts to carry out the research ("Research") 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.

2. PRINCIPAL INVESTIGATOR

Institution's Principal Investigator is \_\_\_\_\_ (Name), who will be responsible for the direction of the Research 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 12.

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 12. The effective period may be extended by the mutual written consent of the parties hereto, as provided in Article 13. No Research may begin until approval is received from the Institutional Review Board.

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.

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. Payment shall be made to the Institution according to the attached budget appended hereto and incorporated herein by reference. All costs outlined on the budget shall remain firm for the duration of the Research, unless otherwise agreed in writing by the Institution and Sponsor. If not budgeted, a one-time clinical trial review and monitoring 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. Institution will accept only information from the Sponsor which is required for approval and conduct of the Research study and which must be retained for Institution's records. All such information accepted from the Sponsor must be in writing and marked confidential. Obligations of confidentiality under this Section will terminate three (3) years after the termination of this Agreement.
- B. If Sponsor desires to furnish any confidential information to Institution personnel, Sponsor may request such individual to sign a Confidentiality Agreement with Sponsor in an approved form such as the attached "Agreement between Sponsor and Principal Investigator concerning Sponsor Confidential Information". Institution bears no institutional responsibility for maintaining the confidentiality of any confidential information of Sponsor provided under such an individual agreement.
- C. In the event the Sponsor shall come into contact or otherwise have access to Research Subject's medical records, the Sponsor shall hold in confidence the identity of the patient 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 authorization document used in the Study. Sponsor agrees that, should Sponsor gain access to any protected health information of Research Subjects, Sponsor will treat such protected health information in accordance with the informed consent document, any authorization document, and all applicable laws and regulations. If Sponsor gains access to any protected health information that is not covered by the informed Consent or 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 Institution and Principal Investigator shall have the right to publish the results and data of Research and any background information provided by Sponsor that is necessary to include in any publication of research results or necessary for other scholars to verify such research results. Prior to submission for publication or presentation, the Institution will provide the Sponsor thirty (30) days for review of a manuscript. Expedited reviews for abstracts, poster presentations or other materials will be arranged by the Sponsor and the Institution and Principal Investigator. If requested in writing and with reasonable justification, the Institution and Principal Investigator will withhold such publication for up to an additional sixty (60) days to allow for filing of a patent application. Publications and presentations of results and data generated under this Agreement will adhere to the policies and requirements of (i) the Vancouver Group, (ii) the International Committee of Medical Journal Editors, or (iii) the major medical journals.
- B. If a particular Study is part of a multicenter study, the Institution and the Principal Investigator for such Study agree that the first Publication of the results of such Study shall be made in conjunction with the presentation of a joint, multicenter publication of the Study results with the investigators and the institutions from all appropriate sites contributing data, analyses and comments. However, the Institution and/or Principal Investigator may publish the results from the Institution's site individually twelve (12) months (i) after conclusion, abandonment or termination of the Study at all sites, or (ii) after Sponsor confirms there will be no multicenter Study publication, which ever occurs first.

8. PATENTS AND INVENTIONS

- A. "New Invention or Discovery" shall mean any invention or discovery conceived or reduced to practice during and as part of the Research performed pursuant to this Agreement by Institution's Principal Investigator, faculty, staff, employees, or students or jointly by such an individual or individuals with one or more employees or the Sponsor.

The terms "conceived" and "reduced to practice" shall be given the meaning of those terms as they appear in 35 U.S.C. Section 102(g).

New Inventions or Discoveries made solely by Institution's Principal Investigator, faculty, staff, employees, or students shall be owned solely by Institution.

New Inventions or Discoveries made jointly with one or more employees of the Sponsor shall be owned jointly by the Institution and the Sponsor.

- B. Principal Investigator shall provide to Institution and Sponsor a complete written disclosure of a New Invention or Discovery reasonably considered patentable. Sponsor shall advise Institution in writing, no later than thirty (30) days after receipt of such disclosure, whether it requests Institution to file and prosecute patent applications related to such New Invention or Discovery.
- C. Sponsor shall reimburse Institution upon receipt of invoice for all documented expenses incurred in connection with the filing and prosecution of the patent applications and maintenance of the patents that Sponsor has requested Institution to file and prosecute. If Sponsor does not request Institution to file and prosecute such patent applications, Institution may proceed with such preparation and prosecution at its own cost and expense, without any further obligation to Sponsor.
- D. All of the Institution's rights to any New Invention or Discovery which are related to an indication, use or dosage for the study drug or device, which is disclosed in the Protocol, will be

licensed to Company upon its request on commercially reasonable terms at the time the Invention is made.

Royalties may be based on product sales, the License scope and rates conventionally granted for inventions with reasonably similar commercial potential and should fairly reflect the relative contributions of the parties to the Invention and the subsequent cost of development needed to bring the Invention to the marketplace. Contingent royalty schemes (e.g. based on patent issuance or non-issuance or other customary provisions) may be provided. A royalty-free license may be granted if it is deemed to be commercially reasonable under the circumstances of the invention.

For New Inventions or Discoveries, which are not related to an indication, use or dosage for the study drug or device, Institution grants Sponsor a first option to negotiate to acquire a royalty-bearing license to practice such New Inventions or Discoveries.

Institution and Sponsor will negotiate in good faith to determine the terms of a license agreement as to each New Invention or Discovery for which Sponsor has agreed to make payment for intellectual property expenses as provided for in Paragraph C, above. If Sponsor and Institution fail to execute a license agreement within six (6) months after disclosure of the New Inventions or Discovery to Sponsor or if Sponsor fails to make payment for intellectual property expenses as provided for in Paragraph C, Institution shall be free to license the New Invention or Discovery to any party upon such terms as Institution deems appropriate, without any further obligation to Sponsor.

- E. Any license granted to Sponsor pursuant to Paragraph D hereof shall be subject, if applicable, to the rights of the United States government reserved under Public Laws 96-517, 97-256 and 98-620, codified at 35 U.S.C. 200-212, and any regulations issued thereunder.
- F. It is agreed that neither the Sponsor nor the Institution transfers to the other by operation of this Agreement any patent right, copyright right, or other proprietary right of either party, except as specifically set forth herein.

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

- A. 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 Research. 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 Research site and the Research staff as participants in the Research.
- B. The Sponsor will not use, nor authorize others to use, the name, symbols, or marks of the Institution in any advertising or publicity material or make any form of representation or statement in relation to the Research which would constitute an expressed or implied endorsement by the Institution of any commercial product or service without prior written approval from the Institution.

10. NOTICE

Any notice required or permitted hereinunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by Registered or Certified Mail or overnight courier, postage prepaid, return receipt requested and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing::

FOR TECHNICAL MATTERS:

FOR TECHNICAL MATTERS:

\_\_\_\_\_  
SPONSOR'S NAME

\_\_\_\_\_  
PRINCIPAL INVESTIGATOR

\_\_\_\_\_  
ADDRESS

\_\_\_\_\_  
INSTITUTION ADDRESS

\_\_\_\_\_  
CITY STATE ZIP CODE

\_\_\_\_\_  
CITY STATE ZIP CODE

FOR ADMINISTRATIVE MATTERS:

FOR ADMINISTRATIVE MATTERS:

\_\_\_\_\_  
SPONSOR'S NAME

\_\_\_\_\_  
EXECUTIVE DIRECTOR  
OFFICE OF RESEARCH SERVICES  
UNIVERSITY OF PENNSYLVANIA  
P-221 FRANKLIN BUILDING  
3451 WALNUT STREET  
PHILADELPHIA, PA 19104-6205

\_\_\_\_\_  
ADDRESS

\_\_\_\_\_  
CITY STATE ZIP CODE

11. INDEMNIFICATION

A. Sponsor shall defend, indemnify and hold harmless the Institution, the Principal Investigator and faculty, students, trustees, officers, agents and employees of Institution from any and all liabilities, claims, actions or suits arising out of or in connection with the performance of the Research. The obligation to indemnify shall not apply to:

(1) the extent the loss is due to Institution's failure to conduct the Research in accordance with the Protocol; or

(2) to the extent it has been ultimately determined that, on a comparative basis between Institution and Sponsor, such loss arises out of the negligence or willful misconduct of any Indemnitee. Deviations from the terms of the Protocol that may arise out of necessity or for health or safety issues do not per se constitute negligence or willful misconduct, provided that Institution shall promptly notify Sponsor of any such deviations.

B. The Institution and the Principal Investigator shall reasonably cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement. In the event a claim or action is or may be asserted, the Institution shall have the right to select and to obtain representation by separate legal counsel. If the Institution exercises such right, all costs and expenses incurred by Institution for such separate counsel shall be borne by Institution and Sponsor shall reasonably cooperate with Institution and its legal representatives in the investigation and defense of any such claim or action.

- C. Sponsor will maintain during the performance of this Agreement a policy or policies of comprehensive general liability Insurance including 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. Such insurance shall be issued by an insurance carrier with an A.M Best rating of "A" or better. Sponsor will provide institution with a certificate of insurance evidencing such coverage upon signing of this Agreement. Such certificate to be forwarded to:

Executive Director  
Research Services  
University of Pennsylvania  
P-221 Franklin Building  
3451 Walnut Street  
Philadelphia, PA 19104-6205

Sponsor shall provide institution with thirty (30) days advance written notice of cancellation or of material change in the policy or policies of insurance required.

- D. The Sponsor shall reimburse Research subjects or Institution for medical expenses incurred as a result of participation in study. The Research subject or his/her third party payor, if any, may be billed for medical expenses associated with this Research study only if they are deemed medically necessary and if such expenses would have been incurred independent of the study.

## 12. 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:
- (1) All services rendered and monies expended by the Institution until the date of termination not yet paid for; and
  - (2) Non-cancelable obligations incurred for the Research 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, 6, 7, 8, 9, 10, and 11 survive the termination or expiration of this Agreement.

## 13. Miscellaneous

- A. This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania without regard to its principles of conflict of law. Each party consents to the exclusive personal jurisdiction and venue of the courts located in the Commonwealth of Pennsylvania, Philadelphia County, both state and federal, with regard to any lawsuit or cause of action arising under or out of this Agreement.
- B. 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 an agreement between Principal Investigator and

Sponsor, 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.

- C. Neither party hereto may assign, cede or transfer any of its rights or obligations under this Agreement without the written consent of the other party, which consent may not be unreasonably withheld; provided, however, without such consent either party may assign this Agreement in connection with the transfer or sale of all or substantially all of its assets or business or its merger or consolidation with another company. Either party may assign this Agreement in whole or in part to any corporate affiliate without consent of the other party. This Agreement shall inure to the benefit of and be binding upon each party signatory hereto, its successors and permitted assigns. No assignment shall relieve either party of the performance of any accrued obligation which such party may then have under this Agreement.
- D. The headings and captions used in this Agreement are for convenience of reference only and shall not affect its construction or interpretation. No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.
- E. 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.
- F. Neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty or representation as to any matter. Neither party shall be bound by the acts or conduct of the other.
- G. Institution and Sponsor shall not unlawfully discriminate against any employee or applicant for employment because of race, color, gender, sexual preference, marital status, age, religion, national or ethnic origin, disability or status as a veteran.
- H. 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.
- I. This Agreement represents the entire agreement between the parties and supersedes any and all prior agreements, whether written or oral, concerning the clinical trial which is the subject of this Agreement and any and all prior agreements between Sponsor and Principal Investigator.
- J. Institution will not use in any capacity the services of any individual, corporation, partnership or association which:
  - (1) has been debarred under 21 U.S.C. 335a
  - (2) 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: \_\_\_\_\_

\_\_\_\_\_  
(PRINT OR TYPE NAME)

\_\_\_\_\_  
(PRINT OR TYPE NAME)

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 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 Agreement and the related Confidentiality Agreements, if any.

ACKNOWLEDGED AND AGREED TO BY PRINCIPAL INVESTIGATOR(S)

BY: \_\_\_\_\_  
(SIGNATURE)

BY: \_\_\_\_\_  
(PRINT OR TYPE NAME)

TITLE: \_\_\_\_\_

EXHIBIT A

PROTOCOL AND BUDGET

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

ATTACHMENT

SPONSOR CONFIDENTIAL INFORMATION

The free publication and dissemination of research results and information is an essential and long-standing policy of the University of Pennsylvania (the "University"). Because of the negative impact confidentiality obligations have on the free communication of research results, the University does not undertake to keep proprietary information provided by a commercial sponsor confidential. Under certain circumstances, however, the University permits its investigators to accept confidential information of a clinical trial sponsor under the terms and conditions of the agreement between the sponsor and investigator stated below.

Agreement between Sponsor and Principal Investigator  
Concerning Sponsor Confidential Information

In connection with a clinical trial sponsored by [Insert name of clinical trial sponsor] ("Sponsor") titled [Insert title of the study] ("Study"), Sponsor desires to provide [Insert name of Principal Investigator] ("Investigator") with certain information pertaining to the compound [insert name of compound] ("Study Drug") which Sponsor considers confidential.

1. For purposes of this Agreement, "Confidential Information" means only confidential information of Sponsor related to the Study Drug or to the Study which is disclosed to the Investigator by Sponsor in writing and conspicuously marked as confidential and proprietary at the time of disclosure, or, if disclosed visually or orally, is stated to be confidential and proprietary at the time of disclosure and confirmed by a written summary describing the information in reasonable detail delivered by Sponsor to Investigator within seven (7) days after disclosure. Notwithstanding anything to the contrary contained in this Agreement or the markings on any document disclosed by Sponsor, Confidential Information does not include information that:

- (a) is necessary to include in any publication of the results of the Study or that is necessary for other scholars to verify those results;
- (b) is in the public domain at the time Sponsor discloses it to Investigator or that thereafter enters the public domain through no fault of Investigator;
- (c) was known to Investigator or to the University before the date Sponsor discloses it to Investigator, or that becomes known to Investigator or the University through a third party having an apparent bona fide right to disclose the information;
- (d) is independently developed by University personnel;
- (e) is disclosed by Investigator or the University in accordance with the terms of Sponsor's written approval;
- (f) is required to be disclosed for compliance with any Federal, state or local law or regulation, or required to be disclosed by a court of law or governmental authority.

2. The Investigator retains the right to refuse to accept any Confidential Information that the Investigator does not consider to be essential to the performance of the Study.

3. For a period of three (3) years after Investigator's acceptance of Confidential Information, Investigator agrees to use efforts no less than those Investigator employs with respect to Investigator's own confidential information:

- (a) to limit disclosure of the Confidential Information to those persons with a need to know it in order to carry out the Study and who have been informed of the confidential nature of the information; and
- (b) not to disclose the Confidential Information to third parties without Sponsor's consent to such disclosure.

4. This Agreement sets forth the entire understanding of Sponsor and Investigator with respect to the subject matter hereof, supersedes any prior agreement between Sponsor and Investigator, and there are no other understandings or agreements, written or oral, between them relating to such subject matter. The Agreement may not be changed or supplemented in any way except by a written agreement duly executed by both Sponsor and Investigator. This Agreement shall be governed by, enforced and interpreted in accordance with the laws of the Commonwealth of Pennsylvania, without giving effect to its principles of conflict of laws.

SPONSOR

INVESTIGATOR

\_\_\_\_\_

\_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_