

CLINICAL TRIAL RESEARCH AGREEMENT

This Agreement is entered into by and between The University of North Carolina at Chapel Hill for its School of Medicine, with its principal place of business at 440 W. Franklin St., CB 1350, Chapel Hill, NC 27599-1350, hereinafter called "Institution," and _____ a corporation with its principal office and place of business at _____ hereinafter called, "Sponsor".

W I T N E S S E T H

WHEREAS, 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, research and public service objectives in a manner consistent with its status as an educational institution.

WHEREAS, Protocol No. _____ which will guide the performance of this Agreement has been written by the Sponsor and accepted by the Institution and the Institution agrees it is fully able to perform the research program in a professional, competent manner with strict adherence to its terms and the Institution will utilize its best efforts to do so.

WHEREAS, the Institution is uniquely equipped to perform the research program.

NOW THEREFORE, the parties hereto 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 entitled _____ and attached hereto as Exhibit A ("Protocol") in accordance with this Agreement.

2. PRINCIPAL INVESTIGATOR

Institution's Principal Investigator is ____, who will be responsible for the direction of the Research. 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 shall be terminated as provided in Article 14.

3. PERFORMANCE PERIOD

The effective period of this Agreement will be from through unless otherwise terminated in accordance with Article 14. The effective period may be extended by mutual agreement as provided in Article 15.

4. RECORDKEEPING, REPORTING AND ACCESS

- A. During the term of this Agreement, the Sponsor's authorized representative(s), and regulatory authorities to the extent permitted by law, may, during regular business hours, arrange in advance with the Principal Investigator and Institution to:
- (1) examine and inspect the Institution's facilities required for performance of the Research; and
 - (2) inspect and copy all data and work products relating to the Research.
- B. Institution shall cooperate with any regulatory authority and allow regulators access to applicable records and data.
- C. The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:
- (1) preparation and maintenance of complete, accurately written records, accounts, notes, reports and data of the Research;
 - (2) preparation and submission to Sponsor of all original case report forms ("Case Reports") for each patient or subject participating in the Research ("Research Subject") as provided in the Protocol; and
 - (3) All Case Reports will be delivered to Sponsor by Institution in a timely manner throughout the performance of Study.
- D. All data and work products relating to the Research shall be owned by the Institution. The Institution may use the data and work products it generates hereunder in accordance with this Agreement.

5. COST AND PAYMENT

- A. Upon execution of this Agreement, Sponsor shall pay Institution a nonrefundable IRB review fee of \$1500. [For industry-sponsored studies.]
- B. As consideration for performance under the terms of this Agreement, Sponsor shall pay the Institution a total sum of \$___ as set forth in the budget and payment schedule attached hereto as Exhibit B.
- C. Checks will be made payable to: "The University of North Carolina at Chapel Hill". Checks will reference this Agreement and will be sent to:

[Institution Address]

56-6001393: Institution Tax Identification Number

- D. Partial payment for Research Subject(s) who do not complete the Protocol and/or are lost to follow up will be made in accordance with Exhibit B.

6. CONFIDENTIAL INFORMATION

- A. The Institution and the Principal Investigator shall not disclose or use for any purpose other than performance of the Research, any and all trade secrets, privileged records or other confidential or proprietary information (collectively "Information") disclosed to the institution by Sponsor pursuant to this Agreement. Such Information shall be disclosed to the Institution thereunder in writing, or if disclosed orally or in other than documentary form shall be reduced to writing thirty (30) days thereafter. Information which is not in oral or written form, such as but not limited to data tapes, shall be designated in writing as confidential within thirty (30) days after disclosure. The obligation of non-disclosure shall not apply to the following:
 - (1) Information at or after such time that it is or becomes publicly available through no fault of the Institution;
 - (2) Information that is already independently known to the Institution as shown by its prior written records, provided that the Institution so advises the Sponsor promptly upon the Institution's discovery that the Information is already independently known to the Institution; or
 - (3) Information at or after such time that it is disclosed to the Institution on a non-confidential basis by a third party with the legal right to do so.

- (4) Information independently developed by Institution personnel not involved in the Research and not privy to the Information.
- B. The obligations of the Institution under this Article shall survive and continue for three (3) year(s) after termination of this Agreement.
- C. In the event the Sponsor shall come into contact with Research subjects' 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.
- D. In the event the Institution finds it necessary to disclose Information to a proper authority to permit the Institution to defend its research against an allegation of fraud or other misconduct in science the Institution shall first notify the Sponsor and the Institution and Sponsor shall agree to a mutually satisfactory way to disclose such Information as necessary for this limited purpose.

7. PUBLICATIONS

The Institution shall have the right to publish the results of Research provided such publication does not constitute a violation of Article 6. Prior to submission for publication or presentation, the Institution will provide the Sponsor thirty (30) days for review and comment upon the manuscript or other material for such publication. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the Sponsor and the Institution or Principal Investigator. The Sponsor shall be permitted to advise as to the implications of timing of the publication if the same clinical trials set forth in Protocol are still in progress at other sites. In addition, if requested in writing and with reasonable justification, the Institution will withhold such publication an additional sixty (60) days to allow for filing a patent application or taking such other measures as Sponsor deems appropriate to establish and preserve its proprietary rights. Notwithstanding the foregoing, Institution agrees that if the Research is part of a multi-center study, the first publication of the results of the Research shall be made in conjunction with the results from the Investigators at the other study centers. The manner in which the publication will be generated will be negotiated between Sponsor and Principal Investigators prior to initiation of Research. However, in the event no publication of the multi-center study has been made within one year of the completion of the study at all centers, then Institution will be free to publish its own results.

8. INTELLECTUAL PROPERTY

- A. "New Invention or Discovery" shall mean any invention or discovery conceived or reduced to practice during and as a 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 of the Sponsor. New Inventions or Discoveries made solely by Institution's Principal Investigator, faculty, staff, employees, or students shall be the sole property of the Institution. New Inventions or Discoveries made jointly by Institution's faculty, staff, employees, or students with one or more employees of the Sponsor shall be owned jointly by the Institution and the Sponsor.
- B. The Institution or its designated patent agent, consistent with the Institution's patent policy and to the extent Institution is able to do so, will offer Sponsor the first opportunity to enter into a royalty bearing license agreement to practice such New Invention or Discovery, by exercise of the option provided for in Article 8.C. Such license shall be exclusive and worldwide except for those countries in which patents are valid and enforceable for which Sponsor does not reasonably assume out-of-pocket costs associated with obtaining and maintaining Letters Patent therein. 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.
- C. The Institution shall promptly notify Sponsor, in writing, of any New Invention or Discovery. The notice shall provide a full written description of the New Invention or Discovery. Sponsor shall have ninety (90) days after such notice to exercise the option to obtain the license identified in Article 8.B with respect to the identified New Invention or Discovery by written notification to the Institution. Failure by the Sponsor to timely notify the Institution shall be deemed a waiver of the 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.
- D. The right of publication by the Institution or its faculty, staff, employees or students, as indicated in Article 7, shall not be affected by license to any New Invention or Discovery.
- E. 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

- 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 or publicity in connection with the Research. 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. APPLICABLE LAW

This Agreement shall be governed by the laws of the State of North Carolina.

11. 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, postage prepaid, return receipt requested, or received by facsimile 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:

If to Sponsor:

If to Institution:

Tony G. Waldrop
Vice Chancellor for Research and Economic Development
440 W. Franklin St., CB 1350
Chapel Hill, NC 27599-1350

12. INDEMNIFICATION

Sponsor hereby agrees to indemnify, defend and hold harmless the Institution, its schools, departments and employees from any and all liability arising out of the Institution's performance of the Agreement in accordance with the Protocol.

13. SUBJECT INJURY

The Sponsor shall reimburse the Research Subjects for reasonable and necessary medical expenses incurred by Research Subjects as a direct result of the treatment of adverse reactions from study drugs or devices following their administration or use in accordance with the Protocol, provided such expenses are in no way attributable to the negligence or misconduct of any agent or employee of the Institution. No other compensation of any type will be provided by the Sponsor to the Research Subjects.

14. TERMINATION

- A. This Agreement may be terminated by either party, upon immediate prior notice, if any of the following conditions occur:
- (1) if the authorization and approval to perform the Research in the United States is withdrawn by the U.S. Food and Drug Administration;
 - (2) if animal, human and/or toxicological test results, in the opinion of either the Sponsor or the Institution, support termination of the Research;
 - (3) if the emergence of any adverse reaction or side effect with the drug administered or the device employed in the Research is of such magnitude or incidence in the opinion of either the Sponsor or the Institution to support termination.
- B. This Agreement may be terminated by either party upon ten (10) days prior written notice. if any of the following conditions occur:
- (1) If either party fails to comply with the terms of the Agreement after receipt of written notice with opportunity to cure, from the other party.
 - (2) If the Principal Investigator is unwilling or unable to continue to serve and a successor acceptable to both the Institution and the Sponsor is not available.

- C. This Agreement may be terminated by either party for any other reason, other than those listed in 14 A(1), (2), (3), 14 B(1), (2), above, upon thirty (30) days prior written notice.
- D. Upon the effective date of termination, there shall be an accounting conducted by the Institution, subject to verification by the Sponsor. Within thirty (30) days after receipt of adequate documentation therefore, the Sponsor will make payment to the Institution for:
 - (1) all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and
 - (2) reasonable non-cancelable obligations properly incurred for the Research by the Institution prior to the effective date of termination; unless the Sponsor objects to any charge, in which case, the parties shall use best efforts to resolve expeditiously any disagreement.
- E. The Institution will credit or return to the Sponsor any funds not expended or obligated by the Institution in connection with the Research prior to the effective termination date of the notice of termination.
- F. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Research Subjects into the Protocol and shall cease conducting procedures on Research Subjects already enrolled in the Protocol as directed by the Sponsor, to the extent medically permissible.
- G. 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 4, 6, 7, 8, 9, 10, 11, 12, 14, 23 and 24 survive the termination or expiration of this Agreement.
- H. If this Agreement is terminated prior to completion, Institution shall furnish Sponsor an acceptable Investigator's report for the Research completed.

15. AMENDMENTS

This Agreement and the Protocol may only be extended, renewed or otherwise amended by the mutual written consent of parties hereto.

16. ENTIRE AGREEMENT

This Agreement represents the entire understanding of the parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern.

17. SEVERABILITY

This 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.

18. INTEGRATION

The Exhibits A and B are incorporated in this Agreement by reference.

19. ASSIGNMENT

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. The Sponsor may assign this Agreement in whole or in part to any corporate affiliate without consent of the Institution.

This Agreement shall insure 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.

20. INDEPENDENT CONTRACTOR

- A. In the performance 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.
- B. 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.

21. CHANGES TO THE PROTOCOL

If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between the Sponsor and the Institution. If such changes affect the charge for the Research, the Institution will submit to the Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Research Subjects requires a deviation from the Protocol, such standards will be followed. In such case, the party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the party.

22. DELIVERY TO THE SPONSOR OF UNUSED MATERIALS

Upon termination or completion of the Research, all unused compounds, drugs, devices, Case Reports, whether or not completed, and other related materials that were furnished to the Institution by or on behalf of the Sponsor shall be returned to the Sponsor at the Sponsor's expense.

23. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution shall perform the Research in conformance with generally accepted standards of good clinical practice, with the Protocol, instructions provided by Sponsor and with all applicable local, state and federal laws and regulations governing the performance of clinical investigations including but not limited to the Federal Food, Drug and Cosmetic Act and regulations of the Food and Drug Administration. The Institution shall retain all records resulting from the Research for the time required by applicable federal regulations (the Sponsor will notify the Institution of the FDA Application filing and approval status), and to allow for inspection of all such records including the Research Subjects medical records.

The parties understand that as part of this Agreement there will be an exchange of "protected health information" ("PHI") as that term is defined under the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations set forth in 45 CFR §§ 160 and 164 ("HIPAA Privacy Rule"). Sponsor agrees to comply with the subject authorization (which shall be signed by each subject as part of or in addition to the informed consent document) regarding Sponsor's use and disclosure of such information. In addition, Sponsor agrees to the following: (i) to use appropriate safeguards to prevent uses or disclosures of PHI other than those uses and disclosures set forth in the authorization; (ii) to take appropriate steps to ensure that any agents or contractors to whom Sponsor provides PHI agree to the same restrictions and conditions that apply to Sponsor with respect to such PHI; and (iii) to make no attempt to identify or contact the individual to whom the PHI pertains unless such identification or contact is required by law or authorized by the subject or permitted by a waiver of authorization granted by an appropriate ethical review board or privacy board. Additionally should Sponsor wish to review PHI for the purposes of quality, safety or effectiveness as provided in the subject authorization, Sponsor shall limit such review of PHI to the minimum necessary information.

24. WAIVER

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.

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

SPONSOR:

INSTITUTION:

BY

BY

(signature)

(signature)

(print or type name)

(print or type name)

Title

Title

Date

Date

PRINCIPAL INVESTIGATOR:

Agreed to:

BY

(signature)

(print or type name)

Title

Date

