

## CLINICAL TRIAL RESEARCH AGREEMENT

This Agreement is entered into by and between: THOMAS JEFFERSON UNIVERSITY, a Pennsylvania non-profit corporation through its \_\_\_\_\_ with an address at Office of Research Administration, 201 S. 11<sup>th</sup> Street, Suite 303 Martin Building, Philadelphia, PA 19107 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. In consideration of the promises and mutual covenants contained herein, and intending to be legally bound hereby, the parties hereto agree as follows:

### 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. This Agreement is contingent on the Principal Investigator successfully obtaining IRB approval as applicable to the scope of project work, and complying with all Institution human subject policies. Sponsor agrees that the Protocol shall be amended to the extent the institution's IRB makes or conditions other requirements. In such an event, Sponsor shall have the right, 30 days after notification of such, to terminate this agreement. The parties agree that in the event of a conflict between the Protocol and this Agreement, the terms of this Agreement shall govern, except in the case of matters relating directly to clinical procedures, with respect to which the terms of the Protocol shall prevail.

#### 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. Approval of the replacement Principal Investigator shall not be unreasonably withheld by either party.

#### 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 20. The effective period may be extended by the mutual written consent of the parties hereto, as provided in Article 22. The parties agree that approval of the

Protocol by Institution's IRB is a condition precedent to the parties' rights and duties hereunder with respect to such Protocol. Work shall not begin until such time as all IRB requirements are fully met.

#### **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 permit Sponsor and/or Sponsor designee(s), during normal business hours, access to Study site to monitor the conduct of the Study as well as to audit records, CRFs, source documents, and other data relating to the Study, in order to verify Institution's compliance with their obligations herein, provided that Sponsor provides Institution with reasonable advance notice.
- D. Sponsor will notify Investigator within 30 days after 21 CFR §312.62 records retention requirements expire, or compensate Investigator \$\_\_\_/month/box plus interest at \_\_\_%/month for continued storage.

#### **5. PATIENT SAFETY**

Sponsor shall report to Institution any adverse events, findings or research results of which Sponsor becomes aware relating to the Study, pursuant to 21 C.F.R. §§312.50. Sponsor also agrees to furnish a copy of any safety report to Institution at the time it is furnished to the FDA which could affect the safety of participants or their willingness to continue participation, influence the conduct of the Study or alter the IRB's approval to continue the Study.

#### **6. DRUG SAFETY**

Sponsor will provide Institution with a Protocol and supporting information necessary for Institution to conduct the Study. The Protocol will be considered effective following its approval by Sponsor, IRB, Investigator, and, if applicable, the FDA or other applicable regulatory authority. Institution will conduct the Study in accordance with the Protocol. However, Institution may deviate from the Protocol to protect Subject safety and welfare. Any such deviation will not constitute a failure to comply with the Protocol. Only the Sponsor may modify the Protocol or add an addendum to the Study. Any modification or addendum to the Protocol must be approved by the IRB to become effective. If the IRB does not approve a modification within 20 days, Sponsor may terminate this Agreement. If, in Institution's judgment, any modifications or addendums, collectively from the beginning of the Study at Institution, increase Institution's costs, Sponsor will increase the Budget accordingly or Institution may terminate this Agreement.

Sponsor will provide Institution with a comprehensive and accurate Protocol and Investigator's Brochure, especially with respect to information pertaining to the safety of the Study Drug. Sponsor will advise Institution of all information for inclusion in the informed consent form that is material to Study Subjects' decision to participate or to continue to participate in the Study. Sponsor will inform Institution in a timely manner of new information pertaining to the safety of the Study Drug, and information or findings that could influence the conduct of the Study or the Protocol, affect the safety

of the Research Subjects or their willingness to continue participation in the Study, or alter the IRB's approval to continue the Study. Sponsor will inform Institution in advance of any requirements beyond GCP. Sponsor will respond to Institution and/or Principal Investigator questions and issues in a prompt and timely manner.

When Research Subject safety or medical care could be directly affected by Study results, whether final results or an interim analysis of results, Sponsor will promptly notify Institution of such results and possible affects, and Institution shall communicate such results and possible affects to the Research Subject in an appropriate manner. During the Study and after the conclusion of the Study, Sponsor will continue to inform Institution of observed Study Drug side effects so Institution, if appropriate, can inform Subjects.

Sponsor warrants that:

1. It has obtained all necessary governmental and regulatory approvals to conduct the Study and provide the Study Drug including without limitation, all applicable FDA approvals; and that all approvals will be in full force and effect during the Study.
2. Study Drug has been manufactured and passed quality control tests in accordance with applicable regulations.
3. It has disclosed to Institution and applicable government authorities all relevant, material information concerning the safety, use, efficacy and Study Drug experience.
4. Use of the Study Drug for Study purposes will not infringe the rights, patent or otherwise, of any third-party.
5. Any hazardous material packaging provided by Sponsor meets regulatory requirements for Institution's use according to the Protocol.
6. It is in compliance with federal, state, and local legal requirements relating to the manufacture and formulation of any investigational Study drug and other materials supplied by Sponsor for use in the Study, and other applicable legal requirements.

## **7. OWNERSHIP**

The Institution retains ownership of all medical records.

## **8. 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 Study, unless otherwise agreed in writing by the Institution and Sponsor. If not separately listed in the budget for payments to Site, an IRB fee of \$2,500 will be assessed by Site for initial IRB review and approval. Institution will assess IRB fees of \$750 for full IRB reviews of amendments to protocols and/or consent forms and for annual reviews. Sponsor will reimburse Institution upon receipt of invoice.

- B. Checks will be made payable to: "Thomas Jefferson University." Checks or accompanying letter will reference this Agreement and the Principal Investigator's name and will be sent to:

Thomas Jefferson University

Institution Tax Identification Number - 23-1352651

## **9. CONFIDENTIAL INFORMATION**

All such information in order to be considered "Confidential" must be appropriately marked, treated, and/or disclosed as Confidential by sponsor. If such information is communicated orally or visually, it must be reduced to writing within fifteen (15) days of the disclosure in order to be treated as "Confidential".

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

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) information that is reasonably required by scientific standards for publication of the Study results, or any information that is necessary for other scholars to verify the results of the Study;
- (b) is in the public domain at the time Sponsor discloses it to Institution or that thereafter enters the public domain through no fault of Institution;
- (c) was known to Institution before the date Sponsor discloses it to Investigator, or that becomes known to Institution through a third party having an apparent bona fide right to disclose the information;
- (d) Is independently developed by Institution;
- (e) Is disclosed by Institution 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 government authority.

Institution may maintain copies of the confidential information for non-commercial, archival purposes.

The obligations of this Section shall survive termination or expiration of this Agreement for a period of three (3) years.

## **10. DISCLOSURE TO THIRD PARTY**

Institution reserves the right to disclose information to third party payors or government agencies in order to obtain reimbursement for medical services provided to study enrollees that are not otherwise reimbursed by the sponsor.

## **11. INTERNAL COMMITTEES**

Sponsor shall cooperate and authorize release of data, which is the subject of this Study, to Institution's internal committees as required by accrediting agencies or other governmental agencies. If required to report such data to any governmental authority or agency, Institution shall use all reasonable efforts to maintain the confidentiality of such data.

## **12. PUBLICATIONS**

The Principal Investigator and Institution shall be free to publish and present the results and data of the Study provided that the manuscript or abstract proposed to be published or presented shall be submitted to Sponsor at least sixty (60) days prior to submission for publication to permit Sponsor to request removal of any Confidential Information provided by Sponsor and contained therein and to protect its rights to any patentable inventions set forth therein. However, other than ensuring protection of the Confidential Information, Sponsor shall not exercise editorial control over the proposed publication. Any such publication shall acknowledge the contribution of Sponsor, its employees, agents and representatives as appropriate.

If this 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.

## **13. PATENTS AND INVENTIONS**

Any inventions or discoveries conceived and/or reduced to practice as a direct result of Study Drug related to the Protocol shall be the sole property of Sponsor. Institution and/or Investigator shall assist Sponsor, at Sponsor's expense, in the preparation of all documentation necessary to effectuate and perfect Sponsor's rights in such invention or discoveries. In the event that a patent application on such an invention is filed by Sponsor, for each such invention Sponsor hereby grants Institution a non-exclusive, non-transferable, royalty-free license for internal research and educational purposes.

Inventions made by the Institution that extend beyond the description in the Protocol shall belong to the Institution. Sponsor shall be notified of any such invention promptly after a disclosure is received by the Institution's Office of Technology Transfer. Institution (i) may file a patent application at its own discretion or (ii) shall do so at the request of Sponsor and at Sponsor's expense. The Institution grants the Sponsor an option to negotiate an exclusive, royalty-bearing license to any such invention upon customary commercial terms for a six (6) month period following disclosure to Sponsor by the Institution.

#### **14. 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.

#### **15. 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:

INSTITUTION:

SPONSOR:

INVESTIGATOR:

#### **16. INDEMNIFICATION**

Sponsor agrees to indemnify, defend and hold harmless the Institution, Institution's IRB, its trustees, officers, agents, employees, Principal Investigator, and affiliates, including Jefferson University Physicians and Thomas Jefferson University Hospitals, Inc., from any and all liability arising out of the conduct of the Study. The obligation of indemnification under this section shall not apply to liabilities to the extent resulting from Institution and/or Principal Investigator not using Study Materials in accordance with the Protocol or other written instructions of Sponsor, or the negligence or willful misconduct of the Principal Investigator or any other employee of Institution. 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. Sponsor shall not dispose or settle any claim admitting liability on the part of the Institution without Institution's prior consent.

#### **17. 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, including broad form and contractual liability and product liability, in a minimum amount of \$3,000,000 combined single limit per occurrence and \$6,000,000 in the aggregate with respect to personal injury, bodily injury and property damage.

#### **18. HIPAA**

Notwithstanding anything to the contrary in this agreement, all individually identifiable health information shall be treated as confidential by the parties in accordance with all applicable federal, state or local laws and regulations governing the confidentiality and privacy of individually identifiable health information, including without limitation, the Health Insurance Portability and Accountability

Act of 1996 ("HIPAA") and any regulations and official guidelines promulgated thereunder, and the parties agree to take such additional steps and/or to negotiate such amendments to this agreement as may be required to ensure that the parties are and remain in compliance with the HIPAA regulations and official guidance.

## **19. SUBJECT INJURY**

Sponsor agrees that in the event a patient who consents to participate in the Study in accordance with the Clinical Protocol should require additional medical or surgical care as a consequence of the Study, then Sponsor will provide payment for reasonable and necessary medical expenses incurred by the patient as a direct result of the Study.

## **20. 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 reimburse 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 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, 6, 7, 8, 9, 10, 11, 12 and 13 survive the termination or expiration of this Agreement.

## **21. APPLICABLE LAW:**

This Agreement shall be governed by the laws of the Commonwealth of Pennsylvania, without regard to its principles of conflict of law provisions thereof. Parties agree that disputes will be litigated in the courts of the Commonwealth of Pennsylvania.

## **22. 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, the protocol 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. Neither this Agreement nor the rights or obligations hereunder shall be assignable or otherwise transferred or subcontracted without the other party's prior consent.

## **23. INDEPENDENT CONTRACTOR**

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.

## **24. SUBCONTRACTS (IF APPLICABLE)**

Both parties have agreed that Institution shall subcontract the study to other institutions whom will function as satellite sites. Institution agrees that subcontracts shall not be executed and work shall not begin at such satellite sites until Institution has received written approval from the Site Monitor or another designated representative of Sponsor.

## **25. FORCE MAJEURE**

No party will be liable for failure or delay in performing its obligations under this Agreement if the failure or delay is required to (a) comply with a government law, regulation or order (not the result of its own conduct), or (b) is caused by other circumstances beyond the reasonable control of such party, that could not have been avoided by that party's due care, 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. A party claiming force majeure will notify the other party in writing, with an explanation, within seven days of the start of the force majeure delay. It will use its reasonable efforts to resume performance of its obligations under this Agreement. If it is unable to resume performance within thirty days after the force majeure event begins, the other party may terminate this Agreement.

## **26. DEBARMENT**

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.

## **27. ASSIGNMENT**

Neither party shall assign its rights or duties under this Agreement, in their entirety or in part, to another entity without prior written consent of the other party.

**28. INTEGRATION CLAUSE**

This agreement constitutes the full and complete agreement between the parties and supersedes all previous agreements on this matter. There are no other written or oral agreements, representations or understanding with respect to the subject matter of this contract. No other verbal or written agreement shall, in any way, vary or alter any provisions of this agreement except in the case of a written amendment to this agreement signed by the authorized representative of both parties.

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

SPONSOR:

INSTITUTION:

\_\_\_\_\_

Thomas Jefferson University

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

BY: \_\_\_\_\_

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

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

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

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

DATE: \_\_\_\_\_

DATE: \_\_\_\_\_

PRINCIPAL INVESTIGATOR:

(READ AND ACKNOWLEDGED)

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.