NOTE: This document is only a template. It is subject to change depending upon the specific needs of a study. In order for it to be considered ready for execution, it must be reviewed by the IU Office of Clinical Research and agreed upon by the applicable parties. If you have any questions, please contact the IU Office of Clinical Research at 317-278-2546 and/or ocr@iu.edu

CLINICAL TRIALS AGREEMENT

THIS CLINICAL TRIALS AGREEMENT (hereinafter referred to as the "Agreement"), effective as of [ ] (hereinafter referred to as the "**Effective Date**") is by and between [ ], a corporation organized under the laws of the State of [ ] whose offices are located at [ ], (hereinafter referred to as "Sponsor"); and the **Trustees of Indiana University**, an educational institution organized under the laws of the State of Indiana, whose address is Indiana University, Attn: Office of Clinical Research, 410 West 10th Street, 1020, Indianapolis, IN 46202 (hereinafter referred to as "Institution"). Sponsor and Institution may be referred to individually as "Party" or collectively as "Parties."

I. Scope of Work.

A. Institution will use reasonable efforts to perform the experiments and studies described in the protocol entitled "[ ]" incorporated herein by reference (hereinafter referred to as the "Study"). Any modifications to the protocol will be made by written agreement between the Parties and subsequent Institutional Review Board (hereinafter referred to as "IRB") approval, except for deviations necessary to protect the safety, rights, or welfare of any Study participants, in which case such modifications will be made immediately and will subsequently be confirmed by the Parties and the Institution's IRB.

B. Sponsor acknowledges that the primary mission of Institution is health care, education, and the advancement of knowledge, and consequently, all services provided by Institution under this Agreement will be performed in a manner best suited to carry out that mission. Institution does not guarantee specific results of the Study.

II. Principal Investigator.

The Study will be performed under the direction of an employee of the Institution, [ ] (hereinafter referred to as "Principal Investigator"). Principal Investigator will personally conduct and supervise the Study in accordance with the aforementioned protocol, this Agreement, the investigational plan, and any and all applicable laws, regulations, and conditions of approval imposed by the IRB and the Food and Drug Administration ("FDA"). Principal Investigator will also ensure that all employees of Institution assisting in the conduct of the Study are informed about Institution's obligations to Sponsor per this Agreement. In the event the Principal Investigator is unable or unwilling to continue with the Study, the Party first learning of this inability or unwillingness will notify the other Party in writing. The Parties will attempt to find a mutually acceptable substitute. In the event a mutually acceptable substitute is not found, the Agreement may be terminated in accordance with Section XI.

III. Confidentiality.

A. Institution acknowledges that Sponsor may, prior to and during the term of this Agreement, provide Institution with scientific, technical, trade secret, business, or other information which is treated by Sponsor as confidential or proprietary (hereinafter referred to as "Confidential Information"). Both Parties agree that in order to ensure that each Party understands which information is deemed to be confidential, all Confidential Information provided by the Sponsor shall be clearly marked as "Confidential." If the Confidential Information is initially disclosed in oral or some other non-written form, the Sponsor shall provide the Confidential Information in written form, clearly marked as "Confidential," and deliver such document to the Institution within thirty (30) days of initial disclosure. Institution shall hold such Confidential Information in strict confidence and shall treat such information in the same manner as it treats its own confidential information. The Confidential Information provided to Institution by Sponsor will remain the property of the Sponsor, and will be disclosed only to those persons necessary for the performance of this Agreement. The obligation of non-disclosure will not apply to any part of the Confidential Information that:

   (i) is already known to Institution prior to the effective date, as evidenced by Institution's records;
   (ii) becomes publicly known without the wrongful act or breach of this Agreement by Institution;
   (iii) has been or is disclosed to Institution by a third party who was not, or is not, under any obligation of confidence or secrecy to Sponsor at the time said third party discloses to Institution, or has the legal right to do so;
   (iv) is developed independently by employees of Institution who had no access to or knowledge of the Confidential Information, as evidenced by Institution's records;
   (v) is approved for release by written authorization of the Sponsor;
   (vi) is required to be disclosed by law (including Indiana's Open Record Act) or governmental regulation or to any governmental entity with jurisdiction, provided Institution promptly notifies Sponsor, if reasonably practical or possible, in writing of such lawful disclosure.

B. The obligation of Institution to maintain the Confidential Information under this Agreement will survive Study completion or termination for five (5) years.

C. If Sponsor provides Institution with any proprietary Study drugs and/or devices for use under the Study, such Sponsor proprietary materials will be used solely for the Study and not for any other purposes. Institution and Principal Investigator shall be responsible for compliance with all applicable laws and regulations regarding the destruction or disposition of the Sponsor proprietary materials that are used under the Study.

D. Institution and Principal Investigator will inform all potential Study participants that the proprietary Study drugs and/or devices are being used for investigational purposes.

IV. Compliance with Informed Consent Form/HIPAA Authorization and Use of Study Data.

A. Institution agrees to comply with all applicable state and federal laws and regulations, including the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. § 1320d ("HIPAA") and any current and future regulations promulgated thereunder.

B. Institution shall obtain from each subject, prior to subject's participation in the Study, a signed informed consent form and HIPAA authorization form, in a form approved in writing by the IRB. The informed consent form shall comply with all of the requirements of 45 CFR 46.116 and 21 CFR 50.25 ("ICF"); the HIPAA authorization form shall comply with the requirements of 45 CFR 164.506 and 45 CFR 164.508 ("HIPAA Authorization"). Both Parties agree that the use of data generated under this Study shall be governed by the terms and conditions of the ICF and HIPAA Authorization which have been or will be approved by Sponsor and IRB. Terms and conditions of this Agreement shall not supersede or modify the use of data terms and conditions listed in the ICF and HIPAA Authorization.

V. Reporting Requirements.

A. Within ___ days following the completion or premature termination of the Study, Institution will furnish Sponsor with the final report on the Study prepared by the Principal Investigator [as well as all data, reports and other information generated by the Study and reasonably requested by the Sponsor.

B. If such Sponsor proprietary materials are used, Institution and/or Principal Investigator agree to report any significant adverse observations, which may include any experience that suggests a significant hazardous contraindication, side effect, or precaution, to Sponsor within two (2) days of such observation in accordance with 21CFR312.64 or other applicable laws, rules, regulations. Prior to using any proprietary Study drugs and/or devices of the Sponsor, Principal Investigator shall read and understand all information in the investigator's brochure, including the potential risks and side effects of the Study drugs and/or devices. Upon completion or termination of this Study, Institution shall return or destroy any remaining Sponsor proprietary materials at the direction and request of Sponsor.

C. In accordance with 21 C.F.R. § 312.50 and 21 C.F.R. § 312.55, Sponsor shall promptly notify Principal Investigator of new observations discovered by or reported to Sponsor on the Study drug/ device, particularly with respect to adverse effects and safe use, and shall ensure that Principal Investigator is promptly informed of significant adverse effects or risks with respect to the Study Drug. Principal Investigator shall promptly report any such information to the IRB, per the IRB's policies.

D. Further, if at any time Sponsor becomes aware of Study results that could, in its reasonable opinion, directly affect the safety or medical care of current or former participants, Sponsor shall promptly notify the Institution In accordance with the IRB's policies, the IRB will be notified by Institution and/or the Principal Investigator of this

information, and the Principal Investigator and IRB will determine, as applicable, whether to and the best way to notify the Study participants.

VI. Record Retention.

All Study records shall be retained by Institution for whichever applicable period of time is greatest: (a) three (3) years after completion or termination of the Study; (b) two (2) years after the date of marketing application approval for the Study drug investigated under the Study, (c) two (2) years after the FDA is notified by Sponsor of discontinuation of the IND; or (d) such longer period of time as may be required by applicable laws, rules, or regulations. The Principal Investigator will maintain adequate and accurate records in accordance with 21CFR312.62, and will make those records available for inspection in accordance with 21CFR312.68.

VII. Access to Records/Audits.

A. Institution will permit Sponsor, during normal business hours and at mutually agreeable times with prior written notice, to inspect and make abstracts of records and reports collected and generated by Institution in the course of conducting the Study and to inspect the facilities at which the Study is conducted to verify compliance with this Agreement and the applicable Protocol.

B. Principal Investigator and Institution agree to take any reasonable actions requested by Sponsor to cure deficiencies noted during an FDA audit or inspection. In addition, Sponsor shall retain the right to review any correspondence to the FDA generated as a result of a FDA inspection prior to submission by Principal Investigator or Institution. Principal Investigator and Institution have the sole right to reply to the FDA, and will duly consider any comments provided by Sponsor.

VIII. Publications.

A. Sponsor acknowledges that the free dissemination of information is an important policy of Institution. No restrictions are acceptable that limit the use and distribution of any Institution student's research and/or thesis conducted in conjunction with his/her academic program. In accordance with its policies, Institution may retain a copy of the Study data arising out of the performance of this Study, and retains the right to use such data or results for its own publication, presentation, instructional or non-commercial research objectives (hereinafter referred to as "Publication") provided that the Publication does not disclose any Confidential Information furnished by Sponsor under Section III.

B. Institution agrees that any proposed Publication relating to the Study conducted under this Agreement will be submitted to Sponsor for review at least thirty (30) days prior to submission for Publication to remove Confidential Information. As such, the scope of Confidential Information in this publication context does not include the results arising out of the performance of this Agreement. In the event that the proposed Publication contains patentable subject matter which needs protection, Institution will, upon written request from Sponsor within the initial thirty (30) day review period, delay the Publication for a maximum of an additional ninety (90) days to allow Sponsor to file a patent application.

C. If this Study is a trial being conducted in multiple study centers and it is intended that the results of the Study will be initially published and/or presented in an integrated manner reflecting the results observed across all centers and/or will be published under group authorship, Institution agrees to delay any Publication. However, subsequent to the publication of the results of the Study, or if the multicenter publication has not been submitted for publication within twelve (12) months of completion of the data analyses of the Study, Institution will have the right to publish in accordance with the aforementioned terms of this Section.

IX. Registration of Study.

In accordance with Title VIII of the Food and Drug Administration Amendments of 2007, 42 U.S.C. 282(j) et seq., Clinical Trial Databases, Sponsor acknowledges that it is the responsible Party with respect to this Study. Accordingly, Sponsor agrees to fully register this Study with the public registry clinicaltrials.gov before enrollment of the first subject at Institution and to submit all required results information to clinicaltrials.gov in a timely manner. To the extent possible within the context of clinicaltrials.gov, Sponsor agrees to submit results information in a manner acceptable to the International Committee of Medical Journal Editors.

X. Intellectual Property.

A. All improvements, enhancements or modifications of, or new uses for the Sponsor's proprietary materials discovered under the Sponsor's Protocol will be the sole property of the Sponsor (hereinafter referred to as "Sponsor Inventions"). Institution personnel will cooperate with the Sponsor in obtaining whatever patent protection or other protection that may be available on the same, and will execute documents deemed necessary by the Sponsor for the purposes of securing such patent protection or other protection. The Sponsor will reimburse Institution for reasonable expenses incurred in such efforts.

B. All inventions not covered by Section X.A., made solely by employees of Institution, will be the sole property of Institution (hereinafter referred to as "Institution Inventions"). All other inventions made jointly by employees of Sponsor and Institution will be owned jointly by the Sponsor and Institution (hereinafter referred to as "Joint Inventions"). In either case, the inventions mentioned in this Section X.B. refer to inventions in connection with work conducted under this Agreement.

C. Institution hereby grants to the Sponsor the first option for a worldwide, exclusive, royalty-bearing license to make, use, and sell with a right to sublicense to the Institution Inventions and to the Institution's interest in Joint Inventions as described in Section X.B. The terms of such license will be reasonable in the circumstances and will be negotiated in good faith between the Sponsor and Institution. The option to license any invention will extend for a time period of six (6) months from the date of its original disclosure to Sponsor.

D. Title to, and the right to determine the disposition of, any copyrights or copyrightable material, first produced or composed in the performance of this Study, shall remain with the Institution.

E. Title to any equipment purchased by Institution in the performance of the Study whether or not purchased with funds provided under this Agreement will remain with Institution and will be free of all claims, liens, or encumbrances of the Sponsor.

XI. Termination.

A. Provisions of this Agreement which by their nature contemplate rights and obligations of the Parties to be enjoyed or performed after the expiration or termination of this Agreement for any reason will not relieve either Party of its obligations under this Agreement previous to the effective date of such termination.

B. In the event that either Party defaults or breaches any material provision of this Agreement, the other Party may terminate this Agreement upon thirty (30) days written notice to the Party in default or breach; provided, however, that if the Party defaulting, breaching, or failing, within thirty (30) days of the receipt of such notice cures the said default, breach or failure; the Agreement will continue in force and effect.

C. This Agreement may be terminated by either Party, upon immediate prior notice (i) if the authorization and approval to perform the Study in the United States is withdrawn by the FDA; or (ii) if the emergence of any adverse reaction or side effect with the drug administered or the device employed in the Study is of such magnitude or incidence in the opinion of either the Sponsor or the Institution to support termination.

D. If either Party should become insolvent or should make any assignment for the benefit of creditors, or should be adjudged bankrupt, or should file a petition in bankruptcy, or is named as debtor in an involuntary bankruptcy proceeding, or if a receiver or trustee of the property of either Party is appointed, then this Agreement, at the option of the other Party, will terminate, effective on the date notice of such termination is given.

E. Upon termination of this Agreement, Sponsor will compensate and reimburse Institution for Study work performed and for all expenditures and non-cancelable commitments incurred prior to termination which Sponsor has agreed to pay as part of the Study under this Agreement not to exceed the total amount of the Agreement. If the Study was never initiated because of disapproval by the IRB, Sponsor will reimburse Institution for IRB fees and for any other expenses that were prospectively approved, in writing, by Sponsor.

XII. Indemnification.

The Sponsor will defend, indemnify and hold harmless the Institution, its affiliated hospitals and institutes, and their trustees, officers, employees, agents, and third parties acting on its/their behalf or with its/their authorization (hereafter collectively referred to as "Institution Indemnitees") from any and all suits, actions, claims, demands, judgments, expenses, costs or liabilities (including attorneys' fees and court costs at the trial and appellate levels) (hereafter collectively referred to as "Claims") for any loss, damage, injury, or loss of life caused by or related to (i) the actions of Sponsor or its officers, employees, agents, or of third parties acting on behalf of or under authorization from Sponsor; (ii) the Institution Indemnitees' proper performance of the Protocol; or (iii) Sponsor's use of the data, results, or materials, including any products and tangible items developed or made as a result of the data, results, information, or materials received from the Institution Indemnitees, provided that (a) Institution promptly

notifies Sponsor in writing after Institution receives notice of any claim, and (b) Sponsor is given the opportunity, at its option, to participate and associate with Institution in the control, defense and trial of any claim and related settlement negotiations. Sponsor may not settle any such Claim without Institution's prior written consent and may not admit liability or wrongdoing by an Institution Indemnitee without prior written consent of the Institution.

XIII. Patient Injury Reimbursement.

A. Institution's policy requires that all subjects be provided with any and all medical treatment reasonably necessary for any injury sustained as a direct result of the Study drug/ device or any Study procedure.

B. Sponsor agrees to reimburse Institution for the reasonable costs of treatment of a subject injury to a Subject which, in the reasonable judgment of Institution and Sponsor, directly results from the Study Drug or Study procedure used in the Study, and to the extent that Subject's injuries are not attributable to a failure to adhere to the terms of the Protocol, to the negligence or misconduct of Institution and/or Principal Investigator, or to the pre-existing abnormal medical conditions or underlying disease of the Subject, or to accidents unrelated to participation in the Study.

XIV. Insurance.

Institution and Sponsor each shall secure and maintain in full force and effect throughout the performance of the Study (and following termination of the Study to cover any claims arising from the Study) insurance coverage for: (i) medical professional and/or medical malpractice liability; (ii) general liability; and (iii) workmen's compensation, each such insurance coverage in amounts appropriate to their respective performance of the Protocol and the services contemplated by the Study and in conformance with applicable legal and regulatory requirements. Each Party shall supply the other with evidence of such coverage upon reasonable request.

XV. Publicity.

A. The Parties agree that neither Party will use the names or trademarks of the other Party, nor any adaptation thereof in any advertising, promotional or sales activities without prior written consent obtained from the other Party.

B. Sponsor acknowledges that the names and affiliations of Sponsor and the general purposes and budget of the Study are to be made public by Institution to satisfy its reporting obligations or as required by law or regulation.

XVI. Debarment.

Institution and Principal Investigator agree that neither Institution, Principal Investigator nor Institution's employees are or have been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that neither Institution nor Principal Investigator will use or involve any person or organization in connection with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Institution, Principal Investigator or any person or organization uses or involves in connection with the Study should

become debarred or disqualified during the course of the Study, Institution and Principal Investigator agree to promptly notify Sponsor in writing.

XVII. Cost and Billings.

A. In consideration for the Study, Sponsor agrees to pay Institution in accordance with the payment schedule attached as Exhibit A. Payment will be payable to Trustees of Indiana Institution, referring to this Agreement, and will be sent by mail to:

[APPLICABLE ADDRESS TO BE INSERTED, I.E., CHECKS OR ELECTRONIC PAYMENTS]

B. Sponsor may add to or modify the Protocol during the term of this Agreement, and shall provide Institution with additional compensation, beyond that listed in Exhibit A, acceptable to Institution for the additional work to be performed. If the Protocol is amended and the amendment to the Protocol causes a change to the procedures conducted or the effort in conducting these procedures is modified, an updated budget shall be negotiated.

C. In the event that any additional work is requested by the Sponsor six (6) months or more after Institution has completed the last patient visit, Sponsor shall negotiate additional reasonable compensation that is mutually acceptable to cover the personnel and other costs associated with this request.

D. If the Study was never initiated because of disapproval by the IRB, Sponsor will reimburse Institution for IRB fees and for any other expenses that were prospectively approved, in writing, by Sponsor.

XVIII. Term.

The term of this Agreement is from the Effective Date until Study is completed or terminated in accordance with Section XI.

XIX. Disputes.

Both Parties shall work together in good faith in attempt to resolve any dispute arising under this Agreement. Any dispute or proceeding under this Agreement shall be subject to the jurisdiction and venue of the courts of the State of Indiana, United States of America or the United States Federal courts having jurisdiction in Indiana, and both Parties hereby consent to the personal jurisdiction and venue of these courts.

XX. Independent Contractor.

Nothing contained herein will be construed as establishing an employer-employee, joint venture, or principal-agent relationship between the Parties. In addition, neither Party will have the right to incur any debt or expense for the account of the other Party except as may expressly be agreed upon by separate written agreement.

XXI. Assignment.

Neither Party may assign this Agreement or any part of it without the written consent of the other Party.

XXII. Miscellaneous.

A. The headings in this Agreement are intended solely for convenience or reference and will be given no effect in the construction or interpretation of this Agreement.

B. This Agreement, including attached appendices, supersedes all prior oral and written proposals and communications, if any, and sets forth the entire Agreement of the Parties with respect to the subject matter hereof and may not be altered or amended except in writing, signed by an authorized representative of each Party hereto. The terms in this Agreement take precedence over the protocol.

C. The construction and enforcement of this Agreement will be governed by the laws of the State of Indiana, United States of America, without regard to principles of choice of law. The Parties acknowledge that this contract is entered into and will be performed in Indiana.

D. No waiver of any default, condition, provision or breach of this Agreement will be deemed to imply or constitute a waiver of any other like default, condition, provision or breach of this Agreement.

E. If any paragraph, term, condition or provision of this Agreement will be found, by a court of competent jurisdiction, to be invalid or unenforceable, or if any paragraph, term, condition or provision is found to violate or contravene the laws of the State of Indiana, then the paragraph, term condition or provision so found will be deemed severed from this Agreement, but all other paragraphs, terms, conditions and provisions will remain in full force and effect.

XXIII. Notices.

Notices to be provided between the Parties shall be provided to the following individuals for each Party:

SPONSOR:

INSTITUTION:

Programmatic Notices:

Contractual Notices:
Indiana University
Attn: Office of Clinical Research
410 West 10th Street
Suite 1020
Indianapolis, IN 46202

Phone: (317) 278-2546
Email: cto@iu.edu

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement signed by their respective officers duly authorized as the date and year written.

TRUSTEES OF INDIANA UNIVERSITY	**SPONSOR**
Signed: _____	Signed: _____
Name : _____	Name : _____
Title : _____	Title : _____
Date : _____	Date : _____

READ AND ACKNOWLEDGED:
PRINCIPAL INVESTIGATOR

Signed: _____
Name : _____
Title : _____
Date : _____

Attachments:

Exhibit A: Payment Schedule