

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 TRIAL AGREEMENT for INVESTIGATOR-INITIATED STUDY

THIS AGREEMENT is by and between _____, a corporation organized under the laws of the State of _____, whose offices are located at _____ (hereinafter referred to as “Company”); and the **Trustees of Indiana University**, an educational institution organized under the laws of the State of Indiana, whose address is Office of Clinical Research, 410 West 10th Street, 1020, Indianapolis, IN 46202-5167 (hereinafter referred to as “University”), on behalf of its employee, _____.

Scope of Work. University will use reasonable efforts to perform the experiments and studies described in the investigator-initiated protocol entitled _____

_____ incorporated herein by reference (hereinafter referred to as the “Study”). Company acknowledges that the primary mission of University is health care, education, and the advancement of knowledge, and consequently, all services provided by University under this Agreement will be performed in a manner best suited to carry out that mission. University does not guarantee specific results of the Study.

- 1. Principal Investigator.** The Study will be performed under the direction of _____ (hereinafter referred to as “Principal Investigator”). Principal Investigator will conduct and supervise the Study in accordance with the aforementioned protocol, this Agreement, the investigational plan, and any and all applicable laws, regulations (including FDA regulations), and conditions of approval imposed by the IRB or the FDA, and will comply with all requirements regarding the obligations of clinical investigators and all pertinent requirements thereunder, including 21CFR312. Principal Investigator will also ensure that all associates, colleagues, and employees of University assisting in the conduct of the Study are informed about their obligations to Company 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 and 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 Paragraph 10.
- 2. Term.** The term of this Agreement is from the effective date of August 1, 2012 through August 31, 2014. The term of this Agreement may be extended by a written amendment signed by the authorized representative of both parties.

3. **Reports.** Upon completion of the research or termination of the Agreement, University will submit a written study report. This report will be due sixty (60) days after termination of this Agreement.
4. **Free Product.** Company agrees to provide University _____ in support for the Study.
5. **Equipment.** Title to any equipment purchased by University in the performance of the Study whether or not purchased with funds provided under this Agreement will remain with University and will be free of all claims, liens, or encumbrances of the Company.
6. **Publications.** Company acknowledges that the free dissemination of information is an important policy of University. Nothing herein shall prevent University or Principal Investigator from using such Study Data for ordinary, non-commercial research and educational purposes of a university, including its own publication, presentation, and instructional objectives, provided that the publication, presentation or use does not disclose Confidential Information furnished by Sponsor. University agrees that any proposed publication or presentation relating to the Study conducted under this Agreement will be submitted to Company for review at least thirty (30) days prior to submission for publication or presentation 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 or presentation contains patentable subject matter which needs protection, University will, upon written request from Company within the initial thirty (30) day review period, delay the publication or presentation for a maximum of an additional ninety (90) days to allow Company or University to file a patent application.
7. **Compensation:** Compensation for this Study shall be as outlined in the budget, attached hereto as Exhibit A.
8. **Intellectual Property.**
 - 8.1. As this Agreement is for an investigator-initiated Study, University will promptly disclose to Company, in confidence, all creative ideas, developments and inventions, whether or not patentable, conceived or first reduced to practice as a result of the Project ("Inventions"). University hereby grants to Company the first option for a worldwide, exclusive, royalty-bearing license to make, have made, use, and sell with a right to sublicense, Inventions. The terms of such license will be reasonable in the circumstances and will be negotiated in good faith between the Company and University. The option to license any Invention will extend for a time period of six (6) months from the date of its original disclosure to Company.
 - 8.2. 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 University.

9. Confidentiality and Record Retention.

- 9.1. University acknowledges that Company may, prior to and during the term of this Agreement, provide University with scientific, technical, trade secret, business, or other information which is treated by Company as confidential or proprietary (hereinafter referred to as “Confidential Information”). In recognition that University is a non-commercial, academic institution, Company agrees to limit to the extent possible the delivery of confidential information to University. Both parties agree that in order to ensure that each party understands which information is deemed to be confidential, all Confidential Information will be in written form and clearly marked as “Confidential,” and if the Confidential Information is initially disclosed in oral or some other non-written form, it will be confirmed in writing and clearly marked as “Confidential” within thirty (30) days of disclosure. University 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 University retains the right to refuse to accept any such information or data from Company which it does not consider to be essential to the completion of the Study or which it believes to be improperly designated. The Confidential Information provided to University by Company will remain the property of the Company, and will be disclosed only to those persons necessary for the performance of this Agreement. No indirect or consequential damages or damages based on loss of profits or market share are contemplated or recoverable for breach of confidentiality.
- 9.2. The obligation of University to maintain the Confidential Information under this Agreement will survive its expiration or termination and will endure for five (5) years from the date of disclosure.
- 9.3. The obligation of non-disclosure will not apply to any part of the Information that:
- (a) is already known to University prior to the effective date, as evidenced by University’s records;
 - (b) becomes publicly known without the wrongful act or breach of this Agreement by University;
 - (c) has been or is disclosed to University by a third party who was not, or is not, under any obligation of confidence or secrecy to Company at the time said third party discloses to University, or has the legal right to do so;
 - (d) is developed independently by employees of University who had no access to or knowledge of the Information, as evidenced by University’s records;
 - (e) is approved for release by written authorization of the Company;
 - (f) is required to be disclosed by law or governmental regulation or to any governmental entity with jurisdiction, provided University promptly notifies Company, if reasonably practical or possible, in writing of such lawful disclosure.
- 9.4. If Company provides University with any proprietary study drugs and/or devices for use under the Study, such Company proprietary materials will be used solely for the Study and not for any other purposes. University and Principal Investigator shall be

responsible for compliance with all laws and regulations applicable to any destruction or disposition of Company proprietary materials used under the Study. University and Principal Investigator will inform all potential Study participants that the proprietary study drugs and/or devices are being used for investigational purposes. Prior to using any proprietary study drugs and/or devices of Company, Principal Investigator shall read and understand all information in the investigator's brochure, including the potential risks and side effects of the drug. Upon completion or termination of this Study, University shall return, at Company's expense, or destroy any remaining Company proprietary materials at the direction and request of Company.

10. Termination.

- 10.1. 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.
- 10.2. 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.
- 10.3. This Agreement may be terminated by either party, upon immediate prior notice, if the authorization and approval to perform the Study in the United States is withdrawn by the FDA or, 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 Company or the Institution to support termination.
- 10.4. 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.
- 10.5. Should Company terminate this Agreement, Company will reimburse University for all expenditures and non-cancelable commitments incurred prior to termination not to exceed the total amount of the Agreement.

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

12. Indemnification.

12.1. The Company will defend, indemnify and hold harmless the Principal Investigator, the Trustees of Indiana University (“University”), 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 “Indemnitees”) from any and all suits, actions, claims, demands, judgments, costs or liabilities, including attorneys fees and court costs at the trial and appellate levels, for any loss, damage, injury, or loss of life arising from the manufacture of any study drugs or devices provided by Company to University for use in the Study, or arising from products and tangible items developed or made as a result of information or materials received from the University, provided that (i) University promptly notifies Company in writing after University receives notice of any claim, (ii) Company is given the opportunity, at its option, to participate and associate with University in the control, defense and trial of any claim and related settlement negotiations.

12.2. University shall be liable to the extent allowed under Indiana Law.

13. Publicity.

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.

Company acknowledges that the names and affiliations of Company 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.

14. Compliance with HIPAA and Use of Study Data.

University 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. Both parties agree that the use of data generated under this Study shall be governed by the terms and conditions of the Informed Consent and HIPAA authorization forms, which have been or will be approved by University’s IRB. Terms and conditions of this Agreement shall not supersede or modify the use of data terms and conditions listed in the Informed Consent and HIPAA authorization forms. Principal Investigator will ensure that the requirements relating to and obtaining Informed Consent and IRB review and approval are met.

15. 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.

16. 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.

17. Miscellaneous.

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.

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.

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.

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.

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.

18. Notices. Notices to be provided between the parties shall be provided to the following individuals for each party:

COMPANY:

UNIVERSITY:

Programmatic Notices:

Contractual and Financial Notices:

Indiana University
Clinical Trials Office
410 West 10th Street, 1020
Indianapolis, IN 46202-5167
Phone: (317) 274-CLIN (2546)

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

THE TRUSTEES OF INDIANA UNIVERSITY **COMPANY**

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

READ AND ACKNOWLEDGED:
PRINCIPAL INVESTIGATOR

Signed: _____ Date: _____
Name: _____