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

THIS MASTER CLINICAL TRIAL AGREEMENT (the "**Agreement**") is made and entered into as of the _____ day of _____, 2016 (hereinafter, the "**Effective Date**"), by and between **_____[Insert Sponsor Name]**, (hereinafter, "**SPONSOR**"), on behalf of itself, and its affiliates, with offices at_____ [Insert Sponsor Address}, and **TRUSTEES OF INDIANA UNIVERSITY** (hereinafter, "**INSTITUTION**"), with offices at Office of Clinical Research, 410 West 10th Street, Suite 1020, Indianapolis, IN 46202. For purposes of this Agreement, SPONSOR and INSTITUTION (as defined below) may be referred to individually as a "**Party,**" and collectively as the "**Parties.**"

BACKGROUND

WHEREAS, SPONSOR has requested INSTITUTION and its employees to conduct certain clinical trials/research studies (each a "**Study**" and collectively, the "**Studies**"), involving certain SPONSOR study drugs (hereinafter, "**Study Drugs**"), according to certain SPONSOR protocols (hereinafter, each a "**Protocol**" and collectively, the "**Protocols**"), as well as certain Work Orders (each a "**Work Order**" and collectively, the "**Work Order**"). A copy of the applicable Protocol and Study budget for a Study shall be attached as exhibits to each Work Order. A copy of the Work Order template is attached hereto as Exhbit A; and

WHEREAS, an employee of the INSTITUTION, serving as the principal investigator, shall conduct and supervise the Study at the INSTITUTION (hereinafter, "PRINCIPAL INVESTIGATOR").

WHEREAS, INSTITUTION is equipped to undertake the Studies and INSTITUTION and PRINCIPAL INVESTIGATOR have agreed to perform the Studies on the terms and conditions hereinafter set forth.

NOW, **THEREFORE**, in consideration of the premises and the mutual promises and covenants expressed herein, the Parties agree as follows:

1. PERFORMANCE OF STUDIES

A. Compliance with Agreement, Protocol and Applicable Law. INSTITUTION shall, and will ensure that PRINCIPAL INVESTIGATOR and all Study Personnel (as defined in Paragraph 1(E) hereof) shall, perform the Studies in a professional manner, consistent with industry standards, in accordance with the terms and conditions of this Agreement, and, as applicable, in compliance with the Protocols (except as set forth in Paragraph 1(B)) and any written instructions provided to INSTITUTION and/or PRINCIPAL INVESTIGATOR by SPONSOR in advance of providing the applicable Studies related services. In addition, INSTITUTION shall, and will ensure that PRINCIPAL INVESTIGATOR and all Study Personnel shall, perform any and all Study-related services in compliance with any and all relevant federal, national, state, local or other jurisdictional laws, rules, regulations, policies, guidelines and governmental requirements ("**Applicable Law**" or "**Law**"), including, without limitation:

(i) all applicable requirements of the U.S. Federal Food, Drug and Cosmetic Act ("**FDCA**"), and any similar or successor legislation;

(ii) all applicable rules, policies or guidance issued by the U.S. Food and Drug Administration ("**FDA**"), including the Code of Federal Regulations Title 21 ("**21 C.F.R.**");

(iii) all applicable requirements of the U.S. Federal Controlled Substances Act, as enforced by the U.S. Drug Enforcement Administration ("**DEA**");

(iv) all applicable International Conference on Harmonisation ("**ICH**") Guidelines for Good Clinical Practices as adopted or issued by FDA (collectively, ""**GCP**" or "**GCP Guidelines**");

(v) all applicable rules, policies or guidance for Good Laboratory practices as promulgated under the FDA at 21 C.F.R. Part 58, as the same may be amended or re-enacted from time to time, and ("**GLP**");

(vi) all applicable local, state, federal and national laws and regulations regarding the protection of privacy, personal data and medical data, including the Health Insurance Portability and Accountability Act of 1996 and any regulations and official guidance promulgated thereunder ("**HIPAA**") (collectively, the "**Privacy Regulations**");

(vii) all applicable local, state, federal and national laws and regulations regarding the reporting of any fees and other expenditures paid to healthcare professionals, including without limitation, the Physician Payment Sunshine Provision set forth in Section 1128G(e)(6) of the Social Security Act, added in by Section 6002 of the Affordable Care Act (the "**US Federal Sunshine Act**");

(viii) all applicable anti-bribery legislation, including without limitation, the Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, et seq., and the rules and regulations promulgated thereto; and

(ix) all applicable requirements of the U.S. Federal Anti-Kickback law.

B. Protocol Violations and Deviations: Notwithstanding the foregoing, PRINCIPAL INVESTIGATOR may, in accordance with applicable GCP Guidelines, deviate from the Protocols to protect a Study subject from an immediate hazard. Any such deviation will not constitute a failure to comply with the Protocols. INSTITUTION and/or PRINCIPAL INVESTIGATOR will notify SPONSOR and INSTITUTION's Institutional Review Board ("**IRB**") prompltly upon becoming aware of any such Protocol violation, and shall ensure that all such deviations from Protocols are properly recorded in the Study records. To the extent possible, INSTITUTION and PRINCIPAL INVESTIGATOR will use best efforts to quickly remedy violations and deviations and return to strict Protocol compliance.

C. Delegation of PRINCIPAL INVESTIGATOR Duties. PRINCIPAL INVESTIGATOR shall supervise the Studies and may not delegate this duty. He/she may, however, delegate other duties to qualified personnel per Protocol and regulatory requirements. INSTITUTION may not replace PRINCIPAL INVESTIGATOR without SPONSOR's prior written approval. If PRINCIPAL INVESTIGATOR is to be temporarily absent from INSTITUTION, INSTITUTION shall designate a qualified sub-investigator to temporarily supervise the Studies on PRINCIPAL INVESTIGATOR's behalf.

D. PRINCIPAL INVESTIGATOR Replacement

(i) In the event that PRINCIPAL INVESTIGATOR becomes either unable or unwilling to perform the duties required by this Agreement, or is no longer affiliated with INSTITUTION, INSTITUTION shall cooperate to find a replacement investigator acceptable to SPONSOR; provided, however, that the INSTITUTION shall continue to be bound by all obligations and conditions stipulated in this Agreement until a replacement investigator acceptable to the SPONSOR is found. In the event an acceptable replacement investigator is not found within thirty (30) days (or such longer period as mutually agreed upon by the Parties), SPONSOR may immediately terminate this Agreement in accordance with the terms hereof. The Parties hereto agree, in the event that a replacement investigator is designated pursuant to this Paragraph 1(D), that such replacement investigator shall be bound by all terms of this Agreement.

(ii) INSTITUTION shall ensure that PRINCIPAL INVESTIGATOR provides SPONSOR with a copy of the PRINCIPAL INVESTIGATOR's curriculum vitae, which shall include a description of the PRINCIPAL INVESTIGATOR's relevant experience.

(iii) INSTITUTION shall ensure that PRINCIPAL INVESTIGATOR provides SPONSOR with sufficient accurate financial disclosure information to permit SPONSOR to submit a complete and accurate certification or disclosure statement as required by 21 C.F.R. Part 54, and will promptly update the information if any relevant changes occur during the course of the Studies, and for one (1) year following completion of the Studies.

E. Study Personnel. Upon the prior written consent of SPONSOR, INSTITUTION may use other employees of INSTITUTION and contractors, including the personnel of any Study facility named in PRINCIPAL INVESTIGATOR's FDA Form 1575, to perform any Study-related services under this Agreement (together with PRINCIPAL INVESTIGATOR, "**Study Personnel**"). INSTITUTION shall ensure that:

(i) Adequate numbers of qualified Study Personnel are assigned to the Studies to meet its obligations under this Agreement;

(ii) All Study Personnel perform their Study responsibilities and fulfill their obligations under this Agreement;

(iii) All Study Personnel have the necessary licenses and certifications as may be required to perform their Study responsibilities, and shall, upon request of SPONSOR, provide such documented evidence of any such licenses and certifications;

(iv) All Study Personnel receive the necessary information, education, and training in any applicable regulatory requirements, proper performance of the Protocols, GCP Guidelines, and any other applicable guidelines relevant to the Studies and performance of the Protocols, and shall, upon request of SPONSOR, provide such documented evidence of any such education and training; and

(v) Any Study Personnel not employed by INSTITUTION shall comply with the same terms to those Study Personnel employeed by the INSTITUTIONhereunder.

F. Facilities. INSTITUTION shall, and will ensure that PRINCIPAL INVESTIGATOR shall, conduct the Studies only at facilities that are listed on its Form FDA 1572. Any modification to INSTITUTION's Form FDA 1572 with regard to such facilities that amend, alter or supplement the terms hereof, shall be made by means of a written amendment or other document, signed by the duly authorized representatives of each of the Parties. INSTITUTION shall notify SPONSOR immediately in writing upon learning of any such change to the location of any Study facility.

2. TERM AND TERMINATION

A. Term. The term of this Agreement shall begin on the Effective Date and shall end on the later of (1) _____ [INSERT DATE], or (2) six (6) months following final database lock, unless otherwise terminated sooner as provided in this Agreement. The Parties agree that the term may be extended by mutual written agreement if events beyond the Parties' control delay completion of the Studies beyond the expiration date.

B. Termination by SPONSOR. Notwithstanding the terms set forth in Paragraph 2(A), this Agreement or a Work Order may be terminated by SPONSOR at any time for any reason in the exercise of its sole discretion upon fifteen (15) business days' prior written notice to PRINCIPAL INVESTIGATOR and INSTITUTION.

C. WORK ORDER TERMINATION. Any Work Order may be terminated by either Party immediately upon written notice if any of the following conditions occur:

(i) If the authorization and approval to perform the Study in the United States is withdrawn by the U.S. Food and Drug Administration, IRB or any other applicable regulatory authority;

(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 SPONSOR, INSTITUTION, or PRINCIPAL INVESTIGATOR to support termination of the Study; or

(iii) If SPONSOR 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 its property is appointed.

D. Post-Termination Procedures. Immediately upon receipt or delivery of notice of termination, the INSTITUTION shall (i) comply with any and all post-termination procedures included in the Protocols, if any, and (ii) unless otherwise directed by SPONSOR, cease enrolling Study subjects into

the Study/Studies, and cease the Study-related treatment of Study subjects already enrolled in the Study/Studies, except if the safety of such enrolled Study subjects could be compromised. Notwithstanding the forgoing, nothing contained herein shall cause the INSTITUTION from continuing to provide follow-up care to Study subjects, separate and apart from the Study/Studies, as long as necessary to ensure the safety of such enrolled Study subjects.

E. Effect of Termination. In the event of termination of this Agreement or Work Order, the INSTITUTION shall, upon receipt or delivery of notice of termination, make all reasonable efforts to minimize incurring further costs. In the event of such early termination, SPONSOR shall make a final payment to the INSTITUTION for uncancellable commitments or services performed in accordance herewith and for reasonable, actual, direct costs incurred through the date of notice of termination. Upon reasonable request by SPONSOR, INSTITUTION shall provide SPONSOR with all documentation of any and all costs and expenses incurred through the date of the notice of termination.

F. Final Disposition of Confidential Information and Study Drug. INSTITUTION and PRINCIPAL INVESTIGATOR shall return to SPONSOR all unused Study Drug in accordance with Section 15 of this Agreement or Work Order, and all Confidential Information, as defined in the Confidentiality Section of this Agreement, including all Study Results, at the earlier of the conclusion of the Studies at INSTITUTION or termination of this Agreement.

3. INSTITUTIONAL REVIEW BOARD APPROVALS

A. Informed Consent; HIPAA Authorization. INSTITUTION and PRINCIPAL INVESTIGATOR shall be responsible for obtaining an informed consent document, and, as applicable; a HIPAA Privacy Regulations authorization form, signed by or on behalf of each Study subject, permitting the disclosure of confidential Study subject information in connection with the Studies, as well as any alteration to or waiver of any Study subject authorization, and any other documentation or material as may be provided to Study subjects when and as required by the Studies or Applicable Law ("**Informed Consent Documents**"). All such Informed Consent Documents shall be approved by SPONSOR and INSTITUTION's IRB prior to the Study subject's participation in the Studies. INSTITUTION shall provide documentation to SPONSOR verifying review and approval by the IRB of all such Informed Consent Documents.

B. Protocol and Study Advertisements. INSTITUTION and PRINCIPAL INVESTIGATOR shall be responsible for obtaining and providing to SPONSOR, IRB approval of the Protocols prior to commencement of the Studies, and of any Study advertisements prior to their use.

C. Changes to the Protocol and Informed Consent Documents. In the event the IRB requires changes in the Protocols or Informed Consent Documents, such changes shall not be implemented until SPONSOR is notified and gives its written approval. The Protocols and the Informed Consent Documents shall not be revised without the prior written agreement of SPONSOR and the IRB.

D. Legal Age and Competency Requirements. All Study subjects must meet the legal age and competency requirements of the state in which the Study is to be conducted. In the event that a Study subject is a minor or otherwise is incompetent under the laws of such state, the parent(s) or legally authorized representative(s) of such Study subject shall provide written consent prior to the Study subject's actual participation in the Studies.

4. OWNERSHIP OF STUDY RESULTS / CONFIDENTIALITY

A. Ownership of Study Results. All completed case report forms ("**CRFs**"), and other data and results (including without limitation, written, printed, graphic, video and audio material, and information contained in any computer data base or computer readable form) generated by INSTITUTION, PRINCIPAL INVESTIGATOR and/or Study Personnel per the Protocols, this Agreement or other written instruction of SPONSOR (the "**Study Results**") shall be provided to SPONSOR promptly, and shall be the sole and exclusive property of SPONSOR, and SPONSOR shall be free to utilize the Study Results in any way it deems appropriate, subject to and in accordance with any applicable Privacy Regulations. Any copyrightable work created in connection with performance of the Study and contained in the Study Results shall be property of SPONSOR as author and owner of copyright in such work. Copyrights for publications developed under the Publication Section of this Agreement by INSTITUTION, PRINCIPAL INVESTIGATOR and/or Study Personnel shall be owned by INSTITUTION, PRINCIPAL INVESTIGATOR and/or Study Personnel, respectively.

B. Confidentiality. All information, including, but not limited to, information regarding the Study Drug or SPONSOR's or its Affiliates' operations, shall be treated as confidential and/or proprietary, as it relates to SPONSOR, its present or future products, sales, suppliers, clients, customers, employees, investors, or business and shall be deemed "Confidential Information." Without limiting the generality of the foregoing, Confidential Information shall include any non-public information regarding or related to SPONSOR's business, products, drugs, compounds, or chemical structures. Moreoever, all information, data, reports and knowledge developed by INSTITUTION, PRINCIPAL INVESTIGATOR and/or Study Personnel as a result of the performance of any and all Study-related services shall be considered proprietary, Confidential Information, and shall remain the sole property of SPONSOR. Both during and after the term of this Agreement, INSTITUTION and PRINCIPAL INVESTIGATOR shall use diligent efforts to maintain in confidence, and use only for the purposes contemplated in this Agreement, Confidential Information, and shall cause all Study Personnel to protect the confidence of all Confidential Information. Confidential Information shall be disclosed only to those individuals who have a need to know such Confidential Information in order to conduct the Studies and process the data and other results from the Studies.

C. The preceding obligations shall **not** apply to information or Study Results which:

(i) has been published or otherwise made public through no fault of INSTITUTION, PRINCIPAL INVESTIGATOR, or Study Personnel, or which is published in accordance with the Publication Section of this Agreement;

(ii) is in the public domain or which later becomes part of the public domain other than by breach of this Agreement by INSTITUTION, PRINCIPAL INVESTIGATOR, or Study Personnel;

(iii) INSTITUTION can demonstrate through contemporaneous written records was in its possession prior to disclosure by SPONSOR, and which was not provided to INSTITUTION, PRINCIPAL INVESTIGATOR, or Study Personnel pursuant to a prior confidentiality agreement;

(iv) which is lawfully disclosed to INSTITUTION, PRINCIPAL INVESTIGATOR, or Study Personnel by a third party not obligated to SPONSOR to keep the information confidential;

(v) can be demonstrated by written record to have been independently developed by or on behalf of the INSTITUTION, PRINCIPAL INVESTIGATOR, or Study Personnel without the aid, use, or application of the Confidential Information received hereunder;

(vi) SPONSOR agrees in writing, may be used or disclosed; or

(vii) which is required by law (including Indiana's Open Record Act), judicial order issued by a court of competent jurisdiction, or at the request of regulatory authorities, provided that INSTITUTION shall immediately notify SPONSOR, and provide SPONSOR an opportunity to object to such disclosure, prior to making any such disclosure. In no event shall INSTITUTION disclose more than the minimum amount of Confidential Information required to be disclosed to comply with such order or request. Further, INSTITUTION shall reasonably cooperate, at SPONSOR's expense, with SPONSOR to enable SPONSOR to challenge or limit such disclosure.

D. The obligations of confidentiality and non-disclosure under this Agreement shall survive the expiration or earlier termination of the applicable Work Order for five (5) years.

5. PUBLICATION AND REGISTRATION

A. For purposes of this Agreement "**Publication**" shall mean, any paper, article, manuscript, report, regulatory filing, poster, internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the form of a written summary), or other public disclosure of the Study Results, in printed, electronic, oral or any other form.

B. Publication by SPONSOR. SPONSOR shall have the right to submit for Publication, the Study Results, and any background information generated from or related to the performance of the Studies hereunder, that is necessary to include in any Publication of Study Results, or necessary for other

scholars to verify such Study Results, without approval from INSTITUTION or PRINCIPAL INVESTIGATOR.

C. Publication by INSTITUTION and PRINCIPAL INVESTIGATOR. Subject to the terms of Paragraph 5(D), below, INSTITUTION and PRINCIPAL INVESTIGATOR shall have the right to submit for Publication, the Study Results, and any background information generated from the performance of the Studies hereunder, or provided by SPONSOR, that is necessary to include in any Publication of Study Results, or necessary for other scholars to verify such Study Results. PRINCIPAL INVESTIGATOR, or INSTITUTION as the case may be, shall include a statement in any such Publication that creation of the Study Results was supported in whole or in part by SPONSOR, as applicable. Prior to submission for publication, INSTITUTION shall provide SPONSOR with at least 30 days for review of a Publication. Notwithstanding the foregoing, no Publication that incorporates Confidential Information or which contains information outside of data generated from the Studies shall be submitted for Publication without SPONSOR's prior written consent. If requested in writing, INSTITUTION and PRINCIPAL INVESTIGATOR shall withhold submission of such Publication for up to an additional sixty (60) days to allow for filing of a patent application and / or other protective filing.

D. Multicenter Publication. If a Study is part of a multicenter study, INSTITUTION and PRINCIPAL INVESTIGATOR agree that the first Publication of the Study Results, as compiled and analyzed by SPONSOR, shall be made by SPONSOR in conjunction with SPONSOR's presentation of a joint, multicenter Publication of such compiled and analyzed Study Results, from all participating Study sites. If such multicenter Publication is not submitted for Publication by SPONSOR within twelve (12) months after conclusion, abandonment or earlier termination of a Study at all participating sites, INSTITUTION and/or PRINCIPAL INVESTIGATOR may publish, or otherwise make public, the Study Results from INSTITUTION site, individually, provided that any such Publication submitted by INSTITUTION and/or PRINCIPAL INVESTIGATOR shall reference the multicenter nature of the Study, and state which, if any, Study site(s) and investigators provided the Study Results presented in such Publication.

E. Registration of Studies. SPONSOR will register the Studies at (i) www.clinicaltrials.gov, or (ii) any other trial registry as may be required by Applicable Law and guidelines on trial registration of the International Committee of Medical Journal Editors ("ICMJE") (as in effect at initiation of the Studies), in order for the Study results to be eligible for publication in an ICMJE journal.

F. INSTITUTION warrants the compliance of all Study Personnel with the provisions of this paragraph.

6. INVENTIONS OR PATENTS

All rights to any discoveries, inventions, innovations, improvements, new uses, processes, whether or not patentable, that are conceived, derived, reduced to practice, made or developed as a result of the work conducted under this Agreement in accordance with the Protocols, including all Study Results, or which in any way relies upon or incorporates any Confidential Information shall belong to SPONSOR. INSTITUTION and PRINCIPAL INVESTIGATOR each agree to assign to SPONSOR, and hereby do assign to SPONSOR, the sole and exclusive right, title and ownership thereto. INSTITUTION and PRINCIPAL INVESTIGATOR shall promptly disclose to SPONSOR any invention or discovery arising under this Agreement. INSTITUTION and PRINCIPAL INVESTIGATOR shall execute, and shall have its employees execute, all documents necessary to transfer all right, title and interest in and to any such invention or discovery to SPONSOR. SPONSOR will reimburse INSTITUTION for reasonable expenses incurred in such efforts.

7. REPORTING OF DATA AND RECORDS

A. Case Report Form ("**CRF**") Submission. PRINCIPAL INVESTIGATOR and INSTITUTION agree to provide SPONSOR periodically and in a timely manner during the term of this Agreement with the Study Results called for in the Protocols on properly completed CRFs. CRFs shall be submitted pursuant to the Protocols

B. Serious Adverse Event Reporting. PRINCIPAL INVESTIGATOR and INSTITUTION shall notify SPONSOR as soon as is practicable, but no later than twenty-four (24) hours after learning of any serious adverse drug event (as defined in the Protocols) ("**SAE**") affecting any Study subject in the Studies, and shall provide a written confirmation report of such SAE promptly thereafter. PRINCIPAL

INVESTIGATOR and INSTITUTION shall be responsible for reporting and tracking of all SAE's in compliance with Applicable Law, and as specified in the Protocols. PRINCIPAL INVESTIGATOR shall be responsible for updating all SAEs, including any expedited safety reports. PRINCIPAL INVESTIGATOR and INSTITUTION shall promptly provide SPONSOR with all information in their possession or control as may be needed to assist SPONSOR in the identification and resolution of problems or unexpected occurrences involving the Study Drug or its use in the Studies.

C. Study Reports. Upon the reasonable request of SPONSOR, INSTITUTION and PRINCIPAL INVESTIGATOR shall submit reports (whether orally or in writing which will be stipulated by SPONSOR at the time of the request) on the progress of the Studies; written reports, including but not limited to, status of the budget, and Studies subject recruitment, which will be provided within thirty (30) days of a request from SPONSOR.

D. Study Records. INSTITUTION shall ensure that PRINCIPAL INVESTIGATOR retain, maintain, update, and store complete, accurate and legible records relating to the Studies, including without limitation, all records that he/she is obligated to maintain in accordance with Applicable Law, including GCP and 21 C.F.R. Part 312 (the "**Records**"), and for such period, and in such manner, required by Applicable Law, including GCP and 21 C.F.R. Part 312. Further, at SPONSOR's request and expense, INSTITUTION shall retain all such Records for up to three (3) years beyond the period required by Applicable Law.

8. INSPECTIONS / AUDITS / MONITORING OF STUDY

A. Inspections / Audits. INSTITUTION and PRINCIPAL INVESTIGATOR agree to permit representatives of SPONSOR (including monitors, auditors and inspectors), the FDA, and any other appropriate governmental authority, to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw Study Results including original Source Documents (as defined by current ICH Guidelines), regardless of media, if allowed under the terms of the Informed Consent, (iii) EDC equipment and/or EDC documentation system, and (d) any other relevant information (and to make copies) necessary for SPONSOR to confirm that the Study is being conducted in conformance with the Protocols and in compliance with Applicable Law.

B. Inspection by SPONSOR. INSTITUTION and PRINCIPAL INVESTIGATOR agree to assist SPONSOR, to the extent deemed reasonable by Parties, in order to facilitate SPONSOR's representatives' examination, inspection, auditing and copying of materials relating to the Studies and in order to enforce the rights granted to SPONSOR hereunder.

C. Regulatory Inspections. INSTITUTION shall immediately notify SPONSOR or its designee if the FDA or any other appropriate governmental or regulatory authority schedules or, without scheduling, begins an inspection of the facilities or the Records relating to the Studies. If not prohibited by Applicable Law, SPONSOR shall have the right to be present during and participate in any such inspection, audit, investigation, or regulatory action. INSTITUTION or PRINCIPAL INVESTIGATOR shall promptly, upon issuance, provide SPONSOR with copies of any FDA or any other appropriate governmental or regulatory authority correspondence resulting from any such inspection.

D. Corrective Action. INSTITUTION and PRINCIPAL INVESTIGATOR agree to take any reasonable actions requested by the FDA or any other appropriate governmental or regulatory authority to cure deficiencies noted during an audit or inspection.

E. Monitoring of Study by SPONSOR. SPONSOR monitors will be suitably qualified by training and experience. INSTITUTION and/or PRINCIPAL INVESTIGATOR will ensure that Study Records are ready for review prior to each visit. Visits will be at the mutual convenience of the Parties. SPONSOR agrees that its personnel will abide by INSTITUTION's policies and procedures while present at the Study facilities.

F. Report of Findings Relating to Patient Safety. In accordance with Applicable Law, SPONSOR shall report to INSTITUTION findings detected during monitoring of the Studies at all participating Study sites that could affect the safety of Study subjects or their willingness to continue participation, influence the conduct of the Studies, or alter the IRB's approval to continue the Studies. If Study subject safety or medical care is directly affected by such findings, SPONSOR shall cooperate to ensure that such findings are communicated to Study subjects. SPONSOR shall communicate findings to

INSTITUTION and/or PRINCIPAL INVESTIGATOR, who will then participate with the IRB to communicate the findings and/or results to Study subjects.
For each Study, SPONSOR will be responsible for the cost of the diagnosis and medical treatment of any Study-related injury.

9. CONFLICT WITH LAW / THIRD PARTY PAYER PROGRAM COMPLIANCE / DEBARMENT / NOTICE TO STUDY PERSONNEL

A. Conflict of Agreement with Applicable Law. In the event that any part of this Agreement is determined to be in violation of, or conflict with, any Applicable Law, the Parties agree to negotiate in good faith revisions to the offending provision or provisions. In the event the Parties are unable to agree to new or modified terms as required to bring the entire Agreement into compliance with Applicable Law, either Party may terminate this Agreement upon sixty (60) days' written notice to the other Party, and the relevant provisions of the Term and Termination Section of this Agreement shall apply.

B. Medicare, Medicaid, and Other Third Party Payer Program Compliance. It is INSTITUTION's policy to conduct activities in accordance any Applicable Law regarding Medicare, Medicaid, and other third party payer programs. Therefore, INSTITUTION certifies that:

(i) Neither it nor any of its employees or Affiliates is excluded from participation in any state or federal healthcare program, as defined in 42 USC Section 1320a-7b(f) for the provision of items or services for which payment may be made by a federal healthcare program;

(ii) It has not entered into an agreement with any contractor, agent, vendor or vendor's Affiliate knowing that the contracting party is excluded from participation in any state or federal healthcare program; and

(iii) No final adverse action, as defined in 42 USC Section 1320a-7e(g)(1) and 42 USC Section 1320a-7a(g), has occurred or is pending against it or its Affiliates or contractors.

(iv) By signing this Agreement, INSTITUTION agrees to notify SPONSOR of any final adverse action, discovery of contract with an excluded entity or individual, or exclusion (as defined above) within thirty (30) days of such action.

C. Debarment. INSTITUTION shall not employ, contract with or retain any person directly or indirectly to perform services under this Agreement if such a person is:

(i) excluded from a Federal health care program as outlined in Sections 1128 and 1156 of the Social Security Act (see the Office of Inspector General of the Department of Health and Human Services List of Excluded Individuals/Entities at http://www.oig.hhs.gov/Fraud/exclusions/listofexcluded.html);

(ii) debarred by the FDA under 21 U.S.C. 335a (see the FDA Office of Regulatory Affairs Debarment List at http://www.fda.gov/ora/compliance_ref/debar/); or

(iii) excluded from contracting with the federal government (see the Excluded Parties Listing System at http://epls.arnet.gov.

D. INSTITUTION shall provide all information to SPONSOR necessary to comply with any disclosure requirements mandated by the FDA, or other Applicable Law, including any information required to be disclosed in connection with any financial relationship between SPONSOR and PRINCIPAL INVESTIGATOR, or between SPONSOR and any other Study Personnel, and/or any other agent or employee of INSTITUTION.

E. INSTITUTION agrees to immediately inform SPONSOR in writing if any Study Personnel or other person who is performing services hereunder meets one or more of the criteria in (C)(i),(ii) or (iii) above, or if to the best of INSTITUTION'S, any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of INSTITUTION'S knowledge, is threatened, relating to the debarment of INSTITUTION, PRINCIPAL INVESTIGATOR, Study Personnel, or any person performing services hereunder.

10. INDEMNIFICATION

A. SPONSOR Indemnification. SPONSOR agrees to indemnify, defend and hold harmless INSTITUTION, its trustees, officers, employees, staff, contractors, affiliated hospitals, agents and Study Personnel ("**INSTITUTION Indemnitees**") against any independent third party claims, losses, injuries, or other damages (each, a "**Third Party Claim**") arising out of:

(i) any theory of product liability concerning the Study Drug;

(ii) any side-effect or adverse reaction, illness or injury directly resulting from use of the Study Drug in the Studies;

(iii) the proper performance of the Protocol; or

(iv) SPONSOR's use of the data/results provided to it by INSTITUTION and/or PRINCIPAL INVESTIGATOR as part of the Study, including any products or tangible items developed or made therefrom.

The foregoing indemnity will not apply to the extent a Third Party Claim arises out of:

(i) the negligence, omission or willful misconduct or professional malpractice of any INSTITUTION Indemnitee; or

(ii) the failure of any INSTITUTION Indemnitee to adhere to the terms of this Agreement, the Protocols or any written instructions from SPONSOR or its designee or to comply with Applicable Law.

B. INSTITUTION Indemnification. INSTITUTION agrees to indemnify, defend and hold harmless the SPONSOR, its directors, officers, employees, staff and agents (the "**SPONSOR Indemnitees**") against any Third Party Claim arising out of the;

(i) negligence, omission or willful misconduct of any INSTITUTION Indemnitee; or

(ii) failure of any INSTITUTION Indemnitee to adhere to the terms of this Agreement, the Protocols or any written instructions from the SPONSOR or its designee or to comply with Applicable Law.

INSTITUTION 's obligation to indemnify and hold SPONSOR Indemnitees harmless shall be limited in substance by statutes designed to protect and limit the exposure and liability of INSTITUTION as an instrumentality of the State of Indiana (e.g., actions and conditions as to which INSTITUTION is immunized by the Indiana Medical Malpractice Act, the Indiana Tort Claims Act, dollar limits stated in such Acts, exemption from punitive damages, and the continued ability to defeat a claim by reason of contributory negligence or fault of the claimant), so that INSTITUTION 's liability to defend, indemnify and hold harmless shall not exceed what might have been its liability to claimant if sued directly by claimant and all appropriate defenses had been raised by INSTITUTION.

C. Indemnification Procedure. The Party or Parties seeking indemnification under this Section 11 shall;

(i) give prompt written notice to the indemnifying Party after receiving any Third Party Claim or learning of any potential Third Party Claim; and

(ii) permit the indemnifying Party to assume the defense and/or disposition of any such Third Party Claim or related litigation, provided that counsel selected by such indemnifying Party is reasonably acceptable to the Party or Parties seeking indemnification.

D. The indemnifying Party under this Section 11 shall not enter into any settlement agreement with a Third Party claimant or admit fault or liability without the prior written permission of the Party or Parties seeking indemnification, which permission shall not be unreasonably withheld.

11. INSURANCE

INSTITUTION and PRINCIPAL INVESTIGATOR shall secure and maintain in full force and effect through the performance of the Studies by PRINCIPAL INVESTIGATOR and Study Personnel (and following termination of the Studies to cover any claims arising from the Studies. Upon request of SPONSOR, copies of certificates evidencing such insurance coverage will be made available to

SPONSOR and INSTITUTION shall provide thirty (30) days prior written notice to SPONSOR in the event of cancellation or any material change in such insurance. If requested by SPONSOR, SPONSOR shall be named as an additional insured on all insurance policies.

12. CONFLICT OF INTEREST

INSTITUTION and PRINCIPAL INVESTIGATOR (i) have no conflict of interest that would affect conduct of the Studies, and (ii) have received no offer by SPONSOR, or on SPONSOR's behalf, of extra benefit for participation in the Studies, including offers to family members. INSTITUTION and PRINCIPAL INVESTIGATOR shall promptly notify SPONSOR if any conflict of interest arises during the term of this Agreement. INSTITUTION and PRINCIPAL INVESTIGATOR shall enter into no financial security transaction based on the Study Results. INSTITUTION has policies and procedures to discover, manage, report, and, where possible, eliminate conflicts of interest.

13. STUDY DRUG

A. SPONSOR shall make commercially reasonable efforts to provide sufficient quantities of Study Drugs on a timely basis. All Study Drugs shall be used by the INSTITUTION and Study Personnel under the supervision of PRINCIPAL INVESTIGATOR. INSTITUTION shall be responsible for ensuring that:

(i) all Study Drugs are kept in a locked, secured area at all times, and that complete, up-to-date records are maintained showing receipt, dispensing, and returns of the Study Drugs as required by the Protocols, this Agreement, and Applicable Law;

(ii) all Study Drugs are stored at such temperature and other conditions as reasonably required by SPONSOR.

(iii) PRINCIPAL INVESTIGATOR does not supply Study Drugs to any person not authorized under Applicable Law.

(iv) PRINCIPAL INVESTIGATOR shall be responsible for the control of, access to and administration of the Study Drugs in compliance with Applicable Law.

B. INSTITUTION shall not, and will ensure that Study Personnel, including PRINCIPAL INVESTIGATOR, shall not, make any use whatsoever of Study Drugs provided by SPONSOR other than for the performance of the Studies, nor conduct any research activities with the Study Drugs which are contrary to the provisions of the Protocols or outside the scope of the Protocols or this Agreement.

C. Upon completion or earlier termination of this Agreement, INSTITUTION will ensure that use of the Study Drugs shall immediately cease, and all unused Study Drugs shall be accounted for and promptly returned to SPONSOR or its designee or destroyed if so directed by SPONSOR.

D. PRINCIPAL INVESTIGATOR, AND INSTITUTION UNDERSTAND, ACKNOWLEDGE, AND AGREE THAT THE STUDY DRUG IS INVESTIGATIONAL IN NATURE AND THAT NO WARRANTY, EITHER EXPRESSED OR IMPLIED, IS MADE REGARDING THE STUDY DRUGS. WITHOUT LIMITING THE FOREGOING, SPONSOR EXPRESSLY DISCLAIMS ANY WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE OF STUDY DRUGS.

14. INDEPENDENT CONTRACTOR

INSTITUTION and PRINCIPAL INVESTIGATOR are acting in the capacity of independent contractors hereunder and not as employees or agents of SPONSOR, and shall not, and will ensure that Study Personnel shall not, make any claim against SPONSOR for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers' compensation, disability or unemployment benefits or employee benefits of any kind.

15. PUBLICITY

None of the Parties shall use the name of any other Party for promotional purposes without the prior written consent of the Party whose name is proposed to be used, nor shall either Party disclose the existence or substance of this Agreement except as required by Law.

16. CONTROLLING LAW

This Agreement shall be governed by and construed in accordance with the laws of the State of Indiana without regard to any conflicts of laws provisions.

17. NOTICE

All notices hereunder shall be in writing and shall be deemed to have been duly given when delivered personally or by overnight courier, telecommunicated, sent by prepaid telegram or mailed by certified mail, postage prepaid, to the Parties set forth below. The addresses and/or contact persons may be changed by either Party by providing notice to the other in the manner set forth herein.

(i)TO SPONSOR:
(ii)TO INSTITUTION:
Indiana University
Attn: Clinical Trials Office
410 West 10th Street
Suite 1020
Indianapolis, IN 46202

18. FORCE MAJEURE

If the performance of this Agreement is prevented, restricted, interfered with or delayed, (either totally or in part) by reason of any cause beyond the reasonable control of the Parties (such as acts of God, explosion, disease, weather, war, terrorism, insurrection, civil strike, riots or power failure), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable best efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. For purposes of this Section, a lack of funds shall not be considered a cause beyond the reasonable control of the Parties.

19. AGREEMENT MODIFICATIONS

No agreements amending, altering or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of each of the Parties.

20. ASSIGNMENT

SPONSOR shall have the right to assign this Agreement to an Affiliate of SPONSOR upon prior written notice to INSTITUTION. In all other instances, neither Party shall assign its rights or duties under this Agreement to another without prior written consent of the other Party. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective Parties and their successors and assigns.

21. CONFLICT WITH PROTOCOL

If a provision of this Agreement conflicts with a provision of the Protocols, the Protocols takes precedence on matters of medicine, science and conduct of the Studies. This Agreement takes precedence in any other conflicts.

22. WAIVER AND SEVERABILITY

No waiver by either Party of any breach of any provision hereof shall constitute a waiver of any other breach of that or of any other provision hereof. In the event that a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, and they shall continue in full force and effect.

23. SURVIVAL

The rights and obligations of SPONSOR, INSTITUTION and PRINCIPAL INVESTIGATOR, which by intent or meaning have validity beyond termination of this Agreement (including, but not limited to, rights with respect to ownership, patents, confidentiality, and indemnification) shall survive the termination of this Agreement.

24. HEADINGS

Headings used in this Agreement are for the purpose of convenience only and do not affect the interpretation or construction of the Agreement itself.

25. ENTIRE AGREEMENT

This Agreement together with all attachments hereto constitutes the entire agreement among the Parties with respect to the subject matter hereof, and all prior negotiations, representations, agreements and understandings are superseded hereby. The terms of this Agreement, which are legally binding, shall prevail in all respects over the rules or guidelines of any group or association of healthcare professionals (collectively "**Guidelines**") to which INSTITUTION may be affiliated at any time during the term of this Agreement, and INSTITUTION expressly agrees and acknowledges that in the event of a conflict between this Agreement and such Guidelines, the terms of this Agreement shall prevail.

26. COUNTERPART SIGNATURES

This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original copy of the Agreement, and all of which, when taken together, shall be deemed to constitute one and the same Agreement. Signatures to this Agreement transmitted by fax, by electronic mail in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of the Agreement, shall have the same effect as physical delivery of the paper document bearing the original signature. Further, the Parties consent to use DocuSign, ISO/IEC 27001 certified e-signature service for purposes of electronically signing this Areement, which e-signature shall be given the same legal force and effect as the physical delivery of this Agreement bearing an original manual signature.

27. AUTHORIZED REPRESENTATIVES

Each signatory to this Agreement personally represents that, to the best of his/her knowledge, he/she has authority to legally bind his/her respective Party to this Agreement. The signatories are not otherwise Parties to this Agreement, except as elsewhere set forth in this Agreement.

[SIGNATURES ON NEXT PAGE]

IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound, have caused this Agreement to be executed by their duly authorized representatives, as of the Effective Date.

SPONSOR, INC.

By: _____

_____
Name

_____
Title

TRUSTEES OF INDIANA UNIVERSITY

By: _____

_____
Name

_____
Title

Attachments:

EXHIBIT A: Work Order Template

EXHIBIT A

WORK ORDER TEMPLATE

This Work Order ("WO"), effective as of ENTER DATE ("Effective Date"), is by and between **SPONSOR, INC.**, (hereinafter, "**SPONSOR**"), on behalf of itself, and its affiliates, with offices at_____, and **TRUSTEES OF INDIANA UNIVERSITY** (hereinafter, "**INSTITUTION**"), with offices atClinical Trials Office, 550 University Boulevard, AOC 5012, Indianapolis, IN 46202. SPONSOR and INSTITUTION shall be referred to individually as a "Party" or collectively referred to as the "Parties".

WHEREAS, SPONSOR and INSTITUTION are Parties to a Master Clincial Trial Agreement effective ENTER DATE ("Master Agreement"). Under the Master Agreement, SPONSOR and INSTITUTION are executing this WO to contract for the following Study (as described below).

1. **The Study.** The Study will be conducted under the direction ans supervision of an employee of the INSTITUTION, ENTER NAME, with assistance from associates as may be required ("the PRINCIPAL INVESTIGATOR"). The INSTITUTION and PRINCIPAL INVESTIGATOR shall use any equipment, property, or materials received from SPONSOR only in accordance with the terms hereof, and not for any purpose other than in connection with the Study. Upon termination or discontinuance of the Study for any reason, all unused supplies of materials and other equipment or property shall be returned to SPONSOR. The Protocol is included as Exhibit A.

Protocol: ENTER INFO
Study Drug: ENTER INFO

2. **Study Site Information.**

PRINCIPAL INVESTIGATOR: ENTER INFO
PRINCIPAL INVESTIGATOR Address: ENTER INFO

4. **Incorporation by Reference.** The terms and conditions of the Master Agreement are hereby incorporated by reference and made a part of this WO. All defined terms in the Master Agreement shall have the same meaning when used in this WO.

5. **Entire Agreement.** This WO represents the entire and integrated agreement between SPONSOR and INSTITUTION and supersedes all prior negotiations, representations or agreements, either written or oral, regarding the Study.

IN WITNESS WHEREOF, the parties have caused this Study Specific Agreement to be duly executed by their authorized representatives.

SPONSOR	THE TRUSTEES OF INDIANA UNIVERSITY
By:_____	By:_____
Name: _____	Name: _____
Title: _____	Title: _____
Date:_____	Date:_____

By my signature, I indicate that INSTITUTION has made the Master Agreement available to me and that I am aware of its terms and also indicate my agreement to fulfill the role and obligations of PRINCIPAL INVESTIGATOR under this WO and Master Agreement.

_____ _____

Principal Investigator Date

Exhibit A

[Attach Study Protocol]

Exhibit B

[Attach Study Budget]

Authorized Payee/ Address: Trustees of Indiana University

Tax Identification Number: