

**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](mailto:ocr@iu.edu)**

## **FACILITY USE AGREEMENT**

**THIS FACILITY USE AGREEMENT** (“Agreement”) is entered into by and between Indiana University Health, Inc., an Indiana corporation under the state laws of Indiana, located at 340 W. 10<sup>th</sup> Street, Suite 6100, Indianapolis, Indiana 46202 (“Hospital”) and **INSERT SPONSOR INFORMATION** (“Sponsor”) (individually a “party”; collectively “parties”).

**WHEREAS**, The Trustees of Indiana University, an educational institution with an address Office of Clinical Research, 550 University Boulevard, AOC 5012, Indianapolis, IN 46202 (“Institution”) has entered into an agreement with Hospital, whereby Hospital permits credentialed principal investigators who are employees of Institution to use its facilities to perform research;

**WHEREAS**, Sponsor and Institution have entered into a clinical trial agreement (“Clinical Trial Agreement”) to conduct a study under the Protocol No. **ENTER NUMBER** which is entitled “**STUDY NAME**” (the “Protocol” or the “Study”) to be conducted by **PI NAME**, M.D., an employee of the Institution (“Principal Investigator”), in accordance with the Clinical Trial Agreement, all applicable federal, state and local laws, and the IRB/IEC (defined below) approved Protocol, as properly amended and any other written instructions that may be provided from time to time by Sponsor; and

**WHEREAS**, Principal Investigator and Institution will utilize Hospital and certain Hospital facilities and equipment to conduct certain Study procedures.

**NOW THEREFORE**, in consideration of the above recitals, mutual covenants and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby wish to agree to the following terms and conditions to provide for the use of Hospital’s facility as follows:

1. Conduct of Study.

- (a) Hospital shall ensure that its research office approves the Study prior to the initiation of the Study at Hospital. The parties agree that the Study procedures performed at the Hospital are performed under the supervision and direction of Principal Investigator. Subject to the direction of Principal Investigator, Hospital shall strictly adhere to the terms of the Protocol applicable to Hospital and with Sponsor’s written instructions provided to Hospital by Institution.
- (b) Hospital shall arrange for qualified medical, technical, laboratory, and personnel services necessary to support its obligations under the Protocol in accordance with this Agreement.

**CONFIDENTIAL**

## 2. Compliance with Law.

- (a) Hospital represents, warrants and covenants that it will participate in the Study and perform its obligations under this Agreement in compliance with all applicable federal, state and local laws, regulations and guidelines, including but not limited to, the Medicare/Medicaid Anti-kickback statute, the Social Security Act of 1935, as amended, the Controlled Substances Act, as amended, and the regulations promulgated thereunder, including the U.S. Drug Enforcement Agency (“DEA”) regulations at 21 C.F.R. § 1300 et seq, the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”), and the regulations promulgated thereunder, and the Federal Food, Drug and Cosmetic Act of 1938, as amended (the “Act”), and all applicable regulations promulgated thereunder including regulations of the United States Food and Drug Administration (the “FDA”) or its foreign equivalent, including, without limitation, 21 C.F.R. Parts 50, 54, 56, 312 and 11 (the regulations governing the protection of human subjects, financial disclosure of clinical investigators, Institutional Review Boards or its foreign equivalent (“IRB”), and investigational new drug applications; electronic records; electronic signatures). Hospital will comply with the directives of the IRB or Independent Ethics Committee (“IEC”) or both, as applicable, respecting the conduct of the Study, and will notify Principal Investigator and Sponsor to the extent any such directives vary from the Protocol.
- (b) Hospital agrees that, if compounds, materials and information which the Protocol specifies or other materials as Sponsor deems necessary to conduct the Study (together, the “Study Materials”) provided to Hospital and/or other services are paid for or provided without charge by Sponsor, Hospital shall not separately bill or seek reimbursement for such Study Materials and/or services from any third party including, without limitation, the subject, any private provider of insurance, or any federal or state program (e.g., Medicare, Medicaid, Tricare, Department of Veterans Affairs programs, state Children’s Health Insurance Program (CHIP) programs, and block grant programs under titles V and XX of the Social Security Act). If the Study involves subjects whose Study Materials and/or services are covered under global payments systems, such as Diagnosis Related Groups (“DRGs”), Hospital will treat any such Study Materials or services paid for or provided without charge by Sponsor as part of the Study under the billing procedures applicable to such payment system. Hospital will further report receipt of such Study Materials to any applicable federal, state or private insurance program, as may be required by applicable law.

## 3. Monitoring of Study; Record Retention.

- (a) Hospital will permit Sponsor and any Sponsor designee access to Study sites during normal business hours to monitor the conduct of the Study as well as to audit records, source documents, and other data relating to the Study to verify Hospital’s, Institution’s and Principal Investigator’s compliance with their respective obligations, provided that Hospital may redact such records, source documents, and other data as may be legally required to protect subject confidentiality. Hospital shall retain the Study documents in accordance with the applicable laws and regulations or the Protocol, whichever retention period is longer. Sponsor’s right to audit shall survive the expiration of this Agreement. If, as a result of Study monitoring, Sponsor requests corrective and/or preventive action,

**CONFIDENTIAL**

Institution shall comply with the timely creation and implementation of a corrective action and/or preventive action plan. At all times Sponsor shall remain the sole owner of all Study records; provided however, Hospital shall remain the sole owner of original source documents.

- (b) Hospital will, to the extent permitted by applicable law, notify Sponsor immediately upon receiving any requests by any properly authorized officer or employee of any regulatory authority to inspect and/or have access to documents related to the Study and will promptly provide Sponsor with a copy of any documents received from or provided to regulatory authorities. In the event a regulatory citation or notice (e.g. Form FDA 483) is issued which relates to the services under this Agreement, Hospital agrees, to the extent permitted by law, to furnish to Sponsor of such regulatory citation or notice, a summary of such regulatory citation or notice that includes an explanation of the issues identified by the regulatory authority, an explanation of any response to the significant issues identified by the regulatory authority, and an explanation of the applicability of such regulatory citation or notice to the service(s) provided hereunder.
4. Compensation. Except as provided in Section 13 (Subject Direct Injury) herein, Hospital acknowledges and agrees that Sponsor shall make no payments directly to Hospital and that all payments from Sponsor in connection with the Study shall be paid to Institution. Institution shall be fully and solely responsible for making any and all payments to Hospital, for its Study-related services and expenses in connection with fulfilling its obligations herein.
5. Confidentiality.
- (a) During the Term of this Agreement, including any extensions thereof, and for a period of seven (7) years after the expiration or termination of this Agreement, Hospital, its employees, agents, subcontractors and affiliates (collectively, “Receiving Party”) shall not disclose Confidential Information (other than to Institution, Principal Investigator, Sponsor or Sponsor-designated parties) without Sponsor's prior written consent. Notwithstanding the foregoing, obligations of confidentiality and non-use with respect to any Confidential Information identified as a trade secret by Sponsor shall survive indefinitely. “Confidential Information” shall include any information provided to Receiving Party by or on behalf of Sponsor, including but not limited to the Protocol, Study Materials, and all materials and information concerning Sponsor or the Study or developed as a result of the Study, except any portion thereof which:
- (i) is known to the Receiving Party prior to receipt thereof under this Agreement, as evidenced by its written records;
  - (ii) is disclosed to the Receiving Party after acceptance of this Agreement by a third party who has a right to make such disclosure in a non-confidential manner;
  - (iii) is or becomes part of the public domain through no fault of the Receiving Party;
  - (iv) is developed independently by employees of the Receiving Party who had no access to or knowledge of the Confidential Information, as evidenced by Receiving Party's records;

**CONFIDENTIAL**

- (v) is approved for release by written authorization of the Sponsor; or
  - (vi) is required to be disclosed by applicable law (including Indiana's Open Records 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 request.
- (b) During the Term and thereafter, the Receiving Party shall not use Confidential Information for any purpose other than that indicated in this Agreement without Sponsor's prior written approval.
- (c) Nothing in this Agreement will be construed to restrict Receiving Party from disclosing Confidential Information as required by applicable law or court order or other governmental order or request, provided in each case Receiving Party shall give Sponsor prompt written notice in order to allow Sponsor to take whatever action it deems necessary to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Sponsor waives compliance with the terms of this Section 5, Receiving Party shall furnish only that portion of the Confidential Information which it is advised by counsel as being legally required. In addition, Receiving Party will permit Sponsor to attempt to limit such disclosure by appropriate legal means.
- (d) None of Hospital, Hospital's employees, agents, subcontractors or affiliates will disclose to Sponsor any information which is confidential or proprietary to a third party unless Hospital has first obtained the prior written approval of both such third party and Sponsor.

6. Subject Confidentiality; Data Protection.

- (a) The parties agree to abide by all applicable laws and regulations regarding subject confidentiality and data protection. Hospital acknowledges that Principal Investigator shall be responsible for ensuring that all consents and authorizations required by applicable law are obtained from Study subjects, in accordance with the Clinical Study Agreement and applicable law.
- (b) Where Hospital collects, retains, processes or discloses information identifying or, in combination with other information, identifiable to a living individual, including Study subjects and others, participating in or associated with the Study ("Personal Data"), in performing its obligations under this Agreement, it shall only do so in accordance with this Agreement, with all applicable laws and Sponsor's written instructions or Hospital's documented standard operating procedures. Hospital shall adopt appropriate safeguards to ensure the confidentiality and security of the Personal Data. Hospital shall promptly inform Sponsor about any unauthorized access to or disclosure of Personal Data ("Security Breach"), including the timing and nature of the Security Breach, and take all reasonable measures to remedy the Security Breach. Where applicable data protection laws require that the parties enter into additional agreements or undertakings, including international data transfer agreements, Hospital will undertake to ensure that all necessary agreements are implemented and in place.

**CONFIDENTIAL**

7. Publicity. Except as may be required by applicable law, Hospital shall not and shall ensure that Receiving Party shall not disclose the existence or terms of this Agreement or use the name, trademark, servicemark or logo of Sponsor in any publicity, advertising or information, which is disseminated to any third person or to the general public without Sponsor's prior written approval. Hospital understands and agrees that the terms and conditions of this Agreement, including the amount of any payment made hereunder, may be disclosed and made public by Sponsor as required by applicable law or regulation or where Sponsor deems appropriate.
8. Inventions. Any information, invention, data or discovery (whether patentable or copyrightable or not), innovation, communication or report, conceived, reduced to practice, made, generated or developed by the Receiving Party that either results from use of any of the Study Materials or results from conduct of the Study will be promptly disclosed to Sponsor, assigned to Sponsor and will be the sole property of Sponsor. Hospital agrees, upon Sponsor's request and at Sponsor's expense, to execute or cause to have executed such documents and to take such other actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name covering any of the foregoing.
9. Publications and Presentations. Hospital shall not present or publish, or submit for publication, any work resulting from the services hereunder or Study without Sponsor's prior written approval.
10. Representations and Warranties.
- (a) Each party represents and warrants that:
- (i) neither this Agreement nor any payment that may be made hereunder in exchange for any explicit or implicit agreement or understanding that Hospital purchase, lease, order, prescribe, recommend or otherwise arrange for, or provide formulary or other preferential or qualifying status for the use of Sponsor products; and
  - (ii) the total payment for Hospital's Study-related services and/or expenses under this Agreement represents the fair market value for the services and/or expense and has not been determined in any manner that takes into account the volume or value of any referrals or business between Hospital and Sponsor.
- (b) Hospital represents and warrants:
- (i) that the terms of this Agreement are valid and binding obligations of Hospital, and are not inconsistent with any other contractual or legal obligation it may have or with Hospital's policies and procedures or the policies and procedures of any institution or company with which each of Hospital is associated;
  - (ii) Hospital shall obtain and keep in full force and effect any licenses, certifications, accreditations, permits or registrations necessary for Hospital to provide its facilities and services under this Agreement;

**CONFIDENTIAL**

- (iii) If performance of the services under this Agreement involves the recording or transmittal to Sponsor of electronic data, Hospital shall comply with the applicable laws and regulations regarding electronic data obligations; and
- (iv) Hospital shall observe safe and diligent handling procedures of provided Study Materials.
- (c) During the term of this Agreement, if any significant changes occur with regard to the circumstances surrounding this Agreement (e.g., there is a change in a policy or procedure that could reasonably be interpreted to affect the propriety of Hospital's involvement in this Agreement), Hospital agrees to immediately notify Sponsor in writing of any such changes.

#### 11. Term and Termination.

- (a) The term of this Agreement shall begin upon full execution by the parties (the "Effective Date") and shall continue until the obligations under the Clinical Trial Agreement are accomplished, unless terminated earlier as provided in this Section 11.
- (b) Either party may terminate this Agreement upon written notice to the other party if: (A) the other party has breached a material term of this Agreement; or (B) in the event of termination of the Study by the FDA or any other governmental or regulatory authority.
- (c) Sponsor may immediately terminate this Agreement upon written notice to Hospital if: (A) in Sponsor's sole judgment, an adverse safety concern with respect to Study Materials makes continued testing unadvisable; or (B) Hospital, its employees or agents providing services for the Study under this Agreement becomes a Debarred, Excluded, or Convicted Entity or Individual, or becomes the subject of a proceeding which could lead to that party becoming a Debarred, Excluded, or Convicted Entity or Individual; or becomes added to FDA's Disqualified/Restricted List for clinical investigators pursuant to Section 15 (Debarment and Exclusion) of this Agreement.
- (d) Sponsor may terminate this Agreement without cause upon at least thirty (30) days prior written notice to Institution.
- (e) Termination or expiration of this Agreement will not affect any rights or obligations which have accrued prior thereto.

#### 12. Indemnification.

- (a) Sponsor will indemnify, defend, and hold harmless Hospital, Hospital's officers, and all other employees of Hospital or contractors in their capacity as agents of Hospital working under the direct supervision of the Principal Investigator ("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 (collectively, "Losses") made by a third-party related to the conduct of the Study in accordance with the Study Protocol ("Procedures") or 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.

**CONFIDENTIAL**

Sponsor's indemnification obligation hereunder will not apply to the extent any Losses are attributable, whether directly or indirectly, to the negligence, recklessness or willful misconduct of any of the Indemnitees, or their employees, agents, subcontractors, affiliates or third parties. Notwithstanding anything herein to the contrary, Sponsor's obligation to defend and indemnify Indemnitees hereunder will not in any event exceed an aggregate amount, including any and all Losses claimed hereunder, of Five Million Dollars (\$5,000,000).

(b) The foregoing agreement to indemnify Indemnitees is conditioned upon the following obligations of Indemnitees to:

- (i) advise Sponsor of any claim or lawsuit, in writing addressed to Sponsor, Attention: **INSERT ADDRESS**
- (ii) assist Sponsor and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and
- (iii) not compromise or otherwise settle any such claim or lawsuit without Sponsor's prior written consent.

### 13. Subject Direct Injury.

If during the course of the Study any injury occurs to a subject as a direct result of the Study Product or Procedures required by the Protocol ("Subject Direct Injury"), Sponsor agrees to pay all reasonable medical expenses necessary to treat such Subject Direct Injury, provided that the Study subject follows the directions of the investigators. The foregoing shall not apply where the Subject Direct Injury is due to the negligence, recklessness or willful misconduct of Hospital, its officers, agents, or employees, or their failure to follow the Protocol. Hospital and Sponsor agree that Hospital will only seek reimbursement of medical expenses for a Subject Direct Injury from Sponsor.

### 14. Insurance.

- (a) Each party agrees to maintain, at its own cost and expense, in full force and effect a policy or policies of insurance sufficient to satisfy its respective duties and obligations under this Agreement to the extent such duties and obligations are commercially insurable. Specifically, Hospital agrees to procure and maintain in full force and effect throughout the Term policies of (i) public/general liability and professional liability insurance; (ii) worker's compensation and occupational disease insurance with statutory limits and employer's liability coverage with a minimum limit as may be required by applicable law; and (iii) automobile liability insurance covering all owned, non-owned and hired vehicles in limits as may be required by applicable law.
- (b) Each party further agrees to promptly provide written evidence of such insurance (including certificates of insurance and/or other evidence providing reasonable assurances and proof of financial stability) to the other party following receipt of written request by the other party therefore.

### 15. Debarment and Exclusion.

**CONFIDENTIAL**

- (a) Hospital represents and warrants that none of Hospital, any Hospital employees, agents and subcontractors performing hereunder, have ever been, are currently, or are the subject of a proceeding that could lead to Hospital or such employees, agents or subcontractors becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual, nor are they listed on the FDA's Disqualified/Restricted List for clinical investigators. Hospital further covenants, represents and warrants that if, during the Term, Hospital, or any of Hospital's employees, agents or subcontractors, performing hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual, or added to FDA's Disqualified/Restricted List for clinical investigators, Hospital will immediately notify Sponsor, and Sponsor will have the right to immediately terminate this Agreement. This provision will survive termination or expiration of this Agreement.
- (b) Sponsor hereby certifies that as of October, 2010, it has not been, and their principals have not been, debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. §335a(a) and (b), or sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. Sec. 1320 a-7b(f)), including, but not limited to the federal Medicare or a state Medicaid program, or debarred, suspended, excluded or otherwise declared ineligible from any Federal agency or program. In the event that during the term of this Agreement, Sponsor (i) becomes Debarred, suspended, Excluded, sanctioned, or otherwise declared ineligible; or (ii) receives notice of an action or threat of an action with respect to any such debarment, suspension, exclusion, sanction, or ineligibility, Sponsor shall immediately notify Hospital. Sponsor also agrees that, in the event that either it or its principals becomes Debarred, suspended, Excluded, sanctioned, or otherwise declared ineligible, Sponsor shall immediately notify the Hospital.
- (c) For purposes of this provision, the following definitions will apply:
- (ii) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to Title 21 of the United States Code ("USC") Section 335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application.
  - (iii) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to Title 21 of USC Section 335a(a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.
  - (iv) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services; or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

**CONFIDENTIAL**

- (v) A “Convicted Individual” or “Convicted Entity” is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of Title 21 of USC Section 335a(a) or Title 42 of USC Section 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.
- (vi) “FDA’s Disqualified/Restricted List” is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.

16. Independent Contractor. Hospital’s relationship to Sponsor under this Agreement is that of an independent contractor, and Hospital does not have the authority to bind or act on behalf of Sponsor. Hospital represents and warrants that neither the Institution nor the Principal Investigator is an employee, agent, representative, partner or joint venture of the Hospital, and neither is authorized to act on behalf of or bind the Hospital.

17. Assignment.

Hospital may not assign this Agreement to any other party, or subcontract any of its services hereunder, without Sponsor’s prior written consent. Any attempted assignment without Sponsor’s prior written consent will be null and void and will constitute a material breach of this Agreement. Any permitted assignee shall assume all obligations of Institution under this Agreement. Assignment shall not relieve Hospital of responsibility for the performance of any accrued obligation. Further, in the event that Hospital is permitted to subcontract any duty hereunder to any third party, such subcontractor shall execute an agreement in a form acceptable to Sponsor obligating such subcontractor to comply with the terms and conditions hereof, and Hospital shall remain responsible and liable for the acts or omissions of such subcontractor activities as if such activities had been performed by Hospital.

18. Notices. Any notice required or otherwise made pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile.

If to Hospital:

With a copy to:

If to Sponsor:

19. Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement, will remain in full force and effect.

**CONFIDENTIAL**

20. Severability. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

21. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.

Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto.

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

**SPONSOR**

**INDIANA UNIVERSITY HEALTH,  
INC.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**CONFIDENTIAL**