

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 Clinical Trials Office and agreed upon by the applicable parties. If you have any questions, please contact the IU Clinical Trials Office at 317-278-2546 and/or cto@iu.edu

DATE:	TBD
TO:	Indiana University Clinical Trials Office 410 West 10 th Street Suite 1020 Indianapolis, IN 46202
RE:	STUDY START-UP AGREEMENT
PROTOCOL:	“ INSERT PROTOCOL TITLE ”, Protocol #----- (the “Study”)

On behalf of **INSERT COMPANY’S LEGAL NAME AND ADDRESS** (“**INSERT COMPANY NAME**”) and the **Trustees of Indiana University, an educational institution organized under the laws of the State of Indiana, whose address is Clinical Trials Office, 410 West 10th Street, Suite 1020, Indianapolis, IN 46202** (“Institution”) intend to conduct the above-referenced Study and enter into a written Clinical Trial Agreement (“CTA”) between them. Before a full written CTA is completed, **INSERT COMPANY NAME** authorizes Institution, and Institution agrees that it may perform Study start-up activities in accordance with this Study Start-Up Agreement (“Agreement”).

Following receipt by **INSERT COMPANY NAME** of this fully executed Agreement, Institution’s federal form W-9 and Institution’s invoice shall be submitted to **INSERT COMPANY NAME** in accordance with the attached instructions. Upon **INSERT COMPANY NAME**’s confirmation of the completion of the following start-up activities, **INSERT COMPANY NAME** will:

1. Pay Institution a non-refundable Administration fee of \$_____ USD, without additional overhead charges for:
 - (a) Proper completion and submission to **INSERT COMPANY NAME** of all regulatory documents, including, but not limited to, FDA form 1572 and financial disclosure documents.
 - (b) Preparation of documentation required for Institutional Review Board (“IRB”) review, and submission of this documentation to the appropriate IRB.
 - (c) *Other activity fees as determined between the Parties?*
2. Pay Institution the following fee(s), without additional overhead charges:
 - (a) A one-time IRB review and approval fee upon receipt of Institution’s invoice accompanied by IRB invoice. If necessary, additional IRB review fees will be paid upon receipt of Institution’s invoice accompanied by IRB invoice.
 - (b) *Other?*
3. The parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities and that no payments by **INSERT COMPANY NAME** pursuant to this Agreement shall be passed in whole or in part, directly or indirectly, to any third party as a rebate or discount for the purchase of **INSERT COMPANY NAME** products.
4. Institution agrees that **INSERT COMPANY NAME** may make public the amount of funding provided to Institution by **INSERT COMPANY NAME** for this Agreement and may identify Institution and Investigator as part of this disclosure.

5. Either party may terminate this Agreement upon written notice to the other party. Notice by Institution via email to the designated Study Investigator, including a communication that **INSERT COMPANYNAME** is cancelling the planned Study, will constitute appropriate notice to Institution. In the event the parties are unable to fully execute a final written CTA or either party terminates this Agreement, **INSERT COMPANY NAME** will pay Institution as described above for completed activities and related fee(s) under this Agreement following receipt of an invoice submitted to **INSERT COMPANYNAME** in accordance with **INSERT COMPANY NAME** written instructions. The parties agree to in good faith discuss any additional work completed in connection with the Study and fair payment for such additional work as the case may be.

The parties acknowledge acceptance of this Agreement by countersigning below and returning a fully executed Agreement, both signatures having been completed by authorized signatories of the parties.

INSERT COMPANY NAME

By: _____

Name: _____

Title: _____

Date: _____

TRUSTEES OF INDIANA UNIVERSITY

By: _____

Name: _____

Title: _____

Date: _____

INSTITUTION FEDERAL TAX ID #: _____

Attachment A: Invoice Requirements

Attachment A:
Invoice Requirements

DRAFT