

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

LETTER OF INDEMNIFICATION

PROTOCOL: Protocol Number [REDACTED] ("Protocol")

STUDY: [REDACTED] ("Study")

This Letter of Indemnification ("LOI") is entered into by and between the Trustees of Indiana University, an educational institution organized under the laws of the State of Indiana, with an address Office of Clinical Research, 410 West 10th Street, Suite 1020, Indianapolis, IN 46202 ("Institution") and **INSERT SPONSOR INFORMATION** ("SPONSOR") (individually a "party"; collectively "parties"). [REDACTED], an employee of the Institution, shall serve as the principal investigator for this Study at the Institution ("Principal Investigator").

Indemnification

SPONSOR agrees to indemnify, defend, and hold harmless Institution, trustees, officers, employees, agents, affiliated hospitals, and directors (each a "Institution Indemnitee", collectively "Institution Indemnitees") from and against any suits, actions, claims, demands or judgments ("Claims") against Institution Indemnitees for any damages, liabilities, costs, and expenses (including reasonable attorneys' fees and costs of litigation at the trial and appellate levels) for Claims related to or arising from (i) the proper performance of the Study in accordance with the Protocol; (ii) the 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; and/or (iii) the negligence or willful misconduct of SPONSOR, SPONSOR's officers, employees, agents, or affiliates; ("Institution Claim"); provided that SPONSOR shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

- (i) failure by Institution Indemnitees to conduct the Study in accordance with the Study or applicable law; or
- (ii) the negligence or willful misconduct or material breach of statutory duty of Institution Indemnitees.

SPONSOR's indemnification obligation with respect to an Institution Claim is conditioned on:

- (i) Prompt written notification to the SPONSOR of the Institution Claim;
- (ii) Institution Indemnitees' agreement that SPONSOR has full control over the defense or settlement of the Institution Claim and to reasonably cooperate with

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SPONSOR in the defense or settlement of the Institution Claim; provided, that, SPONSOR will not settle any such Institution Claim without the written approval of the Institution nor admit any liability or wrongdoing by an Institution Indemnitee (such consent will not be unreasonably withheld); provided, however, that Institution shall have the right to employ separate legal counsel of its own choice and at its own expense; and

- (iii) Institution Indemnitees' agreement not to make any admission in respect of such Institution Claim or take any action relating to such Institution Claim prejudicial to the defense of it without the written consent of SPONSOR.

Study-related Injury

SPONSOR will pay all reasonable and customary fees for standard-of-care diagnosis, care, and treatment of any Study injury or illness provided, however, that:

- (i) the injury or illness was not caused by Institution Indemnitees' deviation from the Study, other current written instructions provided by SPONSOR to Institution, applicable laws and regulations, except to protect the safety and welfare of the Study subject;
- (ii) the injury or illness was not caused by the negligence or misconduct of Institution Indemnitees;
- (iii) the injury or illness is not attributable to any underlying illness, unless such injury or illness was exacerbated by the Study; and
- (iv) the Study drug/device was used and/or Study procedures were performed in accordance with the Study.

Any notice, request or other communication permitted or required under this LOI shall be in writing, shall refer specifically to this agreement and shall be deemed given only if hand delivered or sent by an internationally recognized overnight delivery service, costs prepaid, or by facsimile (with transmission confirmed), addressed to the parties at:

To SPONSOR	To Institution
INSERT INFORMATION	Indiana University 410 West 10 th Street, Suite 1020, Indianapolis Indianapolis, IN 46202 Attn: Office of Clinical Research

or to such other address as the party to whom notice is to be given may have provided to the other parties in accordance with this section. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile.

SPONSOR by signing below, represents that the above LOI is correct and in full force to the extent outlined above.

SIGNATURE PAGE FOLLOWS

Letter of Indemnification

SPONSOR

Name: _____

Title: _____

Date: _____

TRUSTEES OF INDIANA UNIVERSITY

Name: _____

Title: _____

Date: _____

DRAFT