

**NON-DISCLOSURE AGREEMENT
FOR EVALUATION OF CLINICAL STUDIES**

Effective Date: _____

This Non-Disclosure Agreement (“Agreement”) is made as of the Effective Date by and between (“Discloser”) having an address at:

and the Regents of the University of Michigan (“Institution”) having business offices at 3003 S. State St., 1000 Wolverine Tower, Ann Arbor, MI 48109-1274.

1. Background. From time to time during the term of this Agreement, Discloser may disclose to Institution certain confidential information concerning Discloser’s clinical studies for the purpose of permitting Institution to evaluate whether to conduct clinical studies sponsored by Discloser (the Purpose”). A general description of the confidential information to be disclosed is attached as Appendix A.

2. Confidential Information. “Confidential Information” means any information, including investigator’s brochures, case report forms and protocols, disclosed by or on behalf of Disclosure identified as confidential when first disclosed and provided in tangible form, or if disclosed orally summarized in a writing provided by the Discloser to Institution within twenty (20) days after oral disclosure, other than information that:

- (a) is or becomes generally available to the public other than as a result of disclosure by Institution;
- (b) is already known by or in the possession of Institution at the time of disclosure by Discloser;
- (c) is independently developed by Institution without use of or reference to Discloser’s Confidential Information; or
- (d) is obtained by Institution from a third party that has not breached any obligations of confidentiality.

3. Maintenance of Confidentiality

3.1 Use. Institution agrees to use the Confidential Information only for evaluation purposes to determine whether to conduct clinical studies sponsored by Discloser. Institution shall not use the Confidential Information for its own benefit or the benefit of another.

Version 2.1	Last Revised Date: 8/2/16
Approved by:	Last Revised By: C.Colthorp

3.2 Non-Disclosure. Institution agrees not to disclose or otherwise make available any of the Confidential Information to anyone except those employees and agents of Institution who need to know the Confidential Information to carry out the Purpose and who are bound by obligations of non-use and non-disclosure substantially similar to those set forth herein. Institution shall be responsible for any disclosure or use of the Confidential Information by its employees or agents.

3.3 Care. Institution shall protect Discloser's Confidential Information using not less than the same care it uses with respect to its own confidential information, but at all times at least reasonable care.

3.4 Required Disclosure. Institution may disclose the Confidential Information to the extent that such disclosure is required by law or court order, provided, however, that Institution promptly provides to Discloser prior written notice of such disclosure.

4. Ownership of Confidential Information. Institution agrees that Discloser shall retain all rights to the Confidential Information. No license of any such rights to Institution is granted or implied.

5. Term and Continuing Obligations

5.1 Term. This Agreement shall commence as of the Effective Date, and continue for a period of one (1) year, or until earlier terminated by one party providing written notice of termination to the other, whichever comes first.

5.2 Survival. Institution's duty to protect Discloser's Confidential Information shall survive the termination or expiration of this Agreement for a period of five (5) years.

5.3 Return or Destroy. Institution shall promptly return or, at Discloser's option, destroy, all Discloser's Confidential Information related to a clinical study if Institution does not participate in such clinical study, upon termination or expiration of this Agreement, or upon written request by the Discloser, provided however, that Institution may retain in confidence under this Agreement one archived copy of the Discloser's Confidential Information solely for the purpose of administering Institution's obligations hereunder.

6. Injunctive Relief. Institution agrees that (i) any breach of this Agreement may result in significant and irreparable damage to Discloser, and (ii) Discloser shall be entitled, in addition to any other remedies available at law, to seek injunctive or other equitable relief by a court of appropriate jurisdiction in the event of any breach of this Agreement.

7. Miscellaneous

7.1 No Obligation. This Agreement does not obligate the parties to enter into negotiations or any subsequent agreement. Any agreement concerning a relationship can only be made in a definitive written agreement, executed on behalf of each party by an authorized representative.

7.2 Entire Agreement. This Agreement is the entire agreement between the parties relating to the subject matter hereof and supersedes all prior agreements between the parties relating to the subject matter hereof. No agreement modifying or waiving any provision of this Agreement shall be binding unless made in a writing that references this Agreement and is signed by the parties. Facsimile or electronic signed copies shall have the same effect as originals.

Version 2.1	Last Revised Date: 8/2/16
Approved by:	Last Revised By: C. Colthorp

IN WITNESS WHEREOF, the duly authorized representatives designated below have executed this Agreement as of the Effective Date.

DISCLOSER

**THE REGENTS OF THE
UNIVERSITY OF MICHIGAN**

Signature: _____
Authorized Representative:
Title:
Date:

Signature: _____
Authorized Representative:
Title:
Office of Research and Sponsored Projects
Date:

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Appendix A

Clinical Study Information

Protocol Title:

Name of Clinical Drug or Device:

Clinical Trial Phase:

Disease or condition to be studied:

Recipient Investigator's Contact Information:

Name:

Department:

Phone:

E-mail:

Version No. 21	Last Revised Date: 2/2/16
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Appendix B

Investigator Acknowledgement¹

I have read and understood my obligations as an employee of the University of Michigan:

Investigator's Signature: _____

Date:

¹ U-M does not require this Acknowledgment. However, the Disclosing Party may request ORSP to obtain prior to executing the NDA.

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