University of Michigan
Office of Research & Sponsored Projects

Standard Operating Procedures & Policies

Category:	Post-Submission / Pre-Award
Procedure No.:	300.03
Title:	Preferred Award Terms and Conditions for Sponsor-Initiated Clinical Research

I. Purpose & Overview

To state ORSP's standard, and preferred, award terms and conditions for clinical research agreements with Sponsors.

II. Procedure / Policy

The following language represents the preferred language for all research related agreements negotiated by ORSP, by category. ORSP will attempt to obtain sponsor approval to use this preferred language.

Category	University of Michigan's Position	Example Preferred Language
Confidentiality and Publication	The University is a state agency subject to the Michigan Freedom of Information Act. The FOIA provides that information in the University's possession is subject to disclosure. The University has some ability to protect confidential information provided by the Sponsor if the information is provided in a way that allows the University to fulfill the administrative requirements of the FOIA. These include the requirement that the confidential information provided by a Sponsor be designated as confidential by the Sponsor prior to or at the time of disclosure and that the University record a description of the information with the chief freedom of information officer of the University. These sections are negotiable but significant variation may seriously compromise, if not negate, the University's ability to	All confidential information given to the University by the Company in connection with this Agreement or the conduct of the Protocol shall be marked confidential and provided in written or tangible form, or, if orally disclosed, confirmed as confidential in writing within twenty (20) days of disclosure and identified as confidential when first disclosed ("Confidential Information"). University shall not publish or disclose Confidential Information to a third-party without the prior written consent of the Company. This paragraph shall not apply to information which: ▪ is in the public domain at the time of receipt by the University; ▪ is made public by a third party after the University receives it, unless such publication was improper; ▪ was in the possession of the University before receipt from the Company or was developed independently without the use of, or reference to, Confidential Information, or acquired directly or indirectly from a source wholly independent of the Company without knowledge of origination in Company or obligation of confidence; or ▪ is the subject of a valid subpoena or is otherwise required by law to be disclosed, provided that prompt notice is given to the Company of the requirement of such disclosure, if possible. University's obligations of confidentiality shall survive the termination of the Agreement for a period of _____ (__) years. The University shall have the right to publish and/or disclose information and/or data arising from the Protocol or Study, provided, however, that the text of any such publication and/or public disclosure shall be submitted to the Company for review and comment at least thirty (30) days prior to submission for

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	protect the Sponsor's confidential information from disclosure pursuant to a FOIA request.	publication or other disclosure. However, at the Company's request, such submission shall be deferred for a further period not exceeding one hundred twenty (120) days to enable the Company to protect it's rights in such information. The parties acknowledge that use of protected health information is subject to the conditions described in the relevant informed consent document.
Governing Law	The University prefers to specify Michigan law as controlling law but as a compromise, would delete this provision or, in rare cases, specify the controlling law of a neutral jurisdiction.	This Agreement shall be governed and construed in accordance with the laws of the State of Michigan, without reference to such state's conflicts of laws principles.
Indemnification	The University cannot extend the full faith and credit of the State of Michigan to indemnify any third party except as authorized by law. Additional warranty disclaimer, insurance and indemnification provisions can be included as appropriate to the project and mutually agreed.	Except as set forth below, the Company agrees to defend, indemnify and hold harmless the Principal Investigator(s) and University, its trustees, officers, agents and employees from any liability, loss, damage and expense, including attorneys' fees and costs, in connection with any claim or lawsuit, regardless of merit, brought against the Principal Investigator(s) and/or the University for personal injuries (including death) or property damage allegedly arising from the Protocol. As a condition of such indemnity, The Company shall have the exclusive right to manage claims and control litigation, including compromise or settlement; however, if the University is a named party to any litigation, the Company shall be allowed to control defense and settle same with the written consent of University. Such consent shall not be unreasonably withheld. In the event that the University shall not consent to a settlement recommended by the Company, Company's liability for indemnification of University shall be limited to the amount of the proposed settlement. The University shall then be responsible for the amount by which any settlement exceeds the proposed settlement and all legal expenses from the date that the proposed settlement was rejected. The Company's obligations under this paragraph shall survive the termination of this Agreement. Notwithstanding the foregoing, the Company shall have no obligations pursuant to this Agreement to defend or indemnify the Principal Investigator(s) and University from liability, loss, damage or expense arising from: (1) the negligence or willful misconduct of the Principal Investigator(s) (2) the Principal Investigator(s)'s failure to adhere to the terms of the Protocol or the Company's written instructions with respect to the Protocol; or (3) the Principal Investigator(s)'s failure to comply with state or federal regulations, including FDA regulations. In addition, the Company shall have no obligations under this Article unless the Principal

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		Investigator(s) and/or the University (1) gives the Company prompt notice of any claim or lawsuit for which it seeks to be indemnified under this Agreement; and (2) cooperates fully with the Company and its agents in defense of the claim or lawsuit. Deviations in the care or treatment of study participants which arise out of necessity and which do not contribute to any injury shall not constitute failure to adhere to the Protocol or Company's written instructions.
Insurance		The Company shall maintain comprehensive general liability insurance, primary insurance and/or excess umbrella insurance in amounts not less than $2,000,000.00 per incident and $5,000,000.00 annual aggregate. Such insurance shall provide (1) product liability coverage and (2) broad form contractual liability coverage. Upon written request, the Company shall provide the University with written evidence of its insurance.
Inventions & Discoveries	The example language substantially deviates from the standard Intellectual Property provisions normally acceptable to the University in routine research projects, in recognition of the fact that there is a low probability of the University Investigator creating University Intellectual Property in Sponsor-Initiated clinical trials. The definitions of "University Inventions," "Company Inventions," and "Joint Inventions" are applicable mainly to potentially patentable inventions. If applicable, clauses specific to copyright and a definition of "Company Background Intellectual Property" or "University Intellectual Property" can also be added if needed.	The Company shall solely own all patentable inventions and discoveries which are enhancements, modifications or improvements of the Study Drug or which are otherwise reasonably anticipated by the Protocol and that are made in performance of and as a result of the Study. Whenever requested to do so by Company, University will at Company's expense, execute any and all documents or other instruments that Company shall deem necessary to apply for and obtain patent(s) in any country or to otherwise protect Company's interest therein. These obligations shall continue beyond the termination of this Agreement and shall be binding upon University's assigns, administrators, and other legal representatives. All other patentable inventions or discoveries which may arise during the performance of the Study (1) which are made solely by one or more employees of University, shall be owned by the University ("University Inventions"); (2) which are made by an employee or agent of Company solely, shall be owned by Company ("Company Inventions"); and (3) which are made jointly by one or more employees of University and an employee or agent of Company shall be owned jointly by the University and Company ("Joint Inventions"). Company Inventions shall not be subject to the terms of this Agreement. Rights to Joint Inventions shall be determined according to U.S. Patent Law. University hereby grants to Company a non-exclusive, royalty-free license to use University Inventions for any noncommercial purpose. University grants to Company an option, at its sole election, to negotiate rights to University Inventions, pursuant to either a non-exclusive, royalty-bearing license for any purpose except sublicensing or to an exclusive, royalty-bearing license for any purpose with the right to sublicense. University also grants to Company an option to

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		negotiate an exclusive, royalty-bearing license to Joint Inventions for any purpose with the right to sublicense. Such options shall exist for six months from the date of written disclosure of University Inventions or Joint Inventions by University to Company. University shall retain an irrevocable nontransferable, royalty-free right to use for its own internal noncommercial research and educational purposes, all Inventions licensed or assigned to Company hereunder.
Legal Name and Signatory for University	University of Michigan employees acting within the scope of their employment cannot be independent parties to the agreement. However, an Acknowledgment block may be added for the Project Director's signature at Company's option.	The Regents of the University of Michigan, a non-profit educational University of the State of Michigan (hereinafter "University").
Publicity	University policy does not allow explicit or implied endorsements, and requires that the University be able to disclose the existence of an agreement, the identity of the parties, and the nature and scope of the project being supported. This is not negotiable.	Company will not use the name of University, nor of any member of University's staff, in any advertising, news release or other promotional activity without the prior written approval of an authorized representative of University. University will not use the name of Company, or any employee of Company, in any advertising or other promotional activity without the prior written approval of Company. Nothing herein shall restrict either party's right to disclose the existence of this Agreement, the identity of the parties, or the general nature and scope of the Study.
Subject Complications, Injuries or Illness	In order to avoid any Medicare Secondary Payer (MSP) regulatory concerns, the University takes the position that the sponsor should agree to cover research-related injuries in the sponsor agreement regardless of the patient/trial participant's health plan coverage. This avoids not only the MSP issue but also protects patients who have no health plan coverage or whose	The Company shall promptly reimburse University (or its sub-sites, if applicable) for reasonable and necessary medical expenses incurred by Subjects for medical care, including hospitalization, in the diagnosis and treatment of complications, injuries or illness caused by research procedures or the Study drug/device following their administration or use in accordance with the Protocol, which are not attributable to the negligence or misconduct of any person in the employment of University and that would not be expected from the standard treatment using currently approved therapies. The term "complications, injuries or illness" does not mean the natural progression of an underlying or pre-existing condition or events that would have been expected from the standard treatment using currently approved therapies for the Subject's condition. This section shall survive termination of this Agreement.

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	health plan will not cover research-related injuries. Most health plans will not cover the cost of medical care associated with an injury that arises from a research trial so the University position protects the University from inadvertently billing for services that are either not a covered benefit by many commercial health plans or that would trigger MSP concerns. However, some negotiation may be acceptable.	

III. Frequently Asked Questions

Q: What if a Sponsor will not agree to the above preferred terms and conditions?

A: ORSP will work with the Sponsor to negotiate deviations, if possible and appropriate for the situation. Please contact the appropriate ORSP Project Representative for more information.

IV. Resources

Websites:

http://orsp.umich.edu/
https://orsp.umich.edu/policies-procedures/foia-criia
https://foia.vpcomm.umich.edu/
https://research.medicine.umich.edu/our-units/calendar-review-analysis-office