University of Rochester
Institutional Risk Assessment Process for
Principal Investigator-Initiated, Externally-Funded Clinical Studies

The University of Rochester may make an exception to the standard policy of requiring full indemnification from the clinical study sponsor in the cases of investigator-initiated studies. In order to determine if an exception should be made, the University requires a risk assessment. The purpose of this procedural summary is to standardize the process for conducting the risk assessment of these investigator-initiated research protocols.

The risk assessment is conducted by an ad hoc committee convened by the School of Medicine and Dentistry Dean's Office to assess and recommend whether the University will assume all or substantial liability risk related to an investigator-initiated protocol. The Senior Associate Dean for Clinical Research (SADCR) is responsible for making the decision on whether the investigator-initiated protocol should proceed. This process will be utilized when full indemnification is not offered or made available in the clinical trial agreement by the study sponsor[1] [i.e., for injuries (or death) sustained during participation in a study, for product liability, and/or payment for subject injury] and conducted in accordance with the level of risk inherent in a clinical study.

The School of Medicine and Dentistry has determined that the risk to the University is acceptable in the following types of investigator-initiated studies; these do NOT require a risk assessment:

- Protocols previously reviewed via a peer review process, (e.g., federally-funded studies or studies supported by most voluntary health or large foundation grants) when the IND/IDE is held by someone other than the University investigator;
- Studies that are not categorized as greater than minimal risk by the Research Subjects Review Board (RSRB), e.g., observational studies, registry studies, etc.

The Principal Investigator (PI) must submit the protocol and consent form to the Research Subjects Review Board (RSRB) and the clinical trial agreement to the Office of Research and Project Administration (ORPA) for review. If ORPA and the RSRB determine that a risk assessment is needed an ad hoc committee ("Committee") will be convened to assess the University's risk and potential benefits of conducting the study. The committee will be responsible for providing a recommendation to the Senior Associate Dean for Clinical Research (SADCR).

The Committee will consist of a representative from RSRB/OHSP, ORPA and the Office of Counsel. In addition, the committee must include at least one faculty member with relevant medical expertise. The following information will be provided to the Committee:

a. Principal Investigator (PI) and contact information
b. List of study personnel
c. RSRB application
d. Finalized protocol

[1] In the cases of Investigator-initiated studies, sponsorship is generally defined as providing monetary support to the study, not that the sponsoring entity is responsible for the filing of the investigational new drug application (IND) or investigational device exemption (IDE) with the FDA.

e. Draft consent form
f. Level of indemnification offered by sponsor
g. A summary of discussions, if any, between ORPA and Office of Counsel relevant to indemnification provisions, including any written communications. For Phase I trials, this may include a summary of communications between ORPA and UR Ventures relevant to the negotiation of intellectual property rights.

The Committee will provide the following in writing, in a timely fashion (usually within two weeks unless complicated or incomplete information is provided) to the SADCR. Incomplete protocols or inadequate information may result in return to the PI without a judgment.

a. Assessment of the possible risks to the study subject. This may require contact with the PI to quantify risks such as the likelihood of untoward effects of the device or drug which could lead to damages, claims, or payment of protocol-related expenses.
b. Brief assessment of the possible benefit to study subjects and the importance of the scientific knowledge to be gained from the research.
c. A recommendation as to whether the University should accept the risks as assessed, in light of the possible risks to subjects, the limited indemnification offered by the sponsor, the University's compensation obligation as expressed in the consent form and University compensation policy and the University's insurance coverage.

The risk assessment and recommendation will be sent by the Committee to the SADCR. The PI receives a copy of the assessment outcome after approval by the SADCR. The PI may not share the Risk Assessment information with the sponsor without the prior written consent of ORPA. The SADCR has the responsibility to accept or reject the Committee's recommendation, and may consult with the Dean of the School of Medicine and Dentistry or the Senior Vice President for Health Affairs, as necessary.

If the study proceeds, the risk assessment will be kept on file in ORPA, in the RSRB, and the SADCR office for the life of the protocol.

Last Revised: February 2016