

University of Rochester
Institutional Risk Assessment Process for
Principal Investigator Initiated Externally Sponsored 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. The purpose of this procedural summary is to standardize the risk/benefit analysis of investigator-originated clinical research protocols that determines whether such an exception should be made. This analysis is conducted by the School of Medicine and Dentistry Dean's Office, specifically by the Senior Associate Dean for Clinical Research (SADCR), to assess whether the University will assume all or substantial liability risk related to an investigator-initiated protocol.

This process will be utilized when full indemnification is not offered or made available in the clinical trial agreement by the study sponsor [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 need to undergo an assessment process by the Dean's Office:

- Protocols that have been reviewed via a peer review process, e.g., federally funded studies or studies supported by most voluntary health or large foundation grants;
- 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 specific procedures that are followed in conducting a risk assessment are:

1. The Principal Investigator (PI) should submit the protocol and consent form to RSRB and the clinical trial agreement to the Office of Research and Project Administration (ORPA). If the clinical trial agreement has not yet been obtained, the PI should provide ORPA with the name of a contact at the sponsoring organization.
2. ORPA will review the clinical trial agreement for level of risk as presented by the sponsor's indemnification provisions. RSRB will review the protocol and determine whether the study is categorized as greater than minimal risk and thus required to undergo full board review.
3. All protocols and consent forms must be approved by RSRB prior to undergoing institutional risk assessment. After RSRB review, the Principal Investigator is responsible for submitting the RSRB approval letter, the approved protocol and consent form to ORPA.
4. The following information will be submitted by ORPA to the SADCR and the Office of Counsel to the Medical Center (OCMC):
 - a. Principal Investigator (PI) and contact information
 - b. Copy of the RSRB application
 - c. RSRB approval letter
 - d. The complete RSRB-approved protocol
 - e. Approved consent form (describes the risks that the RSRB determined were important to disclose to subjects)

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- f. Date needed for risk/benefit analysis completion (as determined by the PI)
 - g. ORPA special concerns (if any)
 - h. Level of indemnification offered by sponsor
 - i. A summary of discussions, if any, between ORPA and OCMC relevant to indemnification provisions, including any written communications
5. In addition, in the case of a Phase I trial, the following information will be provided to the SADCR and OCMC:
- a. The latest version of the proposed clinical trial agreement
 - b. A summary of discussions, if any, between ORPA, OCMC, or the Office of Technology Transfer relevant to the negotiation of intellectual property rights, including any relevant written communications

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

- a. Assessment of the risks to the study subject. This may require review of RSRB approved consent form, 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 benefits to study subjects, the faculty, the Medical Center, and to scientific knowledge.
- c. A judgment as to whether the University should accept the risks as assessed.
- d. In making the above assessment, the SADCR will consult with OCMC to discuss the liability risk in light of the identified medical 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 liability risk/benefit analysis will be sent to ORPA, with a copy to the PI. The PI may not share this document with the sponsor without the prior written consent of ORPA.

The judgment may be rebutted and/or appealed by the PI to the SADCR. The judgment may be reversed by provision of additional information on risk or benefit not provided previously.

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

Last Revised: March 9, 2006