
Useful Info

Contacting ORPA
University of Rochester
Office of Research and Project
Administration
Hylan Bldg., Box 270140
Rochester, NY 14627-0140
Tel (585) 275-4031
Fax (585) 275-9492
<http://www.rochester.edu/orpa>

Contacting OHSP
University of Rochester
Office for Human Subject
Protection
Medical Center
601 Elmwood Avenue
Box 628
Rochester, New York 14642
Tel (585) 273-4127
Fax (585) 273-1174
<http://www.urmc.rochester.edu/ohsp/>

Contacting RSRB
University of Rochester
Research Subject Review Board
Medical Center
601 Elmwood Avenue
Box 315
Rochester, New York 14642
Tel (585) 275-2398
Fax (585) 275-7896
<http://www.urmc.rochester.edu/rsrb>

ORPAGuide

Guidance for University Approval of Sponsored Clinical Trials

What is a Clinical Trial?

Clinical trials are clinical research studies designed to test the safety and efficacy of a drug, vaccine or device. They are typically sponsored by private industry, primarily pharmaceutical companies and conducted according to a clearly defined research plan (the protocol). The costs of clinical trials are normally reimbursed by the sponsor on a per patient basis. The research itself is heavily regulated by the Food and Drug Administration (and by the Office for Human Research Protections for clinical trials funded by Federal agencies).

Who Do You Contact for Protocol, Consent Form, Institutional Risk/Benefit Review, and Study Agreement Approval?

The Office for Human Subject Protection (OHSP), the Research Subjects Review Board (RSRB), the Senior Associate Dean for Clinical Research (SAD-CR), and the Office of Research and Project Administration (ORPA) are the four offices that coordinate University approval and set up of sponsored clinical trials.

Office for Human Subject Protection (OHSP)

OHSP coordinates the human subjects review and routing of **industry sponsored clinical trial protocols**.

- The **Western Institutional Review Board (WIRB)** of Olympia, Washington reviews protocols and consent forms for clinical trials that are greater than minimal risk and which are industry-sponsored and industry-initiated. Set fees are charged for the initial protocol review, annual review and any amendments. These fees are a part of the cost of conducting the clinical trial and should be included in budget negotiations with the industry sponsor. In most cases, WIRB will bill the sponsor directly at department request. At the time of budget negotiations, it is strongly suggested that the individual responsible for budget negotiations make sure the sponsor is aware that WIRB will bill them directly. A copy of the fee schedule can be obtained from OHSP.
- The **University of Rochester's Research Subjects Review Board (RSRB)** reviews and approves all other clinical trial protocols and consent forms, including those industry-sponsored that are no greater than minimal risk or those trials which are industry-sponsored, but investigator-initiated. (Please see the section below under Research Subjects Review Board regarding other types of industry-sponsored clinical trials.)

All clinical trial protocols submitted to the OHSP for routing and review must use the "Application Face Page for Industry-Sponsored Clinical Research Review". This form must be completed (be sure to include the HSPP or EPRP number*) and sent to OHSP along with required WIRB/RSRB materials when the protocol is finalized.

Once the face page is completed, OHSP will send the information overnight to WIRB via an express mail service or forward it to RSRB, whichever is appropriate according to the above criteria. University policy requires that the subject injury language in the clinical study agreement must match the University's standard subject injury language in the consent form. If during ORPA's negotiation process it becomes apparent that the agreement language will offer the subject more than the University's standard consent form language does, OHSP will be notified and the consent form will be modified appropriately. The application form can be obtained through the OHSP homepage at <http://www.urmc.rochester.edu/ohsp/>

<p>Mandatory Education Testing</p> <p>*OHSP coordinates the required education testing for human subject researchers. As of January 1, 2001, all principal, co- and sub- investigators, along with coordinators and any individual administering informed consent must complete and pass either the "Human Subjects Protection Program" (HSPP) (for greater than minimal risk studies) or the "Ethical Principles in Research Program" (EPRP) (for research that does not involve greater than minimal risk, such as surveys and interviews). After passing the appropriate test, the individual will be assigned either an HSPP number or an EPRP number. The OHSP homepage contains directions on how to obtain and take the appropriate test.</p> <p>http://www.urmc.rochester.edu/ohsp/</p>
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Research Subjects Review Board (RSRB)

RSRB coordinates review of all non-industry-sponsored clinical trial protocols and industry-sponsored studies that are involve gene transfer, are less than minimal risk, and/or investigator-initiated. RSRB also reviews those studies with the sole intent to give expanded access to drugs/devices for treatment use.

- As of June 1, 2000, the National Institutes of Health (NIH) began a "just-in-time" procedure for human subjects use approvals on NIH grant applications. In other words, institutional review for these proposals is not required until NIH is ready to make an award. Most foundations and other federal agencies operate in the same manner; human subject use approval is not required until an award is about to be funded. However, there are exceptions where approval is required at submission by the sponsor, so please check with RSRB or ORPA prior to submitting the proposal. RSRB requires review prior to submission for any investigator who has been restricted by the review board. Investigators are required to certify on the University Sign-Off form whether such a condition exists. The form is available at <http://www.rochester.edu/ORPA/Fo rms>.
- RSRB also reviews industry-sponsored clinical trial protocols that place the subjects involved at minimal risk or less and industry-sponsored, investigator-initiated clinical trial protocols. RSRB also reviews studies involving gene transfer and studies whose sole intent is to give expanded access to drugs/devices for treatment use. For industry-sponsored protocols, set fees are charged for the initial protocol review, annual review and any amendments. These fees are a part of the cost of conducting the

clinical trial and should be included in budget negotiations with the industry sponsor. A copy of the fee schedule can be obtained from RSRB.

The "RSRB Application for Research Review" is used for all RSRB reviewed clinical studies. The HSPP or EPRP number(s) must be included on this sheet. (Please see the OHSP home page at <http://www.urmc.rochester.edu/ohsp/> for directions on how to obtain these numbers.) The form can be obtained through the RSRB homepage at <http://www.urmc.rochester.edu/rsrb/>.

Senior Associate Dean for Clinical Research (SAD-CR) Institutional Risk & Indemnification Process

University policy requires full indemnification from industry sponsors of clinical trials. (See the Kuncil/Rosier "Compensation for Injury" memo at http://www.rochester.edu/ORPA/clinical_trial/provost_memo1.pdf.) However, the University may make an exception to that policy in the case of investigator-initiated studies. In those instances, a risk/benefit analysis will be conducted by the SMD Dean's Office, specifically, the Senior Associate Dean for Clinical Research (SAD-CR) to assess whether the University will assume all or substantial liability risk related to an investigator-initiated protocol. The procedure for the risk assessment is outlined in the University of Rochester "Institutional Risk Assessment Process for Principal Investigator Initiated Externally Sponsored Clinical Studies" policy located on the ORPA home page at http://www.rochester.edu/ORPA/policies/risk_%20assessment.pdf.

Office of Research and Project Administration (ORPA)

ORPA negotiates clinical trial agreements with industry sponsors, coordinates the risk assessment process, requests ledger 5 accounts and produces the Notice of Award (NOA).

- ORPA will negotiate a clinical trial agreement with the sponsor that adheres to University of Rochester policies regarding such contract terms as subject injury, indemnification, publication, confidentiality and retention of data. Please note that University policy does allow for the vesting of ownership rights to the industry sponsor for intellectual property developed under the clinical trial IF the sponsor developed the protocol and IF the invention results from University adherence to that protocol. However, it is important to remember that there may be an opportunity for University intellectual property development and commercialization in clinical trials when the protocol is developed by the investigator. If an investigator believes he/she has conceived of or wants to develop potentially patentable or commercially valuable technology, he/she should note it on the "University of Rochester Proposal Sign-Off Form for Industry-Sponsored Clinical Trials" or contact the Office of Technology Transfer, Medical Center at x3-3743. The form is available at the web site noted in the paragraph below. A more detailed outline of these issues is available in the ORPA Manual at <http://www.rochester.edu/ORPA/manual/>.
- During the negotiation process with the industry sponsor, it is advised that the investigator or department administrator send an internal budget and a brief description of the protocol as

submitted to WIRB or RSRB through the University sign-off process, using the "University of Rochester Proposal Sign-Off Form for Industry-Sponsored Clinical Trials." The "Research Profile for Industry-Sponsored Clinical Trials" (second page of the sign-off form) must be completed by the PI. Because the forms are updated as necessary, please print the forms directly from the ORPA homepage as needed. Both forms are available on the ORPA home page at <http://www.rochester.edu/ORPA/Forms/>.

The sign-off procedure for industry-supported clinical trials is streamlined as much as possible. The Department Chair is ultimately responsible for reviewing the description of the protocol and study budget, **but it is the responsibility of the PI, the department administrator or the study coordinator to negotiate the budget for the proposed clinical trial.** Guidelines for clinical trial budgets can be found on the ORPA home page at <http://www.rochester.edu/ORPA/policies>. The Dean's Office will only review if there is one or more of the following:

- Cost sharing;
- A waiver or reduction of the 25% industry clinical trial F&A cost rate;
- Or additional space or renovation of current space is needed.

Once the contract has been negotiated, ORPA will sign on behalf of the University and the Principal Investigator (PI) will sign in acknowledgement of his/her responsibilities in the trial.

- When the contract is fully-executed, ORPA will request a ledger 5 account number for the clinical trial and this account number will be communicated to the principal investigator and the

department administrator. ORPA will set up a Notice of Award (NOA) once the first payment has been received from the sponsor.

- For clinical studies supported by non-industry sponsors, such as the National Institutes of Health, New York State, voluntary health organization, other universities or other agencies, the awards usually require little or no negotiation by ORPA. These sponsored studies must go through the University sign-off process using the standard University Proposal Sign-off form available at <http://www.rochester.edu/ORPA/Forms>. At the time when funding of NIH-sponsored clinical studies seems likely, NIH will require (among other documentation) that ORPA provide a letter certifying that key personnel listed in the grant proposal have completed education in the use of human subjects in research. When the award is made, ORPA will request a ledger 5 account and notify the principal investigator and department administrator when it is available. A NOA will be issued from ORPA at the time of the award or when the first payment has been received from the sponsor, whichever is appropriate.