

The University of Rochester
Margaret S. Warner Graduate School of Education and Human Development
Process for obtaining approval for research involving human subjects

TRAINING

*The Warner School offers an RSRB training course on the last Friday of each month to students. This training course is **STRONGLY ENCOURAGED**, as the RSRB process can be onerous. The Office of Student Services will provide advance notice of these training courses via email and flyers.*

Step 1 – APPLY FOR AN EPRP OR HSPP NUMBER

An EPRP or HSPP number is required even if the study may be exempt. You may apply to the university's Research Subjects Review Board (RSRB) for an EPRP or an HSPP number at any time.

EPRP – Ethical Principles in Research Program – applies to research that poses **no greater than minimal risk** to human subjects. See the discussion on the RSRB website (<http://www.urmc.rochester.edu/rsrb>).

HSPP – Human Subjects Protection Program – applies to studies that involve **more than minimal risk** to human subjects. See the discussion on the RSRB website.

To Apply for an EPRP Number:

- Download the Belmont Report and the EPRP test from the RSRB website (<http://www.urmc.rochester.edu/rsrb/belmont.htm>).
- Take the EPRP test and mail the answer sheet to the Office of Human Subject Protections (OHSP). (Call 273-4127 with any questions.)

To Apply for an HSPP Number:

- Call OHSP (273-4127) for a copy of the materials needed to complete this program and for information about the HSPP examination.

The OHSP will send you a letter with your EPRP or HSPP number after you have passed the appropriate exam. You will include this number in your RSRB study application. You should get this requirement completed in sufficient time before the application needs to be submitted, as it may take 48 hours or longer to issue your EPRP or especially your HSPP number.

Step 2 – APPROVAL FROM SPONSOR

Students who are applying for an exempt study (see Step 4), along with their dissertation sponsor, must complete an "Evaluation for Scientific Merit for Dissertations Involving Human Subjects" (Form C – see at end of document). This completed form

must be submitted to Alfred Vitale in the Warner Center for Professional Development and Education Reform prior to submitting your application.

Step 3 – REGISTER WITH RSRB FOR ON-LINE APPLICATIONS

All RSRB applications must now be submitted electronically, that is, on line via the RSRB web site.

In order to submit an on-line application, you must first register with the on-line application system in order to register a username and password. To do that:

1. Go to www.urmc.rochester.edu/rsrb.
2. Click on “Forms and Guidelines”
3. Scroll down to and click on “RSRB Electronic Submission System”
4. Click on “Login”.
5. Click on “Account Self-Registration.
6. Follow the instructions from there.
7. Warner DOCTORAL students should check the “Warner Doctoral Students” box to indicate their status as doctoral students.

It takes up to 24 hours after registering to receive confirmation of your user name and password. After that you can submit an application on line. So to avoid any delays, you should register well before you need to submit the application

Step 4 – COMPLETE THE APPLICATION

You do this by going to the RSRB website and following the steps above—except when you get to the log-in stage, you log in by entering your user name and password. This puts you into the system so you then can complete your application on line.

To aid you in completing your application, here is some additional information about some parts of the application. The on-line application process is new to all of us, so if you see any way to improve these instructions for Warner School faculty or students, please let us know.

DOES YOUR STUDY NEED REGULAR REVIEW OR IS IT “EXEMPT”?

Regular review means it is reviewed by the entire RSRB at their monthly meeting (“full board review”) or through an expedited process (“expedited review”). *Exempt* means your study is exempt from full-board review or expedited review, but it is still reviewed by the departmental RSRB staff. Exempt review usually goes faster than regular reviews. Depending on how you answer some of the initial questions, the system lets you know whether you will need regular review or exempt review and guides you to the appropriate questions on the application.

WHO IS THE PRINCIPAL INVESTIGATOR OR CO-INVESTIGATOR?

For Students:

If you are requesting approval for a study that requires **regular** RSRB review:

- The PI must be a **faculty member**.
- The **student** is the Co-Principal Investigator

If you are submitting a request for **study exemption**:

- The **student** is the Principal Investigator.

For Faculty:

- The **faculty member** is always the PI for regular and exempt studies.

WHAT GOES IN THE PROTOCOL?

See “Guidelines for Writing Research Protocol” on the RSRB website.

The protocol should include at least:

- Study Objectives.
- Research Procedures.
- Method(s) of Subject Recruitment or Data Procurement.
- Number of Subjects.
- Analysis of Risks and Benefits

HOW ARE CONSENT FORMS HANDLED?

Read the instructions on the RSRB website for composing consent forms.

Consent forms are printed on blank paper, leaving room at the top so they may eventually be photocopied onto Warner School letterhead. Consent forms must be attached to the electronic application as .doc files; hard copies are not accepted.

HOW ARE APPROVAL LETTERS HANDLED ON LINE?

You must include approval letters from the location(s) where you will conduct your research, if these sites are at a location other than the University of Rochester. An authorized official must sign these letters, which must be written on the letterhead of the school or organization or site used in the study. These documents must be attached to your electronic application.

HOW ARE QUESTIONNAIRES OR OTHER ATTACHMENTS HANDLED ON LINE?

Copies of all questionnaires, pencil and paper tests, interviewing schedules, etc., must be submitted electronically along with your application.

Step 5 –AFTER YOU SUBMIT

After you submit your application electronically, it is forwarded to the Warner School's Human Subjects Committee. The Warner School committee needs two weeks to complete its review. Within that period, the chair of the Warner School Human Subjects Committee will notify you of any changes or additional documentation required. You then make these changes and/or supply the additional documentation.

When the application is complete and ready, the chair of the Warner School Human Subjects Committee, upon committee approval, electronically "signs" the application. It is then automatically forwarded to RSRB.

OTHER RSRB GUIDELINES AND INFORMATION

You may not undertake research involving human subjects until you have received an approval notice from RSRB. RSRB meets on the first Thursday of each month. RSRB asks to receive all materials from the Warner School human subjects committee and university departments 30 days prior to the desired review date. Please allow sufficient time to obtain Warner School and university approval.

RSRB approval is for a specified time period that does not exceed one year. For expedited or full-board review studies, RSRB will send an annual Progress Report to the individual listed as PI on the application form about 3 months prior to the approved expiration date. Studies that qualify as exempt will not receive, and are not required to complete the annual review. However, any changes to studies, exempt or otherwise, must first be submitted to the RSRB as an amendment request.

Contact Alfred Vitale at 585-275-8270 if you have procedural questions. Contact Joanne Larson at 275-0900, Sherri Lauver at 275-0057, or Alfred Vitale with substantive questions.

FORM C

EVALUATION FOR SCIENTIFIC MERIT FOR DISSERTATIONS INVOLVING HUMAN SUBJECTS

In accordance with Federal guidelines, the University has established a system of ethical review boards (RSRB) to review research projects involving human subjects, including dissertation studies. Prior to submitting a dissertation research protocol to RSRB for approval, the student's dissertation sponsor must first attest to the "scientific merit" of the proposed study.

To be completed by Doctoral Candidate:

Candidate Name: _____

Sponsor's Name: _____

Proposal Title: _____

EPRP#: _____ Expiration Date: _____

To be completed by Dissertation Sponsor:

Please use the following criteria as evidence of scientific merit:

- This research uses procedures consistent with sound research design.
- The investigator is qualified and has the time and resources to conduct the research.
- The research method is sufficiently sound to reasonably expect that the research question will be answered.
- The knowledge expected to result from this study is sufficiently important/needed.
- The data monitoring plan is appropriate to safeguard the rights and welfare of subjects.
- The use of healthy volunteers or vulnerable subjects, if any, is appropriate.
- Any Conflict of Interest issues have been addressed according to University Policy.

I attest that I have reviewed the proposal for scientific merit as described above and believe that this proposal meets the criteria.

Sponsor's Signature: _____ Date: _____

This form should be submitted to Alfred Vitale at the Warner Center for Professional Development and Education Reform, in Dewey 1-219B.