

The University of Rochester
Warner Graduate School of Education and Human Development

Process for obtaining approval for research involving human subjects

Checklist:

- ☐ Receive your minimal risk certification through CITI
- ☐ Attend a Warner School RSRB Training session (MANDATORY)
 - Complete Independent Pre-Workshop Activities
 - Attend Synchronous Training Session
 - Complete Post-Workshop Activities
- ☐ Obtain Approval from your Faculty Sponsor/ submit Form C to the Warner School Human Subjects Department Reviewers
- ☐ Complete your Study Protocol and other required documents
- ☐ Submit your application in [Click® IRB](#)
- ☐ Work with the Warner reviewer(s) to clarify all your intended procedures for recruitment, obtaining consent and collecting data.
- ☐ Work with the RSRB reviewer(s) to finalize all your intended procedures for recruitment, obtaining consent and collecting data and respond to their questions.
- ☐ **Wait** for the RSRB **Final Approval Letter** prior to beginning official recruitment of subjects and data collection.
- ☐ Use **Watermarked** documents found in the finalized column in your Click study space under documents for all your recruitment procedures.

Contact Warner Human Subjects Department Reviewers at
RSRB@Warner.rochester.edu if you have questions.

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Margaret S. Warner Graduate School of Education and Human Development
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Step 1 – APPLY FOR A MINIMAL RISK NUMBER through CITI

A Minimal Risk number is required even if the study may be exempt. You may apply to the university's Research Subjects Review Board (RSRB) for a Minimal Risk number (or an HSPP number for more than minimal risk studies) at any time via the CITI website (see the link below or found through the link on the OHSP webpage labelled **Human Subject Protection Training**). If you have a role as a research assistant, your advisor may have already asked you to obtain certification through the system.

To Apply for a Minimal Risk Number:

- Go online to the CITI Certification site found at the following link:

<http://www.rochester.edu/ohsp/education/certification/initialCertification.html>

New in 2019: The link will send you to the directions for accessing the online modules at CITI with important information such as **using your UR email** in order for the system to be seamless (and save you extra work).

Use your University of Rochester email when registering so that you will be automatically enrolled in the **Click® IRB** (Click) system once the modules are successfully completed. Choose the Social-Behavioral-Educational Researchers and Minimal Risk options when selecting the correct training. Note: The certification expires after three years and you may need to recertify.

Step 2 – ATTEND THE WARNER SCHOOL TRAINING

Training is required for all doctoral students and can significantly reduce the time spent in getting approval to begin research with human subjects. Students ready to begin the proposal stage of their dissertation (i.e. working on their comprehensive exams and/or ready to write their research proposal) should attend the training prior to scheduling their proposal defense.

This updated RSRB training for any Warner doctoral level student applying for IRB approval of human subjects research will be held on a Friday evening from 6:30-8pm. The training is offered twice per semester and dates can be found in the Warner Calendar and sent in the monthly student newsletter. This training has a **new format** consisting of three parts: independent pre-workshop activities (asynchronous), training workshop (synchronous), and independent post-workshop activities (asynchronous). The entire training is designed to be accomplished in 3 hours, with a 1.5 hour training workshop held via Zoom.

What:	Independent Pre-training Workshop Activities (via Blackboard)	Training Workshop (held via Zoom)	Independent Post-training Workshop Activities (via Blackboard)
When:	Two Days Prior to Training Workshop	Friday Evening 6:30 - 8pm	After Synchronous Training Workshop
Time:	Approximately 45 minutes	1.5 Hours	Approximately 45 minutes

Step 3 – APPROVAL FROM FACULTY SPONSOR

All doctoral candidates who are applying for a study, along with their faculty advisor/dissertation sponsor, must complete an “Evaluation for Scientific Merit for Dissertations Involving Human Subjects” (Form C – see the end of this document). This completed form must be submitted to Warner School Human Subjects committee (send to: RSRB@Warner.rochester.edu) prior to completing your application.

For dissertation research, your application should not be submitted until you have completed the Oral Defense of your Proposal.

Step 4 – COMPLETE THE APPLICATION

All RSRB applications must now be submitted electronically, that is, on line via [Click® IRB](#) found on the OHSP website:

- Go to the Office of Human Subjects Protection website: <http://www.rochester.edu/ohsp>
- Click on the online submission system login tab: [Click® IRB Login](#)
- Note, for access outside of the university, you will need DUO authorization.

KEY POINTS to consider when submitting your application:

1. In [Click® IRB](#), the application is streamlined thus the **Study Protocol** must be clear and detailed. **Prepare it first** by using an appropriate template found at: <http://www.rochester.edu/ohsp/rsrb/docTemplates/protocolTemplates.html>

For most research, choose the [Protocol Template Social Behavioral Educational](#).

2. Include in the **Brief Description** on page one of the application that your research is for your Warner School Dissertation (or other research connected to Warner).
3. Add **your Faculty Adviser** to the list of Study Team Members in the application, and then assign your adviser as a PI Proxy.

4. The only document that should be included in the protocol section on page one of the application is your **Study Protocol**. (See Point 1 above!)
5. Create and Upload the remaining required documents under...

Local Site Documents:

- Consent forms – e.g. Information Sheet, Signed Consent, Parent Permission Form
- Recruitment Materials – e.g. email script, phone script, Flyer
- Other attachments – e.g. Support Letters from local sites
- Study Measures – e.g. Surveys, interview protocols
- Data Security Assessment Form
- Risk Assessment Form (if not using an university owned machine)
- Screen shoot verifying encryption program on non-university owned machine

*What goes in the **Study Protocol**?*

Refer to the materials found from Warner School **RSRB Training** (found on Blackboard).

Also: Inside the Click system there's a Researcher's Quick Reference and links to guidelines at the 'question' icons within the application. Many guidelines are also available electronically on the OHSP/RSRB website to review prior to beginning the submission process:

<http://www.rochester.edu/ohsp/rsrb/index.html>

Step 5 –AFTER YOU SUBMIT

After you submit your application electronically, it is forwarded to the University of Rochester RSRB team who will do an initial review as part of the pool of university applications prior to assigning it to the Warner Department Reviewers. The Warner School group needs at least two weeks to complete its review with your active participation. Within that period, the representative of the Warner School Human Subjects group will notify you of any changes or additional documentation required. You then make these changes and/or supply the additional documentation or review the requests via email with the Warner reviewer.

Once you are in the feedback loop contact will be from the following email address:

irb@urmc.rochester.edu

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 returned to the university RSRB committee for further review and approval. This RSRB review may take several weeks of additional clarifications and revisions. The feedback loop will continue to use the email address indicated above and be documented in the Click system – using the system is essential to the history/tracking system used by the RSRB reviewers.

OTHER RSRB GUIDELINES AND INFORMATION

You may not undertake research involving human subjects until you have received an approval notice from RSRB. RSRB asks to receive all materials from the Warner School Human Subjects committee and university departments 30 days prior to the desired approval 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 a request for 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 Click as a Modification.

Further information regarding the process and help with decisions can be found on the OHSP/RSRB website.

FORM C

EVALUATION FOR SCIENTIFIC MERIT FOR DISSERTATIONS AND OTHER STUDENT-LED STUDIES 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 an application for a research project to RSRB for approval, the student's sponsor must first attest to the "scientific merit" of the proposed study and review the **protocol** to be sure it clearly reflects the research design as indicated below. All student projects require a Faculty Advisor.

To be completed by Doctoral Candidate/Student:

Candidate Name: _____

Sponsor's Name: _____

Proposal Title: _____

Minimal Risk#: _____ Expiration Date: _____

To be completed by Dissertation Sponsor/Faculty Supervisor:

For Dissertations provide successful Proposal Defense Date: _____

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 protocol for scientific merit as described above and believe that this protocol meets the criteria.

Sponsor's Signature: _____ Date: _____

This form, signed by a Faculty Sponsor, to be submitted via email at RSRB@warner.rochester.edu