

CONDUCTING HUMAN SUBJECTS RESEARCH

August 2004

Does My Project Need IRB Approval?

When there is research involving "human subjects" as defined in 45 CFR 46, a research protocol must be submitted to the appropriate UIC Institutional Review Board. (IRB).

"Human subjects research" is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." (URL: <http://research.uic.edu/protocolreview/index.shtml>)

Generally, projects that may require IRB approval include the doctoral dissertation, master's thesis, and field

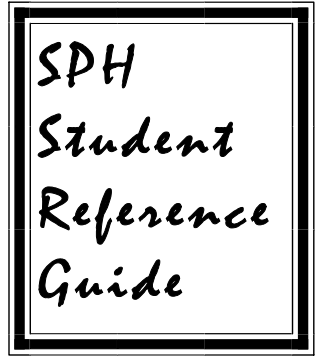
research. Field research that is conducted to satisfy the MPH field practicum requirement may be considered "human subjects research" UNLESS the student is carrying out the activities as an employee or intern of the preceptor site AND the student does not intend to use the results for publication or a presentation at a meeting open to the public.

The Office for the Protection of Research Subjects (OPRS) has recently determined that a **MPH capstone** that is only submitted in writing to faculty reviewers and/or presented at a forum open

ONLY to the SPH community will not require IRB approval.

However, if MPH students plan to submit their capstone paper for publication or for presentation at meetings open to the public (e.g., a regional conference), they must seek the appropriate level of review through OPRS and the IRB as they may be conducting "human subjects research."

Your advisor will help you determine if your project will require IRB approval.



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What Kind of Investigator Training Do I Need?

Initial Training

All SPH students who are planning to submit a human subjects research protocol must complete the initial human subjects protection education requirement prior to submitting ANY research protocol for IRB review.

There are 2 ways to meet this training requirement:

1. Attendance at UIC's "Investigator 101 Training Session" - Investigator 101 training sessions are held throughout the year. Dates are

announced on the OPRS website (URL: <http://www.research.uic.edu/protocolreview/irb/education/index.shtml>)

You must pass the quiz at the end of the session.

2. Take the UIC's Web-based "Collaborative IRB Training Initiative" (CITI) Course.

Upon successful completion of either option, a certificate will be sent to you.

Continuing Education

Once an investigator has received the initial human subjects research protection training, two hours of continuing education in human subjects research is required every two years during each succeeding year the investigator is conducting human subjects research at UIC.

A schedule of continuing education opportunities is available in OPRS' calendar of events.

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What Are the Steps in Submitting My Protocol?

Step 1—Plan early! It may take several months for your protocol to be approved. This is a MUST before you start any data collection.

Step 2— Review the OPRS website (URL: <http://www.research.uic.edu/protocolreview/index.shtml>) for submission dates of protocols, forms, policies, bulletins, and instructions.

Step 3— Complete the Forms!

Review the forms on the OPRS Website carefully to ensure that you are completing the correct forms. These forms can be downloaded from the OPRS website. Your research protocol application will consist of one of the following:

- *Claim of Exemption from IRB Review*
- *Initial IRB Review - Social and Behavioral Sciences (expedited/ full review) or*
- *Initial IRB Review - Health and Biological Sciences (expedited/full review)*

When completing the IRB forms consult your faculty advisor or the project director if your research is part of a larger study.

Your application may also require forms covering the following situations:

- *Informed Consent (see the Templates and Guidelines)*
- *Use of Drugs, Devices and/or Biologic Products*
- *Involving Children as Subjects in Research*
- *Involving Prisoners as Subjects in Research*
- *Databases/DNA/Tissue/Sample Banks*

Step 4 - Obtain the necessary signatures on your forms. Don't forget to sign the protocol application!

Step 5— Submit your protocol to OPRS

A. Exempt/Expedited Reviews

Investigators are responsible for photocopying (check your application package for the number of required copies) and submitting their exempt or expedited protocols to OPRS.

Deliver your protocol to Rm. 203, Administrative Office Building, 1737 W. Polk St., M/C 672, Ph: 996-1711, Fax: 413-2929

B. Full Reviews

Submit your protocol to SPH DRC

If your protocol is a full review, the protocol must be first submitted to the Departmental Review Committee (DRC) at the School of Public Health (Rm. 1150 SPH-PI). Upon completion of the review process, Appendix F is completed by each of the DRC Committee members. Please see the SPH Submission Process for Full Reviews flowchart located on the SPH web site.

Step 6— Revisions from OPRS are sent directly to the investigator. You are responsible for responding to issues raised by OPRS.

Step 7 — Protocols are generally approved for one year. If your project lasts longer than one year, you will need to submit a "Continuing Review" application prior to the expiration of your IRB approval. The investigator submits the completed application directly to OPRS with the appropriate number of copies.

Step 8—If your project is over, you need to submit an end of the study report to OPRS.