

Committee on Human Research (CHR) Guidance on Student Projects

Students carry out activities that may or may not involve human subjects. Questions frequently arise as to whether a student activity requires review and approval by CHR, what kind of application to CHR is required, and what roles students and their faculty advisors play in the activity. This document provides guidance on these issues. Students are also encouraged to seek guidance from their advisors or from the staff of the Office for Research Subjects (ORS). CHR policies, guidelines and forms are available on the CHR website: <http://www.jhsph.edu/chr/>.

To determine whether CHR must review and approve an activity, it is first necessary to determine whether the activity is *research* that involves *human subjects*.

Is the project research?

Research is a systematic investigation that is designed to develop or contribute to *generalizable knowledge*. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, a survey to gather information that would be used to strengthen an educational program for HIV/AIDS prevention would be research if the investigators believed their results could be applied to other populations and intended to publish them. If, however, the results were intended only to benefit the HIV/AIDS prevention program in the population from which the data were obtained, the activity would not be generalizable and would not be considered research.

If an activity does not meet the definition of research, CHR review and approval are not required.

Does the research involve human subjects?

Human subjects research is research that involves a *living individual* about whom an investigator obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information. *Identifiable private information* is information about (1) a behavior in which an individual can reasonably expect that no observation or recording is taking place, or (2) information disclosed for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g., school or medical records. *Private information* must be individually identifiable, i.e. the information can identify, or be associated, with a specific individual. *Data* includes information, specimens, and all types of recordings.

Since the regulations define a human subject as a living individual, research involving the deceased is *not* subject to the Federal regulations for research involving human subjects and does not require review by CHR.

CHR review and approval are required for all activities that meet the definition of human subjects research. Approval must be obtained before the research can begin.

What activities require review by CHR? (Also see attached flowchart)

1. Projects based on existing human data or specimens

The following table and attached chart summarize the review requirements for research on existing human data or specimens:

Existing Data or Specimens	Review
Publicly available: unidentifiable, not linkable	Not Human Subjects Research; CHR review not required
Publicly available: identifiable or linkable	ORS may certify as Exempt From Federal Regulations; use exempt research application
Not publicly available: collected as linkable, BUT links and identifiers are removed before data is given to investigator and the investigator cannot re-establish linkage	Not Human Subjects Research; CHR review not required
Not publicly available: collected as linkable and investigator has access to linkable or identifiable data, BUT records the data without links or identifiers and cannot re-establish linkage	ORS may certify as Exempt From Federal Regulations; use exempt research application
Not publicly available: identifiable or linkable	Requires review by CHR; use full application

Research on existing human data or specimens that originally contained personal identifiers, but from which all links and identifiers have been removed, may be either exempt from Federal regulations or classified as not human subjects research, depending on how the individual identifiers or links to identifiers were removed.

Note: If a faculty member serving as PI for a student *research* project has identifiable human data, removes all identifiers from the data, and provides the unidentifiable data to the student for analysis, this is *exempt research*. The project must be submitted to ORS using the exempt research application.

CHR does *not* review research using existing human data or specimens, whether publicly available or not, that does not contain personal identifiers and cannot be linked to personal identifiers. This is *not* human subjects research as defined by Federal regulations.

2. Projects in which data will be collected prospectively

Certain types of human subjects research are *exempt* from Federal regulations. These are described in CHR Form N, the Exempt Research Application, which is available on the CHR website (see also [Exempt Review](#)). Research submitted with the Exempt Research Application must be reviewed and certified as exempt. *This can only be done by the Office for Research Subjects.*

All other research that involves human data, human samples, or people themselves must be submitted as a full research application, using CHR Form A, and be reviewed and approved by CHR before the research can begin.

3. Educational projects or professional practice

If a project is *only* an educational experience to fulfill a course requirement or is a professional practice project, providing professional service that does not meet the definition of research, and the results are not generalizable and are not intended for publication, it is not research and CHR review and approval are *not* required (see also [What Needs Review by CHR](#)).

Who can serve as Principal Investigator? What IRB reviews the proposal?

- If a student will carry out a specific part of a study that has already been approved by CHR, or will conduct research within the aims of the approved study, the JHSPH Principal Investigator may request that the student be added as a named *student investigator*. The investigator should submit a memorandum to ORS indicating the name of the project, the CHR project number, the name(s) of the student investigator(s), a description of the role of the student(s), and evidence of human subjects training for the student(s). Alternatively, the Principal Investigator may choose to submit a separate application for the work to be done by the student naming him or her as a student investigator.
- If a student's JHSPH project is a separate study with different research aims, not previously approved by CHR, a JHSPH faculty member must submit a new application (using Form N or Form A) for CHR review and approval, naming him or herself as Principal Investigator and listing the student as a *student investigator*
- If a student is doing his or her dissertation research at another institution, he or she will most likely need to submit an application to the CHR. It is recommended that students contact the ORS for further guidance if his or her research applies to this category.

- If a student has initiated his or her research at another institution, but will analyze the data at JHSPH, an application must be submitted to CHR by a JHSPH Principal Investigator with the student named as a *student investigator*. The application should describe in detail only the data analysis. The collection of the data should be briefly described as part of the background.
- Remember:
 - Only a JHSPH faculty member can serve as Principal Investigator on a project submitted for CHR review.
 - If a JHSPH faculty member will have oversight responsibility for the research, CHR review and approval are required.
 - The JHSPH Office for Graduate Education and Research must be notified by letter of all student research being done at another institution (including the Johns Hopkins School of Medicine) and provided a copy of approval by the institution's IRB.
 - Students must successfully complete the human subjects training module on the CHR website before submitting a research proposal to CHR for review.

MPH Capstone Submissions

The MPH Capstone Project may or may not be human subjects research. Students who are unsure as to whether their planned project is human subjects research are encouraged to discuss their project with staff of the Office for Research Subjects. This may be done by memo, e-mail or in person and should take place during the *planning phase* of the project.

Proposals for Capstone projects that require review by CHR must be submitted to the ORS between November 1 and December 1. All proposals will be reviewed and approved by January 2. This will not be guaranteed, however, unless all items listed below are received by December 1.

For Capstone projects that are human subjects research, submissions must include:

1. A cover memo from the Principal Investigator to Stephanie Gaudreau or Tobey Harvey, ORS:
 - a. indicating he or she is seeking review and approval for a Capstone project,
 - b. providing the name(s) of the students taking part in the project with the date(s) human subjects training was completed or copies of the certificates, and
 - c. including a brief description of the proposed research activity.

- 2.If the project is research, a completed CHR Form N or CHR Form A should be attached to the memo.

An email reminder will be sent in April/May to remind students to keep the ORS informed of the status of their project. Students will be asked to submit (if applicable) an inactivation report, progress report or memo updating the status of the project

How long does the review process typically take?

Exempt review: The study must be in an allowable category for exempt review (see [Exempt Review](#)). Review will take approximately 2 weeks.

Expedited Review: The study must be no more than minimal risk and be in an allowable category for expedited review (see [Expedited Review](#)). Review will take approximately 3-4 weeks.

Full Committee Review: The study is more than minimal risk. Review will take approximately 6 weeks (see [Full Committee Review](#)).

Remember that CHR must approve human subjects research before it begins. CHR will not approve research that has already taken place.

Resources for CHR-related questions

1. CHR policies, guidelines and forms are also available on the CHR website: <http://www.jhsph.edu/chr/>.
2. As part of its continuing education activities, the ORS offers an open Brown Bag Session at which faculty and ORS staff review important aspects of the School's Human Research Protection Program and procedures for preparing, submitting and reviewing human subjects research proposals. Brown Bag Sessions are held monthly at mid-day. The schedule for upcoming sessions is posted on the CHR website. Announcements are also posted throughout the School.
3. Students are encouraged to discuss their proposed research with staff of the Office for Research Subjects, located in the Wolfe Street Building, Suite E-1100, 410-955-3193. ORS staff are also available to meet with student groups to discuss the CHR review process.