

The purpose of this document is to provide an overview of the **Homewood Institutional Review Board (HIRB)** application process for faculty and staff planning to conduct an educational research study. This quick guide is only an introduction. Each project is reviewed independently and project-specific research designs may require you to contact the HIRB directly. Researchers should review the HIRB website or contact the HIRB staff for more details: <http://web.jhu.edu/Homewood-IRB> or 410-516-6580.



Submitting an **IRB** application for Education Research

What is the IRB and why do I need to submit an application?

All human subjects research (HSR) conducted under the auspices of JHU is evaluated by an institutional review board (IRB) to ensure that the rights and welfare of participants are fully protected in keeping with accepted ethical principles and Federal regulations governing human participant research, as well as other applicable Federal, international, state, and local laws and regulations. Research in an educational setting, such as JHU, often involves data collection about or through interaction with students, faculty, and staff. Much of this research activity is ultimately determined to be minimal-risk HSR requiring IRB review and approval. However, only an IRB can make a determination about whether or not an activity is HSR and its risk level.

When do I have to submit an application?

IRB approval IS REQUIRED if the data collected or the data analysis will be shared publicly, for example, through a journal publication or conference presentation. IRB approval is needed even if the analysis will contain no identifiable information about participants in the study. An IRB application must be submitted *and approved by the IRB* before data collection begins if the researchers know the results will be publicly shared.

Faculty and staff do NOT have to submit an IRB application when they are collecting data from students and instructors for internal institutional purposes. For example, IRB approval is not required to collect data for accreditation purposes or if a faculty member wants feedback from students to improve a course or a program.

How long does it take HIRB to review an application once it is submitted?

A decision is usually finalized within six weeks depending on a number of factors, including the quantity and quality of IRB applications currently under review and the availability of the volunteer HIRB members. It is typical to experience a dialog with the HIRB as questions and comments are raised during the review process. It is recommended that researchers submit their application at least two months before the semester in which data collection will begin.



What is Human Subjects Research?

Human subjects research (HSR) is any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge that involves human subjects. A human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. See 45 CFR 46.101 and 46.102 for more information: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

All HSR projects have some degree of risk. Many educational research projects fall into the category of "minimal risk." Minimal risk generally means that the probability and magnitude of physical or psychological harm anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life. One of the biggest concerns in educational research is the risk of a loss of confidentiality. Research teams should be aware of this risk and take appropriate steps to mitigate it whenever possible with an adequate data security plan (e.g., use of random codes, password protection, locked computers, data encryption).

How do I submit an application?

Applications are submitted via eHIRB, the electronic protocol system: <http://ehirb.jhu.edu>. Detailed instructions are available on the HIRB website (<http://web.jhu.edu/Homewood-IRB/eHIRB.html>). The online application includes page-specific help buttons. The following page provides an overview of best practices to consider when submitting an application for educational research.

Required Training

All individuals listed on the application must complete CITI training (Collaborative Institutional Training Initiative) before an IRB application is reviewed. This includes the faculty principal investigator for a graduate student project. The training modules are online and self-paced. The training can take several hours to complete but does not need to be completed in one session. The HIRB website includes information about which training modules applicants must complete (<http://web.jhu.edu/Homewood-IRB>). With some exceptions, HIRB policies require that researchers choose the Johns Hopkins University (JHU) option in CITI as opposed to Johns Hopkins Medical Institution (JHMI).

Application Best Practices

Recruiting Students

Faculty must respect student concerns about feeling pressured to participate in educational research administered by their instructor. Faculty or graduate students may not directly recruit any student they teach or advise (See Data Collection Independence and Assistance section for recruitment assistance). If extra credit is offered for participation, then non-participation alternatives for earning extra credit must also be available. Monetary incentives are permissible but must be guided by the same considerations and constraints as those applicable to all human subjects. Please see the Student Recruitment Policy for more details: http://jhuresearch.jhu.edu/Policy_on_Student_Participation_in_Research_2.pdf.

Graduate and undergraduate student research

Undergraduate and graduate students cannot be the principal investigator (PI) on an IRB application (including applications for thesis and dissertation research). A faculty or senior staff member is required to serve as the PI, having ultimate responsibility for the conduct of the study and overseeing the student's progress. While the student researcher may prepare a new IRB submission or further study action, such as a change in research design on an existing HSR protocol, only the PI has the ability to officially submit the IRB application in eHIRB.

Data Collection Independence and Assistance

The Center for Educational Resources (CER) conducts educational research in partnership with faculty. CER staff can facilitate sensitive conversations (focus groups, interviews) and conduct surveys as independent data collectors. This ensures that student anonymity is maintained when data is reported back to instructors and teaching assistants. CER staff have expertise in advanced statistical methods and will assist faculty in designing studies and analyzing data. CER contact information is available at www.cer.jhu.edu/contact.html.

Data Collection Instruments

Examples of data collection instruments should be submitted for approval through the eHIRB application. This includes recruitment scripts (e.g., emails, posters) and consent forms. The IRB Office will stamp these documents to indicate that they are approved. If necessary, describe why sample instruments cannot be submitted. For example, focus group protocols may need to be drafted based on survey responses conducted at the start of the study.

De-identifying Data

Students may not feel comfortable answering surveys or participating in focus groups if they think their responses will be recognized by

the instructor. Researchers may need to de-identify data to ensure confidentiality. This can be done in a number of ways including creating a system in which personal identifiers such as student names, emails, or JHED IDs are replaced by unique codes. Using the codes, data can be associated across documents without identifying the students. A code book, a separate password encrypted spreadsheet accessible only to select team members, would show the unique codes associated with the student identifiers. If data (apart from summarized results) are to be shared, further steps to protect personal identifiers from disclosure should be considered. The Sheridan Libraries Data and Sociology Librarian or the JHU Data Management Services staff can consult on these practices: <http://dmp.data.jhu.edu>.

Consent

According to the Belmont Report, created for the protection of research subjects, "Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection." Even in educational research, whenever possible potential study participants must be fully informed of the study and provided the opportunity to decline participation without coercion or consequence. It is the investigator's responsibility to obtain, document, and maintain records of informed consent for each participant (or their legally authorized representative). The HIRB website provides sample consent forms; however, investigators may create their own consent documents as long as basic elements are included. For minimal risk educational research, the consent process must include the research purposes and procedures; duration of participation; any experimental procedures; risks and discomforts; anticipated benefits; alternative procedures; provisions for maintenance of confidentiality and planned or required disclosure of identifying information; whom to contact for questions or concerns; and a statement that participation is voluntary and that participation or withdrawal will involve no penalty or loss of benefits. Additional elements may be required as appropriate. With some exceptions, HIRB has the authority to approve a waiver or alteration of the informed consent process if the research meets specific criteria. Consult HIRB's Standard Operating Policies and Procedures, the Investigator's Manual, and/or HIRB staff for more details about informed consent requirements.

Data Storage

The proposal should describe how the student data will be stored during the research and analysis period, who will have access to it, how the data will be archived, and how long the archive will be maintained. JHU Data Management Services offer consultations on developing data management and preservation plans (<http://dmp.data.jhu.edu>).

Types of Reviews

There are three types of IRB reviews, which are described below. Some educational research qualifies for approval under an exempt category as defined in 45 CFR 46. Despite qualifying as exempt, data collection cannot begin until the HIRB has officially determined that the project is exempt.

- **Exempt** - Studies involving minimal risk to research participants may apply for an exemption from further formal review. The application must fall under one or more of the six categories of research that qualifies as exempt. Two categories are specifically for research conducted in educational settings (category 1) and using educational methods (category 2). *Please note that although the regulations do not require formal written consent from participants for exempt research, there is an ethical imperative for full disclosure whenever possible.*
- **Category 1** - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- **Category 2** - Research involving the use of educational tests (e.g., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. *You may not apply for an exemption if your research population includes students under 18 (i.e., minors), which is not uncommon in a freshmen course.* These students can either be removed from the study population or the study can be approved under an expedited category.
- **Expedited** - Research which is minimal risk in nature, but does not qualify for an exemption, may be considered for approval under one or more of the nine expedited categories if it does not employ sensitive populations or topics and includes appropriate consent procedures.
- **Full Board Review** - A formal review of the application by the fully convened HIRB. Full board review is designated for research that involves greater than minimal risk (physical, medical, psychological, social, or legal/economic), or focuses on particular vulnerable populations.