

Homewood IRB Approval Quick Guide

Why is IRB approval required before my award can be set up?

The Homewood Institutional Review Board (HIRB) holds a Federal Wide Assurance (FWA) from the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (DHHS). The FWA is a binding agreement between DHHS and the Johns Hopkins University (JHU). Through the FWA, JHU assures the Federal government that it will comply with all Federal requirements (including Title 45, Part 46 of the Code of Federal Regulations also known as the “[Common Rule](#)”) for all human participant research supported by the divisions served by HIRB and/or conducted by faculty, students, or staff in these divisions, regardless of whether the research is funded and, if funded, irrespective of the funding source. Section 46.122 of the ‘Common Rule’ states that “Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied”.

In order to assure that JHU meets this responsibility of the “Common Rule” and specifically section 46.122, IRB approval must be in place before an award can be setup and funds expended.

What if my project doesn’t initially involve human subject’s research and we need the funds released to cover non-human subject activities?

If your study does not initially involve human participants, submit the study application to the Homewood IRB for review. During this process, HIRB can provide “approval” to allow only the planning stages of the project to proceed. The HIRB determination letter will clearly indicate that approval is granted for only the planning phase of the research. Once the human subjects research portion of the project approaches, an eHIRB application amendment can be submitted to gain approval of the next phase of the study.

When is it appropriate to contact the Homewood Institutional Review Board (HIRB)?

All individuals, including students (undergraduate, masters, and doctoral students), faculty, and staff, who plan to do human subjects research, must have IRB approval before working with human subjects, their data or samples, and before study recruitment begins.

Contact the Homewood IRB early in the development of your research plan.

What is Human Subjects Research?

The term “human subjects research” is broadly defined to include any activity about or involving living humans that seeks to test a hypothesis, answer a scientific question, or otherwise contribute to generalizable knowledge.

A “human subject” means 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. Note: This can include both secondary data analysis as well as research involving direct contact with human participants.

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. An IRB determination is needed even if the analysis will contain no identifiable information about participants in the study.

A HIRB application must be submitted and approved before the research activity begins.

What will the PI and study team be expected to do?

If your study involves human subjects, you will need to submit an HIRB application.

Applications are created and 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>). To create an account, users should log in to eHIRB using their JHED ID and password.

All study team members are required to take human subjects research training through the CITI (Collaborative Institutional Training Initiative,) program *before the* application is approved. Create an account at www.citiprogram.org, affiliate with Johns Hopkins University, and complete the online training modules. Training certification is valid for five years.

Do I need to submit a HIRB application if the project is exempt?

Yes. Only the HIRB can make the determination that a project is exempt from IRB requirements and will issue documentation of this determination to the PI.

When should a PI apply for IRB approval?

An electronic study application should be created and submitted to eHIRB . Please contact the HIRB either during the proposal stage of an application or as soon as the PI is notified that an award is being issued.

Depending on the nature of the research, the quality of an application, and the volume of submissions under review, IRB approval can take between two to eight weeks, so plan accordingly.

What happens next?

After eHIRB submission, your study application is administratively pre-reviewed and categorized as Exempt, Minimal Risk or Greater Than Minimal Risk.

Then, one of three types of IRB reviews will take place (Exempt, Expedited, or Full Board) by the HIRB. The HIRB includes faculty from different JHU divisions and with relevant expertise in various academic disciplines. The HIRB also includes a community member who is unaffiliated with JHU.

Where can I find a sample HIRB application?

Samples are available at <http://web.jhu.edu/Homewood-IRB/applications.html>

How do I contact the HIRB?

Homewood Institutional Review Board (HIRB)
Wyman 468
Phone Number: (410) 516-6580

Email: HIRB@JHU.EDU
Website: <http://web.jhu.edu/Homewood-IRB/index.html>

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