JHSPH IRB Approval Quick Guide

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

Institutional policy requires that all human subjects research projects (U.S. funded or funded by other entities) be approved before they commence. In addition, JHSPH holds a Federal Wide Assurance (FWA 00000287) under which it promises to follow the U.S. human subjects research regulations funded by the U.S. government. Studies with U.S. funding from NIH or other granting agencies vary as to when that approval is required, and the type of approval the agency will accept, before an award may be set up. No funds may be expended on a human subjects research project before IRB approval.

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, you may submit a planning phase application to the JHSPH IRB through the PHIRST system. Planning Phase applications state the intent to complete formative work in preparation for a human subjects research study. The JHSPH IRB may provide approval for the Planning Phase, and will limit that approval to activities that do not involve human subjects. The full application should follow and will be reviewed independent of the Planning Phase.

Note: Some NIH funding agencies now require the full application approval prior to releasing funds; this means that the Planning Phase approval will not be accepted for these awards.

When is it appropriate to contact the JHSPH IRB?

Contact the JHSPH IRB Office at any time. We are available at 410-955-3193, or through our office email address: jhsph.irboffice@jhu.edu. We are located at 615 North Wolfe St., Suite E1100.

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 of identifiable data 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 may be needed even if the analysis will contain no identifiable information about participants in the study.

A JHSPH IRB application must be submitted through the PHIRST system, and approved, before the research activity begins.

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

Follow the steps in the PHIRST User Guide (http://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/PHIRST%20User%20Guide%20for%20Investigators%20and%20Study%20Team_21Mar16.pdf) and contact the JHSPH IRB Office if you have any problems.

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 IRB application if the project is exempt?

Yes. Only the JHSPH IRB 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 JHSPH IRB . Please contact the JHSPH IRB 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 JHSPH IRB 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 JHSPH IRB. The JHSPH IRB includes faculty from different JHU divisions and with relevant expertise in various academic disciplines. The JHSPH IRB also includes a community member who is unaffiliated with JHU.

Where can I find a sample JHSPH IRB Research Plan and Consent Forms?

Samples are available at http://www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/

How do I contact the IRB?

Johns Hopkins Bloomberg School of Public Health Institutional Review Board
615 N. Wolfe Street Suite E1100 Email: JHSPH.irboffice@jhu.edu
Phone Number: (410) 955-3193 Website: http://www.jhsph.edu/offices-and-services/institutional-review-board/