FAQs by Topic

Introduction

We have posted our IRB process related FAQs in a searchable PDF format. You may search by using the CTRL/F key combination. Just type the search word in the box that appears. You may also scroll through the Table of Contents and click on the topic or question of interest.

The FAQs are broken into 4 categories: General Topics; PHIRST (our electronic application system); Student Information; and CITI.

Student FAQs

1. **If I am doing data analysis only that does not involve contact with human subjects, do I have to submit to the IRB?**

All student-initiated research projects that include information collected from or about humans must be submitted to the IRB for a formal determination as to whether the project is or is not human subjects research.

2. **Can I obtain a preliminary determination as to whether my project involves human subjects research?**

You should visit the JHSPH IRB website www.jhsph.edu/irb where there are "determination request forms" students and post-docs may use (in consultation with their advisors) to obtain from us a preliminary determination as to whether or not your project involves human subjects research and requires IRB oversight.

If you seek information about using existing data, you may submit the IRB Office Determination Request Form for Secondary Data Analysis

If the project involves prospective collection of new data, you may submit the IRB Office for Determination Request Form: Primary (New) Data Collection.

The completed determination request form may be submitted to the IRB Office email address at JHSPH.IRBOffice@jhu.edu, and the student's advisor should be included in the email submission.

3. **Do I need IRB approval if the results of my project are not going to be published, presented at an academic conference, or otherwise disseminated beyond the classroom?**

Federal regulations do not require IRB approval for activities that fall under the "practice" rather than "research" designation. But the distinction between "public health practice" and "public health research" is very difficult to define. You should submit your proposed project to the IRB for a formal determination.

4. **Do I need IRB approval if my project involves key informant interviews?**

Your proposed research requires a formal determination as to whether your project constitutes human subjects research. You may submit the IRB Office Determination Request Form for Primary (New) Data Collection, and include a copy of the survey, questionnaire, interview guide, or a list of the questions that you propose to use to conduct interviews.

5. **Do I have to submit my entire research proposal for IRB review if I have received IRB approval at another institution?**

All other students must submit an IRB Office Determination Request Form to the IRB Office even if you have IRB approval for your project from another institution's IRB.

6. **Do I need to include researchers as co-investigators on my IRB application if they will not be involved in the data analysis?**

If your project involves only existing data, and no further prospective data collection, you do not have to list on your application the researchers will not be involved in data analysis, even if they original collected the data. You may explain the source of the data in your **IRB Office Determination Request Form** or research plan (if your projects require the submission of a new application). Authorship requirements are separate from IRB requirements.

7. **Can I tell people about the research if my application is pending IRB approval?**

You can tell people about the study, but no recruitment, consenting, or data collection may take place because the IRB must review and approve any recruitment material you will use to convey that information.

8. **Can I be added to an active, ongoing IRB-approved study?**

The PI of an ongoing, active IRB-approved study may add you as a student investigator by submitting an Administrative Amendment Application through the PHIRST system.

9. **Do I have to submit a new application if my capstone project involves data analysis of existing data with no identifiers or linkage?**

All student projects that involve information collected from, or about humans, require IRB review for a formal determination as to whether your project involves human subjects research.

10. **Do I need a research plan for my dissertation research using secondary data analysis, when the data have identifiers, are linked or coded, and/or qualify as a limited data set under HIPAA?**

A research plan is required if your project involves human subjects research and must be uploaded into your PHIRST system when creating a new application. This should not be your proposal. Instead, make it clear that the data have already been collected, their source, whether you have access to identifiers if they exist, and so on. Include only a brief description of your rationale and analysis plans.

11. **If I am listed as a student researcher on a study that was closed, can I still write manuscripts and make dissertation presentations?**

The IRB must continue to oversee the use of identifiable or coded study data. If the study has been terminated and you wish to do additional data analysis on identifiable or coded data, then the PI may submit a new application through the PHIRST system for secondary data analysis. The IRB will look to see whether the proposed new use of the data is consistent with any consent forms signed under the original approved research proposal. If the use is new and not mentioned in the original consent form, the IRB will review the proposal to see if it is ethical to proceed.

12. Do I have to submit a new application if I am listed as a researcher on an existing IRB approval at JHSOM IRB?

If you are listed as an investigator on an IRB-approved study at the Johns Hopkins School of Medicine (SOM) IRB, the approval letter from the SOM IRB will suffice. Please submit a copy of that letter for your student academic file to the Office of Academic Affairs to Melissa Cooke's attention at mjcooke@jhu.edu.

13. What happens after the External IRB approves the study and the Reliance Agreement is complete? Is BSPH IRB Continuing Review required?

The BSPH IRB will record in PHIRST the approval date provided by the External IRB and will use that date for monitoring continuing review. For Reliance studies reviewed by an External IRB with annual continuing review (or more frequent), the BSPH IRB will send out a reminder to the BSPH PI requesting documentation of the External IRB's continuing review approval. If the external IRB reviews the study and makes a minimal risk determination via expedited review, and the external IRB requires no continuing review, the BSPH IRB requires a Continuing Review submission every 3 years to facilitate BSPH monitoring of study progress and the timing of terminating the study and Reliance Agreement. The PHIRST system will send out these reminders.