

## Student Research and the BSPH IRB Office FAQs

### Frequently Asked Questions

*Please note that the questions and answers are here to serve as a basic resource and do not cover every project type/scenario. Please reach out to [bsph.irboffice@jhu.edu](mailto:bsph.irboffice@jhu.edu) with questions related to your specific project type/scenario.*

### Preliminary Determination Basics

#### **Q: What is an IRB preliminary determination?**

**A:** An IRB preliminary determination is a decision made by the BSPH IRB Office that determines if your project needs IRB oversight.

#### **Q: Do I have to get an IRB preliminary determination?**

**A:** An IRB Student Determination Request Form is a helpful tool for students and post-doctoral fellows to use to facilitate an IRB preliminary determination about projects conducted in fulfillment of a degree or educational requirement (e.g., practicum, capstone, etc.), including student projects that have received IRB approval or determination from another institution.

#### **Q: Do I have to get an IRB preliminary determination?**

**A:** If you are uncertain about the regulatory pathway for your student project or your project requires documentation for your program, your project requires an IRB determination. Complete the Student Determination Request Form with your [Project Advisor](#) and email this to the BSPH IRB Office, [bsph.irboffice@jhu.edu](mailto:bsph.irboffice@jhu.edu). We recommend reviewing all details on the determination request form before submitting. The BSPH IRB Office will review your submission to determine if your project requires IRB oversight. When the preliminary review process is completed, you and your Project Advisor will receive an email from the BSPH IRB Office with further guidance or a formal IRB determination.

#### **Q: How long does it take for a preliminary determination to be processed?**

**A:** Preliminary determinations typically could take up to 2 weeks to be processed. Please keep in mind that you must receive a formal IRB approval or email determination from the IRB to begin work on your project. If you have not heard back about your preliminary determination two weeks after your submission, please follow up with the BSPH IRB Office at [bsph.irboffice@jhu.edu](mailto:bsph.irboffice@jhu.edu).

## **Preliminary Determination Outcomes**

**Q: If the IRB preliminary determination outcome is that no IRB oversight is needed, am I all set with IRB requirements?**

**A:** Yes. If the determination is that no IRB oversight is needed, you will not need any additional IRB review, unless your project changes. Note: IRB determination is separate and distinct from any degree program requirements (e.g., approvals needed for the practicum or capstone, etc.). After receiving the IRB determination or outcome email, students are responsible for following up and sharing all necessary documentation with the appropriate program office(s).

**Q: If the IRB's preliminary determination outcome is that "Yes, IRB oversight is needed," do I then need to obtain additional IRB review and approval?**

**A:** Yes. The BSPH IRB Office will provide you with specific instructions on how to submit an IRB application through the PHIRST system. If a PHIRST application is required, the BSPH IRB Office will provide guidance and will reach out to the IRB Navigator, [IRBNav@jh.edu](mailto:IRBNav@jh.edu), who will be available to provide input on your PHIRST application.

## **Project Advisors and Principal Investigators (PIs)**

**Q: What is a Principal Investigator (PI)?**

**A:** PI stands for Pincipal Investigator. A faculty member must have a primary appointment status here at BSPH to serve in that role of PI on an IRB PHIRST application.

**Q: Can my Project Advisor serve as a Principal Investigator (PI)?**

**A:** If the BSPH IRB Office determines that your student project involves human subjects research, you will need to complete an IRB application in PHIRST. The PI for the PHIRST application must be a faculty member with a primary appointment at the BSPH. If your Project Advisor does not meet those criteria, they may be included as a co-investigator on the application, but they may NOT serve as the research project PI. If your student project does not involve human subjects research, your Project Advisor does not need to be a faculty member with a primary appointment at the BSPH and can be affiliated with an external institution.

**Q: If I am working on a project with an external, non-Hopkins organization, how do I find a Hopkins faculty member to serve as the PI/Project Advisor for an IRB submission?**

**A:** Students may ask their Academic Network Advisor or other faculty members whose work aligns to the project focus. The identified faculty member would support your IRB submission but does not need to formally be a preceptor for your project. However, to serve as a PI on the project, they will need to be familiar with the project and the specific work that is being proposed and be willing to assume responsibility for the conduct of the project to the IRB.

### **Specific Situations**

**Q: My project already has IRB approval through BSPH. Does this mean I do not need to submit a Student Determination Request Form?**

**A:** Correct. If the BSPH IRB has already reviewed and approved the project, you will just need to be added to the existing IRB protocol (ask the project PI). If work you will be doing on the project is in support of your degree, you will need to ask the PI to add you as a student investigator to an active PHIRST study.

**Q: My project already has IRB approval through another institution. Do I still need to submit a Student Determination Request Form?**

**A:** Yes. Your student project still needs to be reviewed by the BSPH IRB Office. Depending on what the scope is of your project, you may or may not need IRB approval from the BSPH, or to enter into a reliance agreement with another institution. The BSPH IRB Office will help you navigate these pathways based on the information provided in the Student Determination Request Form.

**Q: My project involves quantitative or qualitative primary data collection or secondary data analysis, but all outputs and deliverables will only be for the partner organization's internal use. Do I still need to submit a Student Determination Request Form?**

**A:** Yes. The Student Determination Request Form should be submitted for any student project used to fulfill a degree program requirement (e.g., practicum, capstone, etc.) that is not part of an existing BSPH IRB application.

**Q: My project involves quantitative or qualitative primary data collection or secondary data analysis, but the external organization or preceptor I will be working with told me that no IRB is necessary from their end. Do I still need to submit the Student Determination Request Form?**

**A:** Yes. The Student Determination Request Form should be submitted for any student project used to fulfill a degree program requirement (e.g., practicum, capstone, etc.) that is not part of an existing BSPH IRB application.

**Q: I have specific IRB questions about my project. Who can I reach out to for help?**

**A:** If you have questions, the BSPH IRB Office is here to help. Please email us at [bsph.irboffice@jhu.edu](mailto:bsph.irboffice@jhu.edu). You can also reach out to the IRB Navigator [IRBNav@jh.edu](mailto:IRBNav@jh.edu) for help with your PHIRST submission.