



JOHNS HOPKINS  
BLOOMBERG  
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# Navigating the JHSPH Institutional Review Board (IRB):

## A Primer for Students and Postdoctoral Fellows



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## Navigating the JHSPH Institutional Review Board (IRB) A Primer for Students and Postdoctoral Fellows

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The JHBSPH IRB office is charged with assuring that research studies conducted in the school comply with internal and external regulations designed to protect human subjects. The process can seem overwhelming to individuals new to it so the goal of this document is to help students and post-doctoral fellows understand and navigate the system.

Most of this process, which can often seem arbitrary and excessively time-consuming, is a direct result of policies implemented by the federal Office for Human Research Protections (OHRP), U.S. Department of Health & Human Services. All masters and doctoral students who plan to do human subjects research *must* have IRB approval *before* working with human data or samples or *before* contact with human subjects commences. Human subjects research is broadly defined as any activity involving living humans that seeks to test a hypothesis or answer a scientific question. This can include both secondary data analysis as well as research involving direct contact with subjects.

As a student, you cannot submit your own IRB protocol; instead, your advisor or other faculty member must serve as the Principal Investigator on the protocol you submit to the IRB. However, since you can prepare the application yourself, it's to your advantage to understand as much about the process and issues that you can so that your protocol can move smoothly and quickly through the system. The best way to ensure a rapid review is to prepare your protocol so that it answers all of the questions the IRB office is required to ask.

### **Types of review:**

There are three main categories of review for a research protocol. Most of the research done in the JHBSPH fall into the first two categories. Underlined words reflect key elements of the definitions:

- 1. Exempt.** Research involving the prospective collection and use of testing, surveys, interviews, or observation of public behavior without collection of identifiers or research involving existing data, documents, records, specimens that do not contain identifiers. "Identifiers" include information such as social security numbers, names, addresses, hospital IDs, or other information that can link an individual subject. **You cannot determine that your study is exempt; instead you must submit an application and await IRB determination, in the form of a letter, certifying that the study is exempt.**

Analysis of datasets that are publicly available, such as Census data, state court records, and National Households Survey of Drug Abuse are designated as "not Human Subjects Research". However, because the distinction of what is and is not "publicly available" is often unclear, we require that you submit a brief application, and in turn, will provide you with a letter certifying that your research does not involve human subjects research.

2. **Expedited.** Research qualifies for expedited review if the data that are collected contain identifiers but involve no more than minimal risk. Minimal risk is defined by federal guidelines as:  
“the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”  
The list of minimal risk categories includes such procedures as blood draws, collection of anthropometric or physiological data such as height and weight or electrocardiogram, behavioral assessments, interviews and psychological questionnaires.
3. **Full committee.** This is the highest level of review and is used for research that involves greater than minimal risk (physical, psychological, social, or economic) or focuses on particular vulnerable populations (e.g., prisoners). Research in this category includes clinical trials involving therapeutic or behavioral interventions as well as other types of studies with elevated risk.

### **How the JHSPH IRB operates**

Protocol reviews are conducted by members of the IRB boards, who are JHBSPH faculty members. Applications are submitted through an electronic system, PHIRST. Each protocol is evaluated as belonging to one of the categories listed above, and subsequent review is conducted accordingly. Both expedited and full committee protocols are evaluated during convened meetings. Expedited protocols are reviewed during weekly meetings, full committee protocols are reviewed during meetings held every other week. The IRB office is located near the E. Monument Street entrance.

### **Getting approval to do your research**

- The easiest approach for students whose research falls within the general scope and aims of a completed or on-going project conducted by a full-time faculty member in the JHBSPH is to be added to an existing IRB protocol as a student. This is called an amendment, and the amendment request can be submitted on paper (as opposed to electronically) as a letter written by the Principal Investigator to the IRB office asking that you be added to that protocol. Please remember that such requests are not considered approved until the Principal Investigator hears back from the IRB.
- If you are adding an additional activity involving human subjects contact to an already approved protocol (e.g., some new questionnaires, an additional blood draw), the PI needs to submit an amended research plan describing this addition and add you as a student investigator. Again, such requests are not considered approved until the Principal Investigator hears back from the IRB.

- If you are initiating a new research project, the normal protocol submission procedures, with a full-time faculty member as the PI and yourself as a student investigator, must be followed.
- If you are using data generated by a faculty member at another U.S.-based institution and that protocol has received approval from that institution's Institutional Review Board, it may be possible to designate that institution as the "IRB of record", which is done by our IRB in communication with that institution. However, depending on the nature of student involvement, it may be necessary to submit a new application. Check with the IRB office.
- If you plan to use data generated by a researcher who is not affiliated with JHBSPH and is internationally-based, it is probable that a new application will need to be submitted. Check with the IRB office.

### **What you need to do to get started**

1. Complete CITI, the on-line human subjects training module. This takes approximately 1 hour and you can do this at any time. Instructions are provided in the CITI FAQs document (pgs 5-6).

2. Register in the JHBSPH electronic application system. Instructions are provided in the PHIRST FAQs document (pg 7-9).

### **Special considerations by degree type**

The general procedures for evaluation of student research projects are the same, regardless of degree. However, some special degree-specific considerations apply.

1. MPH capstones. MPH capstones typically fall into one of four categories.
  - Simulated grant proposal or research plan. This is not research and does not need IRB approval.
  - Public health program proposal that is not conducted. Again, not research/no approval needed.
  - Research report: data collection and/or analysis. By definition, this is research and requires IRB approval. See sections above for information.
  - Analysis of a public health problem. This is a more complex issue because some activities that involve program evaluation require IRB approval while others do not. The rule of thumb is that if your activity will generate knowledge that will apply beyond the specific program you are evaluating or if you ever plan to publish or disseminate this information to groups that do not include the agency, then it is research and requires IRB approval. The IRB office can help you make this determination.

To facilitate the timetable of the capstones, an IRB liaison has been established within the MPH office to expedite and assist in the process for MPH students. Please direct your initial questions to Janet Carn ([jcarn@jhsph.edu](mailto:jcarn@jhsph.edu)) who will work with the IRB office to provide guidance based on your particular circumstances.

## 2. Doctoral research

IRB approval should be sought as soon as you have a final proposal for your dissertation research project. In order to graduate, certification that you are a student on an IRB approved protocol (either on a new application or as an amendment to an existing protocol) that is the basis for your dissertation **MUST** be on file in the Office of Graduate Education and Research, which is provided to that office by the IRB. Please don't put the ability to graduate or ever publish your results in jeopardy by not seeking IRB approval for the work, which must be done before you begin your research. If your department requires a written proposal, attach that with your application in PHIRST. There has been some confusion in the past as to whether a copy of your dissertation is required; it is not because you should have secured IRB approval before conducting your dissertation work.

## CITI FAQs

### **What is CITI?**

The Collaborative IRB Training Initiative (CITI) is a web-based training program on issues relating to human subjects research. The CITI web site is maintained by the University of Miami, with content developed by a national consortium. CITI contains modules on topics such as informed consent, vulnerable populations, ethical principles and IRB regulations. Each module has short quiz at the end to assess understanding.

### **Who is required to complete the CITI modules?**

The training is required of all faculty, staff and students who are engaged in research at JHBSPH. A total score of at least 80% is required to pass.

### **Do I have to take CITI again if I took it at another institution?**

No.

### **Are non-JHSPH researchers/collaborators required to complete CITI?**

Investigators from other institutions who can provide the JHBSPH IRB office with documentation of human subjects training from their own institution do not need to complete CITI.

### **Is CITI available in any languages other than English?**

CITI has modules in Spanish, French, Portuguese and Chinese. These are available at the CITI website under "International Course Site".

### **Where do I go for help?**

If you are having problems with the CITI site or course, contact the CITI office at [citisupport@med.miami.edu](mailto:citisupport@med.miami.edu) or at (305) 243-7970. If you have questions about JHBSPH requirements, contact the office at [irboffice@jhsph.edu](mailto:irboffice@jhsph.edu) or (410) 955-3193

### **How do I register?**

1. Go to <http://www.citiprogram.org/>
- OR*
2. Go to [www.jhsph.edu/irb](http://www.jhsph.edu/irb). Click the "Education" Link. At the end of the 1<sup>st</sup> paragraph under "Online Human Subjects Training Module" heading, [Click to access the training module.](#)
3. Go to New Users "**Register Here**" Link.
4. On the next page, Complete Course Registration Steps 1-4.
5. Select Johns Hopkins Bloomberg School of Public Health from the "Participating Institutions" drop down menu.
6. Select your Username and Password.
7. Enter your name.
8. Enter your email address.
9. Click the submit button.
10. Next, complete the required fields marked with an asterisk (\*).
11. Click the submit button.

12. Select the group appropriate to your research activities.
13. Choose one (most of the time this will be "a"):
  - a. **Biomedical Research Investigators:** This Learner group is mandatory for all Principal Investigators, Co-investigators, Student Investigators and Study Staff.
  - b. **Good Clinical Practice and ICH:** Required for all Clinical Researchers. This would include investigators conducting clinical trials and research subject to FDA regulations. This course consists of 13 modules on GCP (Good Clinical Practice) and ICH E6 (International Conference on Harmonisation –efficacy topic 6). These courses should be taken after completing the set described in a. (above). Choose this learner group and follow the Link to the Basic Course.
  - c. **IRB Board Members / IRB Staff and Institutional Official:** This group is required for IRB Board Members and IRB Staff and Institutional Official
14. Click the submit button.
15. You will see that you have registered with the Johns Hopkins Bloomberg School of Public Health. At this point you can register with another institution.
16. Check "Yes" to affiliate with another institution.
17. Check "No" to continue with your current selection.
18. On the next page, you will see the Learner's Menu.
19. Under Status, Click "Enter" Link to begin required training modules.

## PHIRST FAQs

### I. Getting started

#### **What is PHIRST?**

PHIRST stands for Public Health Institutional Review Submission and Tracking. It is a web-based system that allows investigators to submit and track their human subjects research projects. Submission, review and approval of research studies involving human subjects are conducted online.

#### **How do I register?**

Go to [www.jhsph.edu/irb](http://www.jhsph.edu/irb). Click the Registration link on the IRB website home page located at the top right corner of the screen. You will see a statement "Find out more about . . .". Click on Registration link and follow the instructions provided. Complete all required fields. Your user ID must be your JHED ID; make sure that you supply your correct email address. Once you submit the registration form, you will receive an email indicating your PHIRST account has been created. This email will also provide you with a temporary password and you can also upload a copy of your human subjects training certificate, and a copy of your biosketch, resume or CV at that time. You will then receive a second email within 1 business day that confirms your user roles along with instructions to complete the registration process. You will be required to change your password the first time you sign into PHIRST.

#### **How can I upload documents (Training Certificate, biosketch/resume/CV) to my PHIRST Account?**

To upload documents to your PHIRST user account or to change account information:

1. Log-in
2. Click on your name located at the top right corner of the study workspace page (next to the My Home icon)
3. Upload the required information
4. Click Apply located at the bottom right corner of the study workspace page

Your user account information will automatically be updated and you will not be asked to upload this information again. You may upload documents in WORD or pdf format.

#### **Where can I get help with PHIRST?**

You may contact the PHIRST helpmail at [phirsthelp@jhsph.edu](mailto:phirsthelp@jhsph.edu) or PHIRST helpline at 410-502-5780. You will receive a response to your e-mail communication or phone message within 1 business day. If you need immediate assistance, call the IRB office at (410) 955-3193.

**Do I need training to use PHIRST?**

You shouldn't need formal training to submit an application in PHIRST as most of the questions are self-explanatory and/or contain links for more information. If you get stuck, contact the PHIRST helpline.

**What browser/operating system do we need for using PHIRST?**

There is no specific hardware or operating system requirement to access and use the PHIRST website. You are only required to have one of the following standard Internet browsers:

<b>Platform</b>	<b>Browser</b>
Microsoft Windows (all versions)	Microsoft Internet Explorer, version 5.5 or later Netscape Navigator, version 7.1 or later Mozilla, version 1.5X or later Firefox 1.0X or later Opera version 7.10 or later
Macintosh OS X or later	Netscape Navigator, version 7.1X or later Safari 1.1 or later Mozilla, version 1.5X or later

Every browser and version behaves differently. Though support for a particular browser is indicated, there will always be occasions when the presentation appears different on different browsers and platforms.

**Where can I find a copy of my CITI or Human Subjects training certificates?**

If you completed your training on the JHSPH modules (prior to January 2007) but do not have a copy, contact the IRB office to gain access to print your certificate. To print a copy of your CITI certificate:

Go to <http://www.citiprogram.org>, enter your username and password, and click the submit button. Under the "Learner's Menu," you will see a table in the middle of the page that has the headings "My Courses," "Status," and "Completion Reports." Under the "Completion Reports" heading, you will see a "Print" link. Click the "Print" link. This will take you to a page that lists the available certificates to print. Choose the certificate you would like to print and click the "Print Completion Report" link.

**I don't have access to a scanner. Can I submit a paper copy of my training certificate?**

CITI provides an electronic document of your certification but the old CHR training module does not. If you don't have access to a scanner, please bring your certificate to the IRB office to be scanned.

**II. Submitting a research application**

**Who can submit an application?**

Applications can only be submitted by a full-time faculty member in the Johns Hopkins Bloomberg School of Public Health.

**How can I receive the role of principal investigator to submit an online, PHIRST application?**

A faculty member must have a full-time appointment to be a principal investigator on an IRB application. If your faculty status is part-time, you may meet the requirements of a co-investigator.

**What if I'm a student or post-doctoral fellow?**

A student or postdoc can prepare an application if previously registered in PHIRST, but only a faculty member can submit the application and be listed as the Principal Investigator. The faculty member who agrees to be listed as the principal investigator will take responsibility for the conduct of the study.

**Where and how can I submit electronic versions of documents that supplement my applications?**

As you move through the PHIRST application, there will be a number of places that allow you to upload documents. Please follow those instructions.

**Why can't I submit my continuing review in PHIRST?**

PHIRST will only accept new application submissions. This means that for previously approved studies, all further study actions (i.e., continuing reviews and amendments) must still be submitted via paper. You can link to the templates for those forms on the IRB website at [www.jhsph.edu/irb](http://www.jhsph.edu/irb). Adverse events can be submitted through PHIRST for previously approved PHIRST studies.

**How can I add an investigator who is not affiliated with Hopkins to the study team?**

If you are not affiliated with JHSPH, you should visit the IRB website at [www.jhsph.edu/irb](http://www.jhsph.edu/irb) to complete the JHU PHIRST Account Registration for Non-JHU employees. When you click the **Registration** link located on the home page of the IRB website, you will see the Self Registration link for Non-JHU on the left side of the screen.

**Where do I find comments or concerns regarding the application?**

Under "My Activities", click on the "Respond to Concerns" link.

**Who do I contact if I have questions about whether the study falls under HIPAA regulations?**

Margi Joshi, Research Regulations Specialist, handles HIPAA related questions and clarifications. She can be reached at: [mjoshi@jhsph.edu](mailto:mjoshi@jhsph.edu) or (410) 502-0433.

**Can I submit my application from off-campus, including internationally?**

Yes.

**Who should I contact if I am locked out of the PHIRST system?**

If you have trouble accessing the system, phone the main IRB office number at (410) 955-3193 during normal business hours and your password will be reprogrammed. For all other PHIRST-related questions, or if you are locked out during non-business hours, contact the PHIRST helpmail at [phirsthelp@jhsph.edu](mailto:phirsthelp@jhsph.edu) or PHIRST helpline at (410) 502-5780. You will receive a response to your e-mail communication or phone message within 1 business day.

**Where can I view my application?**

When you log into PHIRST, you are taken to your personal folder, My Home, which displays and has links to most items applicable to you as an investigator. You should select the "Study Staff" role to view applications in your study workspace.

**Future considerations**

At some point in 2008, PHIRST will be replaced with the electronic application system currently in use in the School of Medicine called eIRB. You're encouraged to participate in eIRB training sessions as they become available.