



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

The JHSPH IRB Office is charged with assuring that human subject research studies conducted in the school comply with internal school policies 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 the School's obligation to comply with the regulations implemented by the federal Office for Human Research Protections (OHRP) in the Department of Health & Human Services (DHHS). Masters and doctoral students who plan to do human subjects research must have IRB approval before working with human data or samples and/or **before** contacting human subjects. "Human subjects research" is broadly defined to include 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 agree to serve as the Principal Investigator on the protocol you submit to the IRB. This means that they accept the full responsibility for compliance with IRB requirements. 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 JHSPH IRB Office is required to ask.

If you are listed as a study team member on a human subjects research application at a different institution, the PI of that protocol and the approving IRB of that institution are responsible for your involvement in the research. The JHSPH IRB does not need to review the protocol.

Types of review:

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

- 1. Exempt.** Research may be designated as "exempt" if it involves the prospective collection of information, including the use of testing, surveys, interviews, or observation of public behavior without collection of identifiers or involves 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 make the determination that a project is exempt. Instead you must submit an application and await a communication from the IRB that will inform you of its decision.**

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" and therefore does not require IRB approval. However, as a student, we require you to submit your protocol to us and we will provide you with a final determination. This protects you in the event that your project is challenged as being human subjects research further along in your degree program.

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 research activities considered to be minimal risk include 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. Research that involves greater than minimal risk (physical, medical, psychological, social, or legal/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. Interview, focus group, or questionnaire studies which ask about sensitive topics (domestic abuse, sexual or drug use behavior, etc.) may qualify for the category of risk.

How the JHSPH IRB operates

Protocol reviews are conducted by JHSPH faculty or representatives of the local community who serve as members of one of two JHSPH IRBs. IRBX reviews protocols that are determined to qualify for expedited review; IRBFC reviews protocols that are considered to involve “greater than minimal risk”. New applications are submitted through an electronic system, PHIRST. Both expedited and full committee protocols are evaluated during weekly meetings. The JHSPH IRB Office is located near the East 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 IRB approved project conducted by a full-time faculty member in the JHSPH is to be added to an existing IRB protocol as a student investigator. This addition requires an amendment to the ongoing study. The amendment request is submitted on paper (as opposed to electronically) using the amendment form posted on the IRB website. The Principal Investigator must sign and submit the amendment to the JHSPH 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 amendment with a revised research plan describing this addition and adding 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 through study by a faculty member at another academic institution and that protocol has received approval from that institution’s Institutional Review Board, you may ask

the PI of that protocol to add you to that study. However, depending on the nature of your involvement, it may be necessary to submit a new application. Check with the JHSPH IRB Office.

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.

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 to submit the project to the IRB for consideration. The IRB reviewers will determine whether or not your project is “public health practice” or “human subjects research”. In general, public health practice means that: 1) your activity will not generate knowledge that would be useful beyond the specific program you are evaluating, and 2) you do not plan to ever publish or otherwise disseminate this information to groups that do not include the agency. The JHSPH IRB Office will provide you with documentation of a determination.

To facilitate the timetable of the capstones, two IRB liaisons have 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) if you are a full-time student or to David Earle (dearle@jhsph.edu) if you are a part-time student. They will work with the JHSPH IRB Office to provide guidance based on your particular circumstances. If you have IRB approval for your project from another IRB, submit a copy of the IRB approval letter, research plan, and any other documentation of your participation to:

MPH Program Office
615 N. Wolfe Street, Room W1015
Baltimore, MD 21205
mphprog@jhsph.edu

Doctoral Research

Initiate the IRB application process once you have a final protocol 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. You will also receive a form to complete regarding your IRB approval status three months after passing your preliminary oral exam. If your work has not been conducted through

JHSPH, you may be listed on an approval granted by another institution; if so, please contact the JHSPH IRB Office to clarify your situation. Please don't put your 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 research proposal that you plan to follow, attach that with your application in PHIRST. Finally, there has been some confusion in the past as to whether a copy of your dissertation is required; it is **not** even after you have completed the work. If you have IRB approval for your project from another IRB, submit a copy of the IRB approval letter, research plan, and any other documentation of your participation to Margi Joshi:

JHSPH Graduate Education & Research Office

615 N. Wolfe Street, Room W1033

Baltimore, MD 21205

mjoshi@jhsph.edu

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.
2. Register in the JHSPH electronic application system. Instructions are provided in the PHIRST FAQs document.
3. Start preparing your research plan. Go to the JHSPH IRB website at www.jhsph.edu/irb and click on the link for "Forms and Templates" to get the Research Plan template. Your research plan should answer the questions provided in the template that pertain to your study.

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. 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.

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

Yes, your proposed research requires IRB review.

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

No, the submission of a new application is not required. If you are listed on a pre-existing IRB-approved study at another institution that involves human subjects research, the PI of that protocol and the approving IRB of that institution are responsible for your involvement as a student researcher in the research, and you do not have to submit a research application for IRB review at JHSPH. However, copies of the IRB approval letter, research plan, and any documentation of your participation as a student researcher should be submitted to the MPH Program Office (for MPH students) or the JHSPH Graduate Education and Research Office (for other masters and doctoral students).

5. 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 the researchers who originally collected the data. You should explain the source of the data in your research plan

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

Yes, you can tell people about the study, but no recruitment, consenting, or data collection may take place.

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

Yes, if the PI has agreed to add you as a student investigator on an active, ongoing IRB-approved study, the submission of an Amendment Application signed by the PI is required.

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

Yes, all student projects that involve information collected from, or about humans, require IRB review.

9. Do I need a research plan for my dissertation research using secondary data analysis?

Yes, a research plan is required and must be uploaded into the 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.

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

Yes. However, the study would have to remain open if the data were still able to be linked to identifiers. If the study has been closed and you wish to do additional data analysis/dissemination then the PI can submit a new proposal for a secondary data analysis.

11. Do I need JHSPH IRB approval to submit a manuscript for publication for research conducted at another institution?

Since the research itself did not occur under the jurisdiction of the JHSPH IRB, you do not need to submit the project to the JHSPH IRB, as long as:

1. JHU is not mentioned (i.e., you cannot state your current JHSPH affiliation) and,
2. You are not going to use the research results for any JHSPH degree requirements (thesis, capstone, etc.).

CITI FAQs

1. 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.

2. Who is required to complete the CITI modules?

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

3. Do I have to take CITI again if I took it at another institution?

No.

4. Are non-JHSPH researchers/collaborators required to complete CITI?

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

5. 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".

6. 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 or at (305) 243-7970. If you have questions about JHSPH requirements, contact the office at irboffice@jhsp.h.edu or (410) 955-3193.

7. How do I register?

1. Go to <http://www.citiprogram.org/>
2. Go to www.jhsph.edu/irb. Click the "Education" Link. At the end of the 1st 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.

8. How do I find a copy of my CITI or JHSPH Human Subject Training (HST) Certificate?

CITI HST Certificate

To enter the CITI course site <http://www.citiprogram.org>, you must create a username, password below, and click on the submit button.

To print a copy of your CITI human subjects training certificate, select the following link under the heading "*Johns Hopkins Bloomberg School of Public Health Learner Utilities*":

[View course completion history for Johns Hopkins Bloomberg School of Public Health and print completion certificates](#)

You will see a "print completion report" link to print your report.

JHSPH HST Certificate

To print a copy of the JHSPH human subjects training certificate, please open the link below. You should select your name from the list and press GO. Your certificate will appear after you have selected your name.

http://apps2.jhsph.edu/chr/cbt/admin/frm_cert_on_demand.cfm

9. I have had training at my old or another institution, am I required to take the modules through CITI?

Yes, we'd appreciate it if you would take the CITI training.

10. Which CITI modules do I have to take?

All individuals listed as PI, co-investigator, student investigator, or study contact should take the basic human subject research training. If you will be involved with an FDA regulated clinical trial, you should also take the GCP training.

PHIRST FAQs

1. What is PHIRST (pronounced FIRST)?

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 wherever they are. Submission, review and approval of research studies involving human subjects are conducted online.

2. I am not a JHU employee, can I still register for PHIRST and How? OR How do I add someone who is not affiliated with Hopkins?

Please visit our website: www.jhsph.edu/irb

Click 'Registration' and fill in fields.

NON-JHU Employees: After clicking 'Registration'; there is another link to the left to click and fill out form.

3. There is a required field on the application for a completion date for Human Subjects Training. What is that?

Effective March 11, 2008, all registered PHIRST users must upload a copy of a human subjects training certificate before a new application can be submitted to the JHSPH IRB office. This means that the IRB office cannot accept any new applications until all principal investigators, co-investigators, student investigators and study contacts listed on a new application have uploaded this information.

Account information will automatically be updated and users will not be asked to upload this information again. All new PHIRST registrants will be advised of this requirement via email at the time of registration. Failure to upload this information will affect the submission of new applications.

4. I still don't see my role displayed on my screen.

When you register as a user, a PHIRST account is created for you with a "Personal Folder/My Home" workspace based on your user role. Study Staff/Investigator workspaces are designed for you to create new research applications, then monitor the progress of those applications through the IRB process. If you do not see any role other than "Registered User" listed, you have not yet been assigned your user role in the PHIRST system.

Once you select your user role as a PI, co-investigator, student investigator, or study contact for each new application, the IRB Office will verify it based on your JHSPH status (full-time faculty, student, outside collaborator, etc.), and JHED ID, and then will confirm the selected user role in the PHIRST system. You may be assigned one or more user roles in your PHIRST account if you are involved with more than one study, but the level and type of access you will have to a specific application depends on your assigned user role for that specific project.

When you log in to your personal folder/workspace, it will display both the role of “*registered user*” and “**study staff**.” Always click the role of “**study staff**” to allow you to create and/or access a new research application. If you are assigned the role of PI, you will be able to complete and submit an application through the role of “**study staff**.”

5. How do I create a new application in PHIRST?

Once you are assigned a study staff role as a PI, co-investigator, student investigator, or study contact, you can create a new study application by using the [NEW APPLICATION] button on your personal folder. By clicking on this button, you will be taken to a new application and asked to fill in the identifying information for your project. Your IRB number will be assigned once you complete the information on the first screen and save it.

6. How do I upload my documents to the registration server to complete my profile?

Please follow the instructions below:

1. Log-in to the PHIRST website using your user ID that you created and password.
2. Click on your name located at the top right hand corner of the study workspace (next to the My Home icon)
3. Scroll down the page to the 'Human Subject Training Certificate' section to upload your document, click the 'add' button to upload the required information.
4. Click Apply

Failure to upload this information will affect the submission of new applications.

7. Where can I find the comments or concerns to the study team from the IRB staff?

The email communication from PHIRST contains an IRB number that, if clicked, will reveal all the PHIRST activities available to you on the left side of the screen. Under “My Activities”, click on the link called “Respond to Concerns”. Next, click “Respond” to review the concern sent to you. Enter your response in the text box provided. When you have finished your response, select “Yes” under “Send to IRB”, then **CLICK “OK”**. If you fail to click “OK”, the response will not go to the IRB.

8. I've responded to the concerns, but haven't heard anything back from the IRB. What's wrong?

You may not have clicked the “submit” button that sends your response in to the IRB. Check to make sure that you have done that. If you still have problems, contact the IRB at irboffice@jhspk.edu.

9. How do I gain access to view my faculty member's projects?

The answer depends on who you are and whether you are listed as a co-investigator, student investigator, or study contact in a PHIRST application. If you are listed as one of these three roles, you may access the PHIRST application. If you are not, you can't. See guidance on Who Should be Listed on a Research Application?

10. What should I do if I cannot remember my password or JHED ID to log in to PHIRST?

You will be locked out of PHIRST if you have too many failed attempts to access your account. To avoid being locked out of PHIRST, make sure you keep your user name and password someplace accessible to you. If you have forgotten your password, click the "forgot password?" link under PHIRST Login. This will allow you to reset your password. If you are still having trouble or have forgotten your user name, feel free to contact the PHIRST Helpdesk at 410-502-5780 or email phirsthelp@jhsph.edu

11. Can a student investigator submit an online PHIRST application?

No, a student investigator cannot submit an online application. The new application **must be** submitted by the principal investigator. The principal investigator must be a **full-time** faculty member who is willing to take responsibility for the study. However, a student may complete the application then let the PI know that it's ready for review and PI submission. At present, there is no activity built in the PHIRST system that would automatically notify the PI when a new application is ready for submission. We suggest you either email or call the PI to let him/her know when the new application is ready for PI review and submission.

12. Where and how can I submit electronic versions of documents that supplement my application?

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

13. My advisor or the principal investigator's name does not appear in the dropdown list, how can I add a principal investigator to my online application?

Your advisor or the principal investigator must be a registered user to be added to your application. If you have trouble adding them to your application from the dropdown list, contact the PHIRST helpdesk or the PI to be sure that registration has been completed.

14. How can I receive the role of principal investigator to submit an electronic PHIRST application?

A faculty member must have **full-time** status at the School of Public Health to be indicated as a principal investigator on an IRB application. Co-investigators may include other JHSPH faculty or staff, as well as collaborators from other institutions.

15. How can I add more than one study contact to the application?

Add the additional study contact(s) to the co-investigator section of the application. All other "study team members" who will have substantive responsibilities for the conduct of the study should be listed as "co-investigator" since we have no other roles to choose from. The study team member will still be able to access under his/her own login and make changes in the PHIRST system.

16. 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:

Platform	Browser
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.

17. Why can't I save the PHIRST application to a disk?

PHIRST is a web-based system that will not allow you to download and complete or save the application on your computer or a disk. The application must be completed within the system. However, you may complete sections to the application, save your answers, and come back to the application at a later time.

18. Why can't I submit my continuing review or amendment?

PHIRST will only accept new application submissions. At this time, the system has not been designed to accept continuing reviews. This means that any study that is currently in review or approved by the IRB and was submitted via paper will remain paper until further notice. In other words, all current paper-based studies will remain paper and all activities on those studies (continuing reviews, amendments, adverse events) will still be submitted via paper or IRB Office email (irboffice@jhsphe.edu).

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

If you have trouble accessing the system, phone the main JHSPH 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 helpdesk at phirsthelp@jhsphe.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.

20. How can I change my user role in the PHIRST system?

Please email the PHIRST helpdesk at phirsthelp@jhsphe.edu, and identify the change you are would like to make. Someone will respond to inform you of the change or to ask any questions regarding the change.

21. I am trying to register another user, but unable to do so, what am I doing wrong?

Please be sure that you are logged out of the PHIRST system under your account. If the problem continues, please contact the PHIRST helpdesk at phirsthelp@jhsph.edu,

22. How long does it take after registration for someone's name to appear in the PHIRST dropdown menu so I can add them to an application?

Instantly! The name will appear once the user completes the registration process by uploading human subjects training certificate.

23. I am just a coordinator for a study; do I have to be listed on in the PHIRST application? If so, what role do I select?

There's no such thing as "just a coordinator". Study coordinators have significant responsibilities that affect the conduct of the study, and the protection of human subjects. Since PHIRST currently has no "study staff" option, you should be listed as a co-investigator.

24. How do I access approved study documents in PHIRST?

If you are listed on the Study Team, you have access to approved study documents. You should go to the Application section of your home page. Click the "Approved" tab. Select the study you are trying to access. All approved documents, including the approval letter and stamped consent forms can be found on the "Approved Documents" tab for any study in the active state.