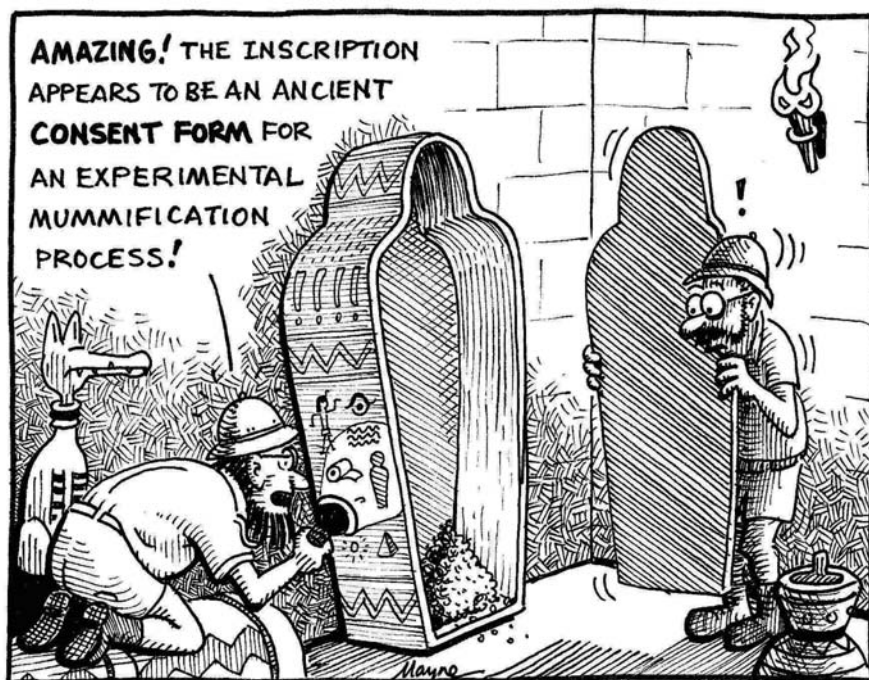




Navigating the JHSPH Institutional Review Board (IRB):

A Primer for Students and Postdoctoral Fellows



Institutional Review Board Office
Johns Hopkins Bloomberg
School of Public Health
615 North Wolfe Street / Suite E1100
Baltimore, MD 21205

Office: 410-955-3193
Fax: 410-502-0584
Toll free: 1-888-262-3242
Email: irboffice@jhsph.edu

On the web: www.jhsph.edu/irb

PHIRST Help Line: 410-502-5780
PHIRST email: phirsthelp@jhsph.edu

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 research application; instead, your advisor or other faculty member must agree to serve as the Principal Investigator on the research application 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 research application can move smoothly and quickly through the system. The best way to ensure a rapid review is to prepare your research application 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 research application and the approving IRB of that institution are responsible for your involvement in the research. The JHSPH IRB does not need to review the research application.

Types of review:

There are three main categories of review for a research application. 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 have a primary faculty member submit an application for your project 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 research application 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, or Single IRB Member Review.** 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. Convened Review.** “Convened” review involves review by a committee, with a meeting agenda and meeting minutes documenting the discussion and determinations. In general, research that involves greater than minimal risk (physical, medical, psychological, social, or legal/economic), or focuses on particular vulnerable populations (e.g., prisoners) requires convened review. 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 this category of risk. The JHSPH IRB reviews in a convened session many studies that other institutions might assign to expedited review because of our work in international settings. The addition of “cultural context” as a consideration when weighing the risk or discomfort of a study requires careful thought and we believe a convened review is appropriate in many cases even when the study procedures might meet the definition of “minimal risk”.

How the JHSPH IRB operates

Research application reviews are conducted by JHSPH faculty or representatives of the local community who serve as members of one of two JHSPH IRBs. IRB-X reviews protocols that are determined to qualify for as minimal risk studies; IRB-FC reviews protocols that are considered to involve “greater than minimal risk”. New applications are submitted through an electronic system called PHIRST (Public Health Institutional Review Submission). Both IRBs meet weekly. The JHSPH IRB Office is located in Suite E1100 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 an active, on-going IRB approved research project conducted by a primary faculty member in the JHSPH is to be added to an existing IRB research application as a student investigator. This addition requires an amendment to the ongoing study. The IRB considers the addition or deletion of study personnel (other than the PI) to be an “administrative” change. To add someone to a study, submit via email an “Administrative Amendment Application for Minor Changes to Research” (our PHIRST system does not yet have Amendment functionality); the form is posted on the IRB website at www.jhsph.edu/irb, under “Applications and Forms/Amendments”. The Principal Investigator (PI) must submit the application to the JHSPH IRB Office email address at jhsph.irboffice@jhu.edu. Please remember that amendment applications are not considered approved until the PI hears back from the IRB and receives an official Amendment Approval Notice.

If you are adding an additional activity involving human subjects contact to an already approved research application (e.g., some new questionnaires, an additional blood draw), the PI needs to submit an Amendment Application with a revised research plan describing this addition or change. Again, you may not implement any change until the Principal Investigator receives the IRB Amendment Approval Notice.

If you are initiating a new human subjects research project, the normal research application submission procedures, with a primary faculty member as the PI and yourself as a student investigator, must be followed.

If you are using human subjects data generated through an IRB approved study by a faculty member at another academic institution, you may ask the PI of that research application to add you to his/her study, and submit the study approval letter to the Academic Affairs office. However, depending on the nature of your involvement, it may be necessary to submit a new application. Check with the JHSPH IRB Office.

All student-initiated¹ projects involving humans or information about humans must be submitted to the IRB for a determination as to whether they qualify as “Not Research” (NR), “Not Human Subjects Research” (NHSR), “Human Subjects Research” (HSR) Exempt from IRB Review, or HSR requiring IRB review. Students may use the IRB Worksheet or the IRB guidance flowchart that are available on the IRB website www.jhsph.edu/irb under the link “Student Projects” to give them some idea as to what that determination is likely to be, but the determination itself must be made by the IRB. The JHSPH IRB Office will provide the student documentation of its determination or advise the student if the submission of a new PHIRST application is required.

The IRB Worksheet is a survey-monkey tool which will assist in directing students towards the correct IRB-related outcome. It may direct the student to complete one of the “IRB Office Determination Request forms” that are available on the IRB website www.jhsph.edu/irb under the link “Student Projects.” These forms may be used for all student- or post-doc initiated projects when it is helpful to have the IRB’s preliminary opinion on whether a project requires a new PHIRST submission for human subjects research activities and IRB review. Specific timelines for submission are provided for MPH students in both forms. Whether or not you complete a worksheet, you will need to complete an IRB Office Determination Request Form unless: (1) the student is working with a Principal Investigator (PI) from another institution or (2) the PI is adding you as a student investigator to an existing, IRB-approved study. There are two types of determination forms that operate as follows:

- If you are using secondary data for analysis, complete the “**IRB Office Determination Request Form for Secondary Data Analysis**” in collaboration with your advisor and submit it to the JHSPH IRB Office email address at jhsph.irboffice@jhu.edu. Be sure to include your advisor in your email submission.
- If you are collecting primary new data, complete the “**IRB Office Determination Request Form for Primary (New) Data Collection**” in collaboration with your advisor and submit it to the JHSPH IRB Office email address at jhsph.irboffice@jhu.edu. Be sure to include your advisor in your email submission.

The JHSPH IRB Office will review the form and let you and your advisor know whether or not a new PHIRST application is required. If a new PHIRST application is not required, the JHSPH IRB Office will provide you and your advisor with formal documentation of its determination.

¹ JHSPH IRB Policy NO. 103.02_Student Investigators [http://www.jhsph.edu/irb/Guidance_and_Policies.html]

Ethical Code for Student Activities that Involve Human Interactions

Regardless of whether IRB review is required, all students should apply ethical principles in their interactions with humans and/or their data.

The mission of the Johns Hopkins Bloomberg School of Public Health is dedicated to the education of a diverse group of research scientists and public health professionals, a process inseparably linked to the discovery and application of new knowledge, and through these activities, to the improvement of health and prevention of disease and disability around the world.

All activities that involve interaction with people or use of their personal information, whether for public health practice, class activities or research projects, require the highest standards of professional and ethical behavior towards others. Although there are times that collecting information from or about people is not technically “human subjects research” the expectation of the School is that all members of the public in general and the local community in particular will be treated with the same level of respect, fairness and protection of their individual rights as are participants in formal research projects that are subject to IRB oversight.

Basic expectations are described below.

1. For direct interactions with individuals, the purpose and nature of the activity must be clearly described and the potential participant be given an opportunity to agree or decline to participate. For research studies this is called “informed consent”; for non- research activities this is a less formal agreement. Such an agreement does not require that a participant sign anything; simply that they have been provided complete information even if it is verbal, with an opportunity for them to ask questions and make sure they understand. In general, parents should be informed of activities involving their children, and provide permission. Elements of informed consent/agreement to participate should include:
 - a. a brief explanation of the purpose of the activity;
 - b. explanation of why the individual was selected for participation;
 - c. what they’re being asked to do;
 - d. the approximate amount of time it will take;
 - e. that the activity is voluntary, meaning they have the right to simply say no if they do not want to participate; and
 - f. that if they do agree to participate, they will have the right to refrain from answering any questions including having the right to stop participating at any time.
2. Respect for Persons: All individuals must be treated with respect, courtesy, and discretion. Be aware that subjects that may be normal topics of discussion with your peers may be viewed as sensitive or intrusive by members of different age groups or cultures. Unless the project is conducted with IRB oversight, do not ask others to report on illegal activities or provide opinions that may compromise their job security. Recognize that children are people too and even if a parent agrees that they can participate, the child must also be allowed to say no.

3. Privacy: All interactions with individuals must be conducted in such a way as to protect their personal privacy. Discussions of sensitive topics must take place where others cannot overhear. Be sensitive to situations in which onlookers may misinterpret your presence or questioning of others. Interacting with adolescents or children raise special concerns, including those outlined in the JHU Child Safety Protocol, and the potential need for parental notification.
4. Data Security and confidentiality: Identifiable personal data, regardless of how seemingly innocuous they may seem, require maximum data protections. The biggest risk of loss occurs during data transport – whether physical transport, or electronic. If you plan to keep identifiers, separate them from the data and use a numeric code system. Use encryption and other protective methodologies when transporting sensitive and identifiable electronic data. The primary source of data loss reported to us is due to theft from vehicles– do not leave data on a laptop or other device in a car for any period longer than absolutely necessary for its transport.

Please make sure you are familiar with **The Ethical Code for Student Activities that involve Human Interactions** that is available on the JHSPH IRB website www.jhsph.edu/irb.

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 (jcarn1@jhu.edu) if you are a full-time student or to David Earle (dearle@jhu.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 and any other relevant documentation of your participation to:

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

Doctoral Research

The Office of Academic Affairs facilitates adherence to the School's policies and procedures for satisfactory degree completion. In fulfillment of this mission, one of Academic Affairs' tasks is to track IRB and/or ACUC approval for doctoral students to ensure that doctoral degree students conduct dissertation research under proper institutional approvals. Once you have a final research application for your dissertation research project, you should initiate the appropriate steps to obtain those approvals. Academic Affairs will send doctoral students an email approximately 3 months after passing their preliminary oral exams and forming a thesis advisory committee. The email reminds students of the requirement to obtain IRB and/or ACUC approval for student dissertation projects, if applicable. Also, the email will contain an attached ***thesis documentation form*** that students must complete. This form documents their IRB/ACUC approval and is signed by both the student advisor and the academic coordinator. The form must either be returned to Office of Academic Affairs in W1033, or sent electronically to Melissa Cooke (mjcooke@jhu.edu) so that it may be placed in the student's academic file.

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. In order to graduate, certification that you are a student on an IRB approved research application that is the basis for your dissertation (either on a new application or listed via an amendment application to an existing research application) **MUST** be on file in the Office of Academic Affairs at the address below. If your work will not be conducted through JHSPH, you may provide documentation of an approval letter granted by another institution's IRB and any other relevant documentation of your participation on the research team to **Melissa Cooke** at the address below:

JHSPH Office of Academic Affairs
615 N. Wolfe Street, Room W1513
Baltimore, MD 21205
mjcooke@jhu.edu

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. For questions concerning these requirements, please contact Melissa Cooke at 410-955-3348 or mjcooke@jhu.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 that is available on the JHSPH IRB website at www.jhsph.edu/irb.
2. Register in the JHSPH electronic application system. Instructions are provided in the PHIRST FAQs document that is available on the JHSPH IRB website at www.jhsph.edu/irb.

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 preexisting 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 Office of Academic Affairs (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 on your application the researchers will not be involved in data analysis, even if they originally collected the data. You should explain the source of the data in your research plan. Authorship requirements are separate from IRB requirements.

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 PI should sign and submit by email an Administrative Amendment Application for Minor Changes to Research.

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, using our template for Secondary Data Analysis when creating the new application, is required and must be uploaded into the PHIRST system. 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 is if the data were still able to be linked to identifiers. If the study has been terminated and you wish to do additional data analysis/dissemination then the PI may submit a new proposal for a secondary data analysis. The IRB will look to see whether the proposed new use of the data are 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.

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 (HSR). The CITI web site is maintained by the University of Miami, with content developed by a national consortium. CITI offers other training, for example Good Clinical Practices (GCP). The HSR training contains modules on topics such as informed consent, vulnerable populations, ethical principles and IRB regulations. Each module has a short quiz at the end to assess your understanding. All of our institutional requirements are listed on the JHSPH IRB website at www.jhsph.edu/irb.

2. Who is required to complete the CITI HSR modules?

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

3. Who is required to take the CITI GCP modules?

Faculty, staff, and students engaged in HSR involving clinical trials with medical interventions.

4. Do I have to take CITI HSR training again if I took it at another institution?

It depends upon when you completed the training. We require that faculty, staff and students renew their CITI HSR training every 5 years.

5. Am I required to refresh my CITI training?

Yes. The Basic Human Subjects Research (HSR) Course certification is good for 5 years. After 5 years, JHSPH faculty, staff, and students who are engaged in HSR must obtain recertification from CITI by taking one of the Refresher courses (1, 2, or 3) offered by CITI.

6. What will happen if my HSR certification expires?

You have 60 days following your certification expiration date to complete a refresher course. You need to print out the updated HSR certificate and upload it into your personal profile page in the PHIRST electronic application system. Once you enter your new completion date, you will retain full access to PHIRST. If you do not upload a new certificate in those 60 days and enter your new completion date into PHIRST, your access to PHIRST will be limited to your home page; you will not be able to submit a new application or access other PHIRST applications.

7. How do I access my Personal Page in PHIRST to upload my new training certificate and enter my new HSR training completion date?

When you log into PHIRST, you should see your personal folder page. If you do not see a mechanism for uploading the new certificate on that page, look at the upper right corner of your page and you should see "[First Name, Last Name](#) | [My Home](#) | [Logoff](#)." Click on your name, and you should reach your Profile Page which has the upload mechanism for your HSR training certificate and a field for entering your new completion date.

8. How will I know if it has been more than 5 years since I completed my CITI HSR training?

Look at your CITI certificate and find the completion date. If you do not have a copy of your certificate, follow the instructions below to access CITI and print out a new copy.

9. Will I be reminded to refresh my CITI certification?

Yes. The CITI system will send out reminders 60 days prior to your certification expiration date, and at several other times up to the day before expiration. **These reminders will go to the email you have provided to CITI, so it is important that you keep this email address current.** After the certification expires, you will receive no further reminders.

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

Investigators from other institutions may use our CITI account to complete the CITI HSR training. Those non-JHSPH investigators who can provide the JHSPH IRB Office with documentation of human subjects training from their own institution, from NIH, or from Family Health International do not need to complete CITI.

11. Is CITI available in any languages other than English?

CITI allows users to select other languages. Here is the current list of offerings (as of February 2013):

- Chinese
- French
- Korean
- Japanese
- Portuguese
- Russian
- Spanish
- Thai

12. 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 jhsph.irboffice@jhu.edu or (410) 955-3193

13. How do I register for CITI training?

- a) Go to <http://www.citiprogram.org/>
- b) Go to New Users “**Register Here**” Link
- c) On the next page, Complete Course Registration Steps 1-4
- d) Select Johns Hopkins Bloomberg School of Public Health from the “Participating Institutions” drop down menu.

- e) Select your Username and Password
- f) Enter your name
- g) Enter your email address
- h) Click the submit button
- i) Next, complete the required fields marked with an asterisk (*) and submit
- j) Follow the instructions for selecting your Learner Group and submit
- k) 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. (If your studies are funded by the Dept. of Navy, you may want to follow this process to affiliate with the “DoN” account.)
- l) Check "Yes" to affiliate with another institution.
- m) Check "No" to continue with your current selection.
- n) On the next page, you will see the Learner’s Menu.
- o) Under Status, Click “Enter” Link to begin required training modules.

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

Yes. If you are faculty, staff, or a student, you must take the JHSPH CITI training.

15. 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 course or a refresher. If you will be involved with an FDA regulated clinical trial, you should also take the GCP training.

16. How do I find a copy of my CITI HSR Certificate?

Access the CITI course site <http://www.citiprogram.org> with your username and password. 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.

PHIRST FAQs

1. What is PHIRST (pronounced FIRST)?

PHIRST stands for **P**ublic **H**ealth Institutional **R**eview **S**ubmission and **T**racking.

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.

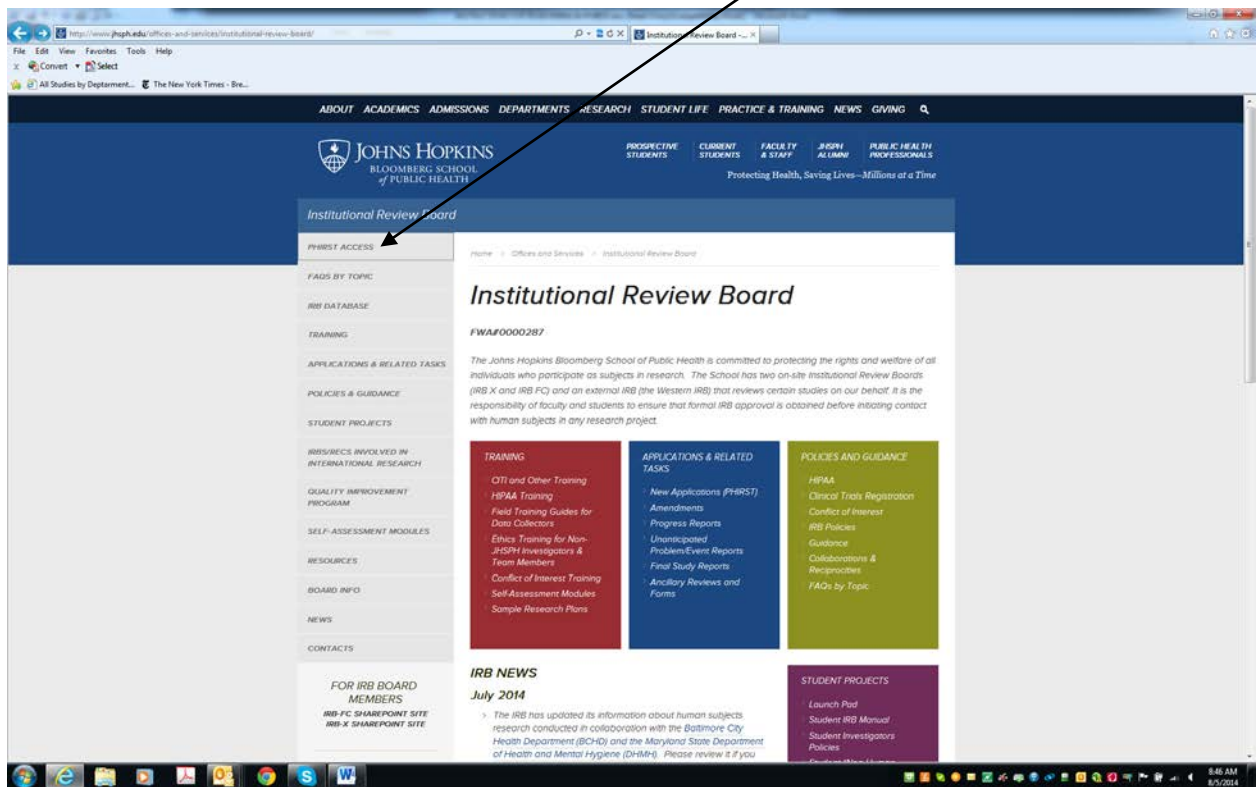
2. I am not a JHU employee, can I still register for PHIRST, and if so, how do I register? If I am a Hopkins employee, how do I add someone to my study who is not affiliated with Hopkins?

- Visit the IRB website www.jhsph.edu/irb
- Click "PHIRST Access" link on the left side of the home page screen
- Click "Home" link at the top of the screen
- Click "Registration" or "Registration – Non JHU" link and fill in the required filed.

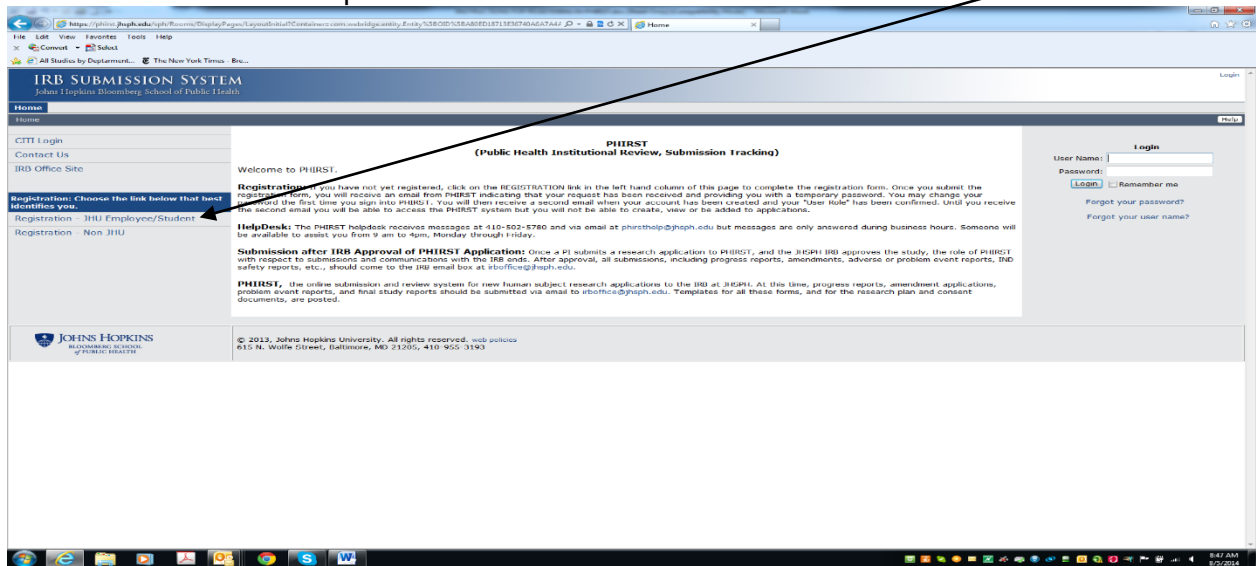
If you have any questions or problems with the PHIRST registration process, please contact the PHIRST Help Desk at jhsph.phirsthelp@jhu.edu or call 410-502-5780.

3. How do I register in PHIRST?

1. Visit the JHSPH IRB website: <http://www.jhsph.edu/offices-and-services/institutional-review-board/>
2. Click “**PHIRST Access**” link” on the left side of the home page screen



- Now you are on the PHIRST Home page. Click the link **“Registration – JHU Employee/Student”** and fill in the required fields.



(Note: If a current user is registering a new user, be sure to log out of your existing PHIRST account. Current users CANNOT be logged into their PHIRST account while registering a new user.)

- Once you have received your welcome email from PHIRST, log in using the temporary password that will be included in your email and follow the instructions described in your email. You will be required to upload a copy of your current human subjects training certificate to complete the PHIRST registration process. The PHIRST Help Desk will assign you the appropriate user roles (student investigator, study contact, co-investigator) and will notify you.

It usually takes about 1-2 business days after Step 4 is complete for you to receive by email your requested user roles.

If you have any problems with the PHIRST registration process, you should contact the PHIRST Help Desk at jhsph.phirsthelp@jhu.edu or call 410-502-5780.

4. 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 JHSPH 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.

5. 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 JHSPH IRB Office will verify it based on your JHSPH status (primary 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**.”

6. 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. When asked to upload your research plan, consent/assent forms, etc., be sure that you are using the most recent templates posted at [jhsph.irboffice@jhu.edu/Applications](mailto:jhsph.irboffice@jhu.edu) and Forms. Your IRB number will be assigned once you complete the information on the first screen and save it.

7. 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.

8. 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”, and then **CLICK “OK”**. If you fail to click “OK”, the response will not go to the IRB.

9. 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 jhsph.irboffice@jhu.edu.

10. 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?

11. 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 Help Desk at 410-502-5780 or email jhsph.phirsthelp@jhu.edu.

12. 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 **primary** 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.

13. 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.

14. 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 Help Desk or the PI to be sure that registration has been completed.

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

A faculty member must have **primary** 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.

16. 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.

17. 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.

18. 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.

19. 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 JHSPH IRB Office email (jhsph.irboffice@jhu.edu).

20. 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 Help Desk at jhsph.phirsthelp@jhu.edu or PHIRST helpline at (410) 502-5780. You will receive a response to your email communication or phone message within 1 business day.

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

Please email the PHIRST Help Desk at jhsph.phirsthelp@jhu.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.

22. 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 Help Desk at jhsph.phirsthelp@jhu.edu.

23. 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.

24. 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.

25. 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.