FAQs by Topic
**Introduction**

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

The FAQs are broken into 3 categories: General Topics; PHIRST (our electronic application system); and Student Information.

**Table of Contents**

**General Topics** ......................................................................................................................... 6

**Amendments and Progress Reports** ............................................................................................. 6

  - How do I submit an amendment request? ..................................................................................... 6
  - What documents do I need to submit with an amendment request? ............................................. 6
  - How can I check on the status of an amendment submission? ....................................................... 7
  - How do I submit a progress report? ................................................................................................ 7
  - How can I check on the status of a progress report submission? ................................................... 7
  - I didn’t submit my progress report in time and my study approval lapsed. What do I do now? 8
  - I submitted my progress report on the day it expired and it may not be reviewed for a few days. What do I do in the meantime? ................................................................. 8
  - Do I need to submit a signed copy of the amendment/progress report or is an unsigned emailed copy OK? ............................................................................................................. 8
  - Can a co-investigator or student investigator sign the amendment/progress report or must it always be the PI? ........................................................................................................... 9

**Cancer Research** ............................................................................................................................ 9

  - Does my application require SKCCC review? ............................................................................... 9

**Categories of Review** ..................................................................................................................... 9

  - Why isn’t my new application exempt? .......................................................................................... 9
  - What is the difference between full, expedited, and exempt review? .......................................... 9

**HIPAA** ............................................................................................................................................. 10

  - Who do I contact if I have questions about whether the study falls under HIPAA regulations? ................................................................................................................................. 10

**IRB Actions** .................................................................................................................................... 10
What does “tabled” mean? .................................................................................................................. 10
What does “approved with administrative changes” mean? ................................................................. 10

**IRB Resources** .................................................................................................................................. 11
I only have a paper copy of a document and need an electronic copy for a submission. Does the IRB have a scanner I can use? ........................................................................................................ 11

**Miscellaneous** .................................................................................................................................. 11
How can I find out which specialist has been assigned to my submission? ........................................ 11
How can I print a list of all studies by investigator? .............................................................................. 11
Do I need to use the stamped instrument in the field or can I keep the stamped instrument on file and use an unstamped approved copy? .................................................................................. 11
What information should be included in a letter of support/collaboration? ....................................... 12

**Planning Phase Review** .................................................................................................................. 12
I have a “just in time” request from a funding agency that asks for human subjects approval, but I don’t have anything developed yet. How do I submit a planning phase? How long does it take for a planning phase to be reviewed? .................................................................................. 12
Can I amend a planning phase application? ......................................................................................... 12

**Training** ........................................................................................................................................... 13
Do I need human subjects training? ...................................................................................................... 13
I need to provide human subjects training to my field workers and they will not have access to a computer. Can you recommend a training resource I can use? ...................................................... 13

**Translations** .................................................................................................................................. 13
What forms need to be translated? ........................................................................................................ 13
Who can translate documents and who can sign the certificate of translation? .................................. 13

**Turnaround Time** ............................................................................................................................ 13
How much time does it take to receive IRB approval of a new application? ........................................ 13
How long does it take to receive my approval notice and approved documents once my submission is approved? ................................................................................................................................ 14

**When to Submit** .............................................................................................................................. 14
Do I need IRB approval? ....................................................................................................................... 14
I am serving as a consultant on a research study at Institution X. Do I need to submit to the JHSPH IRB too? .............................................................................................................................................. 14

**PHIRST** ............................................................................................................................................ 15
What is PHIRST (pronounced FIRST)? ................................................................................................. 15
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? ................................................................. 15

There is a required field on the application for a completion date for Human Subjects Training. What is that? ........................................................................................................ 15

I still don’t see my role displayed on my screen. ........................................................................................................ 15

How do I create a new application in PHIRST? ...................................................................................................... 16

How do I upload my documents to the registration server to complete my profile? .......... 16

Where can I find the comments or concerns to the study team from the IRB staff? .............. 16

I’ve responded to the concerns, but haven’t heard anything back from the IRB. What’s wrong? ....................................................................................................................... 17

How do I gain access to view my faculty member’s projects? .................................................. 17

What should I do if I cannot remember my password or JHED ID to log in to PHIRST? .... 17

Can a student investigator submit an online PHIRST application? .................................... 17

Where and how can I submit electronic versions of documents that supplement my application? ............................................................................................................. 17

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? ................................................................. 17

How can I receive the role of principal investigator to submit an electronic PHIRST application? ............................................................................................................. 18

How can I add more than one study contact to the application? ............................................ 18

How do I find a copy of my CITI or JHSPH Human Subject Training (HST) Certificate? ...... 18

What browser/operating system do we need for using PHIRST? ........................................... 18

Why can’t I save the PHIRST application to a disk? ................................................................. 19

Why can’t I submit my continuing review or amendment? .................................................... 19

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

How can I change my user role in the PHIRST system? ......................................................... 19

I am trying to register another user, but unable to do so, what am I doing wrong? .............. 19

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? ....................................................... 19

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? .................................................................................................. 20

How do I access approved study documents in PHIRST? ..................................................... 20

Where can I find activity and/or state definitions for PHIRST? ............................................. 20

Student Information ......................................................................................................................... 21

If I am doing data analysis only that does not involve contact with human subjects, do I have to submit to the IRB? .......................................................... 21

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? ........................................ 21

Do I need IRB approval if my project involves key informant interviews? .............................. 21
Do I have to submit my entire research proposal for IRB review if I have received IRB approval at another institution? .................................................................21

Do I need to include researchers as co-investigators on my IRB application if they will not be involved in the data analysis? ..................................................................................21

Can I tell people about the research if my application is pending IRB approval? .........................21

Can I be added to an active, ongoing IRB-approved study? ..........................................................22

Do I have to submit a new application if my capstone project involves data analysis of pre-existing data with no identifiers or linkage? .................................................................22

Do I need a research plan for my dissertation research using secondary data analysis? .................22

If I am listed as a student researcher on a study that was closed, can I still write manuscripts and make dissertation presentations? .................................................................22

Do I need JHSPH IRB approval to submit a manuscript for publication for research conducted at another institution? .................................................................22
General Topics

Amendments and Progress Reports

1. How do I submit an amendment request?

It depends on the nature of the changes.

- Making minor changes to already approved instruments and recruitment materials only that are (1) consistent with the original aims of the study and (2) do not increase risk to subjects? If so, you can use our Fast Track Review for your amendment. Click here for Fast Track Review submission instructions.

- Adding a new phase, revising the research plan, submitting a revised consent form, and/or making more substantive changes than those described under the Fast Track Review process? If so, then complete an amendment application, and follow the guidance below:
  1. If you are revising already approved study documents, like the research plan, you must include a tracked and clean copy of the revised document.
  2. If you are submitting a new/revised consent form, please use the current consent form templates and email the new consent form with the amendment application to irboffice@jhsph.edu. The IRB will need an electronic version of the consent form for the approval and logo process.
  3. If you are adding new study team members, submit an investigator agreement signed by each person being added; and human subjects training certificate for each person being added.

We prefer that all amendment requests be submitted via email to irboffice@jhsph.edu. We can accept an unsigned copy of the amendment request form if the amendment request is sent from the PI’s inbox or if the PI provides a separate email confirming submission of the amendment request. Otherwise, please include an authentic digitally signed copy of the amendment request, scanned signed copy of the amendment, or indicate that you will send a signed hardcopy. If you cannot submit the application electronically, we will accept a hard copy version at the IRB office at 615 Wolfe St., Suite E1100. Note: PHIRST does not handle amendments.

If you need more information on submitting an amendment, click here or contact us.

2. What documents do I need to submit with an amendment request?

It depends on the nature of the changes. Please refer to FAQ No. 1, “How do I submit an amendment request?” for more information.
3. How can I check on the status of an amendment submission?

You can check the status of an amendment through the IRB Database. When you enter your study name, or find it under your last name, look at the bottom of the listing for the entry titled “Amendment”. If there is a “yes” beside that entry, click on it and it will lead you to a list of amendments within your study.

4. How do I submit a progress report?

We prefer that all progress reports be submitted via email to irboffice@jhsph.edu. If you cannot send the report in electronically, submit a hardcopy to Suite E1100. Note: PHIRST does not handle progress reports. We can accept an unsigned copy of the progress report if the progress report is sent from the PI’s inbox or if the PI provides a separate email confirming submission of the progress report. Otherwise, please include an authentic digitally signed copy, scanned signed copy, or indicate that you will send a signed hardcopy. Things to remember when submitting a progress report:

1. Always use the most current progress report template. We will return progress reports that use out of date forms.
2. If you are actively enrolling subjects in your study, please consider converting to our perpetual consent form if you have not already done so. For guidance on the perpetual consent process, click here. For the current consent form templates, click here.
   a. If you choose to change to the perpetual consent, please send electronic copies of the new consents to irboffice@jhsph.edu. The electronic version will be needed for the approval and logo process.
   b. If you choose not to change to the perpetual consent, please include clean copies of your consent form that can be re-stamped with the new study expiration date.
3. If you have enrolled subjects using a written consent process since the last approval, submit a copy of a signed and dated consent form (please redact the name) so we may verify that you are using the correct version.
4. When listing co-investigators and student investigators on the progress report, please double check the IRB Database to make sure your list matches our records. If you find any discrepancies, please submit an amendment application to add/remove anyone who should/should not be listed.
5. If you have had any administrative/minor departures from the IRB approved study which do not affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects, please report these as protocol deviations when you submit your progress report using the protocol deviation summary form.
6. If you have had any anticipated problems/events that have been described in the research plan, consent form, and/or investigator’s brochure, please report these when you submit your progress report using the anticipated problem/event summary form.
7. If any other IRBs review your study and have provided an updated approval letter, please be sure to include these with your submission.
8. If you have a Data Safety Monitoring Board, please attach a copy of the last report.
9. If you think any of the information you are providing in your progress report will raise questions with the reviewer (such as discrepancies between last year’s enrollment numbers and this year’s enrollment numbers), please include a comment in Section H of the progress report.

If you need more information on submitting a progress report, click here or contact us.

5. How can I check on the status of a progress report submission?

You can check the status of a progress report through the IRB Database. If the approval date and expiration date have been updated, the progress report has been processed. If not, assume it is still in review and contact us with your specific question.

6. I didn’t submit my progress report in time and my study approval lapsed. What do I do now?

If you did not submit a progress report before the study approval lapsed, all research activity including enrollment, collection of follow-up data from subjects, study visits, and data analysis must stop immediately. The IRB does not have the authority under the regulations to grant any kind of extension. To continue the study, you will need to submit a new PHIRST application for IRB review.

7. I submitted my progress report on the day it expired and it may not be reviewed for a few days. What do I do in the meantime?

If you have subjects in the study who are receiving a therapeutic intervention, you must request permission from the IRB to continue study activity with currently enrolled subjects. With this request, you must provide a rationale as to why it is in the subjects' best interests and ethically justified to continue study intervention during the period of IRB review. If the IRB grants the request, new enrollment, and data analysis may not occur during this time.

If your study does not involve a therapeutic intervention, all research activity including enrollment, collection of follow-up data from subjects, study visits, and data analysis must stop until the study is reapproved.

8. Do I need to submit a signed copy of the amendment/progress report or is an unsigned emailed copy OK?

We will accept an unsigned emailed amendment/progress report submission if the submission is sent from the PI’s inbox OR the PI provides a separate email confirming submission of the amendment/progress report. Simply copying the PI on an unsigned emailed amendment/progress report submission is NOT acceptable. We will also accept
a signed hardcopy, authentic digitally signed electronic copy, or scanned signed (pdf) copy.

9. **Can a co-investigator or student investigator sign the amendment/progress report or must it always be the PI?**

No, an amendment request or progress report must always be signed/submitted by the PI. See FAQ #8 for additional information “Do I need to submit a signed copy of the amendment/progress report or is an unsigned emailed copy OK?”

**Cancer Research**

10. **Does my application require SKCCC review?**

The SKCCC is the Sidney Kimmel Comprehensive Cancer Center. The SKCCC must, as part of its CORE grant, review all cancer-related studies that take place at Johns Hopkins. If you submit a cancer-related new application to the IRB and have not had SKCCC review, we will flag your application and notify the contact person at SKCCC for further guidance. If you obtain SKCCC approval prior to submitting your new application, you can upload a copy of your approval notice in PHIRST. The SKCCC website can be accessed here: [http://cro.onc.jhmi.edu/](http://cro.onc.jhmi.edu/).

**Categories of Review**

11. **Why isn’t my new application exempt?**

The IRB has put in place more stringent policies than those in the federal regulations for exempt studies. For example, there are some survey studies that could qualify as exempt under the federal regulations. However, because of the nature of the questions or the location of the study, the IRB has chosen to have these studies reviewed by IRB – X to provide an extra layer of protection. If your new application is reviewed by IRB – X, there is a chance that it could then be determined to be exempt from further review (meaning you would not have to submit a progress report every year). You will always receive documentation of the determination made by the IRB.

12. **What is the difference between full, expedited, and exempt review?**

The Institutional Review Board (IRB) Office is composed of an exempt team, IRB X, and IRB FC. The Chairs of the two IRBs work with dedicated IRB X or IRB FC staff. Both IRB X and IRB FC meet weekly. An “expedited” review process simply means that a submission to the IRB may be reviewed by a single individual rather than by the whole board. It does not mean “fast”. IRB X and IRB FC perform both full board and expedited review processes.

IRB X handles minimal risk studies that meet the expedited categories listed in the federal regulations ([http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)).
All IRB X new applications receive full board review, meaning that the entire board reviews the study and makes a decision about the outcome of that review. Most IRB X progress reports receive expedited review. Typically, most IRB X amendments receive expedited review; however, if a new phase of the study is being added or substantial changes are being requested, the amendment will receive full board review.

IRB FC reviews studies that pose more than minimal risk to subjects. That risk may be physical, emotional, psychological, economic, social, or legal. Because there are M.D. members on IRB FC and not on IRB X, IRB FC may review some studies which otherwise may qualify as minimal risk studies, but involve minor medical or drug interventions which require medical or P&T expertise as part of the review. IRB FC also handles data coordinating center studies. All IRB FC new applications receive full board review. Typically, all IRB FC progress reports receive full board review until they reach the data analysis phase or are permanently closed to enrollment and followup. IRB FC amendments will receive full board review, unless they involve administrative or minor changes to the approved research.

The exempt team reviews submissions which meet the criteria for “not research”, “not human subjects research”, and exempt studies. This team will determine whether the Principal Investigator (PI) is “engaged in human subjects research” under OHRP guidance. The PIs of all such submissions will receive documentation of these determinations.

**HIPAA**

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

Marla Hallacy handles HIPAA related questions and clarifications. Her email is mhallacy@jhsph.edu and her phone number is 410-502-0433.

**IRB Actions**

14. What does “tabled” mean?

Tabled is an action taken by the Board or a single reviewer (in cases where the submission is being reviewed in an expedited fashion). Tabled means that the Board or reviewer requires additional information before a decision can be made regarding your submission. If your submission is tabled, you will receive a memo from the IRB listing the items that need to be addressed. You should respond to this memo as soon as possible to keep the review process going.

15. What does “approved with administrative changes” mean?

Approved with administrative changes is an action taken by the Board or a single reviewer (in cases where the submission is being reviewed in an expedited fashion).
Approved with administrative changes means the Board or reviewer has approved the submission pending minor changes. If your submission is approved with administrative changes, you will receive a memo from the IRB listing the administrative changes. The IRB will not release your approval notice and approved documents until you respond to the items specified in that memo, and your response is accepted. Typically, your response to the memo will be reviewed by an IRB staff member. **Do not start your study until you have received the actual approval notice and approved documents.**

**IRB Resources**

16. I only have a paper copy of a document and need an electronic copy for a submission. Does the IRB have a scanner I can use?

Yes, you can come down to the IRB Office (Suite E1100) and we can scan a document for you.

**Miscellaneous**

17. How can I find out which specialist has been assigned to my submission?

It depends on whether this is a new application submission or a submission for an already approved study.

Is this a new application? Sign into the PHIRST system and look up the new application in question. You should see a field with the assigned specialist’s name at the top of the screen.

Is this a submission for an already approved study? You can find out which specialist has been assigned to your submission through the IRB Database. Please note that this may not be current until 1-2 business days after we receive your submission.

If you do not have an active submission, the person listed as the specialist is the last person who worked on your study and may not be the person who works on your next submission.

18. How can I print a list of all studies by investigator?

You can print a list of all studies by investigator through the IRB Database.

19. Do I need to use the stamped instrument in the field or can I keep the stamped instrument on file and use an unstamped approved copy?

You do not have to use the stamped instrument in the field. You do however have to keep a stamped copy on file and use the approved version in the field.
20. What information should be included in a letter of support/collaboration?

The letter of support/collaboration should include the name of the organization/investigators that will be collaborating with you, description of their involvement, and agreement to collaborate with you.

**Planning Phase Review**

21. I have a “just in time” request from a funding agency that asks for human subjects approval, but I don’t have anything developed yet. How do I submit a planning phase? How long does it take for a planning phase to be reviewed?

The planning phase application is embedded in the main study application in PHIRST. To submit a planning phase, you need to start a new application in PHIRST. In the Study Identification section in PHIRST, which should be the first screen you are brought to, you will need to answer all of the questions and make sure that you check the box next to question 10.0 that asks if you are submitting a planning phase. This will dictate the next screens you will be directed to within PHIRST. The next screen you come to will ask you to describe why you need the planning phase and the duration of the planning phase. You will then be taken to the Funding and Conflict of Interest section. Please be sure to upload your grant/contract in this section.

Planning phase reviews are usually completed within a few days depending on the completeness of the submission and the timing of the submission. Senior IRB staff may approve these applications. Please note that no human subjects contact may occur through a planning phase submission. You will receive a planning phase review notice through PHIRST once the review is complete.

22. Can I amend a planning phase application?

No, you cannot amend a planning phase. Prior to enrolling human subjects, you need to submit a new application in PHIRST.

23. How can I request for an extension of approval for a Planning Phase?

If the Planning Phase is to continue beyond one year, the PI must submit a written request for an extension to the JHSPH IRB Office irboffice@jhsph.edu or via hard copy to JHSPH IRB Office, E1100 prior to the Planning Phase expiration. *In the memo, include a description of the progress made to date and the reason for the extension request.* An email from the PI’s email address is sufficient, though the office will accept a signed paper copy delivered to the JHSPH IRB Office. All electronic requests must come directly from the PIs mailbox or a confirmation from the PI must accompany the request.
Training

24. Do I need human subjects training?

All investigators, including students, who are “engaged in research” need human subjects training. JHSPH investigators must take CITI. Investigators from other institutions may submit their institution specific training certificate.

25. I need to provide human subjects training to my field workers and they will not have access to a computer. Can you recommend a training resource I can use?

Check out the example training manual we have posted under our Training link.

Translations

26. What forms need to be translated?

At a minimum, we require all consent-related documents to be translated. This could include telephone scripts, if consent is obtained over the phone. To save yourself time and money, you should wait to translate your consent documents until after the IRB approves the English versions. Once the IRB approves your English consent forms, we will request that you submit the translated versions with a certificate of translation. If you would like to have us stamp other translated documents (such as instruments), you will need to submit the translated document with a certificate of translation.

27. Who can translate documents and who can sign the certificate of translation?

Anyone that is fluent in the native language and who is not associated with the study can translate the documents and sign the certificate of translation. The PI will also need to sign the certificate of translation.

Turnaround Time

28. How much time does it take to receive IRB approval of a new application?

This is not an easy question to answer as there are many variables that impact review time, such as when the new application is submitted, how complete the submission is, and which committee the new application is assigned to. Typically, new applications that require review by one of the IRBs are not approved the first time around. The Board usually requires changes and clarifications that need to come back to the Board for review. You may assume that your new application will go to the Board at least twice: once at the initial review, when the application is tabled, and once when the PI response to the tabled letter is reviewed. However, it is quite common for a second round of letters between the IRB and the PI to be exchanged. This process is more efficient when the primary reviewer, who is responsible for presenting the new application to the Board, is able to contact the PI of the study in
advance of the IRB meeting. The primary reviewer is often able to identify issues that a PI may address by phone or email in advance of the meeting, and this exchange helps to move things along more quickly.

Both IRB X and IRB FC meet weekly to review new applications; FC on Wednesdays, X on Thursdays. If a PI submits a new application in PHIRST on a Thursday by 3pm, it will be assigned to a research subject specialist. The specialist will review the application for completion, and when all the parts are in place, the study will be assigned a primary reviewer. If the application is complete, if it is an IRB X study, the application will go on the next Thursday’s IRB X meeting agenda; if it is an IRB FC study, it will go on the meeting agenda for the Wednesday 13 days after submission. Letters after each meeting go out to PIs by the Monday following the IRB meeting. So, the turnaround time from that point on depends on how quickly the PI responds to the IRB’s letters. PI responses are put on agendas up until a day or two before the meeting, unless there is some complication associated with the response.

This schedule does not apply to studies being reviewed as not research, not human subjects research, or exempt by the Exempt team. These applications do not require Board review and are typically, but not always, processed faster.

29. How long does it take to receive my approval notice and approved documents once my submission is approved?

Once a submission has been approved, the research subjects specialist will forward the materials to the appropriate research subjects coordinator to prepare the approval notice and approved documents. The turnaround time for when you receive your approval notice and approved documents depends on the workload of the coordinators. If you need your documents within a certain timeframe, please be sure to communicate this with the specialist in advance, so he/she can work with the coordinator to accommodate your request. Otherwise, approval documents for submissions are processed as received.

When to Submit

30. Do I need IRB approval?

If you are a faculty investigator, it depends on what your study will involve. Please refer to the following flowchart. If in doubt, please submit a new application or contact us.

If you are a student, the answer is always yes. All student projects require IRB review.

31. I am serving as a consultant on a research study at Institution X. Do I need to submit to the JHSPH IRB too?

Please review our guidance on When is an Institution or PI ‘Engaged’ in Human Subjects Research.
PHIRST

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 (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.”

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@jhsph.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 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.

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 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.

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

To enter the CITI course site http://www.citiprogram.org, you must enter the username and password created at registration, 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.

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:

<table>
<thead>
<tr>
<th>Platform</th>
<th>Browser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microsoft Windows (all versions)</td>
<td>Microsoft Internet Explorer, version 5.5 or later</td>
</tr>
<tr>
<td></td>
<td>Netscape Navigator, version 7.1 or later</td>
</tr>
<tr>
<td></td>
<td>Mozilla, version 1.5X or later</td>
</tr>
<tr>
<td></td>
<td>Firefox 1.0X or later</td>
</tr>
<tr>
<td></td>
<td>Opera version 7.10 or later</td>
</tr>
<tr>
<td>Macintosh OS X or later</td>
<td>Netscape Navigator, version 7.1X or later</td>
</tr>
<tr>
<td></td>
<td>Safari 1.1 or later</td>
</tr>
<tr>
<td></td>
<td>Mozilla, version 1.5X or later</td>
</tr>
</tbody>
</table>
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 IRB Office email (irboffice@jhsph.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 helpdesk at 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.

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

Please email the PHIRST helpdesk at phirsthelp@jhsph.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 helpdesk.

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.

26. Where can I find activity and/or state definitions for PHIRST?

Please click here for complete list of activity and state definitions in PHIRST
**Student Information**

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 terminated 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).