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.
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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 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?**

1. Visit our website: [www.jhsph.edu/irb](http://www.jhsph.edu/irb)
2. Click ‘PHIRST Access Link” on the left side of the home page screen
3. Click ‘Home’ link at the top of the screen
4. Click ‘Registration” or ‘Registration – Non JHU” link and fill in the required fields.

**NOTE:** If a current user is registering a new user, be sure to log out of the existing account. Current users can NOT be logged into their Phirst account while registering a new user.

Contact the PHIRST Help Desk phirsthelp@jhsph.edu or 410-502-5780 if you have any problems with the PHIRST registration.

3. **Who qualifies as a PI, Co-I, Student Investigator, and study contact in PHIRST and what are the training requirements?**

<table>
<thead>
<tr>
<th>Study Team Role</th>
<th>Description and Qualifications</th>
<th>Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator (PI)</td>
<td>JHSPH Full Time Faculty, responsible for overseeing the responsibilities described in the roles section of the research plan.</td>
<td>CITI Human Subjects Research Training; GCP (Good Clinical Practice) training if conducting clinical trial; HIPAA training if accessing/using Protected Health Information</td>
</tr>
<tr>
<td>Co-Investigator, JHSPH employee</td>
<td>Faculty, student (in the role as hired staff), staff involved in the project, and responsible for aspects of study operations</td>
<td>CITI Human Subjects Research Training; GCP training if conducting clinical trial; HIPAA training if accessing/using Protected Health Information</td>
</tr>
<tr>
<td>Co-Investigator, non-JHSPH employee</td>
<td>Must have qualifications to perform delegated role and be responsible for aspects of study operations</td>
<td>CITI Human Subjects Research Training; Family Health International (FHI) Training; NIH training; or training from their home institution.</td>
</tr>
<tr>
<td>Student Investigator</td>
<td>JHSPH student; the project must be associated with the student’s academic objective</td>
<td>CITI Human Subjects Research Training; GCP training if conducting clinical trial; HIPAA training if accessing/using Protected Health Information</td>
</tr>
<tr>
<td>Study Staff, JHSPH employee</td>
<td>Must have qualifications to perform delegated role. This category could include research coordinators, data</td>
<td>CITI Human Subjects Research Training; GCP training if conducting clinical trial; HIPAA training if accessing/using Protected Health Information</td>
</tr>
</tbody>
</table>
Study Staff, non-JHSPH employee | Must have qualifications to perform delegated role. This category could include research coordinators, data coordinators, lab personnel who will see identifiers, interviewers, etc. | Any of the computer-based modules mentioned above, or an in-person research ethics training conducted by a qualified person, and approved by the IRB. Curriculum must be IRB approved, like the Field Training Guide found here: http://www.jhsph.edu/irb/Training.html

Study Contact | Administrative role only – receives copies of IRB communications to PI | No training required. Should have no contact with study participants or data (unless listed in one of the above roles).

4. There is a required field on the application for a completion date for Human Subjects Training (HST). 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.

Once a user uploads their HST into PHIRST, their account information will automatically be updated and users will not be asked to upload this information again until expiration. 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. Does the Human Subject Training expire?

Starting June 1, 2012 the training certificate will expire every 5 years from the date of completion. Please make sure your training is always current or it will affect the submission of applications.

6. 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 PHIRST Help Desk 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.”

7. 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.

*NOTE: Your IRB number will be assigned once you complete the information on the first screen and save it.

8. 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. The 'Human Subject Training Certificate' section to upload your document is located at the bottom of the page. Click the 'add' button to upload the required information.
4. Click Apply

Failure to upload this information will affect the submission of new applications.
9. 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.
1. Under “My Activities”, click on the link called “Respond to Concerns”.
2. Next, click “Respond” to review the concern sent to you.
3. Enter your response in the text box provided.
4. When you have finished your response, select “Yes” under “Send to IRB”,
5. Finally CLICK “OK”. If you fail to click “OK”, the response will not go to the IRB.

10. 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.

11. 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?

12. 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.
13. 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.

14. 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.

15. 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.

16. 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.

17. 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 at this time. The study team member will still be able to access under his/her own login and make changes in the PHIRST system.
18. How do I find a copy of my CITI or JHSPH Human Subject Training (HST) Certificate?

**CITI HST Certificate**

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

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

**View course completion history for Johns Hopkins Bloomberg School of Public Health and print completion certificates**

You will see a “print completion report” link to print your report.

**JHSPH HST Certificate**

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

[http://apps2.jhsph.edu/chr/cbt/admin/frm_cert_on_demand.cfm](http://apps2.jhsph.edu/chr/cbt/admin/frm_cert_on_demand.cfm)

19. 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>
</table>
| 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.
20. 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.

21. 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).

22. 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.

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

Send an email to the PHIRST helpdesk at phirsthelp@jhsph.edu, listing your user ID, current role and describing the change or additional role. PHIRST help will update your registration and will send you a confirmation email.

**Please Note:** A faculty member must have a **primary** appointment at the School of Public Health to be registered with the role of “Principal Investigator” on a PHIRST research application. Other JHSPH faculty and non JHSPH collaborators may request the role as co-investigator. Student investigators may request the role of “student investigator.”

24. 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.
25. 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?

Once the user completes the registration process by uploading human subjects training certificate, PHIRSThelp confirms user roles within 24-48 business hours.

26. 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.

27. 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.