

JHSPH IRB's PHIRST SYSTEM
(Public Health Institutional Review System Tracking)

Completing Study Shells

For Investigators, Students, Study Team Members



JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

developed by
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Log in to PHIRST

PHIRST is available at <https://phirst.jhsph.edu>. This address brings you to the PHIRST log in page. Click on the blue button “Log in with JHED”, using your JHED ID and JHED password. If you need to refer to your study in the old PHIRST system, click on the gray “Log into old PHIRST” button. Your user name is now your JHED ID, but your password remains what it has always been for PHIRST.

The screenshot shows the PHIRST login page. At the top left is the Johns Hopkins Bloomberg School of Public Health logo. The title 'PHIRST' is in large blue letters. Below it is the subtitle 'Public Health Institutional Review Submission Tracking'. The main text welcomes users and provides contact information for the IRB Office and PHIRST Help Desk. There are two login buttons: a blue 'Log in with JHED' button and a gray 'Log into old PHIRST' button. Red arrows point from red-bordered boxes containing instructions to these buttons. The blue box says 'Login with JHED ID and JHED password' and points to the blue button. The gray box says 'Login with JHED ID and old PHIRST password' and points to the gray button. There is also a checkbox for 'Remember JHED Login Preference.' and a link to 'JHSPH.phirsthelp@jhu.edu'.

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PHIRST

Public Health Institutional Review Submission Tracking

Welcome to **PHIRST**, the online submission and review system for new human subject research applications to the IRB at JHSPH.

Templates for the research plan and consent documents can be found on the IRB site, www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/.

IRB Office: 410-955-3193
Email: JHSPH.irboffice@jhu.edu
PHIRST Help Desk: JHSPH.phirsthelp@jhu.edu

Remember JHED Login Preference.

If you are not affiliated with JHU and are involved in a study for which you need access to study documents, you may need to register in PHIRST. Contact the PHIRST Help Desk to request an ad-hoc JHED ID:
JHSPH.phirsthelp@jhu.edu

If you have applications under review in the old PHIRST system or just need to access your old applications and files (new applications cannot be created and submitted in old PHIRST):

Annotations:
- Blue button: Log in with JHED → Login with JHED ID and JHED password
- Gray button: Log into old PHIRST → Login with JHED ID and old PHIRST password

Your PHIRST Homepage – My Inbox

When you log in to PHIRST; you will arrive at your PHIRST Homepage called **My Inbox**. All active studies on which you are listed as PI in the IRB will be listed under the blue **New Application** banner. Note that they are all in the “Pre-Submission” state. Be assured that they are all approved studies and they will not have to go through the IRB review process again; we are simply moving them operationally from paper to fully electronic. They must be submitted by you so the IRB can activate them in the updated PHIRST system.

Click on the study title to go to the study Application Workspace.

The screenshot shows the PHIRST My Inbox homepage. The navigation bar includes 'My Inbox', 'PHIRST Resources', and a user greeting 'Hello, [Name]'. The main content area features a 'Welcome to PHIRST' message and an 'ALERT: Action Required-Respond to Study Participation Request' section. Below the alert, a table titled 'New Application' lists several IRB applications, all in the 'Pre Submission' state. A red box highlights the first row of the table, and a red arrow points to the 'Name' column with the text 'Click on study title'.

ID	Name	State	Last State Change	Review Team	PI Last Name
IRB [ID]	[Study Title]	Pre Submission		Exempt	[PI Name]
IRB [ID]	[Study Title]	Pre Submission			[PI Name]
IRB [ID]	[Study Title]	Pre Submission		IRB X	[PI Name]
IRB [ID]	[Study Title]	Pre Submission		IRB X	[PI Name]

The Application Workspace

Many application shells will be pre-populated with the following documents:

- Current approved research plan for the study
- Current approved consent/assent/parental permission form(s) if you have them for your study
- Several other documents may also be included depending on your study

The documents will be found on the relevant application pages, i.e., consent documents will be on the “Informed Consent for Adults” page, assent documents on the “Assent for Minors” page, and so on. You must complete the application questions in order to submit the application to the IRB so that the study can be transitioned into the approved active state.

Click on “Edit Application” to go to the application questions.

JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH PHIRST Hello, [User Name]

My Inbox PHIRST Resources IRB Submissions

IRB Submissions

Application: [Application ID] A Comparison of Risk Adjustment Models in Predicting Health Care Costs in Older Adults based on Traditional Statistical and Machine Learning Techniques

Pre Submission

Edit Application Print Application View Differences

Activities

Request Study Team Participation Submit to IRB

PI: [Name]

Study Contact: [Name]

Date Created: 12/7/2019 4:41 PM Date Submitted: NOT YET SUBMITTED

Checklist for Submission

- All study documents are uploaded
- All key co-investigators, student investigators and study team members are listed on the application
- All listed investigators and study team members have been invited to participate using the “Agree or Decline to Participate” activity

ONLY THE PRINCIPAL INVESTIGATOR (PI) MAY SUBMIT THIS APPLICATION

The PI may submit the PHIRST application by clicking the “Submit” button before all study team members have responded. All study team members must accept participation before the IRB will grant final approval. If a study team member declines participation, the PI must remove that person from the application before the IRB may complete the approval process.

Study Team Responses

Last Name	First Name	Date Invited	Date Accepted	Date Declined	COI	Role on Study
There are no items to display						

Application Questions

The first page of the application will have the study name, short description and PI already filled in. You, as PI, may add co-investigators, student investigators, other study team members and study contact names. If they aren’t readily available in the drop-down list, don’t worry; the IRB has the paper file of all the people you have added to your study to date. You can reconcile your list of study investigators and personnel at a later time.

Your answers to PHIRST questions should reflect the current state of your study as of the last approval. Do not include information that has not yet been reviewed; **THIS IS NOT AN OPPORTUNITY TO UPDATE OR MODIFY YOUR STUDY.** You may later amend your study through the PHIRST system once your study is active. You may upload any study document (instruments, permissions, etc.) that has already been approved by the IRB. (Instructions for uploading documents can be found in the PHIRST User Guide)

Who completes the application – PI or study team member?

Although all application questions must be completed in order to submit, **only the first page must be completed by the PI.** Other study team members, once added to the first page, may complete the rest of the application.

1. On the first page of the application, **Study Team and Study Description**, the PI adds current, approved study team members to either question 5.0 (co-investigator), question 7.0 (student investigator) or question 8.0 (study contact).
2. The PI completes the required questions on the first page (marked with a red * asterisk).
3. The PI clicks “Continue” or “Save” at the top or bottom of the page.
4. The added study team members can now log in to their PHIRST accounts and will see the application listed on their **My Inbox** homepage under the **Action Required** tab.
5. They complete the remaining pages of the application (and upload any additional documents) and alert the PI when finished.
6. Only the PI can submit the application, either from the last page of the application (see below) or using the “Submit to IRB” activity on the left side of the application workspace.

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Edit: IRB Submission - IRB00011077

You Are Here: Repository: Maternal and Chil...

« Back Save Exit Hide/Show Errors Print Jump To » Finish

Final Page

THIS APPLICATION HAS NOT YET BEEN SUBMITTED TO THE JHSPH IRB!

1.0 Use the text area below to communicate any additional information to the IRB Office:

If you are ready to submit this information to the IRB, answer "Yes" to the question below and click "Finish" at top or bottom right of the page.

If you are not ready to submit this information to the IRB at this time, answer "No" to the question below, then click "Finish" and the information you have entered will be saved.

2.0 With this submission, I affirm the following:

- I have read the protocol and this application.
- All questions on this application are answered truthfully and with appropriate completeness.
- Adequate resources and facilities are available to carry out the proposed research.
- Investigators and study team members will adhere to the current state and federal regulations, local law, international law, and institutional policy governing this research.
- I will ensure that all study personnel have the certification and/or credentialing required by law and by institutional policy to perform their assigned study activities, the appropriate training to conduct the portion of this study in which they are involved, and that they understand the study's standard operating procedures.
- I will ensure that all study team members (including students) have completed any and all required ethics, Good Clinical Practice, HIPAA and all other trainings needed for the study.
- I will ensure that the study personnel understand how to conduct the protocol in accordance with the terms of the JHSPH IRB approval and guidance.

Yes No [Clear](#)

« Back Save Exit Hide/Show Errors Print Jump To » Finish

Transitioning to Active – what now?

The IRB staff will review your submitted application to ensure that it is consistent with the approved study file. They will then transition the application to “Active”. Once active, you will be able to submit amendments, continuing reviews, and all other submissions related to your study. All study submissions, including related documents will be available in PHIRST.

For complete instructions on using PHIRST, you may refer to the [PHIRST User Guide](#), available at the [IRB Office](#) website. For questions specific to PHIRST, email the IRB PHIRST Help Desk at JHSPH.phirsthelp@jhu.edu. For other IRB questions, call the IRB Office at 410-955-3193, or email at JHSPH.irboffice@jhu.edu.