

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

Completing Study Shells

For Investigators, Students, Study Team Members



developed by
**Johns Hopkins Bloomberg School of Public Health
Institutional Review Board (IRB) Office**

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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 points to the "Log in with JHED" button with the text "Login with JHED ID and JHED password". The gray box points to the "Log into old PHIRST" button with the text "Login with JHED ID and old PHIRST password". There is also a checkbox for "Remember JHED Login Preference." and a link to the PHIRST Help Desk email.

JOHNS HOPKINS
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of PUBLIC HEALTH

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 header includes the Johns Hopkins Bloomberg School of Public Health logo and the PHIRST logo. The main navigation bar has 'My Inbox' selected. On the left, there are sections for 'Site Links' (with 'Create New Application' checked) and 'My Workspace Templates' (with 'Study Team Workspace'). The main content area has a 'Welcome to PHIRST' message and an 'ALERT: Action Required-Respond to Study Participation Request' section. Below the alert, there is a table of 'New Application' items. The table has columns for ID, Name, State, Last State Change, Review Team, and PI Last Name. The first row shows a study with the state 'Pre Submission', which is circled in red. A red box with the text 'Click on study title' and an arrow points to the study title in the first row.

| ID | Name | State | Last State Change | Review Team | PI Last Name |
|-------------|--|----------------|-------------------|-------------|--------------|
| IRB-1011007 | Research Protocol for the Study of the Effectiveness of the... | Pre Submission | | Exempt | |
| IRB-1011008 | Research Protocol for the Study of the Effectiveness of the... | Pre Submission | | | |
| IRB-1011009 | Research Protocol for the Study of the Effectiveness of the... | Pre Submission | | IRB X | |
| IRB-1011010 | Research Protocol for the Study of the Effectiveness of the... | Pre Submission | | IRB X | |

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.

The screenshot shows the PHIRST application workspace. At the top, there is a navigation bar with the Johns Hopkins Bloomberg School of Public Health logo and the PHIRST name. Below the navigation bar, there are tabs for "My Inbox", "PHIRST Resources", and "IRB Submissions". The "IRB Submissions" tab is active, showing a list of applications. The application title is "A Comparison of Risk Adjustment Models in Predicting Health Care Costs in Older Adults based on Traditional Statistical and Machine Learning Techniques". The application is in the "Pre Submission" state. On the left side, there are buttons for "Edit Application", "Print Application", and "View Differences". The "Edit Application" button is highlighted with a red arrow. Below the application details, there is a "Checklist for Submission" section with three items: "All study documents are uploaded", "All key co-investigators, student investigators and study team members are listed on the application", and "All listed investigators and study team members have been invited to participate using the 'Agree or Decline to Participate' activity". A red warning message states: "ONLY THE PRINCIPAL INVESTIGATOR (PI) MAY SUBMIT THIS APPLICATION". Below the warning, there is a table for "Study Team Responses" with columns for "Last Name", "First Name", "Date Invited", "Date Accepted", "Date Declined", "COI", and "Role on Study". The table is currently empty, with the text "There are no items to display" below it.

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)

Use the "Continue" button at the top or bottom of the page to advance through the application pages. When you are finished entering all your answers, you may submit the application from the Final page by clicking YES to question 2.0 and then clicking "Finish".

The screenshot shows the PHIRST application interface. At the top, it displays the Johns Hopkins Bloomberg School of Public Health logo and the PHIRST title. The user is logged in as 'Edit: IRB Submission - IRB00011077'. Below the header, there is a navigation bar with buttons for 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Finish'. The main content area is titled 'Final Page' and contains a red warning message: 'THIS APPLICATION HAS NOT YET BEEN SUBMITTED TO THE JHSPH IRB!'. Question 1.0 asks the user to provide additional information to the IRB Office, with a large text input area. Below this, there are instructions: '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.' and '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.' Question 2.0 is an affirmation statement: 'With this submission, I affirm the following:'. It lists several bullet points regarding the user's understanding of the protocol, resources, regulations, and training. At the bottom of the question, there are radio buttons for 'Yes' and 'No', and a 'Clear' link. A red arrow points to the 'Yes' radio button. At the bottom of the page, there is another navigation bar with the same buttons as the top, and a red arrow points to the 'Finish' button.

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.