

# JHSPH IRB's PHIRST SYSTEM

# USER GUIDE

*(Public Health Institutional Review System Tracking)*

## **Welcome to PHIRST**

PHIRST is a web-based new research application submission system used by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board (JHSPH IRB) as a portal for all new human subjects research applications.

This user guide was developed specifically for investigators and study team members using the PHIRST system. This manual includes the following topics to get you started:

- ❖ PHIRST registration
- ❖ An overview of the submission and review process
- ❖ Basic methods and terms you need to know to create and submit electronic IRB applications

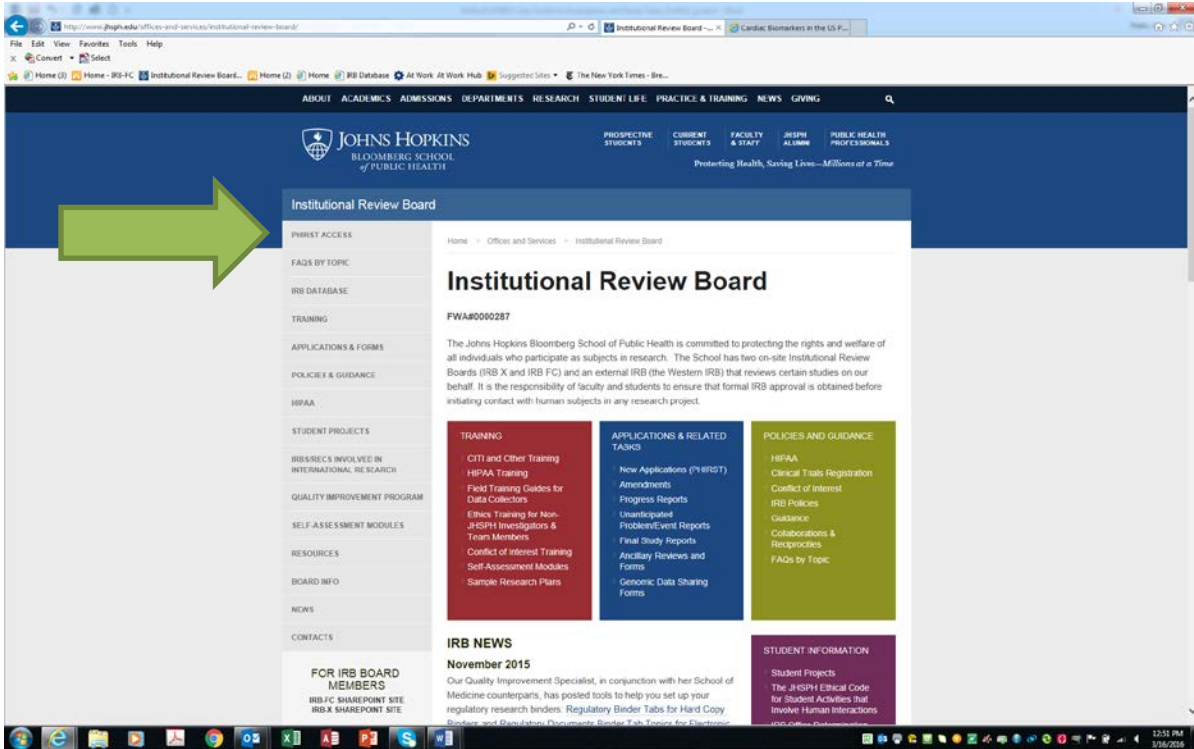
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# ACCESS TO PHIRST

PHIRST is may be accessed from the JHSPH IRB website at [www.jhsph.edu/irb](http://www.jhsph.edu/irb) (see screenshot below). You must register in PHIRST before being able to use its functions to submit research applications, respond to reviewers, and follow the application's progress through its initial review.



## PHIRST REGISTRATION AND ASSIGNMENT OF ROLES

Every person who will be named in one of the following investigator roles on a study must be registered in PHIRST. Registration will include providing certification of research ethics training consistent with JHSPH IRB policy (see:

<http://www.jhsph.edu/offices-and-services/institutional-review-board/training/>).

People who register in PHIRST will be assigned various “roles” depending upon their assigned tasks with respect to research applications. Once assigned a role in a particular application, the PI must invite that person to agree to participate in that role. This ensures that no one is added to an application without their knowledge.

Registered User: Everyone who registers in PHIRST is given this role.

PI: Faculty members who will serve as Principal Investigators (PIs) will receive the PI role. The PI role will allow them to create a new application, invite co-investigators and student investigators to participate in a new application, and they are also the only ones empowered to actually SUBMIT a new application.

Co-Investigator: For IRB purposes, co-investigators include any person who is “engaged” in human subjects research, e.g., interacts with study participants, obtains informed consent, or sees/uses identifiable private information associated with study data or specimens. This role includes individuals who may not be faculty members but who are responsible for substantive aspects of study operations. Students who are employed as study team members and whose activities make them “engaged” in human subjects research should have this role.

Student Investigator: A student investigator is someone who is involved in the study as partial fulfillment of his/her academic objectives.

Study Contact: A study contact is someone who is not engaged in human subjects research but who works with the PI in an administrative capacity.

Other roles: IRB Member, IRB Reviewer

## To Register: Follow the links on the PHIRST home page

The screenshot shows the PHIRST website interface. A green arrow points to the 'Registration' link in the left-hand navigation menu. The main content area contains the following text:

**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. At this time, progress reports, amendment applications, problem event reports, and final study reports should be submitted via email to [JHSPH.irboffice@jhu.edu](mailto:JHSPH.irboffice@jhu.edu). Templates for all these forms and for the research plan and consent documents can be found on the IRB site, [www.jhu.edu/offices-and-services/institutional-review-board/applications-and-forms/](http://www.jhu.edu/offices-and-services/institutional-review-board/applications-and-forms/).

**Registration:** If you have not yet registered, click on the **REGISTRATION** link in the left hand column of this page to complete the registration form. Once you submit the registration form, you will receive an email from PHIRST indicating that your request has been received and providing you with a temporary password. You must change your password the first time you sign into PHIRST. You will then receive a second email when your account has been created and your "user role(s)" has been confirmed. Until you receive the second email you will be able to access the PHIRST system but you will not be able to create, view or be added to applications.

**Submission after IRB Approval of PHIRST Application:** Once a PI submits a research application to PHIRST, and the JHSPH IRB approves the study, the role of PHIRST with respect to submissions and communications with the IRB ends. After approval, all submissions, including progress reports, amendments, adverse or problem event reports, IND safety reports, etc., should come to the IRB email box at [JHSPH.irboffice@jhu.edu](mailto:JHSPH.irboffice@jhu.edu).

**Help Desk:** For assistance, call the PHIRST help desk at **410-502-5700** or send an email to [JHSPH.phirsthelp@jhu.edu](mailto:JHSPH.phirsthelp@jhu.edu). Office hours are 9am to 4pm, Monday through Friday.

On the right side of the page, there is a login form with fields for 'User Name' and 'Password', a 'Login' button, and a 'Remember me' checkbox. Below the form are links for 'Forgot your password?' and 'Forgot your user name?'.

## You will receive the following email; please follow the instructions carefully:

**From:** [rblevins@jhu.edu](mailto:rblevins@jhu.edu) [<mailto:rblevins@jhu.edu>]  
**Sent:** Friday, July 10, 2015 1:10 PM  
**To:** Rick Blevins  
**Subject:** Your account request has been received



Welcome to PHIRST. We have received your registration request.

Please find your name, User ID and a temporary password below. You will be instructed to change this password the first time you log into the PHIRST system.

The JHSPH IRB Office is currently verifying your information and request(s) for User Roles. The verification is not automatic. It takes typically takes 24 business hours.

Please provide a copy of your human subjects training certificate or CITI completion report. You will not be able to submit applications through PHIRST without completing this step.

Please follow the instructions below to upload your certificate or completion report:

1. Log-in to the PHIRST website (<http://phirst.jhsph.edu>) using your user ID that you created and temporary 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

Once we complete this process, we will send you an email notification finalizing your registration. Meanwhile, you are welcome to log in and view PHIRST.

DO NOT REPLY TO THIS EMAIL. If you have questions, please call the PHIRST Help Line at 410-502-5780 or send an email to [phirsthelp@jhsph.edu](mailto:phirsthelp@jhsph.edu).

### **Request Details**

**First Name:** test

**Middle Name:**

**Last Name:** userToo

**User ID:** test\_usertoo

**Temporary Password:** n93wPRkM

**E-mail address:** *(If you are reading this you gave us the correct address)* [rblevins@jhu.edu](mailto:rblevins@jhu.edu)

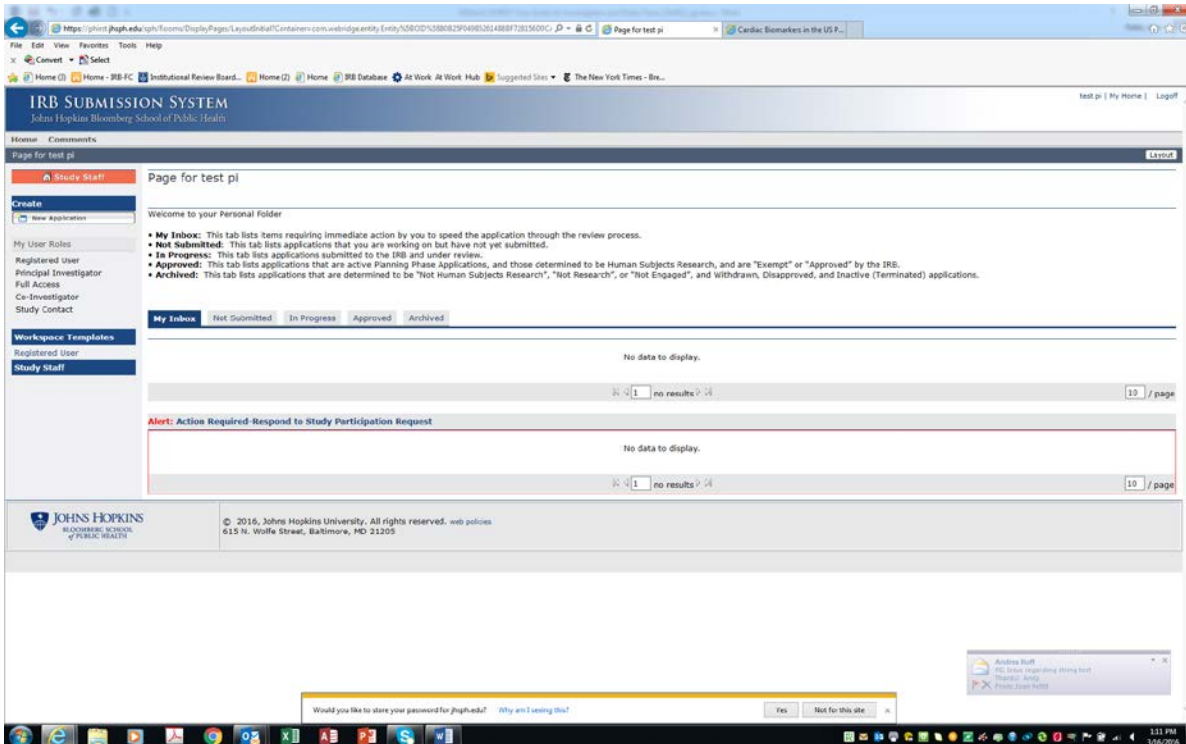
### **Requested Roles:**

Role
Co-Investigator
Study Contact
Study Staff - Other

Final registration confirmation will be sent to you shortly. Thank you and we hope you enjoy using the PHIRST system.

# YOUR PERSONAL FOLDER

Once you have registered, you will have a personal folder. The folder will include your home page, “My Home”, and will link to all the PHIRST applications that include you. Please see the sample My Home page for “test pi” below.



**LEFT PANEL:** At the top of the left panel, you’ll see an **ORANGE BOX** that reads “Study Staff”. The PI, co-investigators, and student investigators are all “Study Staff” as they are involving in submitting and revising research applications. Below that you’ll see a **BLUE BOX** with the word “Create”. Under the blue box is a white box with “**New Application**” and a symbol that looks like a Word page. This white box is a button that opens the New Application function. Below that link is a **GRAY BOX** that lists “My User Roles”. It may be useful if you are assigned more than one role among different PHIRST applications.

## TOP RIGHT CORNER NAVIGATOR PANEL: “test pi”/My Home/Logoff

The Top Navigator is available on almost all project screens and has links to your Name (to change personal account information), My Home (always brings you back to this page, your personal folder), and Logoff (ends your sessions and logs you out of the system).

## PERSONAL FOLDER (CENTER OF SCREEN) TABS

This section of your home page is like a file cabinet. The tabs include the following:

**My Inbox:** This tab lists items requiring immediate action by you to speed the

application through the review process.

**Not Submitted:** This tab lists applications that you are working on but have not yet submitted.

**In Progress:** This tab lists applications submitted to the IRB and under review.

**Approved:** This tab lists applications that are active Planning Phase Applications, and those determined to be Human Subjects Research, and are “Exempt” or “Approved” by the IRB.

**Archived:** This tab lists applications that are determined to be “Not Human Subjects Research”, “Not Research”, or “Not Engaged”, and Withdrawn, Disapproved, and Inactive (Terminated) applications.



# THE APPLICATION WORKSPACE

Every application created in PHIRST is assigned a folder or workspace. When you click on an application to view it, the application's workspace is opened. The workspace displays important information about the application, its Current State in the PHIRST system, activities available at the different process states, and a record of actions taken during processing. As an example, the workspace below is for an application titled “Test study for Co-I”, IRB number 6390. The PI is “Test PI” – and the workspace shows when the application was submitted (3/17/2016). It is in the “Application Submitted” state, and no RSS has yet been assigned to it.

The screenshot shows a web browser window displaying the IRB Submission System interface. The page title is "IRB SUBMISSION SYSTEM" and the user is logged in as "test pi". The main content area shows the workspace for the application "test study for CO-I".

**Current State:** Application Submitted

**Description:** this is a test from IT, please ignore

**PI:** test pi

**Department:** Biochemistry and Molecular Biology

**IRB Number:** IRB00005390

**Contact Person:** test\_studycontact

**Review Type:** [blank]

**Date Submitted:** 3/17/2016

**Date Entered This State:** 3/17/2016 10:16 AM

**Student Investigators:** Table with columns: FIRST name, LAST name. Note: There are no items to display.

**History:** Table with columns: Activity, Author, Activity Date.

Activity	Author	Activity Date
PI submitted application to IRB	pi, test	3/17/2016 10:16 AM EDT
Participation Agreed or Declined	studycontact, test	3/17/2016 10:15 AM EDT
Study Team Participation Requested	pi, test	3/17/2016 10:12 AM EDT

**Footer:** © 2013, Johns Hopkins University. All rights reserved. web policies 615 N. Wolfe Street, Baltimore, MD 21205, 410.516.1277

## Workspace Features

1. The “**Current State**” displays the application’s stage of processing.
2. “**My Activities**” lists all of the available activities you may perform on the application in its current state. You activate them by clicking on the icon and following the instructions in the window that opens. Be sure to scroll down to the bottom of the window to click “Ok” or you will lose your work.
3. The **View Application Form** icon will open the application and smart forms. This button will show when the application has been sent to the IRB; if the IRB sends the application back to the PI, the **Edit Application** button will appear.
4. The **Print Application** icon will open all of the relevant smart form pages in one easy print window.
5. The **History** tab records all actions performed on the study. Each action is recorded with the date, time, and person performing the action. You may click on the activity to see the system details.
6. The **Documents** tab displays all of the documents that have been submitted for review and/or approval.
7. The **Study Team Notes** tab records notes entered by the study team.
8. The **Change Log** tab provides a history of the changes that have been made to the application. These changes are only recorded after the application has been submitted.

# CREATING A NEW APPLICATION

With the PI and study staff user role, you may 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 this project.

1. The **STUDY IDENTIFICATION** page is the first to appear. Once you complete the first page and save it, an IRB number will be assigned to your application.
2. Fill in all required fields marked with a **red asterisk\***.
3. The Navigation Bar contains buttons to Save, Exit, Hide/Show Errors/Print/Jump-To, and go Back or Continue throughout the application.

**Study Identification**

1.0 \* **Study Title** - enter the formal title of your study below:  
test study for CO-1

2.0 Cohort name or acronym for the study:  
test

3.0 Enter a short description of the study below:  
this is a test from IT, please ignore

4.0 \* Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?  
 Yes  No Clear

**STUDY TEAM:**  
Click the SELECT or ADD buttons below and list all members of the study team. If a member of the study team does not appear on the lists, click here for information: [PHIBST Registration](#).

5.0 \* **Principal Investigator:**  
(If no name appears below or if the name is not correct, click on the SELECT button below)  
test pi [Select...] Clear

5.1 \* **PI Faculty Title:**  
Associate Professor

6.0 **Co Investigator(s):**  
(Click on the ADD button below to include any co-investigators on the study)

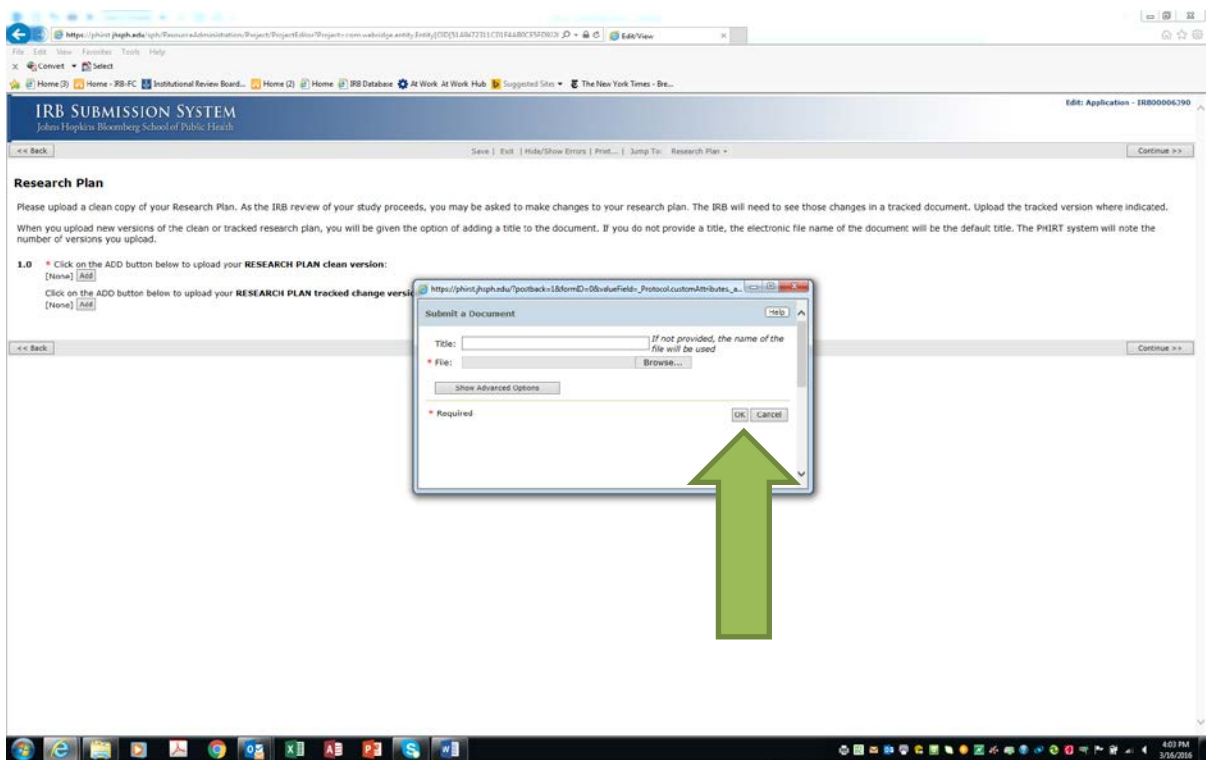
Name	Department	E-mail	HST Certificate	
test coinvestigator	Health Behavior & Society	berita.williams@jhu.edu	About us.do[0.01]	Remove

7.0 **Student Investigator(s):**  
(Click on the ADD button below to include any student investigators on the study)

First Name	Last Name	Department	E-Mail
There are no items to display			

## Uploading Documents

At different places in the PHIRST application you will be prompted to upload certain documents, such as local IRB approval, permission letters from sites where you will conduct the research, research plan, consent documents, etc. If you upload the wrong document or need to replace later the one you uploaded, use the “Edit Application” button in your workspace and the “Jump To” buttons (if you wish) to go to the appropriate page and make that change. Here’s the Research Plan page; just use the “Add” button to browse your computer to find the correct document. You will be given the opportunity to Title the document – we recommend you identify it with a version number or date to help you track each iteration. **BE SURE TO CLICK ‘OK’ AT THE BOTTOM RIGHT OF THE UPLOAD SCREEN.**

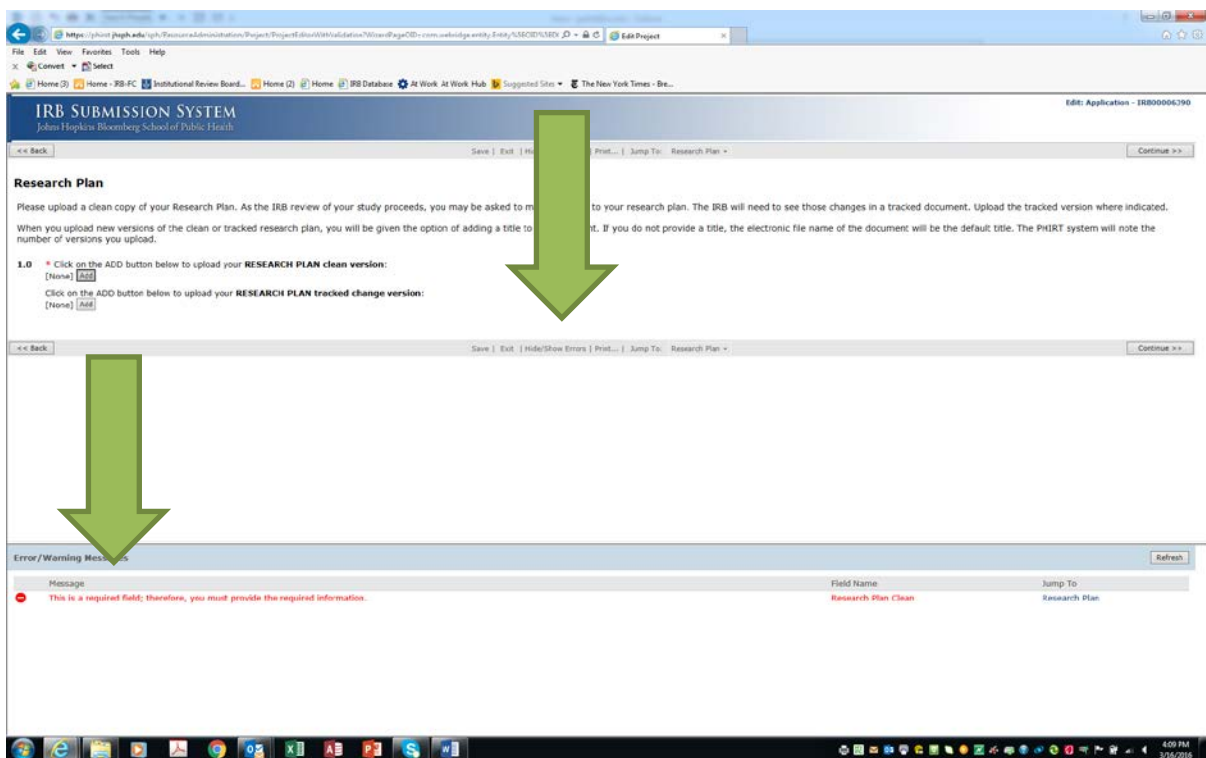


The table below shows where various study documents should be uploaded in the PHIRST system. It's important to follow this guide as RSSs and IRB reviewers will be looking for your documents and we lose time when they aren't readily found in the proper place.

<b>PHIRST Application Page</b>	<b>Section Number</b>	<b>Type of Document</b>
Study Population Page 2	3.6	Letter of support from Cohort PI
Study Information Page 1	8.1	GCRC Approval letter
Research Plan	1.0	Clean version of Research Plan Tracked version of Research Plan
Funding and Conflict of Interest	3.1	Financial Certification or Financial Disclosure Form
Informed Consent for Adults	5.0	Consent Documents, Certificate of Translation
Parental Permission	5.0	Parental Permission forms, Certificate of Translation
Assent	5.0	Assent forms, Certificate of Translation
SKCCC	1.1	Letter of Approval
KKI	1.1	Letter of Approval
Drugs and Devices	1.4-5.0 6.4, 8.0	Drug and IND documentation Device and IDE documentation
Miscellaneous Documents	1.0	Surveys/Instruments/ Questionnaires
	2.0	Recruitment Materials
	4.0	Certificate of Confidentiality
	5.0	All other study documents

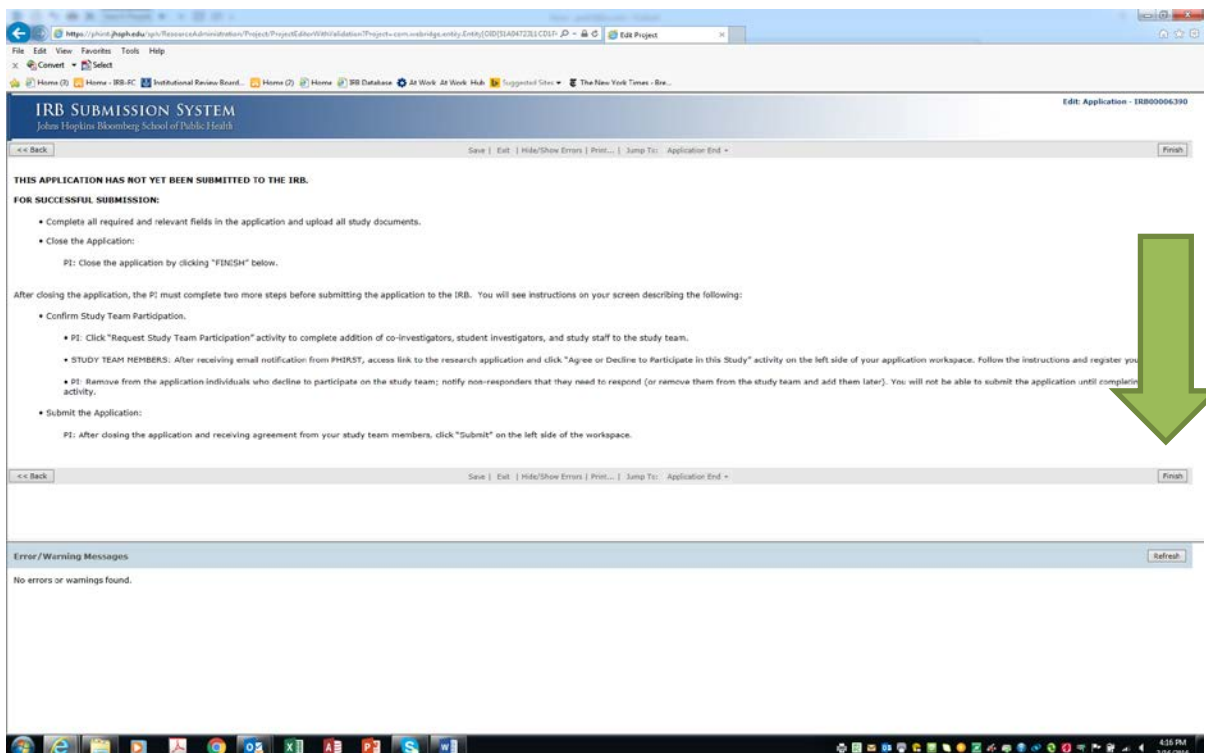
## Checking the application for errors

You can check the application at any time using the Hide/Show Errors feature. Fields that are not completed are displayed in a window at the bottom of the application. For example, in the image below, the “test pi” has not uploaded a Research Plan. After your changes have been made, click on **Save** on each page and then **Refresh**.



## Submitting the application

1. The Principal Investigator must submit the application; no other study team member may do so.
  - *Note: Other members of the study team can complete the application and upload documents but only the PI has the ability to submit the application.*
2. Click on FINISH button on the bottom right corner.
3. The system will run a final check on the entire application before submission. If there are any errors, they will be displayed on the submit activity window. A link to the relevant smart form page will be displayed. The application must be error-free before it can be submitted.



## Inviting Other Study Team Members to Participate in the Application

If you have identified co-investigators or student investigators in the application, they must agree to assume the role in the research that you have identified for them. After you click “Finish”, the application will ask you to use an activity on the left panel of your workspace called “Request Study Team Participation” – only the PI will see this activity on the left side of his/her workspace.

Once the person is invited to participate, that person will have an activity appear on his/her left panel called “Agree to Participate”. The date invited and date accepted or declined will be recorded automatically in the PI’s workspace.

The screenshot displays the IRB Submission System interface for a study titled "test study for CO-1". The left sidebar contains a "My Activities" section with a green arrow pointing to the "Request Study Team Participation" activity. The main content area includes instructions for completing the application and a table for "Study Team Responses".

**Current State**  
Pre Submission  
Edit Application Form  
Print Application

**My Activities**  
PI Withdraw Application  
**Request Study Team Participation**

**Study: test study for CO-1**  
Description: this is a test from IT, please ignore  
PI: test pi  
IRB Number: IRB00005390  
Date Created: 4/9/2015 6:20 PM  
Contact Person: test.studycontact  
Review Type: Not Research  
Date Submitted: Not Yet Submitted

**Instructions for Completing Submission of New Research Application:**

- This application has NOT YET been submitted to the IRB.
- Before the PI may submit the application, the application must be complete and all proposed study team members must respond to the PIs request to join the study.

**Complete Application**

- Make sure that the application is complete and that all relevant documents are uploaded.
- To edit or add information or documents, click the EDIT APPLICATION FORM button on the left side of this page.

**Complete Addition of Study Team Members (co-Investigators, Student Investigators, Study Staff)**

- Each proposed study team member must either agree or decline to join the study team before the PI may submit the application.
- The PI must use the Request Study Team Participation activity on the left side of this page to add study team members to the application.
- Proposed study team members must agree to join the study team, or decline; if they do not respond, the PI may want to remove them from the application and add them after the study is approved.
- The study team members agreement to join the study team will include confirmation of study team role and personal commitment to research ethics principles.
- Once all study team members have responded and have agreed to join the study team, the Submit activity will appear on the left of this page. The PI may submit the application by clicking this icon.

**Adding Additional Study Team Members**

- If you add additional names of individuals to your PHIRST application after using the Request Study Team Participation activity, you must use the activity AGAIN to invite the newly added individuals.

**Please Note: Only the PI may submit this application**

**Study Team Activity Reminder**  
If you are a study team member that has been assigned to this study, please complete the activity 'Agree or Decline to Participate in this Study' in the left column of this page.

Last Name	First Name	Date Invited	Date Accepted	Date Declined	COI
View	colinvestigator	test			
View	studycontact	test			

All Members Have Agreed to Participate: no

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615 N. Wolfe Street, Baltimore, MD 21205

Would you like to store your password for jhgh.edu? Why am I seeing this?  
Yes Not for this site



## FROM APPLICATION SUBMISSION THROUGH REVIEW

The following steps illustrate the basic application review process:

### Step 1 **Principal Investigator & Study Team**

Prepare your application. While in preparation, the application is in your “**Not Submitted**” Tab, and will be in a “**Pre-Submission**” state (see “Current State” box in the upper left corner of your application workspace.) When you are ready, **Submit** the application using the “**Submit Application to IRB**” activity on the left panel of your workspace. The application will move to your “**In Process**” tab after submission.

### Step 2 **IRB Research Subjects Specialist review**

The application arrives in the IRB’s box in a **Pre-Review** state. The Gatekeeper will assign the application to a Sr. Research Subjects Specialist (RSS) to process the application. If the RSS has questions for the PI, s/he will send **Concerns** to the PI for response. The state will change to **Concerns Pending (Pre-Review)**. The PI will receive a notification via email that Concerns are pending, requiring response from the study team. The PI may click the link in the email to access the application, and then will use the **PI RESPOND TO CONCERNS** activity to draft answers to the questions or append any needed documents. After drafting answers, the PI has a choice of sending the response back to the IRB at that time or not – if not, the response will remain as a draft until the PI is ready to send it back. The PI must scroll down to the bottom of the response screen and click “**OK**” to complete and save the response. The PI may also use the “**Edit Application**” button on the upper left panel to make any required changes to the application. Once the PI is ready to finalize the response to concerns and return the communication to the RSS, the PI will use the **PI RESPOND TO CONCERNS** on the left panel.

Once the RSS assignment is complete, the application moves to an **In Review** state. The RSS will complete an administrative review to determine if IRB review is required, and if the study needs IRB review, what kind of review (IRB X or IRB FC). This triage process is driven by regulatory requirements and institutional policies.

Once the RSS is satisfied that the assignment is correct, the RSS will help prepare the application for an IRB member to review by communicating with the PI by using the same **CONCERNS** activities described above as part of the Pre-Review process. The RSS manages the application through the review process from **In Review** through **Approved**. When the RSS sends concerns at this stage of the review process, the application will change state from **In Review** to **Concerns Pending (In Review)**. The PI will use the **PI RESPOND TO CONCERNS** activity to communicate with the RSS.

Step 3 **IRB review**

If your application is assigned to IRB X or IRB FC, an IRB member is assigned as primary reviewer and that person will complete review before the meeting. The primary reviewer may communicate with the PI to address concerns in advance of the meeting; this process makes the review more efficient. When the application is put on an agenda for an IRB meeting, the presumption is that the pre-review communications between the RSS and the PI, and the primary reviewer and the PI will make the application ready for Board review. If responses to concerns that are important to the review are not received in time, the application may be postponed to a later meeting. At the IRB meeting, the primary reviewer presents the application for discussion, the Board makes a determination (Approve, Approve with Administrative Changes, Table for more information, or Disapprove) by majority vote.

## OTHER PHIRST FEATURES

### The Application History Log

Every application has a detailed history log. For auditing purposes, every action performed on the application is recorded in the history log. This information is viewable under the **History** tab. The history log is sorted in chronological order and displays only the actions you have permission to see. Each activity, when performed, is recorded in the history log with a date/time stamp and the name of the person performing the activity. You can click on the name of the activity to view the system details.

### Checking the Status of the Application

Once the application has been submitted to the JHSPH IRB, the application is routed to the required people in the review process. As the PI or contact person, you will automatically receive notifications from the PHIRST system indicating the completion of certain elements of the review process or requesting changes to be made to the application. You can also check the progress of your application by opening the application workspace in PHIRST.

### Receiving Progress Notifications

PHIRST automatically generates email notifications and sends them to the PI and contact person when significant events have occurred in the review process. The PI and contact person will always receive a notification when a reviewer requests changes be made to the application. A direct link to the relevant application is included in the email.

*NOTE: It is important that your email address recorded in PHIRST is current, since the system uses this email address to send notifications about review process.*

### PHIRST System Vocabulary

**Activity** – An action that a person can perform on an application. **Submit Application** is the first activity that is performed on an application. Activities create an entry in the history log and often cause a change in state. Activities also send email notifications.

**State** – The current status of an application. When a study team creates a new application, it is in the state "**Pre-Submission**" until the PI activates the "**Submit to the IRB**" activity. State changes are caused by activities.

**History Log** – A list of events, most recent on top, which chart the movement of an application through the review process. The history log will only display the events that the current user is allowed to see.

**User Role** – A designated role in the system that determines the level and type of access a person has in the system. A person may have multiple user roles such as Committee Member and PI. In this case, the user will have two personal workspaces customized to allow the person to perform the actions of each role.

**Personal Folder/My Home** – A personal area with a layout customized based on user role. Study Staff/Investigator workspaces are designed to initiate and monitor projects while IRB member/IRB staff workspaces are designed to process projects in the review process.

**Application Workspace** – A homepage for an application that allows people to interact with it and monitor its progress through the review process. The application workspace is the base of operations for all application specific actions.

Pre Submission	Application has not been submitted for review
Application Submitted	Application has been submitted for IRB review
Pre Review	Application is in administrative review. Has not been sent to committee for review
Concerns Pending (Pre-Review)	Application is in pre-review and concerns need to be addressed prior to being sent to committee for review
In Review	Administrative review is complete. Application has been sent for committee and ancillary reviews
Concerns Pending (In Review)	Application is currently in review and concerns need to be addressed
Post Review	The application has been moved to the post review process. All committee reviews are complete
Awaiting Approval Signatures	Approval letter awaiting co-chair signature
Document Approvals	Study documents are being stamped for approval
Active	The study is Active.
Inactive	The study has been inactivated
NR/NHSR/NE	NR - It has been determined that the study does not meet the definition of research NHSR - The study has been deemed not human subjects research NE – It has been determined that JHSPH investigators are not engaged in human subjects research.
WIRB	The study has been submitted to Western Institutional Review Board
Withdrawn	The study has been withdrawn from the review process.

## **PHIRST - Study Team Submission Checklist**

The list below is offered as a general guide to assist study teams when creating and submitting online applications to PHIRST. Some documents are required for all applications; others may be required depending on the kind of research you are conducting. Please note that you will need some of the items below in order to successfully submit your application; others will be needed during the review process and prior to final approval.

### **Information for the application:**

- Complete list of study team members and their roles on the study (PI, Co-Investigators, Student Investigators, Study Contact)
- Prior approval from SKCCC (Sidney Kimmel Comprehensive Cancer Center), if applicable
- Prior approval from GCRC (General Clinical Research Center), if applicable
- Prior approval from KKI (Kennedy Krieger Institute), if applicable
- DSMB membership and information if applicable
- COI (Conflict of Interest) explanation/information, if applicable

### **Documents to upload: (documents must be either in Word or a PDF file in order to upload)**

- Complete Research Plan
- Consent, Parental Permission, Assent documents
- Recruitment materials (flyers, advertisements, etc.)
- Surveys and other research instruments
- Local IRB approval document(s)
- Certificate(s) of Translation for local language consents
- Grant or Thesis Proposal
- Certificate of Confidentiality
- Letters of Collaboration
- HIPAA documentation, if applicable
- IND documents: Sponsor's Protocol, Investigator's Brochure, Drug Data Sheet, FDA 1572
- IDE documents: Investigator's Brochure, Device schematics

