User Guide for Investigators and Study Team

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Welcome to PHIRST

PHIRST stands for Public Health Institutional Review Submission and Tracking. PHIRST is a web-based application created to standardize and computerize the Committee on Human Research (CHR) application submission, routing and tracking of research studies involving human subjects. This new system will allow the CHR to serve investigators more efficiently and ensure better protection of research participants.

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

PHIRST requirements and access

Accessing PHIRST is a quick and simple process.

Requirements

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>

Notes:

Every browser and version behave differently. Though support for a particular browser is indicated, there will always be occasions when the presentation appears different on different browsers and platforms.
In order to authenticate, the browser must be configured to accept at least session based cookies. The “Remember Me” feature, which allows users to be automatically logged in the next time they attempt to access a secured page, requires that the browser accept persisted cookies.

Access

PHIRST is located at http://phirst.jhsph.edu and is available via any internet connection made by one of the supported browsers above. PHIRST is accessible 24 hours a day, 7 days a week.

Login access to the system is limited to users with a JHED ID*. Information on registration to obtain a PHIRST account is available on the site. Please note that all fields with a red asterisk are required; and you must submit a valid email address to be granted access to the system.

➢ *Note: If you do not have a JHED ID, contact the CHR helpline at chrhelp@jhsph.edu or 410-502-5780 and a special user ID will be assigned.

By Using PHIRST, you can do the following:

➢ Create and edit an electronic human subjects research application
➢ Add study team members and a primary contact person to assist in the management of the application
➢ Prepare the application via “smart forms” that present only those sections that are applicable and relevant to your study
➢ Attach scanned or electronic documents to the study project
➢ Use context-specific guidance to assist in answering questions consistent with policies and regulations
➢ Check the application for errors before submission to catch common mistakes and reduce the number of changes required after submission
➢ Print out the application in a “printer-friendly” version
➢ Track the progress of the application as it is routed through the review and approval process
➢ Receive email notification when an action is required by the study team
➢ All approved documents are available online and can be downloaded at anytime

PHIRST help and training resources

Downloadable User Guide
Instructional Web Videos
Live training sessions
Open computer labs
Help Line
More information regarding the resources noted above can be found on the PHIRST website.

**PHIRST Personal Folder**

PHIRST is personalized to make working in the system comfortable for you. When you log into PHIRST you are taken to your personal folder, My Home, which displays and has links to most items applicable to you as an investigator.

1. **My Roles** allows you to select between user roles* if you have more than one. This component will only display if you have multiple user roles.
2. The user role icon displays your currently selected user role
3. The Top Navigator is available on almost all project screens and has links to your Name (to change personal 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).
4. The New Application study button allows you to start a new study application
5. The My Inbox tab displays all studies you are a part of that require some task to be done by the study team.
6. The Not Submitted tab displays studies that have not yet been submitted for review
7. The In Progress tab displays all studies with which you have been identified as a study team member that are currently in review by the CHR. This folder will include a list of approved and non-approved studies. For approved studies, this list will include amendments, adverse events or continuing reviews that are in review by the CHR.
*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.

PHIRST Basics

This section begins with an overview of the PHIRST submission and review process, and then explains the following tasks that will get you started in creating and submitting your application:

Create a new application
Edit an application
Upload documents
Submit the application
Check the status of the application
Respond to concerns
View and download approved documents
Submit an adverse event
Submit an amendment
Submit a continuing review (will be added a later date)

Overview of the PHIRST submission and review process

The following steps illustrate the basic application review process:

**Step 1**  *Principal Investigator & Study Team*
Prepare and submit application

**Step 2**  *CHR specialist review*
A research specialist will be assigned to the project.
The specialist will complete an administrative review and manage the review and scheduling of the project.

**Step 3**  *CHR committee review*
The CHR primary reviewer and/or committee as a whole will review the application and provide concerns and/or approval.

**Step 4**  *PI & Study Team*
Conduct research
Report adverse events
Submit requests for amendments
Submit requests for continuing reviews
Creating a New Application

With the PI and study staff user role, you can create a new study application by using the 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. Log into PHIRST. From your PI and study staff personal folder, click the button on the left hand side of the screen.

The first application screen of the project appears. The CHR# will be assigned once the first screen is saved.

2. Enter in the required fields marked with a red asterisk*.

- Note: Some fields that are not marked with a red asterisk are required to be completed prior to final submission of the application. Complete all appropriate fields and use the Hide/Show Errors feature to validate the application.
The application screen
Each page of the application is composed of different types of questions along with helpful guidance.

1. The Navigation Bar contains buttons to Save, Exit, Hide/Show Errors/Print/ Jump To, and go Back or Continue throughout the application.
   - Click Save to save the data entered without moving to a different page.
   - Click Exit to exit the application and return to the Study Workspace. Before exiting, be sure to save your changes with the Save link.
   - Note: Do not use the Back button on your browser window.
   - Click Hide/Show Errors to view a list of required fields that are not completed.
   - Use the Print feature to access a printer friendly version of the screen.
   - Use the Jump-To drop down menu to move to other pages of the application.
   - Click Continue>> to save the current page and proceed to the next page.
   - By using the Continue button on the navigation bar, you take advantage of Smart Form flow, a behind-the-scenes feature that determines which form you see next based upon your answers to previous questions.
   - Note: The system will not allow you to use the Continue button to move to the next page if you have begun work on a section, but have not completed all required fields.
   - Click >>Back to move to the previous page.

2. The assigned IRB#. This number will be used to identify the study for the life of the project.
3. The right hand side of the screen, the “Help section”, provides guidance related to the questions asked on each application page. Definitions and links to regulations and policies and procedures are provided.

4. The clear button can be used on any non required field. If you initially choose ‘yes’ or ‘no’, you can use the clear button to leave the question unanswered.

Assigning study team members and contact person

As the creator of a new study application, you will specify who has permission to page 1 of the application.

<table>
<thead>
<tr>
<th>STUDY TEAM:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 list, click here for information: PHIRST Registration.</td>
</tr>
</tbody>
</table>

6.0 * Principal Investigator:
   (If no name appears below or if the name is not correct, click on the SELECT button below)
   [Stephanie Gauthreaux (PI)] [Select...]

7.0 Co Investigator(s):
   (Click on the ADD button below to include any co-investigators on the study)
   [Add]
<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Department</th>
<th>E-mail</th>
</tr>
</thead>
</table>
   There are no items to display

8.0 Student Investigator(s):
   (Click on the ADD button below to include any student investigators on the study)
   [Add]
<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Department</th>
<th>E-mail</th>
</tr>
</thead>
</table>
   There are no items to display

9.0 * Study Contact:
   (If no name appears below or if the name is not correct, click on the SELECT button below. Please note that the P.I. can also be the Study Contact if there is not another individual to serve in that role.)
   [Name] [Select...]

A study contact person must be selected for each study project. The person listed will receive all study notifications and has the ability to edit and send concerns. Only one contact person may be selected.

- *Note: The Principal Investigator can also be the Study Contact if there is not another individual to serve in that role.*
Uploading Documents

Supporting documents can be uploaded to certain sections of the PHIRST study application.

**Research Plan**

1.0  * Click on the ADD button below to upload your RESEARCH PLAN:

None [Add]

Click the add button to attach supporting documents.

**Submit a Document**

Title: [If not provided, the name of the file will be used]

* File: [Browse...]

[Show Advanced Options]

* Required

Enter a title for the document you are uploading
Use the Browse button to locate the document on your computer.
Select the file to upload
Click Open
Click OK
Checking the application for errors

You can check the progress of 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. Click the links displayed to Jump-To incomplete sections of the application. After your changes have been made, click on Save on each page and then Refresh.

Note: Clicking on Finish at the end of the application does not run an error check. The Hide/Show errors feature must be used. The application is checked for errors when the Principal Investigator submits the application.
Submitting the application

1. The assigned Principal Investigator selects the study ready for submission
   
   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 the Submit activity.

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.

4. Click the OK button at the bottom of the screen to submit the application.

Submit Application

You are about to submit this application to the CHR for review. Please note the following:

- Be sure all information is accurate and complete. Once you submit this application, you cannot make any changes.
- All Study Team members listed on this application (PI, Co-Investigators, Student Investigators and Study Contact) must have completed human subjects training.
- You may enter any additional notes below if you choose (optional).
- When finished, click OK at the bottom of this window. You will receive email notification when any changes, clarifications or revisions are requested during the review process.
- You will be able to log in to this site at any time to check the status of your application.

Additional Notes: (optional)
The Study Workspace

Every study created in PHIRST is assigned a folder or workspace. When you click on a study to view it, the study’s workspace is opened. The workspace displays important information about the study and contains links to help navigate any information contained in the study.

1. The current state displays the progress of this study in the review process
2. My Activities lists all of the available actions you can perform on the study. Click on them to open the activity window to follow the instructions perform the action.
3. The panel displays summary information about the study. The amount of information will change depending on the study’s progress through the review process.
4. The View Application Form icon will open the application and smart forms
5. The Print Application icon will open all of the relevant smart form pages in one easy print window.
6. 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.
7. The Documents tab displays all of the documents that have been submitted for review and/or approval.
8. The Study Team Notes tab records notes entered by the study team
9. 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.
The Study History Log

Every study has a detailed history log. For auditing purposes, every action performed on the study 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 CHR, 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 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 study workspace in PHIRST.

Applications

View all studies by Not Submitted, In Progress, Approved, Archived, and WIRB groupings.

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 study 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. You can check your email address by clicking your name in the top navigation bar.
Responding to Concerns

The study team will receive automated email notifications when the study is sent back to them for requested changes.

Once you have entered the appropriate study, select the activity titled, “Respond to Committee Concerns”. Follow the instruction indicated. Your response will be automatically routed to the appropriate CHR reviewers.

<table>
<thead>
<tr>
<th>Respond to Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions:</td>
</tr>
<tr>
<td>- See below for a list of all Concerns from the CHR for this application which need to be addressed by the Study Team.</td>
</tr>
<tr>
<td>- Click on the RESPOND link to review a concern and enter your response.</td>
</tr>
<tr>
<td>- You can work on your responses over multiple sessions. To save your responses and continue to work on them at another time, select NO under SEND TO CHR and then click OK.</td>
</tr>
<tr>
<td>- When you have completed all your responses and are ready to send them to the CHR, select YES under SEND TO CHR and then click OK. Your responses will be forwarded to the CHR for review.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concerns requiring a response from the Study Team - click on [Respond] for each item:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td>Research plan</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Previous Concerns - Concerns that have been addressed and verified by the IRB.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td>There are no items to display</td>
</tr>
</tbody>
</table>

* **Send to CHR** - If you would like to save your responses and return to them at another time, select NO. When you have completed all your responses and are ready to send them to the CHR, select YES.
  - Yes  - No  - Clear
Accessing approved projects

By selecting the Applications icon on the left hand side of the Personal Folder, you can access all studies for which you are identified as a study team member under the following categories: Not submitted, In progress, Approved, Archived or submitted via WIRB (Western Institutional Review Board).

Note: When you log-in, you will automatically be routed to My Homepage and the Personal Folder that contains your In Box. To access approved studies, you must select the Application icon noted above.

Accessing approved documents

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.
Submitting an adverse event

From the Applications section of your personal folder, click on the Approved tab to display a list of active studies. Then, click on the name of the study to view more detail. Click the New adverse event icon.

The first screen that appears provides information on CHR reporting requirements and definitions of different types of adverse events. Click the Continue>> button to move to the adverse event reporting form.

Complete all required fields marked with an asterisk* and click finish when you have completed the form.

Click Submit. Read the instructions in the adverse event window and click OK.

➢ Note: To track the progress of an adverse event, go to My Home and click on the In Progress tab. Once the adverse event is reviewed and acknowledged, an email notification will be sent to the study team.

By selecting the Adverse Events tab of any active study, you can view a list of all Adverse Events Not Submitted and Adverse Events Submitted to the CHR. The State category will indicate the current state of the event in the review process.
Submitting an amendment

From the Applications section of your personal folder, click on the Approved tab to display a list of active studies. Then, click on the name of the study to view more detail. Click the New Amendment icon.

- Note: Amendments can be submitted on approved studies only. Only one amendment can be in process at a time for each study.

Complete all required fields* of the Amendment Request Form.

Note: On the screen titled, Summary of Amendment Changes, you must select the “Click Here to Continue” button to go directly to the pages of the currently approved application relevant to your amendment request. You may then edit information as needed. Once your amendment request has been submitted, the changes you have made will be visible to the CHR for review purposes.

Please note that you do not need to click FINISH on this page. If you do, you will return to the study workspace without having made the needed changes to the application. Instead, be sure to use the Click here to continue link below to make your changes. If you select Finish and you have not made changes to the application, you must select Edit Amendment Form to return to the form.

Once you have completed the requested information, select the Submit activity. Click OK on the Submit Amendment Activity page. The system will validate the submission for errors.

- Note: To track the progress of an amendment, go to My Home and click on the In Progress tab. Once the amendment is reviewed and approved, an email notification will be sent to the study team.
Submitting a continuing review for the study (will be added at a later date)
PHIRST Study Team Vocabulary

**Activity** – An action that a person can perform on a study. 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 a project. When a study team creates a new Application, it is in the state “Pre-Submission”. State changes are caused by activities.

**History Log** – A list of events, most recent on top, which chart the movement of the project 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/CHR staff workspaces are designed to process projects in the review process.

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

**Activity Definitions**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit</td>
<td>Submit your application, amendment or adverse event for review</td>
</tr>
<tr>
<td>Respond to Concerns</td>
<td>Allows study team to view and respond to concerns</td>
</tr>
<tr>
<td>Review Major Committee Concerns</td>
<td>Allows study team to respond to committee concerns</td>
</tr>
<tr>
<td>Review Minor Committee Concerns</td>
<td>Allows study team to review and respond to minor committee concerns</td>
</tr>
<tr>
<td>Add Further Information</td>
<td>Upload additional documents that have been requested</td>
</tr>
<tr>
<td>Send Note to Specialist</td>
<td>Allows Study Team to send a note to IRB Specialist</td>
</tr>
<tr>
<td>Study Team Withdraw</td>
<td>Withdraw the application from IRB review.</td>
</tr>
<tr>
<td>State Definitions</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Pre Submission</td>
<td>Application has not been submitted for review</td>
</tr>
<tr>
<td>Application Submitted</td>
<td>Application has been submitted for IRB review</td>
</tr>
<tr>
<td>Pre Review</td>
<td>Application is in administrative review. Has not been sent to committee for review</td>
</tr>
<tr>
<td>Concerns Pending (Pre-Review)</td>
<td>Application is in pre-review state and concerns need to be addressed prior to being send to committee for review</td>
</tr>
<tr>
<td>Co-chair review not HRS</td>
<td>The co-chair is reviewing the application for not human subjects research status</td>
</tr>
<tr>
<td>In Review</td>
<td>Administrative review is complete. Application has been sent for committee and ancillary reviews</td>
</tr>
<tr>
<td>Concerns Pending (In Review)</td>
<td>Application is currently in review and concerns need to be addressed</td>
</tr>
<tr>
<td>Pre Meeting</td>
<td>All reviews are complete and application has been sent for full committee review</td>
</tr>
<tr>
<td>Draft Major Committee Concerns</td>
<td>Major committee concerns have resulted from a convened meeting and they are being drafted by the committee</td>
</tr>
<tr>
<td>Edit Draft Major Committee Concerns</td>
<td>Major committee concerns are being edited</td>
</tr>
<tr>
<td>Waiting Co-chair Signature Major Concerns</td>
<td>Draft of Major Concerns has been sent to the co-chair for signature/approval</td>
</tr>
<tr>
<td>Waiting PR Revisions Major Concerns</td>
<td>Waiting for primary reviewer to revise/edit major concerns</td>
</tr>
<tr>
<td>Waiting SR Revisions Major Concerns</td>
<td>Waiting for secondary reviewer to revise/edit major concerns</td>
</tr>
<tr>
<td>Waiting TR Revisions Major Concerns</td>
<td>Waiting for tertiary reviewer to revise/edit major concerns</td>
</tr>
<tr>
<td>Waiting PT Revisions Major Concerns</td>
<td>Waiting for pharmacy and therapeutics reviewer to revise/edit major concerns</td>
</tr>
<tr>
<td>Waiting Radiation Revisions Major Concerns</td>
<td>Waiting for radiation reviewer to revise/edit major concerns</td>
</tr>
<tr>
<td>Major Committee Concerns Pending</td>
<td>Waiting for study team to respond to major committee concerns</td>
</tr>
<tr>
<td>Major Committee Concerns Response</td>
<td>The study team has submitted their response to major committee concerns</td>
</tr>
<tr>
<td>Review Major Concerns Response</td>
<td>The study team response to major committee concerns is in review</td>
</tr>
<tr>
<td>Draft Minor Committee Concerns</td>
<td>Minor committee concerns have resulted from a convened meeting and they are being drafted by the committee</td>
</tr>
<tr>
<td>Waiting Co-Chair Signature Minor Concerns</td>
<td>Draft of Minor Concerns has been sent to the co-chair for signature/approval</td>
</tr>
<tr>
<td>Edit Draft Minor Committee Concerns</td>
<td>Minor committee concerns are being edited</td>
</tr>
<tr>
<td>Waiting PR Revisions to Minor Concerns</td>
<td>Waiting for primary reviewer to revise/edit minor concerns</td>
</tr>
<tr>
<td>Status/Comment</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Waiting SR Revisions Minor Concerns</td>
<td>Waiting for secondary reviewer to revise/edit minor concerns</td>
</tr>
<tr>
<td>Waiting TR Revisions Minor Concerns</td>
<td>Waiting for tertiary reviewer to revise/edit minor concerns</td>
</tr>
<tr>
<td>Waiting PT Revisions Minor Concerns</td>
<td>Waiting for pharmacy and therapeutics reviewer to revise/edit minor concerns</td>
</tr>
<tr>
<td>Waiting Radiation Revisions Minor Concerns</td>
<td>Waiting for radiation reviewer to revise/edit minor concerns</td>
</tr>
<tr>
<td>Minor Committee Concerns Pending</td>
<td>Waiting for study team to respond to minor committee concerns</td>
</tr>
<tr>
<td>Minor Committee Concerns Response</td>
<td>The study team has submitted their response to minor committee concerns</td>
</tr>
<tr>
<td>Review Minor Concerns Response</td>
<td>The study team response to minor committee concerns is in review</td>
</tr>
<tr>
<td>Post Review</td>
<td>The application has been moved to the post review process. All committee reviews are complete</td>
</tr>
<tr>
<td>Pending Further Information</td>
<td>The post review process cannot be completed pending further information</td>
</tr>
<tr>
<td>Awaiting Approval Signature</td>
<td>Approval letter awaiting co-chair signature</td>
</tr>
<tr>
<td>Document Approvals</td>
<td>Study documents are being stamped for approval</td>
</tr>
<tr>
<td>Process Denial</td>
<td>Committee denial is in process</td>
</tr>
<tr>
<td>Awaiting Denial Signature</td>
<td>Denial letter awaiting co-chair signature</td>
</tr>
<tr>
<td>Amendment Open</td>
<td>An amendment has been submitted and is open for review</td>
</tr>
<tr>
<td>Active</td>
<td>The study is Active.</td>
</tr>
<tr>
<td>Denied</td>
<td>The study has been denied by the Committee</td>
</tr>
<tr>
<td>Inactive</td>
<td>The study has been inactivated</td>
</tr>
<tr>
<td>Not Human Subjects Research</td>
<td>The study has been deemed not human subjects research</td>
</tr>
<tr>
<td>Not Research</td>
<td>It has been determined that the study does not meet the definition of research</td>
</tr>
<tr>
<td>Suspended</td>
<td>The study has been suspended by the Committee</td>
</tr>
<tr>
<td>WIRB</td>
<td>The study has been submitted to the Western Institutional Review Board</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>The study has been withdrawn from the review process.</td>
</tr>
</tbody>
</table>
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. Items in green are required for all applications. Other information and documents 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
- Non-US Medical Release Form
- Certificate of Confidentiality
- Letters of Collaboration
- HIPAA documentation if applicable
- IND documents: Sponsor’s Protocol, Investigator’s Brochure, Drug Data Sheet, FDA Form 1572
- IDE documents: Investigator’s Brochure