

# eHIRB User Guide: *How to Submit an Amendment*

Last Update	December 22, 2021
Intended Audience	Principal Investigator/Researcher
Purpose	How to submit an amendment.

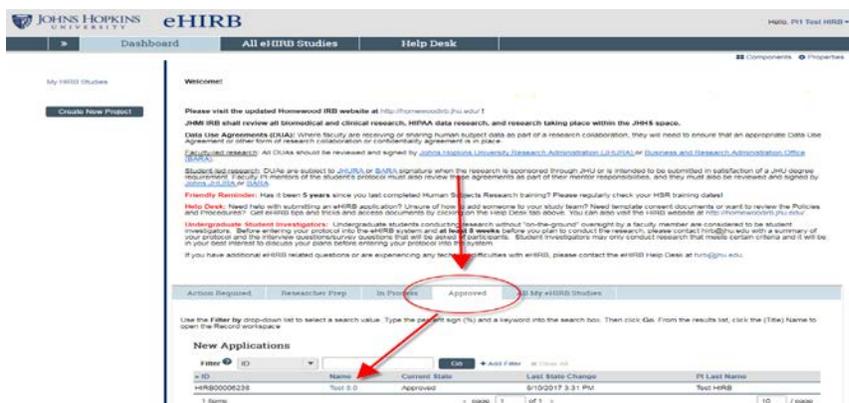
⇒ Refer to the [eHIRB Getting Starting Guide](#) before getting started.

## Important Amendment Facts:

1. Amendments can only be submitted for studies once they have already been approved by the IRB.
2. Any changes the PI would like to make to an IRB-approved application must be submitted as an amendment (i.e. including, but not limited to, changes to the study title, PI, study team members, procedures, recruitment procedures, advertisement materials, consent documents, privacy and confidentiality measures, risks). The changes cannot be implemented until the amendment is approved by the IRB.
3. The system only allows one amendment request to be in review by the IRB at a time.
4. Any study team member can create and fill out the amendment. However, only the PI can submit the amendment.

## Follow the steps below to submit an amendment:

- STEP 1.** Close all open web browsers.
- STEP 2.** Open a new browser and go to: <http://ehirb.jhu.edu>
- STEP 3.** Login using your JHEDID and password.
- The **My eHIRB Studies** workspace should appear, if not, select it from left side.
- STEP 4.** Select the **“Approved”** tab, and then select the approved New Application for which you need to create an amendment.



- STEP 5.** Select the **“Create Future Study Action”** (FSA) button, the SmartForm appears.

**Current Status**

Approved

View Project

Print Project

View Differences

View SmartForm Progress

Contact IRB

Log Comment

Create Further Study Action

**New Application Workspace**

Title: Test 8.0

Number: HIRB00000238

Principal Investigator: PI1 Test HIRB

PI's HSR Training Date:

PI's HSR Training Certificate: There are no items to display

Last Name	First Name	Role	HSR Training Date	HSR Certificate Uploaded
There are no items to display				

Review Type: Expedited

Date Created: 8/10/2017 3:19 PM

Study Expiration: 8/10/2018

Original Approval: 8/10/2017

**STEP 6.** Select the "Amendment" check box.

Further Study Action Chooser

## Creating New: IRB Project

Go to forms menu Help

### Further Study Action Selection

\* Select the type of further study action you would like to create.

- Amendment
- Continuing Review / Progress Report
- Reportable Event
- Study Closure

Exit Save Continue

**STEP 7.** Select "Continue" to save the application and proceed to the next section.

- The system will save the amendment and generate a HIRB ID number for the amendment, which will appear in the right corner of the form.

Validate Compare

1 - General Information

2 - Update Application

3 - Research Personnel

4 - Conflict of Interest

5 - Clinical Trials

6 - Research Sites

7 - Support Information

8 - Informed

## Editing: AM00013982

Go to forms menu Print Help

Amendment  
PI: John Black  
AM00013982 (HIRB0000025409)

### 1 - General Information

1.0

\* Select ALL the categories of amendment(s) you are requesting and thoroughly explain the change as well as the reason for the change(s). If you are changing language in the application, consent form, or other documents, you must provide the new language and the language being removed below in the description of the amendment. You must then make the change(s) to the application as well as upload any new/revised documents to the appropriate section of the application. Do not delete the previous versions.

- Change in Study Title
- Change in Principal Investigator
- Addition of/change in research personnel
- Change to study design, methods or procedures
- Addition of/change to study population
- Addition of/change to recruitment or recruitment materials
- Addition of/change to survey(s), questionnaire(s), or other research instruments
- Addition of/change that would impact privacy and confid
- Addition of/change to informed consent/assent document
- Other changes

Exit Save Continue

**STEP 8. Complete Section 1 – General Information**, by selecting relevant categories for the amendment and providing a short description of each category selected. **It is important to provide rationale and a thorough description for EACH proposed change to ensure a more efficient IRB review.**

- Required fields are indicated with a red asterisk (\*).

If you are trying to add a team member, be sure to provide their name here. You will need to enter them in Section 3 as well. If you cannot find their name in the dropdown list in Section 3, they must log into the eHIRB system so that an account is created for them. You will then be able to add them.

1

**STEP 9. Select “Continue” to proceed to Section 2 – Update Application.**

- This section provides instructions on what to do next. No action is required.

**STEP 10. Select “Continue” to proceed through a copy of your original approved application.** You should make any applicable changes to the application, based on the list of changes described in Section 1, above.

- If additional changes are needed to the application that are not reflected in Section 1, please go back to Section 1 and make adjustments to the categories selected so that the categories reflect the changes made on the application.

**STEP 11. Complete** the remaining sections using the navigation bar

- The navigation bar can be found at the bottom right of the form.
- Select “Continue” to proceed through each page of the application SmartForm.
- When “Continue” is selected the system automatically saves the form.
- You can select “Save” at any time and “Exit” the form. If needed, you can come back later and finish the form.
- Select “Exit” to close the SmartForm. The system will confirm that the form will be saved.
- You can skip to a specific section of the form by choosing a page name from the “Jump To” drop-down menu located on the blue navigation bar.
- **NOTE:** If the “Back” button is selected the system will not automatically save the information entered on that page of the form. Be sure to select “Save” before the “Back” button is selected.

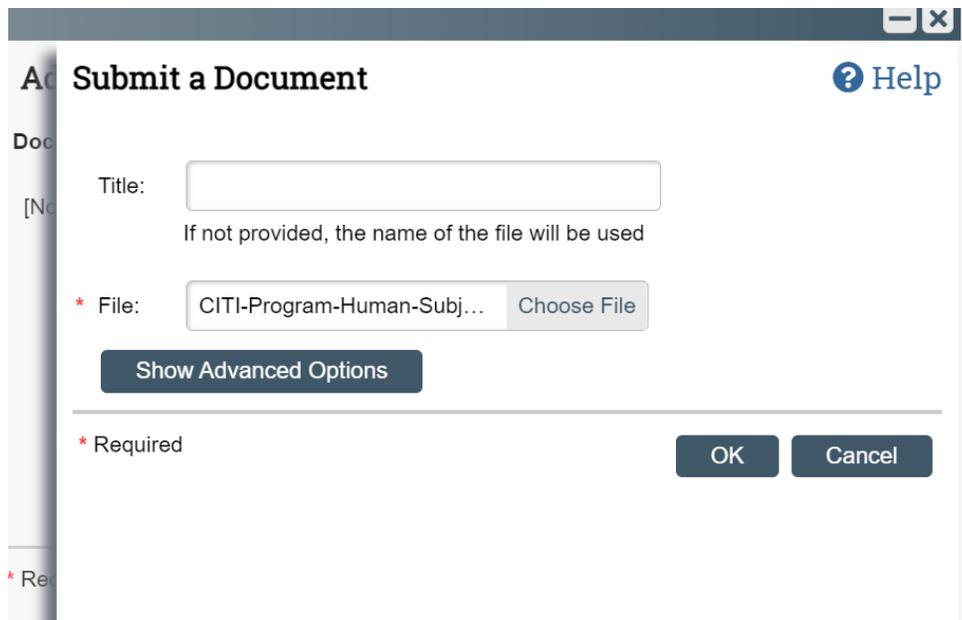
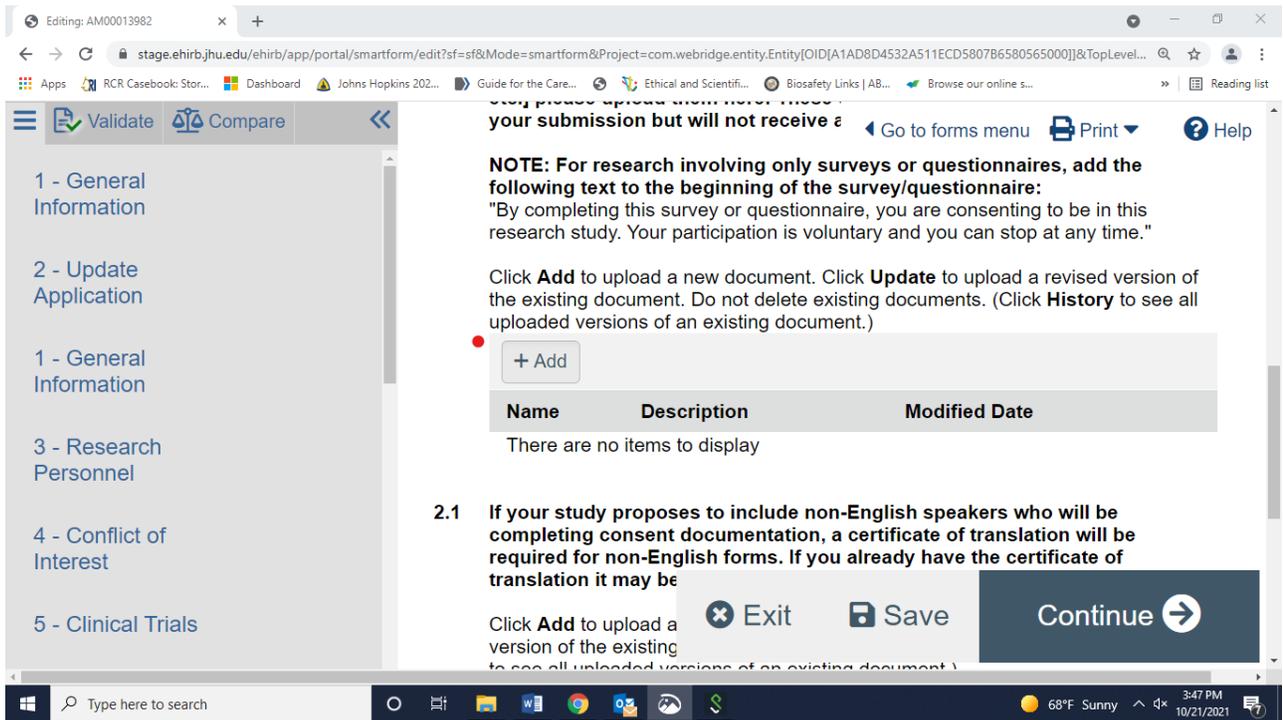
**STEP 12. Make sure all required questions are answered.** The system will not allow the amendment to be submitted to the IRB until all required items are completed on the amendment SmartForm.

- If the page you are working on is not completed, asterisked items are not answered, the system will trigger error messages before the page can be advanced.
- By clicking on Go to first error, the SmartForm will advance to the change that is needed. See the two screen shots below.

The top screenshot shows the SmartForm interface for editing amendment AM00013982. A validation error message is displayed: "Could not update the IRB Project due to one or more errors: Validation Failed: Please review the page and correct any errors..." with a "Go to first error" link. The left sidebar shows a navigation menu with "1 - General Information" selected. The main content area shows "1 - General Information" with a required field "1.0 \* Principal Investigator" and a note: "PI must be faculty or senior staff. Click **Select** to choose a PI, or **Update** to modify..."

The bottom screenshot shows the same SmartForm interface. A required field "5.0 \* Briefly describe your proposed project..." is highlighted. Below the field is a red error message: "This is a required field; therefore, you must provide the required information." The field description reads: "Include the overall objectives, general description of the procedures, and a description of the subject population or the types of data or specimens to be studied. You will be asked to provide more details later in the application." At the bottom, there are buttons for "Exit", "Save", and "Continue".

**STEP 13. Adding and updating documents:**



**STEP 14.** Updating or uploading a revised version of an existing study document

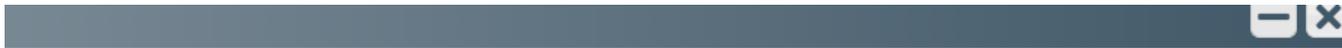
Do NOT upload additional documents if they are revisions of the parent. Only upload new documents as additional documents.

- 1 - General Information
- 2 - Update Application
- 1 - General Information
- 3 - Research Personnel
- 4 - Conflict of

Click **Add** to upload a new document. Click **Update** to update the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)

	Name	Description	Modified Date
 Update	CITI-Program-Human-Subjects-Research-Training_03.16.17.pdf		10/21/2021 3:56 PM

2.1 If your study proposes to include non-English speakers who will be completing consent documentation, a certificate of translation will be required for non-English forms. If you already have the certificate of translation it may be uploaded here.



## Edit Multi Doc

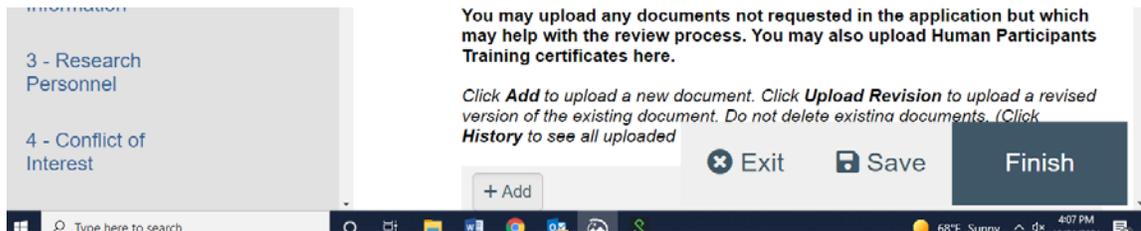
Document:

 CITI-Program-Human-Subjects-Research-Training\_03.16.17.pdf(0.01) 

Required

Click on the ellipse tool circled above, which will bring up options to Download ; Copy; Upload Revision; View History; or Delete. Use these functions to manage the documents. In general, past versions of study documents should NOT be deleted, especially consent forms.

**STEP 15.** Once you have completed the form, Select the “Finish” button on the last section of the SmartForm entitled “Finalize Application”.

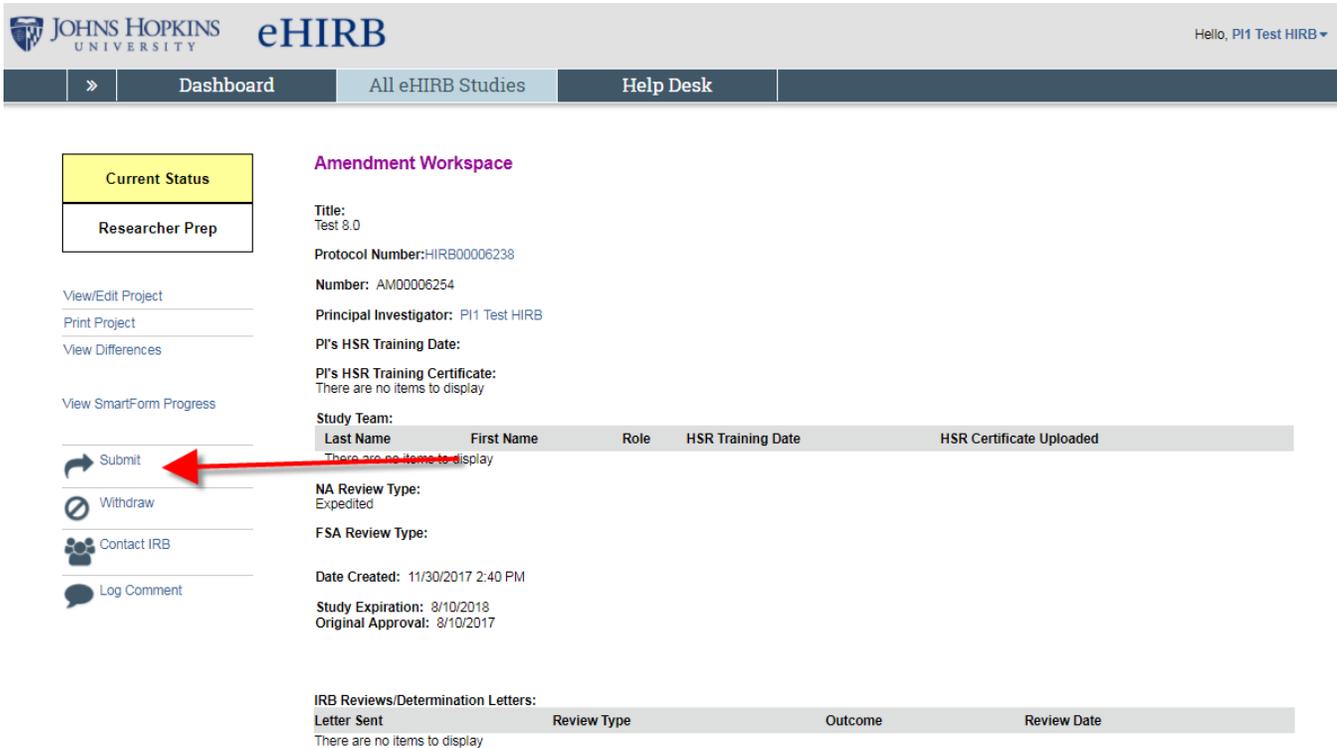


**STEP 16.**

- **NOTE:** You are not done yet.
- The SmartForm will close and you will be taken to the application workspace where you will be able to finally “**Submit**” the application to the IRB.
- The application is NOT sent to the IRB until the “**Submit**” activity on the workspace is run. **NOTE: THE PI MUST SUBMIT THE AMENDMENT.**

**STEP 17. From the application workspace, select the “Submit” activity, located on the left side of the workspace.**

- If additional changes are need on the SmartForm before the amendment is submitted, select the “**View/Edit Form**” activity to open up the form and resume completing it.
- **NOTE:** The PI cannot edit the form after submission, unless the IRB sends it back with questions.



- If the system finds Error/Warning messages they will be displayed.

Message	Field Name	Jump To
This is a required field; therefore, you must provide the required information.	Unexpected Event	<a href="#">1 - General Information</a>
You must describe the addition of/change in research personnel.		<a href="#">1 - General Information</a>

Close

**STEP 18.** To correct error/warning message, select the hyperlinked Section Name in the list and the system will take you directly to the page (ex. 3 – Research Personnel) where the answer can be corrected. Repeat this until all error messages have disappeared from the list. The system will show green check marks to verify completion.

Error/Warning Messages (0)	Refresh
<a href="#">1 - General Information</a>	✓
<a href="#">2 - Update Application</a>	✓
<a href="#">3 - Research Personnel</a>	✓
<a href="#">4 - Conflict of Interest</a>	✓
<a href="#">5 - Clinical Trials</a>	✓
<a href="#">6 - Research Sites</a>	✓

1.0

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- Addition of/change to survey(s), questionnaire(s), or other research instruments
- Addition of/change that would impact privacy and confidentiality
- Addition of/change to informed consent/assent document(s)

**STEP 19.** After all error/warning messages are resolved, select the “Submit” activity again, the PI certification appears.

**STEP 20.** Read the PI Certification text, and then select “OK”.

## Submit

### PI Certification

By submitting this application, the PI is taking responsibility for his or her own research project, or is acting as a supervisor for a student project, for the individual student's research project. PIs overseeing a student research project are expected to work closely with the student in preparing the application for Homewood IRB (HIRB) review, overseeing the conduct of the research, and ensuring that the study is appropriately closed upon completion.

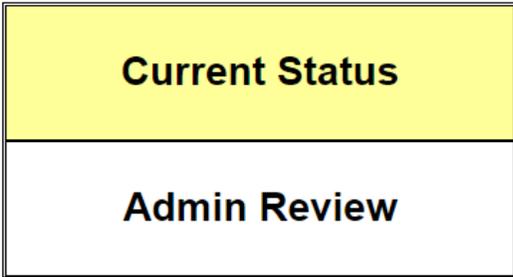
### PI responsibilities include, but are not limited to, the following:

- (a) Reviewing thoroughly the submission materials to ensure that a complete and accurate application is submitted to HIRB.
- (b) Ensuring that the research team members complete the required training in human participant research and have the appropriate knowledge and skills to carry out the research in a manner that protects all participants.
- (c) Monitoring the conduct of the research project to ensure that all research team member fulfills the following responsibilities:
  - Obtaining and documenting the informed consent of each participant or each participant's legally authorized representative (LAR), unless HIRB has waived these requirements. This includes ensuring that each potential participant understands the nature of the research and, unless HIRB specifically waives this requirement, each participant or the participant's LAR receives a copy of the HIRB-approved informed consent document(s) at the time of consent.
  - Informing HIRB of any new personnel to be added to the research team.
  - Ensuring that all members of the research team have completed the required training in the protection and ethical treatment of human research participants and have been appropriately trained for their role in the study.
  - Ensuring that all members of the research team report any potential conflicts of interest regarding the research.
  - Reporting on the progress of approved research to HIRB as often as and in the manner prescribed by HIRB. This includes complying with all requirements for continuing review.
  - Ensuring that HIRB is notified when the research project is complete so that the study may be appropriately closed.
  - Retaining all signed consent documents for at least three years after the completion of the study according to institutional policy.
  - Promptly reporting proposed changes to the research protocol or consent documents to HIRB. The proposed changes may not be initiated without HIRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.
  - Promptly reporting to HIRB any unanticipated problems involving risks to participants or others.
  - Promptly reporting to HIRB any serious or continuing noncompliance with Federal regulations or HIRB policies and procedures.

Click OK below to complete this activity.



- STEP 21.** After submission, select **“My Home”** located on the top left corner to return to your Inbox.
- The system will send an email notification confirming the submission of the amendment.
  - The IRB office will receive the submission and begin reviewing the application.
  - The amendment can no longer be edited by you at this time, unless the IRB office sends it back for clarification and/or changes.
- STEP 22.** To view the amendment that was just submitted, select the **“In Process”** tab located on the **My HIRB Studies** workspace. The top left corner of the amendment workspace will appear as below, Current Status: Admin. Review.



## Amendment Workspace

Title:  
smoke test

Protocol Number: HIRB00009509

Number: AM00013982

[View Project](#)

[Print Project](#)

JOHNS HOPKINS UNIVERSITY eHIRB Hello, PI1 Test HIRB

Dashboard All eHIRB Studies Help Desk

My HIRB Studies **Create New Project**

Welcome!

Please visit the updated HomeWood IRB website at <http://homewoodirb.jhu.edu/>!

JHMI IRB shall review all biomedical and clinical research, HIPAA data research, and research taking place within the JHHS space.

**Data Use Agreements (DUA):** Where faculty are receiving or sharing human subject data as part of a research collaboration, they will need to ensure that an appropriate Data Use Agreement or other form of research collaboration or confidentiality agreement is in place.

**Facultylined research:** All DUAs should be reviewed and signed by [Johns Hopkins University Research Administration \(JHURA\)](#) or [Business and Research Administration Office \(BARA\)](#).

**Studentled research:** DUAs are subject to [JHURA](#) or [BARA](#) signature when the research is sponsored through JHU or is intended to be submitted in satisfaction of a JHU degree requirement. Faculty PI mentors of the student's protocol must also review these agreements as part of their mentor responsibilities, and they must also be reviewed and signed by [Johns JHURA](#) or [BARA](#).

**Friendly Reminder:** Has it been 5 years since you last completed Human Subjects Research training? Please regularly check your HSR training dates!

**Help Desk:** Need help with submitting an eHIRB application? Unsure of how to add someone to your study team? Need template consent documents or want to review the Policies and Procedures? Get eHIRB tips and tricks and access documents by clicking on the Help Desk tab above. You can also visit the HIRB website at <http://homewoodirb.jhu.edu/>.

**Undergraduate Student Investigators:** Undergraduate students conducting research without "on-the-ground" oversight by a faculty member are considered to be student investigators. Before entering your protocol into the eHIRB system and at least 8 weeks before you plan to conduct the research, please contact [hirb@jhu.edu](mailto:hirb@jhu.edu) with a summary of your protocol and the interview questions/survey questions that will be asked of participants. Student investigators may only conduct research that meets certain criteria and it will be in your best interest to discuss your plans before entering your protocol into the system.

If you have additional eHIRB related questions or are experiencing any technical difficulties with eHIRB, please contact the eHIRB Help Desk at [hirb@jhu.edu](mailto:hirb@jhu.edu).

Action Required Researcher Prep In Process Approved All My eHIRB Studies

Use the Filter by drop-down list to select a search value. Type the percent sign (%) and a keyword into the search box. Then click Go. From the results list, click the (Title) Name to open the Record workspace

**New Applications**

Filter ID  Go + Add Filter x Clear All

No data to display.

< page 1 no results > 10 / page

**Amendments**

Filter Name  Go + Add Filter x Clear All

Name	Study Title	Current State	Last State Change	PI Last Name
Amendment: AM00006254 For: HIRB00006238	Test 6.0	Admin Review	11/30/2017 3:17 PM	Test HIRB

1 items < page 1 of 1 > 10 / page

Figure 2

- For questions about the status of an application, **contact** the IRB by selecting the “**Contact IRB**” activity on the application workspace. This sends the IRB Office an email notification containing your question through the eHIRB system.

**STEP 23.** To close out of eHIRB, Select “**Logoff**”, located on the top right corner. to logoff, click on the arrow and select logoff

JOHNS HOPKINS UNIVERSITY eHIRB Hello, PI1 Test HIRB

Figure 3