

eHIRB User Guide:

How to Submit an Amendment

Last Update	March 28, 2017
Intended Audience	Principal Investigator/Researcher
Purpose	To provide the user with step-by-step instructions on 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.

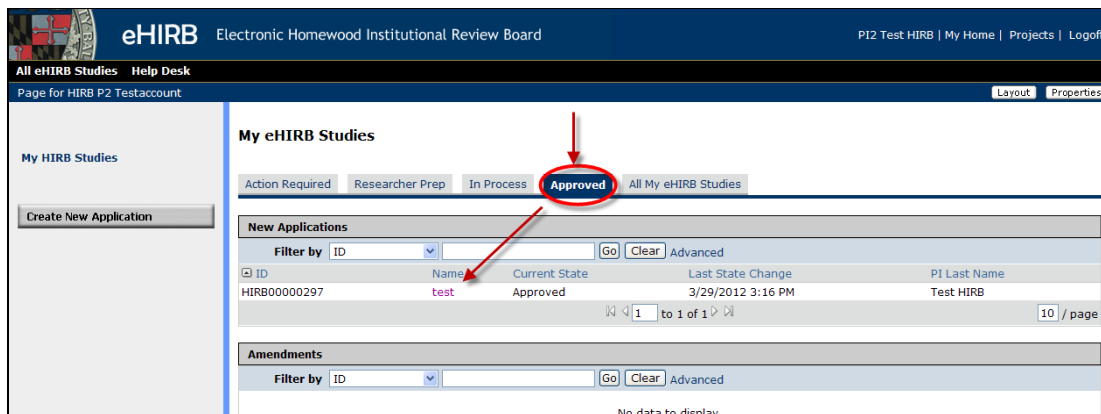


Figure 1

STEP 5. Select the “Create Future Study Action” (FSA) button.

The screenshot shows the eHIRB interface for a 'New Application Workspace'. On the left, there is a menu with buttons: 'View Form', 'Print Friendly View', 'View Differences', 'View Form Progress', 'Contact IRB', 'Log Comment', and 'Create Further Study Action'. A red arrow points to the 'Create Further Study Action' button. The main content area displays application details: Title: test, Protocol Number: HIRB00000297, Principal Investigator: P12 Test HIRB, Review Type: Full Board, Study Expiration: 4/19/2013, and Original Approval: 3/29/2012. There are also tables for 'Study Team' and 'Review Items'.

Figure 2

STEP 6. Select the “Amendment” check box.

The screenshot shows the 'Further Study Action Selection' form. It contains a heading 'Further Study Action Selection' and a red arrow pointing to the 'Amendment' checkbox, which is checked. Other options include 'Continuing Review', 'Reportable Event', and 'Study Closure'. The form has 'Back' and 'Continue' buttons at the top and bottom.

Figure 3

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.

The screenshot shows the eHIRB interface at the bottom of the form. The 'Continue >>' button is circled in red. The top of the page shows 'eHIRB Electronic Homewood Institutional Review Board' and 'Edit: IRB Project - HIRB00000296'. The bottom navigation bar includes 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To: 3 - Research Personnel', and the circled 'Continue >>' button.

Figure 4

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.

STEP 9.

The screenshot shows the eHIRB web application interface. At the top, it says 'eHIRB Electronic Homewood Institutional Review Board' and 'Edit: IRB Project - AM0000301'. Below the navigation bar, the section is titled '1 - General Information'. Section 1.0 contains a red asterisk indicating a required field: '* Select ALL the categories of amendment(s) you are requesting and briefly explain the change as well as the reason for the change(s). 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.' Underneath, the 'Change in Study Title' checkbox is checked. A 'Describe' text area contains the word 'TEST'. Below this, there is a list of other categories with unchecked checkboxes: '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 confidentiality', 'Addition of/change to informed consent/assent document(s)', and 'Other changes'. Section 2.0 contains another red asterisk: '* Are any of these changes the result of something that occurred during human participant interaction or an unexpected event?' with radio buttons for 'Yes', 'No' (selected), and 'Clear'.

Figure 5

STEP 10. Select “Continue” to proceed to Section 2 – Update Application.

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

STEP 11. 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.

Figure 6

STEP 12. Complete the remaining sections using the blue navigation bar (Figure 4, above).

- The navigation bar can be found at the bottom and top of the form.
- You can 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 13. 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.

- To assess completeness of the form, you can **Turn on** the **Hide/Show Errors** feature, from the blue navigation bar, to provide a list of validation errors that the system finds along the way.
- As required questions are answered in each section, the error/warning messages will disappear from the list.
- The hide/show errors feature is optional and can be turned on/off at anytime from the blue navigation bar.

eHIRB Electronic Homewood Institutional Review Board Edit: IRB Project - HIRB00000296

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 3 - Research Personnel Continue >>

New Application

3 - Research Personnel

1.0 * Is this research being submitted as a student research project?
 Yes No Clear

2.0 Other Team Members
 Select all additional members of the research team for this study. DO NOT include the PI in this list.

Add

First Name	Last Name	Degree	Title	Receive Notifications	Role
There are no items to display					

Error/Warning Messages Refresh

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Student Research	3 - Research Personnel
⊖ This is a required field; therefore, you must provide the required information.	Has COI	4 - Conflict of Interest
⊖ This is a required field; therefore, you must provide the required information.	Non Hopkins Entity	5 - Research Sites

Figure 7

STEP 14. Once you have completed the form, Select the “Finish” button on the last section of the SmartForm entitled “Finalize Application”.

- **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.

eHIRB Electronic Homewood Institutional Review Board Edit: IRB Project - AM00000301

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Finalize Application Finish

Amendment

Finalize Application

Additional Documents
 You may upload any documents not requested in the application but which may help with the review process.
 Click Add to upload a new document. Click Upload Revision to upload a revised version of the existing document. Do not delete existing documents. (Click History to see all uploaded versions of an existing document.)

Add

Name	Description	Modified Date
There are no items to display		

To complete this Homewood IRB application:

- Click Hide/Show Errors above or below to check the application for completeness. All required fields must be completed in order to submit.
- Click Finish below to return to the New Application workspace.
- Finally, click Submit on the left side of the workspace.
- **NOTE: ONLY THE PI CAN SUBMIT THE APPLICATION.**

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Finalize Application Finish

Figure 8

STEP 15. 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.

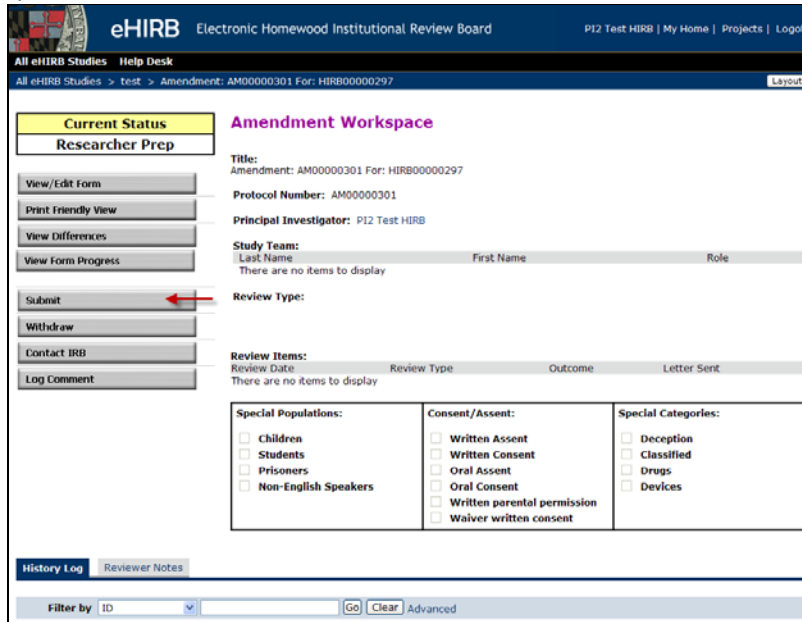


Figure 9

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

STEP 16. 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.

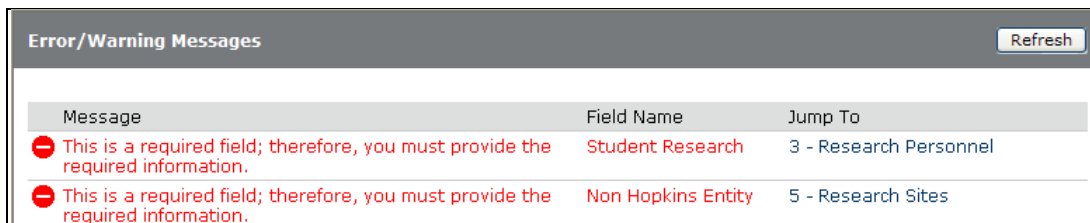


Figure 10

STEP 17. After all error/warning messages are resolved, select the “Submit” activity again, the PI certification appears.

STEP 18. Read the PI Certification text, and then select “OK”.

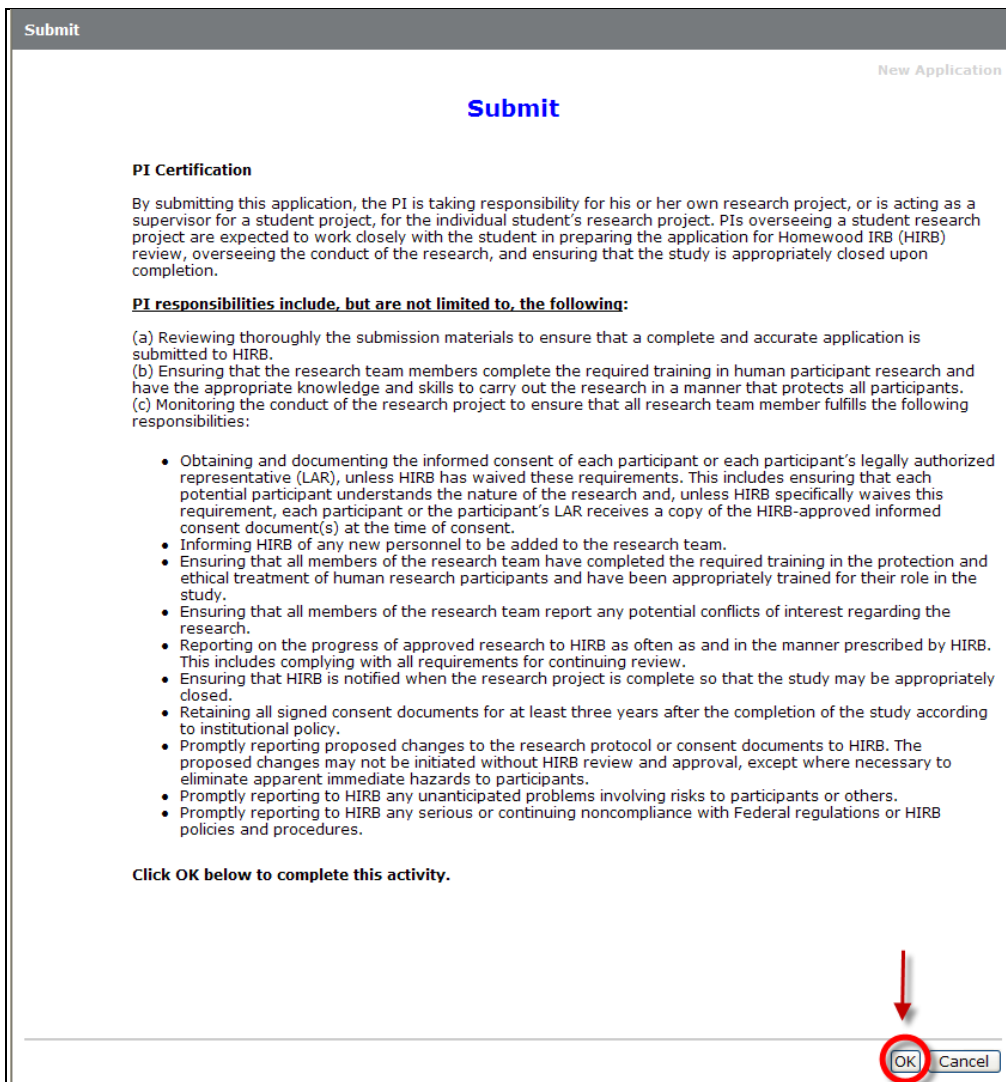


Figure 11

- STEP 19.** 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 20.** To view the amendment that was just submitted, **select the “In Process”** tab located on the **My HIRB Studies** workspace.

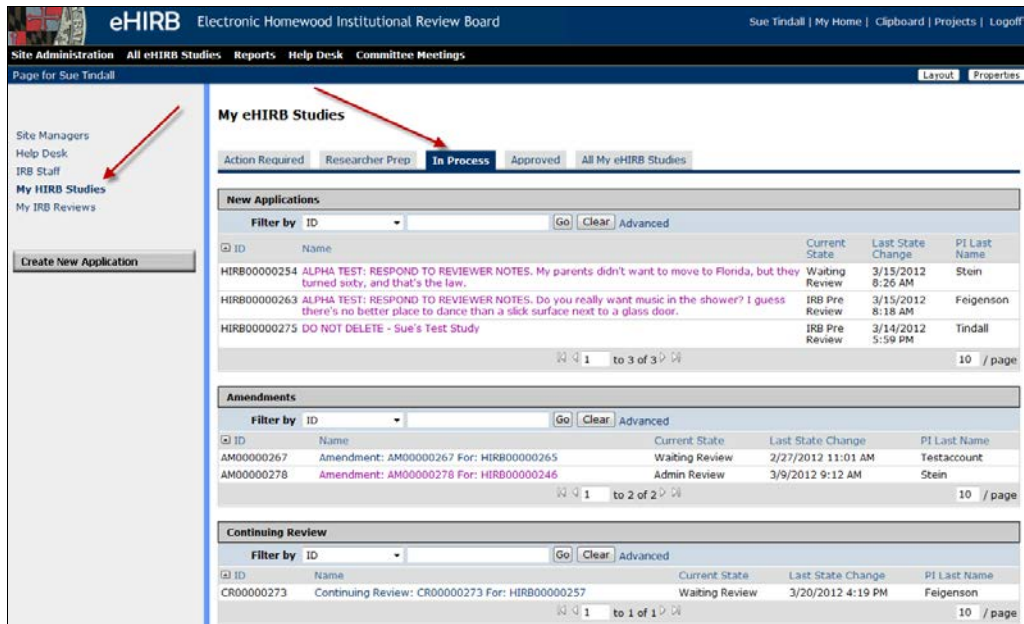


Figure 12

- 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 21. To close out of eHIRB, Select “**Logout**”, located on the top left corner.

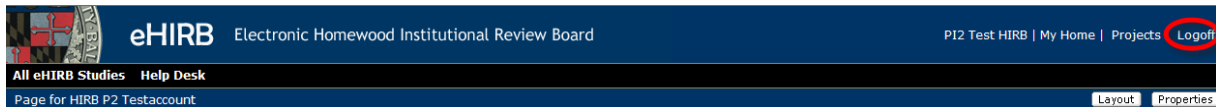


Figure 13