

eHIRB User Guide:

How to Submit a Continuing Review

Last Update	February 7, 2014
Intended Audience	Principal Investigator/Researcher
Purpose	To provide the user with step-by-step instructions on how to submit a continuing review.

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

Important Continuing Review Facts:

1. eHIRB will send notifications to the PI and research team members who selected to receive notifications at 90, 60 and 30 days before a study expires.
2. Only the PI can submit a continuing review, but anyone on the study team can complete the SmartForm.
3. The PI must submit a continuing review before the study expiration date.
4. If a continuing review is not submitted by the PI before the study expiration date, the study will expire and all research must stop. The PI must then submit a new application. **The eHIRB system does not allow for any exceptions.**

Follow the steps below to submit a continuing review:

- STEP 1.** Close all open web browsers.
- STEP 2.** Open a new browser and go to: <https://hirb.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 submit a continuing review.

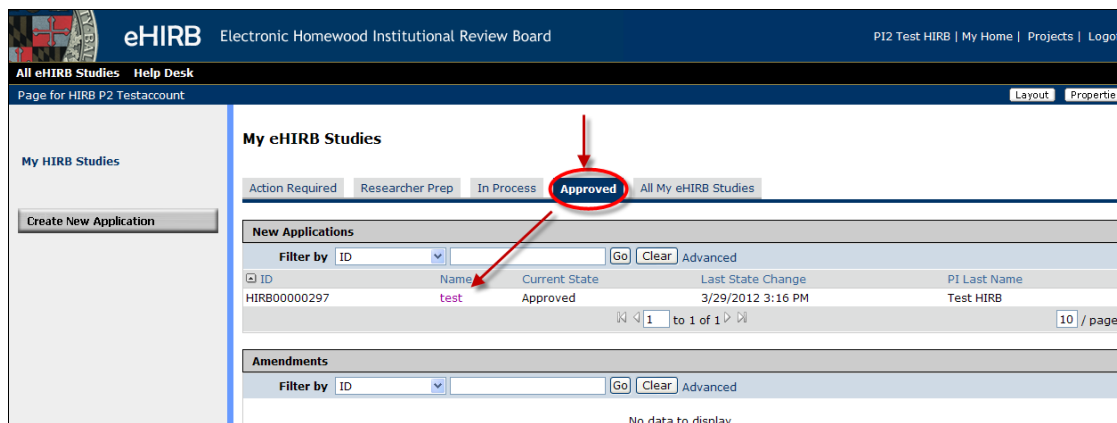


Figure 1

STEP 5. Select the “Create Future Study Action” button, the SmartForm appears.

The screenshot shows the eHIRB interface for a 'New Application Workspace'. On the left sidebar, there are several 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 the following information:

- Title: test
- Protocol Number: HIRB00000297
- Principal Investigator: PI2 Test HIRB
- Study Team: (Empty table with columns: Last Name, First Name, Role)
- Review Type: Full Board
- Study Expiration: 4/19/2013
- Original Approval: 3/29/2012
- Review Items: (Table with columns: Review Date, Review Type, Outcome, Letter Sent)

Figure 2

STEP 6. Select the “Continuing Review” check box.

The screenshot shows the 'Further Study Action Selection' form. It contains a red asterisk and the instruction: '* Select the type of further study action you would like to create.' Below this are four checkboxes:

- Amendment
- Continuing Review
- Reportable Event
- Study Closure

A red arrow points to the 'Continuing Review' checkbox. Another red arrow points to the 'Continue >>' button at the top right of the form.

Figure 3

STEP 7. Select “Continue” to save the application and proceed to the next section.

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

The screenshot shows the eHIRB header area. It includes the eHIRB logo and the text 'Electronic Homewood Institutional Review Board'. On the right side, it says 'Edit: IRB Project - HIRB00000296'. At the bottom, there are navigation buttons: '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: 3 - Research Personnel', and 'Continue >>' (circled in red).

Figure 4

STEP 8. Complete Section 1 – Study Status, by selecting the current status of the study.

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

STEP 9.

The screenshot shows the eHIRB web application interface. At the top, there is a blue header with the eHIRB logo and the text 'Electronic Homewood Institutional Review Board'. To the right of the header, it says 'Edit: IRB Project - CR00000301'. Below the header is a light blue navigation bar with buttons for '<< Back', 'Save | Exit | Hide/Show Errors | Print...', a 'Jump To:' dropdown menu currently set to '1 - Study Status', and a 'Continue >>' button. The main content area has a title '1 - Study Status' in green. Below this, there is a section '1.0 * Select the current status of the study.' with three radio button options: 'Enrollment has not yet begun.' (which is checked), 'Enrollment is in progress.', and 'Enrollment is complete but contact with participants is ongoing.'. Below these options is a text area labeled 'Explain' with the placeholder text 'explain something here.'. At the bottom of the page, there is another identical navigation bar with the same buttons and dropdown menu.

Figure 5

STEP 10. Select “Continue” to 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 11. Make sure required questions are answered. The system will not allow the continuing review to be submitted to the IRB until all required items are completed on the continuing review 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.

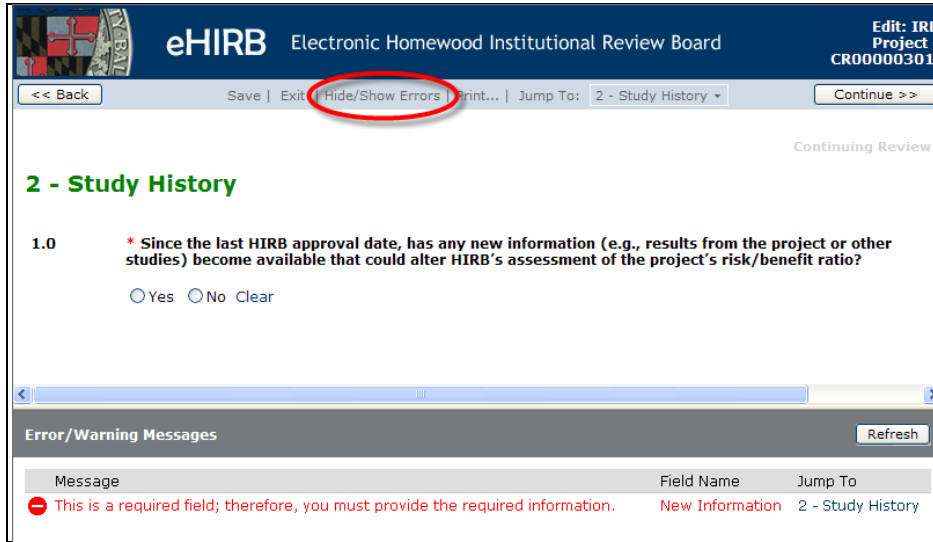


Figure 6

STEP 12. 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 CONTINUING REVIEW.

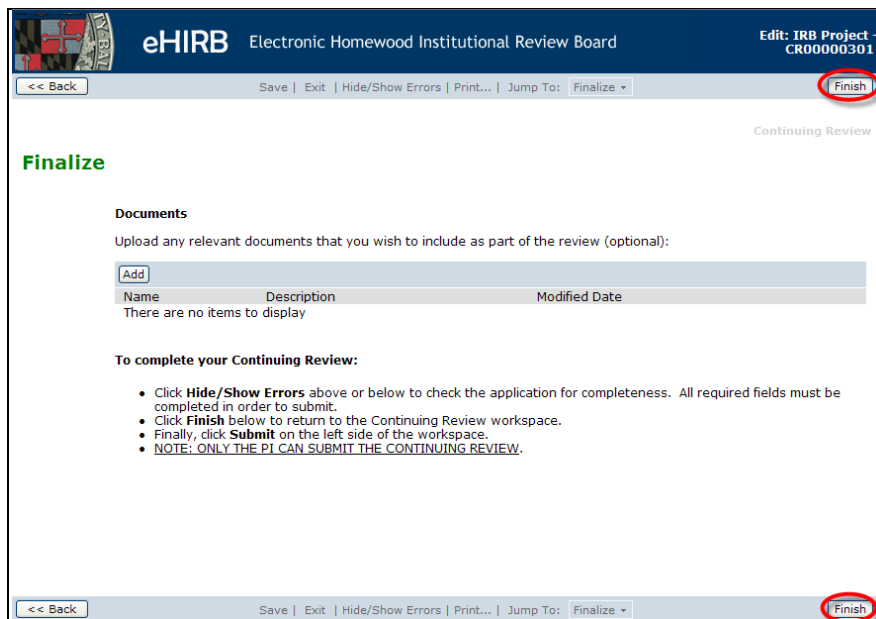


Figure 7

STEP 13. From the application workspace, select the “Submit” activity, located on the left side of the workspace.

- If additional changes are needed on the SmartForm before the continuing review 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.

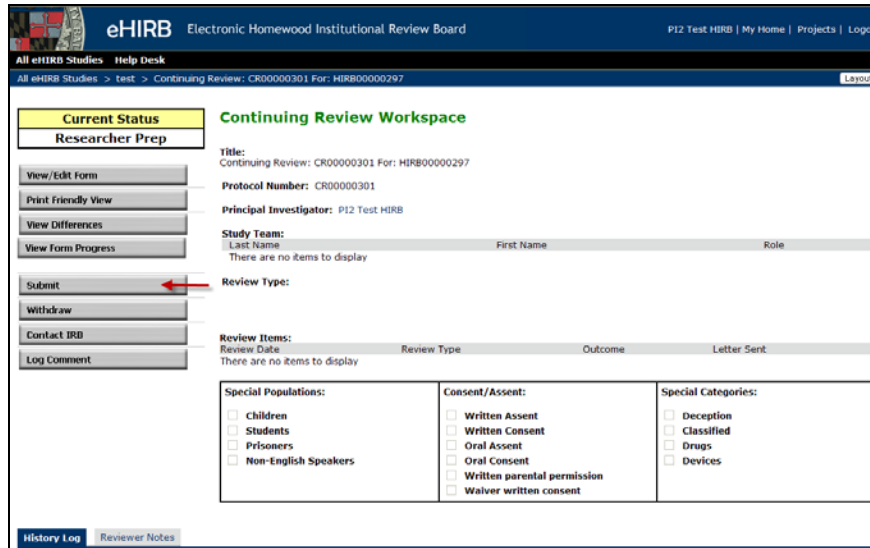


Figure 8

- If the system finds error/warning messages they will be displayed.

STEP 14. To correct error/warning message, select the errors in the list and the system will take you directly to the page where the answer can be corrected, repeat this until all error messages have disappeared from the list.

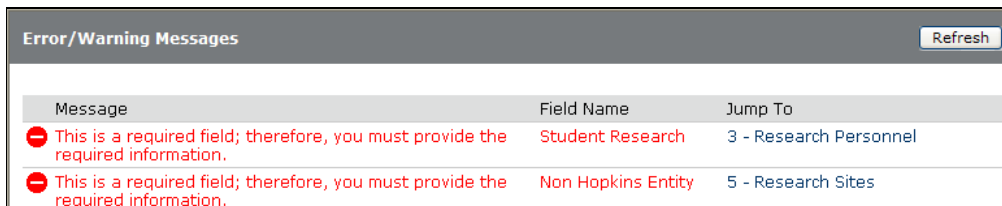


Figure 9

STEP 15. After all error/warning messages are resolved, select the **“Submit”** activity again, the PI certification appears.

STEP 16. Read the PI Certification text, and then select **“OK”**.

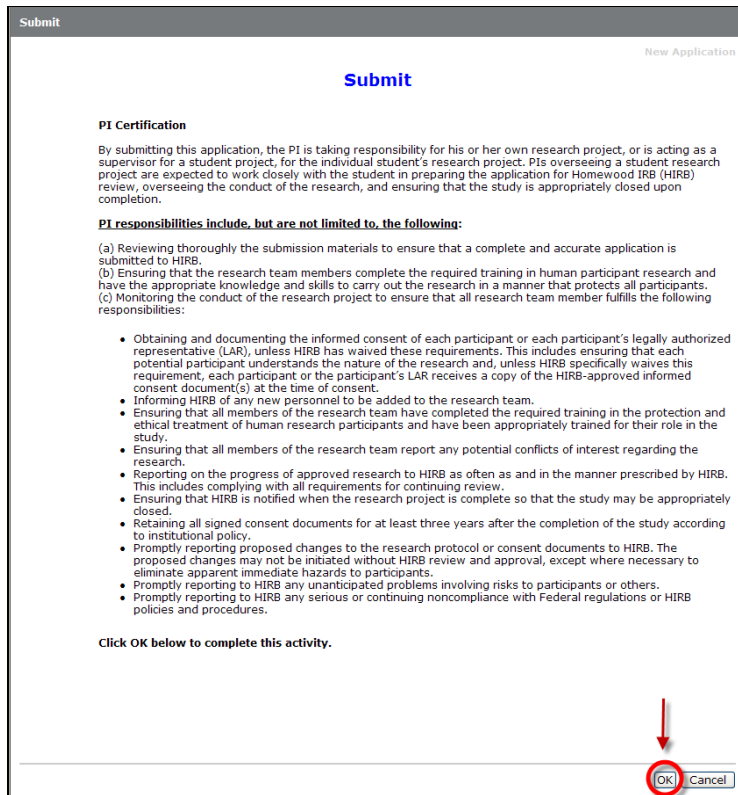


Figure 10

STEP 17. 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 continuing review.
- The IRB office will receive the submission and begin reviewing the application.
- The continuing review can no longer be edited at this time, unless the IRB office sends it back for clarification and/or changes.

STEP 18. To view the continuing review that was just submitted, select the “In Process” tab located on the **My HIRB Studies** workspace.

The screenshot shows the eHIRB interface. The top navigation bar includes 'eHIRB Electronic Homewood Institutional Review Board' and user information 'Sue Tindall | My Home | Clipboard | Projects | Logout'. Below this is a secondary navigation bar with 'Site Administration', 'All eHIRB Studies', 'Reports', 'Help Desk', and 'Committee Meetings'. The main content area is titled 'My eHIRB Studies' and features a sidebar with 'Site Managers', 'Help Desk', 'IRB Staff', 'My eHIRB Studies', and 'My IRB Reviews'. A 'Create New Application' button is also present. The main area has tabs for 'Action Required', 'Researcher Prep', 'In Process', 'Approved', and 'All My eHIRB Studies'. Three tables are displayed: 'New Applications' with 3 rows, 'Amendments' with 2 rows, and 'Continuing Review' with 1 row. Each table has columns for ID, Name, Current State, Last State Change, and PI Last Name.

Figure 11

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

The screenshot shows the top navigation bar of the eHIRB system. It includes the eHIRB logo and name, the user's name 'P12 Test HIRB | My Home | Projects', and a 'Logout' button which is circled in red. Below the navigation bar, there are links for 'All eHIRB Studies' and 'Help Desk'. The page title is 'Page for HIRB P2 Testaccount'.

Figure 12