

eHIRB User Guide:

How to Submit a Study Closure

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 Study Closure.

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

Important Study Closure Facts:

1. The eHIRB Study Closure form may be used to notify the IRB that a study is complete.
2. A study closure cannot be created if one is already in process.
3. Only the PI can submit a Study Closure, but anyone on the study team can complete the SmartForm.

Follow the steps below to submit a Study Closure:

- 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 Study Closure.

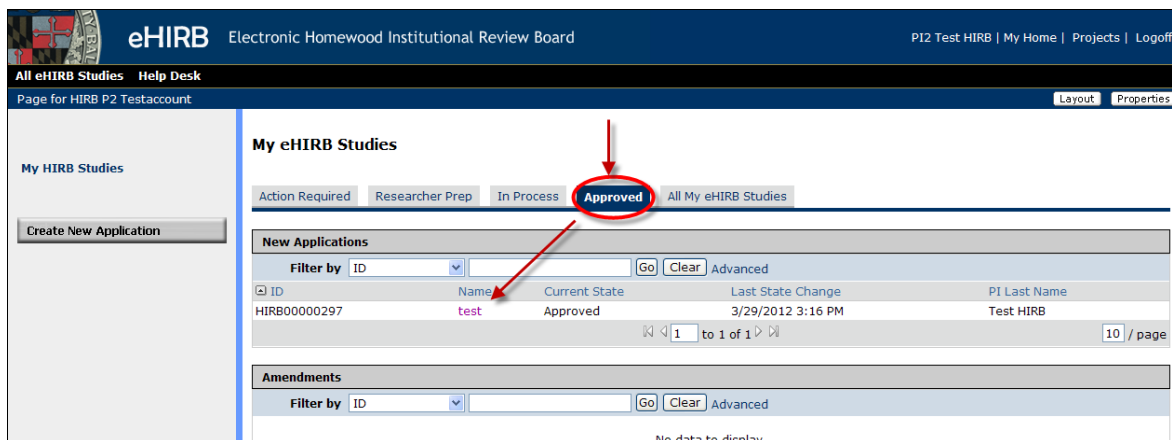


Figure 1

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

The screenshot shows the eHIRB interface for a 'New Application Workspace'. The sidebar on the left contains several buttons, with 'Create Further Study Action' highlighted by a red arrow. The main content area displays the following information:

- Title: test
- Protocol Number: HIRB00000297
- Principal Investigator: P12 Test HIRB
- Review Type: Full Board
- Study Expiration: 4/19/2013
- Original Approval: 3/29/2012

Below this information is a table for 'Review Items':

Review Date	Review Type	Outcome	Letter Sent
3/29/2012	Full Board	Approved/Acknowledged	View Letter

Figure 2

STEP 6. Select the “Study Closure” check box.

The screenshot shows the 'Further Study Action Selection' form. The 'Study Closure' option is selected, indicated by a red circle and a red arrow. Another red arrow points to the 'Continue >>' button in the top right corner.

Figure 3

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

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

The screenshot shows the eHIRB header area. The 'Continue >>' button is circled in red. The HIRB ID number 'HIRB00000296' is visible in the top right corner.

Figure 4

STEP 8. Complete Section 1 – Study Status, by providing answers to all the required questions.

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

1 - Study Status

1.0 * Select a project status.

- Study was never initiated.
- Study is inactive, and there are not plans to resume it.
- The PI is outside the Homewood Schools and Homewood personnel were engaged in the research, but the involvement of all Homewood personnel is complete.
- All recruitment and enrollment of participants, data collection, and analysis of identifiable private data is complete.
- All data analysis is complete, and there are no plans to contact human participants or records (i.e., no plans for follow-up research).

Figure 5

- STEP 9. 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 10. Make sure required questions are answered.** The system will not allow the Study Closure to be submitted to the IRB until all required items are completed on the Study Closure 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 any time from the blue navigation bar.

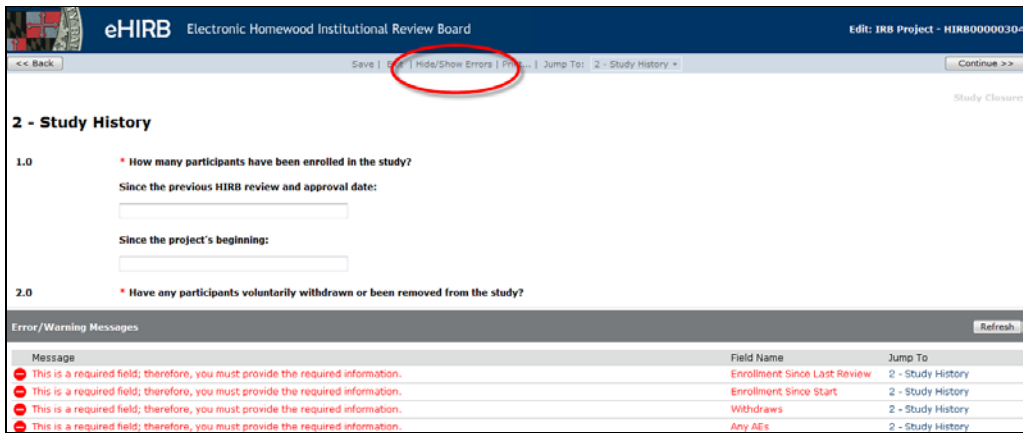


Figure 6

STEP 11. Once you have completed the form, Select the “Finish” button on the last section of the SmartForm entitled “3 – Summary of Progress”.

- 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 STUDY CLOSURE.

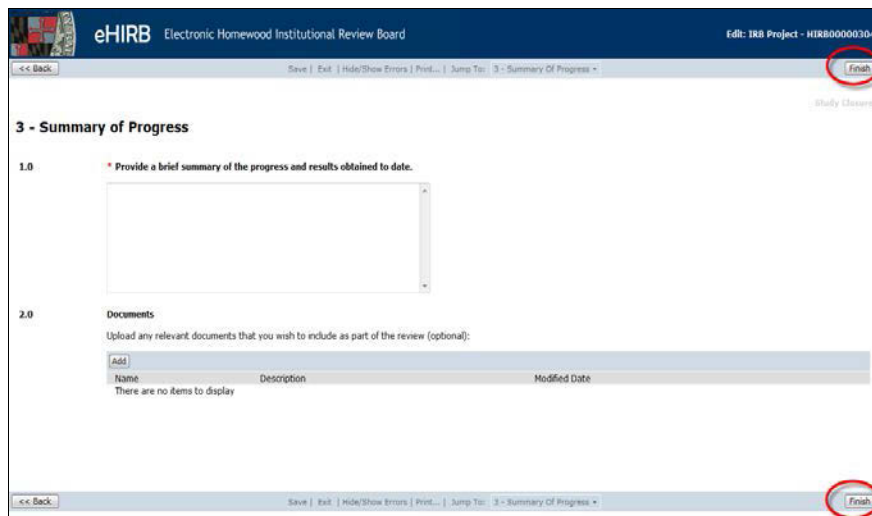


Figure 7

STEP 12. 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 Study Closure is submitted, select the “View/Edit Form” activity to open up the form and resume completing it.
- **WARNING:** The PI cannot edit the form after submission, unless the IRB sends it back with questions.

Current Status
Researcher Prep

Study Closure Workspace

Title: Study Closure: SC00000303 For: HIRB00000243
 Protocol Number: SC00000303
 Principal Investigator: P11 Test HIRB

Study Teams:
 Last Name First Name Role
 There are no items to display

Review Types:
 There are no items to display

Review Items:
 Review Date Review Type Outcome Letter Sent
 There are no items to display

Special Populations:
 Children
 Students
 Prisoners
 Non-English Speakers

Consent/Assent:
 Written Assent
 Written Consent
 Oral Assent
 Oral Consent
 Written parental permission
 Waiver written consent

Special Categories:
 Deception
 Classified
 Drugs
 Devices

Activity	Author	Activity Date
Returned to Study Team	Tindall, Sue	3/30/2012 10:04 AM EDT
Updated on submission	Test HIRB, P11	3/30/2012 10:03 AM EDT
Submitted	Test HIRB, P11	3/30/2012 10:03 AM EDT

Figure 8

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

STEP 13. 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.

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.	Non Hopkins Entity	5 - Research Sites

Figure 9

STEP 14. After all error/warning messages are resolved, select the “Submit” activity again, the PI certification appears.

STEP 15. Read the PI Certification text, and then select “OK”.

Submit
New Application

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.




Figure 10

- STEP 16.** 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 Study Closure.
 - The IRB office will receive the submission and begin reviewing the application.
 - The Study Closure can no longer be edited at this time, unless the IRB office sends it back for clarification and/or changes.
- STEP 17.** To view the Study Closure that was just submitted, **select the “In Process”** tab located on the **My HIRB Studies** workspace.

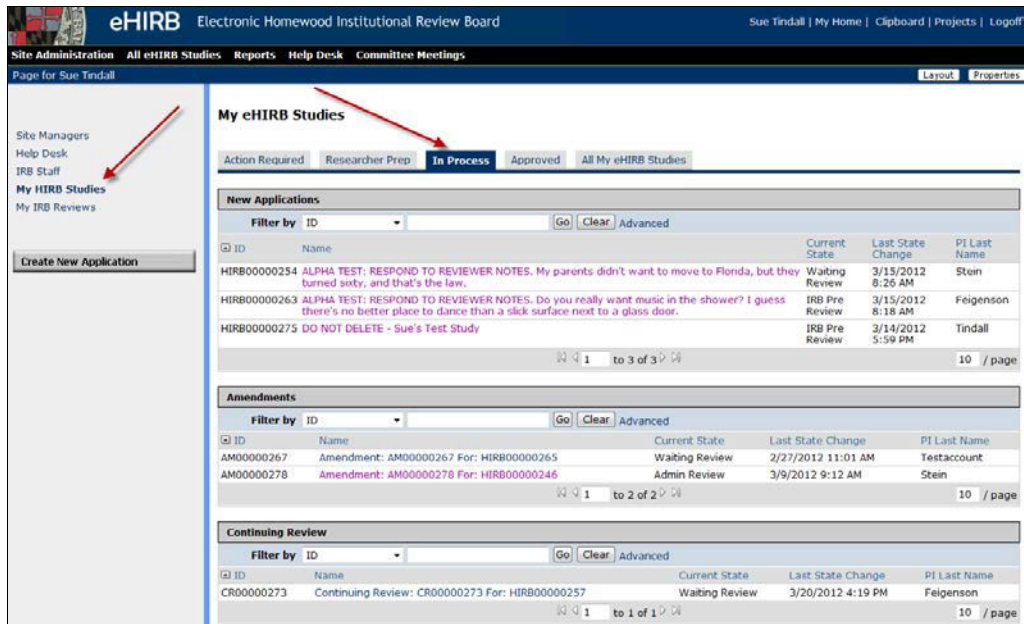


Figure 11

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

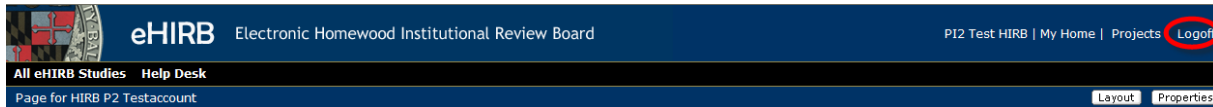


Figure 12