

eHIRB User Guide:

How to Submit a Reportable Event

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 reportable event.

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

Important Reportable Event Facts:

1. PIs are required to submit reportable events to the IRB as soon they become aware of the event.
2. The possible categories of reportable events that must be reported to the IRB include, but are not limited to: protocol deviation, participant complaint, unanticipated problem, adverse event.
3. The eHIRB reportable event form may be used to notify the IRB of a single type of reportable event which occurred in one or more participants.
4. Only the PI can submit a reportable event, but anyone on the study team can complete the SmartForm.

Follow the steps below to submit a reportable event:

- 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 reportable event.

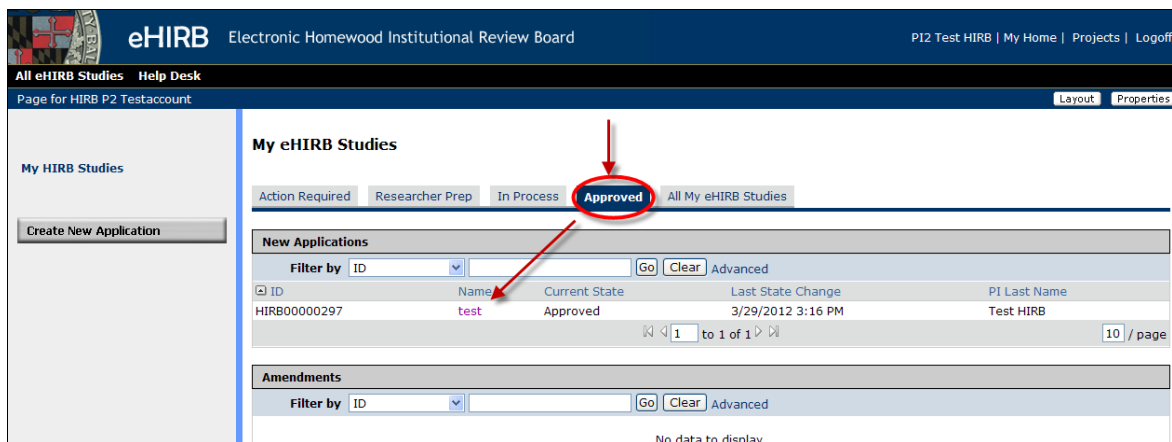


Figure 1

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

The screenshot shows the eHIRB interface for a 'New Application Workspace'. On the left, a sidebar contains 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: P12 Test HIRB, Review Type: Full Board, Study Expiration: 4/19/2013, and Original Approval: 3/29/2012. There are also two empty tables for 'Study Team' and 'Review Items'.

Figure 2

STEP 6. Select the “Reportable Event” check box.

The screenshot shows the 'Further Study Action Selection' page. It features a heading 'Further Study Action Selection' and a sub-heading '* Select the type of further study action you would like to create.' Below this, there are four checkboxes: 'Amendment', 'Continuing Review', 'Reportable Event', and 'Study Closure'. The 'Reportable Event' checkbox is checked and circled in red. A red arrow points to this checkbox. Another red arrow points to the 'Continue >>' button at the top right of the page.

Figure 3

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

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

The screenshot shows the eHIRB interface for editing an IRB project. The page title is 'Edit: IRB Project - HIRB00000296'. The bottom navigation bar includes buttons for '<< Back', 'Save | Exit | Hide/Show Errors | Print...', and 'Continue >>'. The 'Continue >>' button is circled in red.

Figure 4

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

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

eHIRB Electronic Homewood Institutional Review Board Edit: IRB Project - RE00000302

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 1 - Reportable Event >> Continue >>

Reportable Event

1 - Reportable Event

This form may be used to notify the IRB of a single type of Reportable Event which occurred in one or more participants.

1.0 * Select the event type.
 Protocol Deviation

2.0 * Briefly summarize the protocol event. You will be prompted on the following page to describe how the event occurred, specific to each participant (if applicable).

3.0 * Describe any corrective action(s) taken by the study team to date and their outcome. Indicate any actions that were taken without prior approval by HIRB and explain why they were taken (e.g., to eliminate an immediate hazard).

Figure 5

STEP 9. Select “Continue” to proceed to **Section 2 – Participant Information.**

eHIRB Electronic Homewood Institutional Review Board Edit: IRB Project - RE00000302

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 2 - Participant Information >> Continue >>

Reportable Event

2 - Participant Information

1.0 * Click 'Add' to enter information for a new Reportable Event(s), or 'Update' to revise an existing one.

Add

Participant ID	Date of Event	Date Event Discovered	Site Which Event Occurred
12345	3/30/2012	3/5/2012	test site

Update **Delete**

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: 2 - Participant Information >> Continue >>

STEP 10. Select “Add” to enter details about the reportable for each participant that was involved.

- At least one participant information record must be added.

STEP 11. Complete the “Participant View” form, and then select **OK** to save the answers and return to the SmartForm.

Participant View

Please answer the items on this page in relevance to the individual participant identified below.

1.0 * Participant ID
12345

2.0 * Date of event
3/30/2012

3.0 * Date the event was discovered
3/5/2012

4.0 * Site at which event occurred
test site

5.0 * Describe the circumstances leading up to the event specific to this participant.
test describe.

9.0 * Explain how the event harmed participant(s) and/or involved risk to participants or others
test

* Required

OK OK and Add Another Cancel

Figure 6

STEP 12. 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 13. Make sure required questions are answered. The system will not allow the reportable event to be submitted to the IRB until all required items are completed on the reportable event 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.

The screenshot shows the eHIRB interface for a reportable event. The top navigation bar includes 'eHIRB Electronic Homewood Institutional Review Board' and 'Edit: IRB Project - RE0000302'. A menu bar contains 'Save', 'Exit', 'Hide/Show Errors' (circled in red), 'Print...', and 'Jump To: 1 - Reportable Event'. The main content area is titled '1 - Reportable Event' and contains two sections: '1.0 * Select the event type.' with a dropdown menu set to 'Protocol Deviation', and '2.0 * Briefly summarize the protocol event. You will be prompted on the following page to describe how the event occurred, specific to each participant (if applicable).' with a text input area. At the bottom, an 'Error/Warning Messages' table is visible.

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Summary of Event	1 - Reportable Event
⊖ This is a required field; therefore, you must provide the required information.	Explain Corrective Action	1 - Reportable Event

Figure 7

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

- 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 REPORTABLE EVENT.

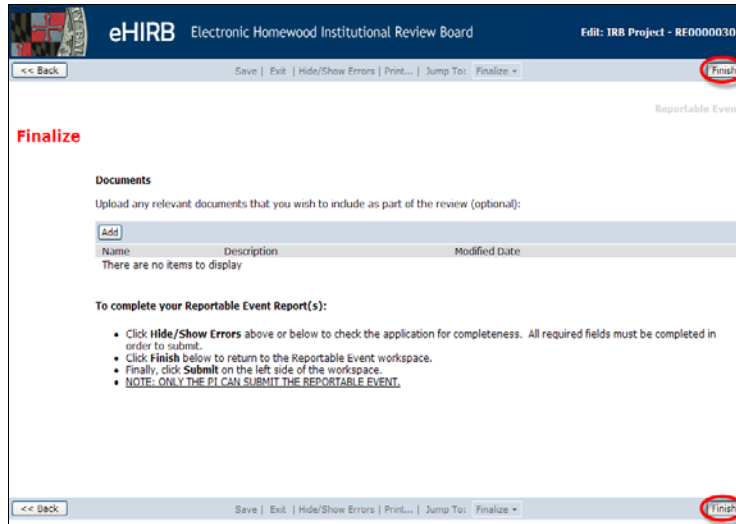


Figure 8

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 reportable event 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.

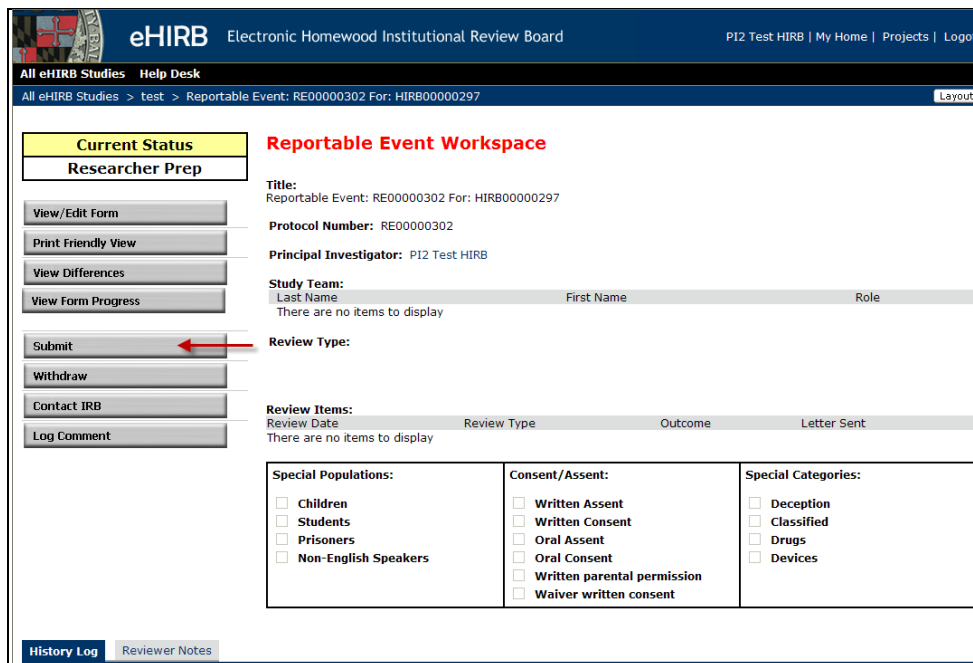


Figure 9

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

STEP 16. 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		
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 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”.

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

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

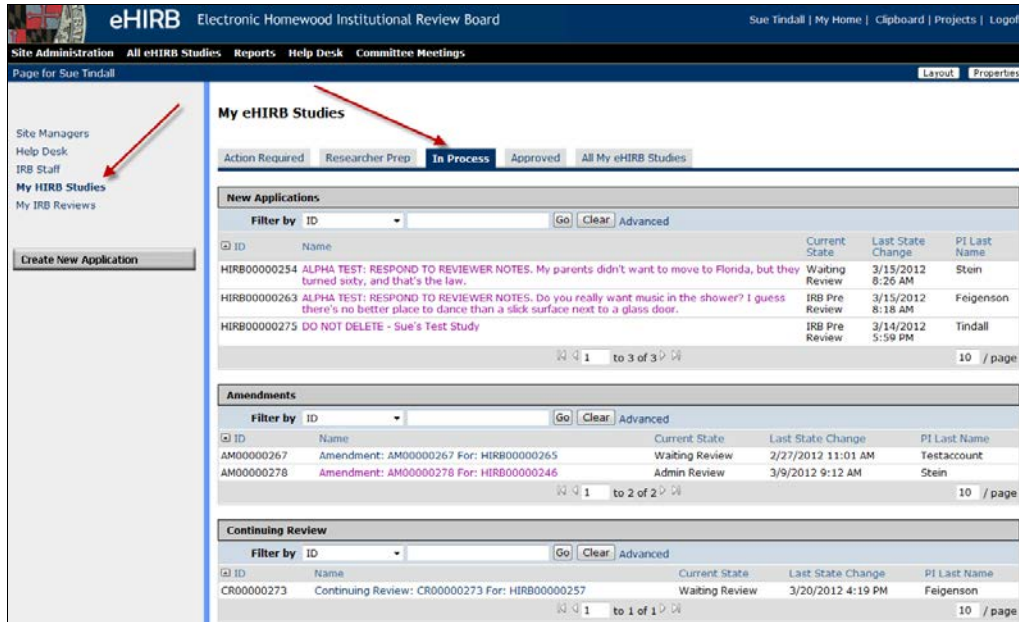


Figure 12

- 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 “Logoff”**, located on the top left corner.

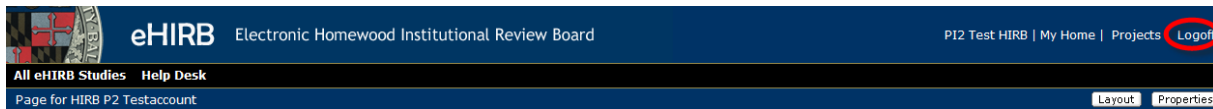


Figure 13