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 <u>eHIRB Getting Starting Guide</u> 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.
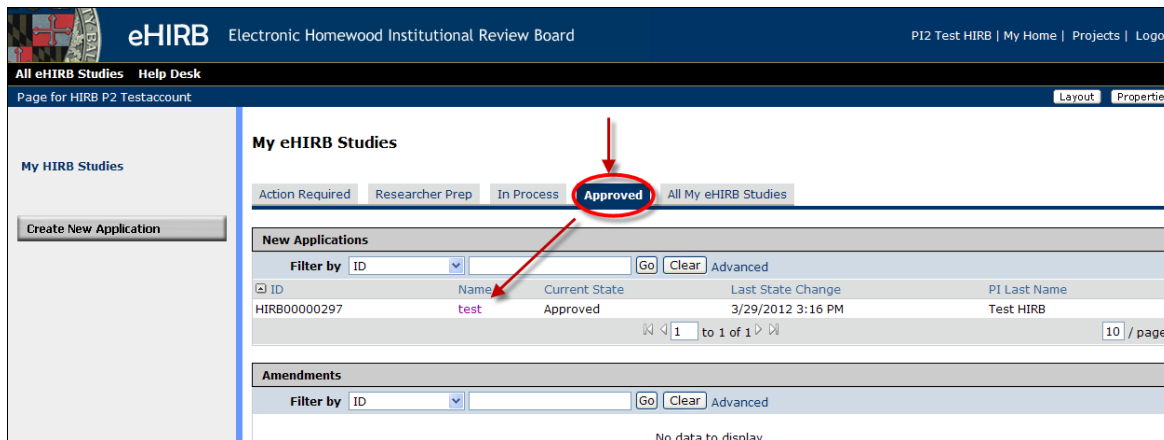

Figure 1

Questions? Contact the HIRB Office at hirb@jhu.edu.

STEP 5. **Select** the "**Create Future Study Action**" button.

Figure 2

STEP 6. **Select** the "**Reportable Event**" check box.

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.

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 $(\textcolor{red}{*})$.

Questions? Contact the HIRB Office at hirb@jhu.edu.

Figure 5

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

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.

Questions? Contact the HIRB Office at hirb@jhu.edu.

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

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.

Questions? Contact the HIRB Office at hirb@jhu.edu.

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.

<p align="center">Figure 7</p>

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.**

<p align="center">**Questions? Contact the HIRB Office at hirb@jhu.edu.**</p>
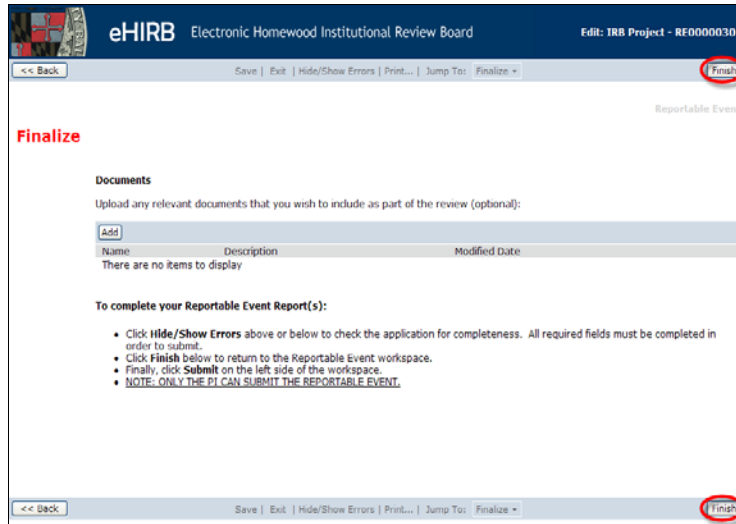
Figure 8

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.

Questions? Contact the HIRB Office at **hirb@jhu.edu.**

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			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	

<div align="center"><strong style="color:#2e74b5">Figure 10</div>

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.

OK   Cancel

<div align="center"><strong style="color:#2e74b5">Figure 11</div>

STEP 19. After submission, **select** "**My Home**" located on the top left corner to return to your Inbox.

Questions? Contact the HIRB Office at hirb@jhu.edu.

> ➢ 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.
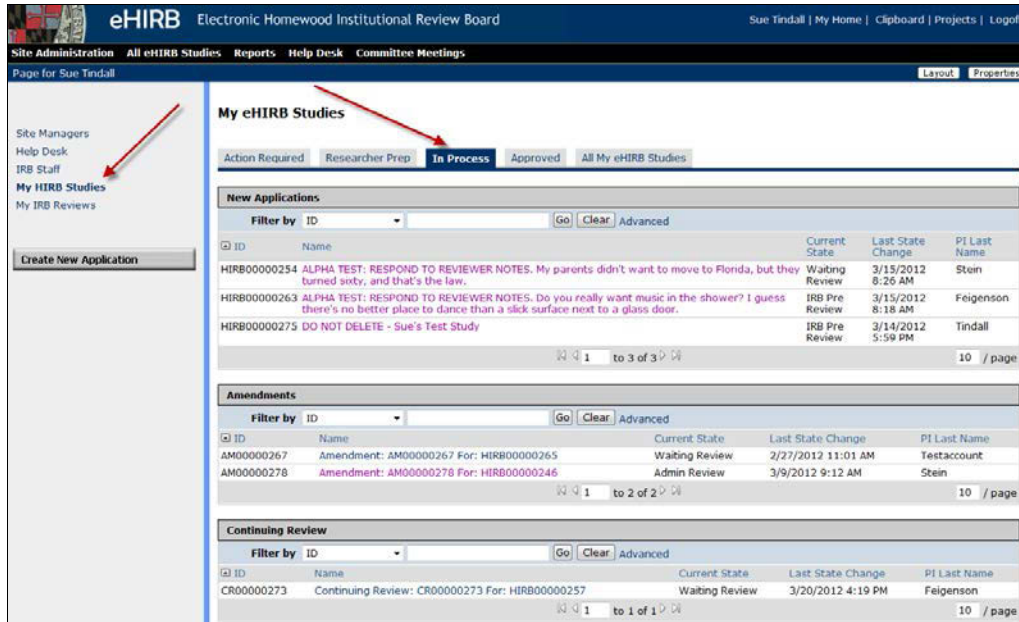

Figure 12

> ➢ 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.

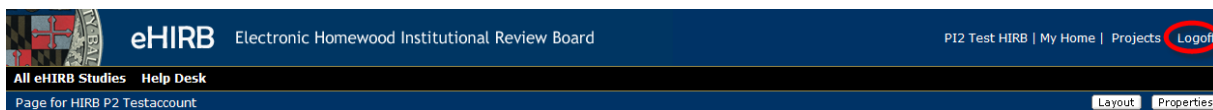**STEP 21.** **To close out of eHIRB, Select** "**Logoff**", located on the top left corner.

Figure 13

Questions? Contact the HIRB Office at hirb@jhu.edu.