eHIRB User Guide:
How to Submit an Amendment

Last Update	**December 22, 2021**
Intended Audience	**Principal Investigator/Researcher**
Purpose	**How to submit an amendment.**

⇒ **Refer to the eHIRB Getting Starting Guide before getting started.**

Important Amendment Facts:

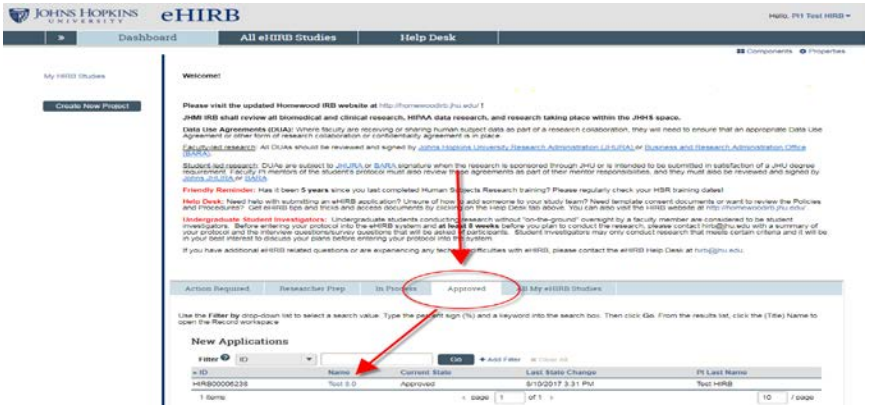
1. Amendments can only be submitted for studies once they have already been approved by the IRB.
2. Any changes the PI would like to make to an IRB-approved application must be submitted as an amendment (i.e. including, but not limited to, changes to the study title, PI, study team members, procedures, 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.

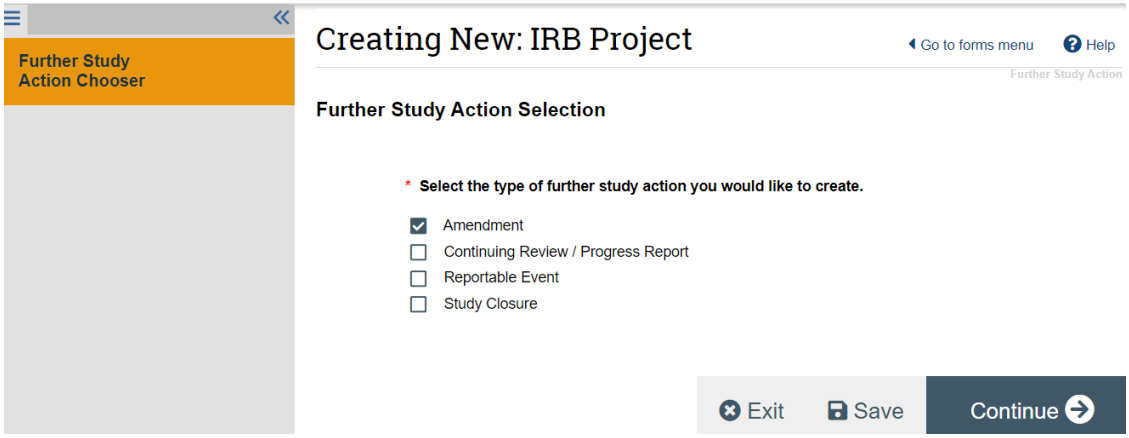
- The **My eHIRB Studies** workspace should appear, if not, select it from left side.

STEP 4. **Select** the "**Approved**" tab, and then select the approved New Application for which you need to create an amendment.



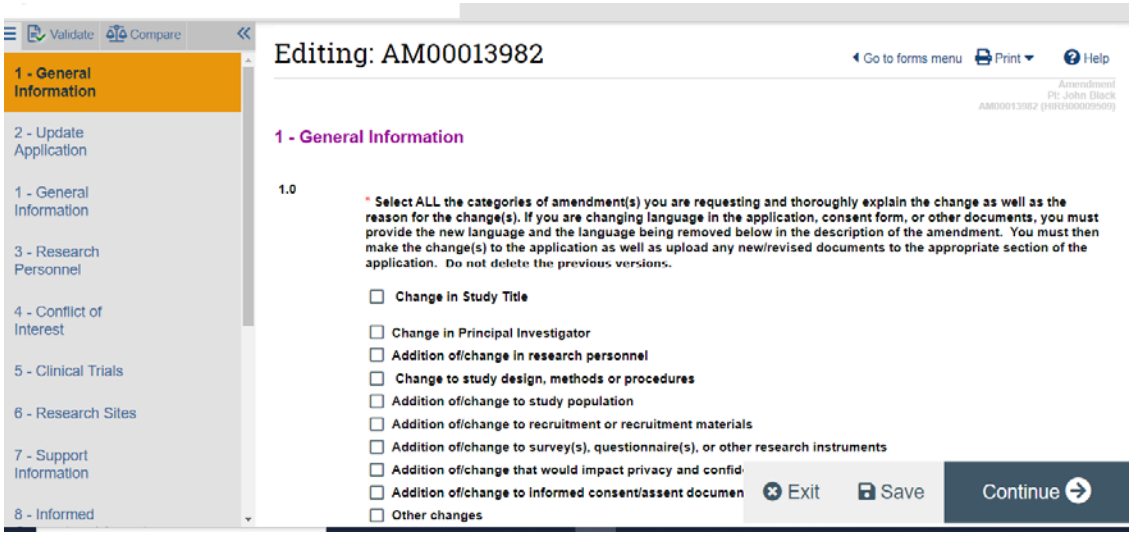
STEP 5. **Select** the "**Create Future Study Action**" (FSA) button, the SmartForm appears.

STEP 6. **Select** the "**Amendment**" check box.



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.



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.

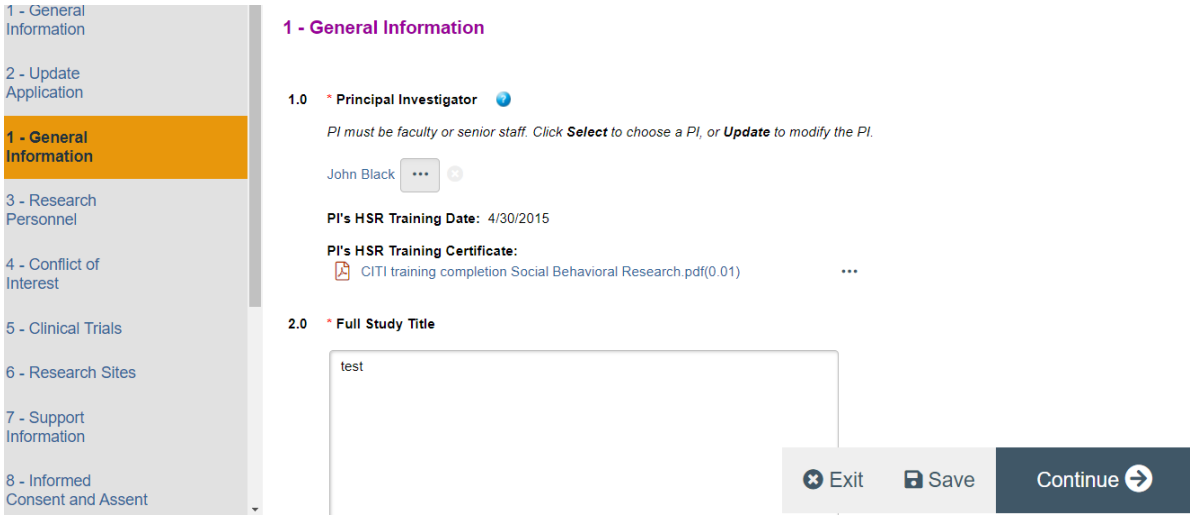
1

STEP 9. **Select** "**Continue**" to proceed to **Section 2 – Update Application**.

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

STEP 10. **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.

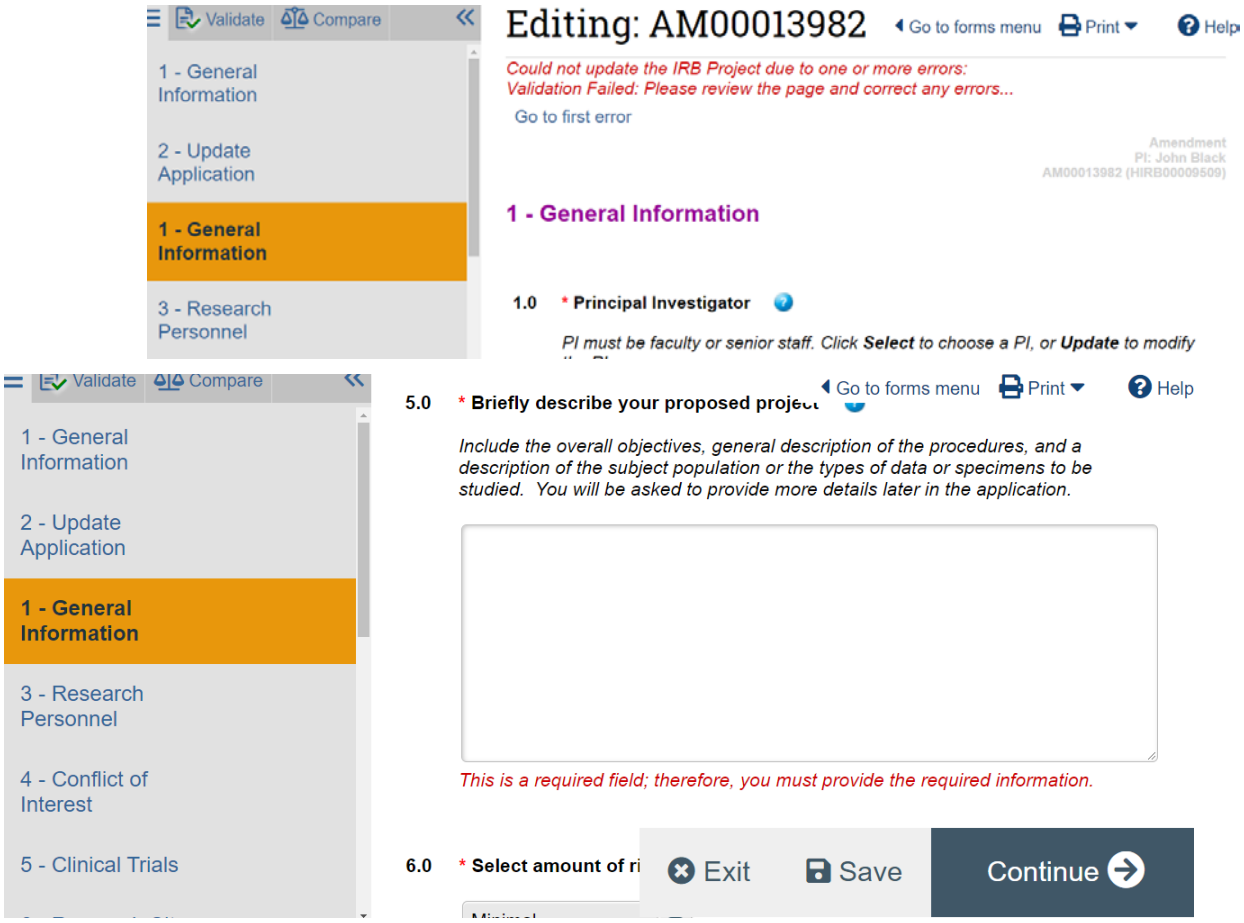


STEP 11. **Complete** the remaining sections using the navigation bar

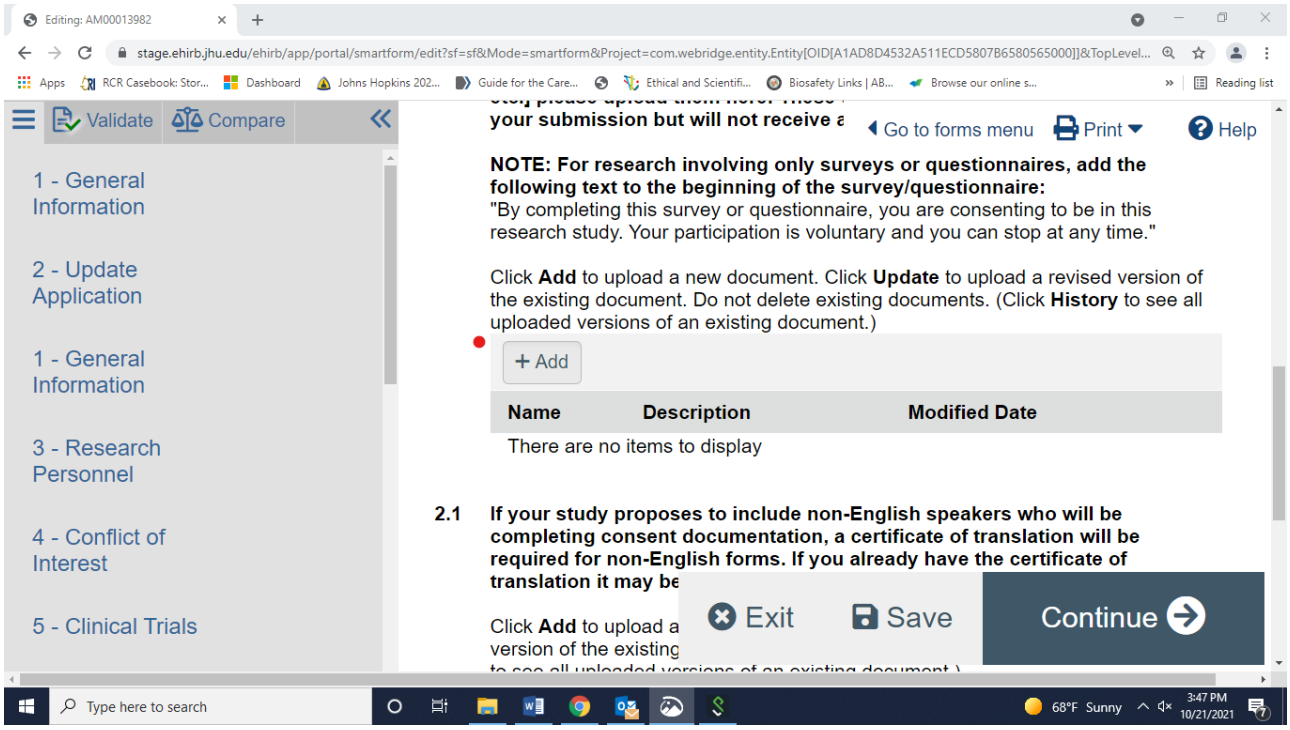
- The navigation bar can be found at the bottom right of the form.
- Select "**Continue** to proceed through each page of the application SmartForm.
- When "**Continue**" is selected the system automatically saves the form.
- You can select "**Save**" at any time and **"Exit"** the form. If needed, you 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.

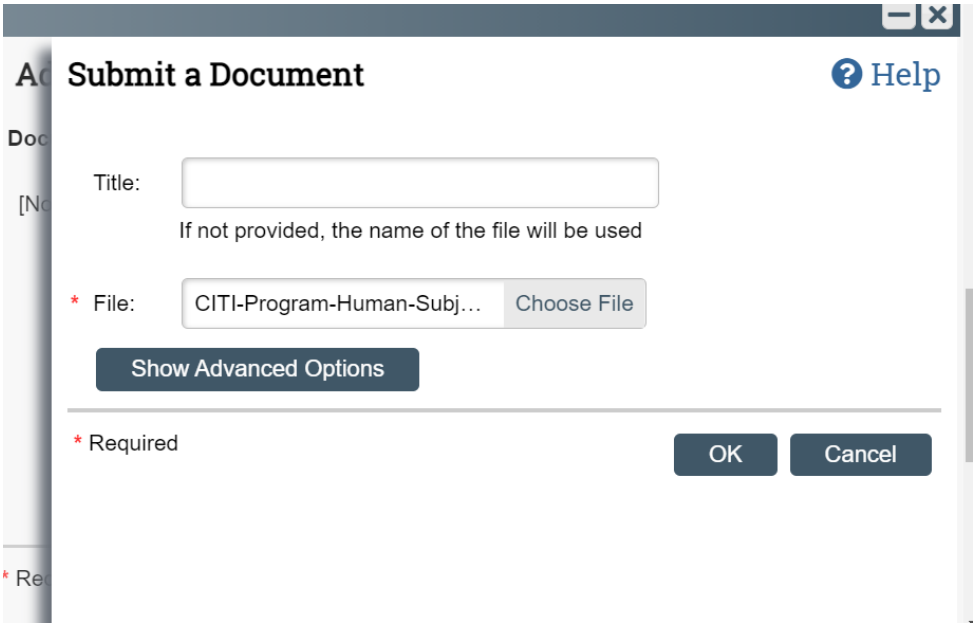
STEP 12. **Make sure all required questions are answered**. The system will not allow the amendment to be submitted to the IRB until all required items are completed on the amendment SmartForm.

- If the page you are working on is not completed, asterisked items are not answered, the system will trigger error messages before the page can be advanced.
- By clicking on Go to first error, the SmartForm will advance to the change that is needed. See the two screen shots below.



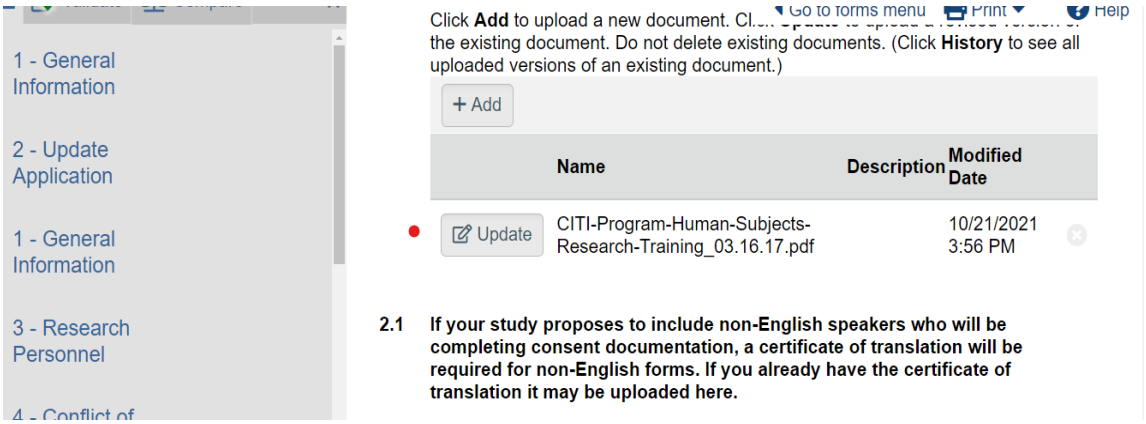
STEP 13. **Adding and updating documents:**

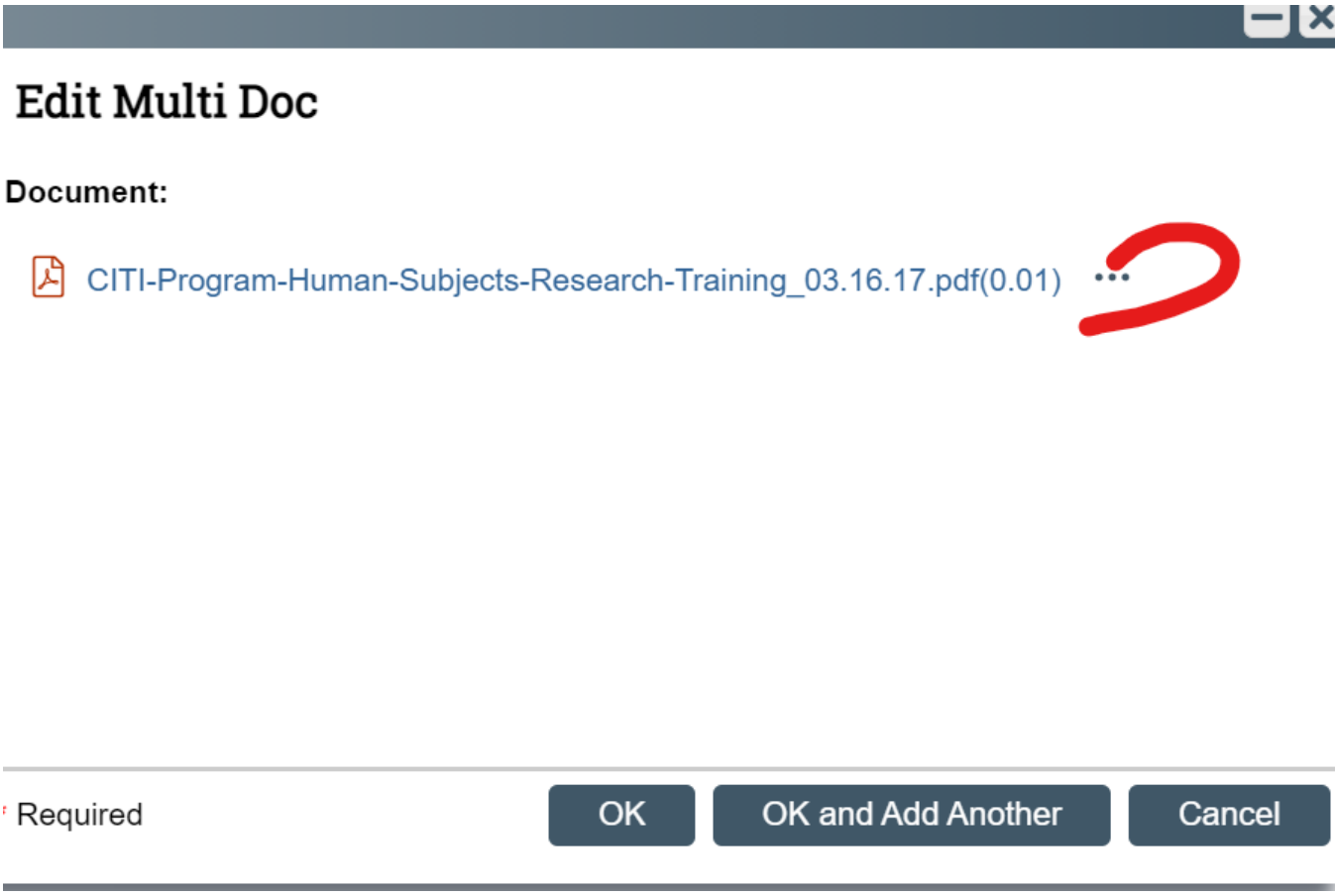




STEP 14. Updating or uploading a revised version of an existing study document

Do NOT upload additional documents if they are revisions of the parent. Only upload new documents as additional documents.

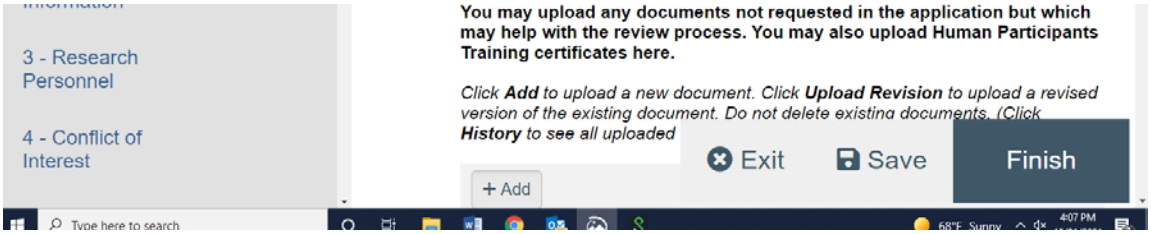




Click on the ellipse tool circled above, which will bring up options to Download ; Copy; Upload Revision; View History; or Delete. Use these functions to manage the documents. In general, past versions of study documents should NOT be deleted, especially consent forms.

STEP 15. **Once you have completed the form, Select** the "**Finish**" button on the last section of the SmartForm entitled "**Finalize Application**".

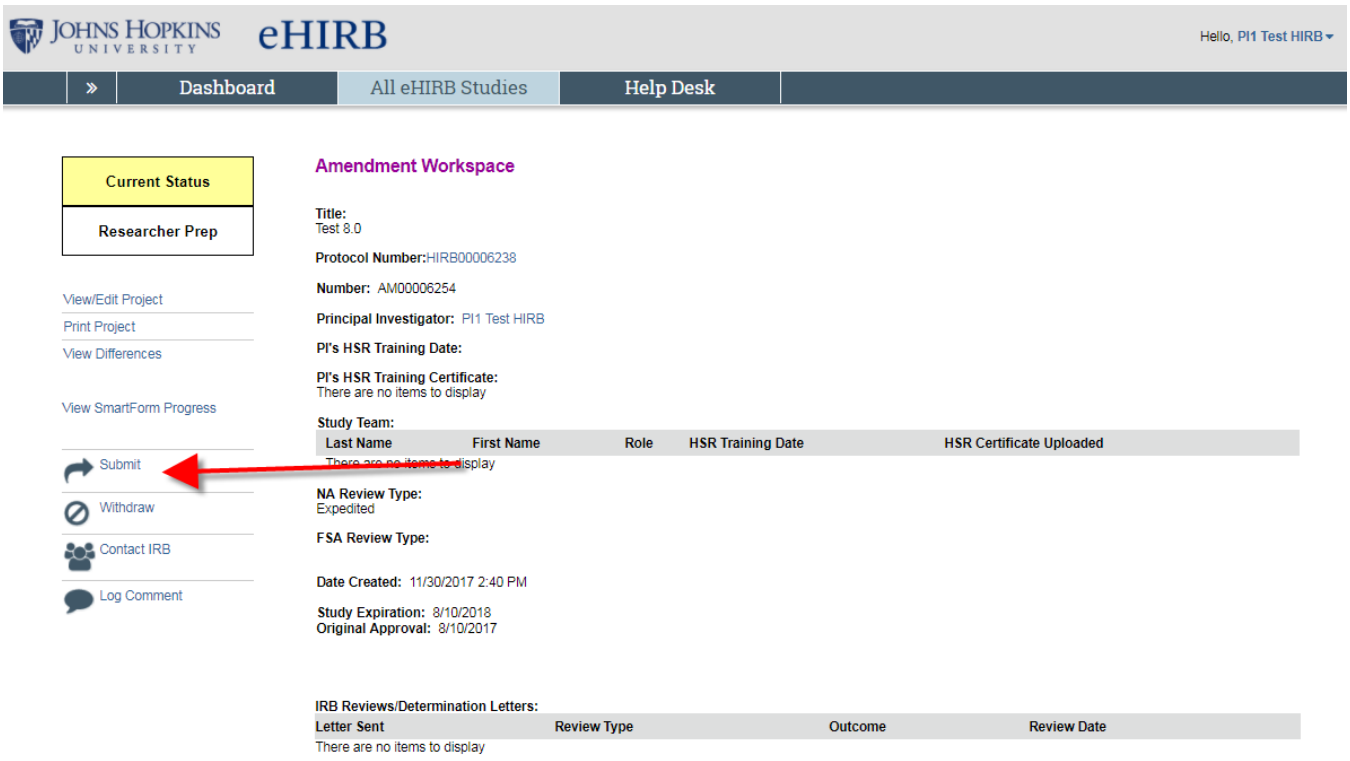
STEP 16.



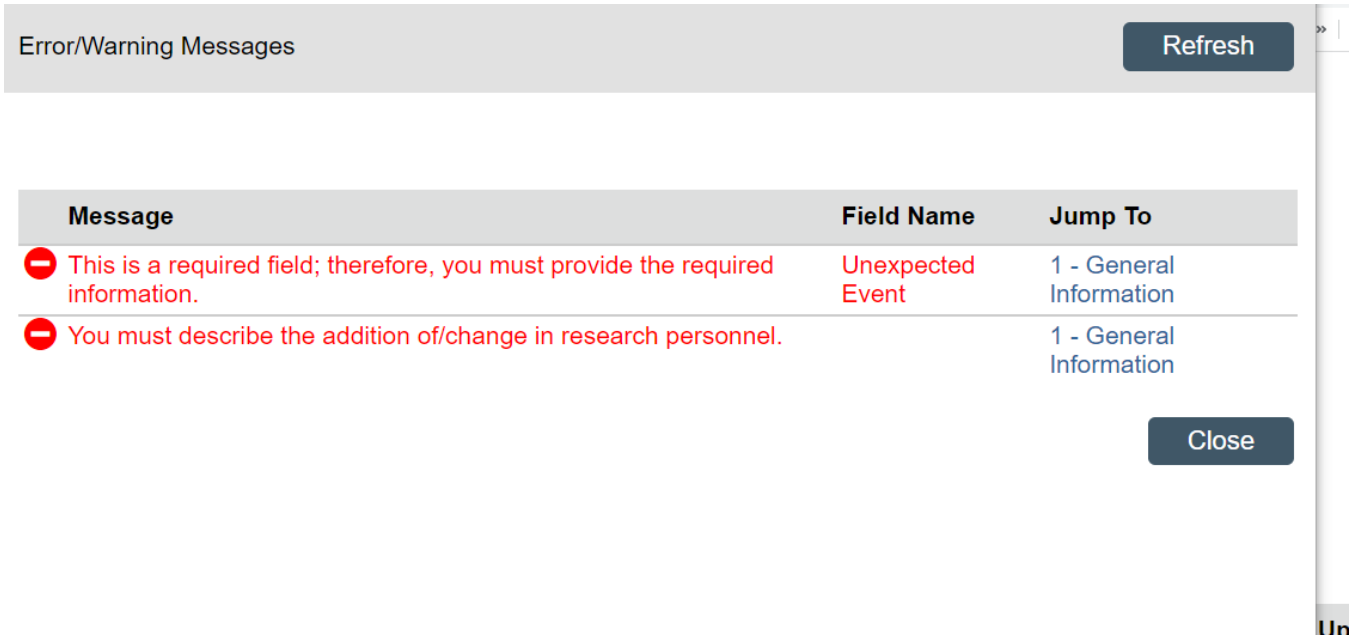
- **NOTE:** You are not done yet.
- The SmartForm will close and you will be taken to the application workspace where you will be able to finally "**Submit"** the application to the IRB.
- The application is NOT sent to the IRB until the **"Submit"** activity on the workspace is run. **NOTE: THE PI MUST SUBMIT THE AMENDMENT.**

STEP 17. **From the application workspace**, **select** the "**Submit**" activity, located on the left side of the workspace.

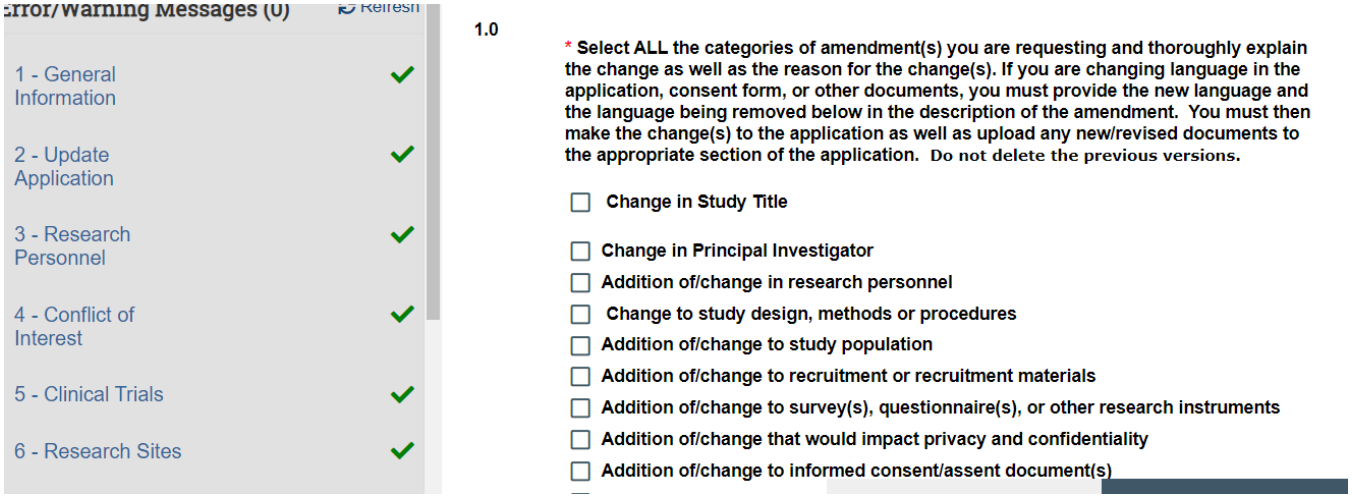
- If additional changes are need on the SmartForm before the amendment is submitted, select the **"View/Edit Form**" activity to open up the form and resume completing it.
- **NOTE**: The PI cannot edit the form after submission, unless the IRB sends it back with questions.



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

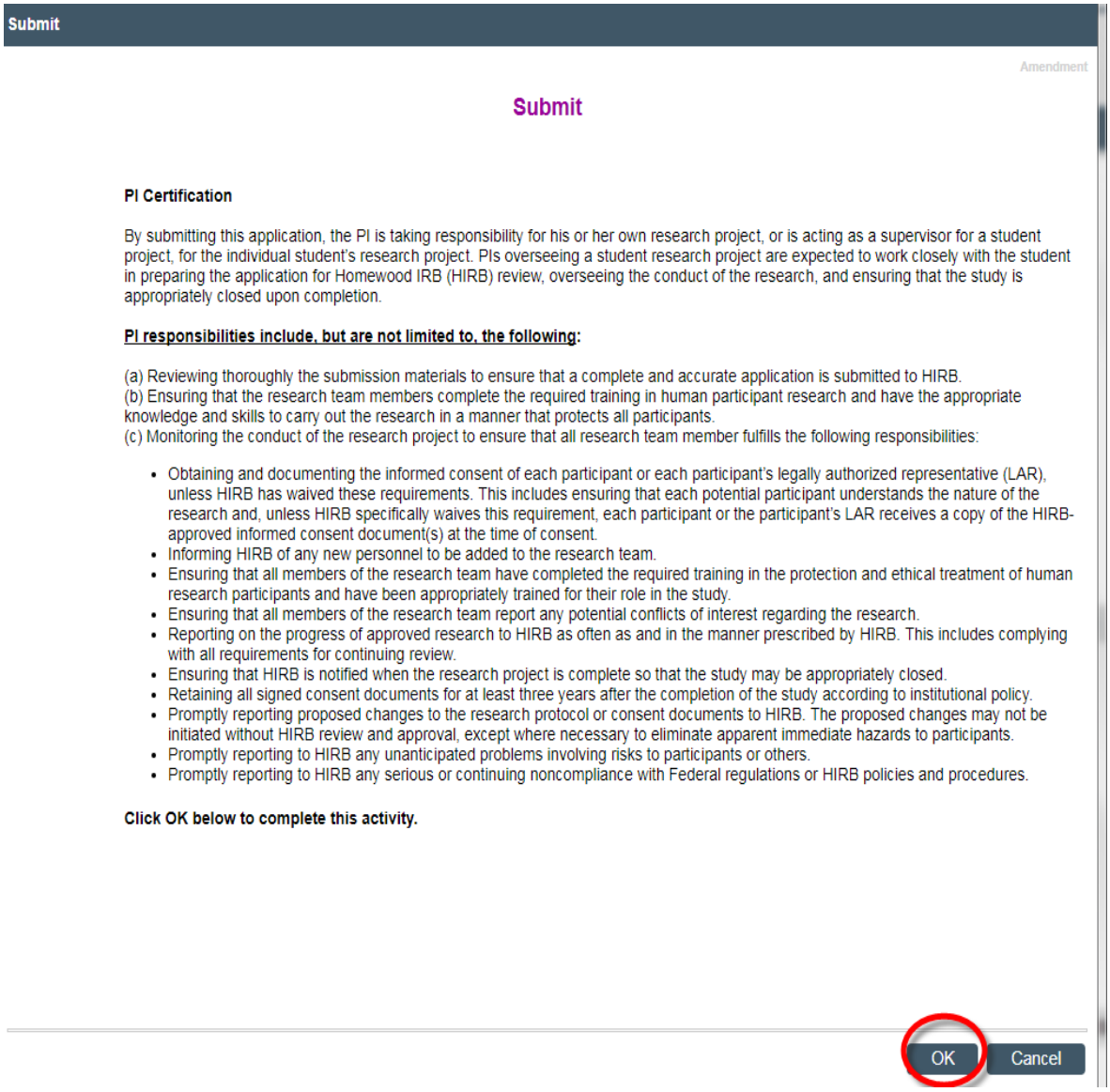


STEP 18. **To correct error/warning message**, **select** the hyperlinked Section Name in the list and the system will take you directly to the page (ex. 3 – Research Personnel) where the answer can be corrected. Repeat this until all error messages have disappeared from the list. The system will show green check marks to verify completion.



STEP 19. After all error/warning messages are resolved, **select** the "**Submit**" activity again, the PI certification appears.

STEP 20. **Read** the PI Certification text, and then select "**OK**".



STEP 21. 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 22. To view the amendment that was just submitted, **select** the "**In Process**" tab located on the **My HIRB Studies** workspace. The top left corner of the amendment workspace will appear as below, Current Status: Admin. Review.

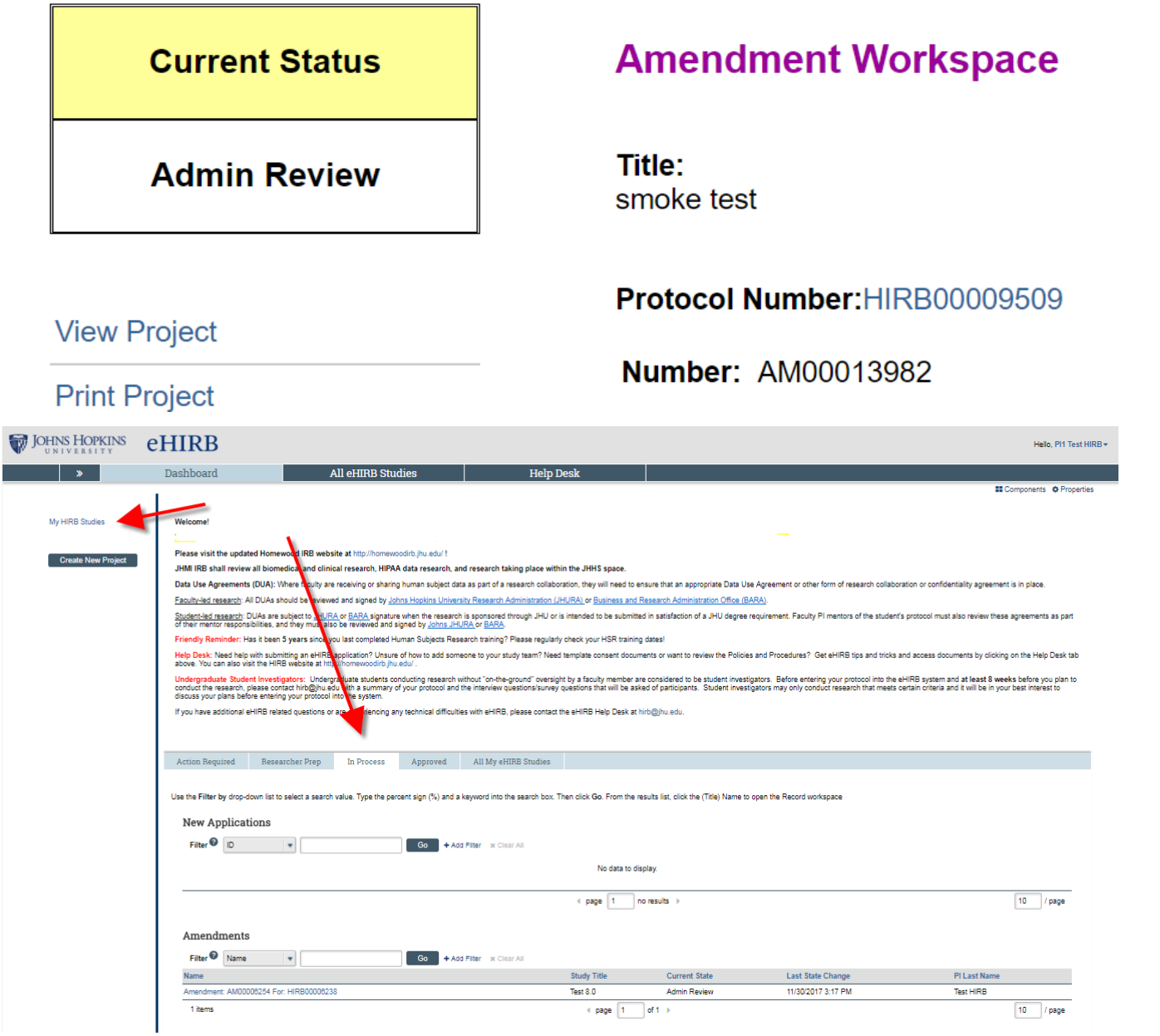


Figure 2

- 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 23. **To close out of eHIRB, Select** "**Logoff**", located on the top right corner. to logoff, click on the arrow and select logoff

Figure 3