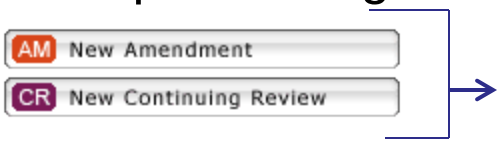
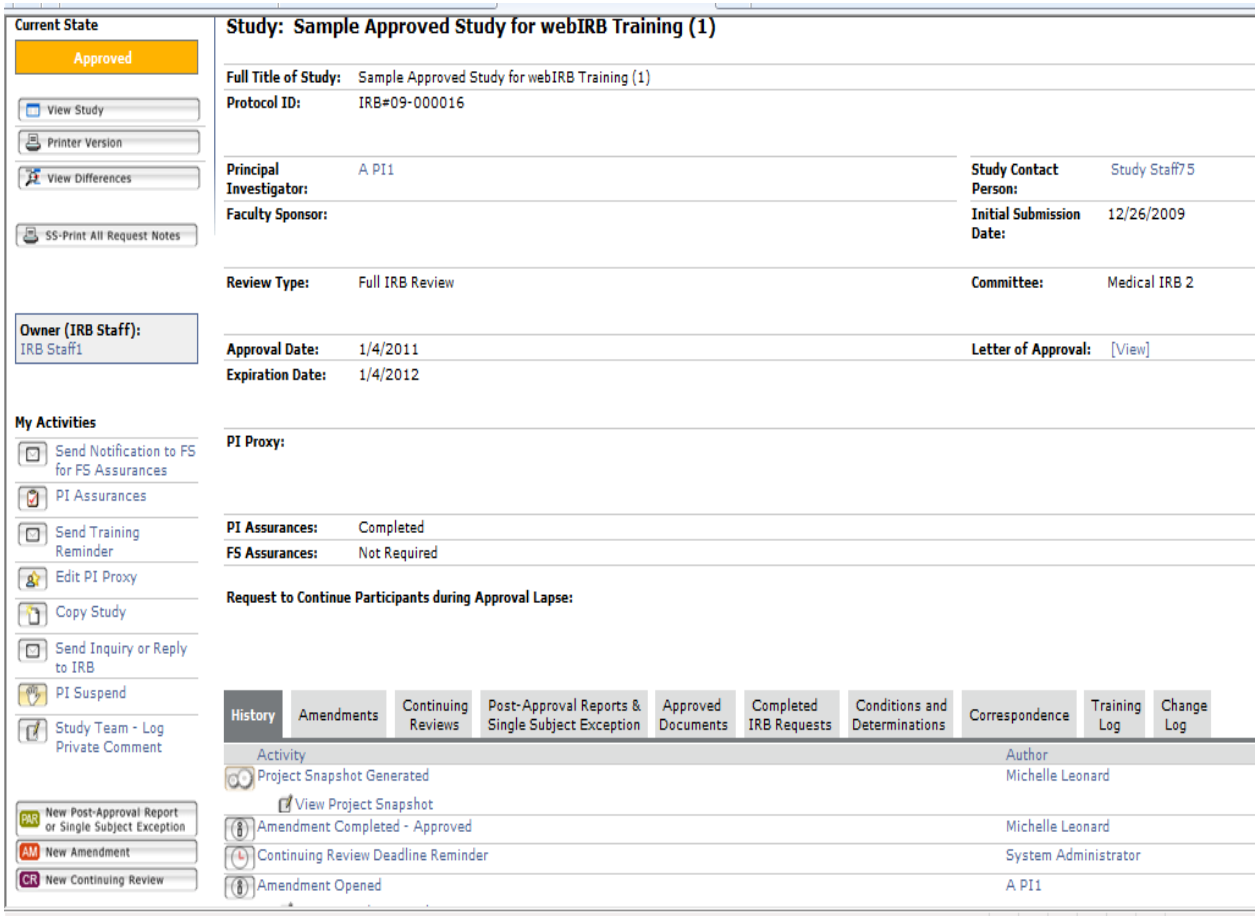
UCLA OHRPP
Office of the Human Research Protection Program

Submitting Amendments and Continuing Reviews in webIRB

Creating Amendments & Continuing Reviews in webIRB

- After approval of a study in webIRB Amendments (AMs) and Continuing Reviews (CRs) are submitted through webIRB.
- AMs and CRs are created in the approved study workspace using:





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Amendments in webIRB

How many AMs can I submit at the same time?

- Only one amendment can be created at a time.
- When an amendment is submitted, the sections of the application that are being modified are locked to further changes until the amendment is reviewed and approved.

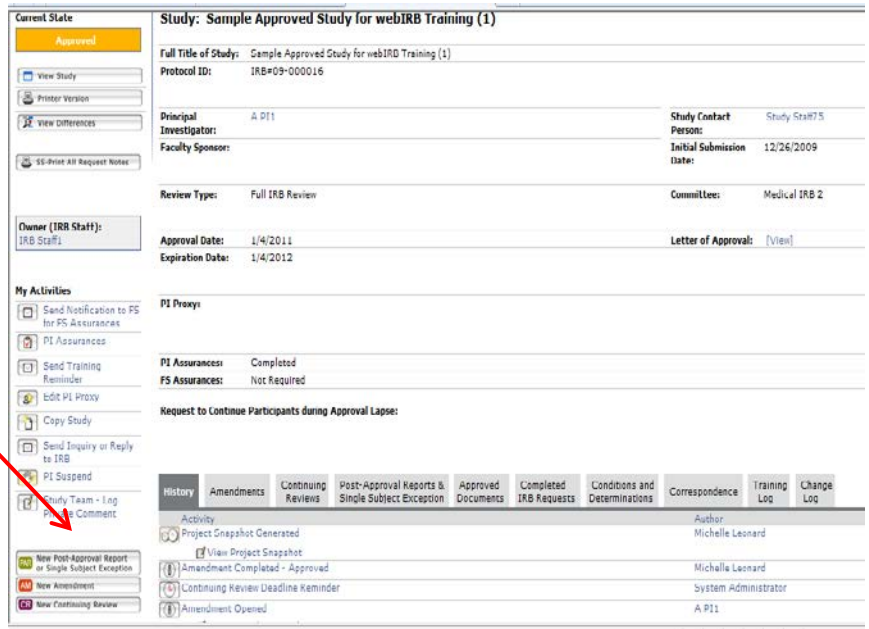
Steps for preparing an AM application

- **Step 1:** Start the AM application by clicking 

in the approved study workspace of the study you are modifying.
- **Step 2:** Describe the amendment (i.e., proposed changes to the study application).
- **Step 3:** Revise the study application and study documents, if applicable.
- **Step 4:** Submit the Amendment.

Step 1: Create an AM

- In the approved study workspace click on: AM New Amendment



- The **Description of Amendment** section will appear.

Note: there is 1 open Amendment for this study.

Warning: Save your work at least every 15 minutes by clicking "Save" or "Continue."

Description of Amendment

1.0 * **Short Title:**
Amendment #8 for webIRB Study IRB#11-000045

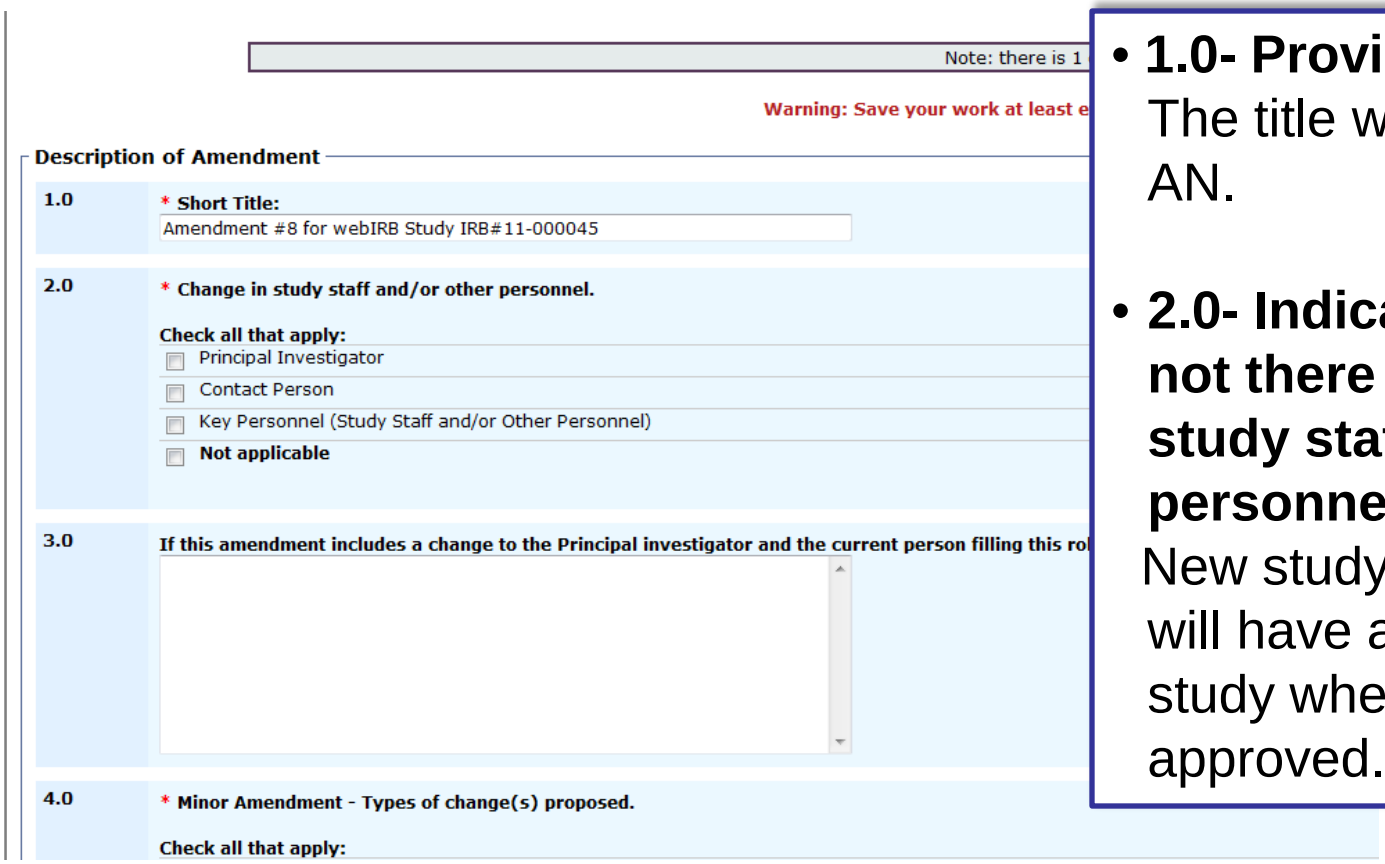
2.0 * **Change in study staff and/or other personnel.**

Check all that apply:

- ☐ Principal Investigator
- ☐ Contact Person
- ☐ Key Personnel (Study Staff and/or Other Personnel)
- ☐ **Not applicable**

Step 2: Describe the Amendment

Complete the **Description of Amendment** section:


Note: there is 1

Warning: Save your work at least e

Description of Amendment

1.0 * **Short Title:**
Amendment #8 for webIRB Study IRB#11-000045

2.0 * **Change in study staff and/or other personnel.**

Check all that apply:
- Principal Investigator
- Contact Person
- Key Personnel (Study Staff and/or Other Personnel)
- **Not applicable**

3.0 **If this amendment includes a change to the Principal investigator and the current person filling this ro**

4.0 * **Minor Amendment - Types of change(s) proposed.**

Check all that apply:

- **1.0- Provide a short title**
  The title will appear on the AN.

- **2.0- Indicate whether or not there is change in study staff and/or key personnel**
  New study staff/personnel will have access to the study when the AM is approved.

Step 2: Describe the amendment (cont'd)

4.0 * **Minor Amendment - Types of change(s) proposed.**

Check all that apply:

- ☐ Clarification or technical change
- ☐ Minor increase/decrease in number of Study participants
- ☐ Narrowing of the inclusion criteria
- ☐ Broadening of the exclusion criteria
- ☐ Changes in the dosage or form (e.g., tablet to liquid) but not the route of administration of an approved drug
- ☐ Increase or decrease in the number of safety monitoring visits provided that there is no impact on subject safety.
- ☐ Addition or deletion of study sites
- ☐ Change in payments to study participants
- ☐ Minor changes to recruitment materials
- ☐ Minor changes to screening procedures
- ☐ Change in funding source(s)
- ☐ Other
- ☐ **None of the above**

5.0 * **Major Amendment - Types of change(s) proposed.**

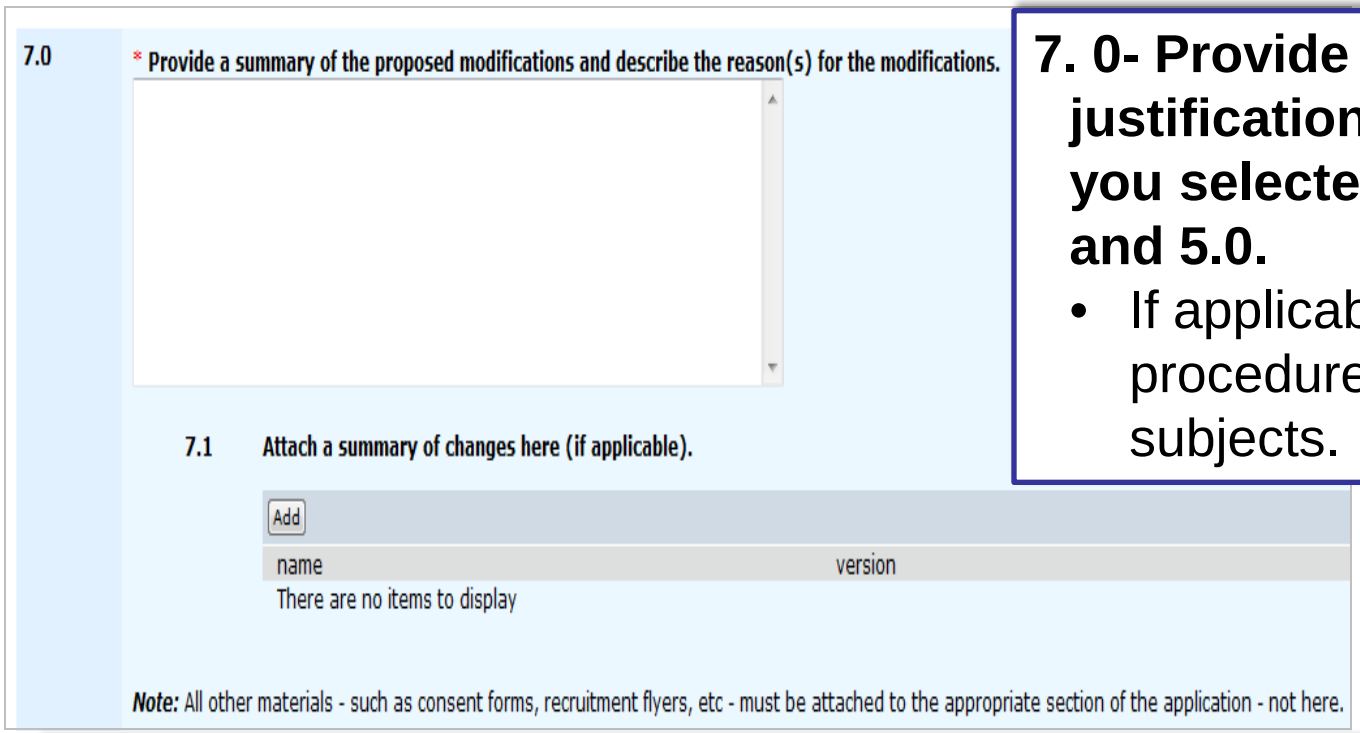
Check all that apply:

- ☐ Change in study design of a protocol approved by the full board of the IRB
- ☐ Change in status of study participants (e.g., study participant becomes prisoner, ward, or pregnant in a protocol not approved for these populations (Note: This primarily applies to medical or treatment studies.)
- ☐ Addition of a procedure not approvable using expedited review procedures (e.g., ionizing radiation)
- ☐ Changes that increase risk or discomfort to study participants
- ☐ Substantive changes to a consent form or other study documents distributed to subjects.
- ☐ Other
- ☐ **None of the above**

6.0 **If you selected "other" to any of the items above, list the type of change.**

Select the check box(es) that best describe the proposed change(s).

Step 2: Describe the amendment (cont'd)



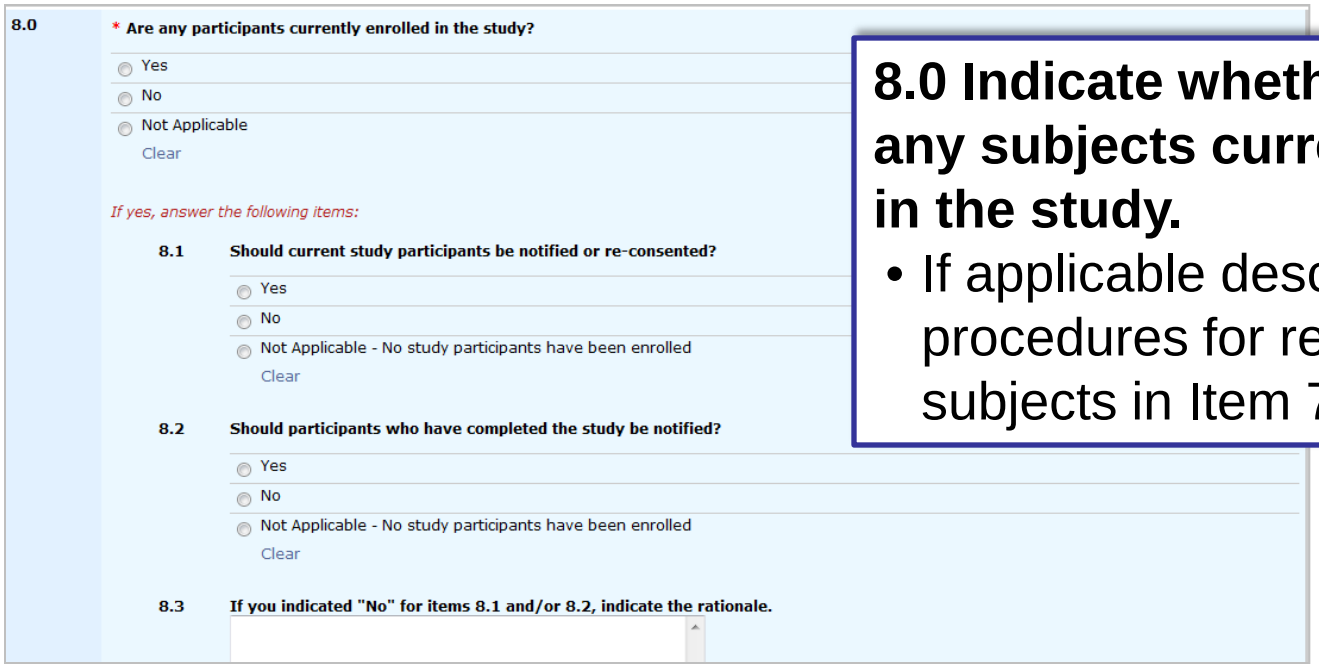
7. 0- Provide a description and justification for the changes you selected in Items 2.0, 4.0, and 5.0.

- If applicable, describe procedures for re-consenting subjects.

7.1- If applicable, attach the summary of changes provided by the sponsor.

- Use Item 7.0 to describe the changes that apply to the study.
- Do not attach new or modified study documents.

Step 2: Describe the amendment (cont'd)



8.0 * Are any participants currently enrolled in the study?

- Yes
- No
- Not Applicable

Clear

If yes, answer the following items:

8.1 Should current study participants be notified or re-consented?

- Yes
- No
- Not Applicable - No study participants have been enrolled

Clear

8.2 Should participants who have completed the study be notified?

- Yes
- No
- Not Applicable - No study participants have been enrolled

Clear

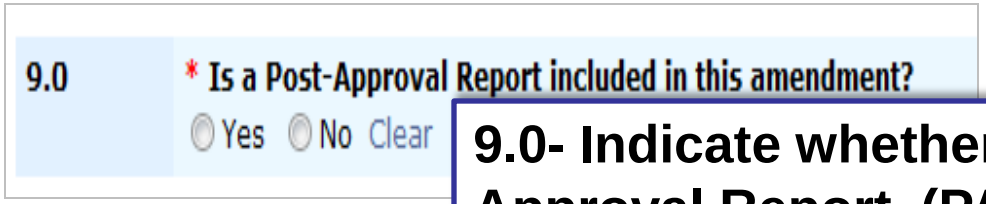
8.3 If you indicated "No" for items 8.1 and/or 8.2, indicate the rationale.

8.0 Indicate whether there are any subjects currently enrolled in the study.

- If applicable describe procedures for re-consenting subjects in Item 7.0.

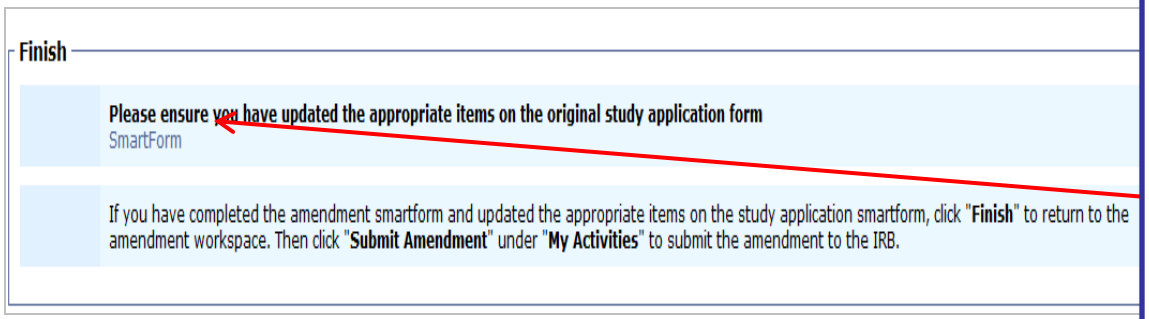
Addendum Consent Templates are available at http://ora.research.ucla.edu/OHRPP/Pages/ConsentTemplates.aspx#addendum

Step 2: Describe the amendment (cont'd)



9.0- Indicate whether you are submitting a Post-Approval Report (PAR) with the Amendment.

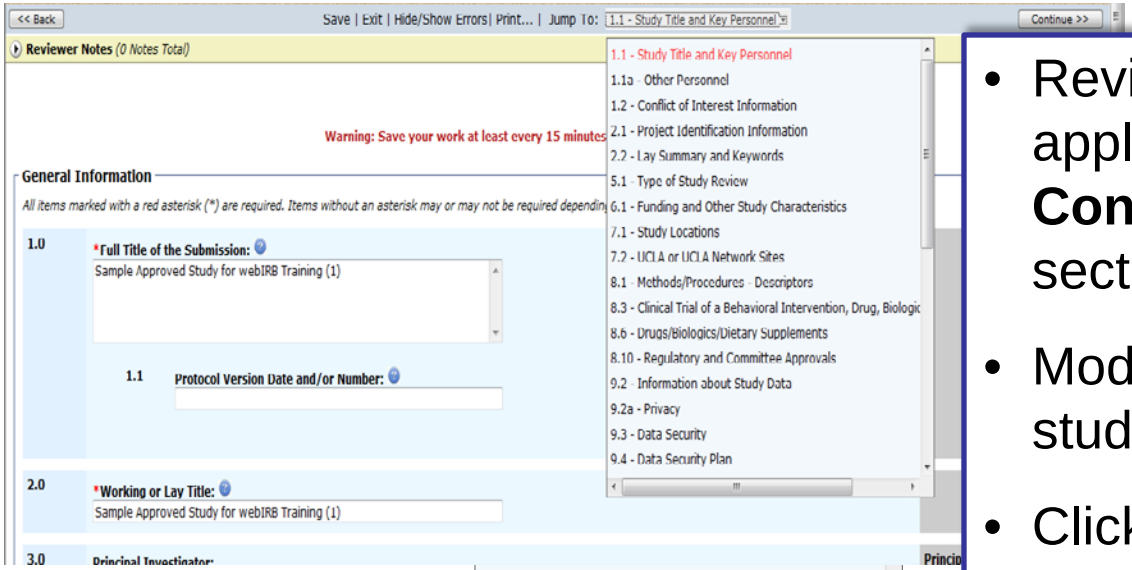
- The application will branch with the PAR questions.
- If the PAR has been submitted as a separate application, select "No".
- Click "Continue" to go to the next section.

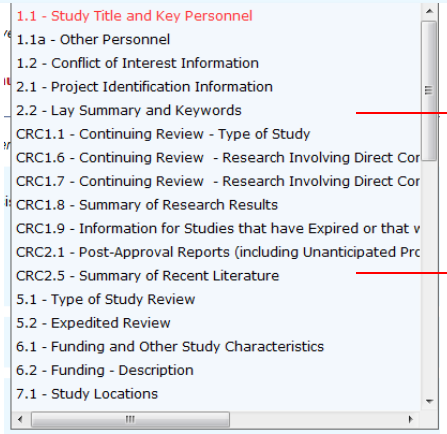


Finish

- When you reach **Finish** click "SmartForm" to go to the study application.
- Section 1.1 of the study application will appear.

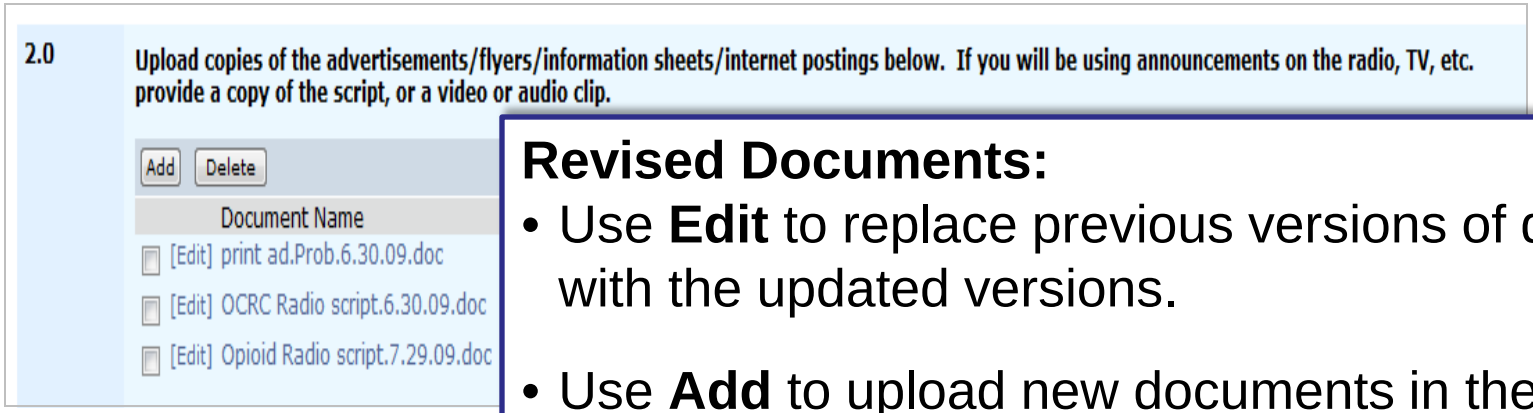
Step 3: Modify the study application





- Review all sections of the study application. Use **Jump To** or **Continue** to navigate through the sections.
- Modify <u>all relevant</u> sections of the study application.
- Click **Save** after revising each section.
- DO NOT modify the response in the CRC sections. Studies converted to webIRB at the time of continuing review contain the CRC sections.

Step 3: Modify the study application (cont'd)



Revised Documents:

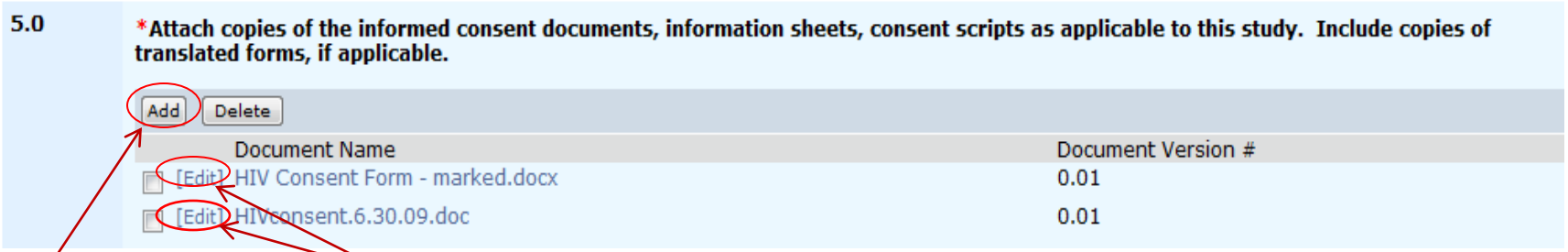
- Use **Edit** to replace previous versions of documents with the updated versions.
- Use **Add** to upload new documents in the application.
- Update the document title to distinguish between the marked and clean copy. Include the version date. (e.g., "child assent_marked_010111", "child asssent_clean_010111").
- To remove documents, click on the checkbox of the document you want to remove. Then click on **Delete**.

Step 3: Modify the study application (cont'd)

Example: The PI is adding a youth assent and revising the HIV consent form in section 20.3.

Modify the consent form and save the marked and clean copy on your desktop. Name them "HIV Consent Form-marked 081211" and "HIV Consent Form- clean 081211".

Section 20.3 before uploading the youth assent and revised consent forms.

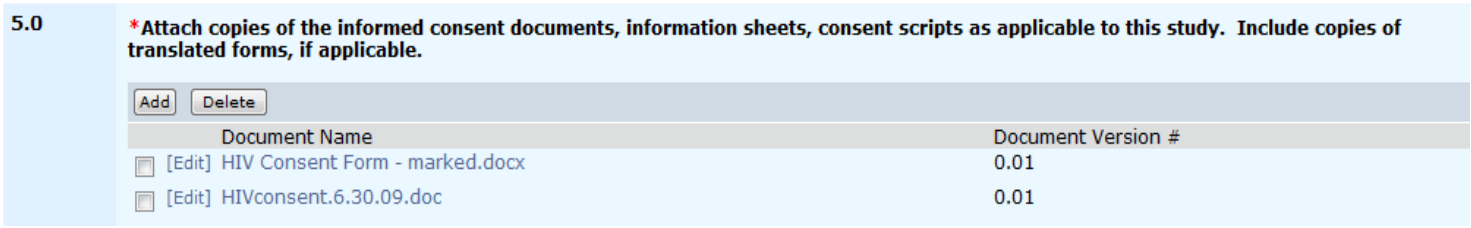


Use **Add** to upload the youth assent.

Use **Edit** to upload the updated marked and clean version of the consent form.

Step 3: Modify the study application (cont'd)

Section 20.3 before uploading the youth assent and revised consent form.



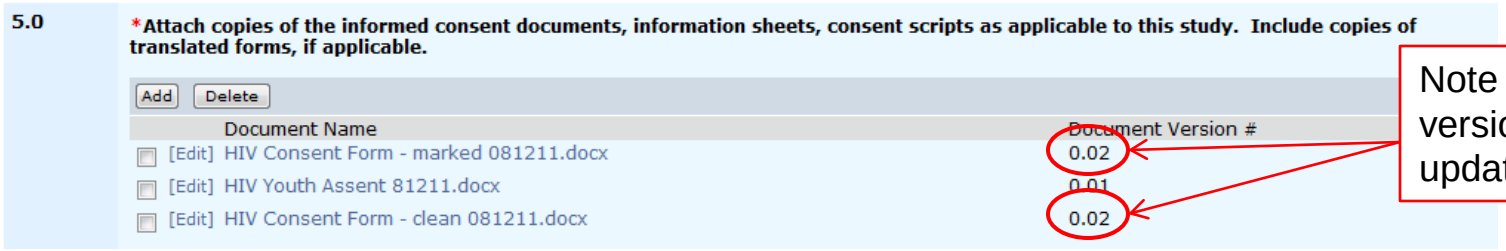
5.0

*Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of translated forms, if applicable.

Add Delete

Document Name	Document Version #
[Edit] HIV Consent Form - marked.docx	0.01
[Edit] HIVconsent.6.30.09.doc	0.01

Section 20.3 after uploading the new youth assent and revised consent form.



5.0

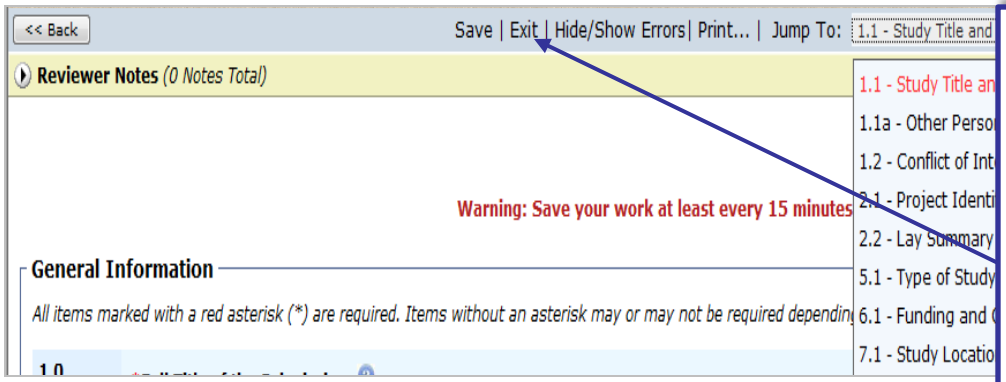
*Attach copies of the informed consent documents, information sheets, consent scripts as applicable to this study. Include copies of translated forms, if applicable.

Add Delete

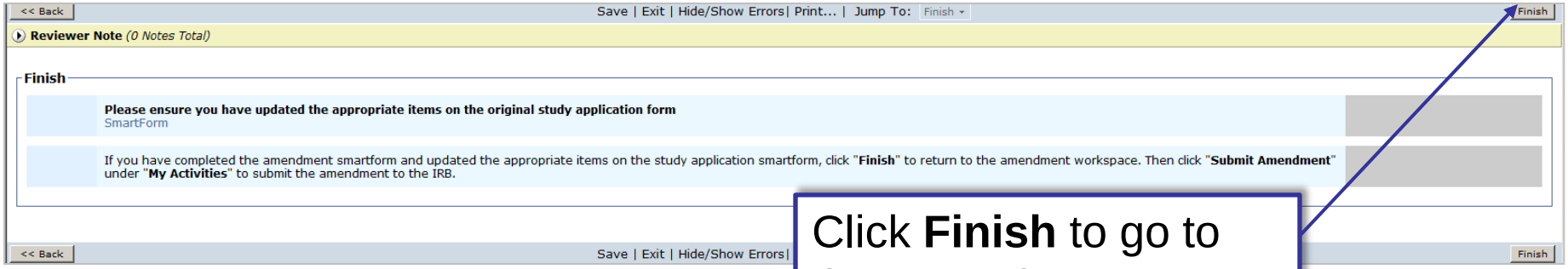
Document Name	Document Version #
[Edit] HIV Consent Form - marked 081211.docx	0.02
[Edit] HIV Youth Assent 81211.docx	0.01
[Edit] HIV Consent Form - clean 081211.docx	0.02

Note document version # of the updated documents.

Step 3: Modify the study application (cont'd)

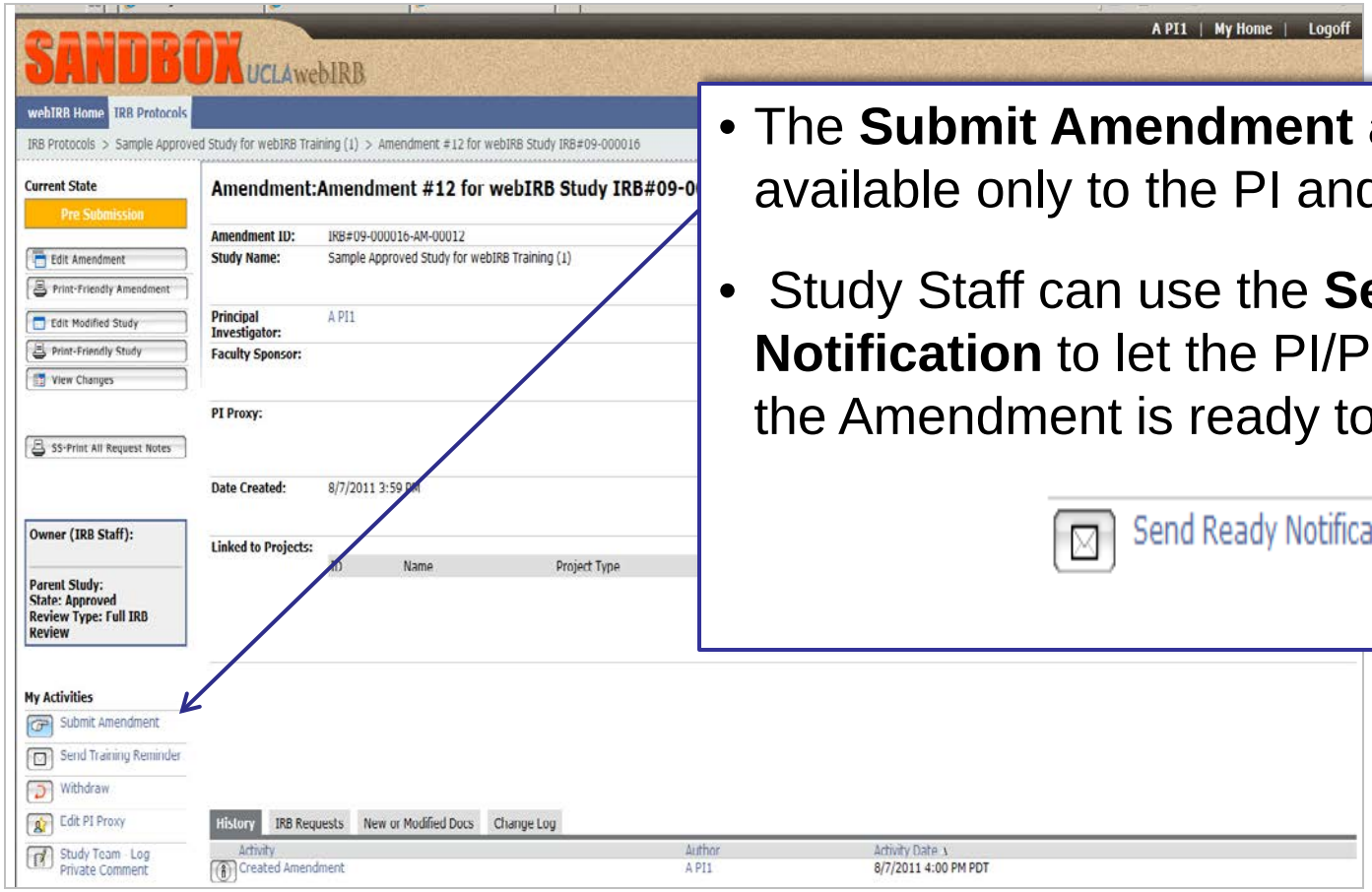


- Click **Exit** when you are done updating the study application.
- You will return to the **Finish** section of the Amendment Smartform.



Click **Finish** to go to the Amendment workspace to submit.

Step 4: Submit



- The **Submit Amendment** activity is available only to the PI and PI Proxy.
- Study Staff can use the **Send Ready Notification** to let the PI/PI Proxy know the Amendment is ready to be submitted.

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Continuing Reviews

Steps for preparing a CR application

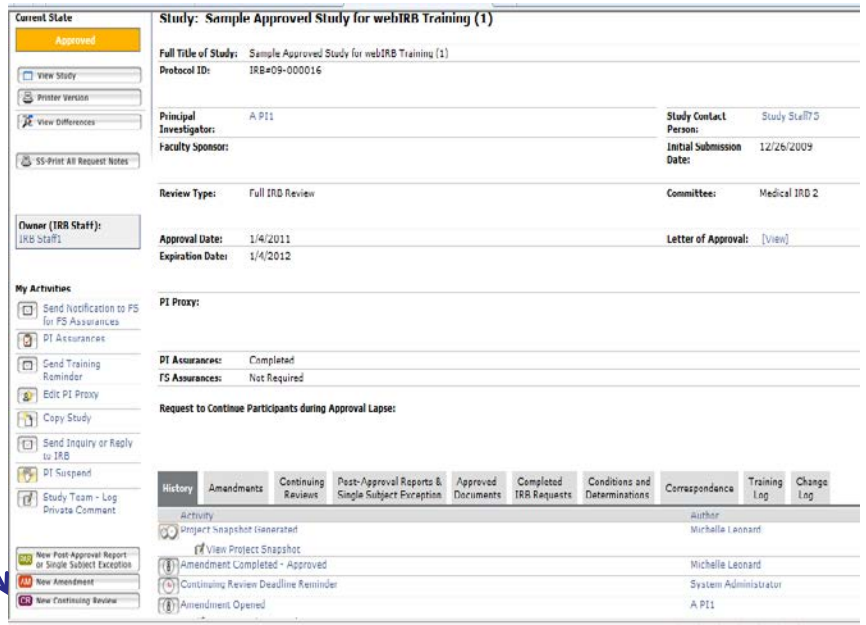
- **Step 1:** Start the CR application by clicking 

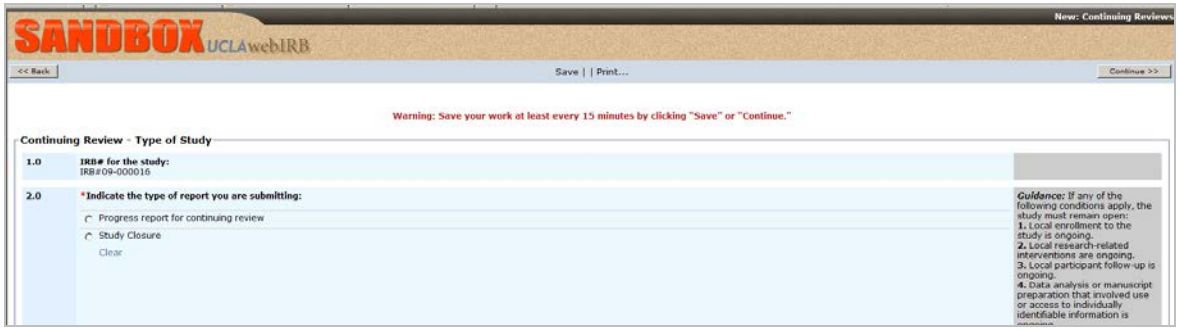
in the approved study workspace.
- **Step 2:** Complete the CR application.
- **Step 3:** Submit the CR.
  - If you are modifying the study application at the time of continuing review, create and submit a separate amendment.
  - If you are submitting a PAR at the time of continuing review, create a PAR in the approved study workspace. The PAR will be reviewed with the CR.

Step 1: Create a CR application

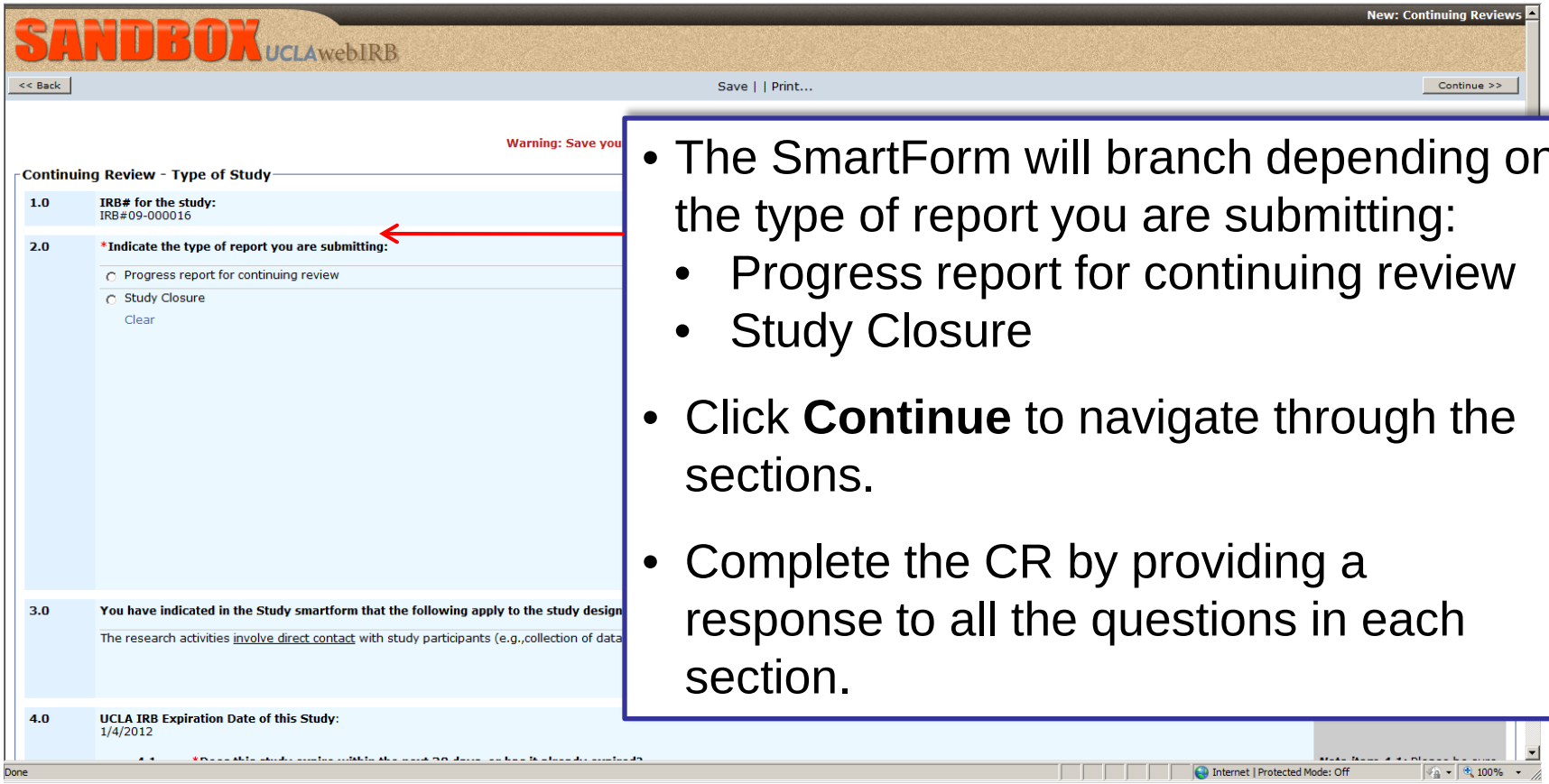
- In the approved study workspace click on:

- The **Continuing Review-Type of Study** section will appear:



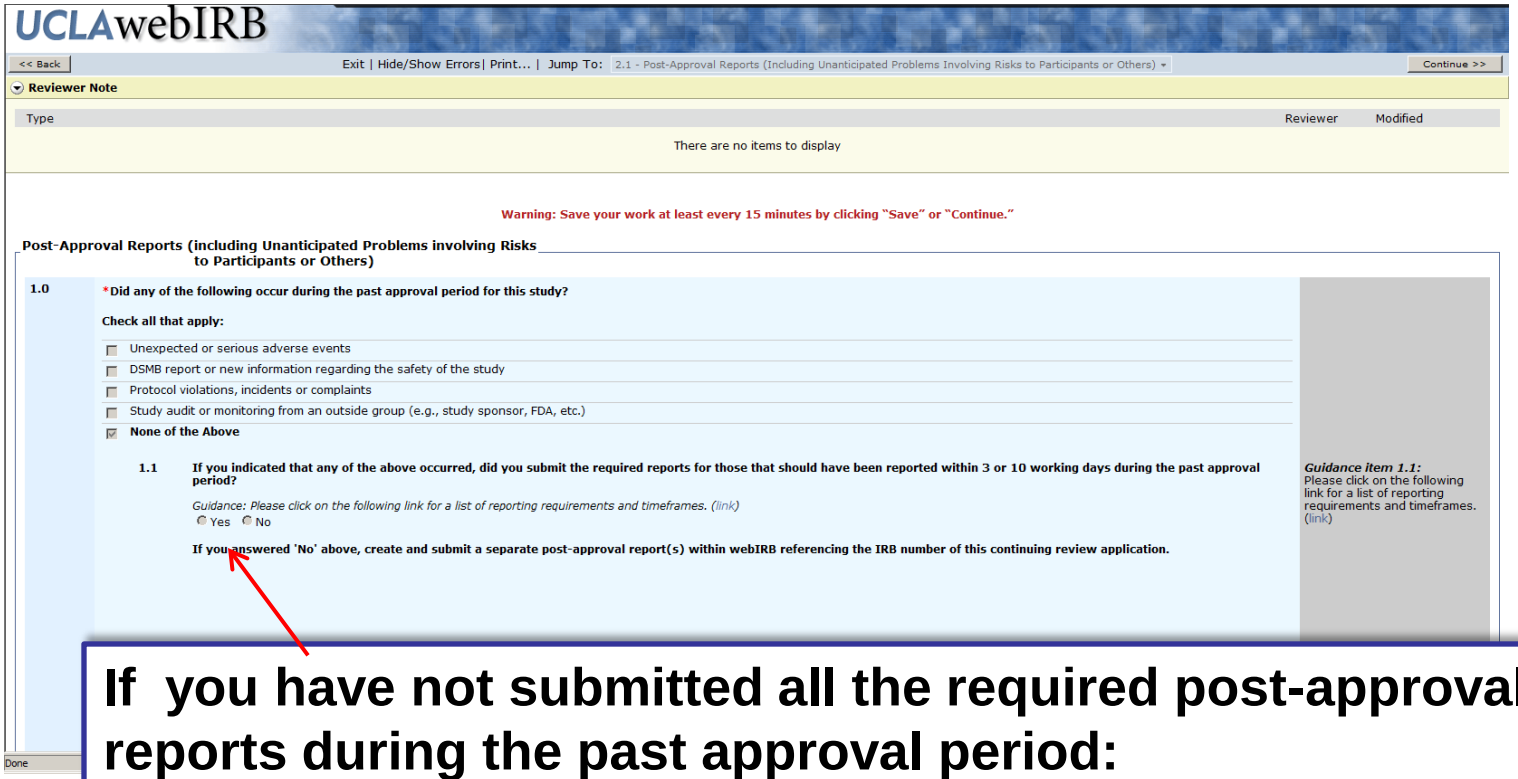


Step 2: Complete the CR application



- The SmartForm will branch depending on the type of report you are submitting:
  - Progress report for continuing review
  - Study Closure
- Click **Continue** to navigate through the sections.
- Complete the CR by providing a response to all the questions in each section.

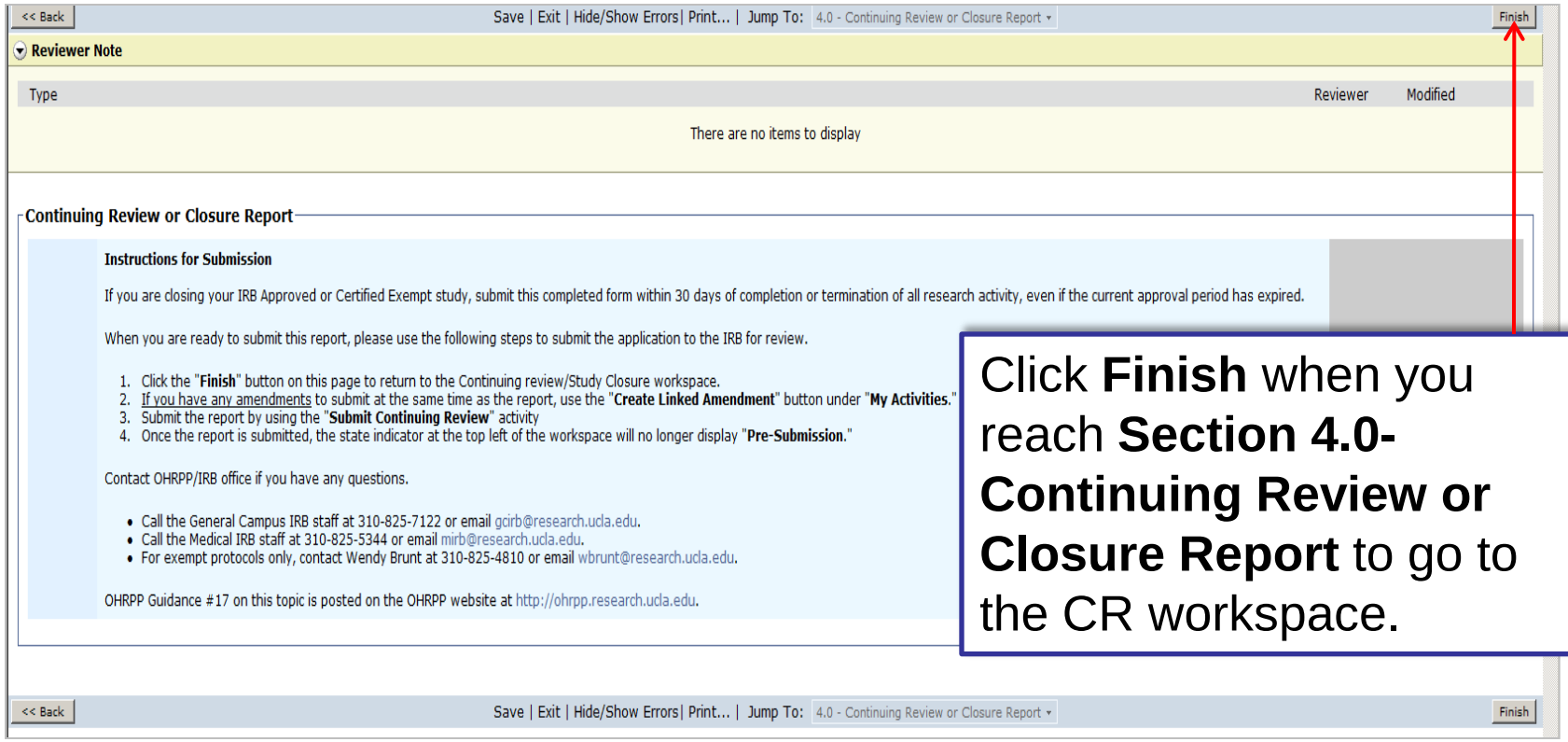
Step 2: Complete the CR application (cont'd)



If you have not submitted all the required post-approval reports during the past approval period:

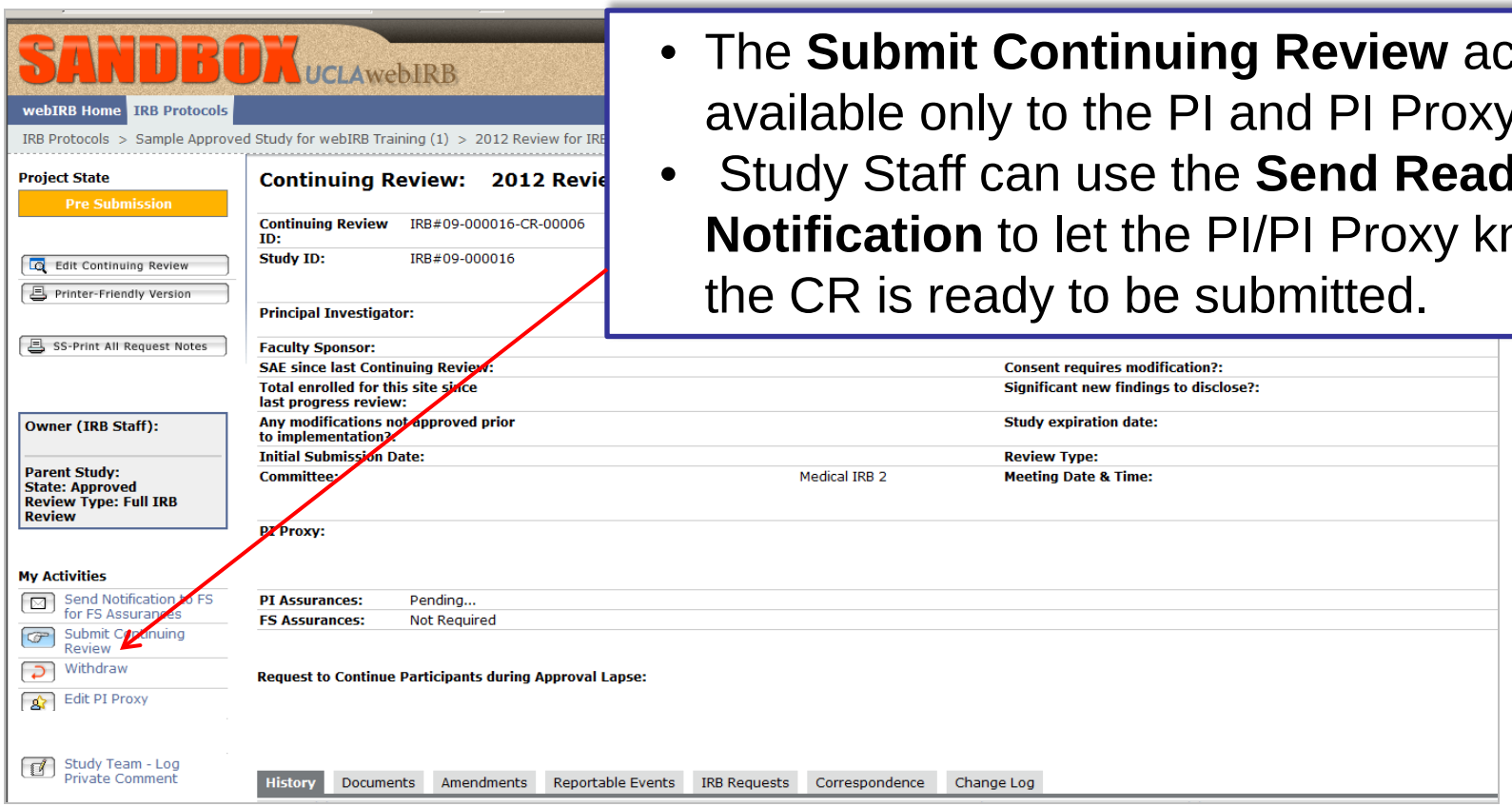
- Go to the approved study workspace and create a PAR.
- The PAR will be reviewed along with the CR.
- Submit the PAR at the same time you submit the CR.

Step 2: Complete the CR application (cont'd)



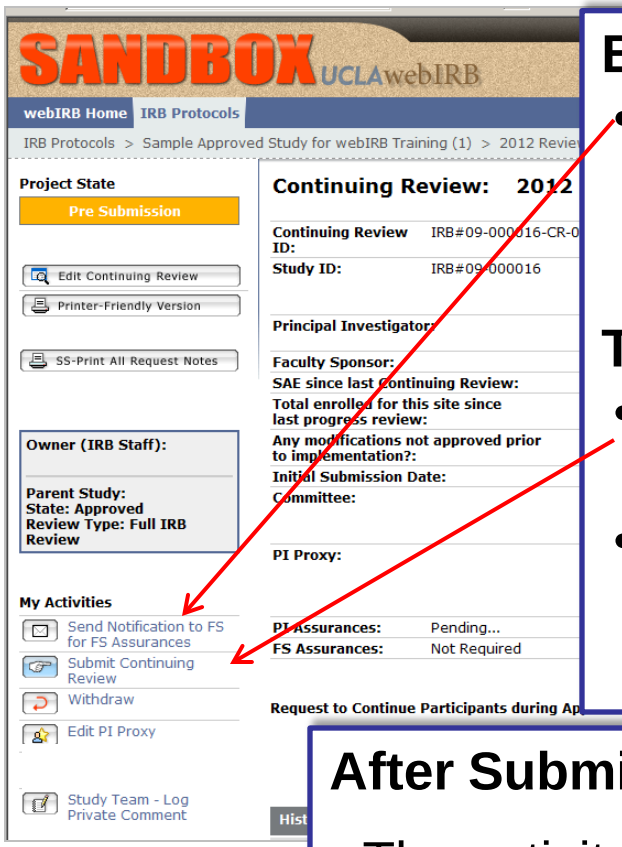
Click **Finish** when you reach **Section 4.0- Continuing Review or Closure Report** to go to the CR workspace.

Step 3: Submit the CR



- The **Submit Continuing Review** activity is available only to the PI and PI Proxy.
- Study Staff can use the **Send Ready Notification** to let the PI/PI Proxy know the CR is ready to be submitted.

Submit the CR



Before submitting:

- If you have a faculty sponsor (FS) use **Send Notification to FS for FS Assurances** to obtain your FS assurances.

To submit the CR:

- **Submit Continuing Review** available only to the PI and PI Proxy.
- **Send Ready Notification** - available only to study staff to let the PI/PI Proxy know the CR is ready to be submitted.

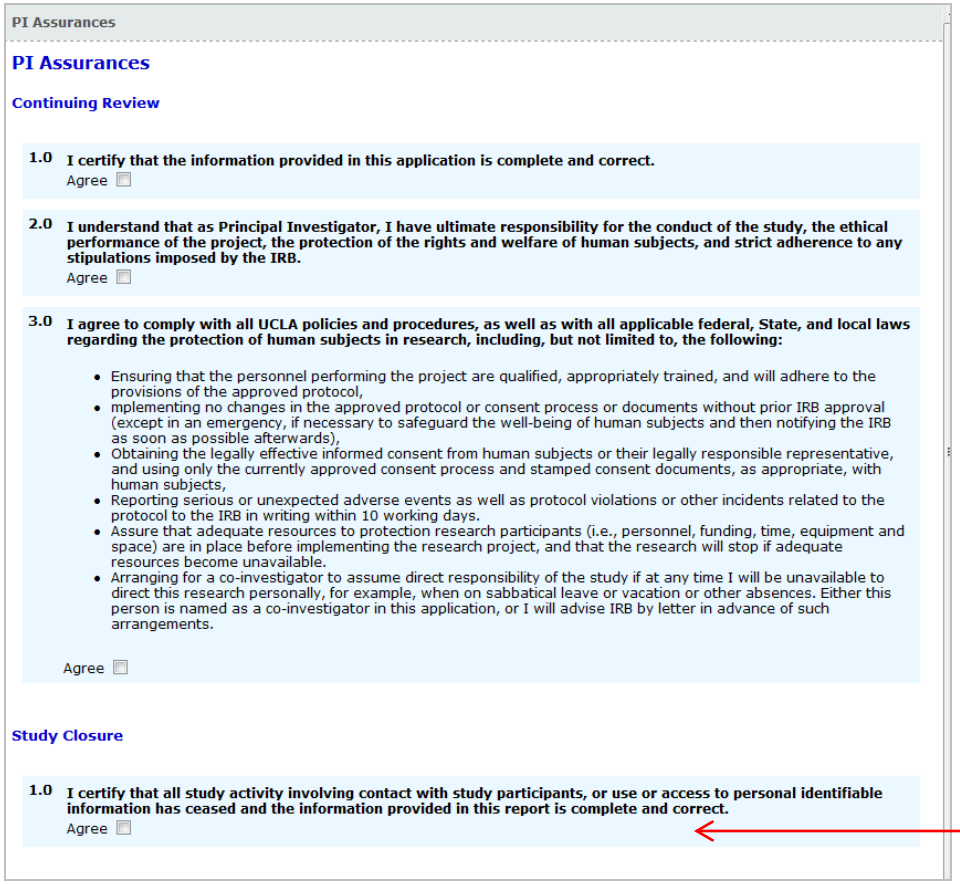
After Submitting:

- The activity  will appear.
- The PI must provide his/her assurance by clicking on this activity.

PI Assurances

The PI must provide the appropriate PI Assurances.

If **Progress Report for Continuing Review** was selected in Section 1.1/item 2.0, the PI must provide the **Continuing Review** Assurances #1-#3.



PI Assurances

PI Assurances

Continuing Review

1.0 **I certify that the information provided in this application is complete and correct.**
Agree ☐

2.0 **I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.**
Agree ☐

3.0 **I agree to comply with all UCLA policies and procedures, as well as with all applicable federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:**

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- mplementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects or their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB in writing within 10 working days.
- Assure that adequate resources to protection research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if at any time I will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as a co-investigator in this application, or I will advise IRB by letter in advance of such arrangements.

Agree ☐

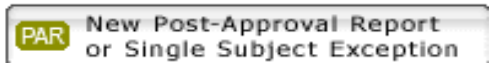
Study Closure

1.0 **I certify that all study activity involving contact with study participants, or use or access to personal identifiable information has ceased and the information provided in this report is complete and correct.**
Agree ☐

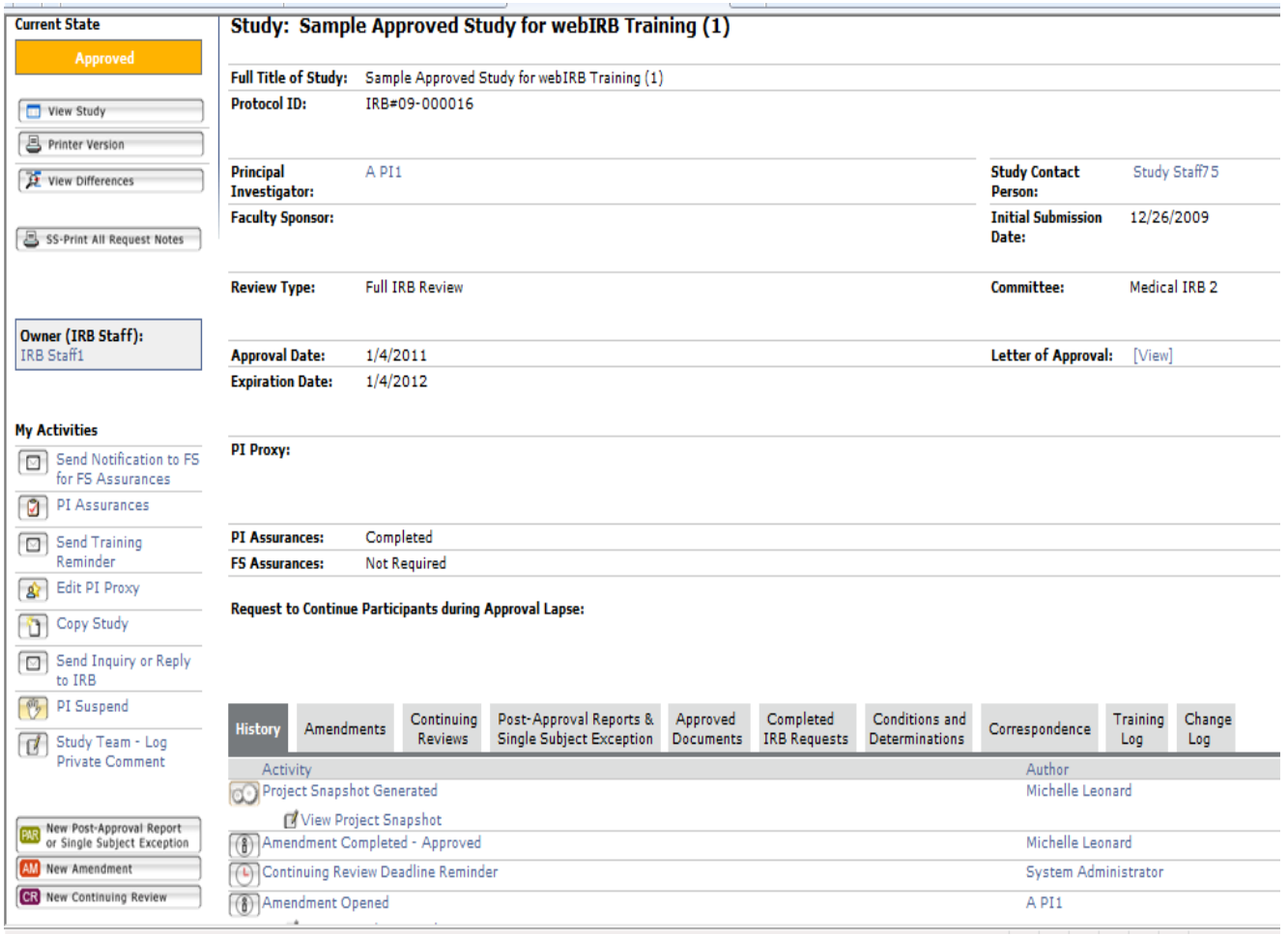
If **Study Closure** was selected in Section 1.1/item 2.0, the PI must provide the **Study Closure** Assurances.

Create and complete the PAR

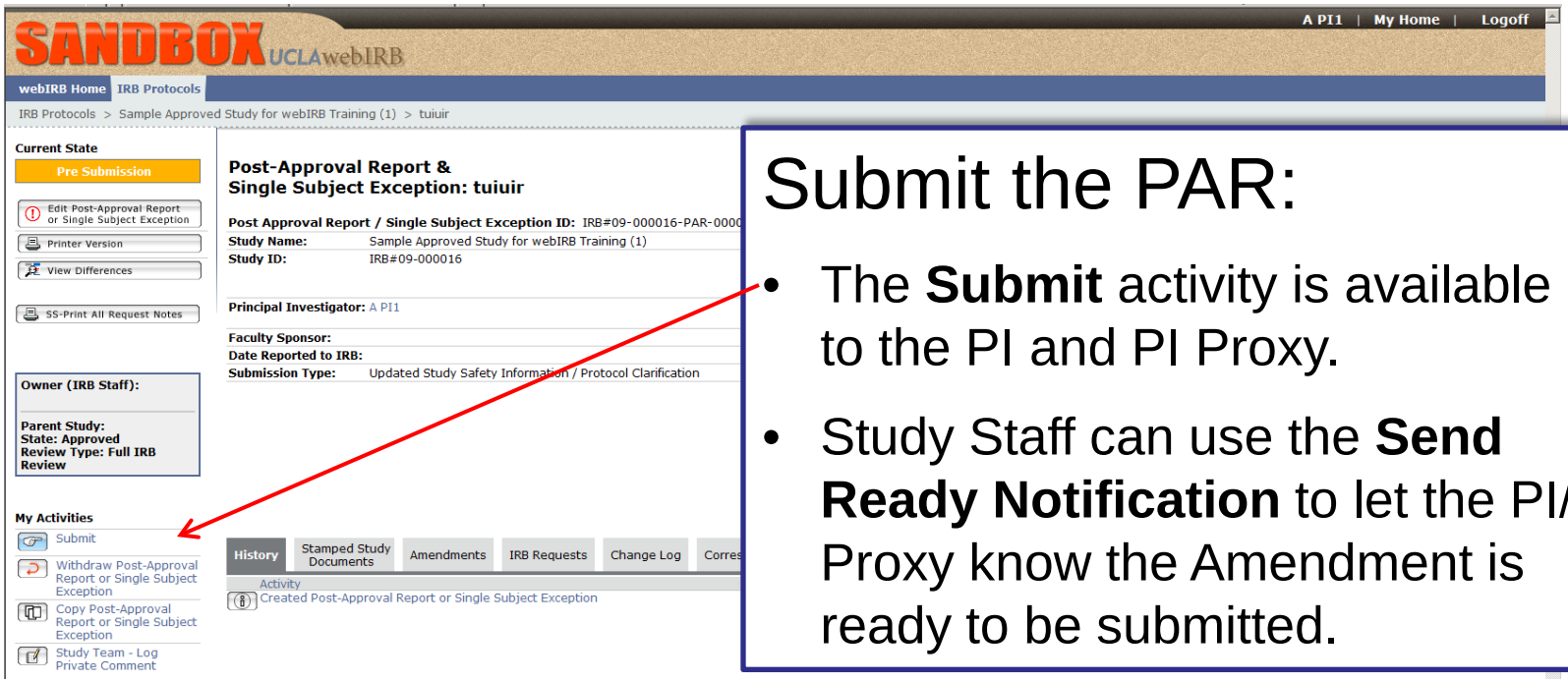
- If you are submitting a PAR with the CR, go to the approved study workspace to create the PAR using:



- The PAR application will appear. Complete the application.
- When you complete the application the PAR workspace will appear.



Submit the PAR



Submit the PAR:

- The **Submit** activity is available only to the PI and PI Proxy.
- Study Staff can use the **Send Ready Notification** to let the PI/PI Proxy know the Amendment is ready to be submitted.

Summary

- Amendments and Continuing Reviews are created in the approved study workspace.

- If you are submitting a PAR the time of continuing review, go to the approved study workspace to create the PAR.

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Questions?