



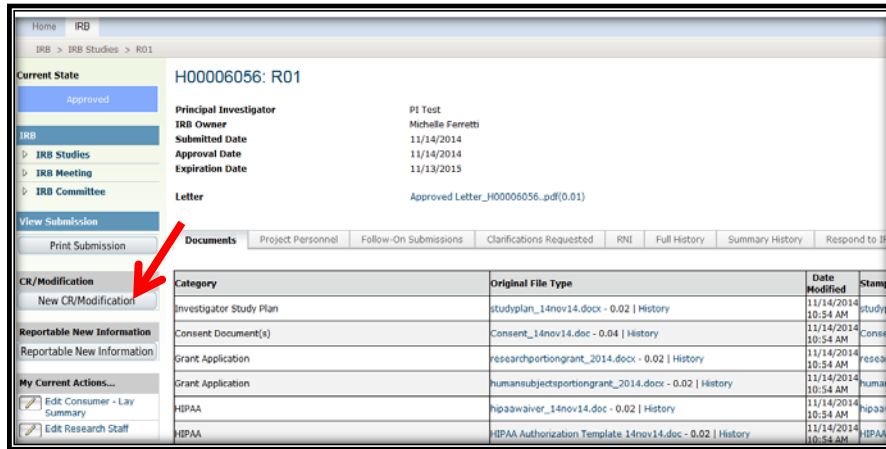
Job Aid Title	How to Submit a Modification
Relevant Users	Principal Investigator (PI), Additional Contact, Study Staff
Covered Topics	How to create and submit a Modification

! Note:

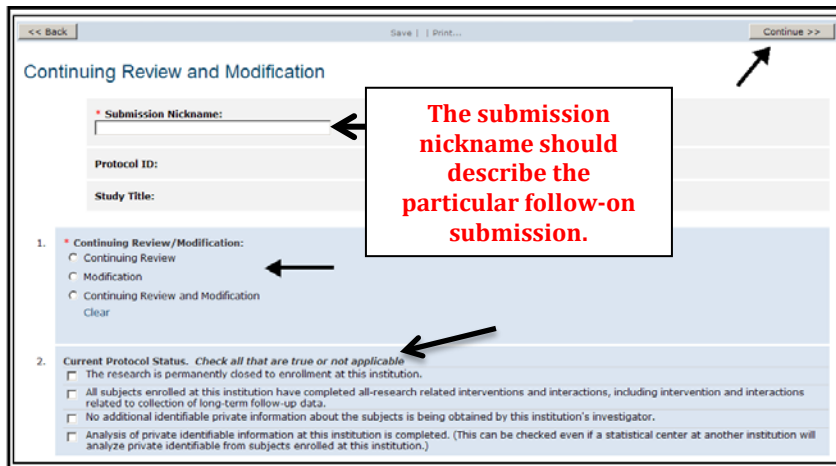
- You can only submit one Modification, Continuing Review, or Continuing Review/Modification submission at a time.
- If you have submitted a plain Modification that has not yet been approved and you need to submit additional Modifications to the study, or you need to submit a Continuing Review, please contact the IRB office for assistance (x6-4261).

• **Create a Modification submission**

- Once in the “Parent” study (i.e. the study’s initial submission in eIRB), select the **New CR/Modification** button as shown below.



- In (1) Select **Modification**. Then review the **Current Protocol Status** in (2) and select any of the four statements that are true or not applicable. Click **Continue**.





- On the **Modification Summary** page, check any of the items in (1) that are true. Then in (2) provide a **description and a justification** of the modification. Include a list of all documents that have been modified. Click **Continue** to proceed to the next page.

!Note: Please avoid copying and pasting document text (e.g. text from a 'Summary of Changes' document) into the Modification Summary. Rather, please reference the relevant pages from the document in the Modification Summary.

- Once you have finished with the **Modification Summary**, click the **Continue** button and you will be taken to a copy of the currently approved study information. Edit the information in the various 'SmartForm' sections (Section 1.0 Study Information, Section 2.0 Funding Information, etc.) as needed.
 - If you would like to revise or add new study documents related to the modification, you may **Jump To** or **Continue** to **Section 7.0 Attachments**.
 - Please refer to the [How to Manage Files in eIRB](#) Job Aid for steps on how to add or update study documents in Section 7.0 Attachments.
- When you have completed the Modification submission, click the **Finish** or **Exit** button to close.

- **Submitting the Modification**

- **For Study Staff:**

- After clicking **Finish** or **Exit** in the submission, select **Ready for PI Review** under **My Current Actions** in the submission workspace. **The PI is the only member of the study team that may submit the Modification to the IRB office.**

Home IRB
IRB > IRB Studies > Training Study > Test: Mod

Pre-submission H00006049_1: Test: Mod

IRB
IRB Studies
IRB Meeting
IRB Committee
Edit CR/Modification
Print CR/Modification

Principal Investigator PI Test
IRB Owner
Study Expiration Date 12/15/2015
Submission Type Modification
Submission Review Date

Documents Clarifications Requested Full History Summary History

My Current Actions...
Cancel
Ready for PI Review

Updated	Document Category	Original Submitted File
	Investigator Study Plan	Investigator Study Plan 11.7.14 - 0.02 History
	Advertisements	Flyer 11.7.14 - 0.01 History
	Consent Document(s)	Informed Consent Form Version 1 dated 11.7.14

My Current Actions...
Cancel
Ready for PI Review

- **For the PI:**

- After clicking **Finish** or **Exit** in the submission, select **Submit** under **My Current Actions** in the submission workspace.

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Pre-submission H00006049_1: Test: Mod

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My Current Actions...
Submit
Ready for PI Review

- You will know that you have submitted successfully when the submission's "state" in the upper left-hand of the screen has changed from **Pre-submission** to **Pre-Review**.

