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

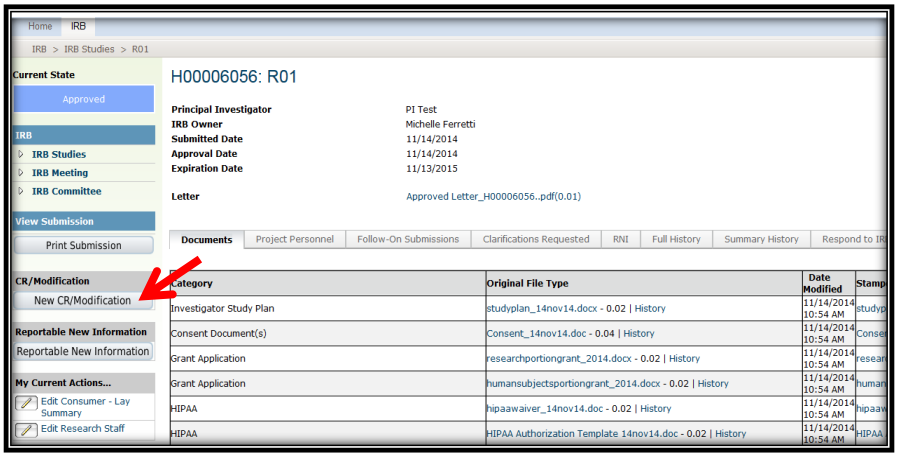
! Note:

- You can only submit one Continuing Review, or Continuing Review/Modification, or Modification submission at a time.
- If you have submitted a plain Continuing Review that has not yet been approved and you need to submit a Modification to the study, please contact the IRB office for assistance (x6-4261).
- If you have submitted a Continuing Review/Modification that has not yet been approved and you no longer want the IRB to review the Modification with the Continuing Review, please contact the IRB office for assistance (x6-4261).

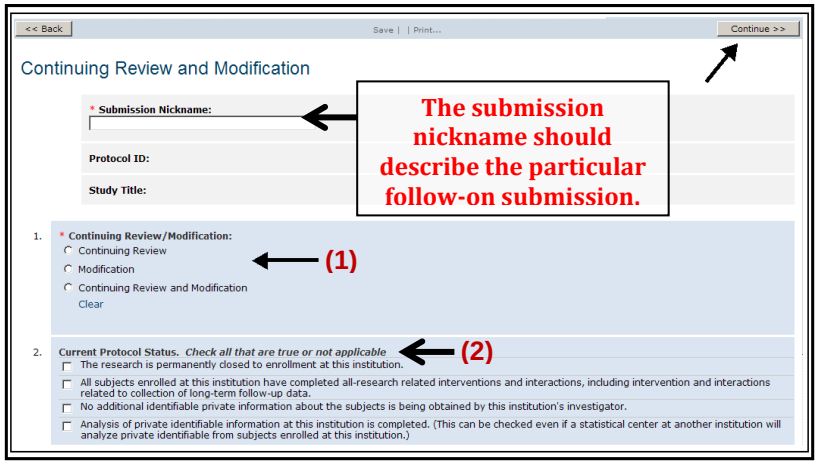
- **Please refer to Section 4 below for Closure Submission instructions.**

1. Create a Continuing Review or Continuing Review/Modification

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



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



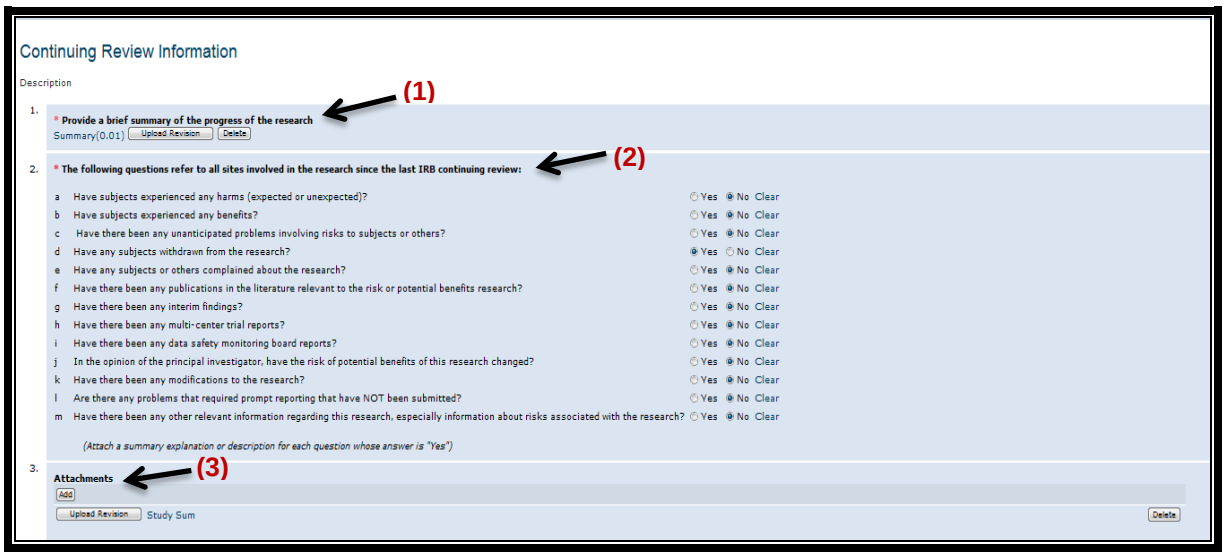
2. Submit a Continuing Review only

- Complete the **Continuing Review Status Section** as required.

- Click **Continue** again to move to the **Continuing Review Information Section** and complete as required.
- Upload a brief summary of the progress of the research in (1).

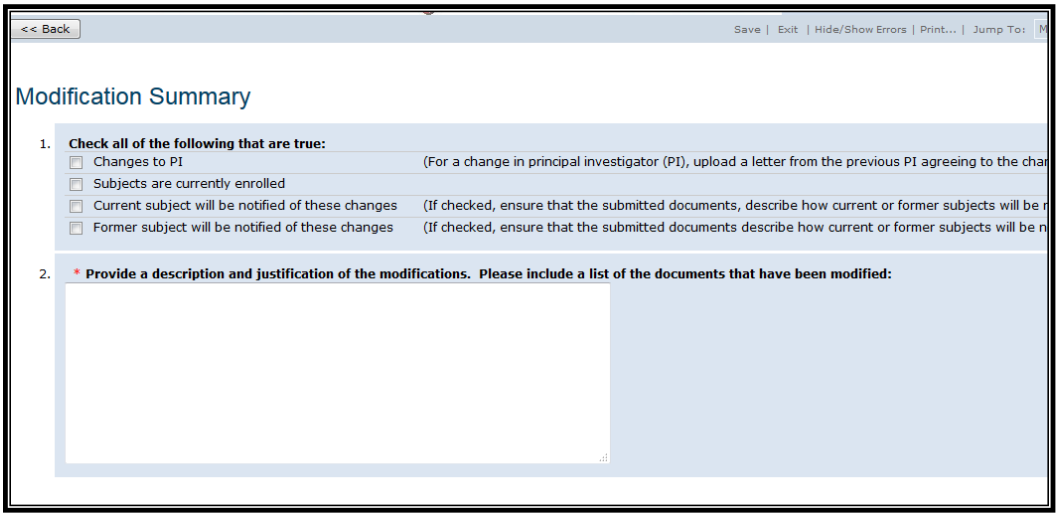
! Note:

- When you click **yes** to any of the questions in (2) shown below, you are required to attach a summary explanation for each item in (3). This is in addition to the brief summary of the progress of the research in (1). You may wish to create one document containing both the brief progress summary and the explanations for each question answered as 'yes.' If you combine into one document, and you have no other attachments to add to (3), you may upload the document in both (1) and (3).
- If UMass Worcester is the primary awardee of federal funds (e.g., NIH), be sure to upload a copy of the most recent **federal progress report** in (3). Or, explain why there is no progress report (e.g., in a no cost extension).



3. Submit a Continuing Review/Modification

- To submit both a Continuing Review and Modification together, you will complete all fields described above. You will then be prompted to complete a modification submission (shown below).
- Refer to the How to Submit a Modification Job Aid for a detailed description of the required elements of a modification submission, as well as step-by-step submission instructions.

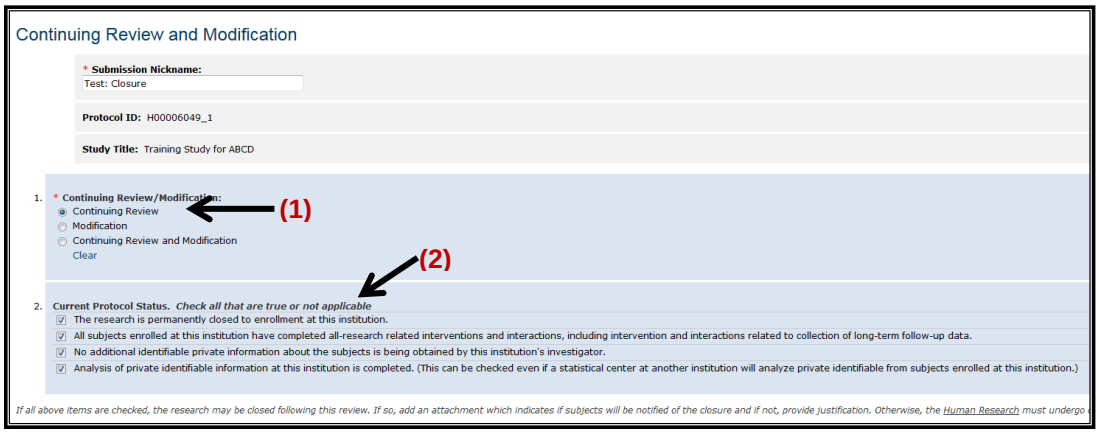


4. Creating a Closure submission

!Note: Closure submissions are submitted as the study's final Continuing Review.

- Create a Continuing Review Submission as instructed above in Section 1, *Create a Continuing Review or Continuing Review/Modification*.
- Select **Continuing Review** in (1).

- In order for the study to meet the criteria for closure, all 4 items under (2) **Current Protocol Status** must be true or not applicable.



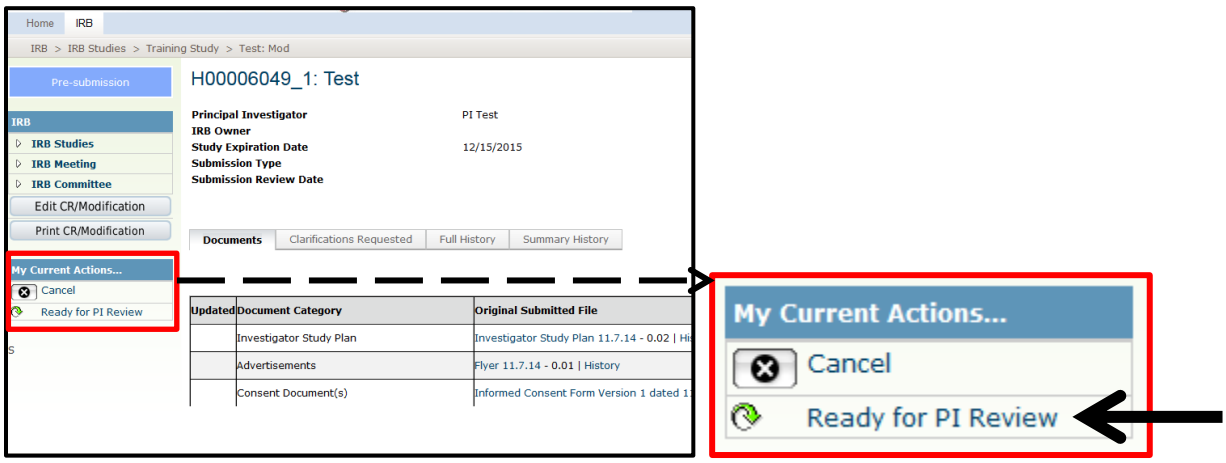
- Complete the submission as you would a plain Continuing Review (detailed above in Section 2, *Submit a Continuing Review only*).

!Note:

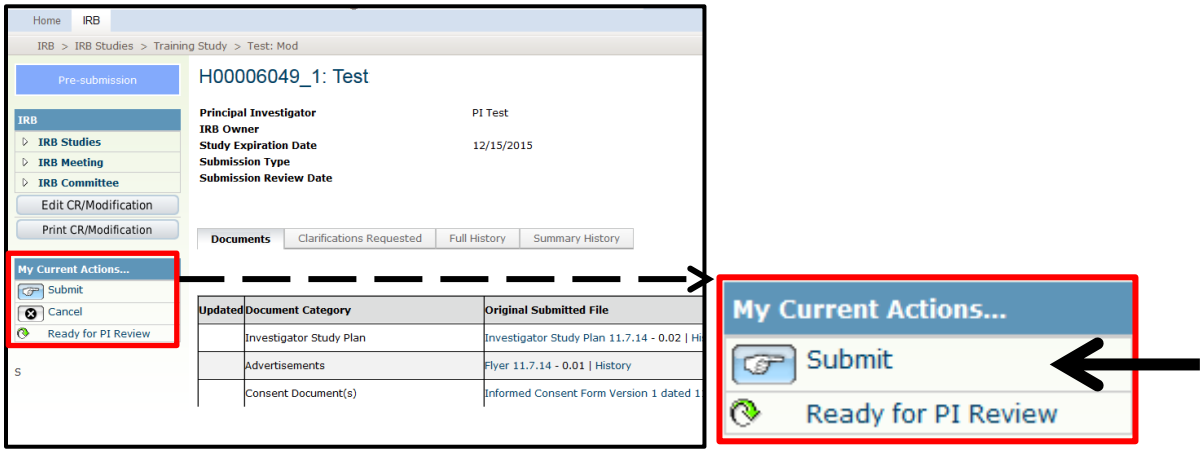
- In the summary of the progress of the research:
  - If applicable, confirm that all subjects have completed all research related interventions and interactions.
  - If applicable, confirm that any remaining data being analyzed has been completely anonymized and does not include subject Protected Health Information (PHI) or Personally Identifiable Information (PII).
- If the research is sponsored by an external funding source (e.g., Industry, Cooperative Group, etc.), upload correspondence from the Sponsor confirming that all closure activities have been completed (as applicable) and that the study may be closed in (3) Attachments (shown above in Section 2, *Submit a Continuing Review only*).

5. Submitting the Continuing Review, Continuing Review/Modification, or Closure Submission

- **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 CR, CR/Mod, or Closure to the IRB office.**



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



- 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.**