



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

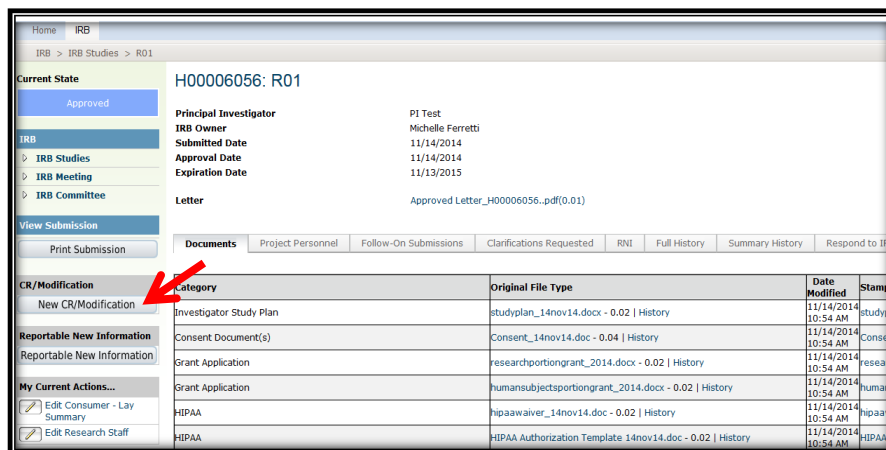
! Note:

- 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**.

Continuing Review and Modification

* Submission Nickname: _____

Protocol ID: _____

Study Title: _____

1. * Continuing Review/Modification:

Continuing Review

Modification

Continuing Review and Modification

Clear

2. Current Protocol Status. Check all that are true or not applicable:

The research is permanently closed to enrollment at this institution.

All subjects enrolled at this institution have completed all-research related interventions and interactions, including intervention and interactions related to collection of long-term follow-up data.

No additional identifiable private information about the subjects is being obtained by this institution's investigator.

Analysis of private identifiable information at this institution is completed. (This can be checked even if a statistical center at another institution will analyze private identifiable from subjects enrolled at this institution.)

2. Submit a Continuing Review only

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

Continuing Review Status

1. Enter enrollment status:

Number of subjects enrolled:	Total	Since last approval
At this site(s):		
Study wide		

Total number of subjects enrolled at this site(s) considered members of vulnerable populations:

Children	Prisoners	Fetuses	Cognitively Impaired Students/Employees	Other/Unknown

2.

The remaining protocol activities are limited to data analysis.

The protocol research remains active only for long-term follow-up of subjects.

3. Do any investigator or research staff have a financial interest related to the research that was not described in a previous application?

Yes No

If Yes, you must insure that the Research Personnel Activity is updated to reflect this information

- 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).



Continuing Review Information

Description

- * Provide a brief summary of the progress of the research** ← (1)

Summary(0.01) [Upload Revision] [Delete]
- * The following questions refer to all sites involved in the research since the last IRB continuing review:** ← (2)

a Have subjects experienced any harms (expected or unexpected)? Yes No Clear

b Have subjects experienced any benefits? Yes No Clear

c Have there been any unanticipated problems involving risks to subjects or others? Yes No Clear

d Have any subjects withdrawn from the research? Yes No Clear

e Have any subjects or others complained about the research? Yes No Clear

f Have there been any publications in the literature relevant to the risk or potential benefits research? Yes No Clear

g Have there been any interim findings? Yes No Clear

h Have there been any multi-center trial reports? Yes No Clear

i Have there been any data safety monitoring board reports? Yes No Clear

j In the opinion of the principal investigator, have the risk of potential benefits of this research changed? Yes No Clear

k Have there been any modifications to the research? Yes No Clear

l Are there any problems that required prompt reporting that have NOT been submitted? Yes No Clear

m Have there been any other relevant information regarding this research, especially information about risks associated with the research? Yes No Clear

(Attach a summary explanation or description for each question whose answer is "Yes")
- Attachments** ← (3)

[Add]

[Upload Revision] Study Sum [Delete]

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.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: M

Modification Summary

- Check all of the following that are true:**

Changes to PI (For a change in principal investigator (PI), upload a letter from the previous PI agreeing to the change)

Subjects are currently enrolled

Current subject will be notified of these changes (If checked, ensure that the submitted documents, describe how current or former subjects will be notified)

Former subject will be notified of these changes (If checked, ensure that the submitted documents describe how current or former subjects will be notified)
- * Provide a description and justification of the modifications. Please include a list of the documents that have been modified:**

[Text Area]

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.

Continuing Review and Modification

* **Submission Nickname:**
Test: Closure

Protocol ID: H00006049_1

Study Title: Training Study for ABCD

1. * **Continuing Review/Modification:**

- Continuing Review ← (1)
- Modification
- Continuing Review and Modification
- Clear

2. **Current Protocol Status. Check all that are true or not applicable**

- The research is permanently closed to enrollment at this institution.
- All subjects enrolled at this institution have completed all-research related interventions and interactions, including intervention and interactions related to collection of long-term follow-up data.
- No additional identifiable private information about the subjects is being obtained by this institution's investigator.
- Analysis of private identifiable information at this institution is completed. (This can be checked even if a statistical center at another institution will analyze private identifiable from subjects enrolled at this institution.)

If all above items are checked, the research may be closed following this review. If so, add an attachment which indicates if subjects will be notified of the closure and if not, provide justification. Otherwise, the Human Research must undergo

- 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.**



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

Pre-submission H00006049_1: Test

Principal Investigator PI Test
IRB Owner
Study Expiration Date 12/15/2015
Submission Type
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 1

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.

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

Pre-submission H00006049_1: Test

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

Documents Clarifications Requested Full History Summary History

My Current Actions...
Submit
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 1

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**.

