

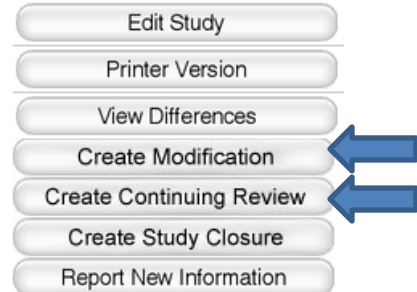


Creating a Continuing Review (CR) or Modification (MOD)

In ESTR, CR means continuing review (in the past, this may have been referred to as a renewal) in ESTR and MOD means modification (in the past, this may have been referred to as an amendment).

1. Log in to irb.harvard.edu
2. Navigate to an approved study workspace
 - This is a submission numbered without letters or with the prefix “IRB”
 - The main study must not be in the middle of review
3. Click the “Create Modification” or “Create Continuing Review” button.

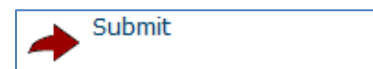
My Current Actions



4. In the SmartForm, select the type of submission you would like to create (either “Continuing review” OR “Modification”). **Note:** if you create two submissions (one CR and one MOD); you will need to manage completing activities and responses from EACH submission workspace.

A screenshot of a SmartForm titled 'Modification or Continuing Review / Study Closure'. It contains a question: '* What is the purpose of this submission? Select Continuing Review to request Study Closure.' Below the question are three radio buttons: 'Continuing Review', 'Modification', and 'Clear'. The 'Modification' button is selected. Below this is a section titled 'Modification Scope (select one or both types of modification, as appropriate):' with two checkboxes: 'Study team member information' and 'Other parts of the study'. A red arrow points to the 'Modification' radio button.

5. If you are creating a modification, select one or both scopes of modification:
 - Note that only one of each type of modification can be created at a time.
 - If you are creating a modification, once you fill out the general information about the modification, you will be walked through a copy of the Study SmartForm. Please make all changes directly into the SmartForm.
6. Once all the information is completed, select “**Submit**” from the ‘My Current Actions’ section on the left side of the submission workspace (*activity marked with a red arrow in the submission workspace*). **Only the PI or Faculty Sponsor on the project (if there is one) will see this activity.**



Tips

- ✓ If you selected the wrong purpose of the submission, select ‘back’ to exit.
- ✓ If you withdraw a modification or continuing review before it is approved, the withdrawal will not affect the review status of the project.

Important! Only the Principal Investigator can submit a Continuing Review or Modification. Any other members of the study team who prepare the application must notify the PI when the application is ready to submit.