

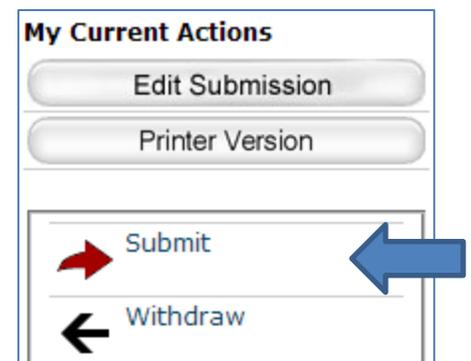


Submitting a Continuing Review or Modification

When a Continuing Review or Modification is in the Pre-Submission state:

- Only the PI will see an activity button labeled “**Submit**.”
- Other study team members and the Primary Contact will not have access to an activity that will move the submission to the IRB.

1. Log in to irb.harvard.edu
2. Navigate to the Continuing Review or Modification workspace.
3. Review the materials.
4. Select “**Submit**” from the ‘My Current Actions’ section on the left side of the screen (*activity marked with a red arrow in the submission workspace*).
5. The system will make sure all the required questions have been answered and will report back findings.
 - If all the required questions have not been answered, a list of the open questions will display in the activity, with a link to that page in the SmartForm.
 - i. Once you link to the appropriate pages and answer all the questions, click on the “**Submit**” activity again.
 - ii. You will see instructions and information on next steps.
6. If all required items have been completed, you will see instructions and information on next steps. Clicking “OK” will submit the study to the IRB, and you will see the study transition to the “Pre-Review” state.



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