

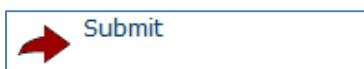


SUBMITTING AN INITIAL STUDY FOR REVIEW

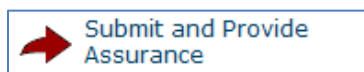
After filling out all the initial SmartForm correctly and attaching relevant files, take the following steps to move the study to the next appropriate state of review:

Important! Any member of the study team may complete these steps, but only the Principal Investigator or Faculty Sponsor can **submit and provide assurance** (see “Providing PI Assurance”).

1. Log in to irb.harvard.edu
2. Click on **My Inbox**.
3. Click on the name of the study in the ‘pre-submission’ state to open the submission workspace.
4. Depending on your role in the study:
 - If you are a member of the study team; Click **Submit** in the My Current Actions list on the left.



- If you are the Principal Investigator OR Faculty Sponsor; Click **Submit and Provide Assurance** in the My Current Actions list on the left. *Note: Principal Investigator MUST “Submit and Provide Assurance” before IRB review of the initial application may be completed.*



5. The system will conduct an ‘error check’ to identify if any required questions were missed.

Important! If any errors or warnings are shown, navigate to the indicated spaces and fill in the required information. When all the required items are complete, don’t forget to select **Submit or Submit and Provide Assurance**, depending on your role.

6. Click **OK** to agree and validate your submission.
7. The submission will transition to the next state of review.

AFTER SUBMITTING A STUDY FOR REVIEW

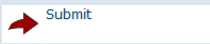
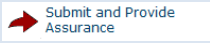



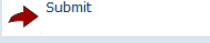
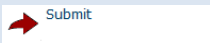
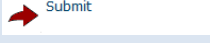
After you submit your study for review a series of activities follow that may necessitate further action from you, such as requests for clarification or modification to your study. Whenever you need to act, you receive an email notification, and the study appears in **My Inbox** when you log into the IRB system.

Important! Make sure the appropriate person is listed as the primary contact to receive the email and see the study in My Inbox, the PI always receives these notifications. By default, the person who created the study is the primary contact.



SUBMITTING OTHER ITEMS

After the initial application is submitted, the ability to submit other items associated with that study depends on your role on the project.

Activity Name	Activity	Submission Type	Role
Submit (without PI assurance)		Initial Application	Study team or Primary Contact
Submit and Provide Assurance		Initial Application	PI and Faculty Sponsor (if there is one)
Submit Changes: Respond to Clarification Request		All Types	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Submit Changes: Respond to Modifications Required or Deferral		All Types	PI and Faculty Sponsor (if there is one)
Create a Modification/CR		Modification, Continuing Review, Study Closure	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Submit		Continuing Review & Modification	PI and Faculty Sponsor (if there is one)
Submit		Reportable New Information (associated with a study)	PI, Primary Contact, Approved Study Team, and Faculty Sponsor (if there is one)
Submit		Reportable New Information (NOT associated with a study)	Any person with an HUID