Create and Submit a New Study

WORK INSTRUCTIONS:

1. Log into the Click Portal and click on the IRB tab in the top navigation menu.
2. Under My Current Actions, select the Create New Study button.
3. Enter the required information on the first page of the SmartForms, Basic Information.

Required information fields are marked with an asterisk (*)

- Enter a Title for the study.
- Enter a Short Title for the study; the Short Title will identify your study in the system.
- Enter a Brief Description of the study.
- By default, you will be listed as the Principal Investigator (PI).

If you are entering a study for another individual who will be serving as the Principal Investigator, please do not change this field to that person’s name until you have completed all of the SmartForms and are ready to have the PI submit the study for review.

- Indicate whether or not the PI has a financial interest in the project.

Financial interests in a research project usually occur where there will be a tangible product related to the research, as opposed to merely generating knowledge to be published. It also occurs when there is corporate sponsorship of a study.

- Indicate whether or not an IRB external to the University will act as the IRB of record for the study.

In all but the rarest of cases at UB and affiliated hospitals, an external IRB will not be acting as the IRB of record. For an external IRB to act as the IRB of record, the institutional officials at both institutions must enter into a written agreement to do so.

- Click the Add button to upload a copy of the protocol.
o Click the Choose File (or Browse) button to locate the file.

o Enter a Name for the document.

o Click the OK button.

4. Click the Continue button at either the top or bottom-right of the form.

5. Navigate through all of the SmartForms and complete all of the required fields
   • Click the Help icon ( HELP ) for more information about a question or field

6. Click the Hide/Show Errors link in the navigation bar at the top or bottom of the SmartForm page
to display any unanswered questions
   • Use the Jump To: link to navigate directly to SmartForm pages that are missing information
   • Protocols with any incomplete information will be redirected to the protocol team for updates

7. When all of the required fields have been completed, click the Finish button in the footer of the last
   SmartForm page to be redirected to the Study Workspace.


Your study has not yet been submitted for review.

8. Assign any additional staff to the study, as necessary:
   • Assign PI Proxy – assigns a user that will have the ability to act on behalf of the PI within
     the IRB module. This individual will have the same access to the study as the PI, and will
     receive the same system-generated email notifications. The PI Proxy must be selected
     from the individuals that were added to the study team.

   • Assign Primary Contact – assigns a user that will receive the same system-generated
     email notifications as the PI. The primary contact will not have the same access to the
     study as the PI.

   • Manage Guest List – manages individuals on the Guest List; guests can read the study
     and any follow-on submissions, but cannot edit them. They will also not receive the same
     system-generated emails that a PI does.
9. To request an ancillary review, click on Manage Ancillary Reviews under My Current Actions.

10. The Principal Investigator (or PI Proxy) must click the Submit activity located under My Current Actions on the left side of the Study Workspace. Read the statement, and then click OK to submit the study for review.

   - The system will check the study to ensure that all required questions have been answered on the SmartForms. If any items have been missed, you will be prompted to answer them.

   - If the submission is successful, the page will refresh and the study will transition from the Pre-Submission state to the Pre-Review state.