



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.



- Click the **Choose File** (or **Browse**) button to locate the file.
 - Enter a **Name** for the document.
 - 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 () 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.

