BUFFALO STATE
The State University of New York

Create and Submit a New Study

There are instances where you will be asked to upload documents, e.g., protocol and consent forms. It is beneficial to have these documents complete and ready for upload before logging in. These documents must contain specific information; therefore, we have provided templates for your convenience. The templates can be found on the Sponsored Programs website at sponsoredprograms.buffalostate.edu/suny-rf-pacs-irb-module, as well as in the SUNY RF PACS Library after you log in.

WORK INSTRUCTIONS:

- Log into the SUNY RF PACS portal and click on the **IRB** tab in the top navigation menu.
- Select the **Create New Study** button.

Basic Information SmartForm

- *Required information fields are marked with an asterisk (*)*
- *Click the Help icon ( ) for more information about a question or field*
- *Be sure to save your work frequently.*

1. Enter a **Title** for the study.
2. Enter a **Short Title** for the study; the **Short Title** will identify your study in the system.
3. Enter a **Brief Description** of the study.
4. 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 <u>do not</u> 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.*

5. Select from the dropdown menu whether the PI is:
   - External Researcher
   - Student – *students will be asked to select their faculty advisor*
   - Fellow
   - Staff
   - Faculty Member

6. Indicate whether or not an **IRB** external to Buffalo State College will act as the **IRB** of record for the study.

   *In all but the rarest of cases, an external **IRB** <u>will not</u> 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.*

7. **Attach the protocol** – You must use the Protocol template found in the **IRB Library**. Click the link to the **IRB Library**, which will open a new tab. Click the **Templates** tab, and select **Protocol Template**. Complete each response and save the document in an accessible location. Return to the **SmartForm** tab (Edit/View) and:
   - Click the **Add** button to upload a copy of the protocol.
   - Click the **Browse** button to locate the file.
   - Enter a **Name** for the document.
   - A **Version number** is not necessary.
   - Click the **OK** button.
   - Click the **Continue** button at either the top or bottom-right of the form.

Funding Sources SmartForm

1. Indicate if this is a funded study.
2. If yes, click **Add** to identify the funding source(s). Click **Select** to choose from a drop-down list **OR** enter a Name and Type. The grant application should be included as an attached file; click the **Add** button to attach it. Click **OK** or **OK and Add Another**.

   When all funding sources have been added or if there are no funding sources, click **Continue**.

Study Team Members SmartForm

1. Click **Add** to identify each additional person involved in the design, conduct, or reporting of the research.
   - Students **must** add their faculty advisor as a Study Team Member.
2. If there are external team members, you will need to complete an **External Team Member Information Template**, which can be found in the **Templates Library**, for each external team member who will be participating in the study. Complete and save the form(s) in an accessible location. Click **Add** and then **Browse** to upload the form(s); click **OK** when all external team members have been added.

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

Study Scope SmartForm

1. Indicate whether or not the investigator will conduct or oversee research at any external sites. ‘External sites’ generally means other institutions that are engaged in the research as a part of the function of the institution. They occur most typically when there is a grant funded study that is being done in collaboration with another institution who is also receiving a portion of the

funding. For example, if an investigator is conducting a study with Research Institute on Addictions (RIA), RIA would be considered an external site. If, however, an investigator is conducting a study at Buffalo Public Schools (BPS) and employees of the district are not involved in the research, BPS would not be considered an external site. If 'Yes' is selected, the **External Site SmartForm** will open. Click **Add** and supply the required information and click **OK** or **OK and Add Another**.

2. Drugs, biologics and supplements are rarely used at Buffalo State, therefore this will almost always be 'No.'
3. Devices are rarely used at Buffalo State, therefore this will almost always be 'No.'

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

Consent Forms and Recruitment Materials SmartForm

1. You must use the appropriate consent template(s) found in the **IRB Library**. Click the link to the **IRB Library**, click the **Templates** tab, and select the correct template. Customize as needed and save the document in an accessible location. On the **SmartForm**, click **Add** and then **Browse** to upload your documents. Click **OK** or **OK and Add Another**.
2. Click **Add** and then **Browse** to upload any recruitment materials. Click **OK** or **OK and Add Another**.

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

CITI Training SmartForm

- CITI Training information will automatically populate for any study team member that has completed the required CITI Training using a **Buffalo State e-mail address**. CITI Training **must** be completed before research can begin.

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

Supporting Documents SmartForm

- Click **Add** and then **Browse** to attach site agreements, surveys, questionnaires or any other study-related documents not attached previously. Click **OK** or **OK and Add Another**.

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

Final Page SmartForm

- When all of the required fields have been completed, click the **Finish** button at either the top or bottom-right of the last **SmartForm** page to be redirected to the **Study Workspace**.

Your study has not yet been submitted for review.

Assign any additional staff to the study, as necessary:

- **<u>Assign PI Proxy</u>** – 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. **Student researchers must assign their faculty advisor as PI Proxy; student research will not be reviewed without faculty advisor approval.**

- **<u>Assign Primary Contact</u>** – 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.

FOR <u>STUDENTS</u> ONLY

Click **Add Comment**

1. In the Comment box, ask your faculty advisor to review your protocol and, if s/he approves it, to click **Submit** on the left side of the workspace. If the faculty advisor requires clarification or further information, s/he should indicate so by adding a comment.
2. Supporting documents are not necessary here.
3. Check all 3 boxes.

Click **OK**. "Comment Added" will appear in the History tab; you can now log off.

The Principal Investigator (or PI Proxy) must click the Submit activity located under My Current Actions on the left side of the Study Workspace.

- 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 there are no errors, a statement will appear in the window. Read the statement and then click **OK** to submit the study for review.

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