**Create and Submit a New Study**



Have the completed Public Health Surveillance Activities form ready for upload before logging 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 Study 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. Select the kind of study.
5. Indicate whether or not an **IRB** external to Buffalo State University will act as the **IRB** of record for the study.

*In all but the rarest of cases, 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.*

1. 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.*

1. Select from the dropdown menu whether the PI is:

* External Researcher
* Student – *students will be asked to select their faculty advisor*
* Fellow
* Staff
* Faculty

1. **Attach the protocol** – You must use the Public Health Surveillance Activities form.
   * Click the **Add** button to upload a copy of the form.
   * Click the **Choose File** 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.

***Study Funding Sources* SmartForm**

1. Indicate if this is a funded study.
2. If yes, click **Add** to identify the funding source(s). Click **···** to search 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**.

***Local 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.
* Select the Study Team Member’s Role
* Indicate whether the Study Team Member is involved in the consent process
* Click OK or OK and Add another

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 **Choose File** 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. Drugs, biologics and supplements are rarely used at Buffalo State, therefore this will almost always be ‘No.’

2. 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.

***Local Research Locations* SmartForm**

1. Click **Add** to provide research locations. Fill in requested information and click **OK** or **OK and Add Another**.

***Local Site Documents* SmartForm** – **at this point, these forms are not required. If the IRB determines that an IRB protocol is necessary, you will be directed to submit a modification and these forms will then be required.**

1. **Consent forms:** You must use the appropriate consent template(s) found in the **IRB Library**. If you have not already prepared your consent forms, **Save** and **Exit** the study to return to the workspace. 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. To return to your study, click the **Submissions** tab, click the **Name** of the study and select **Edit Study**. On the **SmartForm**, click **Add** and then **Choose File** to upload your documents. Click **OK** or **OK and Add Another**.

2. **Recruitment materials:** Click **Add** and then **Choose File** to upload any recruitment materials. Click **OK** or **OK and Add Another**.

3. **Other attachments:** Click **Add** and then **Choose File** to upload other attachments. Select one of the following categories:

* Site Permission Letter
* Surveys/Questionnaires
* Other, e.g., interview questions or any other study-related documents not attached previously

Click **OK** or **OK and Add Another**.

When all attachments have been added, click the **Continue** button at either the top or bottom-right of the form.

***CITI Training* SmartForm – at this point, CITI training is not required. If the IRB determines that an IRB protocol is necessary, you must complete CITI training before beginning any research with human subjects.**

* 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.

***Final Page* SmartForm**

* When all of the required fields have been completed, click the **Save and Continue** 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.

***The Principal Investigator must click Submit located under Next Steps 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.

