Click Portal

IRB Module

Study Submission Guide

July 2020

University at Buffalo
The State University of New York

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IRB Module – Study Submission Guide

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What is the Click Portal?

The SUNY Pre-Award and Compliance System (PACS) is a multi-year collaboration created to support investigators and students along with compliance and research administrative staff by giving them a new administrative tool - the Click Portal.

Click will automate the submission, review, and approval processes while managing all major administrative aspects of the research and compliance lifecycle – from proposal development and submission through compliance checks, negotiations, award setup and award management, to eventual project closeout.

This system integrates the following aspects of grants management into a single system:

- IRB
- IACUC
- Grants Management
- Conflicts of Interest (COI)
- Research Agreements
- Safety

Under the stewardship of UB's Office of the Vice President for Research and Economic Development, this platform will allow the University at Buffalo to achieve a new level of uniformity and efficiency, while also producing valuable data analytics that can guide future decisions.

UB is helping lead this SUNY-wide effort and was the first campus to implement the Click Portal, beginning with the IRB module in Fall 2015.
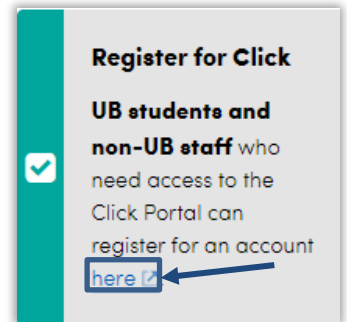
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Getting a Click Account

Accounts have been created for faculty and staff at the University at Buffalo in preparation for campus-wide implementation of the Click Portal. Faculty and staff users will log into the system using their **UBIT Name** and **Password.**

If your login attempt is unsuccessful, or you are a student participating on a research team, please follow the instructions below to request an account:

1. Navigate to the **Click Portal: IRB and Managing Compliance** page at http://www.buffalo.edu/research/research-services/compliance/irb/click-irb.html

2. Locate the **Click Portal Login** area at the top-right of the page, and click on the registration link.

3. Complete the **Request Account** form at the bottom of the page, and then click the **Register** button. Be sure to select the *University at Buffalo* as your **Campus Affiliation.**

You will receive an email notification when your account has been activated.

Logging into the Click Portal

1. Navigate to the **UB Research and Economic Development** page at
http://www.buffalo.edu/research

2. Locate the **Quick Links** section in the center of the page.

3. Click on the **Click Portal Login** link.

QUICK LINKS
> Participate in Research
> UB Rates and Facts for
  Researchers
> Limited Submission
  Opportunities
> UB SWIFT
> Forms Catalog
> CLICK Portal Login
> OnCore Login
> Training Workshops
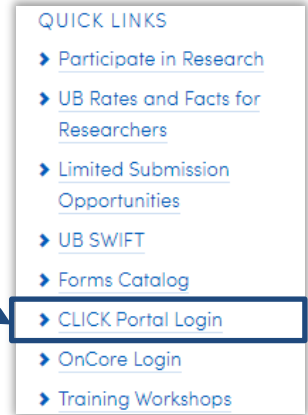
4. Enter your **UBIT Name** and **Password** in the fields, and then click the **Log In** button.

Login Required

👤 jresearcher

🔒 ••••••••
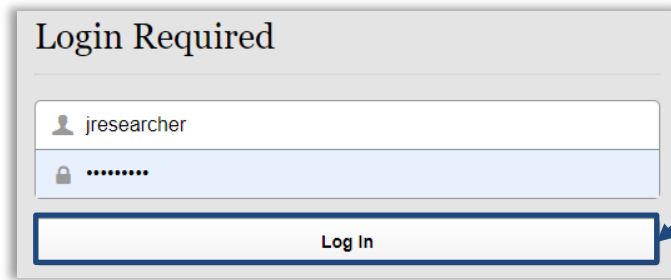
Log In

Basic Navigation

My Inbox

Each time you log into the **Click Portal**, you will be taken to the **Inbox**. This area of the portal contains studies (and/or other submissions) that require you to take action.

My Inbox is divided into two tabbed pages:

- **Compliance Tasks** – At present, this tab contains a list of the IRB, IACUC, and Safety protocols that require action.

- **SPO Tasks** – At present, this tab contains a list of the Agreements, Grants, and COI Disclosures that require action.

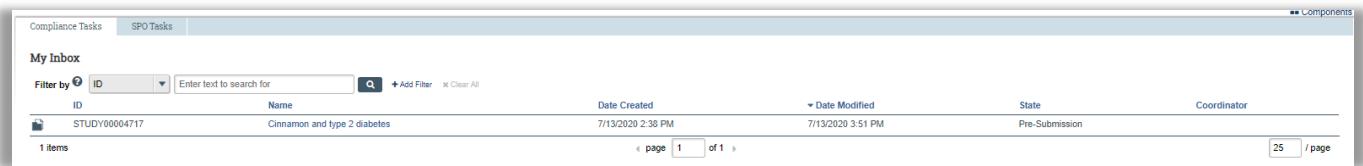The listings within **My Inbox** can be sorted by using the **Filter by** option. This option will allow you to search by **ID** number, **Name**, **Date Created**, **Date Modified**, or **State**.

To determine what type of action you need to take on a submission, look at the **State** column; see the chart below for an explanation of the action required for each **State**.

Your role	Submissions in My Inbox		Not in My Inbox
	State	**Explanation**	
Research team			
Study team member or study's primary contact **Note:** Any team member can make changes to the study, but the PI must personally submit the changes or response to the IRB.	Pre-Submission	Complete the study forms. The PI must submit it to the IRB to let the review begin.	Studies the IRB is reviewing
	Clarification Requested	Change the study to clarify as needed, and provide summary notes to the IRB when submitting the changes. **Note:** If the clarification was requested from Committee Review, you can only provide notes. You are not allowed to change the study.	Approved studies
	Modifications Required	Modify the study to meet IRB requirements and submit it with changes.	Closed studies

- To open a submission, click on its **Name**. When you open a submission, you will be brought to its **Workspace**.

- You can return to **My Inbox** at any time by clicking the **My Inbox** tab in the navigation menu at the top of the screen.
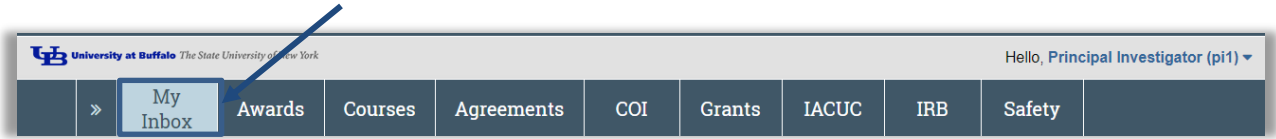
My Submissions

You may navigate directly to the IRB module by clicking the **IRB** tab in the navigation menu at the top of the screen.
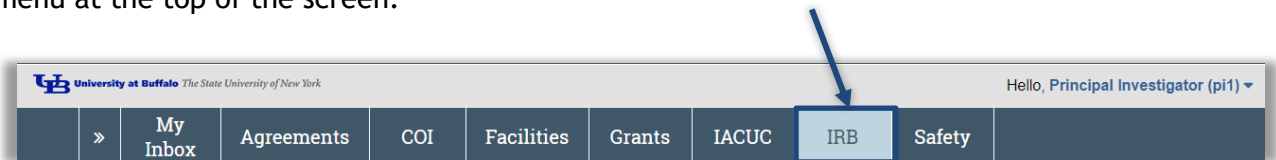
The **My Submissions** area is divided into seven tabs:
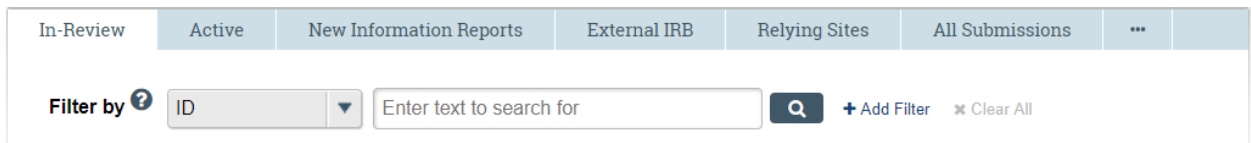
- **In-Review** – This tab lists all of your IRB protocols currently under review (Pre-Review, IRB Review, and Post-Review states).

- **Active** – This tab lists all of your protocols that have been approved by the IRB.

- **New Information Reports** – This tab lists all of your Reportable New Information (RNI) submissions.

- **External IRB** – This tab lists any of your protocols that are being evaluated by an external IRB committee.

- **Relying Sites** – This tab lists all participating sites relying on the local IRB (UB) as the single IRB of record.

- **All Submissions** – This tab shows all your protocols, regardless of state.

- **Archived** – This tab shows expired protocols and protocols that were withdrawn from submission.

On the left side of the screen, you will see links to **Activities** you can perform, as well as **Shortcuts** to other areas of the module.

Activities:

- **Create New Study** – Create and submit a study protocol.

- **Report New Information** – Report new information regarding an approved study protocol.

The Workspace

Once you open a study, you will be taken to the **Study Workspace.**

The **Study Workspace** allows you to:

- View the study contents and details, including all actions performed on it

- Perform actions on the study

The key elements in the **Workspace** are:

- **Top navigation menu** – Links to the different modules within the **Click Portal**

- **Sub-navigation menu** – Links to the sections of the current module

- **Activities** – Actions that can be taken based on a submission's current **State**

- **Resource tabs** – Collected information regarding the submission

- **History** – Actions taken previously on this submission

SmartForms

To open a study from the **Workspace**, click on the **Edit Study** button.

> **NOTE:** This button may also be labeled **View Study**,
> dependent upon the **State** of the study you are opening.

Studies are comprised of several pages known as **SmartForms**. They are referred to as 'smart' because the portal will branch to add additional forms to your study based on your responses to questions on the pages.

The key elements in the **SmartForms** are:

- The **Continue** and **Back** buttons will move you forward or back one page in the study; the **Continue** button also saves your work.

- The navigation bar at the top and bottom of each page will allow you to perform the following actions:

    o **Save** – Saves your work for the current page

    o **Exit** – Exits the study and returns you to the **Study Workspace**

    o **Hide/Show Errors** – Performs a check on every page within the study to ensure that all required fields have been completed

    o **Print** – Prints the current SmartForm page

- o **Jump to:** - Allows you to see and navigate to all pages within the study

- Any item on a **SmartForm** that has a red asterisk (*) next to it is a required field.

- Clicking on the blue icons ( ) next to items will open a window that will offer assistance with completing the field.

Creating a New Study

To begin the process of creating a **New Study**, please complete the
following steps:

1. Log into the **Click Portal**.

2. Click the **IRB** tab in the top navigation menu.

3. Click the **Create New Study** button.
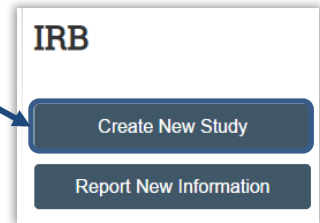
The sections below will provide information on the general **SmartForms** you will be asked to complete as part of a new study.

Basic Study Information

1. Enter a **Title** for the study.

2. Enter a **Short Title** for the study.

> **NOTE:** The **Short Title** becomes the **Name** of the study;
> be sure to make this unique across your projects.

3. Enter a **Brief description** of the study.

4. Indicate what kind of study this is.

5. Indicate whether 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** <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.

   > **NOTE:** Indicating that an external **IRB** will act as the **IRB** of record
   > will lead to a much shorter set of **SmartForms** and an abbreviated workflow routing.

6. Indicate if an external IRB will act as the IRB of record for the study.

   If yes, please indicate who will serve as the **Lead principal investigator**.

   - Click the **Browse** button (⋯).

   - Enter the **Name** of the **Lead principal investigator**.

   - Click the **Go** button.

   - Select the **Name** of the appropriate individual.

   - Click the **OK** button.

7. By default, you will be listed as the **Local 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.

8. Use the dropdown menu to indicate the **PI**'s role at the University.

9. Attach a digital copy of the protocol.

   > **NOTE:** Please use the HRP-503 Template Protocol or
   > HRP-508 Template Site Supplement to Sponsor
   > which can both be located in the **Library** on the **Templates** tab.

   - Click the **Add** button.

   - Click the **Choose File** (or **Browse**) button to locate the file.

   - Enter a **Name** for the document.

   - Click the **OK** button.

   > **NOTE:** If changes to the protocol are requested by the **IRB**, use the **Update** button
   > to replace the current version of the document with an updated one.

Click the **Continue** button to save your work and move to the next page within the **SmartForms.**

Funding Sources

1. Indicate whether this is a funded study. If you answer **Yes**, a second item will appear.

2. If you anticipate funding for the study, click the **Add** button.

> **NOTE:** If your study is unfunded, please click the **Continue** button to move to the next page.

- Click the **Browse** button (⋯).

- Enter the **Name** of the organization. Please do not use abbreviations (e.g., NIH); type the **Name** using complete words.

- Click the **Go** button.

- Select the **Name** of the appropriate organization.

- Click the **OK** button.

> **NOTE:** If you cannot locate the **Name** of the organization using the search tool, please click the **Cancel** button. Then enter the **Name** of the organization in the **Name** field, and indicate its **Type**.

- Enter the **Sponsor's funding ID** number, if known.

- Enter the **Grants office ID** number, if known.

- If this is a grant-funded study, the grant application should be included as an attached file. Click the **Add** button to attach it.

- Click the **OK** button once more to close the window.

3. If there are additional funding sources, please repeat the process above to add them.

Click the **Continue** button to save your work and move to the next page within the **SmartForms**.

Local Study Team Members

The **Local Study Team Members** page is the location for identifying each person involved in the design, conduct, or reporting of the research. There is no need to add the **Principal Investigator** who was listed on the [Basic Study Information](#) page.

Adding Internal Team Members

1. To add internal team members, click the **Add** button.

   - Begin typing the individual's last name in the **Study team member** field. If the last name is very common, you may have to type a comma followed by the first name. You can also sort through an alphabetical list by clicking the **Browse** button.

> NOTE: Most people with active UBIT accounts who have been employed in any capacity at UB (including graduate students on RA/GA/TA lines) will be accessible as internal personnel.

   - Select the individual's **Role** in the research. If a specific **Role** is not in the list, please select the closest match.

   - Indicate whether the team member is involved in the consent process.

   - Indicate whether the team member has a financial interest in the research.

   - Click the **OK** button. If you have additional team members to add, you may click **OK and Add Another** to repeat the process.

Adding External Team Members

1. To add external team members, click the **Add** button.

   - Click the **Choose File** (or **Browse**) button to locate the file.

You will need to complete an [External Team Member Information Template](#) for each external team member who will be participating in the study. This form is available in the **Library** on the **Templates** tab.
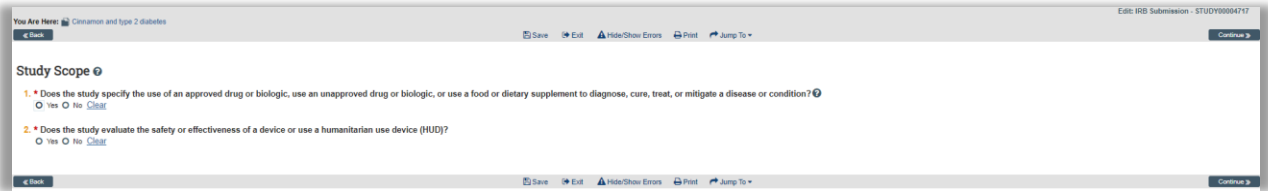
Collaborators who will be covered under their own institution's **IRB** do not need to be added as external team members.

- Enter a **Title** for the document – use the person's last name, first name as the naming convention (e.g., Doe, John).

- Click the **OK** button. If you have additional team members to add, click **OK and Add Another** to repeat the process.

> **NOTE:** External team members will need to obtain a UBIT account if they need to access the protocol and consent forms. These individuals will need a volunteer appointment from your department. Please contact support@research.buffalo.edu for more information.

After you have finished adding team members, click the **Continue** button to save your work and move to the next page within the **SmartForms**.

Study Scope

Answering 'yes' to any of the questions posed on the **Study Scope** page will trigger the addition of additional **SmartForm** pages to the study.

1. Indicate if the study will involve any of the listed conditions:

    -   Specify the use of an approved drug or biologic

    -   Use an unapproved drug or biologic

    -   Use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease

    Answering 'yes' to this question will trigger the addition of the **Drugs** page.

2. Indicate if the study will do any of the following:

    -   Evaluate the safety or effectiveness of a device

    -   Use a humanitarian use device (HUD)

    Answering 'yes' to this question will trigger the addition of the **Devices** page.

After you have finished defining the scope, click the **Continue** button to save your work and move to the next page within the **SmartForms**.

Local Research Locations

1. Identify research locations where research activities will be conducted or overseen by the local investigator.

   - Click the **Add** button.

   - Click the **Browse** button (...).

   - Enter the **Location Name**.

   - Click the **Go** button.

   - Select the **Name** of the appropriate location.

   - Click the **OK** button.

   > **NOTE:** If you cannot locate the **Name** of the location using the search tool, please click the **Cancel** button. Then enter the Location **Name**, **Address**, and **Contact Information** in the fields provided.

   - Click the **OK** button. If you have additional locations to add, click **OK and Add Another** to repeat the process.

   After you have finished adding locations, click the **Continue** button to save your work and move to the next page within the **SmartForms**

Drugs

1. To list a drug, click the **Add** button. You must include <u>all</u> drugs that are a part of the protocol, whether or not they are investigational.

   • Indicate the **Drug Type**.

   • Begin typing the drug's name in the **Select the drug** field. You can also sort through an alphabetical list by clicking the **Browse** button. If you cannot locate the drug, please enter the **Generic Name** and **Brand Name** in the fields provided.

   • Enter an **IND Number** related to the drug, or indicate that the drug is **IND exempt.**

   • Indicate who holds the **IND**; if **Other,** use the field provided to identify the **IND holder.**

   • Click the **Add** button to attach any files related to the drug (e.g., package insert, investigator brochure, product labeling, or verification of **IND Number**).

     All materials related to the drugs utilized in the study protocol should be uploaded using the process outlined above.

   • Click the **OK** button. If you have additional drugs to add, click **OK and Add Another** to repeat the process.

For each **IND**, one of the following must be provided:

Sponsor protocol with the **IND Number**

Communication from the FDA or sponsor with the **IND Number**

2. To attach any files that were not included in the previous step:

   • Click the **Add** button.

   • Click the **Choose File** (or **Browse**) button to locate the file.

- Enter a **Name** for the document.

- Click the **OK** button. If you have additional documents to add, click **OK and Add Another** to repeat the process.

After you have finished adding drug information, click the **Continue** button to save your work and move to the next page within the **SmartForms**.

Devices

1. To select a device, click the **Add** button. Only those devices that are used as an **HUD** or evaluated for safety and effectiveness on human subjects as part of the study need to be listed.

   - Begin typing the device's name in the **Select the device** field. You can also sort through an alphabetical list by clicking the **Browse** button. If you cannot locate the device, please enter the information in the field provided.

   - Indicate whether it is a **Humanitarian Use Device (HUD)**.

2. Select the **Device exemptions** that are applicable to the study.

3. If you have indicated that there are **IDE** and/or **HDE** exemptions, you will need to identify **IDE** and **HDE** numbers.

   - **Investigational Device Exemption (IDE)** number - identifies a device approved by the FDA for use in a clinical study to collect safety and effectiveness data needed to support further applications to the FDA. Approved **IDEs** are exempt from several regulations.

   - **Abbreviated IDE** - The device is considered to pose a non-significant risk of harm. If the **IRB** approves the study—including the device as not posing a significant risk—no FDA approval is needed to proceed with the study.

   - **Humanitarian Device Exemption (HDE)** number - identifies a device approved by the FDA as a **humanitarian use device (HUD)** with limited potential patients, without meeting the effectiveness requirements of premarket approval. The FDA agrees that the device does not pose an unreasonable or significant risk of illness or injury, and the probable benefit to health outweighs the risk of injury or illness from its use.

   - Click the **Add** button to identify the **IDE/HDE Numbers**.

- Enter the **IDE** or **HDE Number**.

- Identify who holds the **IDE** or **HDE Number**.

  If you have selected **Other**, please enter the information in the **Other** field.

- Click the **OK** button. If you have additional **IDE** or **HDE Numbers** to add, click **OK and Add Another** to repeat the process.

4. Click the **Add** button to attach any files related to the device.

> For each **IDE/HDE** number, one of the following must be provided:
>
> Sponsor protocol with the **IDE/HDE** number
>
> Communication from the FDA or sponsor with the **IDE/HDE** number

- Click the **Choose File** (or **Browse**) button to locate the file.

- Enter a **Name** for the document.

- Click the **OK** button. If you have additional documents to add, click **OK and Add Another** to repeat the process.

After you have finished adding device information, click the **Continue** button to save your work and move to the next page within the **SmartForms**.

Local Site Documents

Consent Forms

1. To add a consent form, click the **Add** button.

   - Click the **Choose File** (or **Browse**) button to locate the file.

     Consent Materials to be uploaded include:

     - Signed Consent Documents

     - Assent Documents for Children

     - Parental Permission Documents

     - Verbal Consent Scripts

     - Consent Information Pages (e.g. consent documents for mailed or internet interactions)

   - Enter a **Name** for the document.

   - Click the **OK** button. If you have additional forms to add, click **OK and Add Another** to repeat the process.

### Recruitment Materials

2. To add a recruitment document, click the **Add** button.

   - Click the **Choose File** (or **Browse**) button to locate the file.

     Recruitment Materials to be uploaded include:

        o   Verbal Scripts

        o   Flyers

        o   Mailings

        o   Text for e-mail

        o   Newspaper advertisements

        o   Web pages (links are not acceptable- print the page to a pdf)

        o   Radio or TV ads (or scripts for them if the final form is not yet available). Keep in mind that the final form of any advertisement must be approved by the IRB before it is used so if you only provide the text, you will need to provide the final form via an amendment at a later date.

- Enter a **Name** for the document.

- Click the **OK** button. If you have additional materials to add, click **OK and Add Another** to repeat the process.

3. To attach any files that were not included in the previous steps:

- Click the **Add** button.

- Click the **Choose File** (or **Browse**) button to locate the file.

- Enter a **Name** for the document.

- Click the **OK** button. If you have additional documents to add, click **OK and Add Another** to repeat the process.

After you have finished adding consent and recruitment materials, click the **Continue** button to save your work and move to the next page within the **SmartForms.**

CITI Training
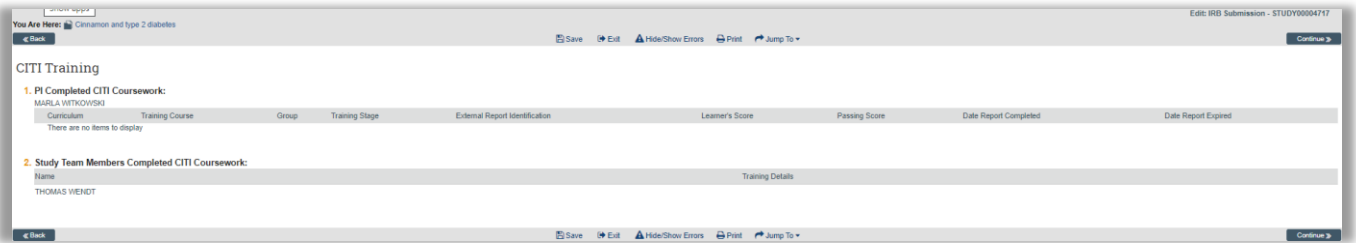
There are no fields to update on this page; a connection between the **Click Portal** and **CITI** will automatically add course information for your study team members. At present there are some issues with integration between the two systems. These issues have caused the **IRB** to manually verify **CITI** completion for all study personnel.

Minimizing Delays

In order to ensure that your protocol is not delayed, you should verify that all study personnel have completed the appropriate **CITI Training**.

1. Ask any person who has a course within 60 days of expiration to log into their **CITI** account and complete the basic or refresher course as required.

2. Ask any person who has not taken the required courses for the type of study being performed to complete them.

3. Obtain verification of completion for any records that do not appear below a person's name and save electronically just in case there is a situation for which the **IRB** cannot locate the records. A screenshot of the **Main Menu** page in **CITI** can serve as verification.

Required CITI Courses

All courses must be the University at Buffalo prescribed **CITI** courses. Similar **CITI** courses from other institutions will not be accepted. However, some of the modules in those courses may be applied automatically by **CITI** to your UB **CITI** courses.

For **Social/Behavioral/Education Research** the following are required:

• *Human Research Curriculum, Social & Behavioral Research Investigators Basic* or *Refresher Course* completed within the past 3 years.

• *Social and Behavioral Responsible Conduct of Research Course Basic* or *Refresher Course* completed within the past 3 years. *

*Currently the in-person **GRP** training for non-clinical researchers conducted by UB can be substituted for the above indicated **RCR** course. The **IRB** has information on the in-person courses on record and will verify this upon protocol submittal.

For **Biomedical/Clinical Research** the following are required:

- *Human Research Curriculum, Biomedical Research Investigators Basic* or *Refresher Course* completed within the past 3 years.

- *CITI Good Clinical Practice Course Basic* or *Refresher Course* completed within the past 3 years. **

Currently the in-person **GRP/GCP training for clinical researchers (parts I and II) conducted by UB can be substituted for the above indicated **RCR** and **GCP** courses. The **IRB** has information on the in-person courses on record and will verify this upon protocol submittal.

> **NOTE:** It is not required that you pay for CME credit for the purpose of meeting UB's human subjects requirement. If you wish to obtain CME credit, you may do so at your own expense.

Logging into CITI

1. Navigate to http://www.citiprogram.org

2. Enter your **Username** and **Password**.

   If you have never had a **CITI** account, create one by clicking the Register button. When creating a new account, be sure to indicate *SUNY-Buffalo (University at Buffalo)* as your institution and use your UBIT email address for any email addresses requested.

   If you have a **CITI** account with another institution, you can log into that account and then add an affiliation with *SUNY-Buffalo (University at Buffalo)* by clicking on the **Click here to affiliate with another institution** link toward the bottom of the **CITI Main Menu** page. Be certain to enter your UBIT email address for any email addresses requested.

After you have verified that study personnel have met the training requirements, click the **Continue** button to move to the next page within the **SmartForms**.

Final Page

1. On the **Final Page**, click the **Save and Continue** button to go to the **Study Workspace**.

2. Clicking **Save and Continue** <u>DOES NOT</u> submit your protocol for review. You must use the **Submit** option in the **Study Workspace** to submit your protocol for review

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Assigning Additional Staff to a Study

Once the study has been created, additional staff and reviewers can be added at the discretion of the **PI** and **IRB** staff.

Assign PI Proxy

A **PI Proxy** can perform all of a **Principal Investigator's** duties, with the exception of assigning additional **PI Proxies** and submitting the protocol for review. The **PI Proxy** <u>must</u> be a member of the study team.

1. From the **Study Workspace**, click **Assign PI Proxy**.

2. Click the **Browse** button to see the **Study Team Members**.

3. Place a checkmark next to the **Name** of the person you wish to be **PI Proxy**.

4. Click **OK**, and then click **OK** once more.

Assign Primary Contact

A person identified as a **Primary Contact** will receive all the system-generated email notifications that a **Principal Investigator** does. By default, the system will assign the **Primary Contact** role to whoever created the study in the system. Follow these steps to change the default to another person.

1. From the **Study Workspace**, click **Assign Primary Contact**.

2. Click the **Browse** button (...), and select an individual to serve as the **Primary Contact**.

3. Click **OK**, and then click **OK** once more.

Manage Ancillary Reviews

The assignment of an **Ancillary Review** allows for the study to be reviewed by individuals, departments, etc., as determined by the **PI** and/or **IRB** staff. **Ancillary Reviews** happen in parallel with the workflow, are optional, and can happen at any point between the states of **Pre-Submission** and **IRB Review**.

1. From the **Study Workspace**, click **Manage Ancillary Reviews**,

2. Click the **Add** button, and select an individual or organization to serve as an **Ancillary Reviewer**.

> **NOTE:** An individual must possess the role of **Ancillary Reviewer**;
> an abbreviated list of individuals will appear.

3. Select a **Review Type** from the drop-down menu.

4. Indicate whether a response is required.

> **NOTE:** If a response is required, the study cannot be approved
> until the **Ancillary Review** has taken place.

5. Click **OK**, and then **OK** once more. An email notification will be sent to the **Ancillary Reviewer** notifying them of their responsibility.

Manage Guest List

Those on the **Guest List** can read the study and any other submissions, but cannot edit them.

1. From the **Study Workspace**, click **Manage Guest List**.

2. A list of individuals with access to the protocol will appear. Click the **Browse** button, and select an individual to include on the **Guest List**.

3. Click **OK**, and then click **OK** once more.

Submitting a Study for Review

When you have completed all of the **SmartForms** for your study, you will be returned to the **Study Workspace**. In order to send the submission for review, the **Principal Investigator**) must complete the following actions:

1. To submit your study for review, click **Submit** under **Next Steps**.

    The **Click Portal** will run a brief check to ensure that all of the required fields have been completed within the **SmartForms**.

    - If an error appears, click the link(s) and update any required fields that were missed. **Save** your changes, **Exit** the **SmartForms**, and then click the **Submit** button again.

    - If there are no errors, a statement will appear in the window.

2. Read the statement and then click **OK** to submit the study for review.

3. Check to ensure that the following things have occurred:

    - The **Status Bar** in the upper-left corner of the **Workspace** will change from **Pre-Submission** to **Pre-Review**.

    - The highlighted state in the workflow image at the top of the page will now be **Pre-Review**.

    - On the **History** tab, the most recent action will be **Submitted**.

The Review Process

Submitting information to the **IRB** initiates a series of activities that may include:
- Review within your department
- Pre-review by an **IRB** staff member
- Review by the **IRB Committee** and/or a **Designated Reviewer**
- Communication of the **IRB** decision to the **Principal Investigator**

Any of these may lead to a request for the study team to take further action, such as providing clarifications or modifying the study. Whenever the study team needs to act, the **PI** (and **PI Proxy**) receives an email notification, and the study appears in **My Inbox** for all study team members when they log in to the **Click Portal**.

Clarification Requests

At several points during the review process, the **IRB** may request clarifications from the study team. Whenever a **Request for Clarification** is made, an email notification will be sent to all study team members, and the study will appear in their **Inbox** with a status of **Clarification Requested**.

The **PI** (or **PI Proxy**) is responsible for making any changes necessary, and for responding to the request.

1. To respond to a request, either click on the link embedded in the email notification or navigate to **My Inbox** and locate the study with the status of **Clarification Requested**. Click on the study's **Name** to open it.

2. On the **History** tab, find the **Clarification Requested** activity and read the comments.

3. Click the **Edit Study** button.

4. If necessary, click the **Jump To:** link to go right to the **SmartForm** that requires edits.

> **Note:** If no changes were needed to the study,
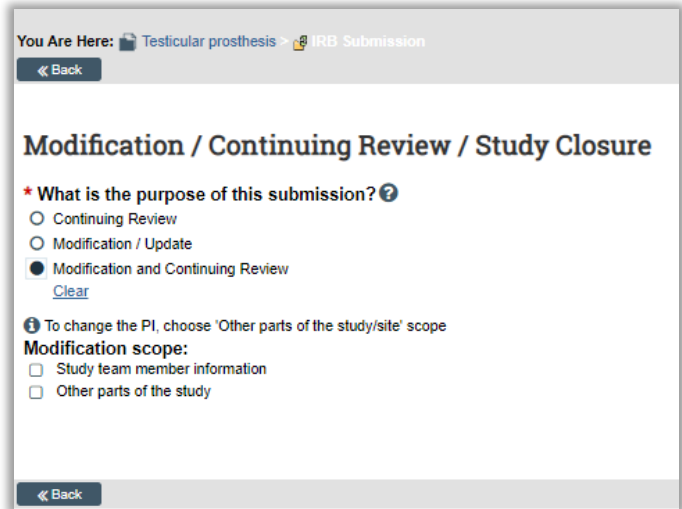> the **PI** would simply respond to the request.

5. Make and **Save** the requested change(s).

6. Click **Exit** on the navigation bar to close the study.

7. Under **Next Steps**, click **Submit Response**.

8. In the window, enter any **Notes** and then click **OK**.

9. Check to ensure that the following things have occurred:

   - The **Status Bar** in the upper-left corner of the **Workspace** will change from **Clarification Requested** to **Pre-Review** or **IRB Review** (dependent upon which state the request was made in).

   - The highlighted state in the workflow image at the top of the page will now be **Pre-Review** or **IRB Review**.

   - On the **History** tab, the most recent action will be **Response Submitted**.

Creating a Modification/CR

Determining the Purpose of the Submission

Upon clicking the **Create Modification/CR** button, you will be taken to a page where you will need to specify the purpose and scope of your submission. Click the appropriate radio buttons and checkboxes to indicate your choices.

> **NOTE:** These selections **cannot** be undone once you click the **Continue** button.

You Are Here: 📁 Testicular prosthesis > 📄 IRB Submission
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Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ❓
○ Continuing Review
○ Modification / Update
● Modification and Continuing Review
Clear

ℹ To change the PI, choose 'Other parts of the study/site' scope
Modification scope:
☐ Study team member information
☐ Other parts of the study

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The following chart can be used to determine the purpose of the submission – which will guide you to which type(s) of submission you should select. In cases where the scope includes changes to both study team members and other parts of the study, both checkboxes should be selected.

Do you need to make any modifications to the Study's information, personnel, protocol, consent documents, recruitment materials, instruments, or any other documentation?				
Yes		**No**		
Are you closing or renewing the Study at this time?		Are you closing the Study and/or the first 4 boxes under **Research Milestones** on the **Continuing Review/Study Closure Information** page will be checked?		
No	**Yes**	**No**		**Yes**
Submit Modification & CR	Submit Modification & CR	Was the Study was previously approved in **IRBNet** and this is the 1st **Modification/CR** in the **Click Portal**?		Submit Modification & CR
		Yes	**No**	
		Submit Modification & CR	Submit Modification & CR	

> **NOTE:** In most cases only <u>one</u> **Modification/CR** can be submitted at one time. There is no way for this system functionality to be overridden by the IRB, so please plan accordingly.

Modification/CR Process

To begin the process of creating a **Modification/CR**, please complete the following steps:

1. Log into the **Click Portal**.

2. Click the **IRB** tab in the top navigation menu.

3. Locate the **Active** tab, and click the **Name** of the **Study** you wish to make changes to.
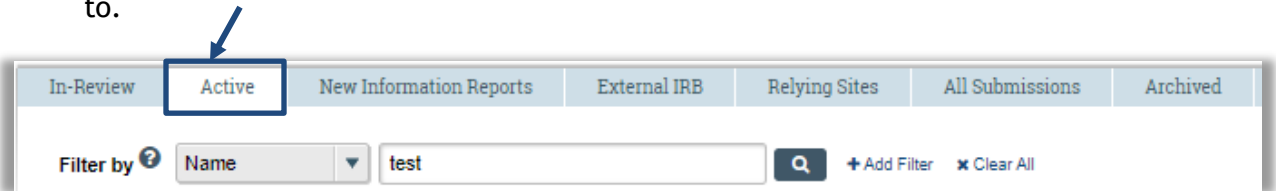
4. You will be taken to the **Study Workspace**; click the **Create Modification/CR** button under **Next Steps**.

> **NOTE:** If the **Create Modification/CR** button is not available,
> it may mean that you have already submitted a **Modification/CR** for this Study.
> You **cannot** create an additional **Modification/CR** until the previous one is approved.

5. Indicate the purpose and scope for your submission, and then click the **Continue** button.

Continuing Review/Study Closure Information

When there are no **Modifications**, this page is the only one that needs to be completed for a **Continuing Review** or **Study Closure**. If you have also requested **Modifications**, you will be taken to an additional page to indicate your changes.

1. **Specify Enrollment Totals**

You must enter totals for all 3 fields:

- When there are multiple groups of participants (e.g., participants who receive interventions and control participants) sum up **all** participants.

- When participants partake in research procedures at more than one point (e.g., pretest and posttest situations), count each person only **once**.

- In cases where an exact count cannot be obtained, you should make your best estimate of the participant number. For example, if participation was anonymous and you collected 45 pretests and 52 posttests – estimate that the participant count was 52.

- To obtain the number **Since Last Approval**, subtract last year's figures from your total. You can check in **IRBNet** on the **Continuing Review** form for this information. Of course, if last year was your initial study approval, last year's count will equal 0.

- Studies that have not happened at multiple sites around the country (e.g., multi-center drug or medical device trials, collaboration with another university) will typically provide the same number for **At this investigator's sites** and **Study-wide**.

2. **Research Milestones**

The **Research Milestones** are very important; the answers you provide here can have a significant impact on the **IRB Review** process, including requests for you to provide further materials or information.

> **NOTE:** If the first four **Research Milestones** are checked the Study will be closed to discontinue IRB oversight because the human subjects' portion of the research is done.

- Statements like **'or no subjects were enrolled'** are included in many of these **Milestones** so that a Study that has been completely called off without any subject participation can be closed by the IRB.

- Check **'Study is permanently closed to enrollment OR was never open for enrollment'** when any of the following are true:

  o No further participants will be added; you are done recruiting and starting people on any interventions or interactions.

> **NOTE:** OHRP Definitions

> - **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the Subject or the Subject's environment that are performed for research purposes.
>
> - **Interaction** includes communication or interpersonal contact between the Investigator and Subject.

  o You decide to call off the entire Study; possible reasons for this would include not receiving the grant or contract that was to pay for the

project, or simply that you decided to completely change your research focus.

- **'All subjects have completed all study-related interventions OR not applicable'**

  o Many studies do not use any interventions. For example, studies that include only records reviews or interview procedures would not usually contain interventions.

- **'Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)'**

  o Keep in mind that while you may still be collecting information from people, as long as the data is never identifiable, you could check off this box. This might mean that for some studies this box could be checked right at the outset.

NOTE: OHRP Definitions:

- **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

- **Private information must be individually identifiable** (i.e., the identity of the Subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- **'Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)'**

  o First, see the above two bullets.

  o If you have **completely de-identified** all data, even though it was at one time identifiable, you could now check this box.

  o If you retain a **master list** that connects identities to the data through a code number, it is not completely de-identified until you **get rid of all** copies of the master list.

  o Names are not the only identifiers. It is especially true that for small participant pools, sometimes a person can be readily identified by combinations of information in the data. For example, consider the pool of Presidents of the United States. If two of the data fields are the State they were born in and their political party, while we might not be able to distinguish between Martin Van Buren and Franklin Roosevelt (both

born in NY and Democrats) based on only this data it does not take much effort to figure out that Theodore Roosevelt is the only Republican from NY and Millard Fillmore was in the Whig Party (Grover Cleveland and Chester Arthur weren't born in NY).

- o You *can sometimes retain identities* and still check this box as long as they are completely separate from your data. For example, a signed consent form would probably have a person's identity in the form of their name but as long as there was no link between the consent form and the private data collected (like a code number in the upper left hand corner of the page) the data is still not readily identifiable.

- o Sometimes the identifiability of data to the researcher *depends upon their ability to easily access other information*. For instance, most people couldn't identify an individual based on a list of courses taken as an undergraduate in college even though they might know the name of the school. However, if you happened to work in the registrar's office of that college, they would be easily identifiable to you.

- **'Remaining study activities are limited to data analysis'**

  - o Writing and publication are also considered a part of 'data analysis'.

  - o Even though your study may be closed with the IRB because the human subjects portion is done, you can still analyze data and write it up.

- **'Study remains active only for long-term follow-up of subjects'**

  - o This usually only applies in clinical studies where tracking factors like recurrence of the disease/condition over time may be an important in analysis of the effectiveness of the new treatment.

3. **Financial Interest Question**

> 3. * Do any investigators or research staff have a financial interest related to the research that was not described in a previous application? ⓘ
> ○ Yes ◉ No   Clear

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.

For additional information:

- **HRP-211 Initial Review Form** available at http://www.buffalo.edu/research/research-services/compliance/irb/policies-procedures-toolkit.html

- **UB's Conflict of Interest page** available at
  http://www.buffalo.edu/research/research-services/compliance/coi.html

4. Checklist of Items

- Most of the time, all of the items in this list can be given a few minutes of thought and then checked off. Just answer them honestly and to the best of your knowledge after checking with your research team to see if they encountered any issues that would not allow a box to be checked. It is expected that in most cases there will be none (or very few) of the items in this list left unchecked.

5. Supporting Documents

- Most of the time, there will be no need to upload any supporting documents.

- If one or more of the items in Step 4 above remains unchecked, then there should be a supporting document(s) to cover each unchecked item. For instance, if both **'No Subjects Withdrew from the Study'** and **'No Data Safety and Monitoring Reports'** are unchecked, you should upload two supporting documents, one giving a description of the withdrawals that occurred along with your evaluation of why they occurred, and a second document containing the **Data Safety and Monitoring Reports**.

- Do NOT upload items that are a parts of the Study itself here (e.g. protocol, consent forms, advertisements, edited study instruments, investigator's brochure, etc.). These are uploaded as a part of the original Study documentation and not as supporting documents for renewal.

Modification Information/Amendments

When there are **Modifications**, either on their own or as a part of a **Continuing Review**, this page will need to be completed. After completing this page, you will be taken to the **SmartForm** pages in order to make the actual **Modifications** to the Study materials and upload any updated documents (e.g., protocol, consent forms, advertisements, edited study instruments, investigator's brochure, etc.).

1. **Study Enrollment Status**

   The **Enrollment Status** is very important because the answers provided here can have a significant impact on the IRB Review process, including requests for you to provide further materials or information.

   > **Note:** If you also submitted a **Continuing Review** with this **Modification**, make sure your responses are consistent with the **Research Milestones** that you indicated for the **Continuing Review**.

   - See the **Research Milestones** section under Continuing Review/Study Closure Information for definitions and guidance relevant to completing this section.

2. **Notification of Subjects**

Not all amendments require procedures for notification of past, current, or even future Subjects as a part of the initial consent process. Participants should, however, be told information that might be pertinent to their well-being and their choice to continue current or future participation in the Study. While the circumstances of each situation are unique, consider the examples of amendments below when deciding on whether changes in the consent process or notification of current/former participants should be undertaken.

- An amendment to add protocol-related information about the risk of increased potential birth defects associated with children of women who have in the past used a study drug would certainly warrant changes to the protocol risk section, the consent document for future enrollees and formal written notification to all current and former women who are/were subjects in the study.

- An amendment to add protocol-related information about a side effect of nausea while on the study drug would certainly warrant changes to the protocol risk/discomfort section, the consent document for future enrollees and formal notification to all current Subjects who have not completed the intervention. Participants who have completed the intervention and former Subjects would not need to be notified.

- An amendment to reduce the number of Study follow-up visits from 16 to 12 would require a change in the protocol, consent document for future enrollees, and notification to current enrollees (probably using a verbal process) at their next visit. There would be no reason to notify former Subjects who had already completed their 16th visit.

- An amendment to delete a few questions in a questionnaire of approximately 100 items that was to be filled out by participants at initial and final Study visits would probably require just a change in the Study instrument itself. A revised protocol would probably not be needed, nor would there be need to update the consent document (as the time it will take to complete the items will still be about the same). Current participants who still need to come for their final Study visit and past participants would probably not need to be notified of this change.

3. Summarize the Modifications

3. * **Summarize the modifications:** ⍰

There are no modifications we are bringing the documents into click for the first time.

- This is not just *for the record*; it also lets the IRB reviewers triage the level of review an amendment will require. Give a brief description in simple language of what is changing and why.

- One common situation encountered is when this is your first transaction in the **Click Portal** but you really are not making any changes at this time. The **Continuing Review** with **Modifications** is just the mechanism that allows you to electronically get the study into the system. Simply state this fact if it is the case.

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