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# IRB Module - Study Submission Guide

## Table of Contents

- What is the Click Portal? ........................................................................................................ 4
  - Getting a Click Account ........................................................................................................ 6
  - Logging into the Click Portal ................................................................................................ 7
- Basic Navigation .................................................................................................................... 8
  - My Inbox .......................................................................................................................... 8
  - My Submissions .................................................................................................................. 9
  - The Workspace .................................................................................................................. 11
  - SmartForms ....................................................................................................................... 12
- Creating a New Study .............................................................................................................. 14
  - Basic Study Information .................................................................................................... 14
  - Funding Sources ............................................................................................................... 17
  - Local Study Team Members ............................................................................................... 18
    - Adding Internal Team Members ....................................................................................... 18
    - Adding External Team Members .................................................................................... 18
  - Study Scope ....................................................................................................................... 20
  - Local Research Locations ................................................................................................. 21
  - Drugs .................................................................................................................................. 22
  - Devices ............................................................................................................................. 24
  - Local Site Documents ........................................................................................................ 26
    - Consent Forms ................................................................................................................ 26
    - Recruitment Materials .................................................................................................... 26
  - CITI Training ..................................................................................................................... 28
    - Minimizing Delays ........................................................................................................... 28
    - Required CITI Courses ................................................................................................. 28
    - Logging into CITI ............................................................................................................ 29
  - Final Page .......................................................................................................................... 30
  - Assigning Additional Staff to a Study .................................................................................. 31
    - Assign PI Proxy ............................................................................................................... 32
Assign Primary Contact .................................................................................................................. 32
Manage Ancillary Reviews .............................................................................................................. 32
Manage Guest List .......................................................................................................................... 33
Submitting a Study for Review ....................................................................................................... 34
The Review Process ....................................................................................................................... 34
Clarification Requests ................................................................................................................... 35
Creating a Modification/CR ........................................................................................................... 36
Determining the Purpose of the Submission .................................................................................... 36
Modification/CR Process ............................................................................................................... 37
Continuing Review/Study Closure Information ............................................................................. 38
Modification Information/Amendments ......................................................................................... 43
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.
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](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.

4. Enter your **UBIT Name** and **Password** in the fields, and then click the **Log In** button.
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**.

<table>
<thead>
<tr>
<th>Your role</th>
<th>Submissions in My Inbox</th>
<th>Not in My Inbox</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study team member or study's primary contact</td>
<td>Pre-Submission</td>
<td>Completed the study forms. The PI must submit it to the IRB to let the review begin.</td>
</tr>
<tr>
<td></td>
<td>Clarification Requested</td>
<td>Change the study to clarify as needed, and provide summary notes to the IRB when submitting the changes.</td>
</tr>
<tr>
<td></td>
<td>Modifications Required</td>
<td>Modify the study to meet IRB requirements and submit it with changes.</td>
</tr>
</tbody>
</table>

**Note:** Any team member can make changes to the study, but the PI must personally submit the changes or response to the IRB.
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.
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

![Workspace Diagram]

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:
  
  - Save - Saves your work for the current page
  - Exit - Exits the study and returns you to the Study Workspace
  - Hide/Show Errors - Performs a check on every page within the study to ensure that all required fields have been completed
  - Print - Prints the current SmartForm page
- **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 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.

\[\text{NOTE: Indicating that an external IRB will act as the IRB of record will lead to a much shorter set of SmartForms and an abbreviated workflow routing.}\]

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 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.

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


\[\text{NOTE: Please use the HRP-503 Template Protocol or HRP-508 Template Site Supplement to Sponsor which can both be located in the Library on the Templates tab.}\]

- 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.

\[\text{NOTE: If changes to the protocol are requested by the IRB, use the Update button to replace the current version of the document with an updated one.}\]
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.
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

NOTE: This page will only appear in the study if you answered ‘yes’ to question 1 on the Study Scope.

1. To list a drug, click the Add button. You must include all 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

**NOTE:** This page will only appear in the study if you answered ‘yes’ to question 2 on the *Study Scope* page.

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.

<table>
<thead>
<tr>
<th>For each IDE/HDE number, one of the following must be provided:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor protocol with the IDE/HDE number</td>
</tr>
<tr>
<td>Communication from the FDA or sponsor with the IDE/HDE number</td>
</tr>
</tbody>
</table>

• 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:
     o Signed Consent Documents
     o Assent Documents for Children
     o Parental Permission Documents
     o Verbal Consent Scripts
     o 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:
• Verbal Scripts
• Flyers
• Mailings
• Text for e-mail
• Newspaper advertisements
• Web pages (links are not acceptable, print the page to a pdf)
• 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](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**.
1. On the Final Page, click the Save and Continue button to go to the Study Workspace.

2. Clicking Save and Continue DOES NOT submit your protocol for review. You must use the Submit option in the Study Workspace to submit your protocol for review.
Page left intentionally blank
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 must 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.

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

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


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.

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.

<table>
<thead>
<tr>
<th>Do you need to make any modifications to the Study’s information, personnel, protocol, consent documents, recruitment materials, instruments, or any other documentation?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you closing or renewing the Study at this time?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>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?</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Submit Modification & CR

Was the Study was previously approved in IRBNet and this is the 1st Modification/CR in the Click Portal?

Yes

No

Submit Modification & CR

Submit Modification & CR

Submit Modification & CR

NOTE: In most cases only one 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.

2. Research milestones: (select all that apply)

- Study is permanently closed to enrollment OR was never open for enrollment
- All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- Remaining study activities are limited to data analysis
- Study remains active only for long term follow up of subjects

Important: If the first four research milestones above are complete, the study will be closed to discontinue the oversight.

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

4. Check the items that are true since the last IRB approval (initial review or last continuing review) for all sites involved in the study:

- No subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- No subjects withdrew from the study
- No unanticipated problems involving risks to subjects or others
- No complaints about the study
- No publications in the literature relevant to risks or potential benefits
- No interim findings
- No multi-center trial results
- No data safety monitoring reports
- No regulatory actions that could affect safety and risk assessments
- No other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

5. Attach supporting documents: (include an explanation of each item left unchecked above)

There are no items to display.
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:
  - 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.
  - 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’
  - 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)’
  - 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)’
  - First, see the above two bullets.
  - If you have **completely de-identified** all data, even though it was at one time identifiable, you could now check this box.
  - 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.
  - 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).

- 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.

- 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’
  - Writing and publication are also considered a part of ‘data analysis’.
  - 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’
  - 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

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
4. Checklist of Items

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

4. Check the items that are true since the last IRB approval (initial review or last continuing review) for all sites involved in the study:

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

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

[Check all that apply]
- Current subjects will be notified of these changes
- Former subjects will be notified of these changes

Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.
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**

   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.