

UB Click IRB Step by Step Guide

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Very Important General Tips

1. **CLOSE ALL OTHER INTERNET SESSIONS IN THE BROWSER THAT YOU ARE USING TO ACCESS CLICK.** The UBIT login mechanism required by CIT sometimes fails when you have other internet sessions open in the same browser.
2. Nothing that you enter is set in stone. You can always go back and freely edit items before submitting. Almost anything can be changed after approval by submitting a modification for subsequent approval. Clicking the help icons (🔗) will give you more information about questions/fields.
3. When completing fields like names of study personnel and funding, **TYPE SLOWLY** so that the internet connection can narrow down the choices based on your typing- try it you will see what I mean.
4. The **Bubbles** near the top of the page are a good way to keep track of the status of your submittal. As the study progresses through the approval process, the highlighted (darker) bubble will progress through the graphical representation. The activities allowed in the **My Current Action** Menu will vary and are dependent on both your role on the study and the status of the submittal. More information on **My Current Actions** is contained later in this guide.

IRB > Football Study

STUDY00000090 : Football Study

Principal investigator: CHRISTIAN MARKS
 Submission type: Initial Study
 Primary contact: [REDACTED]
 IRB office: 030 University at Buffalo (IRB)

Entered IRB: [REDACTED]
 Initial approval: [REDACTED]
 Effective: [REDACTED]
 Approval end: [REDACTED]
 Modified: 1/12/2016 10:38 AM

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested (between Pre-Review and IRB Review)
 Clarification Requested (between IRB Review and Post-Review)
 Modifications Required (between Post-Review and Review Complete)

My Current Actions

Edit Study

History Funding Project Contacts Documents Reviews Snapshots

5. When attaching files like the protocol, consent documents, etc. for the first time, click the **Add** button to bring up an add attachment window. If changes are requested by the IRB or another reviewing board, or when providing an amended version in a subsequent submittal, use the **Update** button to replace your old version with a new version using the edit attachment window so that the document history is maintained.

* Attach the protocol: ?

Add

Document	Category	Date Modified	Document History
Guide to OLD HRP-503.docx(1-12-2016)	IRB Protocol	1/12/2016	History

Update

Use one of the templates in the IRB Library

6. When asked to make changes in a submittal document, or when you need to make a modification/amendment, be sure to upload your documents in the appropriate section of the

study smartform by selecting “Edit Study” so that they can become a part of the approved documents and **NOT in the supporting documents section of a comment window.**

Execute "Add Comment" on STUDY00000090 - Internet Explorer

https://pacsprd1.rfsuny.org/Compliance/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity%5B0ID%5B17BF1A8B

Add Comment

Your comment is visible to anyone who has access to this submission.

1. Comment:

2. Supporting documents:

Add

Name	Description
There are no items to display	

3. Who should receive an e-mail notification?

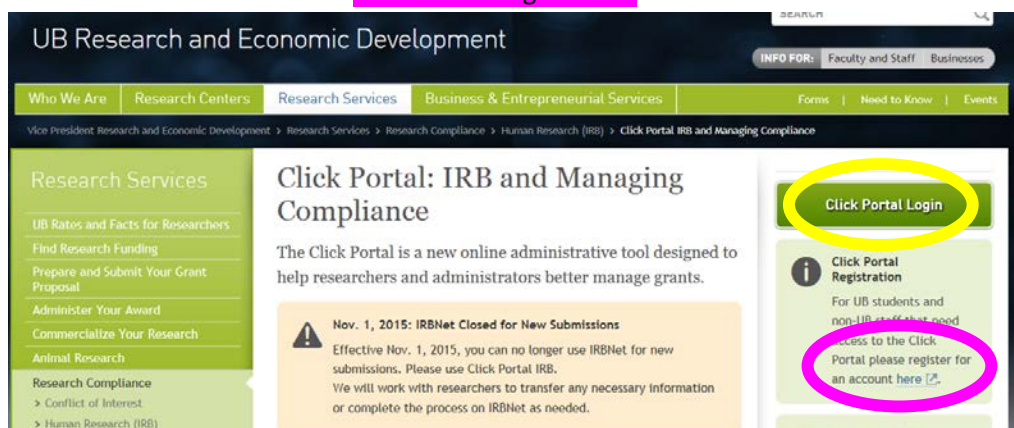
PI/PI Proxy/Primary Contact

7. When editing documents to be uploaded (e.g. protocol, consent documents, etc.), when possible use word document (.docx) file types.
 - a. Indicate changes using the TRACK CHANGES functionality. Use as a starting document whichever is the most current of the following:
 - i. The **MOST RECENT APPROVED** document with all previously reviewed tracked changes accepted.
 - ii. The **most recently reviewed** document (usually you should accept any previously tracked changes before starting a new round of track changes).
 - b. Do NOT highlight, use different colors or strikethrough characters (except of course as they automatically occur using track changes).
 - c. Version dates on documents need to be updated with each modification.
 - d. Before saving the copy for upload, be sure to look at the final (as opposed to the final showing markup) version to verify that your edits do not cause funny things to happen with your pagination and formatting.
 - e. Failure to adhere to the above may result in unsatisfactory appearance of approval documents. In order to correct something like this you will need to wait for a subsequent amendment to be approved.

Accessing / Registering for access to the click system

NOTE- CLOSE ALL OTHER INTERNET SESSIONS IN THE BROWSER THAT YOU ARE USING TO ACCESS CLICK. The UBIT login mechanism required by CIT sometimes fails when you have other internet sessions open in the same browser.

1. Try this first. For UB personnel (with a UBIT name and password)
 - a. Click on the **Click Portal Login** button (see diagram below) on the IRB or other webpage.
 - b. Enter your UBIT name and password.
 - c. If you have forgotten your UBIT name or password, you can use the links on the login page or contact CIT for assistance.
2. If the above does not work, you will probably need to request an account by
 - a. Accessing the click portal implementation page at <http://www.buffalo.edu/research/research-services/compliance/irb/click-irb.html>
 - b. Follow the “here” link under **Click Portal Registration**.



- c. Provide the information requested in the request account section (shown below) and click the register button. Be sure to select UB as your campus affiliation. You will usually receive an e-mail when your account has been activated. Note that there is a **human being** who activates the accounts so it happens only during business hours.

Request Account

If you need an account in this system, please apply by submitting your details using the following form. You will be contacted once your setup is complete.

Please complete the following details

* **First Name:**

* **Last Name:**

* **Campus Email Address:**

Phone Number:

Campus Login ID:

* **Campus Affiliation:** 030 University at Buffalo

* Required

Creating a New Study / Editing an Existing Study

Creating or Accessing a Study

The screenshot shows the Click IRB system interface. At the top, the user is logged in as 'CHRISTIAN MARKS'. The 'Home' link is circled in yellow. The 'My Inbox' link is also circled in yellow. In the 'My Current Actions' section, the 'Create New Study' button is circled in green. The 'Compliance Tasks' and 'SPO Tasks' folder tabs are circled in brown. A table of studies is shown with the 'Football Study' name circled in pink.

ID	Name	Date Created	Date Modified	State	Coordinator
STUDY00000090	Football Study	11/20/2015 1:07 PM	1/12/2016 10:38 AM	Pre-Submission	

When entering Click for the first time you should see a screen much like the one shown above. If not, you may need to click on either **IRB** or **My Inbox** in order to access the IRB module for your own account. You may also need to navigate using the **folder tabs** (these will sometimes differ depending on your view) in order to locate a particular study.

In order to create a new study, click **Create New Study**. This will take you to the Basic Information Page of the SmartForm.

To edit an existing study that has not been submitted yet, click on the study's **Name** in your list and then click on **Edit Study** in the study page (shown below). If your list is long (either because you are listed on a lot of studies or because you are also an IRB member) it can be sorted and filtered by a number of fields so that you can select the study you are interested in working with.

The screenshot shows the Click IRB system study page for 'Football Study'. The 'Edit Study' button in the 'My Current Actions' section is circled in green. The study details and workflow diagram are visible.

STUDY00000090 : Football Study

Principal investigator: CHRISTIAN MARKS
 Submission type: Initial Study
 Primary contact: CHRISTIAN MARKS
 IRB coordinator:

IRB office: 030 University at Buffalo (IRB)

Entered IRB:
 Initial approval:
 Effective:
 Approval end:
 Modified: 1/12/2016 10:38 AM

Workflow diagram: Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete. Clarification Requested and Modifications Required are shown as feedback loops between Pre-Review and IRB Review, and between IRB Review and Post-Review respectively.

My Current Actions: Edit Study (circled in green), View Differences, Submit

History: Funding, Project Contacts, Documents, Reviews, Snapshots

Filter by: Activity, Author, Activity Date

Activity: Attestation Reminder, Author: Administrator, System, Activity Date: 11/30/2015 3:04 AM

Basic Information Page

Click
a smart system

You Are Here: Football Study

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: Basic Information

Continue >>

Update the IRB Submission due to one or more errors:
Please select whether the investigator has a financial interest in the research.

Basic Information

- Title of study:**
Can Charlie Brown Kick that Football without Falling Down?
- Short title:**
Football Study
- Brief description:**
Charlie runs up and tries to kick the ball and it is pulled away from him just as he kicks.
- Principal investigator:**
CHRISTIAN MARKS Select... Clear
- Does the investigator have a financial interest related to this research?**
 Yes No Clear
- Will an external IRB act as the IRB of record for this study?**
 Yes No Clear

Protocol:

Add

Document	Category	Date Modified	Document History
HRP-503.docx(1-12-2016)	IRB Protocol	1/12/2016	History

Update

Delete

Use one of the templates in the IRB Library

Navigation within the pages of the Smartform can be achieved by using the **Back** and **Continue** buttons located at the top and bottom of the page or the **menu in the top center of the page**. You must complete all fields denoted with an asterisk (*) before leaving a page or else you will be given an **error message**.

Clicking the help icons (?) will give you more information about questions/fields.

The **Short Title** is the field that is visible to you in the system so be sure to make this unique across your projects.

Type a last name into the **principal investigator field** to bring up a list of potential UB affiliated personnel to select from. If the last name is very common, you may have to type a comma (,) followed by the first name as well in order to select the correct person. You can also sort through an alphabetical list in the select person pop up window by clicking the select button.

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) or when there is corporate sponsorship of a study. **For additional Financial Interest info See HRP-211 (paper initial review form) and <http://www.buffalo.edu/research/research-services/compliance/coi.html>**

In all but the rarest of cases at UB and affiliated hospitals, **an external IRB will NOT** be acting as the IRB of record; the UBIRB will be the IRB of record. For an external IRB to act as the IRB of record an agreement between the institutional officials (usually upper level administrators in the VP Research office) at both institutions must enter into a written agreement to do so.

Attach Protocol. Only HRP-503 or (HRP-508 and Sponsor’s Protocol) should be attached here. This will mean that there will only ever be 1 or 2 documents (depending upon whether or not this is an industry sponsored trial) attached here. Other documents are uploaded in later sections of the application webpages. When attaching your protocol for the first time, click the **Add** button to bring up an add attachment window. If changes are requested by the IRB or another reviewing board, or when providing an amended version, use the **Update** button to replace your old version with a new version using the edit attachment window so that the document history is maintained.

Funding Sources Page / Add Funding Sources Window

If your project is unfunded, just click the continue button. If you have or anticipate funding for the project, Click the Add button to bring up the **Funding Sources Window (shown below)** and add a funding source to the list. If there are multiple sources for the funding, click add again to add a subsequent funding source.

Add Funding Source

1. ***Funding organization:**

national institute of a

Name	Category	Parent Organization
National Institute of Advanced Industrial Science and Techno	Sponsor	
National Institute of Aerospace	Sponsor	
National Institute of Allergy and Infectious Disease	Government Sponsor	
National Institute of Arthritis Musculoskeletal and Skin	Government Sponsor	

Non-Federal
 Pharma/Device
 Other

2. **Sponsor's funding ID:** (assigned by external sponsor)

3. **Grants office ID:** (assigned internally)

4. **Attach files:** (include any grant applications)

Document	Category	Date Modified	Document History
There are no items to display			

In the **Funding Organization field**, type the first few letters in the name of the funding organization. Give the system a little bit of time to update and search for your source before typing in more letters if needed (see how the example above works to search). Abbreviations such as NSF and NIH do not work so please type out the complete words like National Institutes of Health.

The Sponsor's funding ID and Grants office ID should be provided if known.

The **grant application must be provided** as an upload in the **Attach Files** field.

Study Team Members / Add Study Team Member

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Study Team Members ▾

Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

	Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone	Date Attested
Update	LYNN JAGODZINSKI	Investigator	no	yes	lynnjago@buffalo.edu	(716)888-4843	Delete
Update	Jenna Sunderlin	Study Team Member	no	yes	jls39@buffalo.edu		Delete

2. External team member information:

	Name	Description
Upload Revision	Peppermint Patty Reichardt	
Upload Revision	van Pelt, Lucy	

Who should be listed as Internal Personnel vs. External Personnel

- Identify each additional person involved in the design, conduct, or reporting of the research
- If a person is unknown at this time (e.g. you don't know who the undergrads who will help are yet or have not yet hired your coordinator) don't worry about it- you will just submit a personnel amendment at a later date when they do become known.
- The Principal Investigator given on the Basic Information page need not be relisted.
- Most people with active UBIT Name and passwords who have been "employed" in any capacity at UB (including graduate students on RA/GA/TA lines) will be accessible as internal personnel (see Adding internal personnel below).
- Collaborators who will be covered under their own institution's IRB protocol should **NOT** be listed as personnel on this protocol at all.
- Get a person added as internal if they will need access to the protocol and consent forms from Click. They will need a volunteer appointment from your department to obtain a UBIT name and password. It may take a day or two after they obtain a UBIT name for the list to update.
- External Personnel should not be added unless they are truly external and will be covered under this protocol (for example a one-time assistance from a local teacher in an education project in a school).

Adding Internal Personnel

Add Study Team Member - Windows Internet Explorer

https://pacsprd1.rfsuny.org/Compliance/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=1&form=0&c

Add Study Team Member

1. * **Study team member:**

2. **Role in research:** (check all that apply)

- Research Assistant
- Bio-Statistician
- Study Nurse
- Clinical Coordinator
- Study Coordinator
- Investigator
- Study Team Member
- Faculty Advisor
- Student Researcher

3. * **Is the team member involved in the consent process?**
 Yes No

4. * **Does the team member have a financial interest related to this research?** Yes No

* Required

Type a last name into the **study team member field** to bring up a list of potential UB affiliated personnel to select from (to see the way this works, just try it or look at the funding organization example above). If the last name is very common, you may have to type a comma (,) followed by the first name as well in order to select the correct person. You can also sort through an alphabetical list in the select person pop up window by clicking the select button.

For the **Role in Research**, don't worry that a perfect fit is not in the list, just pick the closest role(s) - e.g. Investigator for Co-PIs, bio-statistician for any type of statistician.

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) or when there is corporate sponsorship of a study. **For additional Financial Interest info See HRP-211 (paper initial review form) and <http://www.buffalo.edu/research/research-services/compliance/coi.html>**

Adding External Personnel

The screenshot shows a web browser window with the address bar displaying <https://pacsprd1.rfsuny.org/Compliance/ResourceAdministration/Document/FormForProperty?postback=18>. The page title is "Submit a Document". The form contains the following elements:

- Title:** A text input field containing "van Pelt, Lucy". To its right is a small "x" icon and the text "If not provided, the name of the file will be used".
- * File:** A text input field with a red asterisk to its left. To its right is a "Browse..." button.
- Show Advanced Options:** A button located below the "File" field.
- * Required:** A label indicating that the "File" field is required.
- Buttons:** "OK", "OK and Add Another", and "Cancel" buttons are located at the bottom of the form.

Each external Person should be uploaded individually to their own line using a separate copy of the **External Study Team Member Information Form** that can be obtained from the Click IRB Library.

For the **Title** of the file, use the person's Last Name comma (,) First Name.

For the **File**, a separate attachment must be provided for each person. Use the Browse button to select the file from your local computer. The **External Study Team Member Information Form** file attachment must be a word document. The form requests the following information about the external person:

- Name
- A brief (1-2) sentence description of their role on the study (use the categories for the internal team member in click for this).
- A statement of whether or not the person has a financial interest related to the research.
- A statement of whether or not the person will be involved in the consent process.
- Contact information (address, phone number, e-mail).
- The name of the Institution/Company that the person is affiliated with.

Study Scope

Study Scope

1. * Are there external sites where the investigator will conduct or oversee the research?

Yes No [Clear](#)

2. * Does the study do any of the following:

- 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 or condition?

Yes No [Clear](#)

3. * Does the study do any of the following:

- Evaluate the safety or effectiveness of a device?
- Use a humanitarian use device (HUD)?

Yes No [Clear](#)

Each question on the study scope page triggers additional pages so if you answer “no” to all three of these, the next three sections of this guide will not be relevant. The last 2 questions are pretty straight forward and require little explanation in that they obviously pertain to the use of drugs and medical devices within the study.

Are there external sites where the investigator will conduct or oversee the research?

This is sometimes a complex question. The bullets below cover the most common situations. Contact the CRO or BRO if you have questions about external sites.

- Kaleida hospitals/clinics and ECMC are considered to be Internal, NOT External.
- The term “external sites” generally means other institutions that are engaged in the research as a part of the function of the institution
 - Businesses performing commercial services related to the research (e.g. the Buffalo News running your advertisement, a lab that is contracted to do standard blood analysis, a transcription service) are NOT engaged and need not be listed as external sites.
 - Conducting interviews at a local Tim Horton’s would NOT be considered an external site.
 - Conducting research at a local school would NOT usually be considered an external site unless the school personnel involved were members of the research team assisting on the project as a condition of their job (as opposed to a couple of teachers who are voluntarily assisting with the research or allowing access to their classroom for you to do the research).
- External sites most often occur when there is a grant funded project that is being done in collaboration with another institution who is also receiving part of the grant funding

External Sites / Edit External Site

External Sites



1. * Identify each external site where the investigator will conduct or oversee the research:

Site	Contact	Phone	E-mail	External IRB Review	Rely on This IRB
There are no items to display					

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: External Sites Continue >>

Add External Site

Edit External Site

- * **Site name:**
- * **Contact name:**
- * **Contact phone:**
- * **Contact e-mail:**
- * **Will the external site's IRB review the research?** 
 Yes No [Clear](#)
- * **Will the external site rely on this institution's IRB?** 
 Yes No [Clear](#)

* Required

The first 4 questions require no significant explanation except to say that the person for whom contact information is provided should probably be the party that is heading up the effort at that site, i.e. the Co-PI or coordinator at that site.

Questions 5 and 6 have institutional ramifications as well as ramifications for the protocol and associated materials to be reviewed by the UBIRB. Usually one of these two items must be a “yes” response.

When an external site will rely on UB’s IRB:

- An agreement between the institutional officials (usually upper level administrators in the VP Research office) at both institutions must have/enter into a written agreement to do so.
- The protocol reviewed by the UBIRB must completely cover the research activities to be carried out at both UB and the other site(s). Personnel from the other institution(s) will need to be specified in this application and may have to meet UB’s requirements for things like training (CITI) and/or Conflict of Interest.

When an external site will NOT rely on UB’s IRB:


- Each site's IRB may review and approve the research activities to be performed at its own site so the protocol reviewed by the UBIRB usually will not need to cover the research activities to be carried out at the other site(s). Personnel from the other institution(s) should not be specified in this application unless otherwise directed to do so by the IRB (after review).

Drugs / Add Drug Information Window

Drugs

1. * List all drugs, biologics, foods, and dietary supplements to be used in the study:

Type	Generic Name	Brand Name	IND Exempt	IND Number	IND Holder	Other Holder	Attachments
There are no items to display							

2. Attach files: (such as IND or other information that was not attached for a specific drug) 

Document	Category	Date Modified	Document History
There are no items to display			

On the Drugs page, question 1 must cover ALL drugs that are a part of the protocol whether or not they are investigational.

On the Drugs page, question 2 should be used only when materials have not already been uploaded for a specific drug in the Drug Information Window. For each IND covered in the study, one of the following must be provided in either this question or the Drug Information Window:

- Sponsor protocol with the IND number
- Communication from the FDA or sponsor with the IND number

Add Drug

Add Drug Information


1. **Drug Type:**

Investigational

Off-label use of a marketed drug

Marketed drug used according to label


Clear

2. **Select the drug:** 

If you cannot find the drug in the list above, enter its information here:

Generic name:

Brand name:

3. **IND Number:** 

OR

This drug is IND exempt:

4. **Who holds the IND?**

Sponsor

Investigator

Other

On the Add Drug Information Window, while none of the questions are marked as required, you should consider them to be so when applicable (i.e. if a drug is indicated as investigational in question 1 and you don't answer question 3, the IRB will return your study to you without reviewing it, resulting in possible significant delays).

Devices and Related Pages

Devices

1. * **Select each device the study will use as an HUD or evaluate for safety or effectiveness:**


Add		
Device	Humanitarian Use Device	Attachment Name
There are no items to display		

2. * **Device exemptions applicable to this study:** 

IDE number
 HDE number
 Claim of abbreviated IDE (nonsignificant risk device)
 Exempt from IDE requirements
[Clear](#)

3. **If applicable, identify each IDE and HDE number:**

Add		
IDE / HDE Number	IDE/ HDE Holder	Other Holder
There are no items to display		

4. **Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device) 

Add			
Document	Category	Date Modified	Document History
There are no items to display			

Like the Drugs Page, while some of the questions are not marked as required, you should consider them to be required when applicable (i.e. if a device is indicated as being studied under an IDE, and you don't provide the IDE number and documentation from the sponsor (such as a copy of investigator brochure and the product labeling/device instructions), the IRB will return your study to you without reviewing it, resulting in significant delays).

The scope of the Devices page is slightly different from that of the Drugs page in that only those devices that are used as an HUD or evaluated for safety and effectiveness on human subjects as part of this study need to be listed. In particular, include all information the IRB needs to identify and evaluate any device with exemptions or claimed exemptions. Also attach information from the study sponsor or the FDA verifying the exemption status of each exempt device.

HUD: The designation of humanitarian use device (HUD) applies to devices intended to benefit patients by treating or diagnosing a disease or condition that manifests itself in fewer than 4,000 individuals in the United States per year. The HUD designation provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

IDE #: An 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.

HDE #: A 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.

Abbreviated IDE: The device is considered to pose nonsignificant 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.

Consent Forms and Recruitment Materials

Consent Forms and Recruitment Materials

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable)

Document	Category	Date Modified	Document History
Adult Consent Form(1)	Consent Form	1/15/2016	History

Refer to the templates and instructional documents in the IRB Library

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

Document	Category	Date Modified	Document History
There are no items to display			

Consent and recruitment materials are the **ONLY** items that should be uploaded on this page. See guidance at the beginning of this document regarding using the **Add** button and **Update** button for attaching documents.

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)

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 provide only the text, you will need to provide the final form via an amendment at a later date.

CITI Training Page

The CITI training page is only available for initial study submittal (not for renewal or modification). There are currently no active controls for changes to be made to this page.

The CITI training page shows CITI course completion for all members of the research team that can be automatically read in by Click. There are currently a few glitches with the system in that the use of different e-mail addresses in the university feed being used to generate accounts and the address used in CITI differ, the automatic read in does not connect to bring in the information.

When the above glitch occurs, the IRB is currently manually verifying CITI completion for all personnel. In order to ensure that your protocol is not delayed, you should verify that all personnel have completed the appropriate CITI training (below Section on Working with CITI).

See the Working with CITI section of this document for further information and UB IRB required courses.

Supporting Documents

Supporting Documents

Attach supporting files, naming them as you want them to appear in the approval letter:

Document	Category	Date Modified	Document History
There are no items to display			

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

See guidance at the beginning of this document regarding using the **Add** button and **Update** button for attaching documents.

- Supporting Documents that are uploaded in other sections **should NOT be uploaded in this section.**
- All other supporting documents (Study Instruments, HRP-504 (Schools), HIPAA docs., Additional Forms.) should be uploaded in this section.
- Name the document **as you want it to appear in the approval letter.** If you don't, and for some reason need to have the document name changed in your approval letter, you will have to wait for another amendment to be approved.
- Do not upload IRB Worksheets or Checklists unless requested by the IRB.

Hide/Show Errors

The screenshot shows the Click IRB submission interface. At the top, the Click logo is visible. Below it, the breadcrumb trail reads "You Are Here: Football Study". A navigation bar contains a "<< Back" button, a "Save" button, a "Hide/Show Errors" link (circled in yellow), a "Print" button, a "Jump To:" dropdown menu, and a "Basic Information" dropdown menu. A red error message is displayed: "Could not update the IRB Submission due to one or more errors: Validation Failed: You must select whether the investigator has a financial interest." Below the error message, the "Basic Information" section is visible, containing three required fields: "1. * Title of study:" with the text "Can Charlie Brown Kick that Football without Falling Down?", "2. * Short title:" with the text "Football Study", and "3. * Brief description:" with the text "Charlie runs up and tries to kick the ball and it is pulled away from him just as he kicks."

Studies with incomplete information will be returned to the research team for updates. After navigating through all of the SmartForms and completing all of the required fields, Click the **Hide/Show Errors link** near the top of the SmartForm page to display any **unanswered questions**.

If there are no error messages, you have entered information in all required fields. This does not however mean that changes will not be needed/requested as the computer can only check whether or not a field is complete but cannot make a qualitative evaluation of what is written/attached.

Submitting

STUDY0000090 : Football Study

Principal investigator: CHRISTIAN MARKS
 Submission type: Initial Study
 Primary contact: CHRISTIAN MARKS
 IRB office: 030 University at Buffalo (IRB)

Entered IRB:
 Initial approval:
 Effective:
 Approval end:
 Modified: 1/15/2016 1:53

IRB coordinators:

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete

Clarification Requested → Clarification Requested → Modifications Required

My Current Actions

Edit Study
 Printer Version
 View Differences
 Submit
 Add Reviewer Grant
 Discard

Activity	Author	Activity Date
Attestation Reminder	Administrator, System	11/30/2015 3:04 AM
Attestation Reminder	Administrator, System	11/29/2015 3:04 AM
Attestation Reminder	Administrator, System	11/28/2015 3:04 AM
Attestation Reminder	Administrator, System	11/26/2015 3:05 AM

Your study has not been submitted just because you have completed the application and clicked the Finish Button on the Final Page. In order to send the submission for review, the **principal investigator** must click **Submit** on the page above. Think of it like this, finishing the application is the equivalent in paper terms of putting everything in an envelope and sealing it but until you put a stamp on it and drop it in the mailbox (by clicking the submit button), consequently the IRB doesn't have your study for review.

When you click the submit button you will see three things happen on the page after it refreshes.

1. The **status bar** in the upper left will change from Pre-Submission to Pre-Review.
2. The darkened bubble in the graphic will move from **Pre-Submission to Pre-Review**.
3. The history will show as the most recent action, a **Submitted activity**.

Working with CITI

YOU DO NOT NEED TO PAY FOR CME CREDIT FOR PURPOSE OF UB'S HUMAN SUBJECTS REQUIREMENTS. If you wish to obtain CME credit, you may do so at your own expense.

The screenshot shows the CITI Training interface. It has a navigation bar at the top with options like '<< Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print...', 'Jump To:', 'CITI Training', and 'Continue >>'. The main content is titled 'CITI Training' and is divided into two sections:

- 1. PI Completed CITI Coursework:** This section shows a table for PI CHRISTIAN MARKS. The table has columns for Curriculum, Group, Stage, and Expire. A message below the table states 'There are no items to display'.
- 2. Study Team Members Completed CITI Coursework:** This section shows a table for study team members. The table has columns for Name, Curriculum, Group, Stage, and Expire. The 'Group' column is highlighted in yellow, and the 'Expire' column is highlighted in pink. The data rows are:

Name	Curriculum	Group	Stage	Expire
Jenna Sunderlin	Human Research	Biomedical Research Investigators	Basic Course	9/23/2013
LYNN JAGODZINSKI	Human Research	Social & Behavioral Research Investigators	Basic Course	9/2/2014
CHRISTIAN MARKS	Human Research	Social & Behavioral Research Investigators	Refresher Course	9/2/2017
SARAH REILLY	Human Research			

There are no fields to update on the CITI Training Page. The page does however allow you to help ensure that your project will not be held up because a member of your research team has not completed the required courses. As stated previously, there are a few glitches with the connectivity between Click and CITI so, even when complete, not all records will show up on this page correctly as completed. When the course shows up **as complete here**, and the **expiration date** is not imminent, you need do nothing. If a completion record for a given person does not show up here, the IRB manually checks to ensure that all required CITI courses are completed before your study will be sent for review.

In order to minimize any delays, you should:

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 (in other words, when you get it from someone, hang on to it just in case).

Logging into CITI

YOU DO NOT NEED TO PAY FOR CME CREDIT FOR PURPOSE OF UB'S HUMAN SUBJECTS REQUIREMENTS. If you wish to obtain CME credit, you may do so at your own expense.

To log into CITI, go to www.citiprogram.org

1. Returning users can then enter their username and password.
2. If you have forgotten your username or password, use the Forgot Username or Password link on the login page.
3. 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 @buffalo.edu e-mail address for any e-mail addresses requested.

English Text size: A A Christian Marks ID: 419218 | Log Out | Help

CITI PROGRAM Collaborative Institutional Training Initiative at the University of Miami Search Knowledge Base

Main Menu My Profiles My CEUs My Reports Support Admin

Main Menu

✔ Your request has been successfully submitted.

- DEMO Courses
- Department of Psychology Courses
- SUNY - Buffalo (University at Buffalo) Courses**

	Status	Completion Report	Survey
Biomedical Research Investigators	Incomplete	Not Earned	
Social & Behavioral Research Investigators	Passed 11/23/2015	Print Report	Post-course evaluation

My Learning Center (SUNY - Buffalo (University at Buffalo))

- Add a Course or Update Learner Groups**
- View Previously Completed Coursework
- Update Institution Profile
- Remove Affiliation

Click here to affiliate with another institution

Affiliate as an Independent Learner

- If you have never had a CITI account, Create a New Account 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 [@buffalo.edu](#) e-mail address for any e-mail addresses requested.

Accessing Required CITI Courses

YOU DO NOT NEED TO PAY FOR CME CREDIT FOR PURPOSE OF UB’S HUMAN SUBJECTS REQUIREMENTS. If you wish to obtain CME credit, you may do so at your own expense.

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 by CITI to your UB CITI courses (please don’t ask the IRB which ones- CITI handles this automatically within its software when you add another institution to a current account).

First, verify that you are affiliated with UB within CITI by checking that you have a listing for “[SUNY-
Buffalo \(University at Buffalo\)](#)” on the CITI main menu page. If not, you must first click on the “[Click here to affiliate with another institution](#)” link toward the bottom of the CITI Main Menu page and select “SUNY-[Buffalo \(University at Buffalo\)](#)” when prompted. Be certain to enter your [@buffalo.edu](#) e-mail address for any e-mail addresses requested.

If the appropriate courses that you want to take are showing as available on the main menu under “UB” then you can just click on the course name to enter the course. If not, you can add the appropriate courses to your UB affiliation by clicking the “[Add a Course or Update Learner Groups](#)” link within your UB affiliation. This will take you to the Select Curriculum - SUNY - Buffalo (University at Buffalo) page where you can select the appropriate courses.

CITI Courses Required

YOU DO NOT NEED TO PAY FOR CME CREDIT FOR PURPOSE OF UB'S HUMAN SUBJECTS REQUIREMENTS. If you wish to obtain CME credit, you may do so at your own expense.

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 (part 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.

Question 2

Human Subjects Research

You are required to take one of the following courses according to the type of research being conducted:

Choose one answer

For protocols submitted and reviewed by the HSIRB or the CYIRB – complete the BIOMEDICAL course

For protocols submitted and reviewed by the SBIRB – complete the SOCIAL/HUMANISTIC/BEHAVIORAL course

Researchers and staff who are conducting both Biomedical and Social/Behavioral research, may have to complete BOTH courses

Refresher

Question 3

Additional Courses

If you would like to take additional courses, please make your selection below.
THESE COURSES DO NOT FULFILL THE HUMAN SUBJECTS RESEARCH EDUCATIONAL REQUIREMENT!

Choose all that apply

Good Clinical Practice Course (GCP)

Health Information Privacy and Security (HIPS/HIPAA)

IRB Chairs

Question 4

RCR-Responsible Conduct of Research

If you want to take Responsible Conduct of Research (RCR) Course, please make your selection below.
THE RCR COURSE DOES NOT FULFILL THE HUMAN SUBJECTS RESEARCH EDUCATIONAL REQUIREMENT!

Choose all that apply

Biomedical Responsible Conduct of Research Course

Social and Behavioral Responsible Conduct of Research Course

Physical Science Responsible Conduct of Research Course

Humanities Responsible Conduct of Research Course

Responsible Conduct of Research for Administrators

You may choose to sign up for any of the other courses presented that UB has subscribed to but these have nothing to do with and will not be credited toward the IRB's educational requirements.

Verification of CITI

As stated previously, if the CITI records show complete in Click, you need do nothing. However, when they are not showing as complete (as the records for Christian Marks are not showing as complete in the Click image at the beginning of the Working with CITI section), you should obtain documentation to verify that all your personnel have completed the required courses. The best way to do this is to get your people to do a Print Screen of their CITI main menu page that, like the image below, shows their **Name**, **UB Affiliation** and the **appropriate UB courses** (minimize any other institutions) with a status of “Passed” within a 3 year time frame. This image can then be pasted into a word document and sent to you and if needed, forwarded to the IRB in Click.

English Text size: A A Christian Marks ID: 41918 | Log Out | Help

CITI PROGRAM Collaborative Institutional Training Initiative at the University of Miami Search Knowledge Base

Main Menu My Profiles My CEUs My Reports Support Admin

Main Menu

✔ Your request has been successfully submitted.

- DEMO Courses
- Department of The Navy Courses
- SUNY - Buffalo (University at Buffalo) Courses**

Course	Status	Completion Report	Survey
Biomedical Research Investigators	Not complete	Not Earned	
Social & Behavioral Research Investigators	Passed 11/23/2015	Print Report	Post-course evaluation

My Learner Tools for SUNY - Buffalo (University at Buffalo)

- Add a Course or Update Learner Groups
- View Previously Completed Coursework
- Update Institution Profile
- Remove Affiliation

Click here to affiliate with another institution

Affiliate as an Independent Learner

Clarification Requested and/or Modifications Required

At several points during the review process, the IRB may request clarifications or require modifications from the research team prior to making a determination.

1. Log into Click Portal and navigate to My Inbox (see Creating or Accessing a Study).
2. Find the submission requiring clarifications or modifications and click on the submission name to navigate to the submission workspace (see Creating or Accessing a Study). Investigators can also navigate directly to the submission workspace by clicking on the link in the email notification and logging into the system.
3. Review the requested information by clicking on the **Clarification Requested** activity (for most situations that are exempt, expedited or prior to full board review) in the history log, or by reviewing the **determination letter** (for most cases after full board review). You may want to copy and paste the changes requested to a separate document and/or print out for ease of reference.

The screenshot displays the Click IRB system interface. At the top, a process flow diagram shows the stages: Pre-Submission, Pre-Review, IRB Review, Post-Review, and Review Complete. Below this, the 'My Current Actions' sidebar is visible, with a pink circle around the 'My Current Actions' header. The main content area shows a 'History' tab with a filter set to 'Activity' and 'Clarification'. A yellow circle highlights the 'Clarification Requested' activity in the history table, which lists the author as 'BROWN, CAROL' and the date as '12/14/2015 2:52 PM'. Below the table, a message states: 'As this study was previously approved, you will need to submit a modification uploading all the previously approved documents. You will need to submit the protocol following the new toolkit template. If enrollment is ongoing, you will need to submit the consent following the new toolkit template. Please refer to number CR000000044 on the modification.' Below this, another 'History' tab is shown with a filter set to 'Activity' and 'letter'. A green circle highlights the 'Letter Sent' activity in the history table, which lists the author as 'MANN, GYLE' and the date as '12/7/2015 11:50 AM'. Below the table, a document link is visible: 'Correspondence_for_STUDY00000014.doc'.

4. Edit the submission by navigating to the SmartForm - click on the Edit Study, Edit Modification/CR, or Edit RNI button under My Current Actions. Make the changes requested and/or provide clarifications as requested (see Creating a New Study and its subheadings for how to edit/add items in the smart form pages).
5. When the changes have been made, the study PI must execute the **Submit Response** activity (listed under **My Current Actions**) to send the submission back to the IRB for review.
 - Anyone listed on the study can execute the Submit Response activity for RNI (Reportable New Information) submissions.

Submitting a Modification / CR (Continuing Review/Renewal/Closure)

Important- in most cases only one Modification/CR can be submitted at a time. There is no way for this functionality to be overridden by the IRB so plan accordingly.

The study you wish to access will not always be visible in the Compliance Tasks Tab of your Inbox because only those items that have a pending compliance task are listed there. In order to locate the study, click on **IRB** and then the **Active Tab** to list all active studies you have access to. If your list is long, you can use the **Filter by** function to more easily locate the study you are interested in working with at the present time. Click the name of the study that you wish to access in the list (See Creating or Accessing a Study).

The screenshot shows the Click IRB interface. In the top left, the 'Click' logo is visible. In the top right, the user is identified as 'CHRISTIAN MARKS | My Inbox | Logoff'. Below the logo, there is a navigation menu with 'Home' and 'IRB' (circled in green). The main content area is titled 'IRB' and contains a sidebar on the left with buttons for 'Create New Study' and 'Report New Information', and a list of 'Submissions', 'Meetings', 'Reports', 'Library', and 'Help Center'. The main area displays a list of studies with tabs for 'In-Review', 'Active', 'Archived', 'New Information Reports', and 'All Submissions'. The 'Active' tab is selected. A 'Filter by' dropdown menu is open, showing 'Last Name' with 'marks' entered in the search field. Below the filter, a table lists studies with columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, Coordinator, and Submission Type. One study is listed: 'STUDY00000090 Football Study' with a date of '1/15/2016 1:53 PM' and state 'Pre-Submission'. The PI names are 'CHRISTIAN' and 'MARKS', and the submission type is 'Initial Study'. At the bottom of the table, it shows '1 items' and 'page 1 of 1'.

Once you access the study page, you will be able to create a Modification / CR by clicking the **Create Modification/CR button** under my current actions. If this button is not available, it may mean that you already have a Modification/CR in the works (look at the **history** to verify this) so you cannot create another one until after the earlier item is approved.

The screenshot shows the study details page for '030-667445 : YWCA Virginia'. The status is 'Approved'. The principal investigator is 'THOMAS NOCHAJSKI'. The submission type is 'Initial Study'. The primary contact and IRB coordinator are listed. The IRB office is '030 University at Buffalo (IRB)' and the letter is 'None'. A flowchart shows the process: Pre-Submission -> Pre-Review -> IRB Review -> Post-Review -> Review Complete. There are also boxes for 'Clarification Requested' and 'Modifications Required'. Below the flowchart, there is a 'My Current Actions' section with buttons for 'View Study', 'History', 'Printer Version', 'Create Modification / CR', and 'Report New Information'. The 'Create Modification / CR' button is circled in blue. The 'History' button is circled in red. Below the 'History' button, there is a table with columns for 'Activity' and 'Author'. The table lists 'Continuing Review Deadline Reminder' with the author 'Administrator, System'.

Upon Clicking the Create Modification/CR you will be taken to the following page where you will need to specify the purpose and scope of the current submission. Click the appropriate radio buttons and checkboxes. Note that these choices **CANNOT BE UNDONE** once you click the continue button.

You Are Here: YWCA Virginia > [_IRBSubmission](#)

[<< Back](#)

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? [?](#)

Continuing Review
 Modification
 Modification and Continuing Review
[Clear](#)

Modification scope:

Study team member information
 Other parts of the study

Active Modification for This Study

[<< Back](#)

Modification, Continuing Review/Closure, or Both?

The following chart can be used to assist in determining which of the “purpose of this submission” options should be chosen. In cases where the modification scope includes changes to both team members and other parts of the study, both checkboxes should be checked.

Do you need to make any modifications to the study information, personnel, protocol, consent documents, recruitment materials, study instruments or any other study 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 Only	Submit Modification & CR	Submit Modification & CR but also indicate in the Modification Information # 3 that there are no changes being made at this time	Submit Continuing Review Only

Continuing Review / Study Closure Information

Continuing Review / Study Closure Information

1. * Specify enrollment totals:

Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:	<input type="text" value="1012"/>	<input type="text" value="1012"/>
Study-wide:	<input type="text" value="1012"/>	

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 IRB 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 [Clear](#)

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

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

Name

There are no items to display

When there are no modifications, the page above is the only one that needs to be completed for CR (renewal) or closure. If you also request modifications at the time of CR, you will then be taken to other pages to complete or make changes on.

1. Specify Enrollment Totals

You must complete all 3 fields by entering the totals.

- When there are multiple groups of participants (e.g. both participants who receive interventions and control participants in a drug trial, Parents, Teachers and Children in an education study, both partners in a study of romantic relationships) SUM UP ALL PARTICIPANTS.
- When a participants partake in research procedures at more than one point in time (e.g. a group of participants may take a pretest and then a posttest after a learning experience) count each person only once.
- In cases where an exact count cannot be obtained (carrying on with the example in the bullet above, if participation was anonymous and you collected 45 pretests and 52 posttests because during the learning experience some people may have left early, arrived late or maybe just chose not to fill one or the other item out) you should make your best estimate of the participation number. In my example here, unless you had other information to base the decision on, I would say that a reasonable estimate would be to say 52 participants.

- To obtain the number since last approval period by subtracting last year's figures from your total. If you need last year's figures, look at last year's renewal in Click or the information you provided last year in IRBNet on the continuing review form. Of course, if last year was your initial study approval, last year's count = 0.
- Studies that are not happening at multiple sites around the country (e.g. multi center drug/medical device trials, collaborative work between you and a researcher at another university) will typically provide the same number for study wide number of participants as for local number of participants at the investigator's sites.

2. Research milestones: (select all that apply)

The research milestones are very important because 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.

- **Important!** If the **first four** research milestones above 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 so that a study that has been completely "called off" without any subjects participation can be closed by the IRB.
- Study is permanently closed to enrollment OR was never open for enrollment. Check this when any of the following are true:
 - No further participants will be added (you are done recruiting and starting people on any study interventions or interactions)
 - You decide to call off the whole 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 and work on a different direction).
- All subjects have completed all study-related **interventions** OR not applicable (e.g. study did not include interventions, no subjects were enrolled).
 - Many studies do not use any interventions. For example, studies that include only records reviews or interview procedures would not usually contain interventions.
 - 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 investigator and subject.
- 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 (even though you don't have to do so until
- 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 Teddy 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 reasonably 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 subject.
 - 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) or when there is corporate sponsorship of a study. **For additional Financial Interest info See HRP-211 (paper initial review form) and <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 to the best of your knowledge after checking with your study staff to see if they encountered any issues that would not allow a box to be checked but do not overthink them. In other words, it is expected that in most cases there will be very few **or none** of the items in this list left unchecked.

5. Supporting Documents for the CR

- Most of the time, there will be no need to upload any supporting documents.
- Do NOT upload items that are a parts of the study itself (e.g. protocol, consent forms, advertisements, edited study instruments, investigator’s brochure, etc.) here. These are uploaded as a part of the study documentation (see the sections under Creating a New Study / Editing an Existing Study for guidance on this), not supporting documents for renewal.
- If one or more of the items in #4 Checklist of Items is 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.

Modification Information / Amendments

Modification Information


1. Study enrollment status:

- No subjects have been enrolled to date
- Subjects are currently enrolled
- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete

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.

3. * Summarize the modifications: 

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

When there are modifications, either on their own or as a part of a CR, the page above will be displayed. 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 modified documents (e.g. protocol, consent forms, advertisements, edited study instruments, investigator's brochure, etc.). See the sections under Creating a New Study / Editing an Existing Study for further guidance as the process uses the exact same smartform pages and is virtually identical.

1. Study Enrollment Status

The enrollment status is very important because 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.

- **Important!** If you also submitted a CR with this modification, make sure your responses are consistent with the Research Milestones that you indicated for the CR.
- **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.

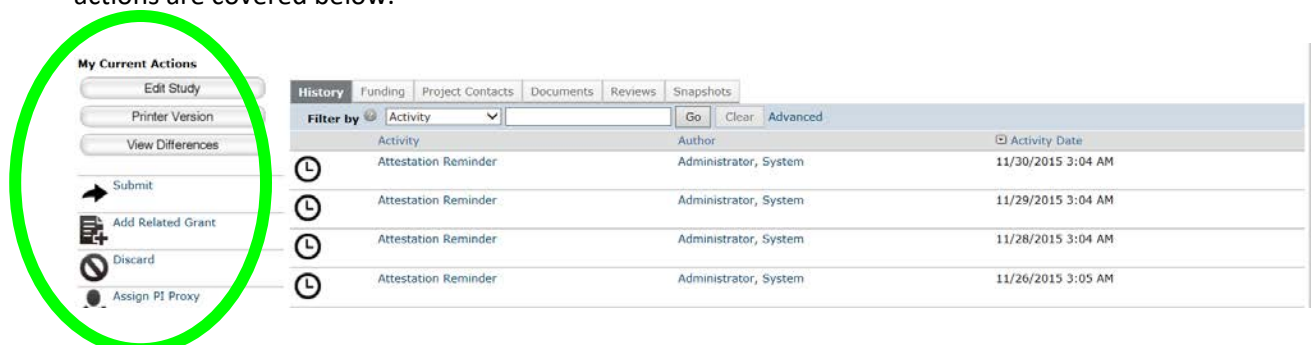
- An amendment to add protocol related information about a side effect of nausea while on the study drug would certainly warrant changes to the protocol risk/discomfort section, the consent document for future enrollees and formal notification to all current subjects who have not completed the intervention.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

- 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 of what is changing and why. Keep it simple and in plain language.
- If you are not making any changes but the page comes up when you are renewing, just say that **you are not making any changes at this time**. The CR with Modifications is just the mechanism that allows you to electronically edit documents if the IRB requests changes later in the CR process.

My Current Actions

The activities allowed in the **My Current Actions** Menu (both buttons and Icons) will vary and are dependent on both your role on the study and the status of the submittal. Some of the most common actions are covered below.



Edit Study- allows you to edit the study smartform including the upload of materials like the protocol, consent documents and other items.

Edit Mod / CR- allows you to edit a Modification or Continuing Review submittal including (in cases where a modification request indicates changes to the study) the study smartform and documents.

Printer Version- Displays a printer friendly version of the Study, Mod or CR.

View Differences- Shows differences in versions of the study

Create Mod/CR- allows creation of a modification or continuing review submittal. Note that in most cases only **one modification at a time** can be submitted to the IRB.

Report New Information (RNI) - Used to create a report of Unanticipated Problems, Deviations, Adverse Events, etc.

Add a Comment- Creates a comment in the study record that is visible to everyone with read access to the study. This can be used if you need to send a message to the coordinator reviewing your study or right after submitting something to give the IRB a heads up on the content of the submittal (e.g. when submitting for not human subjects determination- let the RIB know this with a comment ahead of time).

Submit- Submit the project, CR, Mod, RNI to the IRB workflow.

Add Related Grant- Add or remove related grant with study

Discard- Removes the submittal. CAUTION- DISCARD CAN DELETE INFORMATION.

Withdraw- Removes the study submission from consideration by the IRB so that the research team can edit and resubmit at a later time.

Assign PI Proxy- This activity assigns a proxy to PI that is current study team. There can be only one PI Proxy. The Proxy may submit materials for the PI after the initial submittal has been approved.

Assign Primary Contact- This is used to assign the primary contact. When the study is created, the primary contact is set to the person who created the study.

Manage Ancillary Reviews. Add or update ancillary reviewers. These can be organizations or people. Ancillary reviews may become more important once CLICK is implemented at UB for other compliance areas.

Manage Guest List- Manage list of users who get read access to the IRB Submission. You don't need to edit this for study personnel; they will be able to read things automatically once you add them to the study. The guest list is for persons outside of study personnel you want to give access to (for example, while the faculty sponsor/advisor would be a study team member, the "other" members of a graduate student's dissertation committee would not be study team members but might need to read the materials).

Copy Submission- Copy an IRB Submission into being as another new IRB Submission.