

UB Click IRB Step by Step Guide

Prepared by the UB Social and Behavioral Research Support Office

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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.



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: ?

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

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.
- Indicate changes using the TRACK CHANGES functionality. Use as a starting document whichever is the most current of the following:
 - The **MOST RECENT APPROVED** document with all previously reviewed tracked changes accepted.
 - The **most recently reviewed** document (usually you should accept any previously tracked changes before starting a new round of track changes).
 - 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. The top navigation bar includes 'Home', 'IRB', and 'My Inbox | Logoff'. The 'IRB' link is circled in yellow. Below the navigation bar, the 'My Current Actions' menu is visible, with 'Create New Study' circled in green. The 'Compliance Tasks' tab is circled in brown. The main content area displays a table of studies with columns for ID, Name, Date Created, Date Modified, State, and Coordinator. The 'Football Study' entry is 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 | |

1 items page 1 of 1 25 / page

Campus: 030 University at Buffalo Compliance_Release22g (Mon Nov 23 18:08:01 EST 2015)

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.

Click
a Huron solution

CHRISTIAN MARKS | My Inbox | Logoff

Home IRB

IRB > Football Study

Pre-Submission

STUDY0000090 : 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

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete
Clarification Requested → IRB Review → Clarification Requested → Post-Review → Modifications Required

My Current Actions

Edit Study
View Differences
Submit

History Funding Project Contacts Documents Reviews Snapshots

Filter by Activity Go Clear Advanced

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

Basic Information Page

Click
a Huron solution

Edit: IRB Submission - STUDY0000090

Back Continue >>

Update the IRB Submission due to one or more errors:
If you must select whether the investigator has a financial interest.

Basic Information

1. * Title of study:
Can Charlie Brown Kick that Football without Falling Down?

2. * Short title:
Football Study

3. * Brief description:
Charlie runs up and tries to kick the ball and it is pulled away from him just as he kicks.

4. * Principal investigator:
CHRISTIAN MARKS Select... Clear

5. * Does the investigator have a financial interest related to this research?
 Yes No Clear

6. * Will an external IRB act as the IRB of record for this study?
 Yes No Clear

Document History

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

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.

The screenshot shows a web browser window titled "Add Funding Source - Windows Internet Explorer". The address bar shows the URL: <https://pacsprd1.rfsuny.org/Compliance/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postback=1&form=0&c>. The page title is "Add Funding Source".

The form contains the following fields and elements:

- Funding organization:** A text input field containing "national institute of a" and a "Select..." button. A dropdown menu is open below it, showing search results for "National Institute of". The results are:

| | 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 | |
- Sponsor's funding ID:** (assigned by external sponsor) - An empty text input field.
- Grants office ID:** (assigned internally) - An empty text input field.
- Attach files:** (include any grant applications) - A button labeled "Add" and a file upload area.

Below the "Attach files" section, there is a table with columns: Document, Category, Date Modified, and Document History. The text "There are no items to display" is shown below the table.

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:

| Add | | | | | | | |
|--------|------------------|-------------------|--------------------|---------------------|----------------------|---------------|---------------|
| | 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:

| Add | | |
|-----------------|----------------------------|-------------|
| | Name | Description |
| Upload Revision | Peppermint Patty Reichardt | Delete |
| Upload Revision | van Pelt, Lucy | Delete |

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

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 a required field.
- 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 (highlighted in yellow), a "Print" button, a "Jump To:" dropdown menu, and a "Basic Information" dropdown menu. A red error message is displayed in a box, stating: "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 coordinator:

IRB office: 030 University at Buffalo (IRB)

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

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

My Current Actions

Submit

| 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**.

Start Here

Tracking Progress After Submittal (what to expect)

STUDY0000090 : 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: 1/15/2016 1:53 PM

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

My Current Actions

Submitted

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

Once you submit your study, modification or continuing review you can track the progress of the review by looking at the **bubbles**, but a more useful place to look at is the **History Tab**. Before you do so, verify that the particular item you are looking at is the item of interest by double checking the **tracking number in the title line**. This is particularly important if you are working on a modification or continuing review when you should check that the tracking number indicates a MOD, MODCR or CR and also look at the **dates** to see that they are in the ballpark.

Once you are sure you are looking at the correct package, you can click on the history tab which will by default display a summary of the latest activity taken on the submittal at the top of the list (and can then be reordered by clicking on the activity data heading if you wish). While there may be other items that are logged in the history between these two activities, right after you submit the study the most recent will usually be the **study submittal** while the oldest item in the history will always be the **study creation** as shown below.

The screenshot shows the 'History' tab of an IRB system. The filter bar is set to 'Activity Date' < 3/7/17, 'Author's Last Name' Wald, and 'Activity'. The history table shows two entries:

| Activity | Author | Activity Date |
|---------------|------------------|------------------|
| Submitted | Waldrop, Deborah | 3/6/2017 1:42 PM |
| Study Created | Waldrop, Deborah | 3/6/2017 1:03 PM |

Expedited Review Example

The best way to understand the process used by the IRB review is probably by looking at an example from a protocol that has been approved. We cover the process for an expedited/exempt review in detail here. A brief discussion of the differences in the full board process is given later. Keep in mind that the IRB has a number of people working on your protocol at different points in time and also sometimes needs “ancillary reviews” from other committees (Conflict of Interest, Radiation Safety, Biosafety, etc.) so you may notice the study being passed from one person to another along the way. This is normal and expected. However, in most cases you will see two people Assigned as the IRB coordinator for a given study, one for a pre-check of documentation for completeness and a second who is the designated reviewer. The study history shown below covers all of the steps taken from creation on 3/6/17 1:03 PM to communication of the approval on 3/20/17 1:08 PM. Below the image is an explanation of what occurred for each of the transactions (with some of the icons included).

| Activity | Author | Activity Date |
|--|------------------------|--------------------|
| Letter Sent | Mann, Kyle | 3/20/2017 1:08 PM |
| Correspondence_for_STUDY00001431.doc | | |
| Finalized Documents | Mann, Kyle | 3/20/2017 1:05 PM |
| Response Submitted | Waldrop, Deborah | 3/20/2017 12:15 PM |
| Hello, Thanks very much for your review. I have added signature blocks to the 3 consent forms. Deborah Waldrop | | |
| Clarification Requested by Designated Reviewer | Mann, Kyle | 3/20/2017 10:05 AM |
| Hello, Please add the signature block to the consent forms so that the Participants are able to sign the consent form prior to them giving it back to you after they review the consent form and Information Sheet. Thanks | | |
| Submitted Ancillary Review | Rybij, Patricia | 3/20/2017 10:04 AM |
| Ancillary Review Reminder Sent | Administrator2, System | 3/19/2017 3:05 AM |
| Ancillary Review Reminder Sent | Administrator2, System | 3/13/2017 3:05 AM |
| Comment Added | Waldrop, Deborah | 3/7/2017 1:09 PM |
| Hello, Thank you for your help. I just completed the RPA Initiated Certification. I think it is correct. Please let me know if anything else is needed. Thank you. | | |
| Comment Added | Rybij, Patricia | 3/7/2017 10:37 AM |
| Hello - I am reviewing your study for conflict of interest. I have created research certifications, a study specific way of acknowledging your annual financial disclosure is up to date. If you click on the COI tab, you will see the research certification to submit. Thank you! | | |
| IRB Coordinator Assigned | Brown, Carol | 3/7/2017 9:19 AM |
| Assigned to Kyle Mann | | |
| Pre-Review Submitted | Brown, Carol | 3/7/2017 9:19 AM |
| Managed Ancillary Reviews | Brown, Carol | 3/7/2017 9:18 AM |
| Response Submitted | Waldrop, Deborah | 3/7/2017 9:13 AM |
| Thank you for your review. I have removed the letters from the External Team Member section. | | |
| Clarification Requested | Brown, Carol | 3/7/2017 8:15 AM |
| Please remove the Letters of Support from ECMC and Hospice from the External Team Member Information section as these are correctly uploaded to the Supporting Document section. | | |
| IRB Coordinator Assigned | Brown, Carol | 3/6/2017 1:53 PM |
| Assigned to Carol Brown | | |
| Submitted | Waldrop, Deborah | 3/6/2017 1:42 PM |
| Study Created | Waldrop, Deborah | 3/6/2017 1:03 PM |

On 3/6/2017 1:03 PM The PI created the study and then submitted it at 1:42 PM.

On 3/6/2017 1:53 PM the protocol was assigned to a coordinator  for pre-review processing. The first pre-review usually checks for things like proper uploading of documents, and basic administrative requirements. This step is just a quick scan of the materials and usually does not include any in-depth reading of the study materials. The next morning the coordinator completed the pre-review and then

requested a change  in the materials by returning edit control to the researcher. The researcher

submitted her response  about an hour after that (note that this is not just a comment, it is a response). The pre-review coordinator apparently judged the materials to be substantially complete as in the course of the next 3 transactions (3/7/2017 9:18 AM-9:19 AM) a Pre-Review was submitted



, and ancillary review process for Conflict of Interest was initiated  (you can tell that it was for COI if you click on the hyperlink for "Managed Ancillary Reviews" and see that the person it was assigned to was the COI director, Patricia Rybji), and assignment of the materials was transferred to

another coordinator  who is a designated reviewer for probable expedited/exempt review.

The next group of 5 items (from 3/7/2017 10:37 AM to 3/20/2017 10:04 AM) all deal with the Conflict of Interest Determination. At 10:37 AM the COI Director asked the researcher to provide some

information about her financial disclosures by logging a comment  and a few hours later the researcher acknowledged that the request had been completed. Unfortunately, the Click system does not notify an ancillary reviewer directly and there is no reasonable way for the ancillary reviewer/COI Director to track this so the PI's completion of this went unknown for 12 days prompting the automatic

Ancillary Review Reminders  to be sent. To ensure that this does not happen to you, please e-mail the COI director directly at coiofficer@buffalo.edu if you think you have completed all requests of the COI process AND see an ancillary review reminder (or if it has been more than 5 days since you

completed all requests). On 3/20/2017 10:04 AM the COI director submitted an ancillary review  completing the COI process.

The last 4 items deal with the expedited/exempt review by the coordinator assigned to act on behalf of the IRB in performing an in-depth review of the protocol (the designated reviewer). The protocol

was reviewed (3/20/2017 10:04 AM) and a clarification/change was requested . A couple of

hours later the researcher submitted her response . After lunch, the coordinator verified the response met the request and the study now met the requirements for expedited approval so he

finalized the approval documents  and provided them to the researcher  through the system.

Differences for Full Board Review

There are very few differences for a full board review. Other than technical differences in terminology such as change requests asking for “modification” instead of “clarification” there are very few differences. A couple of notable exceptions are:

1. The Study will at some point in time be scheduled and put on a meeting agenda. Once it is assigned to the agenda, it is in a holding pattern. As there are usually a number of items on each agenda, the board members are typically given at least a week to review all the protocols on the given agenda.
2. Once a protocol is reviewed by the full board, revisions requiring more than the concurrence of the researcher (i.e. changes that are not very specific) will need to be subsequently reviewed by the full board for approval.

How Long Should IRB Approval Take (and what to do if it is taking longer)

The IRB usually posts expectations of average approval times on their website but there is no way to predict how long approval will take for any particular item because the time is dependent you, the IRB and the complexity of the transaction you are requesting to be approved.

However, no matter how good the tools and people are, we all know that in any process where there is a high transaction volume, sometimes things can get misplaced or a miscommunication can occur. It is probably a good idea to keep an eye on your submittal to make sure that it is progressing through the review process. You don't however, want to bother the IRB with an additional request when you have not yet given them a reasonable amount of time to review the material. The following can be used as a guide in not presenting the IRB with an unreasonable request while still ensuring that you receive a timely review.

1. First, **make sure that you did your part correctly** by checking to see whether or not the submittal is actually in the IRB's hands (i.e. the bubbles indicate Pre-Review, IRB Review or Post Review). If not, the next transaction is probably yours to take by sending a response or submittal of the materials to the IRB (under my current actions). One common mistake people make is to update all materials per the IRB's request but then they never just send a comment

and don't actually submit a response  to the IRB to confirm that you want the IRB to again look at the materials.

2. If the bubbles indicate that the study is in the IRB's hands, look at the history.
3. Check to see if there are any outstanding Ancillary reviews, because if there are the IRB cannot

process your submittal. For each ancillary review created,  Managed Ancillary Reviews,

you should see a corresponding  submitted ancillary review completing the ancillary review process. Details about each ancillary review are accessible by clicking on the “Managed Ancillary Reviews” hyperlink. If you have an ancillary review created that has not yet been completed, you should contact the person responsible for the ancillary review to check on its status. Often ancillary reviews for Conflict of Interest determinations require that you or your

staff update financial information before they can be completed by the COI committee so that IRB review can then occur.

4. If there are no outstanding ancillary reviews, determine the “reference date” for the last (newest) transaction that represents an action taken by either the study team or the IRB. Usually this will be the date of the latest transaction but occasionally you may need to look further back if the latest items in the history are reminders, comments not requiring a response, posting of a protocol to an agenda or study team communications. Activities like submitting, requesting and responding to requests for clarifications, and assignment of the study to a new IRB coordinator create a new reference date.
5. **Special note on Continuing Reviews.** If today’s date is not within the 30 days prior to expiration (that is to say you have done the admirable job of submitting early), and you are not making any major changes you should do nothing until your study is within 30 days of expiration so that the IRB is not required to change your annual expiration date (shortening your approval period for the past year).
6. The IRB’s policy under HRP-031 indicates that materials are to be provided to reviewers within 3 business days of receipt of a complete submission. Use this policy as a rule of thumb along with the following information to determine what to do:
 - a. Business days are M-F (excluding holidays). The observed Research Foundation Holidays are also considered to not be a business day. The RF holidays (both those that are mandatory and those on which a person may choose to work and save the time for later use) are as follows: New Year’s Day, Martin Luther King Day, Lincoln’s Birthday, Washington’s Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Election Day, Veterans’ Day, Thanksgiving Day, and Christmas Day.
 - b. Be reasonable when your reference date falls around a holiday. For example, don’t expect anything to happen between December 23 and January 1. When a “major” holiday like Independence Day falls on a Thursday, you can expect that the office will not be fully staffed on the 5th of July so don’t count these periods as business days.
7. When the reference date is not greater than 3 business days ago, just wait as you need to give the IRB a reasonable time to act.
8. If your latest transaction date is greater than 3 business days ago, you should contact the Director of Compliance, Dr. Richard Karalus (karalus@buffalo.edu) via e-mail. Concisely and politely ask him if he could check on the submittal (be sure to give him the transaction number-STUDY00001234 or MODCR00005678) and then either let you know what you need to do or provide a date on which you will have a response from the IRB. Note that this does not mean that it will be approved on this date, just that the next step in the review process will be taken and communicated to you by this date. The date he provides to you should be within 3 business days of your communication to him.
9. You should contact the Institutional Official for Human Subjects Research, Dr. Kenneth Tramosch (kmt1@buffalo.edu) asking him to look into the matter when:
 - a. An unacceptable date outside of the 3 business day window is given to you.
 - b. You do not receive a response from the Director of Compliance within 3 business days.
 - c. The IRB does not provide a response by the date that the director provided to you.

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.

CITI Training

1. PI Completed CITI Coursework:

| Curriculum | Group | Stage | Expire |
|-------------------------------|-------|-------|--------|
| There are no items to display | | | |

2. Study Team Members Completed CITI Coursework:

| Name | Training Details | 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 | | | | | |

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 | 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 workflow diagram shows the process from Pre-Submission to Review Complete, with 'Clarification Requested' and 'Modifications Required' steps. Below this, the 'My Current Actions' sidebar is visible. The main content area shows two activity history tables. The first table, filtered by 'Activity' and 'Clarification', lists a 'Clarification Requested' activity by BROWN, CAROL on 12/14/2015. A note below this activity 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.' The second table, filtered by 'Activity' and 'letter', lists 'Letter Sent' activities by MANN, KYLE and CRONKER, DARLENE.

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).

Click
a Human Subjects

CHRISTIAN MARKS | My Inbox | Logoff

Home IRB

IRB

Create New Study
Report New Information

In-Review Active Archived New Information Reports All Submissions

Filter by Last Name marks Go Clear Advanced

| ID | Name | Date Modified | State | PI First Name | PI Last Name | Coordinator | Submission Type |
|---------------|----------------|-------------------|----------------|---------------|--------------|-------------|-----------------|
| STUDY00000090 | Football Study | 1/15/2016 1:53 PM | Pre-Submission | CHRISTIAN | MARKS | | Initial Study |

1 items page 1 of 1 25 / page

Submissions
Meetings
Reports
Library
Help Center

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.

IRB > YWCA Virginia

Approved

030-667445 : YWCA Virginia

Principal investigator: THOMAS NOCHAJSKI
Submission type: Initial Study
Primary contact:
IRB coordinator:

Entered IRB:
Initial approval:
Effective:
Approval end: 2/25/2016
Modified: 1/26/2016 3:00 AM

IRB office: 030 University at Buffalo (IRB)
Letter: None

Pre-Submission → Pre-Review → IRB Review → Post-Review → Review Complete
Clarification Requested → IRB Review → Post-Review → Review Complete
Modifications Required → Post-Review → Review Complete

My Current Actions

View Study History Funding Project Contacts Documents Follow-on Submissions Reviews Snapshots

Printer Version

Create Modification / CR Report New Information

Assign Coordinator

Activity
Continuing Review Deadline Reminder
Continuing Review Deadline Reminder

Author
Administrator, System
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

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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

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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.

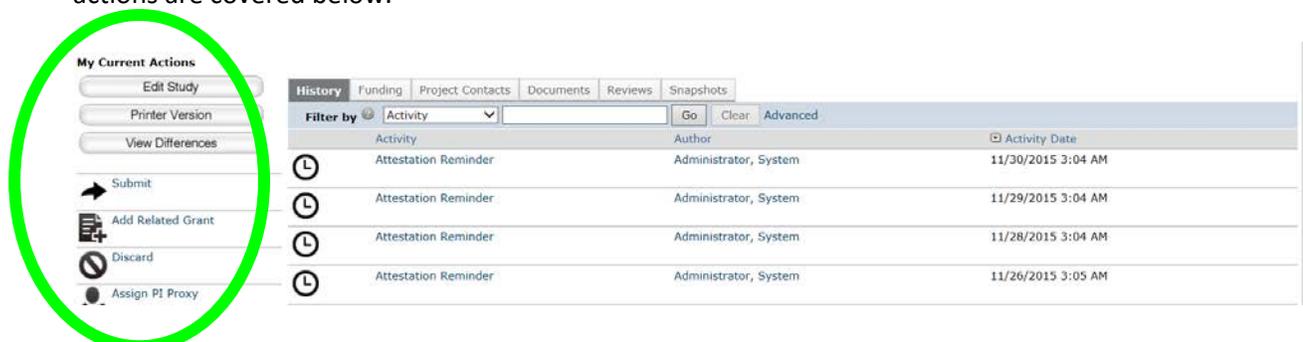
- An amendment to add protocol related information about a side effect of nausea while on the study drug would certainly warrant changes to the protocol risk/discomfort section, the consent document for future enrollees and formal notification to all current subjects who have not completed the intervention.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