



# **Kuali IRB User Manual**

Last Revised: 1/6/2023

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### **All IRB application forms are now embedded within Kualu.**

Legacy studies that were migrated into Kualu will include the original IRB number in the protocol title.

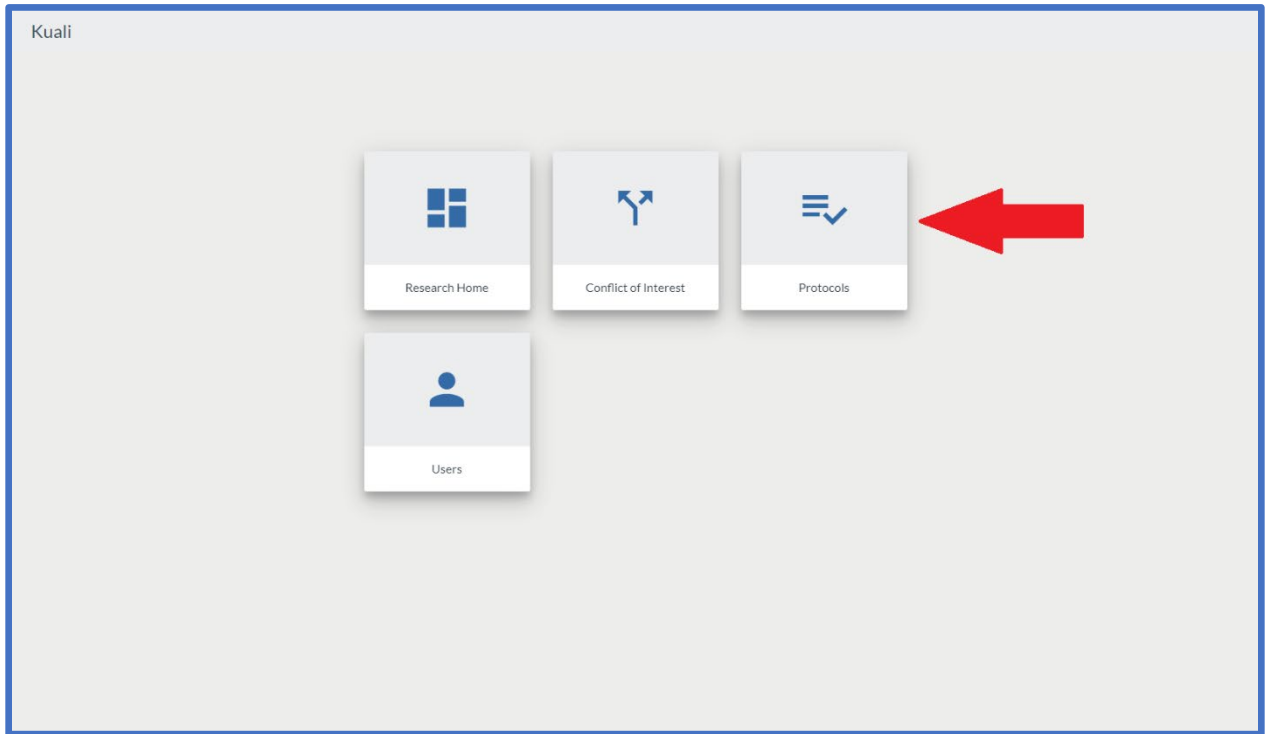
For more information on Kualu, Kualu Resources, or to Log into Kualu, please visit:  
[https://www.umb.edu/orsp/kualu\\_research](https://www.umb.edu/orsp/kualu_research)

For templates (protocol, consent, etc.), please visit:  
[https://www.umb.edu/orsp/research\\_committees/irb/applying](https://www.umb.edu/orsp/research_committees/irb/applying).

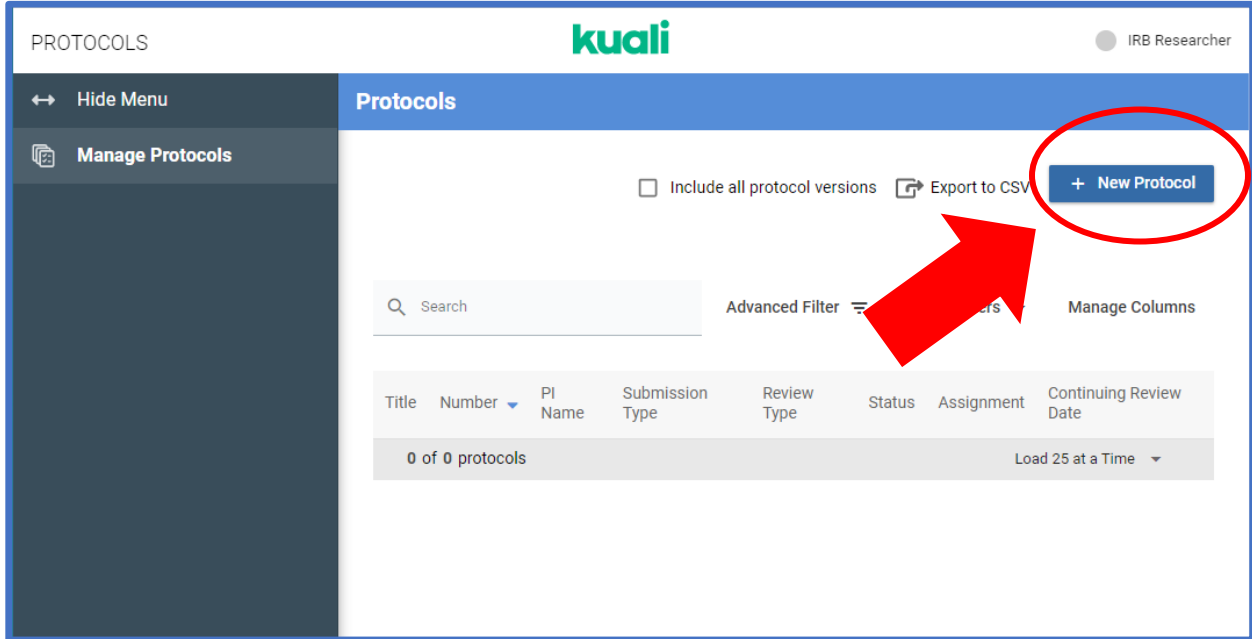
For further assistance or questions not addressed in this manual, please contact our IRB team at [irb@umb.edu](mailto:irb@umb.edu).

## Creating a New IRB Protocol (HRP-211)

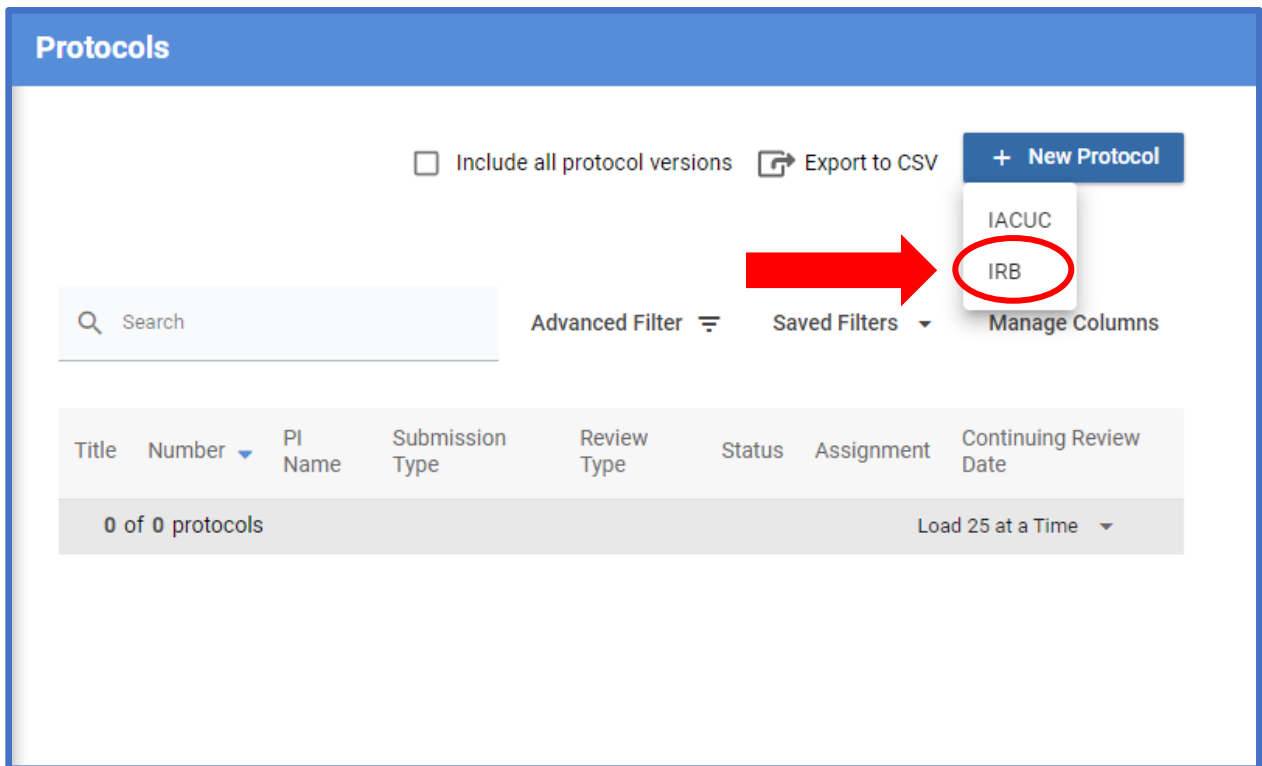
1. Log into Kuali (<https://umb.kuali.co/cor/main/#/apps/>) using your ID and Password
2. Select **Protocols**



3. Click the **+ New Protocol** Button on the top right-hand corner of the screen



4. Clicking on the **+ New Protocol** button will trigger a small pop-up, click on the **IRB** option.



5. Enter the name of the **Principal Investigator**, The Principal Investigator's department (**Lead Unit/ Department**), and the **Study Title** of the protocol.

### IRB - General Information

**UMass Boston**  
**Institutional Review Board (IRB)**

Please complete all sections carefully and completely. For general information, visit the [IRB web site](#). If you have any questions, please contact the IRB Office: [irb@umb.edu](mailto:irb@umb.edu).

|  |                               |
|--|-------------------------------|
| <b>Principal Investigator (PI)</b>   | <b>Lead Unit / Department</b> |
| <small>Undergraduate students should not be listed as Principal Investigator. A faculty member should serve as PI and the undergraduate student listed as co-investigator.</small> | <input type="text"/>          |
| <input type="text"/>   |                               |

**Study Title**

[Click Here to Add Text](#)

✕ Cancel  
→ Next

6. Answer the general questions for ORSP reporting purposes.

**Please answer the following general questions for ORSP reporting purposes:**

Is this a student's project (e.g., dissertation, thesis)?

Yes

No

Will gift cards be requested by the UMass Boston researcher(s) for use in this project?

Yes

No

Will the UMass Boston researcher(s) be traveling internationally for the study?

Yes

No

7. After entering the required information, click **Next**.

### IRB - General Information

**UMass Boston  
Institutional Review Board (IRB)**

Please complete all sections carefully and completely. For general information, visit the [IRB web site](#). If you have any questions, please contact the IRB Office: [irb@umb.edu](mailto:irb@umb.edu).

**Principal Investigator (PI)**  
Undergraduate students should not be listed as Principal Investigator. A faculty member should serve as PI and the undergraduate student listed as co-investigator.

**Lead Unit / Department**  
University of Massachusetts Boston

IRB Researcher

**Study Title**  
Testing Protocol

Cancel  
Next

8. Select **IRB Application (Basic Study Information) (Form HRP-211)**, then click **Next**

← Back    Manage Protocols → IRB: #108 Testing Protocol

→ Next

**Submission Type**

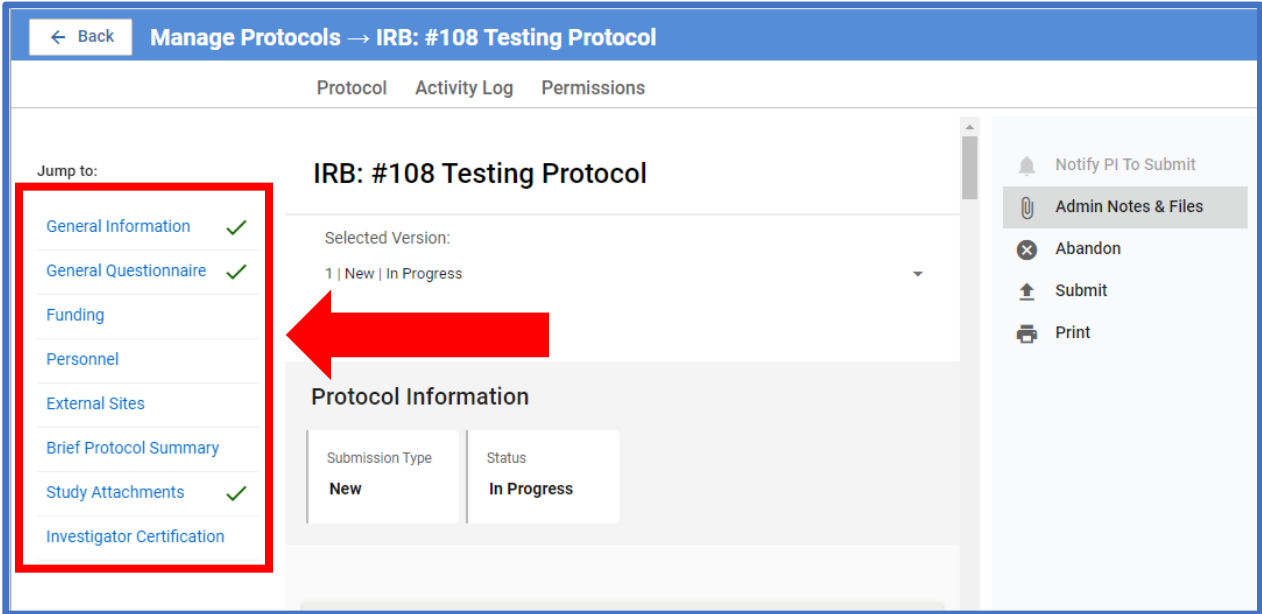
Please select one of the following.

- Select IRB Application (Basic Study Information) to submit a new protocol for UMass Boston IRB review.
- Select Request for External IRB Reliance to submit a request to rely on an outside IRB's review.

IRB Application (Basic Study Information) (Form HRP-211)

Request for External IRB Reliance (Form HRP-811)

9. After answering the questions on the previous page, you will be taken to a single scrollable page that contains the entirety of the protocol. On the left-hand side of the screen, you will see a sidebar listing all the sections of the protocol. No matter what section of the protocol you are in, you can use this sidebar to quickly navigate to another section.





10. Next, indicate whether the study is funded

← Back Manage Protocols → IRB: #108 Testing Protocol

Protocol Activity Log Permissions

Jump to:

- General Information ✓
- General Questionnaire ✓**
- Funding
- Personnel
- External Sites
- Brief Protocol Summary
- Study Attachments ✓
- Investigator Certification

Administrative Details

- Determinations

**General Questionnaire**

• Select Request for External IRB Reliance to submit a request to rely on an outside IRB's review.

- IRB Application (Basic Study Information) (Form HRP-211)
- Request for External IRB Reliance (Form HRP-811)

**Funding**

Is this study funded?

- Yes
- No

**Personnel**

Notify PI To Submit

Admin Notes & Files

Abandon

Submit

Print

**Funding**

Is this study funded?

- Yes
- No

11.If you click yes, a popup will appear. Please indicate whether the study is externally funded or internally funded. More popups will appear on the form according to what selection you make.

The screenshot shows a web interface for managing protocols. At the top, there is a blue header with a back arrow and the text 'Manage Protocols → IRB: #108 Testing Protocol'. Below the header, there are tabs for 'Protocol', 'Activity Log', and 'Permissions'. The main content area is divided into a left sidebar and a main panel. The sidebar has a 'Jump to:' section with links for 'General Information' (checked), 'General Questionnaire' (checked), 'Funding', 'Personnel', 'External Sites', 'Brief Protocol Summary', 'Study Attachments' (checked), and 'Investigator Certification'. The main panel has a 'General Questionnaire' section and a 'Funding' section. The 'Funding' section contains the question 'Is this study funded?' with radio buttons for 'Yes' (selected) and 'No'. Below this is a 'Study Funding' section with the instruction 'Please select all that apply.' and two checkboxes for 'External' and 'Internal'. On the right side of the main panel, there is a vertical menu with icons and labels: 'Notify PI To Submit', 'Admin Notes & Files', 'Abandon', 'Submit', and 'Print'.

This is a close-up view of the 'Funding' section of the form. It features a grey header with the word 'Funding'. Below the header, the question 'Is this study funded?' is followed by a horizontal line. There are two radio buttons: 'Yes' (which is selected) and 'No'. Below this, the section 'Study Funding' is followed by another horizontal line. Underneath, the text 'Please select all that apply.' is displayed. Two checkboxes are listed: 'External' and 'Internal'. A red rectangular box highlights the 'Please select all that apply.' text and the two checkboxes.

12. If your study is externally funded, you will need to look up the ID for the funding using one of the links in blue. If your funding is pending, click on the **Institutional Proposal ID** link. If your funding is active, click on the **Award ID** link. Contact your grant administrator for assistance with your Institutional Proposal ID or Award ID number(s).

### Funding

#### Study Funding

Please select all that apply.

External

Internal

#### External Funding

If your funding is pending enter your [Institutional Proposal ID](#)  
If your funding is active enter your [Award ID](#)

You can use one of the links above to look up your Institutional Proposal or Award funding source. You will need to copy and paste your Kualiti identifier (Institutional Proposal Number, or Award ID respectively) into the field and press **Find and Add**. You must have view access to your grant document to link it in protocols.

Enter a funding source number



Award    Institutional Proposal    Proposal Development



### Institutional Proposal Lookup

\* required field

Institutional Proposal Number:



Proposal Development Number:

Proposal Type:   


Status:   



Account ID:

Project Title:


Unit ID:   


Unit Name:

Proposal Person:  

Sponsor ID:   

Sponsor Name:

Proposal Create Date From:  

Proposal Create Date To:  



### Award Lookup



\* required field

Award ID:


Sponsor Award ID:



Account ID:



Award Status:   


Sponsor ID:   

Award Title:


Investigator:  


Lead Unit ID:   

Lead Unit:   

OSP Administrator Username:  

Archive Location:

Archive Date From:  

Archive Date To:  

Document Status:  Final  Saved  Both  Canceled

13.If you are unable to locate your external funding information through the search links, you may enter the information in the table manually by clicking + **Add Info** and typing directly in the boxes

**Funding**

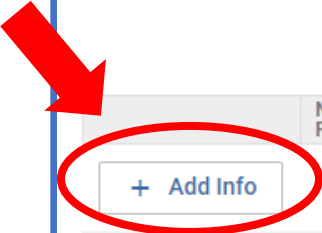
If you are unable to locate your external funding information through the search links above, please enter the information in the table below.

**Instructions to add or update funding**

- Click "+ Add Info" below to add your first entry.
- Click "+ Add Line" to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

[Columns](#) [+ Add Line](#)

|                            | NAME OF EXTERNAL FUNDING SOURCE | GRANT ID NUMBER | GRANT TITLE |
|----------------------------|---------------------------------|-----------------|-------------|
| <a href="#">+ Add Info</a> |                                 |                 |             |



14.If more lines are needed, you can select + **Add Line** to insert additional entries





**Funding**

If you are unable to locate your external funding information through the search links above, please enter the information in the table below.

**Instructions to add or update funding**

- Click "+ Add Info" below to add your first entry.
- Click "+ Add Line" to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

[Columns](#) [+ Add Line](#)

|   | NAME OF EXTERNAL FUNDING SOURCE |  | GRANT ID NUMBER |  | GRANT TITLE |
|---|---------------------------------|--|-----------------|--|-------------|
|    |                                 |  |                 |  |             |
|  |                                 |  |                 |  |             |
|  |                                 |  |                 |  |             |
|  |                                 |  |                 |  |             |

15. For internal funding, select **+ Add info** to directly add funding information to the table. The **+ Add Line** can be used to insert additional entries.

**Funding**

Study Funding

Please select all that apply.

External

Internal

**Internal Funding**

Please enter internal funding information in the table below.

**Instructions to add or update funding**

- Click **" + Add Info"** below to add your first entry.
- Click **" + Add Line"** to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

[Columns](#) [+ Add Line](#)

|  | NAME OF INTERNAL FUNDING SOURCE |  | GRANT ID NUMBER |  | GRANT TITLE |
|--|---------------------------------|--|-----------------|--|-------------|
|--|---------------------------------|--|-----------------|--|-------------|

[+ Add Info](#)

16. Review and edit personnel. If you need to include additional personnel, click the **+ Add Line** button and a popup will show up to add information.

**\*Important!** Please be sure to **add all of the PI's details** by selecting the **Edit Pencil** next to the PI's entry. **Do not skip this step.\***

### Personnel

UMass Boston Personnel

List all **UMass Boston** personnel involved in this protocol's design, conduct, or reporting. **Do not list personnel from other institutions in this section.** Add lines as needed.

If the Principal Investigator is a **graduate student**, a **Faculty Advisor** (in Researcher Role) must be listed below and appointed to oversee the conduct of the research in accordance with the UMass Boston [Investigator Manual \(HRP-103\)](#).



**UMass Boston now uses Single Sign-On (SSO) for all CITI trainings.** If the person's CITI training is not displaying in Kualu, they must log into the SSO at least once to associate their trainings with their UMass Boston ID at: [https://www.umb.edu/orsp/research\\_committees/irb/required\\_training](https://www.umb.edu/orsp/research_committees/irb/required_training)  
Allow 24 hours for CITI information to refresh in Kualu.

**Instructions to add or update personnel**

- Click "+ Add Info" below to add your first entry.
- Click "+ Add Line" to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

**Important!** Please be sure to **add all of the PI's details** by selecting the **Edit Pencil** next to the PI's entry. **Do not skip this step.**

Columns **+ Add Line**

|   | PERSON   | DEGREES | EMAIL ADDRESS    |
|---|--|---------|------------------|
|  |  IRB Researcher |         | testingirb@outlc |



17. Please review the personnel section to make sure the necessary CITI trainings for all personnel is up to date and showing up in the system. If the system indicates that the “IRB Researcher has no training courses on file” but the researcher has completed the trainings under a UMass Boston affiliation, please ask them to follow the instructions at ([https://www.umb.edu/orsp/research\\_committees/irb/required\\_training](https://www.umb.edu/orsp/research_committees/irb/required_training)) and log in through SSO to link their CITI trainings to Kualu. The trainings will take up to a day to refresh in Kualu.

**Personnel**

UMass Boston Personnel

List all **UMass Boston** personnel involved in this protocol's design, conduct, or reporting. **Do not list personnel from other institutions in this section.** Add lines as needed.

If the Principal Investigator is a **graduate student**, a **Faculty Advisor** (in Researcher Role) must be listed below and appointed to oversee the conduct of the research in accordance with the UMass Boston [Investigator Manual \(HRP-103\)](#).




**UMass Boston now uses Single Sign-On (SSO) for all CITI trainings.** If the person's CITI training is not displaying in Kualu, they must log into the SSO at least once to associate their trainings with their UMass Boston ID at: [https://www.umb.edu/orsp/research\\_committees/irb/required\\_training](https://www.umb.edu/orsp/research_committees/irb/required_training)  
Allow 24 hours for CITI information to refresh in Kualu.

**Instructions to add or update personnel**

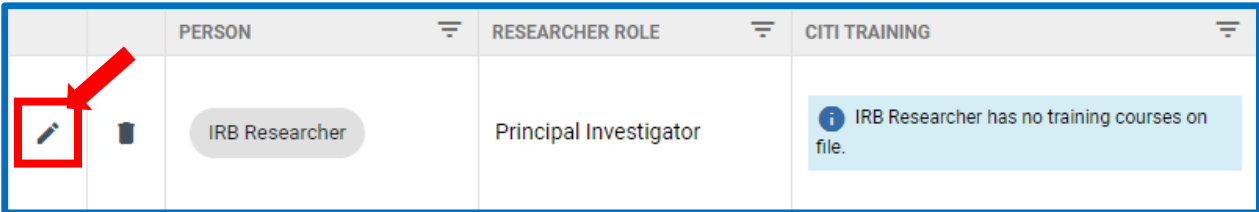
- Click "+ Add Info" below to add your first entry.
- Click "+ Add Line" to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

**Important!** Please be sure to **add all of the PI's details** by selecting the **Edit Pencil** next to the PI's entry. **Do not skip this step.**

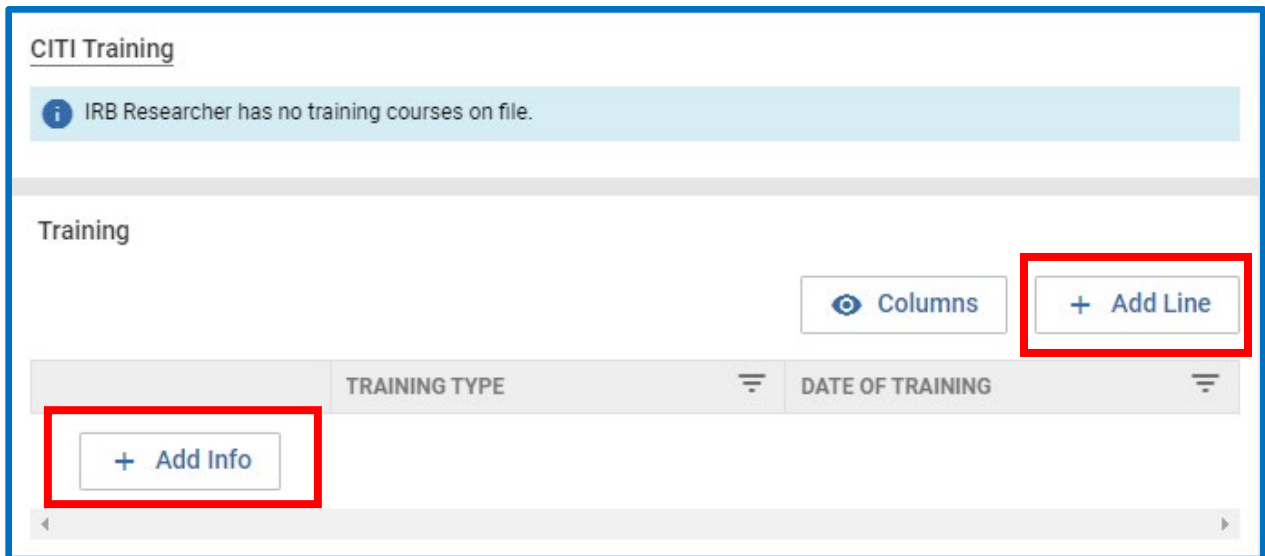
Columns Add Line

|   | PERSON         | RESEARCHER ROLE        | CITI TRAINING   |
|---|----------------|------------------------|---|
|   | IRB Researcher | Principal Investigator |  IRB Researcher has no training courses on file. |

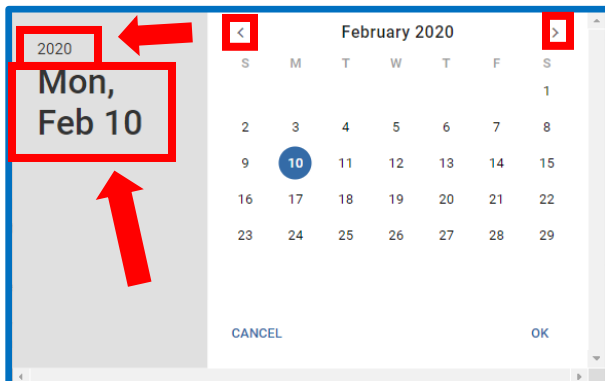
18.If the researcher did not complete the CITI training through UMass Boston, they must upload the CITI training certificate as an attachment. To do this, click the Edit Pencil next to the researcher who has training from an outside institution.



19. Select **+Add Info** to add the training. **+Add Line** can be used if there are additional trainings that need to be added.



**\*Important Tip:** When adding the **Date of Training** click the year and date on the left side to switch between viewing the year and month. Use the arrows to scroll between months and select the correct date.



20. Attach the corresponding external CITI training certificate(s) to the **People Attachments** section by selecting **+Add Info**. More attachments can be added by selecting **+Add Line**. The information on the certificate should match the information you provided in the **Training** section above

Training

[Columns](#) [+ Add Line](#)

|  | TRAINING TYPE                     | DATE OF TRAINING  |
|--|-----------------------------------|-------------------|
|  | CITI Training (other institution) | February 10, 2020 |

People Attachments

You must attach **external CITI training certificates** if completed through another institution. The IRB does not have access to external trainings.

If you answered yes to any **financial interest** related to the research, attach the institution's evaluation of the financial interest here.

**Instructions to add or update attachments**

- Click **"+ Add Info"** below to add your first attachment.
- Click **"+ Add Line"** to insert additional attachments.
- Select the **Edit Pencil** next to an attachment to edit or update.

[Columns](#) [+ Add Line](#)

|                            | ATTACHMENT | ATTACHMENT TYPE |
|----------------------------|------------|-----------------|
| <a href="#">+ Add Info</a> |            |                 |

21. If you want to add personnel that are not affiliated with UMass Boston who will rely on UMass Boston IRB review, select **Yes** to the question, **“Does this protocol include any external researchers relying on UMass Boston IRB review?”** (Do not list external personnel who will use their own IRB for review). A popup will appear, select **+ Add Info** to add external researchers and **+ Add Line** to add additional external researchers.

Does this protocol include any external researchers relying on UMass Boston IRB review?

Yes

No

External Personnel (Non-UMB)

List only those **external research personnel**. Add lines as needed.

**Instructions to add or update personnel**

- Click **+ Add Info** below to add your first entry.
- Click **+ Add Line** to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

[Columns](#) [+ Add Line](#)

|                            | NAME | INSTITUTION/ORGANIZATION/COMPANY |
|----------------------------|------|----------------------------------|
| <a href="#">+ Add Info</a> |      |                                  |

22.If there are external sites where the investigator will oversee the protocol, select **Yes** on the **External Sites** portion of the form and a popup will appear. Select **+ Add Info** to start inputting information and **+ Add Line** if more lines are needed to input addition information.

### External Sites

Are there external sites at which the investigator will conduct or oversee the protocol?

Yes

No

#### External Sites

Complete for each external site at which the investigator will conduct or oversee the protocol.

**Instructions to add or update sites**

- Click "+ Add Info" below to add your first entry.
- Click "+ Add Line" to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

[Columns](#) [+ Add Line](#)

|  | SITE NAME |  | CONTACT PERSON'S NAME AT SITE |  | CONTACT PERSON OR PHONE |
|--|-----------|--|-------------------------------|--|-------------------------|
|--|-----------|--|-------------------------------|--|-------------------------|

[+ Add Info](#)

23. Use the text box to describe the purpose of the protocol

### Brief Protocol Summary

**Protocol Summary**

Describe the purpose in 3-4 succinct sentences or less.

Sans Serif   Normal   **B**   *I*   U   **A**

---

24. Choose how you would like to submit your investigator protocol. You can either upload a word version or build it entirely online in Kuali. **Please keep in mind toggling between the protocol format options will erase the data. We strongly recommend that you save a copy of your protocol outside of Kuali if you are using the online protocol format.**

### Choose Protocol Format

**An Investigator Protocol (HRP-503) is required.** You have the option to either attach a Word version of the Investigator Protocol OR build it entirely online in Kuali.

- If you choose to **attach the Investigator Protocol**, then edit your protocol offline in Word. You will upload the document in the Study Attachments section when you are ready.
- If you choose to **build the Investigator Protocol entirely online**, then the Protocol sections will open below for your editing. You can edit online in Kuali as often as needed. Kual will save your progress. (Not recommended for protocols with complex formatting.)

Please choose how you will be providing a copy of the Investigator Protocol.  
Choose only ONE of the following:

I will be uploading a Word version of the Investigator Protocol as a Study Attachment.

I would like to build my Investigator Protocol entirely online in Kuali using the smartform. I will NOT be uploading the Protocol as an attachment.

25. If you choose to build the investigator protocol online, the form will pop up once you select **“I would like to build my investigator protocol entirely online in Quali using the smart form. I will NOT be uploading the Protocol as an attachment.”**

26. Attach the investigator Protocol in Word format using **+ Add Info**. Add any additional documents by using **+ Add Line**.

**Study Attachments**

**Attach the following documents:**

Please provide materials in Word format if possible so the IRB can provide edits/comments directly within the document(s).

- Protocol (in Word). Use the most recent [PROTOCOL TEMPLATE \(HRP-503\)](#). Required.

If applicable:

- Consent, assent, and parental permission forms (in Word)
- Data Collection Instruments (e.g., questionnaires, surveys, assessments)
- Recruitment Materials (printed, audio, and video)
- Foreign language versions of the above
- Sponsor protocol (if applicable)
- DHHS protocol and DHHS-approved sample consent document (if applicable)
- Evaluation of any Related Financial Interest

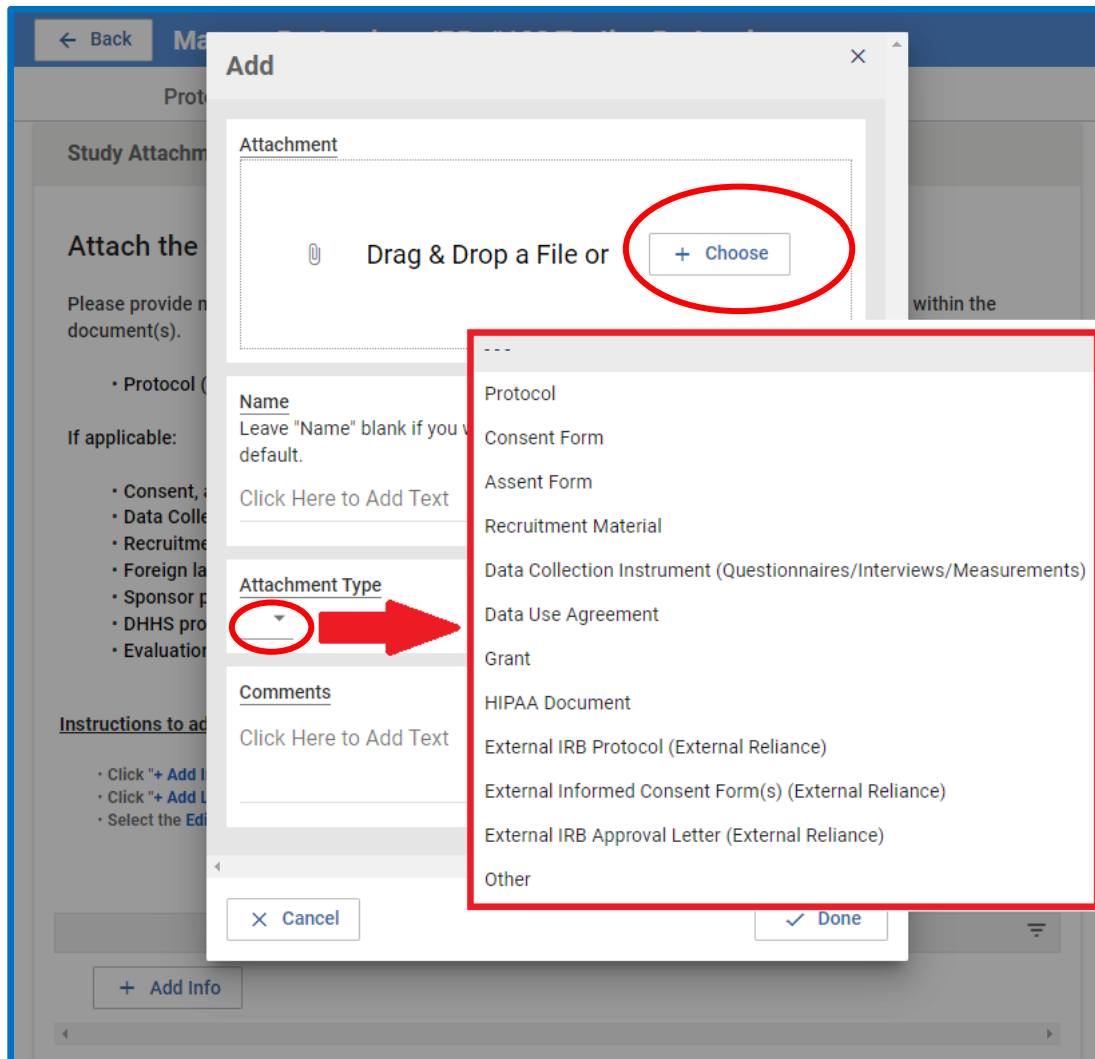
Instructions to add or update attachments

- Click **+ Add Info** below to add your first attachment.
- Click **+ Add Line** to insert additional attachments.
- Select the **Edit Pencil** next to an attachment to edit or update.

Columns **+ Add Line**

|                   | ATTACHMENT | ATTACHMENT TYPE |
|-------------------|------------|-----------------|
| <b>+ Add Info</b> |            |                 |

27. Selecting **+ Add Info** will trigger a popup where you can select the relevant file by selecting **+ Choose** or by dragging and dropping the file directing onto the **Attachment** box. Next you can Name your file using the **Name** text box. Keep this box blank if you would like the file name to be the name of the document. Selecting the Arrow under **Attachment Type** will trigger a popup where you can specify the type of attachment. Click done on the bottom of the popup when done attaching the current file.





28. Check the box under the **Investigator Certification** to certify all actions in the box. The PI must review this certification before submission.

### Investigator Certification

By clicking the Certify checkbox, I certify that:

- I have reviewed the UMass Boston [Investigator Manual \(HRP-103\)](#).
- I will conduct this protocol in accordance with requirements of the UMass Boston IRB.
- (For students) My faculty advisor has reviewed this application and made any necessary comments and revisions.

---

Certify

29. When you are ready to submit for review, hit the **Submit** button on the right sidebar. If you are not the PI, you will need to click **Notify PI to Submit**. **Only the PI has the ability to "Submit" to the IRB.**

The screenshot displays the 'Manage Protocols' interface for 'IRB: #108 Testing Protocol'. The main content area shows the 'Investigator Certification' section, which includes a list of certification statements and a checked 'Certify' checkbox. Two red arrows point from the certification text to the right sidebar. The sidebar contains several action buttons: 'Notify PI To Submit' (highlighted with a red box), 'Admin Notes & Files', 'Abandon', 'Submit' (highlighted with a red box), and 'Print'. The left sidebar shows a 'Jump to:' menu with various protocol sections, each with a green checkmark.

30. Once you submit, a red box with validation errors may pop up. If you have validation errors, scroll back up to the form to fix the errors (in red) then hit the submit button again. **Please note, only the person submitting (the PI) will be able to see these errors.**

← Back Manage Protocols → IRB: #108 Testing Protocol

Protocol Activity Log Permissions

Jump to:

- General Information ✓
- General Questionnaire ✓
- Funding ✓
- Personnel
- External Sites ✓
- Brief Protocol Summary ✓
- Study Attachments ✓
- Investigator Certificati... ✓

Administrative Details

Determinations

Incomplete  
2 fields have validation errors.

Investigator Certification

By clicking the Certify checkbox, you certify that:

- I have reviewed the [Investigator Manual \(HRP-103\)](#).
- I will conduct this protocol in accordance with requirements of the UMass Boston IRB.
- (For students) My faculty advisor has reviewed this application and made any necessary revisions.

Certify

Notify PI To Submit

Admin Notes & Files

Abandon

Submit

Print

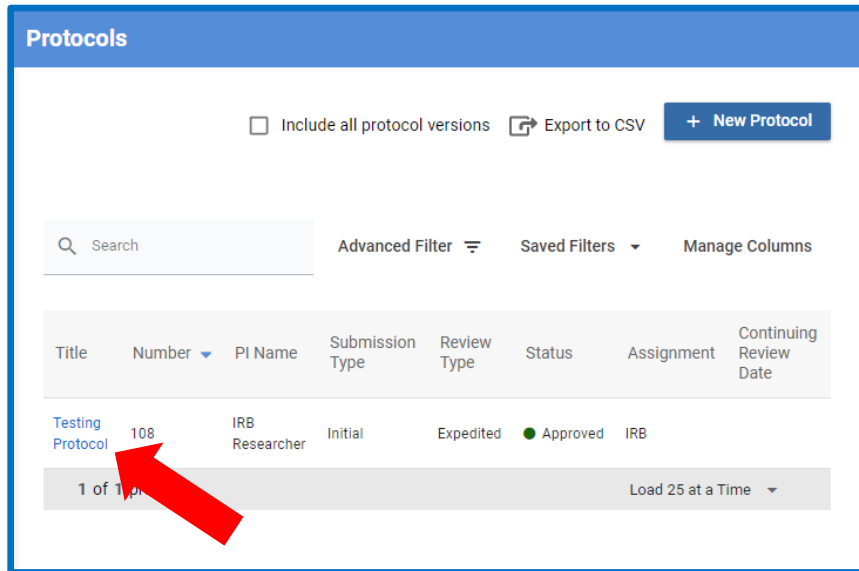
31. You will know your study has been successfully submitted for review by scrolling up and looking at the **Status** box

Protocol Information

| Submission Type | Review Type | Status               | Time in Current Status            |
|-----------------|-------------|----------------------|-----------------------------------|
| New             | --          | Submitted for Review | Since December 13 – a few seconds |

## How to submit an Amendment (Modification HRP-213)

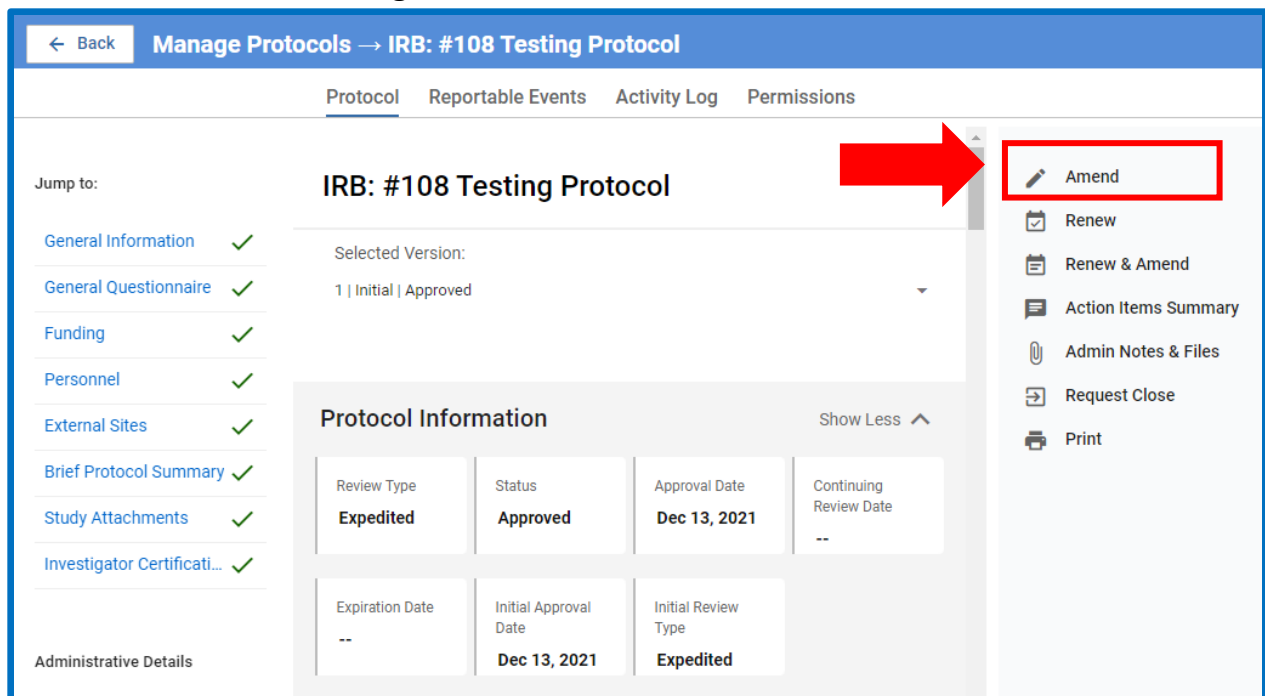
1. Log in to your Kualu IRB Dashboard and click on the title of the protocol you want to Amend. Please note that the system does not allow multiple pending amendments, you may only submit one modification application at a time. The modification application may contain as many amendments as needed.



The screenshot shows the 'Protocols' dashboard. At the top, there are options for 'Include all protocol versions', 'Export to CSV', and a '+ New Protocol' button. Below this is a search bar and filter options. A table lists protocols with columns: Title, Number, PI Name, Submission Type, Review Type, Status, Assignment, and Continuing Review Date. The first row is 'Testing Protocol' with number 108, PI Name 'IRB Researcher', Submission Type 'Initial', Review Type 'Expedited', Status 'Approved', and Assignment 'IRB'. A red arrow points to the 'Testing Protocol' entry.

| Title            | Number | PI Name        | Submission Type | Review Type | Status   | Assignment | Continuing Review Date |
|------------------|--------|----------------|-----------------|-------------|----------|------------|------------------------|
| Testing Protocol | 108    | IRB Researcher | Initial         | Expedited   | Approved | IRB        |                        |

2. Select **Amend** on the right sidebar









The screenshot shows the 'Manage Protocols' page for 'IRB: #108 Testing Protocol'. The page has a navigation bar with 'Back', 'Manage Protocols', and 'IRB: #108 Testing Protocol'. Below the navigation bar are tabs for 'Protocol', 'Reportable Events', 'Activity Log', and 'Permissions'. The main content area shows 'Jump to:' with a list of sections: General Information, General Questionnaire, Funding, Personnel, External Sites, Brief Protocol Summary, Study Attachments, and Investigator Certificati... Each section has a green checkmark. The 'Protocol Information' section is expanded, showing 'Selected Version: 1 | Initial | Approved'. Below this is a table with 'Protocol Information' and 'Administrative Details'. A red arrow points to the 'Amend' button in the right sidebar.

| Review Type | Status   | Approval Date | Continuing Review Date |
|-------------|----------|---------------|------------------------|
| Expedited   | Approved | Dec 13, 2021  | --                     |

| Expiration Date | Initial Approval Date | Initial Review Type |
|-----------------|-----------------------|---------------------|
| --              | Dec 13, 2021          | Expedited           |

3. Provide a description and justification of the modifications in the text box and answer the Yes/No questions that follow.

| Description and Justification  |
|--|
| <p>Provide a description <u>and</u> justification of the modifications.</p> <div style="border: 1px solid #ccc; padding: 5px;"><p>Sans Serif   ▾   Normal   ▾      <b>B</b>   <i>I</i>      <u>U</u>   <b>A</b>            </p><div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div></div> |
| Protocol Status  |
| <p>Please answer the following questions.</p> <p>Is the protocol open to the enrollment of new subjects?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p>Are there any subjects currently enrolled in the study?</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p>  |




4. Check the boxes if current and/or former subjects will be notified of the modifications and provide a description of how they will be notified in the text box that pops up.

Please check if current and/or former subjects will be notified of these changes (leave blank if no or N/A).

Current subjects will be notified of these changes.

Former subjects will be notified of these changes.

Provide a description of how current and/or former subjects will be notified.

Sans Serif   Normal   **B**   *I*   U   A         

5. The PI will need to read and certify the statement

Certification (Modification)

Please certify to the statement below.

I will conduct this protocol in accordance with requirements of the UMass Boston IRB.

**Instructions for Revisions:**

Please remember to complete the Certification section(s) before submitting.

Please continue to the study sections below to make any proposed changes to the study information (e.g., Funding, Personnel, etc.) and/or Study Attachments (e.g., protocol, consent, etc.).

If you are attaching revised or new study documents, you must scroll down to the end of form below and replace/add the documents in the Study Attachments section. Be sure that revisions are clearly visible in revised document(s) or in "tracked changes."

- ?

- Continue to scroll down and review the rest of the application, making the modifications you've listed in the description box. For example, if the modification was adding new personnel, Select the + Add Line button on the right-hand side of the personnel section and input the information in the pop-up.

### Personnel

**UMass Boston Personnel**

List all **UMass Boston** personnel involved in this protocol's design, conduct, or reporting. **Do not list personnel from other institutions in this section.** Add lines as needed.


If the Principal Investigator is a **graduate student**, a **Faculty Advisor** (in Researcher Role) must be listed below and appointed to oversee the conduct of the research in accordance with the UMass Boston [Investigator Manual \(HRP-103\)](#).

**UMass Boston now uses Single Sign-On (SSO) for all CITI trainings.** If the person's CITI training is not displaying in Kualu, they must log into the SSO at least once to associate their trainings with their UMass Boston ID at: [https://www.umb.edu/orsp/research\\_committees/irb/required\\_training](https://www.umb.edu/orsp/research_committees/irb/required_training)  
Allow 24 hours for CITI information to refresh in Kualu.



**Instructions to add or update personnel**

- Click "+ Add Info" below to add your first entry.
- Click "+ Add Line" to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

**Important!** Please be sure to **add all of the PI's details** by selecting the **Edit Pencil** next to the PI's entry **do not skip this step.**



Columns **+ Add Line**

|   | PERSON         | DEGREES | EMAIL ADDRESS          | AF |
|---|----------------|---------|------------------------|----|
|   | IRB Researcher |         | testingirb@outlook.com | F  |

**Add** [Close]

Person

**Required Field**

Degrees

Department

**Email Address**  
Click Here to Add Text


**Affiliation**

Note: Undergraduate students should not be listed as PI. A faculty member should serve as PI and the undergraduate listed as Co-Investigator.

- Faculty
- Graduate Student
- Professional Staff

[Cancel] [Done]

Scroll down to complete all the information then hit Done at the bottom



7. Please review the personnel section to make sure the necessary CITI trainings for all personnel is up to date and showing up in the system. If the system indicates that the “IRB Researcher has no training courses on file” but the researcher has completed the trainings under a UMass Boston affiliation, please ask them to follow the instructions at ([https://www.umb.edu/orsp/research\\_committees/irb/required\\_training](https://www.umb.edu/orsp/research_committees/irb/required_training)) and log in through SSO to link their CITI trainings to Kual. The trainings will take up to a day to refresh in Kual.

**Personnel**

UMass Boston Personnel

List all **UMass Boston** personnel involved in this protocol's design, conduct, or reporting. **Do not list personnel from other institutions in this section.** Add lines as needed.

If the Principal Investigator is a **graduate student**, a **Faculty Advisor** (in Researcher Role) must be listed below and appointed to oversee the conduct of the research in accordance with the UMass Boston [Investigator Manual \(HRP-103\)](#).




**UMass Boston now uses Single Sign-On (SSO) for all CITI trainings.** If the person's CITI training is not displaying in Kual, they must log into the SSO at least once to associate their trainings with their UMass Boston ID at: [https://www.umb.edu/orsp/research\\_committees/irb/required\\_training](https://www.umb.edu/orsp/research_committees/irb/required_training)  
Allow 24 hours for CITI information to refresh in Kual.

**Instructions to add or update personnel**

- Click "+ Add Info" below to add your first entry.
- Click "+ Add Line" to insert additional entries.
- Select the **Edit Pencil** next to an entry to edit or update.

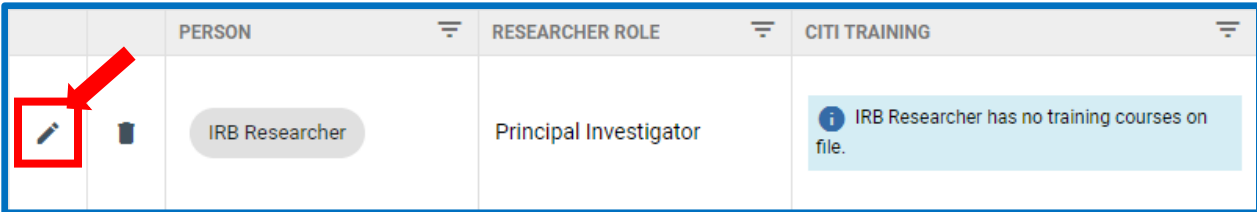
**Important!** Please be sure to **add all of the PI's details** by selecting the **Edit Pencil** next to the PI's entry. **Do not skip this step.**

Columns Add Line

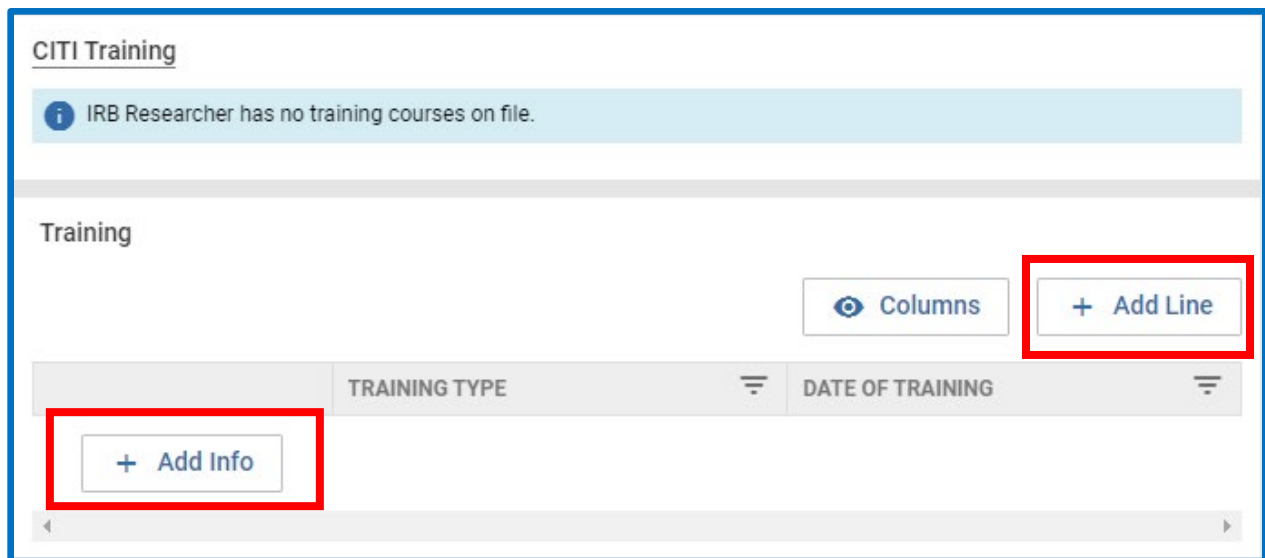
|   | PERSON         | RESEARCHER ROLE        | CITI TRAINING   |
|---|----------------|------------------------|---|
|   | IRB Researcher | Principal Investigator |  IRB Researcher has no training courses on file. |



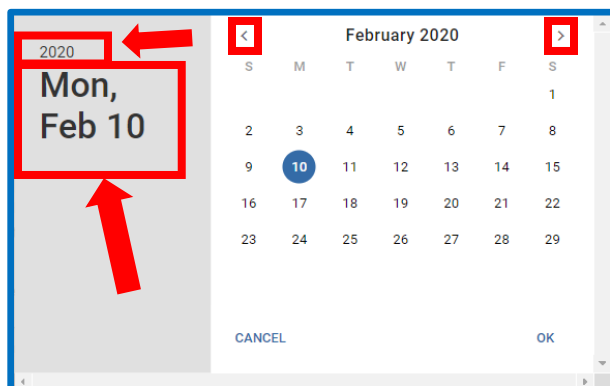
8. If the researcher did not complete the CITI training through UMass Boston, they must upload the CITI training certificate as an attachment. To do this, click the Edit Pencil next to the researcher who has training from an outside institution.



9. Select **+Add Info** to add the training. **+Add Line** can be used if there are additional trainings that need to be added.



**\*Important Tip:** When adding the **Date of Training** click the year and date on the left side to switch between viewing the year and month. Use the arrows to scroll between months and select the correct date.



10. Attach the corresponding external CITI training certificate(s) to the **People Attachments** section by selecting **+Add Info**. More attachments can be added by selecting **+Add Line**. The information on the certificate should match the information you provided in the **Training** section above

**Training**

[Columns](#) [+ Add Line](#)

|  | TRAINING TYPE                       | DATE OF TRAINING  |
|--|-------------------------------------|-------------------|
|  | CITI Training (other institution) ▾ | February 10, 2020 |

**People Attachments**

You must attach **external CITI training certificates** if completed through another institution. The IRB does not have access to external trainings.

If you answered yes to any **financial interest** related to the research, attach the institution's evaluation of the financial interest here.

**Instructions to add or update attachments**

- Click **"+ Add Info"** below to add your first attachment.
- Click **"+ Add Line"** to insert additional attachments.
- Select the **Edit Pencil** next to an attachment to edit or update.

[Columns](#) [+ Add Line](#)

|                            | ATTACHMENT | ATTACHMENT TYPE |
|----------------------------|------------|-----------------|
| <a href="#">+ Add Info</a> |            |                 |

11. If your modification request involves modifications to existing approved study attachments, click the edit pencil next to the original document.

**Study Attachments**

**Attach the following documents:**

Please provide materials in **Word** format if possible so the IRB can provide edits/comments directly within the document(s).

- Protocol (in **Word**). Use the most recent [PROTOCOL TEMPLATE \(HRP-503\)](#). **Required.**





If applicable:

- Consent, assent, and parental permission forms (in **Word**)
- Data Collection Instruments (e.g., questionnaires, surveys, assessments)
- Recruitment Materials (printed, audio, and video)
- Foreign language versions of the above
- Sponsor protocol (if applicable)
- DHHS protocol and DHHS-approved sample consent document (if applicable)
- Evaluation of any Related Financial Interest

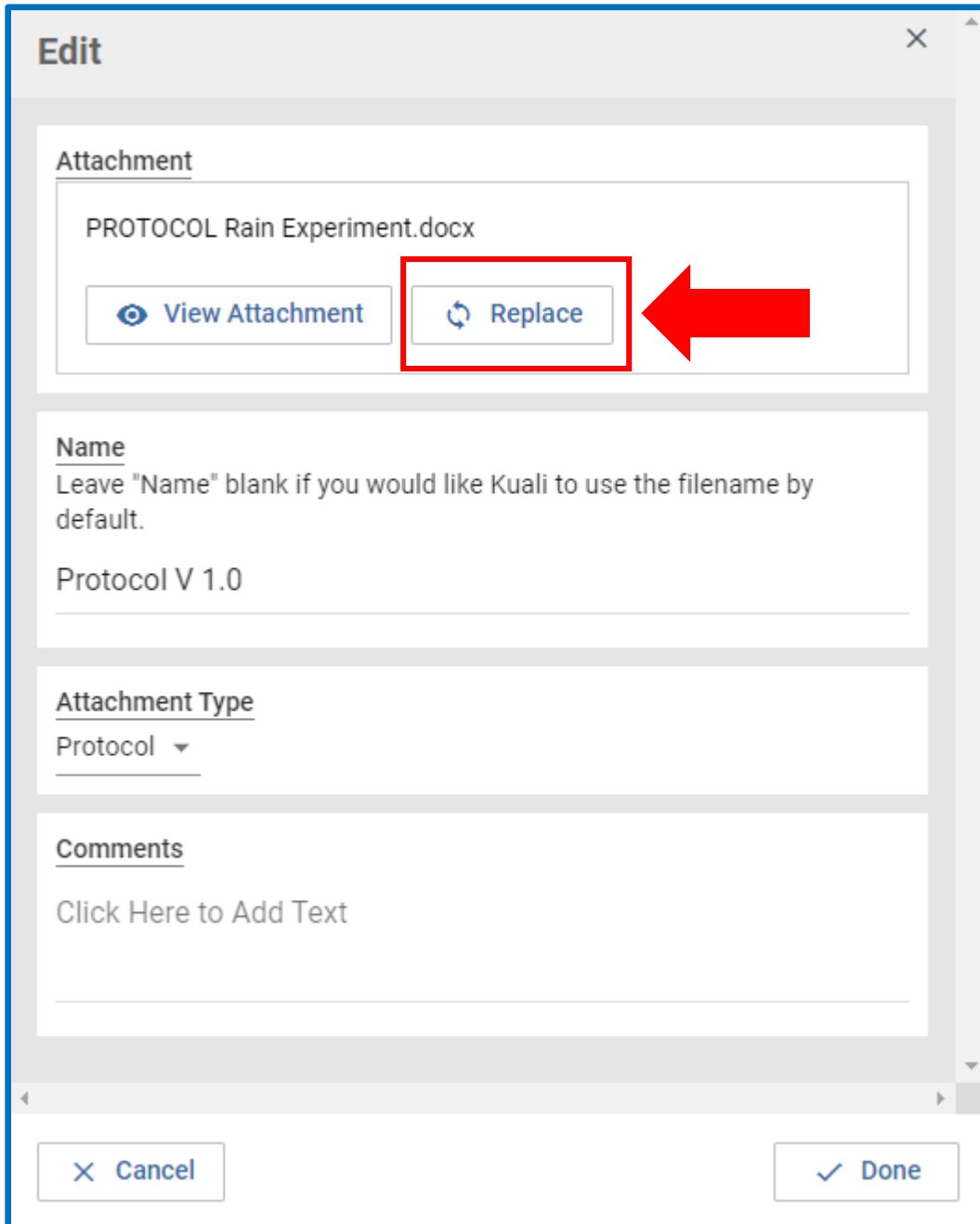
**Instructions to add or update attachments**

- Click "+ Add" below to add your first attachment.
- Click "+ Add" to insert additional attachments.
- Select the [pencil](#) next to an attachment to edit or update.

Columns    + Add Line

|   | ATTACHMENT  | ATTACHMENT TYPE |
|---|---|-----------------|
|  |  <a href="#">PROTOCOL RAIN EXPERIMENT.DOCX</a> | Protocol        |
|  |  <a href="#">CONSENT FORM.DOCX</a>             | Consent Form    |

12. Select **Replace** in the pop-up window to replace the original document with the modified version. Please make sure the modified version of the document has the changes easily visible either via tracked changes in word or highlighting the changes.



The image shows a software dialog box titled "Edit". It contains several sections: "Attachment" with a file name "PROTOCOL Rain Experiment.docx" and two buttons, "View Attachment" and "Replace"; "Name" with a text field containing "Protocol V 1.0"; "Attachment Type" with a dropdown menu set to "Protocol"; and "Comments" with a text area containing "Click Here to Add Text". At the bottom are "Cancel" and "Done" buttons. A red box highlights the "Replace" button, and a red arrow points to it from the right.

13. You may either drag and drop the new document into the attachment box or select **+Choose** to choose a file from your computer

The image shows a dialog box titled "Edit" with a close button (X) in the top right corner. The dialog is divided into several sections:

- Attachment:** A large dashed rectangular area containing a paperclip icon, the text "Drag & Drop a File or", and a button labeled "+ Choose".
- Name:** A section with the heading "Name" and the instruction "Leave 'Name' blank if you would like Kuali to use the filename by default." Below this is a text input field containing "Protocol V 1.0".
- Attachment Type:** A section with the heading "Attachment Type" and a dropdown menu currently set to "Protocol".
- Comments:** A section with the heading "Comments" and the text "Click Here to Add Text" above a text input field.

At the bottom of the dialog, there are two buttons: "Cancel" with a close icon (X) and "Done" with a checkmark icon (✓).

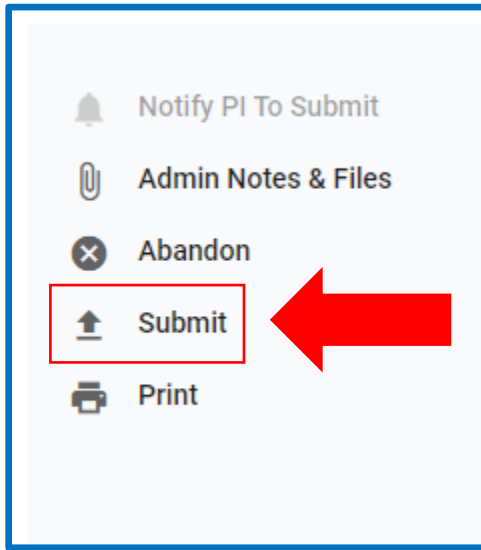
14. Once the revised document is uploaded, make sure the rest of the information in the box is updated and click **Done** at the bottom

The image shows a software dialog box titled "Edit" with a close button (X) in the top right corner. The dialog is divided into several sections:

- Attachment:** A box containing the text "Protocol V 2.0.docx" and two buttons: "View Attachment" (with an eye icon) and "Replace" (with a refresh icon).
- Name:** A section with the instruction "Leave 'Name' blank if you would like Kuali to use the filename by default." Below this is a text input field containing "Protocol V 2.0".
- Attachment Type:** A dropdown menu currently set to "Protocol".
- Comments:** A text area with the placeholder text "Click Here to Add Text".

At the bottom of the dialog, there are two buttons: "Cancel" (with an X icon) on the left and "Done" (with a checkmark icon) on the right. A large red arrow points directly to the "Done" button.

15. Once you've edited the protocol to reflect all changes and uploaded your revised or new documents, you may **submit** your Amend form for IRB review. If you are not the PI, you will need to click Notify PI to Submit. Only the PI has the ability to "Submit" to the IRB. As before, the Kualu system will validate that the form has been fully completed (only the PI who submits will be able to see if there are any validation errors upon submission).

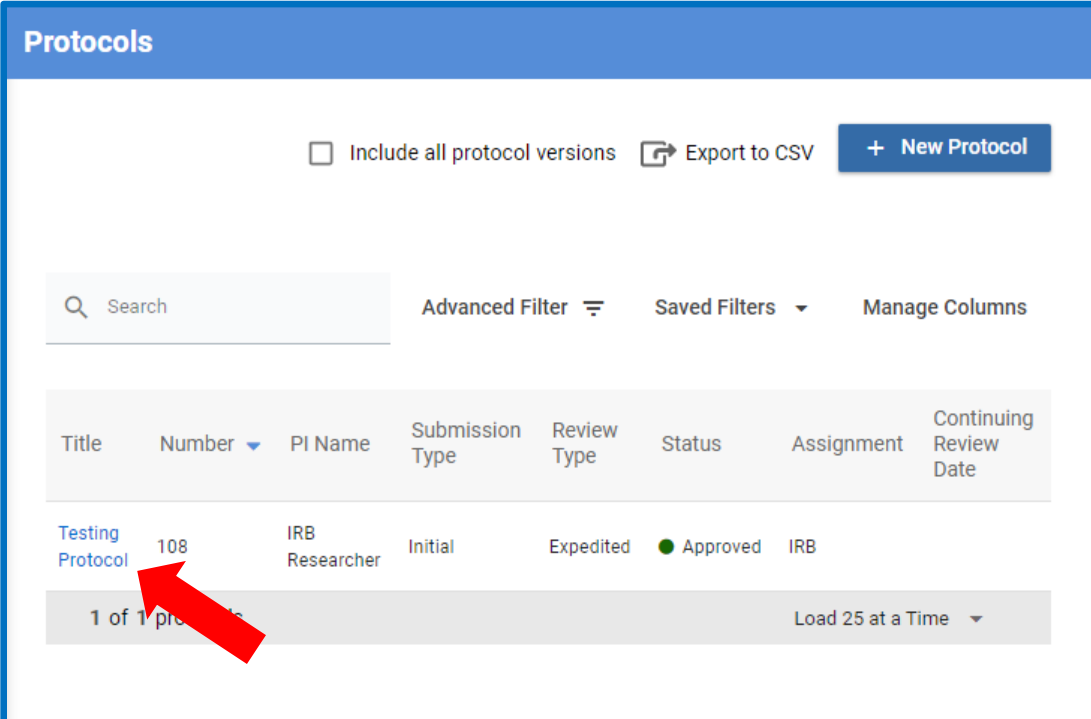


## How to submit Renewal & Amendment (Continuing Review HRP-212 & Modification HRP-213)

**Note:** If you selected "Renew" alone, you will **NOT** be able to make any changes to the study (e.g., adding/removing personnel, revising protocol, etc.). If you selected "Renew" and need to make changes to the study information or study attachments with the continuing review, "Abandon" the submission and select "Renew & Amend" instead.

**We strongly recommend that you select Renew & Amend for ALL renewals (Continuing Reviews HRP-212) even if you do not think you need to amend anything in your study.**

1. Log in to your Kualiti IRB Dashboard and click on the title of the protocol you want to Renew/Amend.



The screenshot shows the 'Protocols' dashboard with the following elements:

- Header: Protocols
- Actions:  Include all protocol versions, Export to CSV, [+ New Protocol](#)
- Search:  Search
- Filters: [Advanced Filter](#), [Saved Filters](#), [Manage Columns](#)
- Table:

| Title            | Number | PI Name        | Submission Type | Review Type | Status   | Assignment | Continuing Review Date |
|------------------|--------|----------------|-----------------|-------------|----------|------------|------------------------|
| Testing Protocol | 108    | IRB Researcher | Initial         | Expedited   | Approved | IRB        |                        |

1 of 1 protocols | Load 25 at a Time



## 2. Select **Renew & Amend** on the right sidebar

The screenshot shows the 'Manage Protocols' interface for 'IRB: #108 Testing Protocol'. The top navigation bar includes a 'Back' button and the title 'Manage Protocols → IRB: #108 Testing Protocol'. Below this, there are tabs for 'Protocol', 'Reportable Events', 'Activity Log', and 'Permissions'. The main content area is titled 'IRB: #108 Testing Protocol' and shows 'Selected Version: 1 | Initial | Approved'. A 'Protocol Information' section contains a table with the following data:

| Review Type | Status   | Approval Date | Continuing Review Date |
|-------------|----------|---------------|------------------------|
| Expedited   | Approved | Dec 13, 2021  | --                     |

| Expiration Date | Initial Approval Date | Initial Review Type |
|-----------------|-----------------------|---------------------|
| --              | Dec 13, 2021          | Expedited           |

The right sidebar contains a list of actions: Amend, Renew, **Renew & Amend** (highlighted with a red box and a red arrow), Action Items Summary, Admin Notes & Files, Request Close, and Print.

3. You will fill out the continuing review form (HRP-212) first, beginning with the **enrollment status** of the study. Note that it is possible for all three boxes to be filled out with the same number.

Renewal (Continuing Review)

**Continuing Review (Form HRP-212)**  
Use to renew an existing protocol.

Please complete all sections of the form below carefully and completely. For general information, visit the [IRB web site](#). If you have any questions, please contact the IRB Office: [irb@umb.edu](mailto:irb@umb.edu).

Note: If you selected "Renew" alone, you will **NOT** be able to make any changes to the study (e.g., adding/removing personnel, revising protocol, etc.). If you need to make changes to the study information or study attachments with the continuing review, "Abandon" this submission and select "Renew & Amend" instead.

**Enrollment Status**

Enter the number (#) of subjects enrolled.

|  |   |
|--|---|
| Total # at this Investigator's Site(s)<br>Click Here to Add Number | # At this Investigator's Site(s) Since Last Approval<br>- ?<br>Click Here to Add Number |
| Total # Study Wide<br>Click Here to Add Number                     |   |

4. Next, the Current Protocol Status needs to be reported. Check off all statements that apply in this section. If all four of the first four statements to appear in the checklist are checked off, the study may be closed with the IRB. To close your study, you will first need to abandon the current Renew & Amend Session by selecting **Abandon** on the right sidebar and then follow the instructions for how to close a study.

Current Protocol Status

Please select all that apply:

If all of the first four items below are checked, the protocol may be closed with the IRB.

The protocol is permanently closed to enrollment.

All subjects enrolled have completed all protocol related interventions and interactions. This includes interventions and interactions related to collection of long-term follow-up data, such as final visits and any follow-up activities (e.g., phone calls, postcard contacts) required by the protocol.

No additional identifiable private information about the subjects is being obtained.

Analysis of private identifiable information is completed.[2] This can be checked even if another organization (e.g., statistical center, sponsor, CRO) will analyze private identifiable information from subjects.

None of the above.

[1]"Current protocol status" refers to the status of the protocol under the supervision of this investigator. For collaborative and multi-site studies with established agreement(s) relying on this institution for IRB review, "current protocol status" refers to all relying sites.

[2] For example, if the only remaining activity of a research project is the analysis of aggregate data sets without individual subject identifiers, no further IRB oversight is necessary.

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The remaining protocol activities are limited to data analysis.

The protocol remains active only for long-term follow-up of subjects.


5. Answer all the Yes or No questions in the “Continuing Review Questions” section. The questions are relative to all sites involved in the protocol since the last IRB continuing review. Answering **Yes** to any of the questions in this section will cause a box to pop up for you to provide a summary, explanation, or description.

### Continuing Review Questions

The following questions are relative to all sites involved in the protocol, since the last IRB continuing review (or since the initial approval if this is the first continuing review submission).

Do any personnel (or an immediate family member of personnel) involved in the design, conduct, or reporting of the protocol have *any* financial interest Related to the Research that has not previously been reported to the IRB?

For definition of financial interest, place your mouse over the "?" or see "[SOP: Definitions \(HRP-001\)](#)".



Yes

No

---

Have any subjects experienced unexpected harm?

Yes

No

Provide a summary explanation or description.

If you answered "Yes" to the above question, you must explain here.

[Click Here to Add Text](#)





6. Complete the Progress Report Section by providing a brief statement of the research question and a brief description of the way the project is currently proceeding in the corresponding text boxes

### Progress Report

Provide a brief summary of the progress of the protocol in the spaces below.

**Include a brief statement of the research question.**





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---

**Include a brief description of the manner in which the project is currently proceeding with an emphasis on human participant interactions/interventions.**

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Sans Serif ▾ Normal ▾ ≡ **B** *I* ~~S~~ U **A**    

---

7. If you have any relevant documents pertaining to the renewal, upload them in the Continuing Review Attachments section by clicking + Add Info. More documents can be uploaded by selecting + Add Line. **This section is not for modified study attachments. Modified study attachments may be uploaded later in the form.**

### Continuing Review Attachments

If you have any relevant documents pertaining to the Continuing Review, please attach in this section (e.g., data safety monitoring report(s), multi-center trial report(s)). **Do not attach any study documents to this section.**

For federally funded research, attach a copy of the most recent annual sponsor's progress report, if applicable.

Instructions to add or update attachments

- Click "+ Add Info" below to add your first attachment.
- Click "+ Add Line" to insert additional attachments.
- Select the [Edit Pencil](#) next to an attachment to edit or update.

[Columns](#) [+ Add Line](#)

|                            | FILE ATTACHMENT | NAME | ATTACHMENT TYPE |
|----------------------------|-----------------|------|-----------------|
| <a href="#">+ Add Info</a> |                 |      |                 |

8. The PI will need to read and certify the statement

### Certification (Renewal)

Please certify to the statement below.

I will conduct this protocol in accordance with requirements of the UMass Boston IRB.

9. The next section is the Amendment (Modification Form HRP-213).

**Amendment (Modification)**





**Modification (Form HRP-213)**  
Use to amend an existing protocol.

Please complete all sections of the form below carefully and completely. For general information, visit the [IRB web site](#). If you have any questions, please contact the IRB Office: [irb@umb.edu](mailto:irb@umb.edu).

10. Provide a description and justification of any modifications made in the provided text box

**Description and Justification**

Provide a description and justification of the modifications.

Sans Serif   ▾   Normal   ▾   ≡   **B**   *I*   ~~S~~   U   **A**            

11. Answer the yes or no questions regarding participant enrollment

**Protocol Status**

Please answer the following questions.

Is the protocol open to the enrollment of new subjects?

Yes

No

Are there any subjects currently enrolled in the study?

Yes

No





12. Indicate whether current/former subjects will be notified of the modifications described above. Selecting either one or both boxes will cause a pop-up text box to appear where a description of how current/former subjects will be notified of the changes is needed

Please check if current and/or former subjects will be notified of these changes (leave blank if no or N/A).

Current subjects will be notified of these changes.

Former subjects will be notified of these changes.

Provide a description of how current and/or former subjects will be notified.

Sans Serif   Normal   **B**   *I*   ~~S~~   U   A            



### 13. The PI will need to read and certify the statement

#### Certification (Modification)

Please certify to the statement below.

I will conduct this protocol in accordance with requirements of the UMass Boston IRB.

14. The next section, starting with General Information, is where you may make any proposed changes to the study information. Fill it out like the original study application, changing anything that you wish to modify.

15. To replace existing approved study attachments with any revised documents, click the edit pencil next to the original document.

#### Study Attachments

Attach the following documents:

Please provide materials in Word format if possible so the IRB can provide edits/comments directly within the document(s).





- Protocol (in Word). Use the most recent [PROTOCOL TEMPLATE \(HRP-503\)](#). Required.

If applicable:

- Consent, assent, and parental permission forms (in Word)
- Data Collection Instruments (e.g., questionnaires, surveys, assessments)
- Recruitment Materials (printed, audio, and video)
- Foreign language versions of the above
- Sponsor protocol (if applicable)
- DHHS protocol and DHHS-approved sample consent document (if applicable)
- Evaluation of any Related Financial Interest

Instructions to add or update attachments

- Click "+ Add Info" below to add your first attachment.
- Click "+ Add Line" to insert additional attachments.
- Select the **Edit Pencil** next to an attachment to edit or update.

|   | ATTACHMENT  | ATTACHMENT TYPE |
|---|---|-----------------|
|  |  PROTOCOL RAIN EXPERIMENT.DOCX | Protocol        |
|  |  CONSENT FORM.DOCX             | Consent Form    |


16. Select **Replace** in the pop-up window to replace the original document with the modified version. Please make sure the modified version of the document has the changes easily visible either via tracked changes in word or highlighting the changes

The image shows a software dialog box titled "Edit". It contains several sections: "Attachment" with the filename "PROTOCOL Rain Experiment.docx" and two buttons, "View Attachment" and "Replace"; "Name" with a text field containing "Protocol V 1.0"; "Attachment Type" with a dropdown menu set to "Protocol"; and "Comments" with a text area containing "Click Here to Add Text". At the bottom are "Cancel" and "Done" buttons. A red box highlights the "Replace" button, and a red arrow points to it from the top right.

17. You may either drag and drop the new document into the attachment box or select **+Choose** to choose a file from your computer

**Edit**

Attachment

 Drag & Drop a File or

Name  
Leave "Name" blank if you would like Kualo to use the filename by default.

Protocol V 1.0

Attachment Type  
Protocol ▾

Comments  
Click Here to Add Text

18. Once the revised document is uploaded, make sure the rest of the information in the box is updated and click **Done** at the bottom

**Edit**

Attachment

Protocol V 2.0.docx

[View Attachment](#) [Replace](#)

Name

Leave "Name" blank if you would like Kuali to use the filename by default.

Protocol V 2.0

Attachment Type

Protocol ▾

Comments

Click Here to Add Text

[Cancel](#) [Done](#)

19. Go through the form and make sure all modifications have been submitted and the **Investigator Certification** is checked off at the bottom then **submit** the form using the submit button on the right sidebar. If you are not the PI, you will need to click Notify PI to Submit. Only the PI has the ability to “Submit” to the IRB. As before, the Quali system will validate that the form has been fully completed (only the PI who submits will be able to see if there are any validation errors upon submission).

### Investigator Certification

By clicking the Certify checkbox, I certify that:

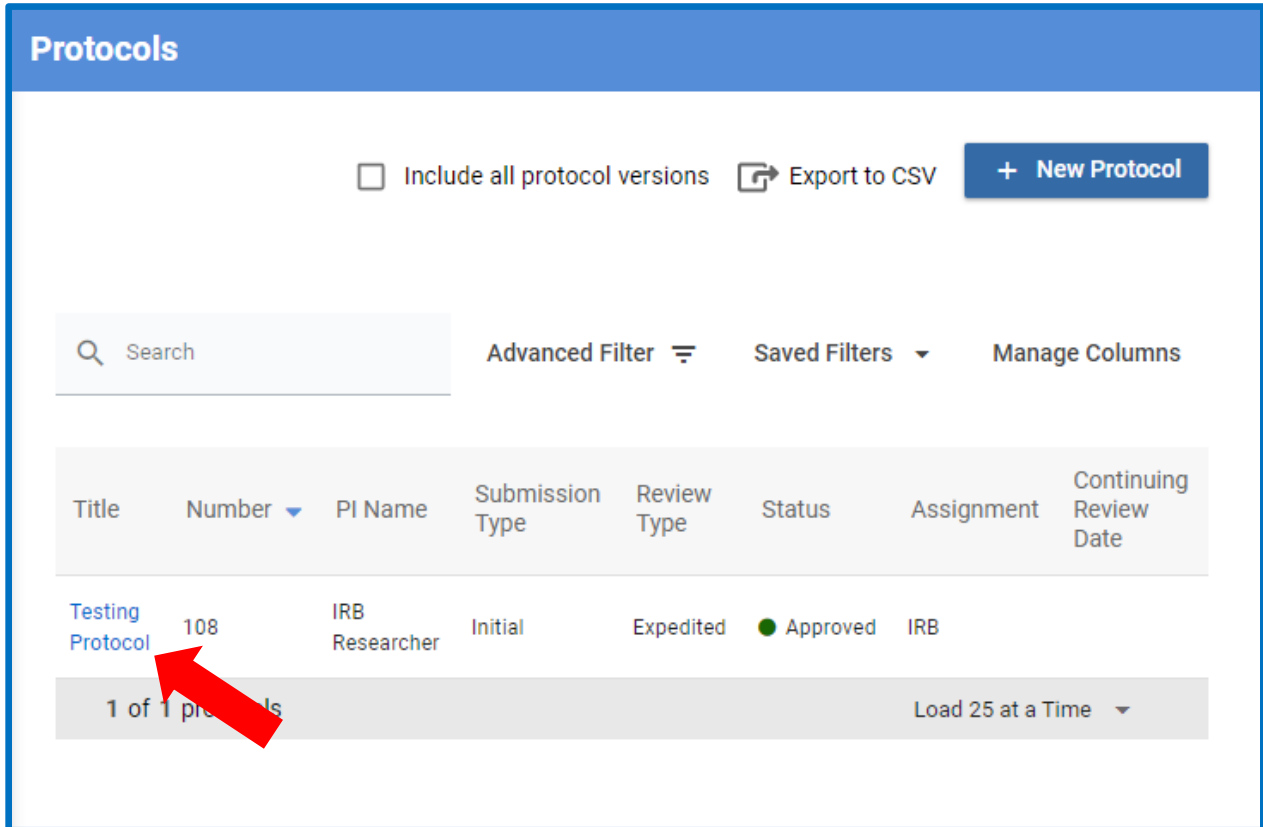
- I have reviewed the UMass Boston [Investigator Manual \(HRP-103\)](#).
- I will conduct this protocol in accordance with requirements of the UMass Boston IRB.
- (For students) My faculty advisor has reviewed this application and made any necessary comments and revisions.

---

Certify

## How to submit a Renewal (Continuing Review HRP-212)

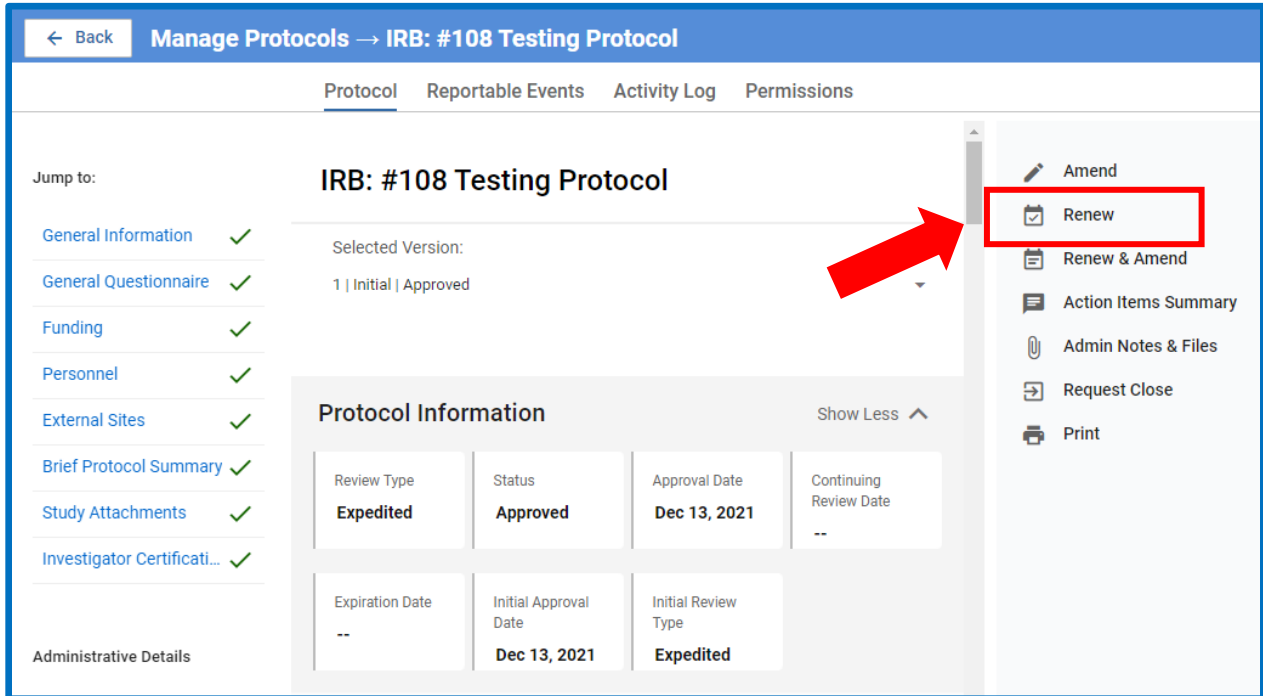
16. Log in to your Quali IRB Dashboard and click on the title of the protocol you want to Renew



The screenshot shows the 'Protocols' dashboard interface. At the top, there is a blue header with the word 'Protocols'. Below the header, there are several controls: a checkbox for 'Include all protocol versions', an 'Export to CSV' button, and a '+ New Protocol' button. A search bar with a magnifying glass icon and the text 'Search' is on the left. To the right of the search bar are 'Advanced Filter' (with a funnel icon), 'Saved Filters' (with a dropdown arrow), and 'Manage Columns'. Below these controls is a table with the following columns: Title, Number (with a dropdown arrow), PI Name, Submission Type, Review Type, Status, Assignment, and Continuing Review Date. The table contains one row with the following data: 'Testing Protocol' (with a blue link), '108', 'IRB Researcher', 'Initial', 'Expedited', 'Approved' (with a green dot), and 'IRB'. At the bottom of the table, there is a footer showing '1 of 1 protocols' and a 'Load 25 at a Time' dropdown menu. A red arrow points to the 'Testing Protocol' link in the table.

| Title                            | Number | PI Name        | Submission Type | Review Type | Status   | Assignment | Continuing Review Date |
|----------------------------------|--------|----------------|-----------------|-------------|----------|------------|------------------------|
| <a href="#">Testing Protocol</a> | 108    | IRB Researcher | Initial         | Expedited   | Approved | IRB        |                        |

## 17. Select **Renew** on the right sidebar



The screenshot shows the 'Manage Protocols' interface for 'IRB: #108 Testing Protocol'. The top navigation bar includes 'Back', 'Manage Protocols', and 'IRB: #108 Testing Protocol'. Below this, there are tabs for 'Protocol', 'Reportable Events', 'Activity Log', and 'Permissions'. The main content area is titled 'IRB: #108 Testing Protocol' and shows 'Selected Version: 1 | Initial | Approved'. A 'Protocol Information' section contains a table with the following data:

| Review Type | Status   | Approval Date | Continuing Review Date |
|-------------|----------|---------------|------------------------|
| Expedited   | Approved | Dec 13, 2021  | --                     |

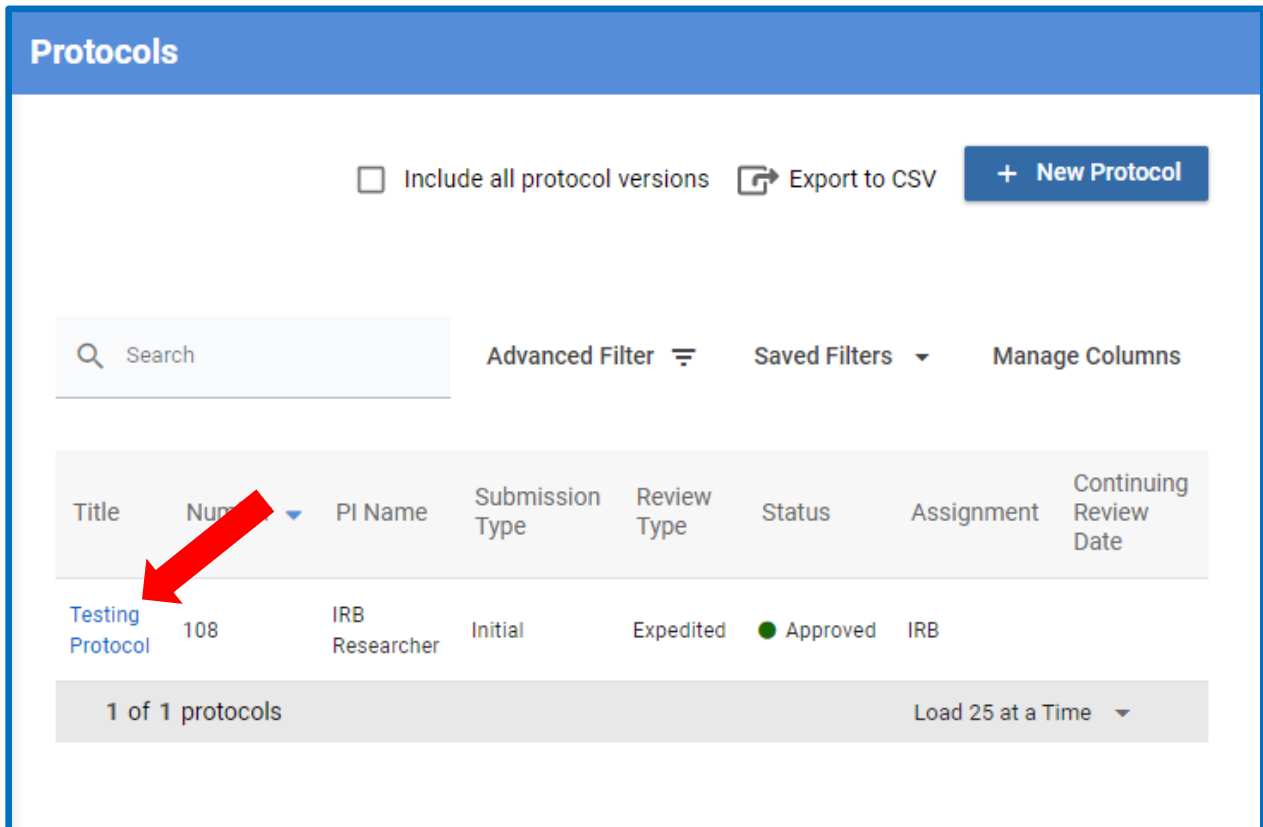
| Expiration Date | Initial Approval Date | Initial Review Type |
|-----------------|-----------------------|---------------------|
| --              | Dec 13, 2021          | Expedited           |

The right sidebar contains several action items: Amend, Renew (highlighted with a red box and a red arrow), Renew & Amend, Action Items Summary, Admin Notes & Files, Request Close, and Print.

18. Fill in the relevant information and submit. If you are not the PI, you will need to click Notify PI to Submit. Only the PI has the ability to “Submit” to the IRB. As before, the Quali system will validate that the form has been fully completed (only the PI who submits will be able to see if there are any validation errors upon submission). For a more detailed explanation of the form, see the Continuing Review instructions in the Renew & Amend instructions Above.


## How to Close Your Protocol/Submit a Final Report (HRP-212)

1. Log in to your Quali IRB Dashboard and click on the title of the protocol you want to close. If there are any outstanding actions such as a pending Revision you will not be able to close the protocol until that action is resolved. **Please be aware that once you close the protocol you will not be able to clone it or re-open it!**



The screenshot shows the 'Protocols' dashboard with a table of protocols. A red arrow points to the 'Testing Protocol' title in the first row of the table.

Protocols

Include all protocol versions     Export to CSV    [+ New Protocol](#)

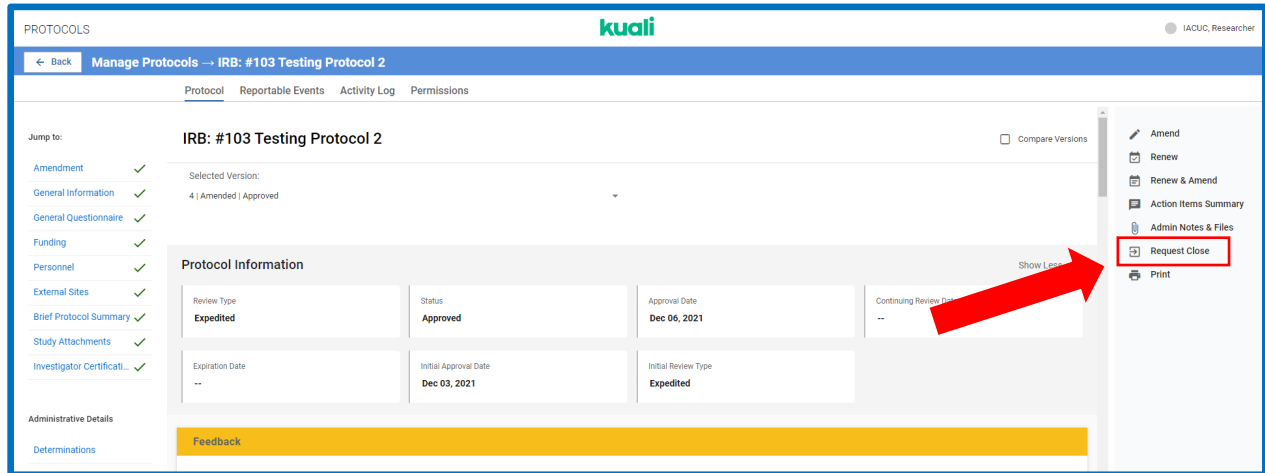
Search    Advanced Filter    Saved Filters    Manage Columns

| Title                            | Number | PI Name        | Submission Type | Review Type | Status     | Assignment | Continuing Review Date |
|----------------------------------|--------|----------------|-----------------|-------------|------------|------------|------------------------|
| <a href="#">Testing Protocol</a> | 108    | IRB Researcher | Initial         | Expedited   | ● Approved | IRB        |                        |

1 of 1 protocols    Load 25 at a Time



2. Once you open the desired protocol, the sidebar on the far-right side will provide you available actions. Click on **Request Close** to initiate this action. If your study is expired you will not be able to select **Request Close**, instead please select **Renew** and note that you wish to close this study in a comment.



3. Clicking **Request Close** will open up the Final Report form. The first section asks the number of subjects enrolled. Please fill out all three boxes with the relevant information. Keep in mind, in certain circumstances all three numbers may be the same.

The 'Enrollment Status' form contains the following fields:

- Total # at this Investigator's Site(s)**: Input field with a red box around it and a 'Click Here to Add Number' link below.
- # At this Investigator's Site(s) Since Last Approval**: Input field with a red box around it, a question mark icon, and a 'Click Here to Add Number' link below.
- Total # Study Wide**: Input field with a red box around it and a 'Click Here to Add Number' link below.

4. Next are four questions relating to the current protocol status. If the answer is **Yes** to all four questions, the protocol may be closed with the IRB. If the answer is **No** to any of the questions, the protocol is not eligible to be closed and this submission should be abandoned.

Current Protocol Status

Please read and answer each of the following questions carefully.

If the answer is "Yes" to **all four questions**, the protocol may be closed with the IRB.

**Question 1:** Is the protocol permanently closed to enrollment?

Yes  
 No

**Question 2:** Have all subjects enrolled completed all protocol related interventions and interactions?

This includes interventions and interactions related to collection of long-term follow-up data (such as final visits and any follow-up activities (e.g., phone calls, postcard contacts) required by the protocol.

Yes  
 No

**Question 3:** Are you no longer obtaining any identifiable private information about the subjects?

Yes  
 No

**Question 4:** Is the analysis of private identifiable information completed?

For example, if you are only analyzing aggregate data sets without individual subject identifiers, you may answer "Yes." ("Yes" can be checked even if another organization (e.g., statistical center, sponsor, CRO) not under this IRB's oversight will analyze private identifiable from subjects.)

Yes  
 No

**All four closure criteria are met. No further IRB oversight is necessary. Please continue completing the form below.**

Current Protocol Status

Please read and answer each of the following questions carefully.

If the answer is "Yes" to **all four questions**, the protocol may be closed with the IRB.

**Question 1:** Is the protocol permanently closed to enrollment?

Yes  
 No

**Question 2:** Have all subjects enrolled completed all protocol related interventions and interactions?

This includes interventions and interactions related to collection of long-term follow-up data (such as final visits and any follow-up activities (e.g., phone calls, postcard contacts) required by the protocol.

Yes  
 No

**Question 3:** Are you no longer obtaining any identifiable private information about the subjects?

Yes  
 No

**Question 4:** Is the analysis of private identifiable information completed?

For example, if you are only analyzing aggregate data sets without individual subject identifiers, you may answer "Yes." ("Yes" can be checked even if another organization (e.g., statistical center, sponsor, CRO) not under this IRB's oversight will analyze private identifiable from subjects.)

Yes  
 No

**This protocol is not eligible to be closed. Please "Abandon" this submission.**

I acknowledge

Notify PI To Submit  
Admin Notes & Files  
**Abandon**  
Submit  
Print

5. Scroll down and answer all the closure questions. Answering Yes to certain questions will prompt a text box to appear where a summary, explanation or description can be written.

**Closure Questions**

The following questions are relative to all sites involved in the protocol, since the last IRB continuing review (or since the initial approval if there have been no continuing reviews).

Do any personnel (or an immediate family member of personnel) involved in the design, conduct, or reporting of the protocol have *any* financial interest Related to the Research that has not previously been reported to the IRB?

For definition of financial interest, place your mouse over the "?" or see "[SOP: Definitions \(HRP-001\)](#)".

- ?

Yes  
 No

**Provide a summary explanation or description.**  
If you answered "Yes" to the above question, you must explain here. Please also scroll down and attach the institution's evaluation of the financial interest in the Closure Attachments section.

[Click Here to Add Text](#)

---

Have any subjects experienced unexpected harm?

Yes  
 No

Have any Anticipated Adverse Events taken place with greater frequency or severity than expected?

Yes  
 No

**Provide a summary explanation or description.**  
If you answered "Yes" to the above question, you must explain here.

[Click Here to Add Text](#)

6. In the boxes, Provide a brief final report summary of the protocol

### Final (Progress) Report

Provide a brief final report summary of the protocol in the spaces below.

Include a brief statement of the research question.

Sans Serif Normal B I S U A [Image] [List] [List] [Link]

---

Include a brief description of the manner in which the project proceeded with an emphasis on human participant interactions/interventions.

Sans Serif Normal B I S U A [Image] [List] [List] [Link]

---

7. Add any relevant documents pertaining to the closure by using + Add Info to add your first attachment and + Add Line to insert additional attachments

### Closure Attachments

If you have any relevant documents pertaining to the Closure (Final Report), please attach in this section (e.g., data safety monitoring report(s), multi-center trial report(s)). Do not attach any study documents to this section.

For federally funded research, attach a copy of the most recent annual sponsor's progress report, if applicable.

Instructions to add or update attachments

- Click **+ Add Info** below to add your first attachment.
- Click **+ Add Line** to insert additional attachments.
- Select the **Edit Pencil** next to an attachment to edit or update.

Columns **+ Add Line**

| ATTACHMENT        | NAME | ATTACHMENT TYPE | COMMENTS |
|-------------------|------|-----------------|----------|
| <b>+ Add Info</b> |      |                 |          |

8. Finally, the PI must **Certify** the closure statement and **submit**.

The screenshot displays a web application interface for managing protocols. The main content area is titled "Closure Attachments" and contains instructions for uploading documents. Below this, there is a table with columns for "ATTACHMENT", "NAME", "TYPE", and "COMMENTS". A red circle highlights the "Certification (Closure)" section, which includes a checkbox labeled "I will follow the requirements of the UMass Boston IRB." A red arrow points from the "Submit" button in the right sidebar to the "Certification (Closure)" section.

Manage Protocols → IRB: #103 Testing Protocol 2

Protocol Reportable Events Activity Log Permissions

Jump to:

- Close Request
- General Information ✓
- General Questionnaire ✓
- Funding ✓
- Personnel ✓
- External Sites ✓
- Brief Protocol Summary ✓
- Study Attachments ✓
- Investigator Certificati... ✓

Administrative Details

Determinations

Closure Attachments

If you have any relevant documents pertaining to the Closure (Final Report), please attach in this section (e.g., data safety monitoring report(s), multi-center trial report(s)). Do not attach any study documents to this section.

For federally funded research, attach a copy of the most recent annual sponsor's progress report, if applicable.

Instructions to add or update attachments

- Click "+ Add Info" below to add your first attachment.
- Click "+ Add Line" to insert additional attachments.
- Select the Edit Pencil next to an attachment to edit or update.

Columns + Add Line

| ATTACHMENT | NAME | TYPE | COMMENTS |
|------------|------|------|----------|
|------------|------|------|----------|

+ Add Info

Certification (Closure)

Please certify to the statement below.

I will follow the requirements of the UMass Boston IRB.

Notify PI To Submit

Admin Notes & Files

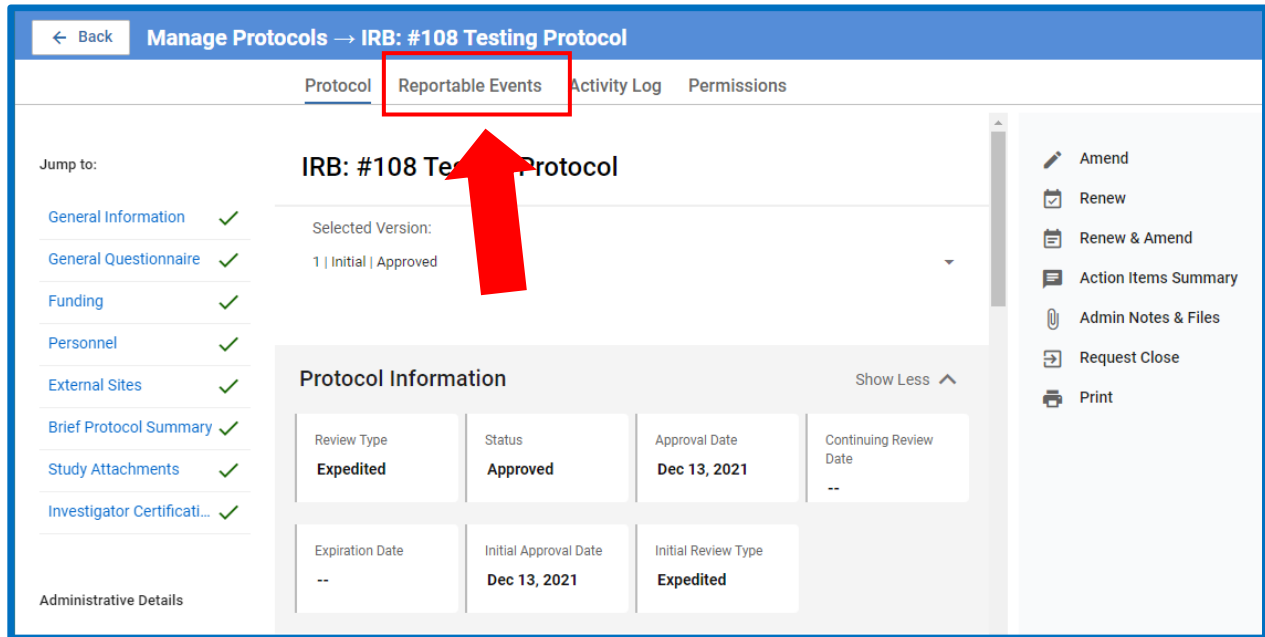
Abandon

Submit

Print

## Submitting a Reportable Event (HRP-214)

1. Log in to your Quali IRB Dashboard and click on the title of the protocol for which you want to submit a **Reportable Event**. Click on **Reportable Event** in the middle of the screen to open the form.

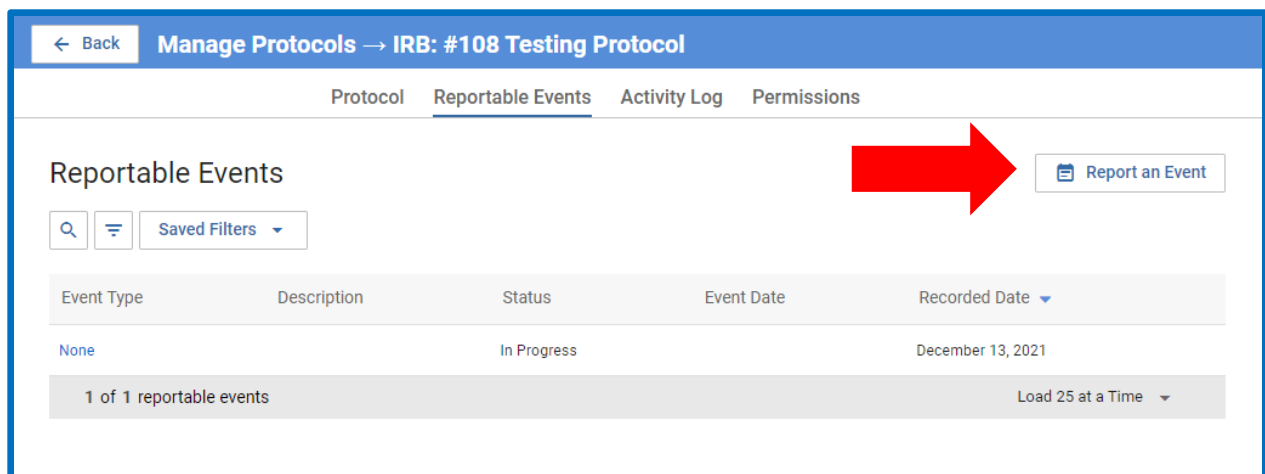


The screenshot shows the 'Manage Protocols' page for 'IRB: #108 Testing Protocol'. The 'Reportable Events' tab is highlighted with a red box and a red arrow. The main content area shows the protocol title 'IRB: #108 Testing Protocol' with a red arrow pointing to it. Below the title, there is a 'Selected Version' dropdown set to '1 | Initial | Approved'. The 'Protocol Information' section contains a table with the following data:

| Review Type     | Status                | Approval Date       | Continuing Review Date |
|-----------------|-----------------------|---------------------|------------------------|
| Expedited       | Approved              | Dec 13, 2021        | --                     |
| Expiration Date | Initial Approval Date | Initial Review Type |                        |
| --              | Dec 13, 2021          | Expedited           |                        |

On the right side, there is a sidebar with several action items: Amend, Renew, Renew & Amend, Action Items Summary, Admin Notes & Files, Request Close, and Print.

2. The **Reportable Event** page will show previously submitted events submitted to the IRB. In order to submit a new Reportable Event click on the **“Report an Event”** button on the right side of the screen.

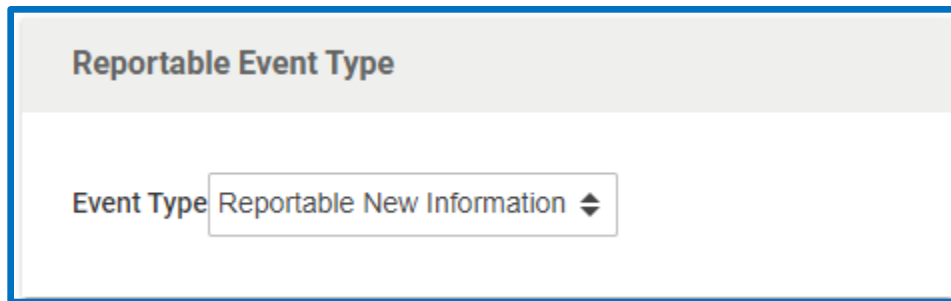


The screenshot shows the 'Reportable Events' page for 'IRB: #108 Testing Protocol'. The 'Reportable Events' tab is selected. The page displays a table with the following data:

| Event Type | Description | Status      | Event Date | Recorded Date     |
|------------|-------------|-------------|------------|-------------------|
| None       |             | In Progress |            | December 13, 2021 |

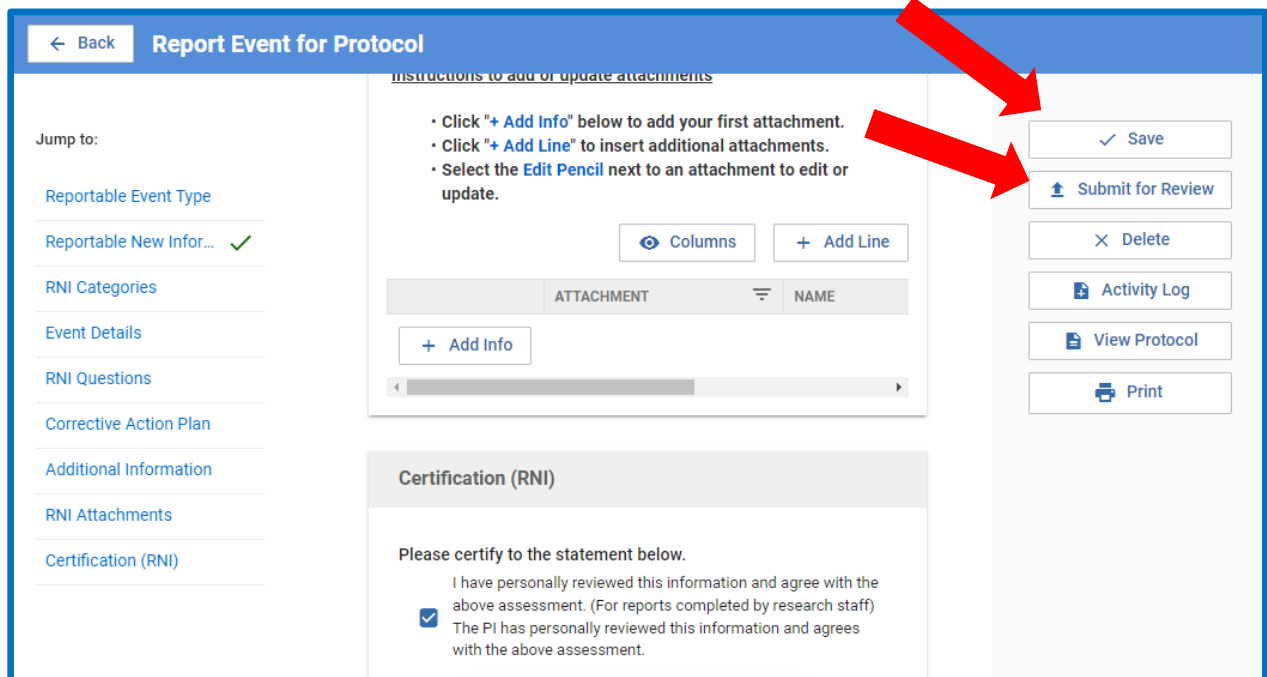
At the bottom of the table, it shows '1 of 1 reportable events' and a 'Load 25 at a Time' dropdown. A red arrow points to the 'Report an Event' button on the right side of the page.

3. On the **Reportable Event Type** Dropdown, select “**Reportable New information**” in the drop-down list. That should be the only option



The screenshot shows a dropdown menu titled "Reportable Event Type". The selected option is "Reportable New Information", which is displayed in a white box with a downward arrow on the right side.

4. Answer all the prompts regarding the reportable event and please click the **Save** button on the right side of the screen often in order to save your work. Once you’ve completed the form and saved your work, please click the **Submit for Review** button on the right side of the screen.



The screenshot shows the "Report Event for Protocol" form. The form is divided into several sections:

- Jump to:** A list of navigation links including "Reportable Event Type", "Reportable New Infor..." (with a green checkmark), "RNI Categories", "Event Details", "RNI Questions", "Corrective Action Plan", "Additional Information", "RNI Attachments", and "Certification (RNI)".
- Instructions to add or update attachments:** A list of instructions: "Click '+ Add Info' below to add your first attachment.", "Click '+ Add Line' to insert additional attachments.", and "Select the Edit Pencil next to an attachment to edit or update." Below these instructions are buttons for "Columns" and "+ Add Line".
- Attachment Table:** A table with columns "ATTACHMENT" and "NAME". Below the table is a "+ Add Info" button.
- Certification (RNI):** A section titled "Certification (RNI)" with the text "Please certify to the statement below." and a checkbox that is checked, followed by the text "I have personally reviewed this information and agree with the above assessment. (For reports completed by research staff) The PI has personally reviewed this information and agrees with the above assessment."
- Right Side Buttons:** A vertical stack of buttons: "Save" (with a checkmark icon), "Submit for Review" (with an upward arrow icon), "Delete" (with an X icon), "Activity Log" (with a document icon), "View Protocol" (with a document icon), and "Print" (with a printer icon). Two red arrows point to the "Save" and "Submit for Review" buttons.

5. Once you click the **Submit for Review** button all the other buttons disappear except for **Activity Log**, **View Protocol**, and **Print**. You've successfully submitted your Reportable Event.

The screenshot displays a web interface titled "Report Event for Protocol". At the top left, there is a "Back" button. Below the title, a "Jump to:" section lists several navigation options: "Reportable Event Type", "Reportable New Infor..." (which is highlighted with a green checkmark), "RNI Categories", "Event Details", "RNI Questions", "Corrective Action Plan", "Additional Information", "RNI Attachments", and "Certification (RNI)".

The main content area is divided into two sections. The first section, titled "Reportable Event Type", shows the selected event type as "Reportable New Information". The second section, titled "Reportable New Information", contains the following text:

**Reportable New Information (Form HRP-214)**  
Use this form to report the information items that fall into one or more of the below categories to the IRB within 5 business days.

Please complete all sections of the form below carefully and completely. For general information, visit the [IRB web site](#). If you have any questions, please contact the IRB Office: [irb@umb.edu](mailto:irb@umb.edu).

On the right side of the interface, there are three buttons: "Activity Log", "View Protocol", and "Print".



## How to Access Your Approval Letter

1. Log in to your Kualu IRB Dashboard and click on the title of the approved protocol for which you want to access the Approval Letter. You can also log in through the link provided in the email notification.

The screenshot shows the 'Protocols' dashboard interface. At the top, there is a blue header with the title 'Protocols'. Below the header, there are several controls: a checkbox for 'Include all protocol versions', an 'Export to CSV' button, and a '+ New Protocol' button. A search bar with a magnifying glass icon and the text 'Search' is on the left. To the right of the search bar are 'Advanced Filter', 'Saved Filters', and 'Manage Columns' options. Below these controls is a table with the following columns: Title, Number, PI Name, Submission Type, Review Type, Status, Assignment, and Continuing Review Date. The first row of the table contains the following data: 'Testing Protocol' (with a red arrow pointing to it), '108', 'IRB Researcher', 'Initial', 'Expedited', 'Approved' (with a green dot), and 'IRB'. At the bottom of the table, there is a pagination bar showing '1 of 108 protocols' and a 'Load 25 at a Time' dropdown menu.

| Title            | Number | PI Name        | Submission Type | Review Type | Status   | Assignment | Continuing Review Date |
|------------------|--------|----------------|-----------------|-------------|----------|------------|------------------------|
| Testing Protocol | 108    | IRB Researcher | Initial         | Expedited   | Approved | IRB        |                        |

- Once you've opened the protocol click on the **Activity Log** in the middle of the screen

← Back Manage Protocols → IRB: #108 Testing Protocol

Protocol Reportable Events **Activity Log** Permissions

Jump to: IRB: #108 Testing Protocol

- General Information ✓
- General Questionnaire ✓
- Funding ✓
- Personnel ✓
- External Sites ✓
- Brief Protocol Summary ✓
- Study Attachments ✓
- Investigator Certificati... ✓

Administrative Details

Selected Version: 1 | Initial | Approved

**Protocol Information** Show Less ^

|                 |                       |                     |                        |
|-----------------|-----------------------|---------------------|------------------------|
| Review Type     | Status                | Approval Date       | Continuing Review Date |
| Expedited       | Approved              | Dec 13, 2021        | --                     |
| Expiration Date | Initial Approval Date | Initial Review Type |                        |
| --              | Dec 13, 2021          | Expedited           |                        |

- Amend
- Renew
- Renew & Amend
- Action Items Summary
- Admin Notes & Files
- Request Close
- Print

- Once you've opened the activity log, click on **Correspondence Generated** to access your approval letter

Protocol Reportable Events **Activity Log** Permissions

Activity Log ^ Collapse All

| Action                                      | User           | Date & Time                 |
|---|----------------|-----------------------------|
| Version (Initial) <a href="#">version 1</a> | IRB Researcher | Dec 13, 2021 @ 09:21 AM EST |
| Submit                                      | IRB Researcher | Dec 13, 2021 @ 10:36 AM EST |
| Approve                                     | Mei, Marissa   | Dec 13, 2021 @ 10:39 AM EST |
| <a href="#">Correspondence Generated</a>    | Mei, Marissa   | Dec 13, 2021 @ 10:39 AM EST |

- To save your letter, **right click** on the approval letter and select **“Print”**. Then change the destination to **“Save as PDF”** and click **“save”** on the bottom right to save to your computer. We strongly recommend saving a copy of the approval letter to your study file outside of Kualii.

The screenshot displays a document viewer interface. On the left, a document titled 'PROTOCOLS' is shown, featuring the UMass Boston Institutional Review Board logo and contact information. The document content includes a date of 'Friday, January 6th 2023', an IRB ID number of '3380', and details about the protocol title 'Testing' and submission type 'Initial'. A key section states: 'The Initial submission for the research study referenced above was reviewed and approved Exempt on Friday, January 6th 2023 by the University of Massachusetts Boston IRB. The UMass Boston IRB expiration date is no date provided.' Below this, there is a paragraph about ongoing IRB review and approval, and a reference to the 'IRB-103 - INVESTIGATOR MANUAL'. Contact information for the Institutional Review Board is provided at the bottom of the document.

On the right side of the interface, a 'Print' menu is open, showing '1 page' to be printed. The 'Destination' dropdown is set to 'Save as PDF', which is highlighted by a red box. A red arrow points to this dropdown. Other options in the menu include 'Pages' set to 'All' and 'Layout' set to 'Portrait'. At the bottom right of the print menu, there are 'Save' and 'Cancel' buttons, with the 'Save' button highlighted by a red box.

## How to Respond to the IRB

1. When the IRB has finished reviewing your study/is requesting clarifications you will receive a notification in your email from **Kuali Notifications** with the subject “IRB (Protocol #): Returned to Researcher/Clarifications Requested” or “IRB (Protocol #): Revisions Required” (It may be in your junk mail. To prevent it from going to the junk folder, **please add Kuali Notifications to safe senders**). You will also see the status of the study as “Returned to Researcher” or “Revisions In Progress” on your Kuali Protocol Dashboard.
2. To start your response to the IRB, click on the title of the study. You can also find the name of the admin assigned to your study by using the filters on this page.

The screenshot shows the 'Protocols' dashboard with a table of protocols. A red arrow points to the 'Testing Protocol' entry, and a red box highlights the 'Returned to Researcher' status.

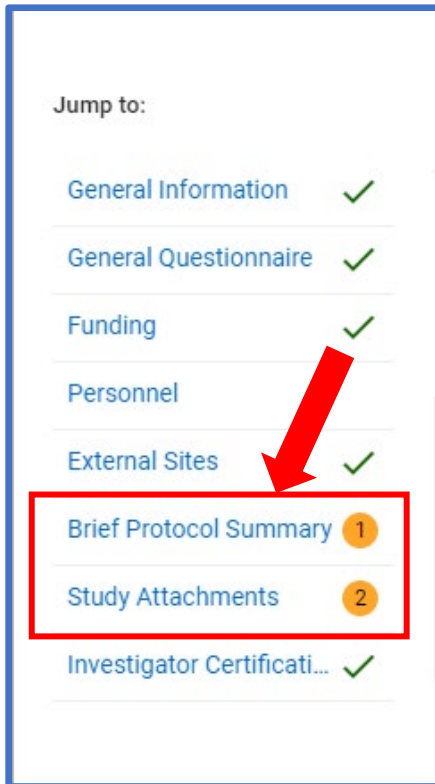
| Title            | Number | PI Name        | Submission Type | Review Type | Status                 | Assignment | Continuing Review Date |
|------------------|--------|----------------|-----------------|-------------|------------------------|------------|------------------------|
| Testing Protocol | 111    | IRB Researcher | New             | Exempt      | Returned to Researcher | IRB        |                        |

1 of 1 protocols Load 25 at a Time

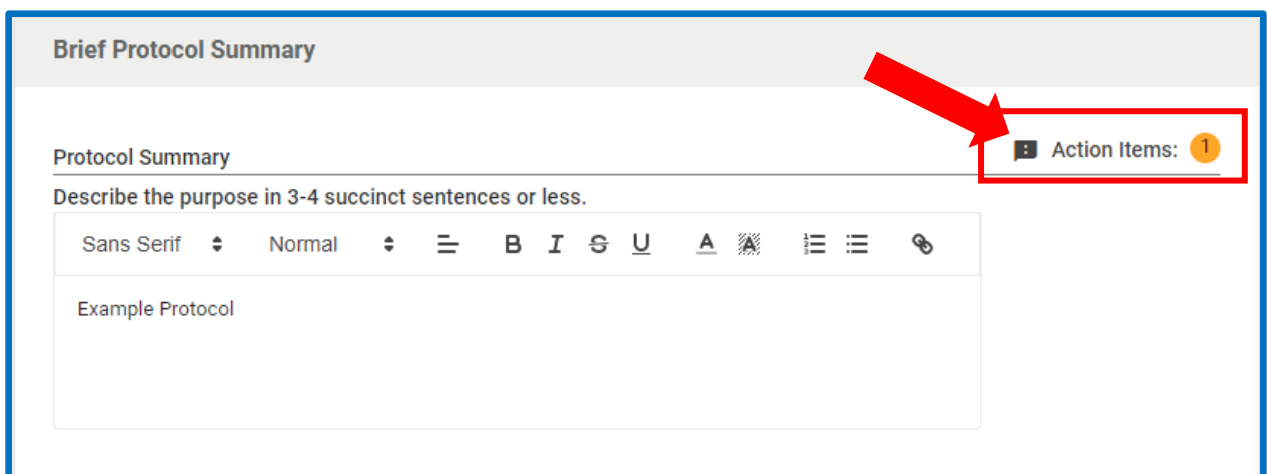
3. To see who the IRB contact is for your specific submission, click on the Activity Log at the top of the page of that specific submission. You will be able to see the name of the IRB team member who **most recently** returned your study to you and direct any questions/concerns to that person.

| Protocol                                | Activity Log | Permissions    |
|---|--------------|----------------|
| Action                                  |              | User           |
| Version (New) <a href="#">version 1</a> |              | IRB Researcher |
| Submit                                  |              | IRB Researcher |
| Return                                  |              | Mei, Marissa   |
| Version (New) <a href="#">version 2</a> |              | Mei, Marissa   |
| ▼ Notification Sent (Returned)          |              | Mei, Marissa   |

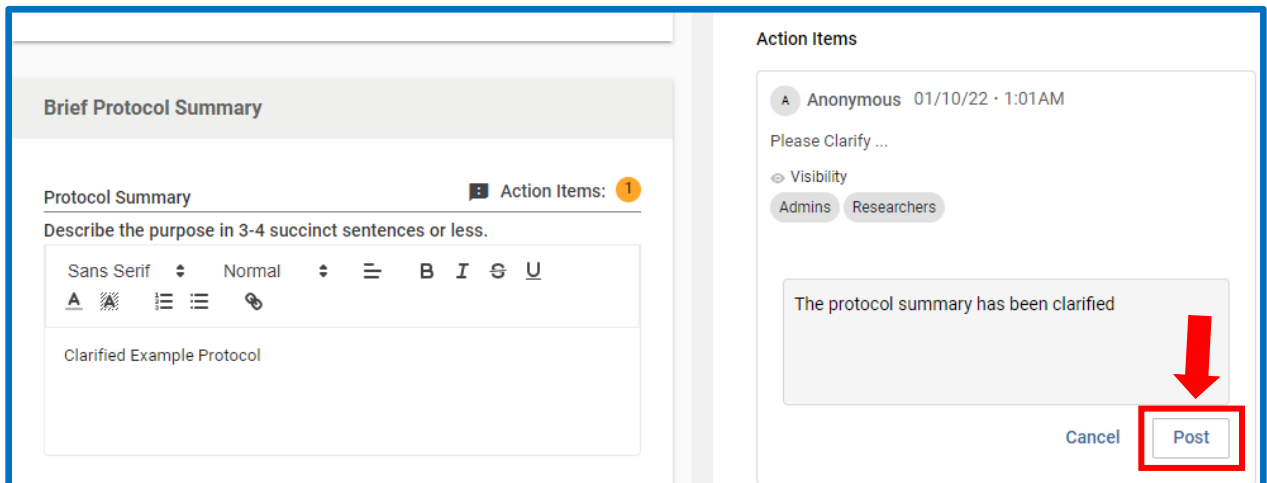
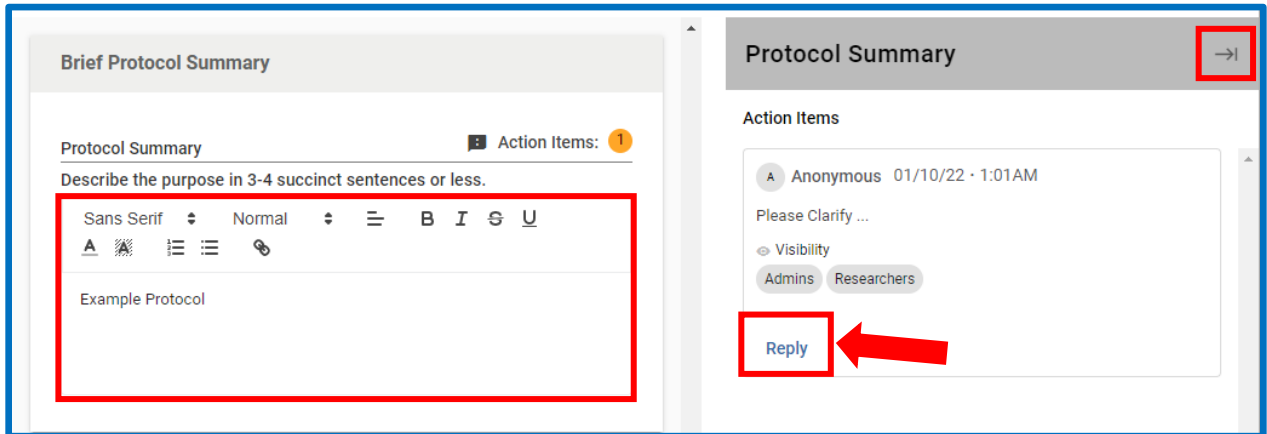
4. On the left sidebar you will be able to see an orange circle with a number in it by certain sections of your study submission. This indicates the comments the IRB reviewers left. You can scroll straight to the section that needs attention by clicking on the section.



5. Clicking the section will automatically scroll you down to the section that needs attention. Click the **Action Items** on the upper right to see the reviewer's comments



6. Clicking the Action Items will cause the reviewer comments to automatically popup on the right side. You may close this popup by clicking the arrow on the top right of the pop up. In this case, the reviewer asked for us to “Please Clarify” the Protocol Summary. We can do this by directly editing in the original text box. You may also **Reply** to the comment telling the reviewer the Protocol Summary has been edited.



7. If there are Action items in the study attachments that say “see attached” or something similar you will need to click the “Admin Notes & Files” tab on the right sidebar. A green circle will indicate if there are new attachments from the IRB in that location.

**Study Attachments**

**Attach the following documents:**

Please provide materials in Word format if possible so the IRB can provide edits/comments directly within the document(s).

- Protocol (in Word). Use the most recent [PROTOCOL TEMPLATE \(HRP-503\)](#). **Required.**

If applicable:

- Consent, assent, and parental permission forms (in Word)
- Data Collection Instruments (e.g., questionnaires, surveys, assessments)
- Recruitment Materials (printed, audio, and video)
- Foreign language versions of the above
- Sponsor protocol (if applicable)
- DHHS protocol and DHHS-approved sample consent document (if applicable)
- Evaluation of any Related Financial Interest

**Instructions to add or update attachments**

- Click “+ Add Info” below to add your first attachment.
- Click “+ Add Line” to insert additional attachments.
- Select the [Edit Pencil](#) next to an attachment to edit or update.

[Columns](#) [+ Add Line](#)

|                 |  |  | ATTACHMENT                          | ATTACHMENT TYPE |
|-----------------|--|--|-------------------------------------|-----------------|
| Action Items: 1 |  |  | <a href="#">PROTOCOL V 2.0.DOCX</a> | Protocol        |
| Action Items: 1 |  |  | <a href="#">CONSENT FORM.DOCX</a>   | Consent Form    |

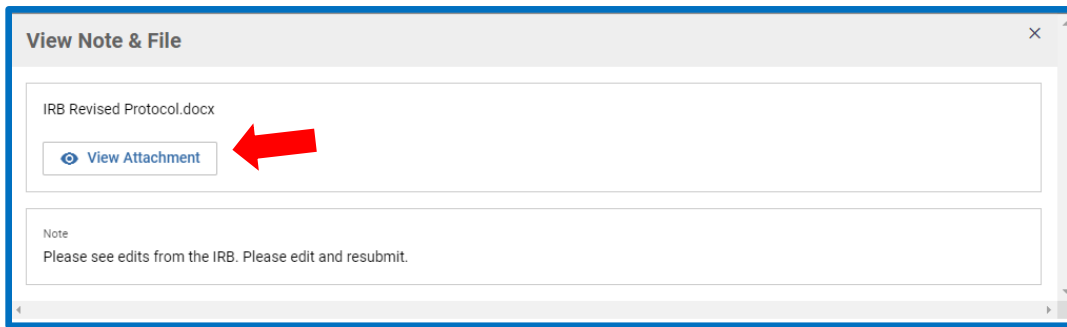
8. A popup with the reviewer attachments and comments will show up after clicking the Admin Notes & Files. Click the file name

**Admin Notes & Files**

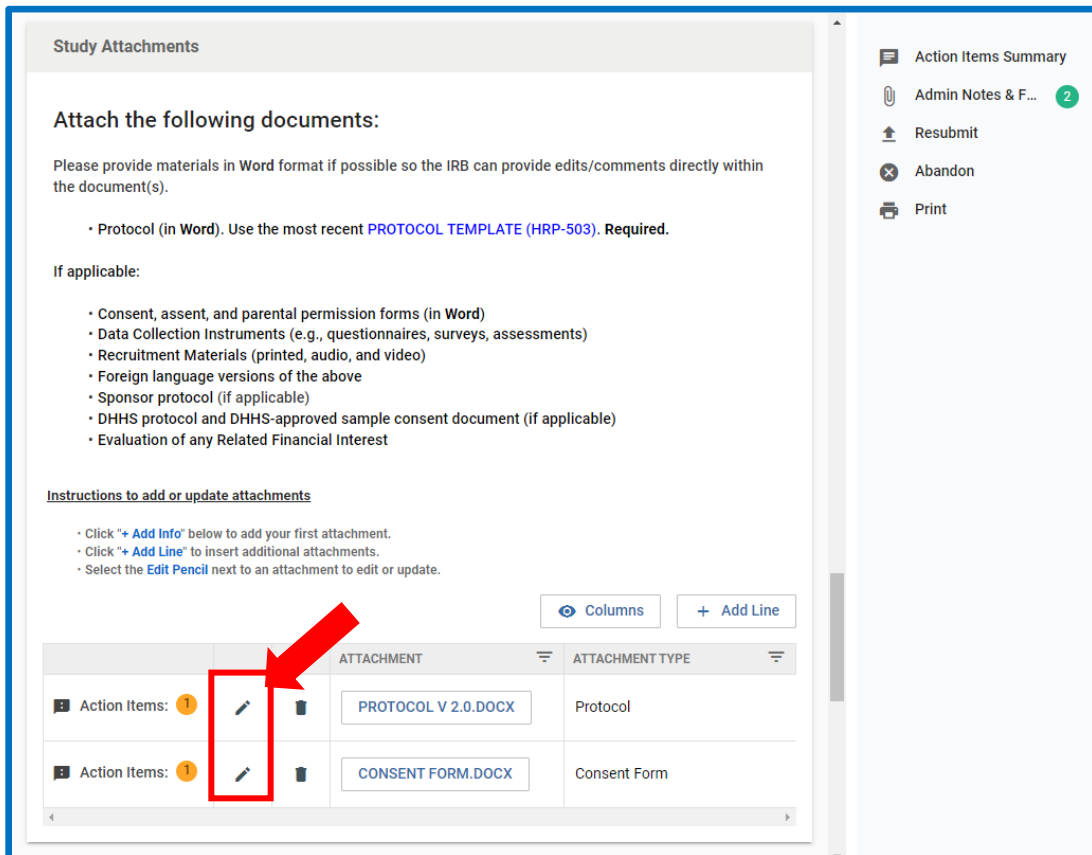
| File                                      | Note   | Date Added           | Added By     |
|---|--|----------------------|--------------|
| <a href="#">IRB Revised Protocol.docx</a> | Please see edits from the IRB. Please edit and resubmit. | Jan 10, 2022 1:01 AM | Mei, Marissa |
| <a href="#">IRB Revised Consent.docx</a>  | Please see IRB edited Consent form. Revise and resubmit  | Jan 10, 2022 1:02 AM | Mei, Marissa |



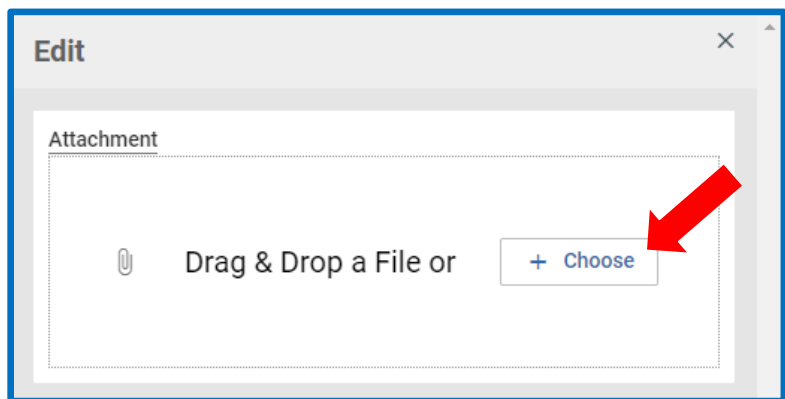
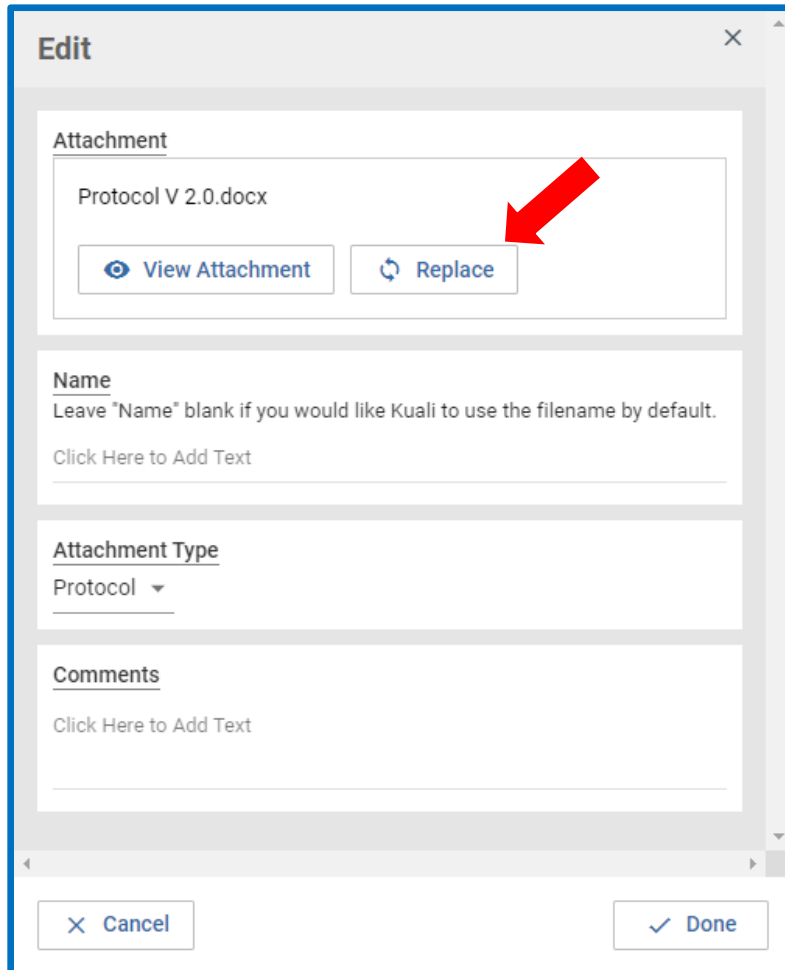
9. Then click **View Attachment to Download** and view the document. You can also see any notes the reviewer left on the bottom of the pop-up



10. After reviewing the IRB reviewer's notes and attachments, make the necessary edits to your documents then click the **edit pencil** next to the original document to replace it with the new edited version.



11. Select **Replace** to replace the original document with the new edited version. You may drag and drop the new document into the attachment box or click **+Choose** to find it in your computer. Select **Done** on the bottom when the attachments have been successfully replaced.



12. Once all necessary edits or changes have been made to the study, click **Resubmit** on the right sidebar to send the study back to the IRB reviewers for review

**Study Attachments**

Please provide materials in **Word** format if possible so the IRB can provide edits/comments directly within the document(s).

- Protocol (in **Word**). Use the most recent [PROTOCOL TEMPLATE \(HRP-503\)](#). **Required.**

If applicable:

- Consent, assent, and parental permission forms (in **Word**)
- Data Collection Instruments (e.g., questionnaires, surveys, assessments)
- Recruitment Materials (printed, audio, and video)
- Foreign language versions of the above
- Sponsor protocol (if applicable)
- DHHS protocol and DHHS-approved sample consent document (if applicable)
- Evaluation of any Related Financial Interest

Instructions to add or update attachments

- Click "+ **Add Info**" below to add your first attachment.
- Click "+ **Add Line**" to insert additional attachments.
- Select the **Edit Pencil** next to an attachment to edit or update.

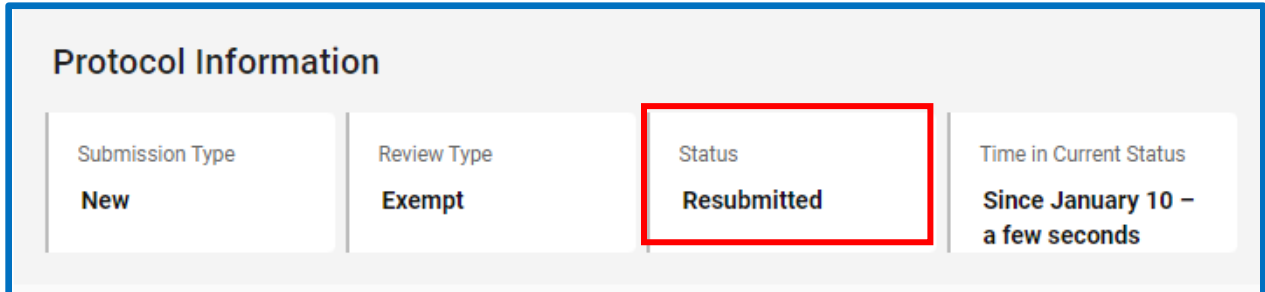
[Columns](#) [+ Add Line](#)

|                              |  |  | ATTACHMENT                               |   |
|------------------------------|--|--|--|---|
| Action Items: <span>1</span> |  |  | <a href="#">PROTOCOL V 3.0.DOCX</a>      | P |
| Action Items: <span>1</span> |  |  | <a href="#">EDITED CONSENT FORM.DOCX</a> | C |

**Right Sidebar:**

- Action Items Summary
- Admin Notes & F... 2
- Resubmit
- Abandon
- Print

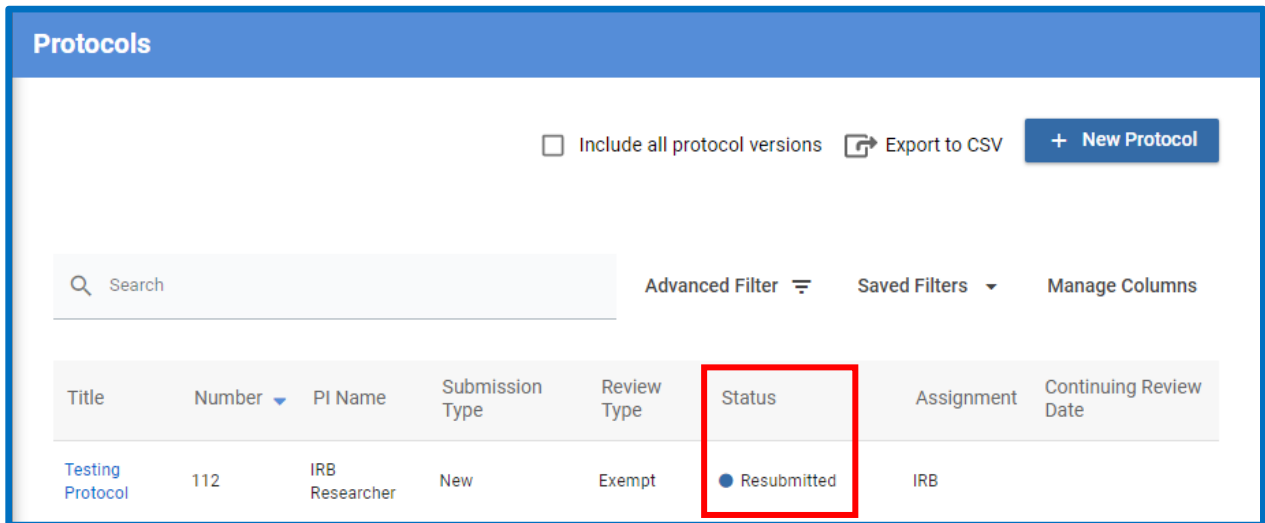
13. You can see that the study has been successfully resubmitted by scrolling up and looking at the **Status** in the **Protocol Information**. You should also receive an email with the subject “IRB Protocol Resubmitted”



The screenshot shows the 'Protocol Information' section with four columns: Submission Type (New), Review Type (Exempt), Status (Resubmitted), and Time in Current Status (Since January 10 – a few seconds). The 'Status' column is highlighted with a red box.

| Submission Type | Review Type | Status      | Time in Current Status           |
|-----------------|-------------|-------------|----------------------------------|
| New             | Exempt      | Resubmitted | Since January 10 – a few seconds |

14. Another place you can see the status of your study is in the Protocols Dashboard



The screenshot shows the 'Protocols' dashboard with a table of protocol entries. The 'Status' column for the 'Testing Protocol' entry is highlighted with a red box.

Protocols

Include all protocol versions [Export to CSV](#) [+ New Protocol](#)

Search  Advanced Filter  Saved Filters  Manage Columns

| Title            | Number | PI Name        | Submission Type | Review Type | Status      | Assignment | Continuing Review Date |
|------------------|--------|----------------|-----------------|-------------|-------------|------------|------------------------|
| Testing Protocol | 112    | IRB Researcher | New             | Exempt      | Resubmitted | IRB        |                        |