Kuali IRB User Manual

Last Revised: 1/6/2023

Table of Contents

> **All IRB application forms are now embedded within Kuali.**
>
> Legacy studies that were migrated into Kuali will include the original IRB number in the protocol title.
>
> For more information on Kuali, Kuali Resources, or to Log into Kuali, please visit: https://www.umb.edu/orsp/kuali_research
>
> For templates (protocol, consent, etc.), please visit: 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.

Creating a New IRB Protocol (HRP-211)
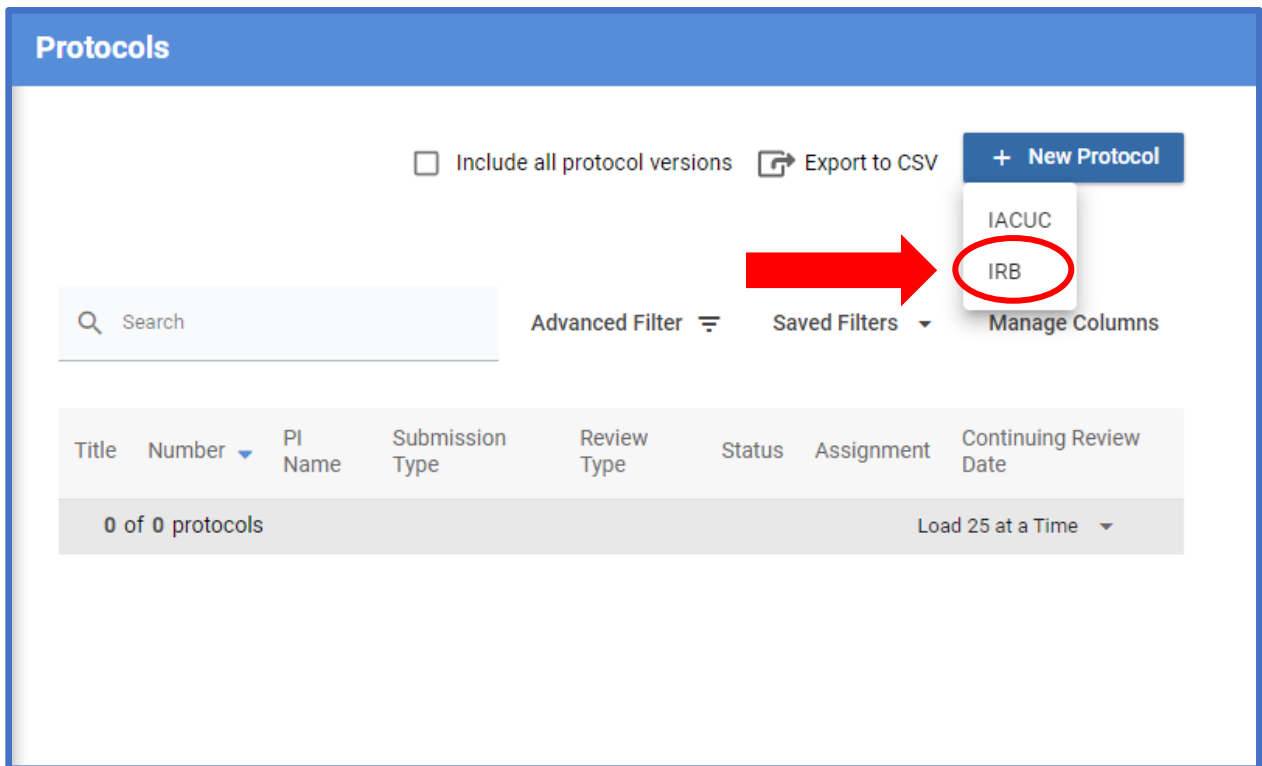
1. Log into Kuali (https://umb.kuali.co/cor/main/#/apps/) using your ID and Password

2. Select **Protocols**
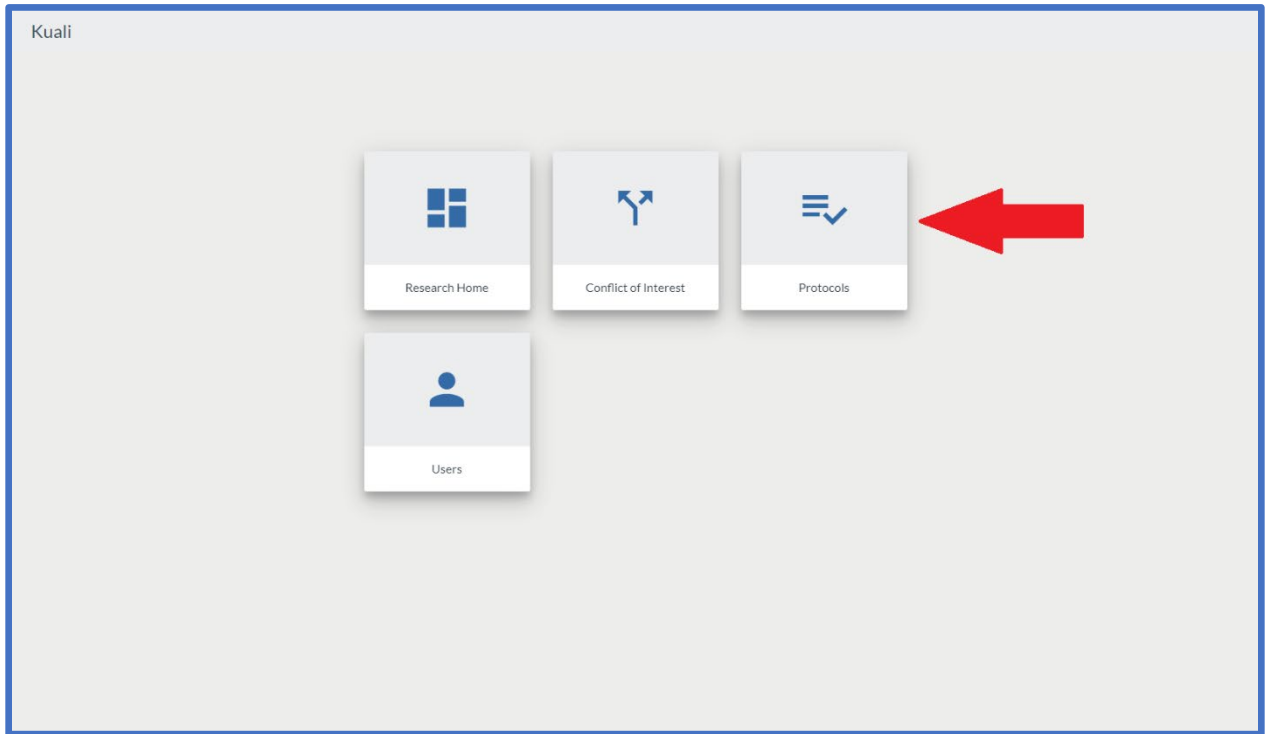
3. Click the **+ New Protocol** Button on the top right-hand corner of the screen
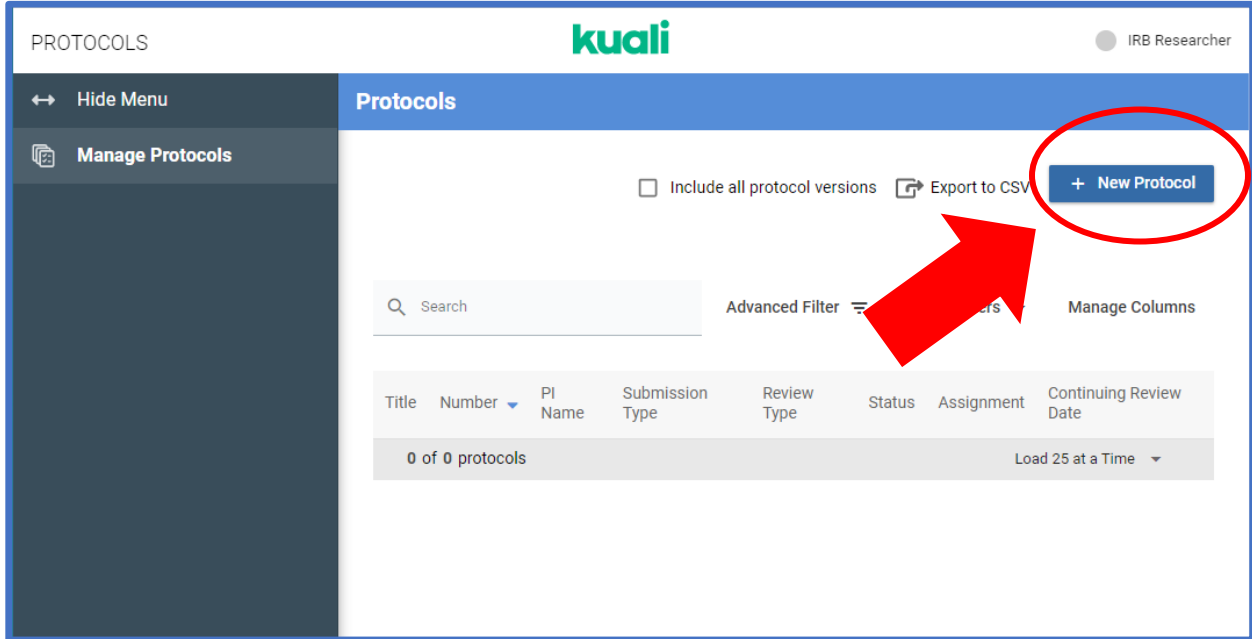
4. Clicking on the **+ New Protocol** button will trigger a small pop-up, click on the **IRB** option.

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

<div>

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.

Principal Investigator (PI)	Lead Unit / Department

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

Study Title

Click Here to Add Text

×	Cancel
→	Next

</div>

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.

✕ Cancel

→ Next

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.

IRB Researcher ✕

Lead Unit / Department

University of Massachusetts Boston ✕

Study Title

Testing Protocol

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

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.
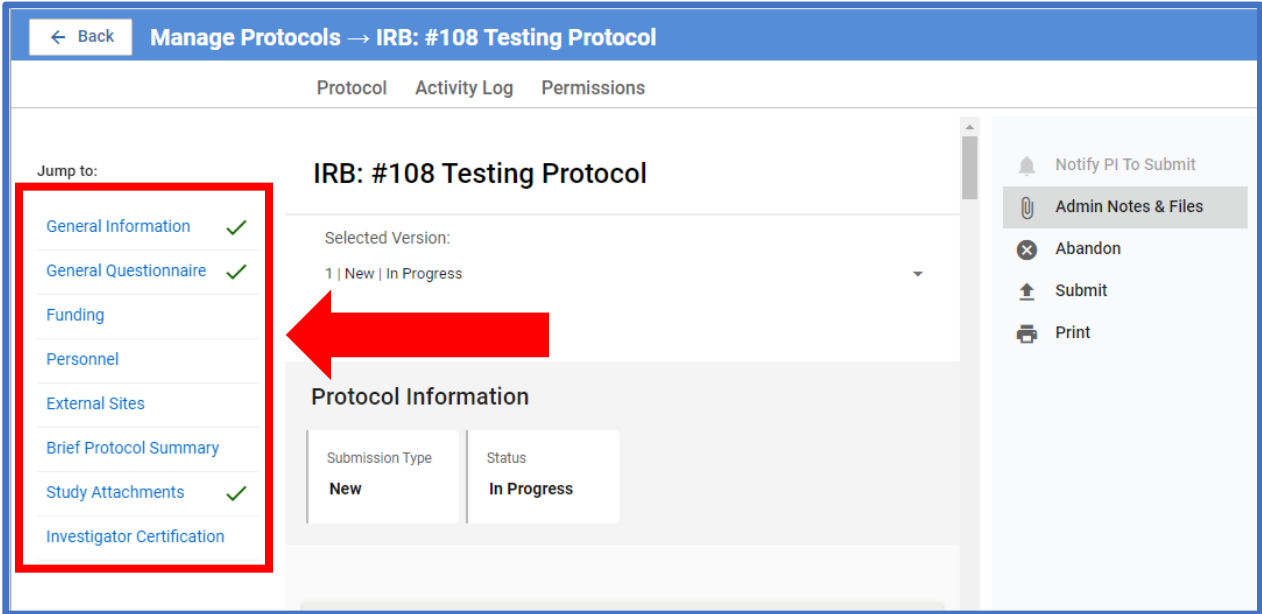
10. Next, indicate whether the study is funded

Manage Protocols → IRB: #108 Testing Protocol

← Back

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.

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 Kuali 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

| | **Find and add** |

◉ Award   ○ Institutional Proposal   ○ Proposal Development

Kuali Research

Institutional Proposal Lookup❓

* required field

Institutional Proposal Number:	
Proposal Development Number:	
Proposal Type:	select
Status:	
Account ID:	
Project Title:	
Unit ID:	
Unit Name:	
Proposal Person:	
Sponsor ID:	
Sponsor Name:	
Proposal Create Date From:	
Proposal Create Date To:	

search   clear   cancel

Kuali Research

Award Lookup❓

* required field

Award ID:	
Sponsor Award ID:	
Account ID:	
Award Status:	select
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

search   clear   cancel

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

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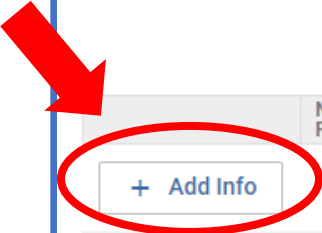
Funding

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

- [x] 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.

> *<u>**Important!**</u> Please be sure to **add all of the PI's details** by selecting the <u>Edit Pencil</u> 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 Kuali, 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 Allow 24 hours for CITI information to refresh in Kuali.

<u>**Instructions to add or update personnel**</u>

- 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.**

	PERSON	DEGREES	EMAIL ADDRESS
✏ 🗑	IRB Researcher		testingirb@outlc

Columns   + Add Line

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) and log in through SSO to link their CITI trainings to Kuali. The trainings will take up to a day to refresh in Kuali.

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 Kuali, 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
Allow 24 hours for CITI information to refresh in Kuali.

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	ℹ IRB Researcher has no training courses on file.

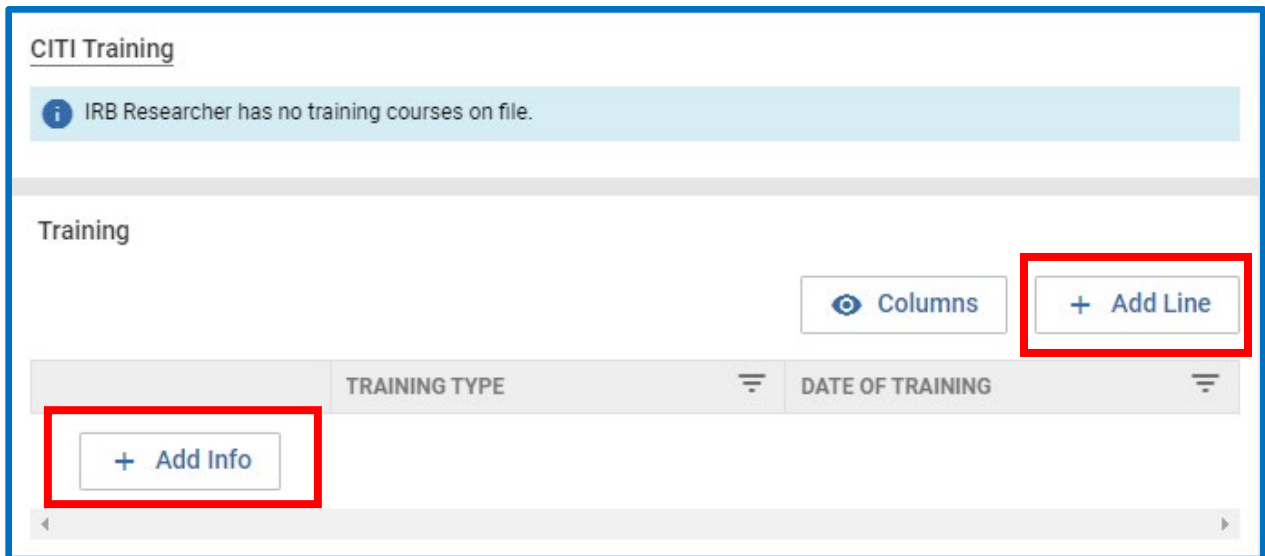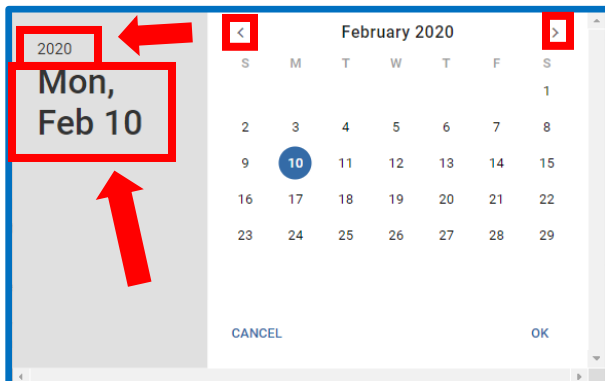18. If the researcher did not complete the CITI training through UMass Boston, they must upload the CITI training certificate as an attachment. To do this, click the Edit Pencil next to the researcher who has training from an outside institution.

		PERSON	RESEARCHER ROLE	CITI TRAINING
✏️	🗑️	IRB Researcher	Principal Investigator	ℹ️ IRB Researcher has no training courses on file.

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

CITI Training

ℹ️ IRB Researcher has no training courses on file.

Training

👁 Columns   + Add Line

	TRAINING TYPE	DATE OF TRAINING
+ Add Info		

*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.

2020	<	February 2020	>

Mon, Feb 10

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

CANCEL   OK

20. Attach the corresponding <u>external CITI training certificate(s)</u> 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

	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
+ Add Info		

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

+ Add Info

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* | S̶ | U̲ | A | A̶ | ⅰ≡ | ≡ | % |

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. Kuali 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 Kuali 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.

	ATTACHMENT		ATTACHMENT TYPE	

⊙ Columns   + Add Line

+ Add Info

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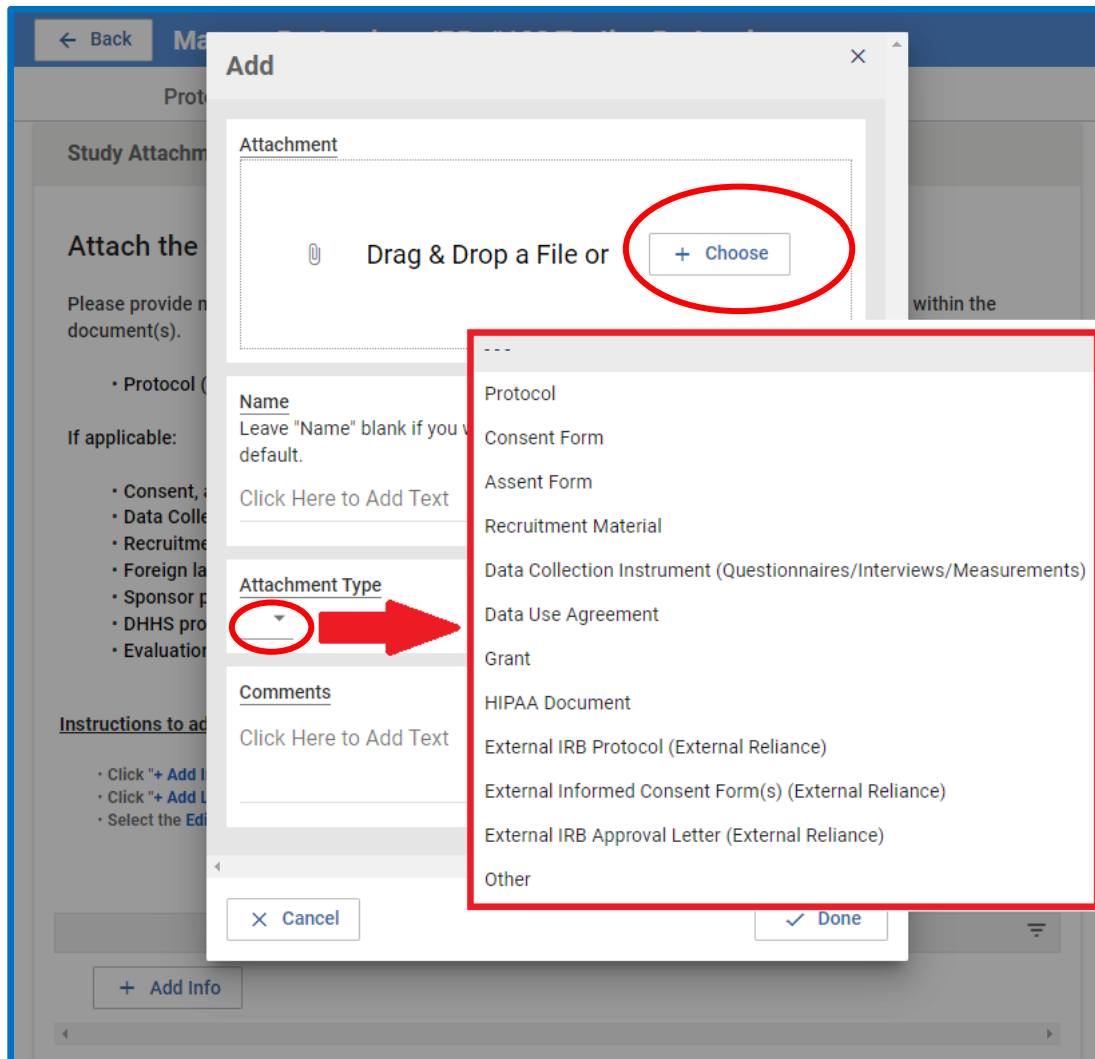
28. Check the box under the **Investigator Certification** to certify all actions in the box. The PI must review this certification before submission.

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.**

← 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... ✓

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

🔔 Notify PI To Submit
📎 Admin Notes & Files
⊗ Abandon
⬆ Submit
🖨 Print

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.**

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

How to submit an Amendment (Modification HRP-213)
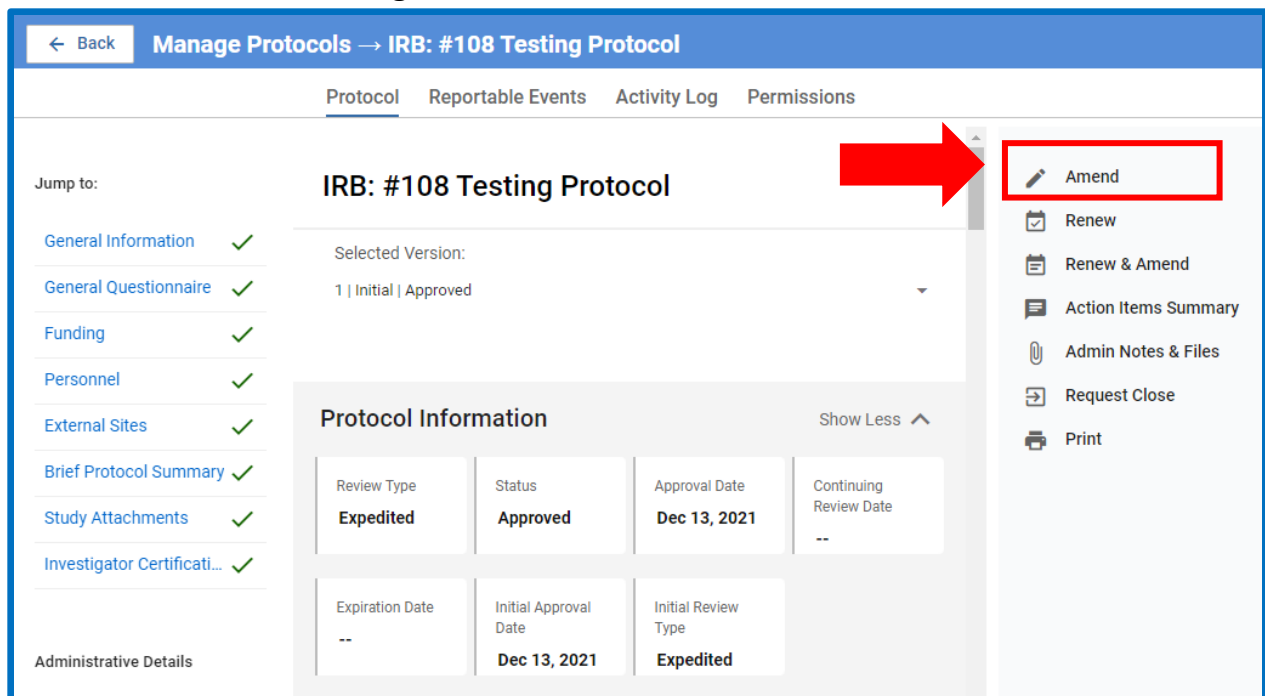
1. Log in to your Kuali IRB Dashboard and click on the title of the protocol you want to Amend. Please note that the system does not allow multiple pending amendments, you may only submit one modification <u>application</u> at a time. The modification application may contain as many amendments as needed.

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

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

Description and Justification

Provide a description and justification of the modifications.

| Sans Serif ⇕ | Normal ⇕ | ☰ | **B** | *I* | S̶ | U̲ | A | A̸ | ☰ | ☰ | ⸦ |

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

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 theses 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* | S̶ | U̲ | A | 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."
- ❓

6. 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 Kuali, 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
Allow 24 hours for CITI information to refresh in Kuali.

Instructions to add or update personnel

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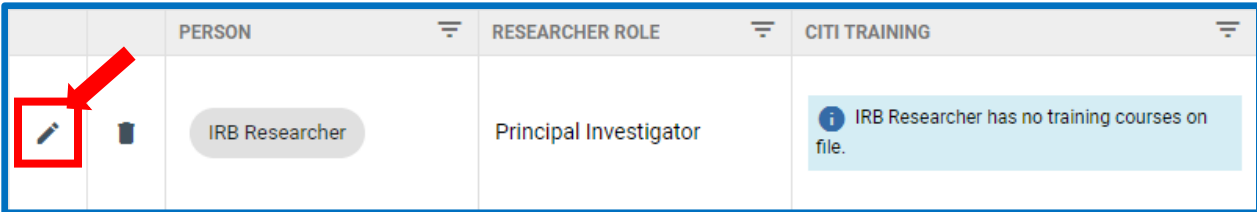- Select the **Edit Pencil** next to an entry to edit or update.

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.**

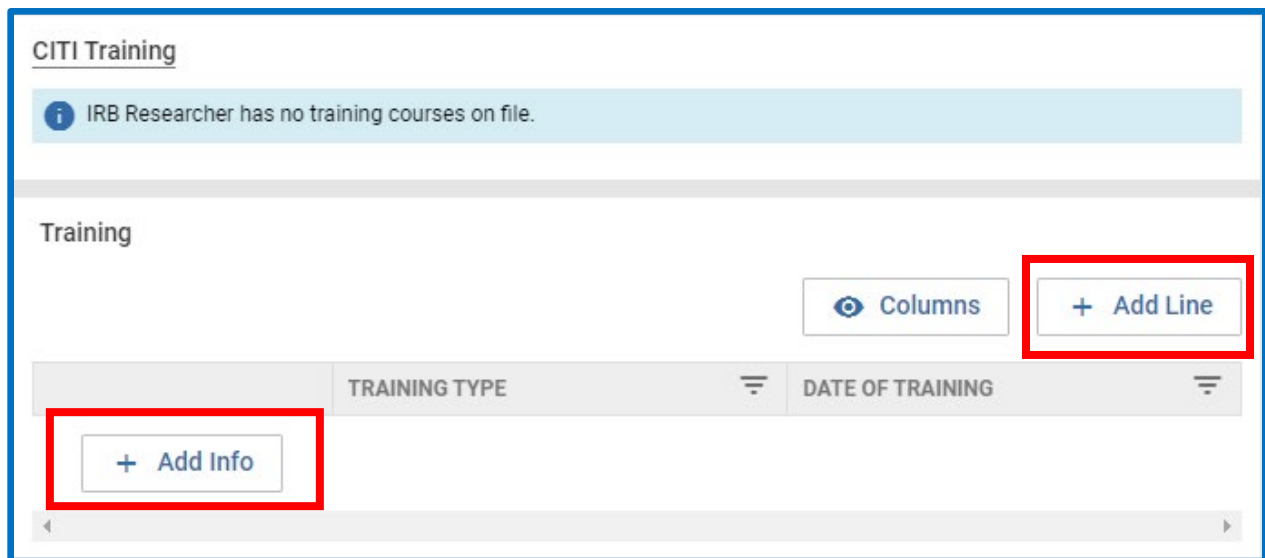|		PERSON	DEGREES	EMAIL ADDRESS	AF
✏	🗑	IRB Researcher		testingirb@outlook.com	Fi

| ⊙ Columns | + Add Line |

Add

Person

⊗ **Required Field**

Degrees

Department

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

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

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) and log in through SSO to link their CITI trainings to Kuali. The trainings will take up to a day to refresh in Kuali.

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.

		PERSON	☰	RESEARCHER ROLE	☰	CITI TRAINING	☰
✏️	🗑️	IRB Researcher		Principal Investigator		ℹ️ IRB Researcher has no training courses on file.	

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

CITI Training

ℹ️ IRB Researcher has no training courses on file.

Training

👁️ Columns   + Add Line

	TRAINING TYPE	☰	DATE OF TRAINING	☰
+ Add Info				

*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.

2020	<	February 2020	>
Mon, Feb 10			

S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

CANCEL   OK

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

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 "**+ Ad** o insert additional attachments.
> · Select th   encil next to an attachment to edit or update.

| | | ⊙ Columns | + Add Line |

		ATTACHMENT ⇟	ATTACHMENT TYPE ⇟
✏	🗑	PROTOCOL RAIN EXPERIMENT.DOCX	Protocol
✏	🗑	CONSENT FORM.DOCX	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.

13. 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   [+ Choose]

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

Protocol V 1.0

Attachment Type
Protocol ▾

Comments

Click Here to Add Text

[✕ Cancel]   [✓ Done]

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

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

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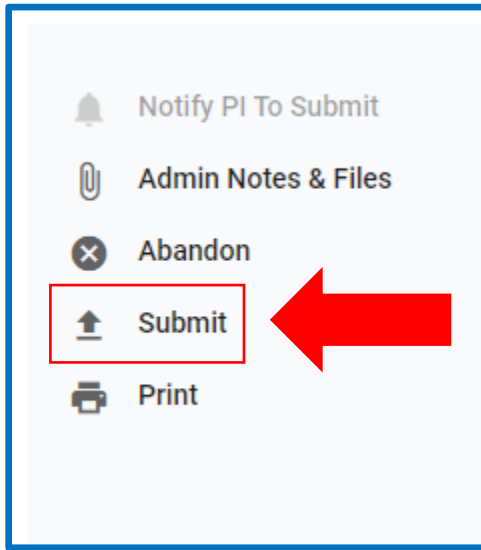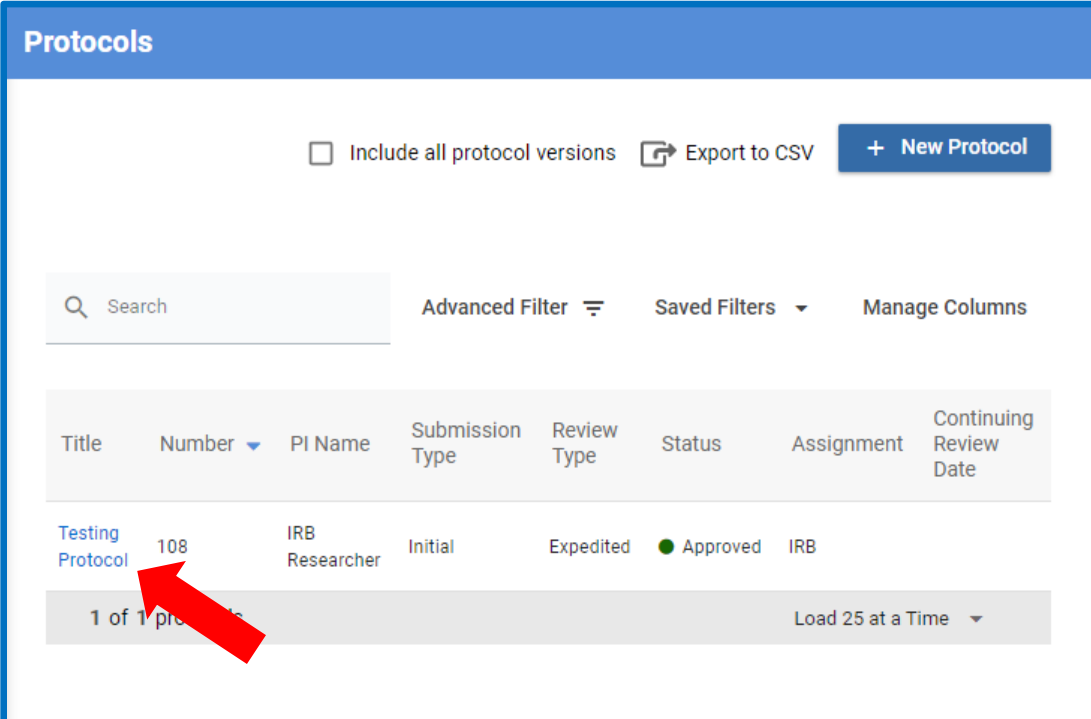
How to submit Renewal & Amendment (Continuing Review HRP-212 & Modification HRP-213)

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 Kuali IRB Dashboard and click on the title of the protocol you want to Renew/Amend.

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

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.

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)

Click Here to Add Number

At this Investigator's Site(s) Since Last Approval
- ❓

Click Here to Add Number

Total # Study Wide

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 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.

☐ 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.

Sans Serif ⬍	Normal ⬍	☰	B	I	S	U	A	A	☰	☰	🔗

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

Sans Serif ⬍	Normal ⬍	☰	B	I	S	U	A	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.**

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

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.

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 theses 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* | S̶ | U̲ | A | A̲ | ☰ | ☰ | 🔗 |

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.

👁 Columns   + Add Line

		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

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   [+ Choose]

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

Protocol V 1.0

Attachment Type
Protocol ▾

Comments

Click Here to Add Text

✕ Cancel   ✓ Done

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

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 Kuali 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
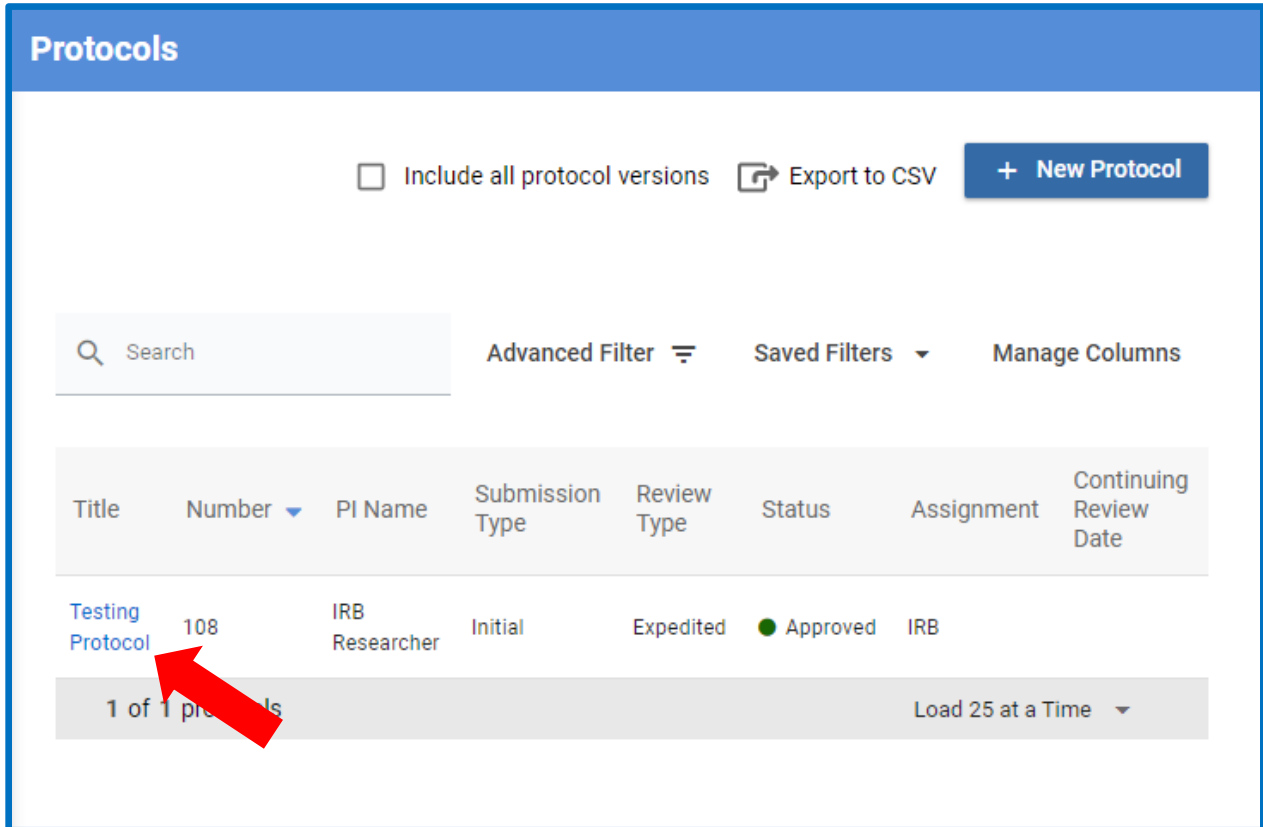
By clicking the Certify checkbox, I certify that:

- 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 Kuali IRB Dashboard and click on the title of the protocol you want to Renew

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	108	IRB Researcher	Initial	Expedited	● Approved	IRB	

1 of 1 protocols   Load 25 at a Time ▾

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

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 Kuali 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 Kuali 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!**

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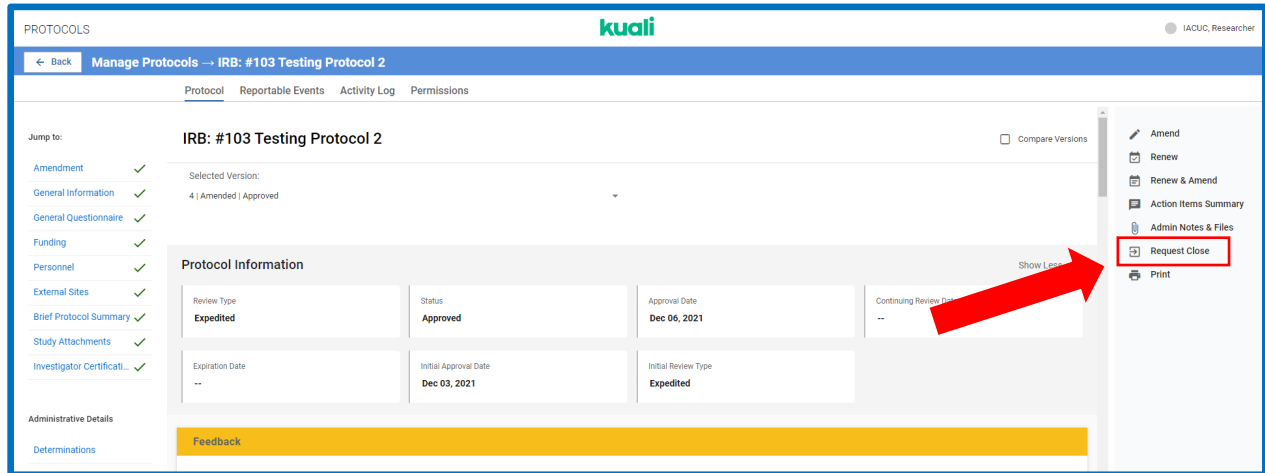
3. Clicking **Request Close** will open up the Final Report form. The first section asks the number of subjects enrolled. Please fill out all three boxes with the relevant information. Keep in mind, in certain circumstances all three numbers may be the same.

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) req
- ⦿ 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." ("... n 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* S̶ U̲ | A ✎ | ☷ ☰ | ⌗ |

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* S̶ U̲ | A ✎ | ☷ ☰ | ⌗ |

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.

<u>Instructions to add or update attachments</u>

- 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
+ Add Info				
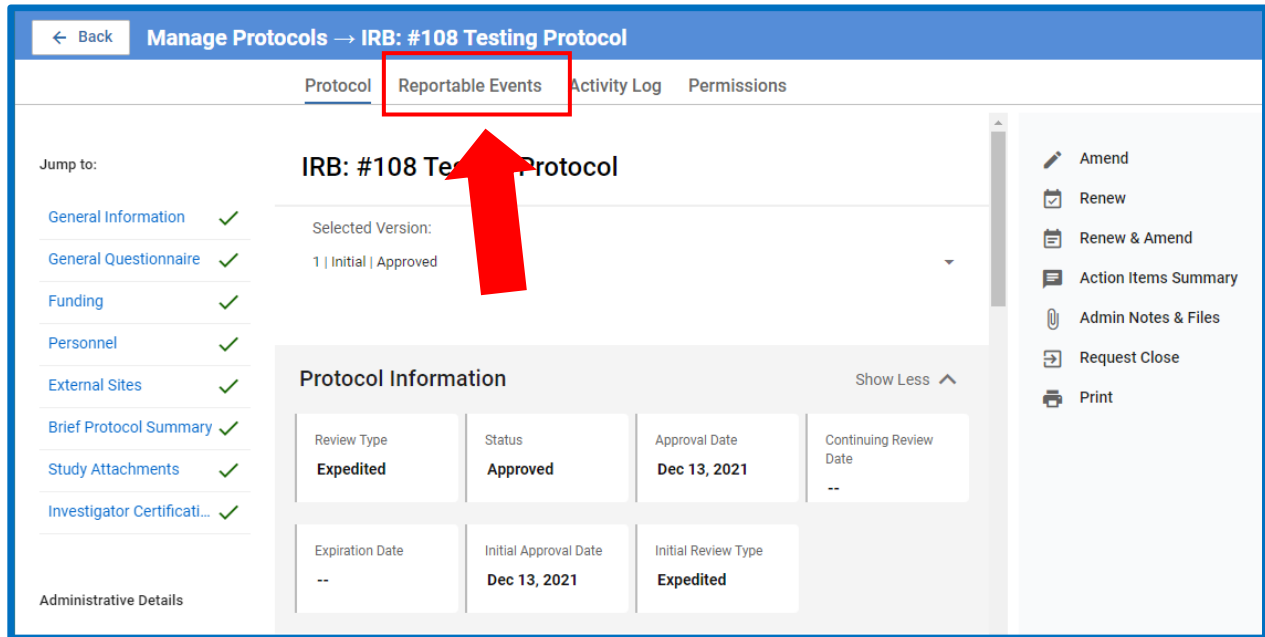
8. Finally, the PI must **Certify** the closure statement and **submit**.

Submitting a Reportable Event (HRP-214)

1. Log in to your Kuali 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.

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.

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

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.

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.

← Back	**Report Event for Protocol**

Jump to:

Reportable Event Type

Reportable New Infor... ✓

RNI Categories

Event Details

RNI Questions

Corrective Action Plan

Additional Information

RNI Attachments

Certification (RNI)

Reportable Event Type

Event Type
Reportable New Information

Reportable New Information

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.

- Activity Log
- View Protocol
- Print

How to Access Your Approval Letter

1. Log in to your Kuali 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.

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

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

4. 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 Kuali.

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.

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.

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.
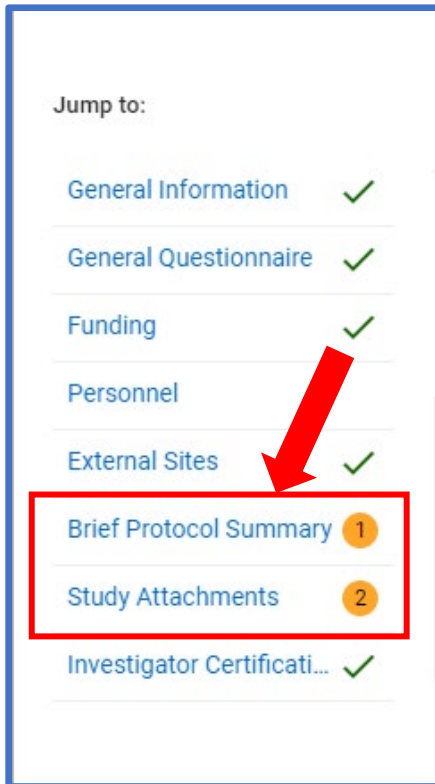
5. Clicking the section will automatically scroll you down to the section that needs attention. Click the **Action Items** on the upper right to see the reviewer's comments
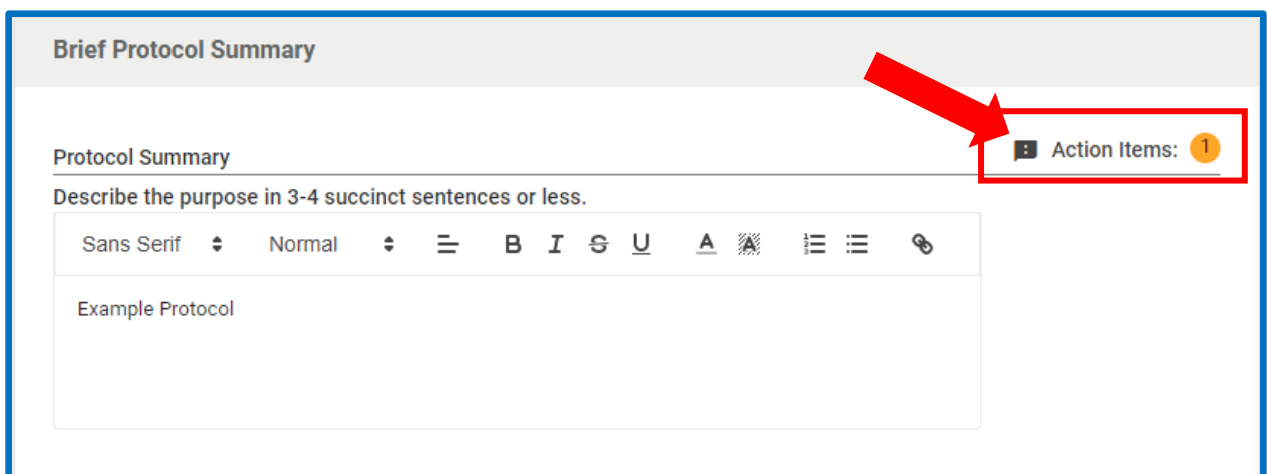
6. Clicking the Action Items will cause the reviewer comments to automatically popup on the right side. You may close this popup by clicking the arrow on the top right of the pop up. In this case, the reviewer asked for us to "Please Clarify" the Protocol Summary. We can do this by directly editing in the original text box. You may also **Reply** to the comment telling the reviewer the Protocol Summary has been edited.
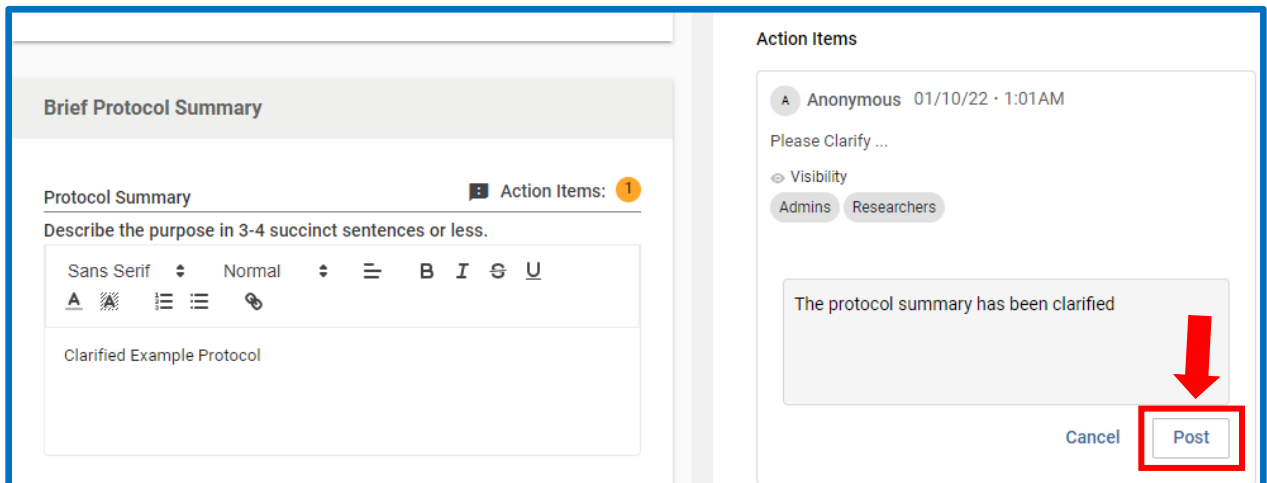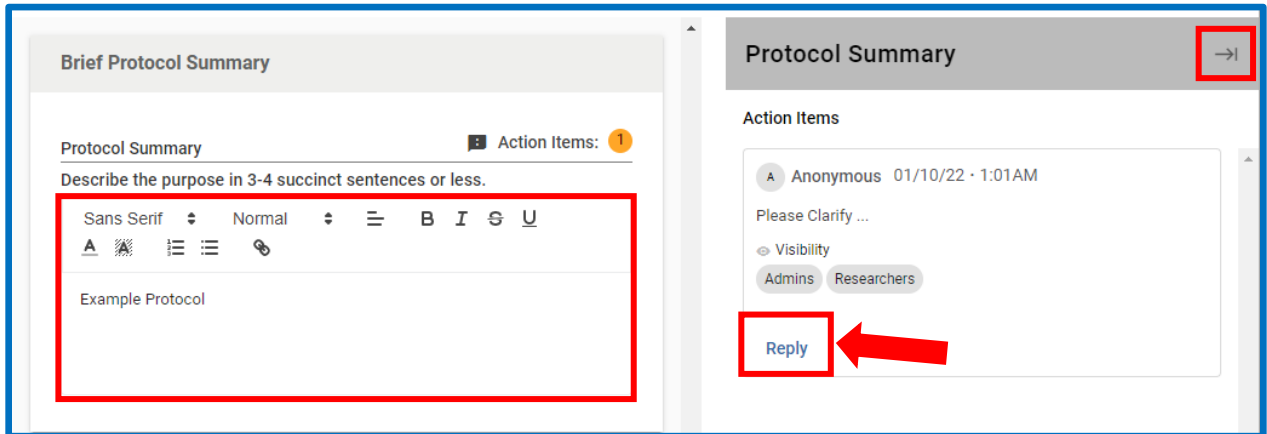
7. If there are Action items in the study attachments that say "see attached" or something similar you will need to click the "Admin Notes & Files" tab on the right sidebar. A green circle will indicate if there are new attachments from the IRB in that location.

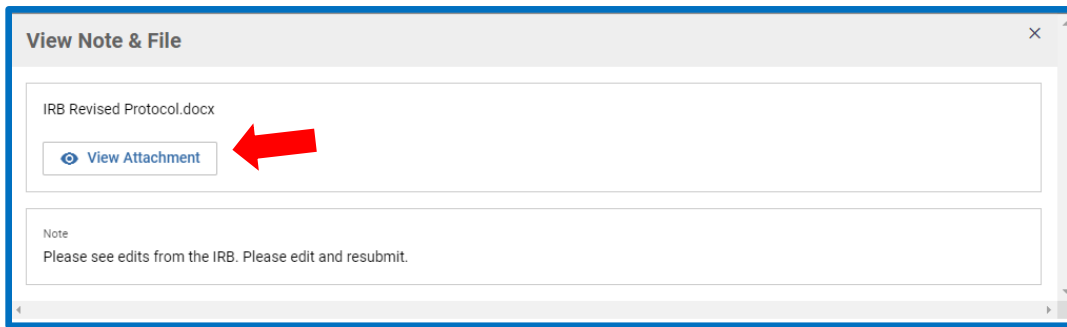
8. A popup with the reviewer attachments and comments will show up after clicking the Admin Notes & Files. Click the file name

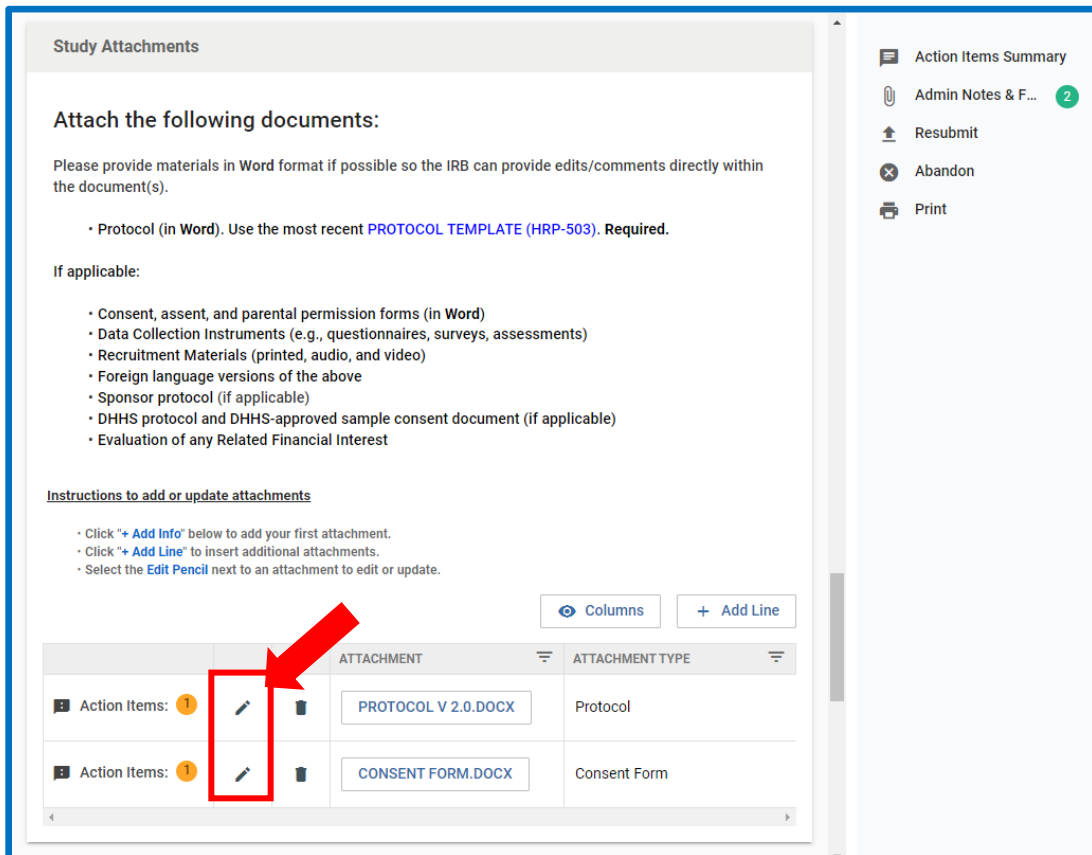9. Then click **View Attachment** to **Download** and view the document. You can also see any notes the reviewer left on the bottom of the pop-up

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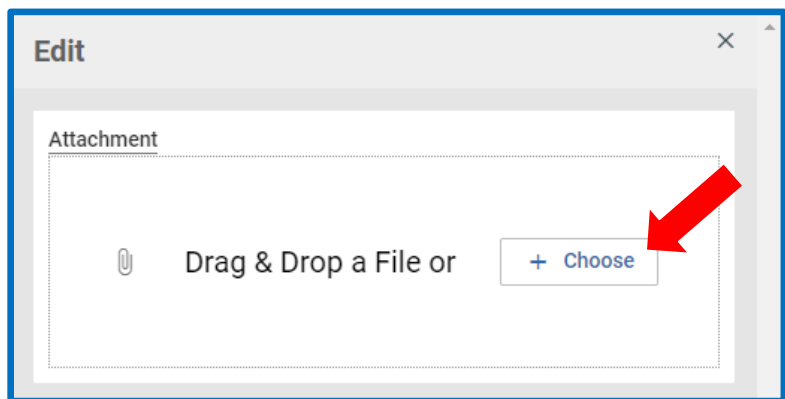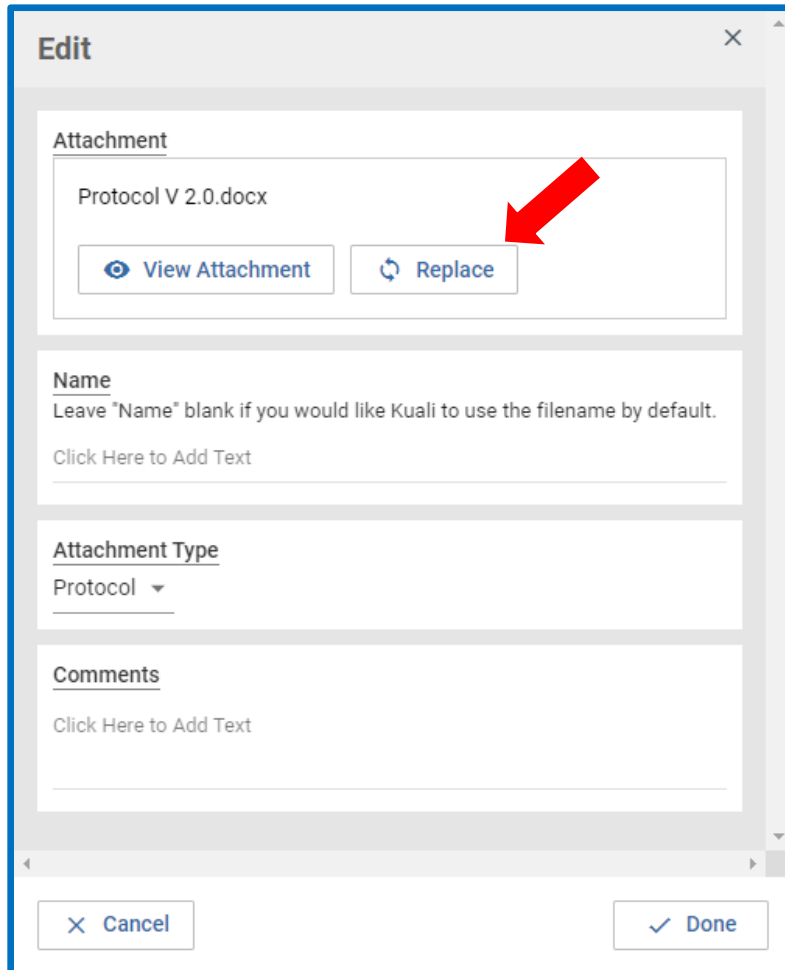
12. Once all necessary edits or changes have been made to the study, click **Resubmit** on the right sidebar to send the study back to the IRB reviewers for review

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.
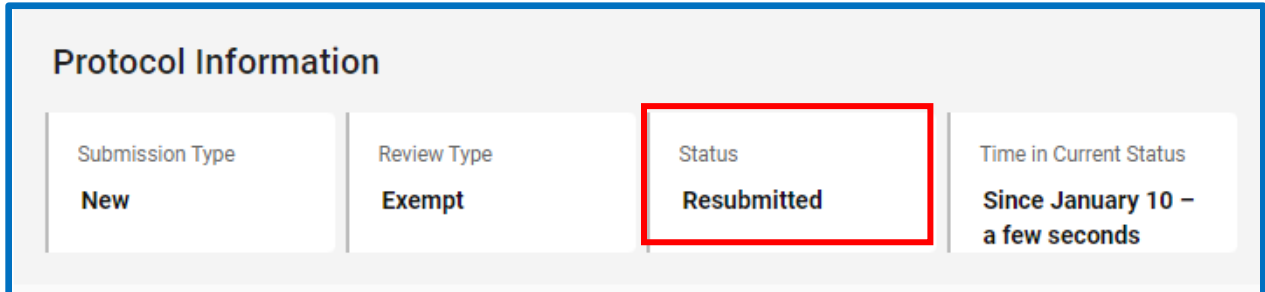- Select the **Edit Pencil** next to an attachment to edit or update.

👁 Columns   + Add Line

			ATTACHMENT ☰	A
💬 Action Items: 1	✏	🗑	PROTOCOL V 3.0.DOCX	P
💬 Action Items: 1	✏	🗑	EDITED CONSENT FORM.DOCX	C

Action Items Summary

📎 Admin Notes & F… 2
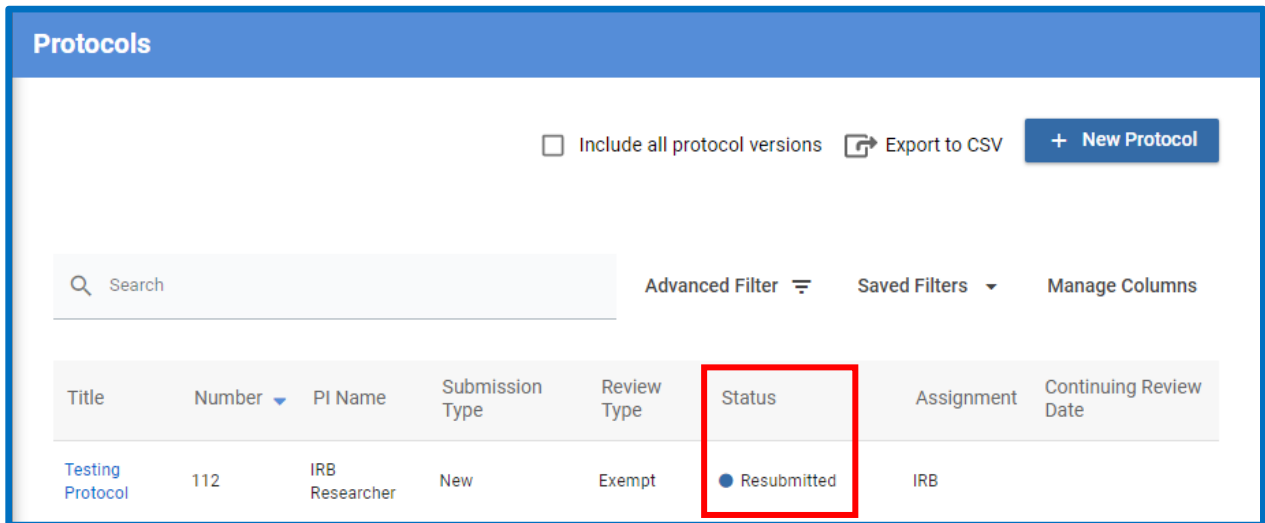
⬆ Resubmit

❌ 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"

Protocol Information

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

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	