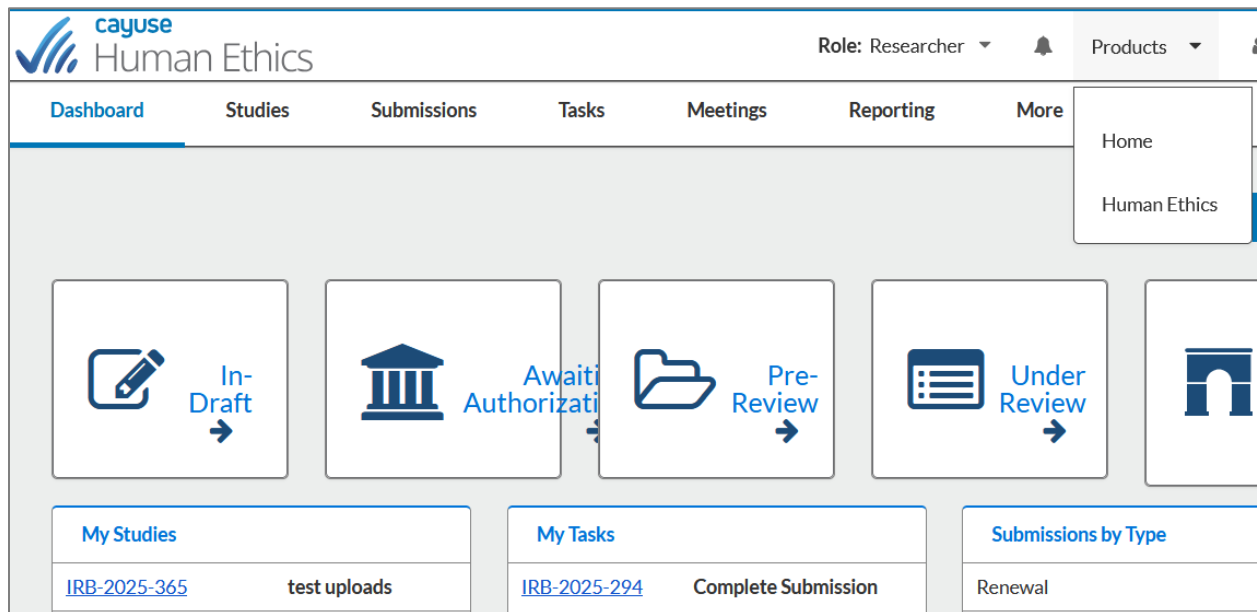


Protocol Completion/Closure

Human Ethics

After logging into Cayuse, select **Human Ethics** from the Products drop-down to get to your Dashboard.

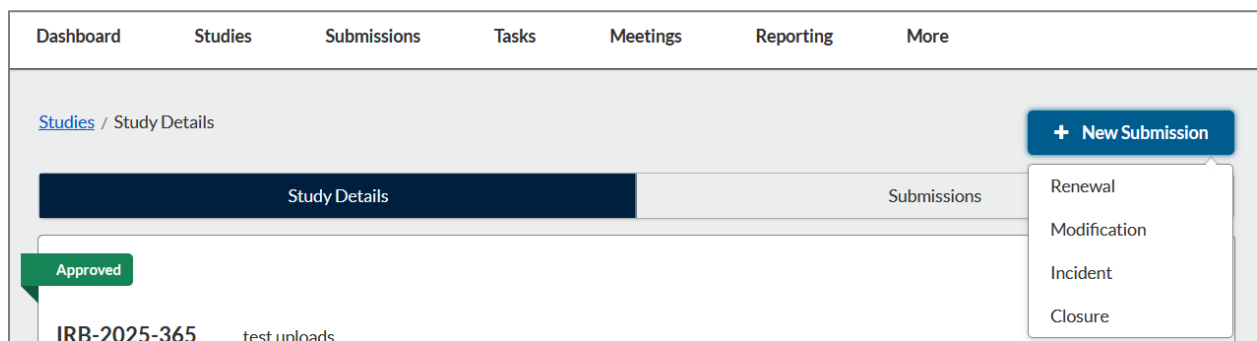


Dashboard

From the Dashboard you can see Approved Studies. Click on the highlighted and underlined protocol number you wish to edit.

Study Details

On the Study Details tab, click the **+New Submissions** button to the right, and choose **Closure** from the drop-down menu.



Submission Details

On Study Details click on the **Edit** button on the left side below the protocol number and title.

Unsubmitted

Closure

IRB-2025-365 - test uploads

Edit

PDF

Delete

PI:	Current Analyst:	Decision:	Policy:	Required Tasks:
Tina Aubut	N/A	N/A	Post-2018 Rule	Complete Submission
Review Type:	Review Board:	Meeting Date:		
N/A	N/A	N/A		

The Project Closure form will open.

Closing Study

Do you wish to close this study?

Yes/No, If yes, Reason for study Closure.

Sections

Project Closure

Project Closure

* Closing Study

Do you wish to close this study?

☒ Yes

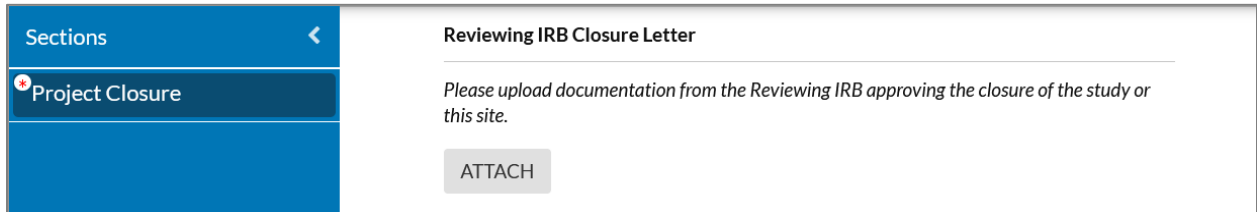
* Reason for study Closure:

B I U

Reviewing IRB Closure Letter

Please upload documentation from the Reviewing IRB approving the closure of the study or this site.

ATTACH button



The screenshot shows a web interface for reviewing IRB closure letters. On the left, a blue sidebar titled 'Sections' contains a link for 'Project Closure' marked with a red asterisk. The main content area has a header 'Reviewing IRB Closure Letter' followed by the instruction: 'Please upload documentation from the Reviewing IRB approving the closure of the study or this site.' Below this instruction is a grey button labeled 'ATTACH'.

Study & Subject Status (image on next page)

Check all that apply.

- ☐ Study has not started or is on hold
- ☐ Study enrollment is open; NO enrollment to date
Open enrollment typically means a study is not ready for Closure. Contact the IRB Office for information on what Study Status is eligible for study closure.
- ☐ Study enrollment/data collection is open and ongoing
Open enrollment typically means a study is not ready for Closure. Contact the IRB Office for information on what Study Status is eligible for study closure.
- ☐ Study enrollment/data collection is closed
- ☐ Treatment and/or active follow-up continues
Active intervention/interaction with subjects typically means a study is not ready for Closure. Contact the IRB Office for information on what Study Status is eligible for study closure.
- ☐ Long-term follow-up only (no intervention/interaction)
- ☐ Remaining activities limited to data analysis

Indicate what kind of data is in use:

- Identifiable data is still in use (including coded data for which a link to the identifiable information is retained)
Continued use of Identifiable Data typically means a study is not ready for Closure. Contact the IRB Office for information on what Study Status is eligible for study closure.
- ONLY Coded data where BOTH are true:
 - ALL links to identifiable information have been destroyed
 - There is NO ability to link the data in use back to identifiable information
- De-identified data ONLY

Sections
Project Closure

*** Study & Subject Status**

Check all that apply.

- ☒ Study has not started or is on hold
- ☒ Study enrollment is open; NO enrollment to date
Open enrollment typically means a study is not ready for Closure. Contact the IRB Office for information on what Study Status is eligible for study closure.
- ☒ Study enrollment/data collection is open and ongoing
Open enrollment typically means a study is not ready for Closure. Contact the IRB Office for information on what Study Status is eligible for study closure.
- ☒ Study enrollment/data collection is closed

Sections
Project Closure

- ☒ Study enrollment/data collection is closed
- ☒ Treatment and/or active follow-up continues
Active intervention/interaction with subjects typically means a study is not ready for Closure. Contact the IRB Office for information on what Study Status is eligible for study closure.
- ☒ Long-term follow-up only (no intervention/interaction)
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*** Indicate what kind of data is in use:**

- ☒ Identifiable data is still in use (including coded data for which a link to the identifiable information is retained)
Continued use of Identifiable Data typically means a study is not ready for Closure. Contact the IRB Office for information on what Study Status is eligible for study closure.
- ☐ ONLY Coded data where BOTH are true:
 - ALL links to identifiable information have been destroyed
 - There is NO ability to link the data in use back to identifiable information
- ☐ De-identified data ONLY

Enrollment/Data Records

For intervention/interaction studies or aims, Enrollment includes subjects who gave consent to participate, either in writing, orally, or by voluntary completion of a survey or participation in a focus group.

For data or specimen studies or aims, Enrollment includes subjects whose identifiable records/specimens have been reviewed.

Total subjects enrolled/data records to date at all sites

Text box

Total subjects enrolled/data records to date at this institution

Text box

Total subjects enrolled/data records at this institution since the last Renewal (or since Initial approval if no Renewals)

Text box

Total number of withdrawals at this institution since start of the study

NOTE: Includes subjects who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.

Text box

Please list the following enrollment/data record numbers for each site (by name) we serve as the Reviewing IRB for in this study:

- Total subjects enrolled to date at site
- Total subjects enrolled at site since the last Renewal (or since Initial approval if this is the first Renewal)

Text box

Sections < ✱ Project Closure	Enrollment/Data Records <i>For intervention/interaction studies or aims, Enrollment includes subjects who gave consent to participate, either in writing, orally, or by voluntary completion of a survey or participation in a focus group.</i> <i>For data or specimen studies or aims, Enrollment includes subjects whose identifiable records/specimens have been reviewed.</i> ✱ Total subjects enrolled/data records to date <u>at all sites</u> ✱ Total subjects enrolled/data records to date <u>at this institution</u> ✱ Total subjects enrolled/data records <u>at this institution</u> since the last Renewal
---	--

Have there been any withdrawals at this institution during the this approval period?

NOTE: Includes subjects who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.

Yes/No, if yes

Number of withdrawals this approval period. Text box

Briefly explain the reason for each withdrawal. Text box

Sections <

Project Closure

* Have there been any withdrawals at this institution during the this approval period?

NOTE: Includes subjects who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.

☒ Yes ☐ No

* Number of withdrawals this approval period

* Briefly explain the reason for each withdrawal.

B I U

Have there been any withdrawals at any other sites during the this approval period for this collaborative study?

Yes/No, if yes

For each site list the following:

- Site name
- Number of withdrawals this approval period
- Briefly explain the reason for each withdrawal

Text box

Sections <

Project Closure

☐ No ☒ Yes

* Have there been any withdrawals at any other sites during the this approval period for this collaborative study?

* For each site list the following:

- Site name
- Number of withdrawals this approval period
- Briefly explain the reason for each withdrawal

B I U

Complaints

Have there been any subject complaints during this approval period?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).

Yes/No, if yes

Describe any subject complaints and if the subject withdrew from the study as a result.

Text box

The screenshot shows a web form interface. On the left is a blue sidebar with a 'Sections' header and a back arrow. Below it, 'Project Closure' is listed with a red asterisk icon. The main content area is titled '* Complaints' and contains the following text: 'Have there been any subject complaints during this approval period?' followed by 'Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).' Below this text are two radio buttons; the 'Yes' option is selected. To the right of the 'Yes' radio button is a red asterisk followed by the text: '* Describe any subject complaints and if the subject withdrew from the study as a result.' At the bottom of the form is a text input field with a rich text editor toolbar above it, featuring icons for bold (B), italic (I), underline (U), strikethrough (ABC), bulleted list, numbered list, link, and image.

Modifications

Have there been any changes to the study during this approval period that you have NOT already submitted as a Modification?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites.

Yes/No, if yes

Please create and submit a Modification with these changes immediately.

The screenshot shows a web form interface. On the left is a blue sidebar with a 'Sections' header and a back arrow. Below it, 'Project Closure' is listed with a red asterisk icon. The main content area is titled '* Modifications' and contains the following text: 'Have there been any changes to the study during this approval period that you have NOT already submitted as a Modification?' followed by 'Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites.' Below this text are two radio buttons; the 'Yes' option is selected. To the right of the 'Yes' radio button is the text: 'Please create and submit a Modification with these changes immediately.' Below the 'Yes' radio button is the 'No' option.

Reportable Events

This includes adverse events or protocol deviations that were required to promptly be submitted as an Incident per IRB Policy.

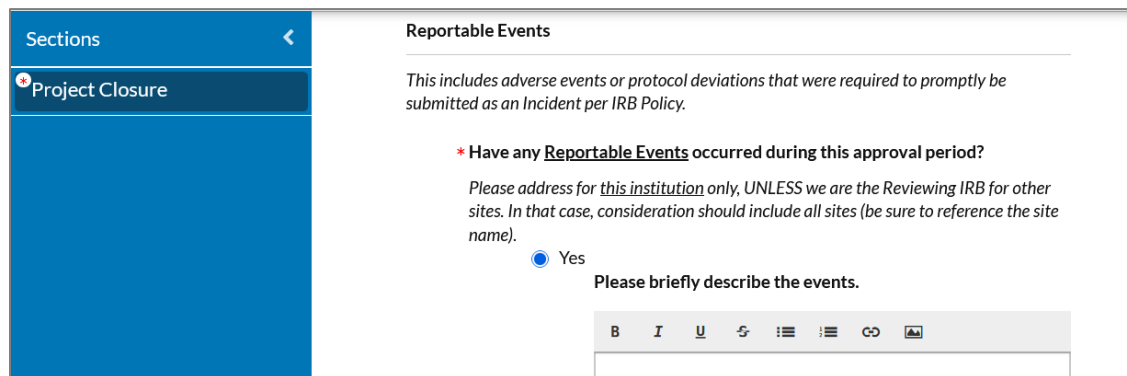
Have any Reportable Events occurred during this approval period?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).

Yes /No, if yes

Please briefly describe the events.

Text box



Unreportable Events

This includes adverse events or protocol deviations that weren't required to promptly be submitted as an Incident per IRB Policy.

Have any Unreportable Events occurred during this approval period?

Yes/No, if yes

Provide a list of the unreportable events that occurred at this institution, including enough information to understand why the events were determined to be unreportable.

Text box

As applicable, provide a list of the unreportable events that occurred across the whole study at all sites, including enough information to understand why the events were determined to be unreportable.

This would ONLY be applicable for studies where we are the Reviewing IRB OR multi-site clinical trials (regardless of who is the IRB of Record).

Text box

Project Closure	Reportable Events
	<i>This includes adverse events or protocol deviations that were required to promptly be submitted as an Incident per IRB Policy.</i>
	* Have any Reportable Events occurred during this approval period? <i>Please address for <u>this institution</u> only, UNLESS we are the Reviewing IRB for other sites. In that case, consideration should include all sites (be sure to reference the site name).</i> ☐ Yes ☒ No
	Unreportable Events
	<i>This includes adverse events or protocol deviations that weren't required to promptly be submitted as an Incident per IRB Policy.</i> * Have any Unreportable Events occurred during this approval period? ☐ Yes ☒ No

Unreportable Events Documentation

Attach any applicable documents for these unreportable events (e.g., event tracker).

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

ATTACH button

Sections	Unreportable Events Documentation
* Project Closure	Attach any applicable documents for these unreportable events (e.g., event tracker). -Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers. ATTACH

New Information

Is there any **New Information** to report for this study?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, entries should include all sites (be sure to reference the site name).

For example:

- Change in funding
- Publications or scientific findings relevant to the risks and benefits to subjects
- Independent Monitor/DSMB/DSMC findings
- Interim analysis

Yes/No, If yes Please describe

Text Box

Sections

Project Closure

*** New Information**

Is there any New Information to report for this study?

Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, entries should include all sites (be sure to reference the site name).

For example:

- Change in funding
- Publications or scientific findings relevant to the risks and benefits to subjects
- Independent Monitor/DSMB/DSMC findings
- Interim analysis

☒ Yes

*** Please describe.**

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Is this Closure being submitted **AFTER** the Study Expiration Date has already passed?

This is applicable **ONLY** to studies that have a Study Expiration Date (e.g., full board studies and some expedited studies), **NOT** studies that have an Admin Check-in Date .

Yes/No, if yes Reason for Expiration

Please explain why the study was allowed to expire (e.g., delay of renewal submission, outstanding information request, delayed documentation from IRB of Record, etc.).

Text Box

Sections

Project Closure

*** Is this Closure being submitted AFTER the Study Expiration Date has already passed?**

This is applicable **ONLY** to studies that have a Study Expiration Date (e.g., full board studies and some expedited studies), **NOT** studies that have an Admin Check-in Date .

☒ Yes

Reason for Expiration

Please explain why the study was allowed to expire (e.g., delay of renewal submission, outstanding information request, delayed documentation from IRB of Record, etc.).

B

I

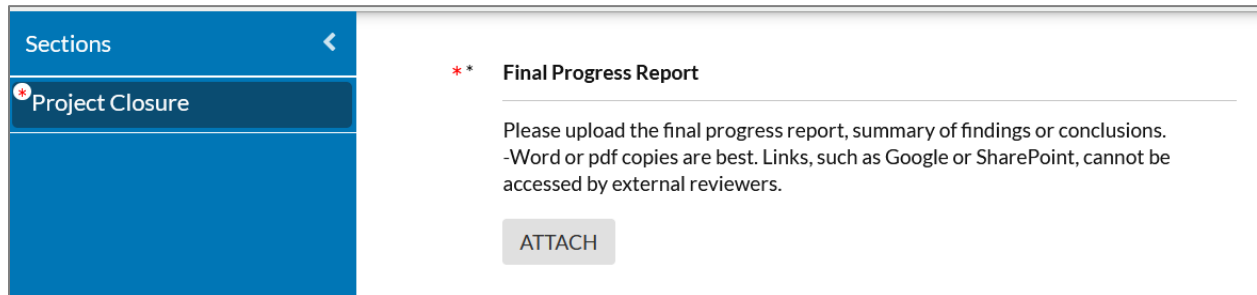
U

Final Progress Report

Please upload the final progress report, summary of findings or conclusions.

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

ATTACH button



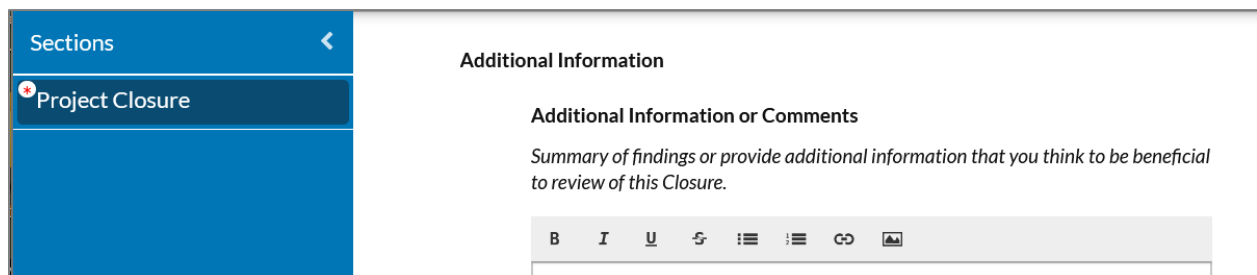
The screenshot shows a web interface with a blue sidebar on the left containing a 'Sections' menu with a back arrow and a 'Project Closure' item marked with a red asterisk. The main content area is titled 'Final Progress Report' with two red asterisks. Below the title, there is instructional text: 'Please upload the final progress report, summary of findings or conclusions. -Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.' At the bottom of this section is a grey 'ATTACH' button.

Additional Information

Additional Information or Comments

Summary of findings or provide additional information that you think to be beneficial to review of this Closure.

Text Box



The screenshot shows the same blue sidebar as the previous section. The main content area is titled 'Additional Information'. Below this is the sub-header 'Additional Information or Comments' followed by the instructional text: 'Summary of findings or provide additional information that you think to be beneficial to review of this Closure.' Below the text is a rich text editor toolbar with icons for Bold (B), Italic (I), Underline (U), Bulleted List, Numbered List, Link, and Image. A text input field is located directly beneath the toolbar.

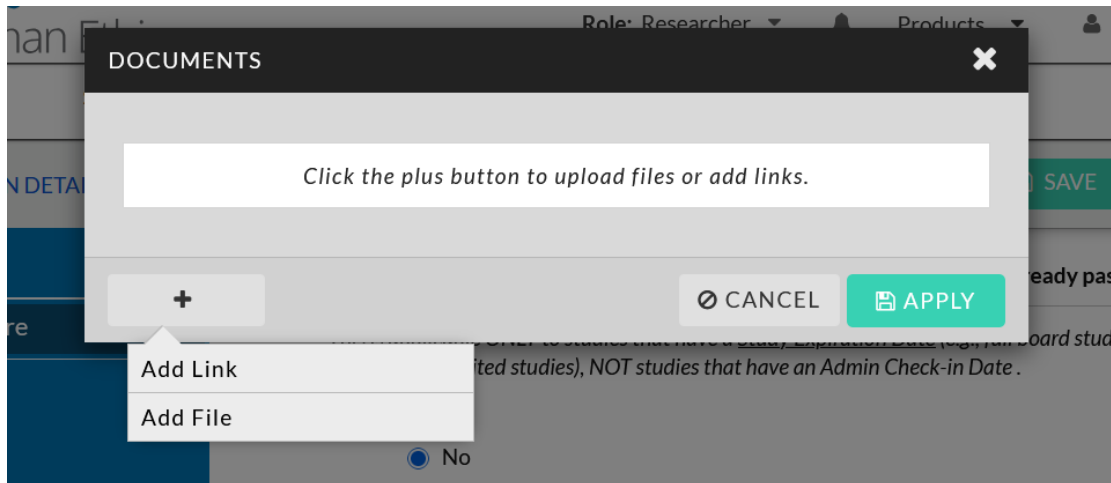
Additional Documentation

If you have any additional documentation to provide for this Closure, upload it here.

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

ATTACH button

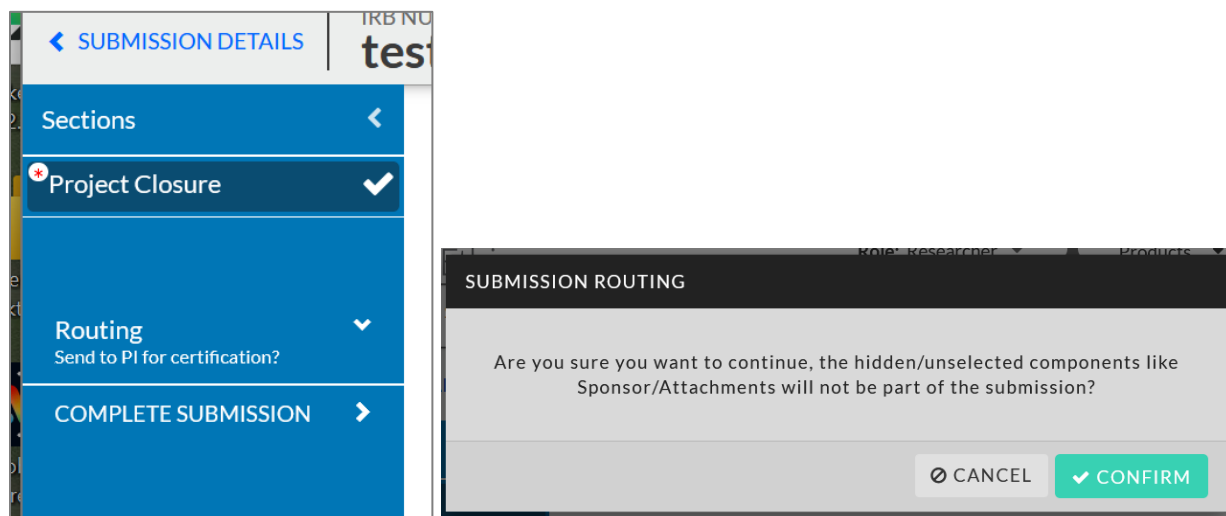
After clicking on the **ATTACH** button a pop-up for Documents will state “Click the plus button to upload files...” After clicking on the plus sign search for the document you wish to attach, click on it and click the green **APPLY** button on the pop-up.



COMPLETE SUBMISSION

When the section is complete, a checkmark will appear to the right of Project Closure.

Scroll down to the bottom of the left blue navigation bar Routing and click on **COMPLETE SUBMISSION**. A message will pop-up asking to confirm the submission. Click the green **CONFIRM** button on the pop-up.



Confirming COMPLETE SUBMISSION returns to Submission Details.

Click on Certify.

Awaiting Certification

Closure

IRB-2025-365 - test uploads

View

PDF

Delete

Routing:

Return

Certify

PI:

Tina Aubut

Current Analyst:

N/A

Decision:

N/A

Policy:

Post-2018 Rule

Required Tasks:

N/A

Review Type:

N/A

Review Board:

N/A

Meeting Date:

N/A

Approvals

Task History

Attachments

A pop-up will ask to confirm certification.

Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Cancel

Confirm