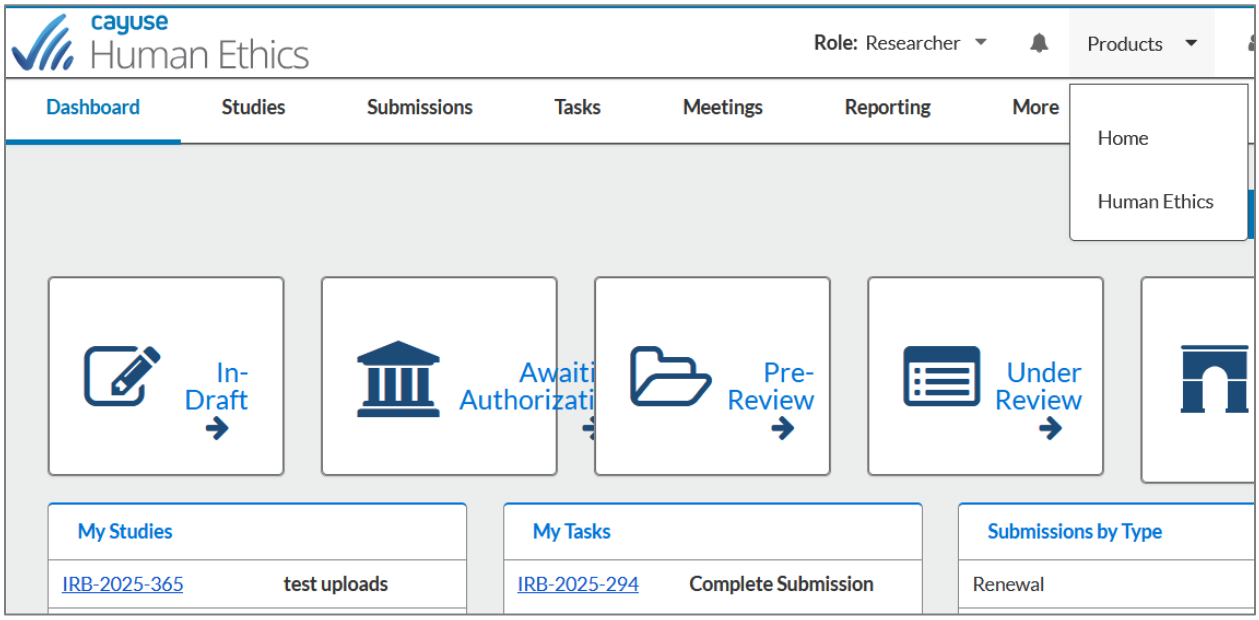
Protocol Completion/Closure

Human Ethics

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

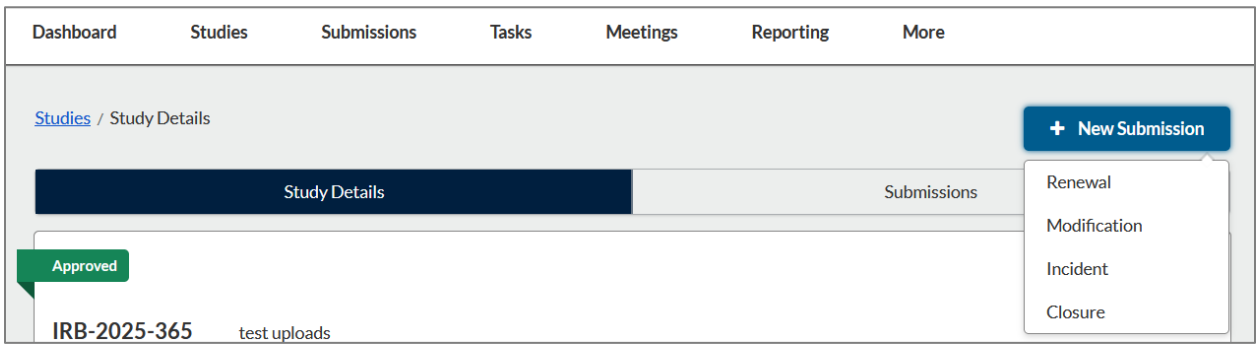


Dashboard

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

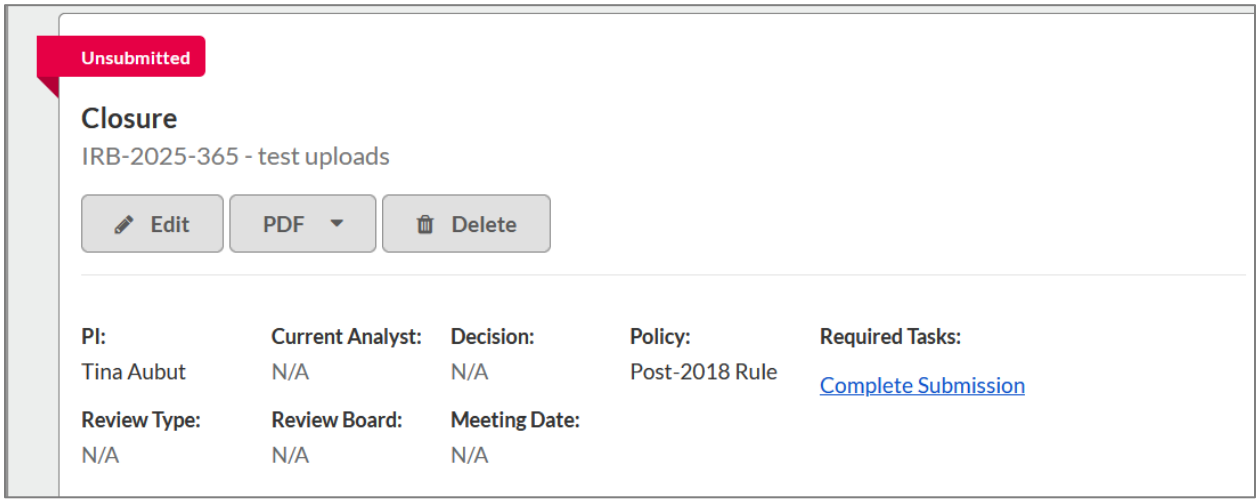
Study Details

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.

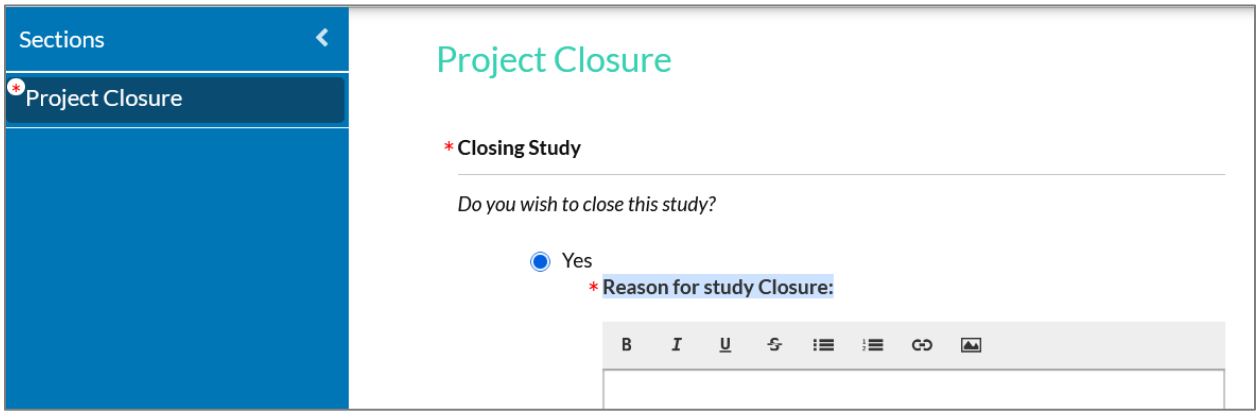


The Project Closure form will open.

Closing Study

Do you wish to close this study?

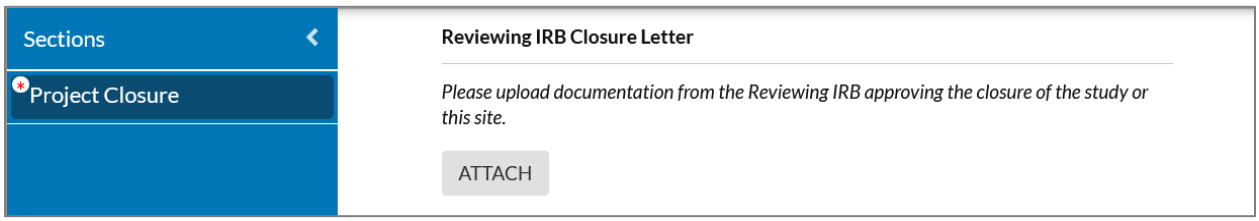
Yes/No, If yes, Reason for study Closure.



Reviewing IRB Closure Letter

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

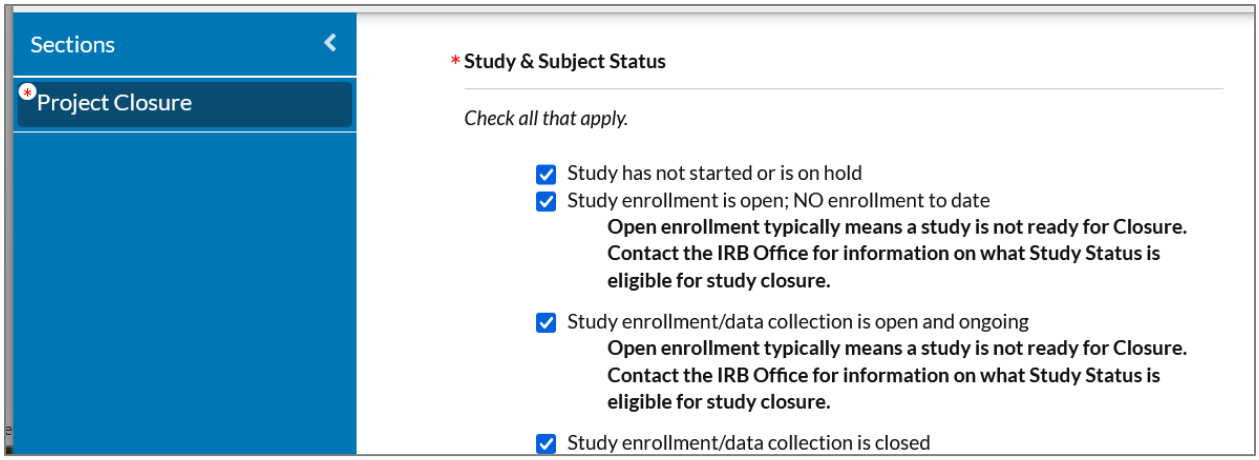
ATTACH button

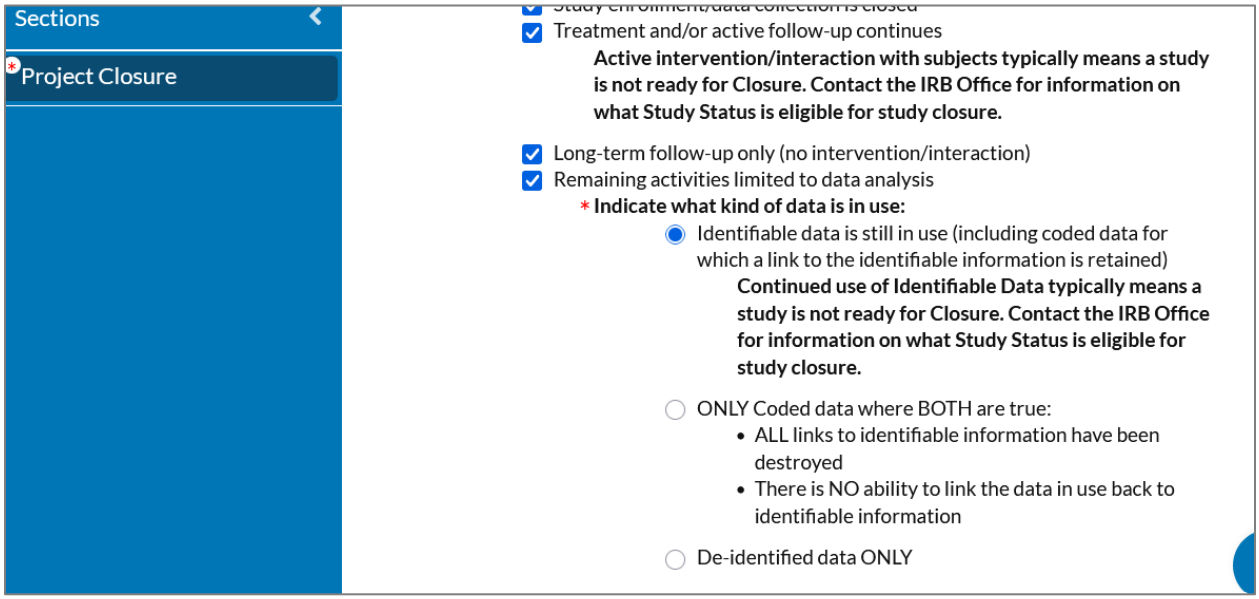


Study & Subject Status (image on next page)

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





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 <u>at all sites</u>

Text box

Total subjects enrolled/data records to date <u>at this institution</u>

Text box

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

Text box

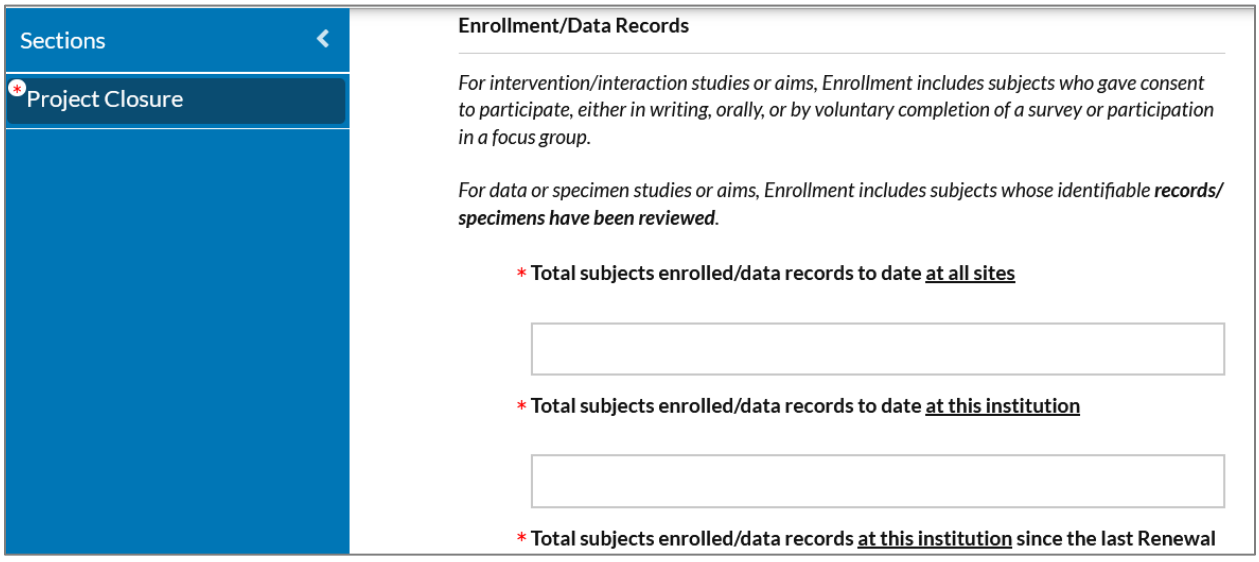
Total number of withdrawals <u>at this institution</u> since start of the study
<u>NOTE:</u> Includes subjects who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.

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

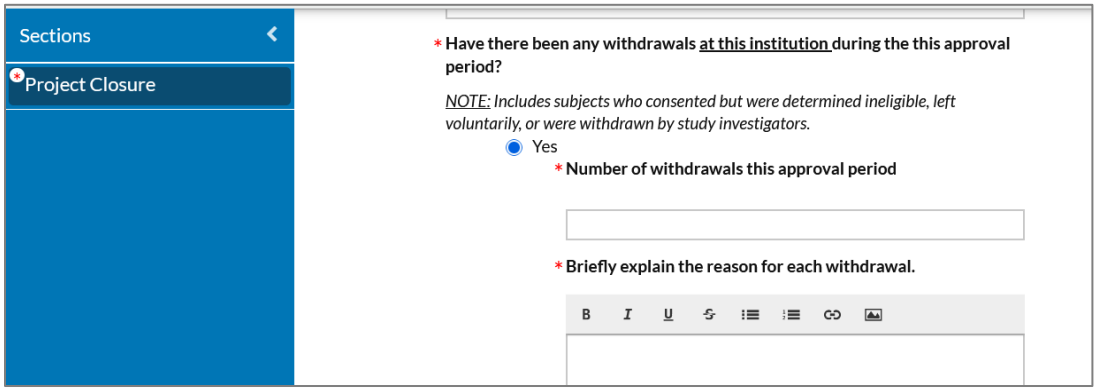


Have there been any withdrawals <u>at this institution</u> during the this approval period?
<u>NOTE:</u> Includes subjects who consented but were determined ineligible, left voluntarily, or were withdrawn by study investigators.

Yes/No, if yes

Number of withdrawals this approval period. Text box

Briefly explain the reason for each withdrawal. Text box



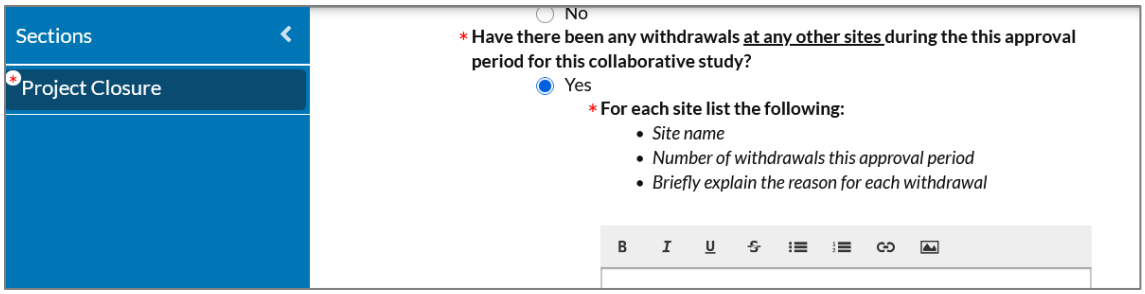
Have there been any withdrawals <u>at any other sites</u> during the this approval period for this collaborative study?

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



Complaints

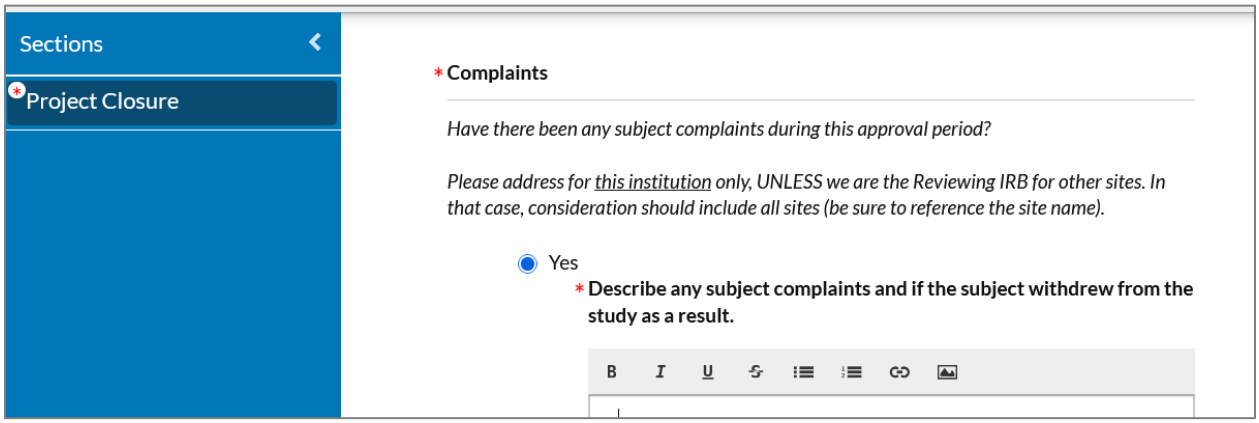
Have there been any subject complaints during this approval period?

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



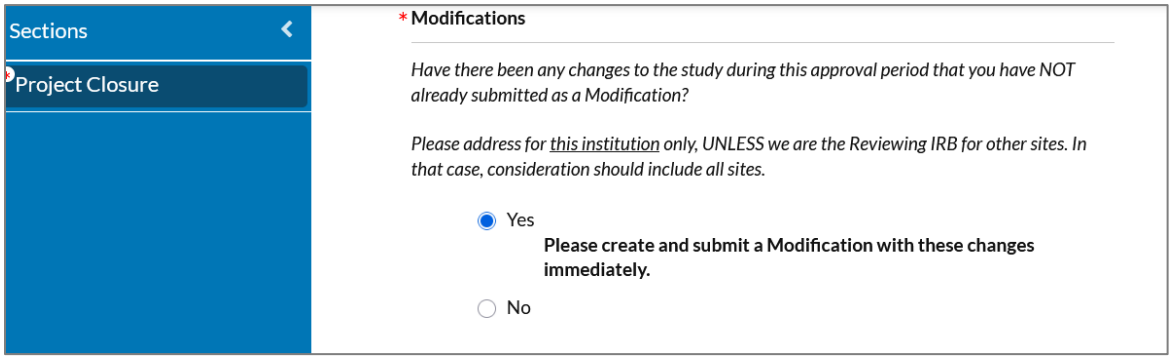
Modifications

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.



Reportable Events

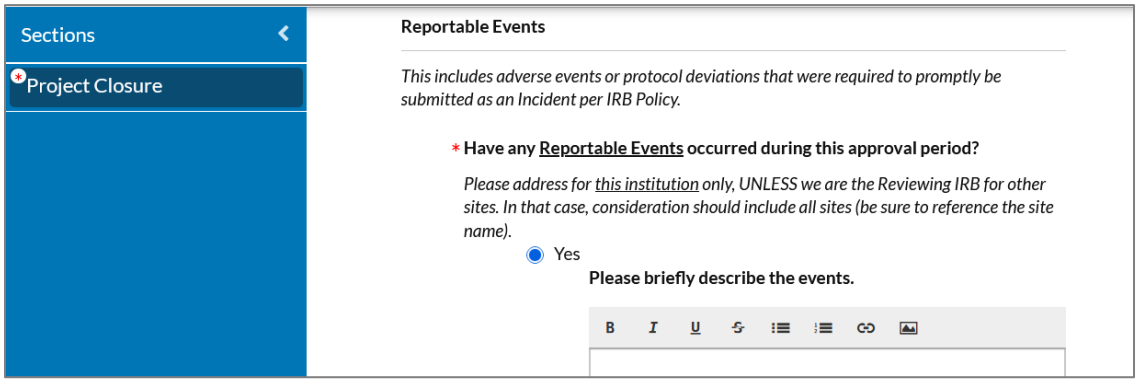
This includes adverse events or protocol deviations that were required to promptly be submitted as an Incident per IRB Policy.

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?

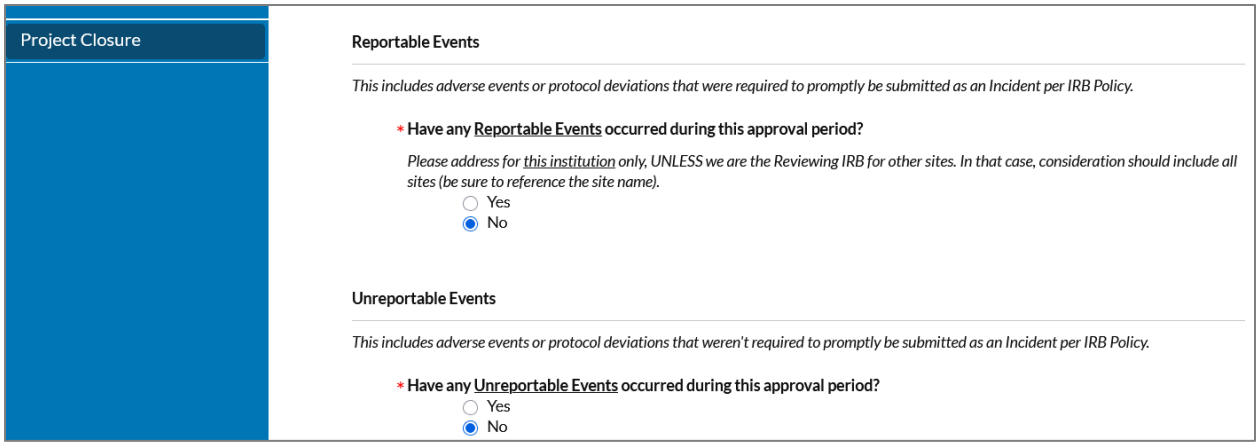
Yes/No, if yes

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

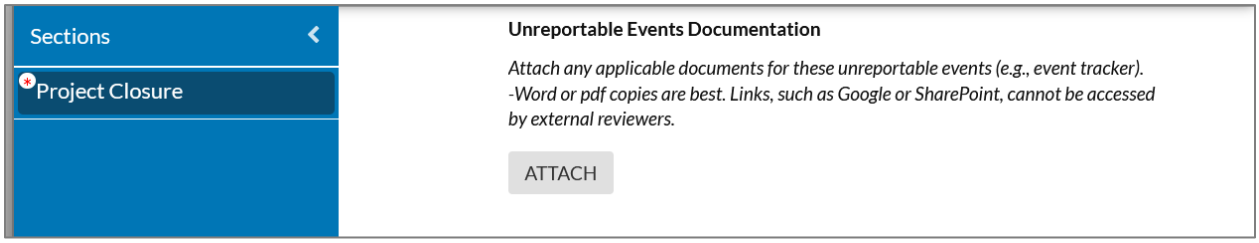


Unreportable Events Documentation

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



New Information

Is there any New Information to report for this study?

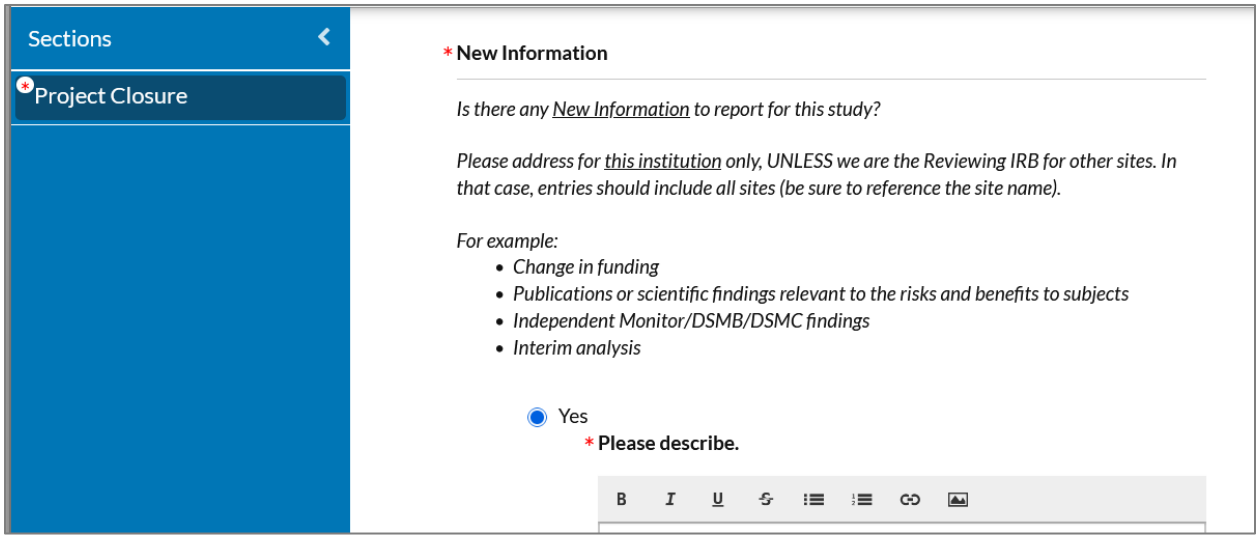
Please address for this institution only, UNLESS we are the Reviewing IRB for other sites. In that case, entries should include all sites (be sure to reference the site name).

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



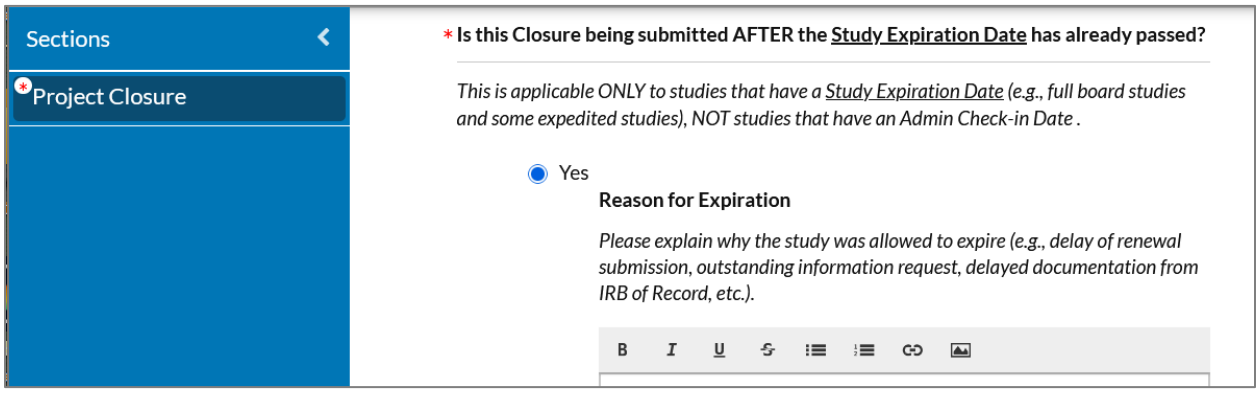
Is this Closure being submitted AFTER the Study Expiration Date has already passed?

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.).

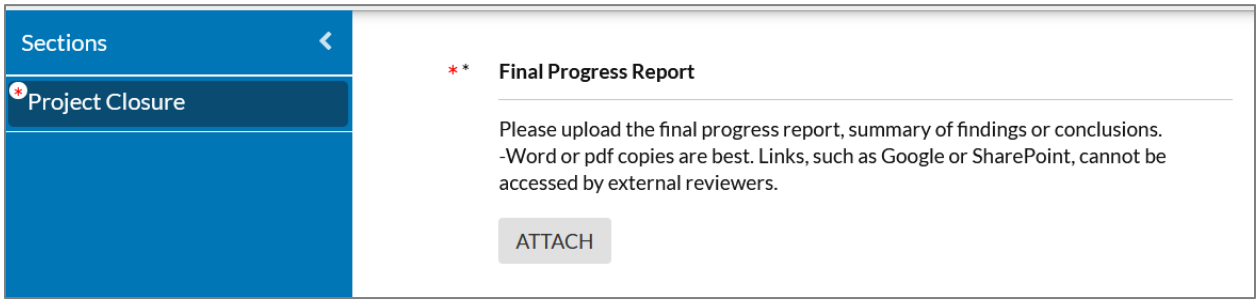
Text Box



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

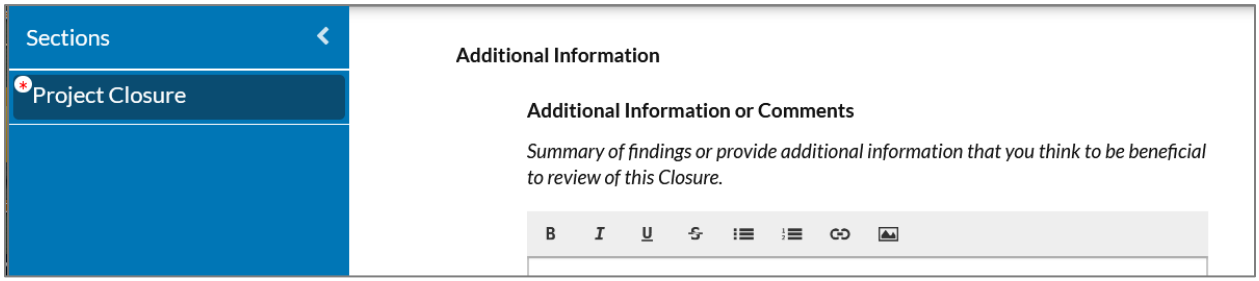


Additional Information

Additional Information or Comments

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

Text Box

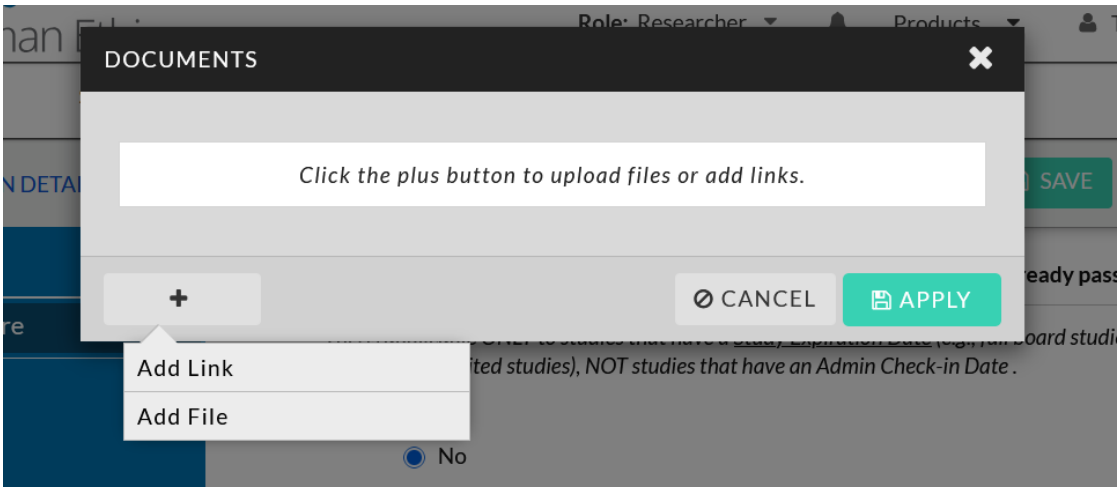


Additional Documentation

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

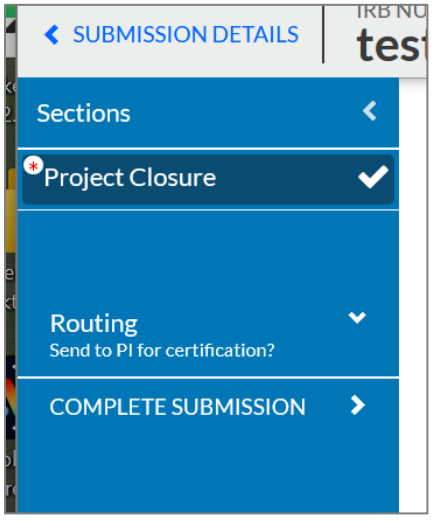
After clicking on the **ATTACH button** a pop-up for Documents will state “Click the plus button to upload files…” After clicking on the plus sign search for the document you wish to attach, click on it and click the green APPLY button on the pop-up.

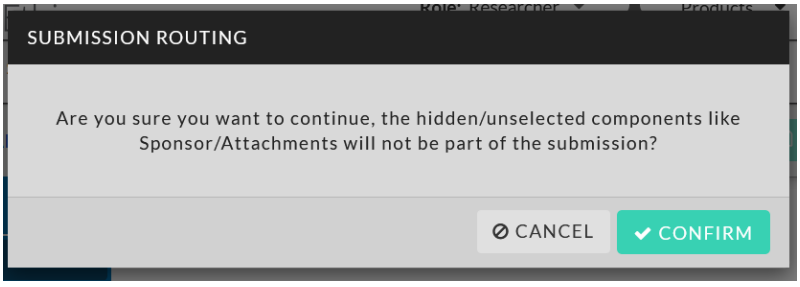


COMPLETE SUBMISSION

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

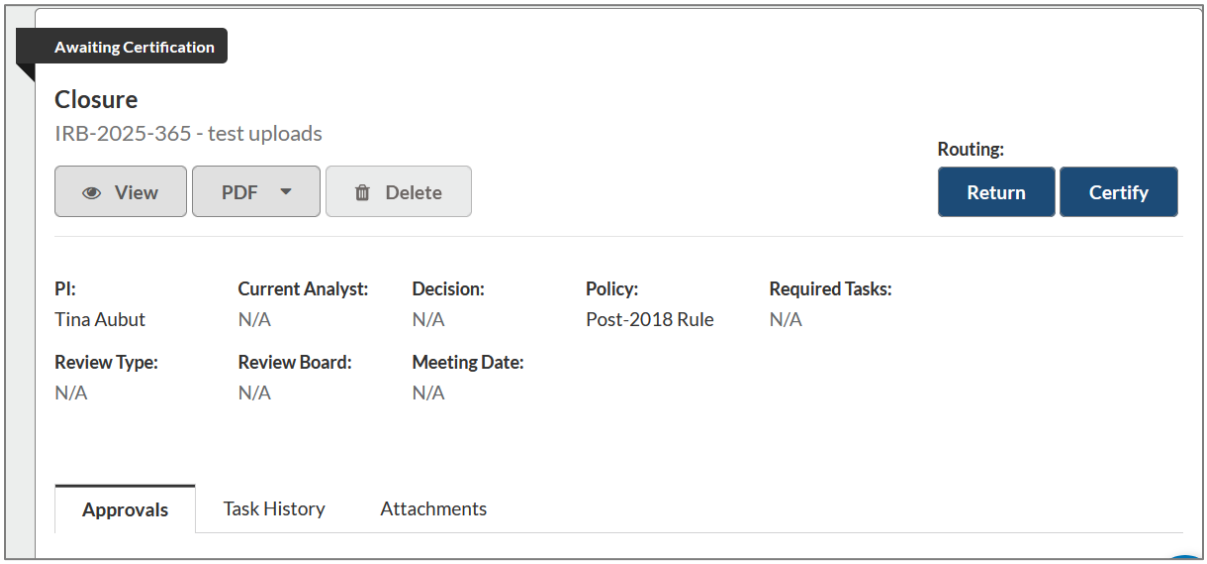
Scroll down to the bottom of the left blue navigation bar Routing and click on COMPLETE SUBMISSION. A message will pop-up asking to confirm the submission. Click the green CONFIRM button on the pop-up.





Confirming COMPLETE SUBMISSON returns to Submission Details.

Click on Certify.



A pop-up will ask to confirm certification.