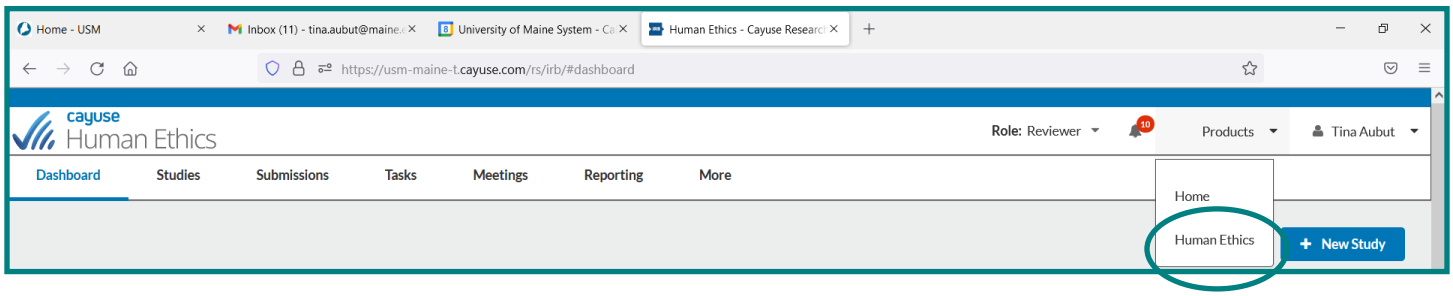
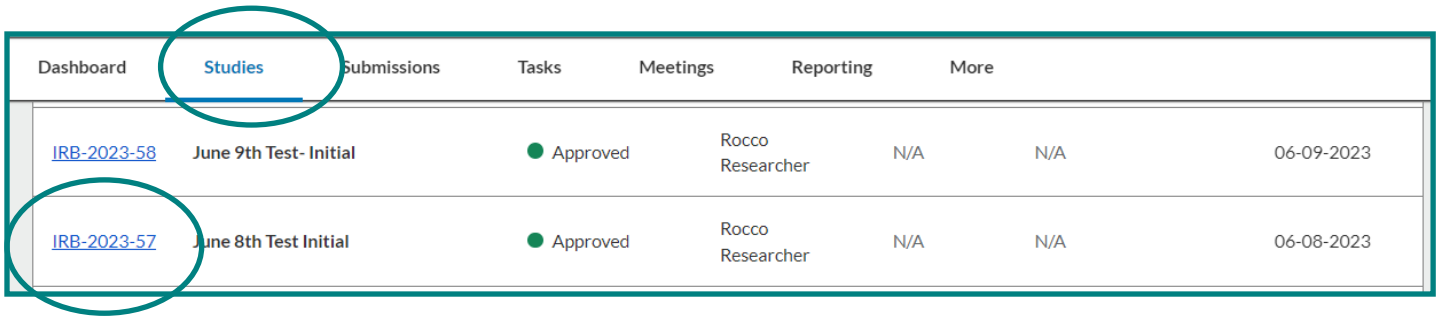
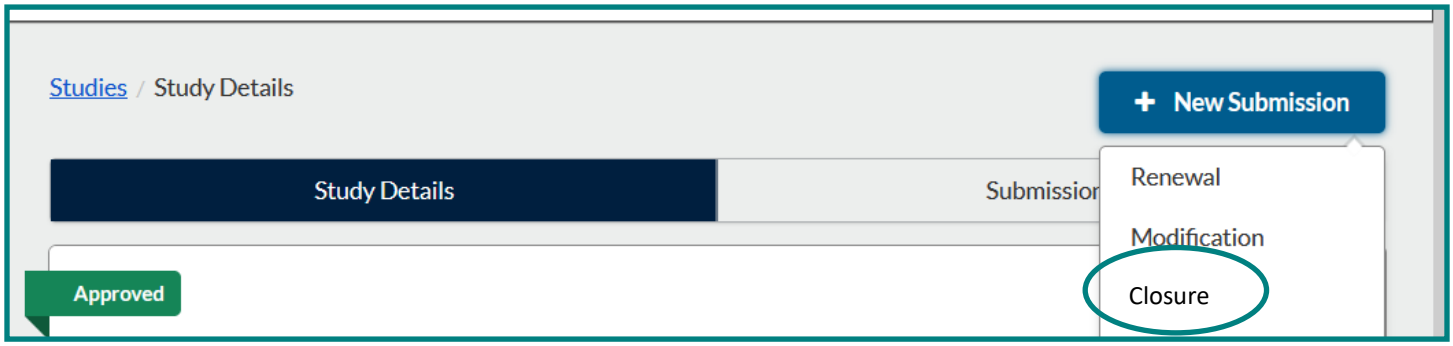
Protocol Completion/Closure

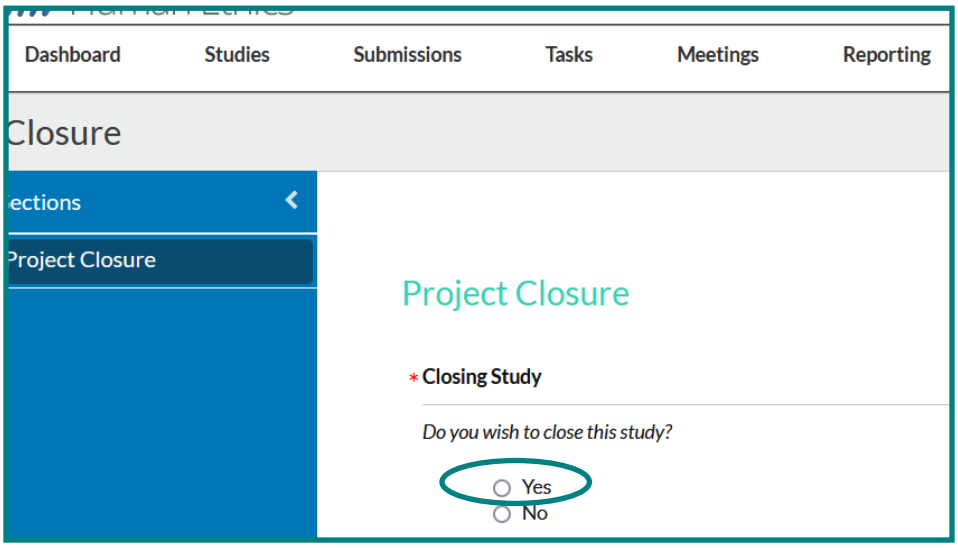
After logging in, select **Human Ethics** from the Products drop-down.



Make sure **Researcher** is selected under the Role drop-down. Click on highlighted protocol , **New Submission** button.







Cayuse is a smart form, you may not have to answer all these questions. It depends on your responses.

For the screenshots we clicked on all possibilities.

* **Closing Study**

Do you wish to close this study?

- (●) Yes

  * **Reason for study Closure:**

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* **IRB Oversight Arrangements**

Indicate how IRB oversight is organized for this study. This should match what is in the latest approved version of this study (latest approved Modification or Initial approval).

- ( ) Study involving 1 site where this site is the Reviewing IRB (IRB of Record)
- ( ) Study involving more than 1 site where each site will conduct their own IRB review
- ( ) Study involving more than 1 site where this site is the Reviewing IRB (IRB of Record) for other sites
- ( ) Study involving more than 1 site where this site is Relying on an External IRB
- ( ) Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is the Reviewing IRB (IRB of Record) for all sites
- (●) Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is Relying on an External IRB

Reviewing IRB Closure Letter

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

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* **Study & Subject Status**

Check all that apply.

- [x] Study has not started or is on hold
- [x] 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.
- [x] Study enrollment 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.
- [x] Study enrollment is closed
- [x] 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.
- [x] Long-term follow-up only (no intervention/interaction)
- [x] 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

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 to date at all sites**

* **Total subjects enrolled to date at this institution**

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

* **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.

* **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

* **Number of withdrawals this approval period**

* **Briefly explain the reason for each withdrawal.**

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* **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

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

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* **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

Please create and submit a Modification with these changes immediately.

- ( ) No

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

Please briefly describe the events.

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- ( ) No

* **Have all Reportable Events during this approval period already been submitted as Incidents?**

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

Please create and submit Incident submissions for these reportable events immediately.

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

* **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.**

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* **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).

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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.

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* **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

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.).

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* **Final Progress Report**

Please upload the final progress report, if applicable.
-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

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Additional Information

Additional Information or Comments

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

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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.

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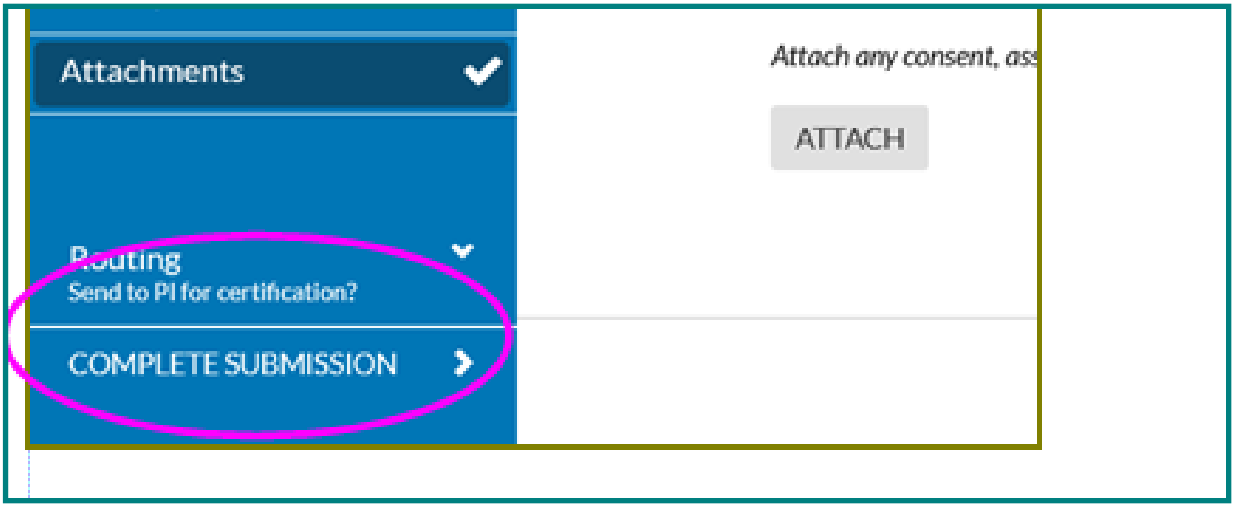
When done, click Complete Submission. Pop-ups will ask you to confirm.



Certify submission: The primary PI is the only one who can certify the submission.

When all certification routing is done, it goes into the que of an ORIO analyst for next steps.