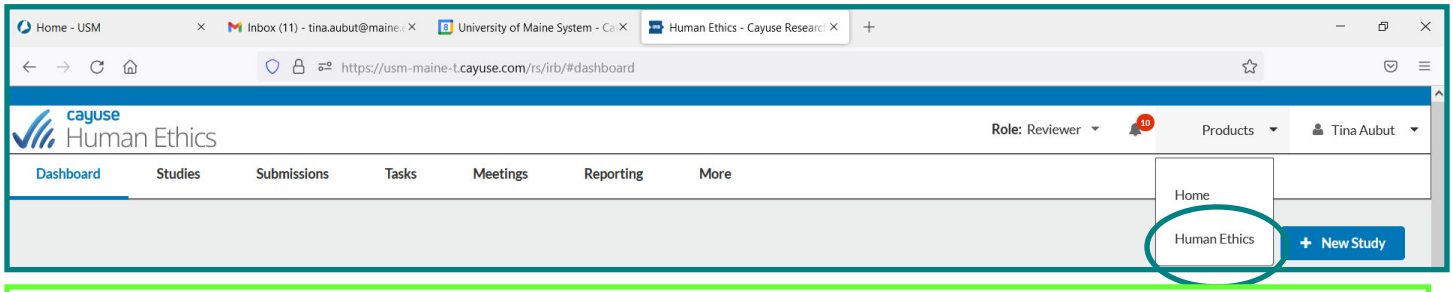
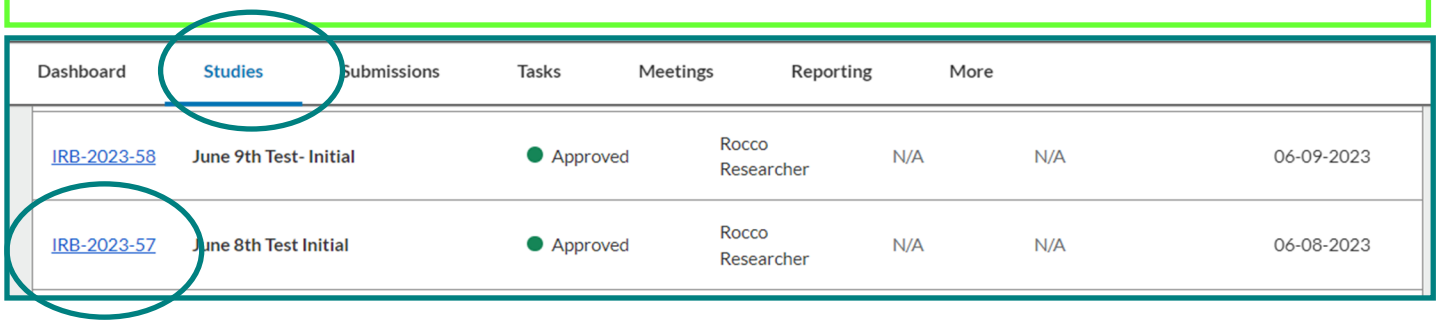
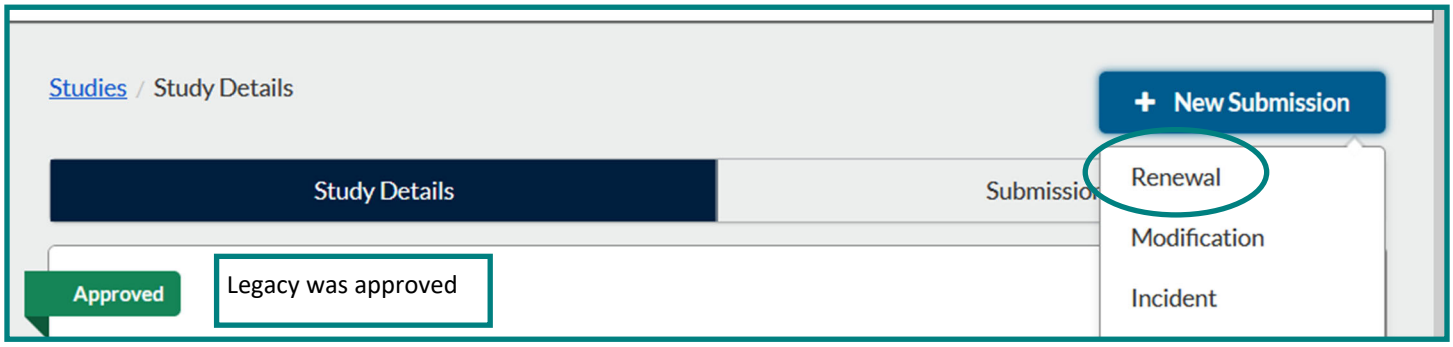
Renewal/Continuing Review from a Legacy Protocol

Notes: Complete Legacy first, if it hasn't been already. If you have any changes to make, submit a Modification **BEFORE** submitting the renewal.
After logging in, select **Human Ethics** from the Products drop-down.

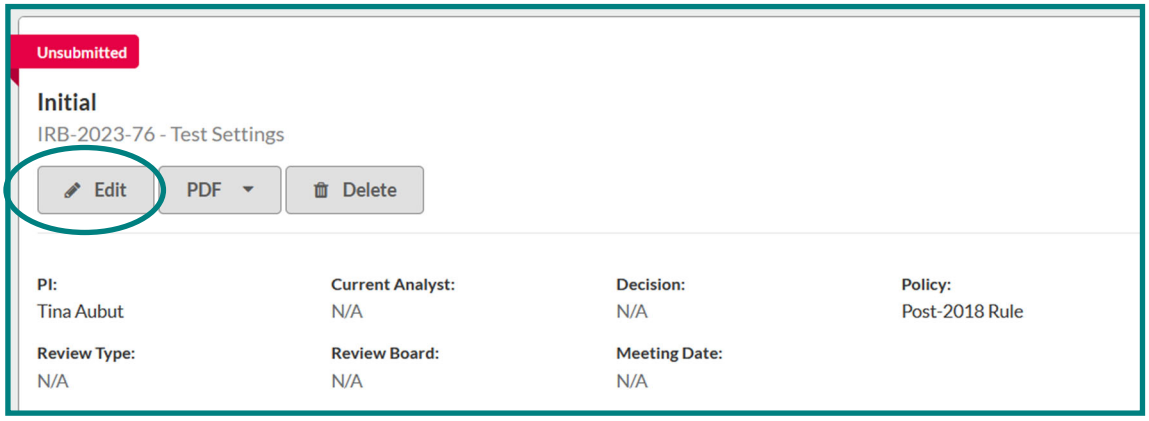


Make sure **Researcher** is selected under the Role drop-down. Click on highlighted protocol , **New Submission** button.





Click Edit



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.

cayuse Human Ethics

Role: Analyst 28 Prod

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Renewal — Preview Only

Sections

Continuing Review

Continuing Review

Submit amendments/modifications separate from the continuing review.

* **Request for More Time**

Are you requesting more time for the project?

- (●) Yes
- ( ) No

Provide a brief summary of activities to date:

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Continuing Review

* **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 this site is the Reviewing IRB (IRB of Record) for other sites
- ( ) 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 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

Sections

Continuing Review

* **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
- [x] Study enrollment is open and ongoing
- [x] Study enrollment is closed
- [x] Treatment and/or active follow-up continues
- [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)
- ( ) 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

Continuing Review

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 this is the first Renewal)**

Sections

Continuing Review

* **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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Sections

Continuing Review

* **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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Sections

Continuing Review

* **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

Sections

Continuing Review

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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Continuing Review

- ( ) 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.

Sections

Continuing Review

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).

ATTACH

Sections

Continuing Review

*** 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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Sections

Continuing Review

*** Is this Renewal 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

Sections

Continuing Review

Renewing an Expired Study

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 .

*** Are you requesting that study activities continue while the study is expired?**

It may be important for subject safety to continue with any study procedures or treatment during the expiration period.

Note: These activities cannot be represented as having "IRB Approval".

(•) Yes

*** Requested Activities**

Please describe the proposed activities and safety rationale for each.

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*** 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.), AND your plan to prevent this study from expiring in the future.

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Sections

Continuing Review

Additional Information

Additional Information or Comments

If applicable, you can provide additional information that you think to be beneficial to review of this Renewal (e.g., summary of project progress, concerns or comments about risks to subjects, etc.).

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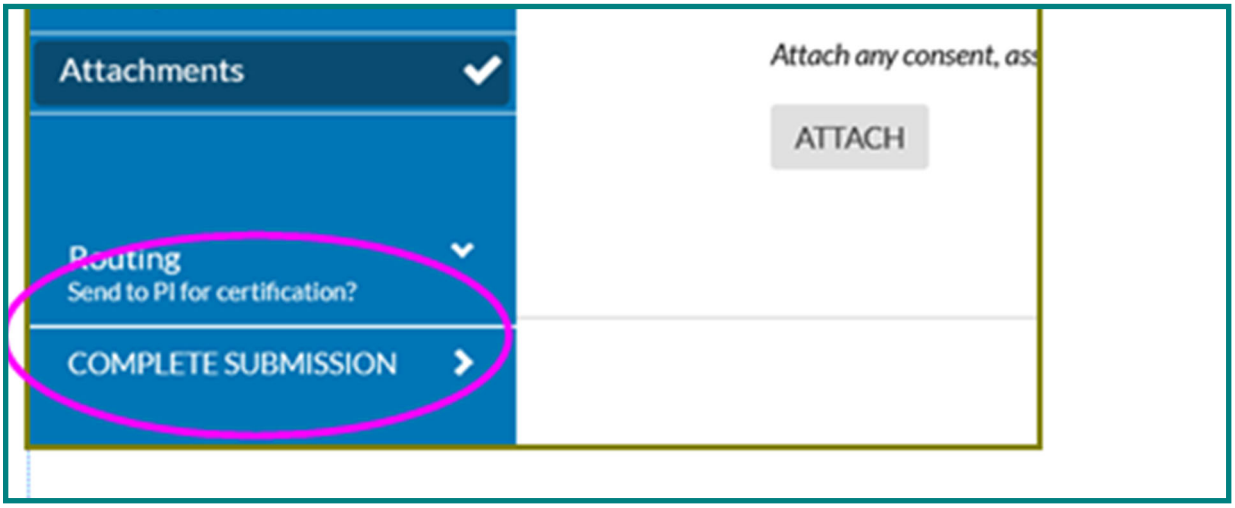
Additional Documentation

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

ATTACH

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



Certify submission: PI, CO-PI, and Faculty Sponsor (Advisor) **ALL** must certify each submission.

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