

## 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.

Home - USM | Inboxes | University of Maine System | Human Ethics - Cayuse Research

Role: Reviewer | Products | Tina Aubut

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

Home | Human Ethics | + New Study

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

Protocol	Title	Status	Researcher	Decision	Review Date
<a href="#">IRB-2023-58</a>	June 9th Test- Initial	Approved	Rocco Researcher	N/A	06-09-2023
<a href="#">IRB-2023-57</a>	June 8th Test Initial	Approved	Rocco Researcher	N/A	06-08-2023

Studies / Study Details

Study Details | Submission

Approved | Legacy was approved

+ New Submission

- Renewal
- Modification
- Incident

Click Edit

Unsubmitted

Initial

IRB-2023-76 - Test Settings

Edit | PDF | Delete

PI: Tina Aubut | Current Analyst: N/A | Decision: N/A | Policy: Post-2018 Rule

Review Type: N/A | Review Board: N/A | Meeting Date: N/A

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.

The screenshot shows the Cayuse Human Ethics interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The user's role is 'Analyst' and there are 28 notifications. The main content area is titled 'Renewal' and 'Preview Only'. The left sidebar shows 'Sections' with 'Continuing Review' selected. The main content area is titled 'Continuing Review' and contains the following text: 'Submit amendments/modifications separate from the continuing review.' Below this is a section titled '\* Request for More Time' with the question 'Are you requesting more time for the project?' and two radio button options: 'Yes' (selected) and 'No'. At the bottom, there is a text area with the prompt 'Provide a brief summary of activities to date:' and a rich text editor toolbar.

This screenshot shows the 'IRB Oversight Arrangements' section. The left sidebar is labeled 'Continuing Review'. The main content area is titled '\* IRB Oversight Arrangements' and includes the instruction: '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).' Below this are six radio button options: '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', and 'Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is Relying on an External IRB'.

This screenshot shows the 'Study & Subject Status' section. The left sidebar is labeled 'Continuing Review'. The main content area is titled '\* Study & Subject Status' and includes the instruction: 'Check all that apply.' Below this are seven checked checkboxes: 'Study has not started or is on hold', 'Study enrollment is open; NO enrollment to date', 'Study enrollment is open and ongoing', 'Study enrollment is closed', 'Treatment and/or active follow-up continues', 'Long-term follow-up only (no intervention/interaction)', and 'Remaining activities limited to data analysis'. Below these is a section titled '\* Indicate what kind of data is in use:' with three radio button options: '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:' (with two sub-bullets: 'ALL links to identifiable information have been destroyed' and 'There is NO ability to link the data in use back to identifiable information'), and 'De-identified data ONLY' (selected).

**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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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

### 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.

Attachments ✓

Attach any consent, ass

ATTACH

Routing  
Send to PI for certification?

COMPLETE SUBMISSION >

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.

Awaiting Certification

**Initial**  
IRB-2023-16 - Test Research Project in Cayuse

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

Research Team

Name	Role	Result	Date
Tina Aubut	Principal Investigator	Pending Certification	

