

# Renewal/Continuing Review

Some changes have been made to the form after initial upload of Legacy data. There may be some variations between a legacy submission and later submissions.

The screenshot shows the Cayuse Human Ethics portal interface. At the top, the logo and name 'cayuse Human Ethics' are on the left, and 'Role: Analyst' and a notification bell with '28' are on the right. A navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. Below this, a 'Renewal' header is present with a 'Preview Only' label. A 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 for '\* 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 of this section 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. It begins with the heading '\* IRB Oversight Arrangements' followed by 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. It starts with the heading '\* Study & Subject Status' and the instruction 'Check all that apply.' Below this is a list of 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'. Under the last checkbox is a sub-section '\* 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 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' (which is 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 <

### 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 <

### 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).

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Sections <

### 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.*

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Participant Protect... ✓

Attachments ✓

Routing

Send to PI for certification? ▾

COMPLETE SUBMISSION >

### Consent & Assent Fo

*Attach any consent, as*

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**Awaiting Certification**

**Initial**

IRB-2023-16 - Test Research Project in Cayuse

View PDF Delete

Routing: Return Certify

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

Approvals Task History Attachments


**Research Team**

Name	Role
Tina Aubut	Principal Investigator

A pop-up will appear to confirm certification before it is routed to the next CO-PI or Faculty to certify.

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

### 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 Certify