

CAYUSE | HUMAN ETHICS

SUBMITTING A STUDY MODIFICATION

This guidance is for investigators making changes to an already approved human ethics or IRB-reviewed research study in Cayuse.

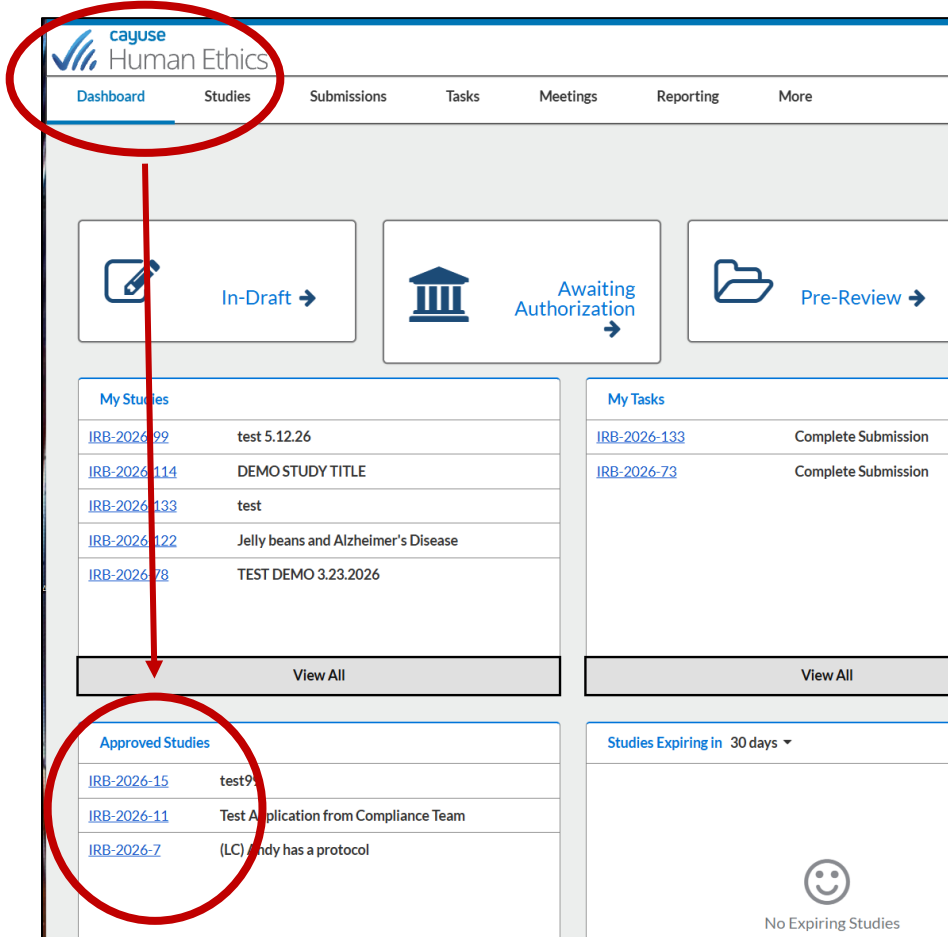
Important Considerations

- Modifications to study protocols must receive approval prior to implementation
- Any personnel, internal or external to Loyola, being added to a study protocol must complete Loyola's Human Research training requirements in the CITI Program; see [here](#) for more information

Key Steps

1) Identify the Study to be Modified:

- a. When logged into Cayuse, under the *Human Ethics* module and *Researcher* role, locate your **Approved Studies** in the lower left corner of the Dashboard
- b. Select the study to be modified



The screenshot displays the Cayuse Human Ethics dashboard. The top navigation bar includes the 'cayuse Human Ethics' logo and tabs for Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. Below the navigation bar are three status cards: 'In-Draft', 'Awaiting Authorization', and 'Pre-Review'. The main content area is divided into two columns. The left column contains a table titled 'My Studies' with five rows of study information. The right column contains a table titled 'My Tasks' with two rows of task information. At the bottom of the dashboard, there are two more sections: 'Approved Studies' on the left and 'Studies Expiring in 30 days' on the right. A red circle highlights the 'cayuse Human Ethics' header and the 'Studies' tab, and a red arrow points from this circle down to another red circle that highlights the 'Approved Studies' section in the bottom left corner.

My Studies	
IRB-2026-99	test 5.12.26
IRB-2026-114	DEMO STUDY TITLE
IRB-2026-133	test
IRB-2026-122	Jelly beans and Alzheimer's Disease
IRB-2026-78	TEST DEMO 3.23.2026

My Tasks	
IRB-2026-133	Complete Submission
IRB-2026-73	Complete Submission

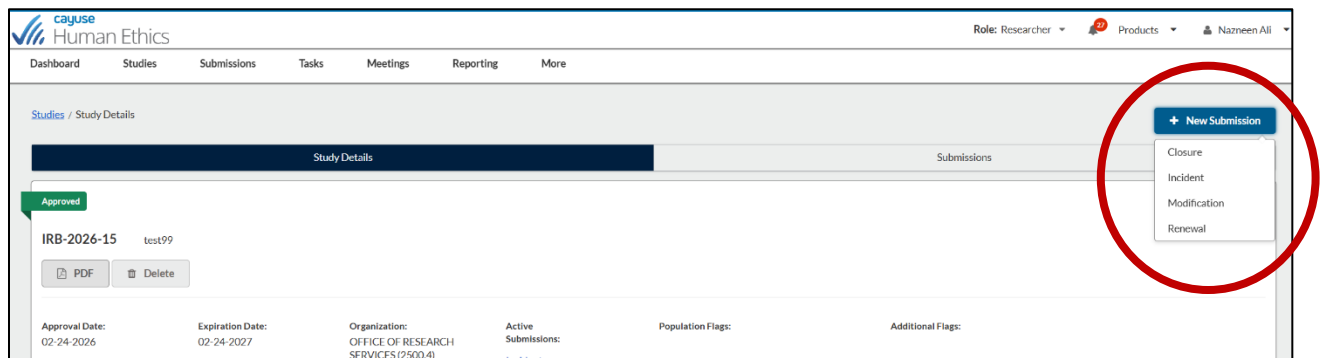
Approved Studies	
IRB-2026-15	test9
IRB-2026-11	Test Application from Compliance Team
IRB-2026-7	(LC) Andy has a protocol

Studies Expiring in 30 days	
No Expiring Studies	

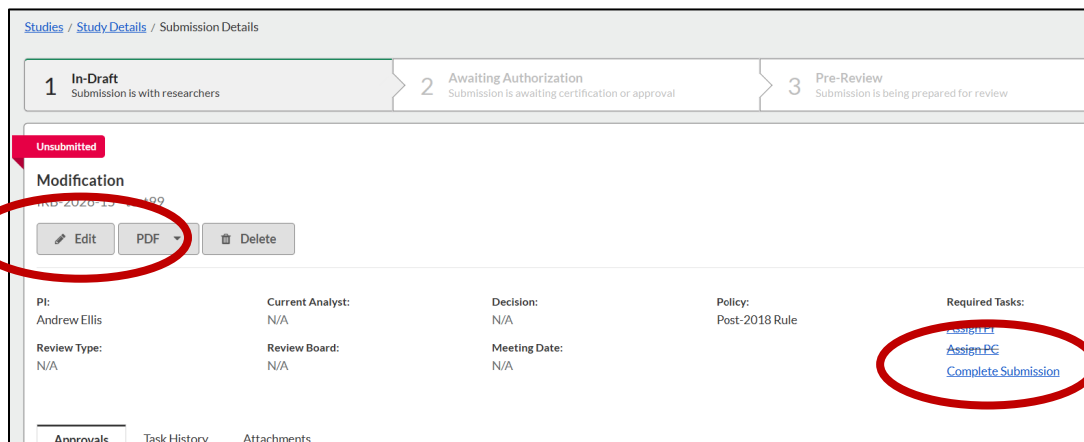
CAYUSE | HUMAN ETHICS

SUBMITTING A STUDY MODIFICATION

- 2) **Create a new Modification submission:** In the upper right corner of the Study Details page, select **+New Submission**; a drop-down list of eligible submissions for that study will appear, select **Modification**



- 3) **Fill in Application:**
- On the Submission Details page, select either **Edit** or **Complete Submission** to start the application process



- The **Modification Information** section requires five (5) questions to be answered; click **Save**; then, select the section from the menu to modify and make necessary updates
 - IMPORTANT:** If modifying documents, *delete* the previously approved/uploaded version/s within the application before uploading the revised version to the Modification application

CAYUSE | HUMAN ETHICS SUBMITTING A STUDY MODIFICATION

Human Ethics

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-2026-11

Test Application from Compliance Team - Modification

Actions

- Modification Information ✓
- Getting Started
- General Information ✓
- Personnel ✓
- Funding ✓
- Research Sites ✓
- Procedures/Summ... ✓
- Risks/Benefits Res... ✓
- Population Researc... ✓
- Informed Consent ✓
- Privacy & Confiden... ✓
- Compensation ✓
- Attachments ✓
- Submission (END f... ✓

Send to PI for certification?

COMPLETE SUBMISSION ➔

Are you making changes to the project?

☒ Yes
Make changes in the sections to the left.
NOTE: If you are modifying documents that have been previously uploaded and approved then DELETE the previously uploaded documents.

☐ No

Justification:

Does the amendment alter, in any way, the assessment of potential risks as described in your approved study protocol?

☒ Yes
Explain how the risk assessment is changed:

test

☐ No

Do Past or Current Participants need to be informed?

☒ No
☐ Yes

Are there changes to the Informed Consent Document(s)?

☐ No
☒ Yes
Upload the modified/new consent document(s) in the attachments section to the left.

4) Save, Complete, and Certify Submission:

- Ensure the green **Save** button in the upper right corner of the page is clicked as modifications are made; when ready, select **Complete Submission** at the bottom the left-side menu; **NOTE:** A system pop-up may appear, select Confirm to continue
- This will route back to the Submission Details page where the submission is Awaiting Certification; select the **Certify** button on the upper right side of the page to submit your Modification application

Studies Study Details / Submission Details

In-Draft
Submission is with researchers

2 Awaiting Authorization
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under-Review
Submission is with reviewers

Awaiting Certification

Modification

IRB-2026-11 Test Application from Compliance Team

View PDF Delete

Routing: **Return** **Certify**

PI: Nazneen Ali
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