

Modification Guidance Instructions for Legacy Projects in Cayuse

Contents

Overview.....	2
Access to Cayuse	2
Step 1: Creating a Modification	3
Step 2: Select the Appropriate Modification Type	4
Research Team: Modification	4
Research Team: Administrative Modification (Limited Submission). ..	5
Step 3: Review the Entire Application (Full Modifications Only)	5
Step 4: Review All Attachments (Full Modifications Only)	5
Step 5: Upload Current CITI Certificates (Full Modifications Only)	6
Appendix A: Modification Selection Guide	7
Appendix B: Final Checklist Before Submission.....	8

Modification Guidance Instructions for Legacy Projects in Cayuse

Overview

For legacy projects, Modifications must be submitted through the existing IRB protocol in Cayuse.

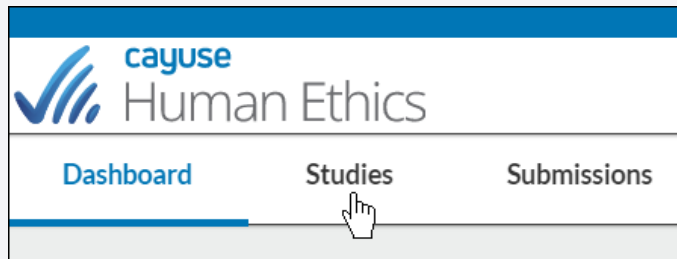
Access to Cayuse

- If you or your key personnel do not have access to the Cayuse Human Ethics (HE) Module, please complete the [Cayuse Access Request Form](#) and submit it for processing before starting your modification. All study team members who need to view, edit, certify, or participate in the submission process must have appropriate Cayuse access.
- You can access the Cayuse system at <https://cuny.app.cayuse.com>.
- Use your CUNY Login credentials (e.g. 'firstname.lastname99@login.cuny.edu') to access the system.
- Refer to the [Quick Guide for Cayuse Human Ethics Users](#) for login instructions.

Modification Guidance Instructions for Legacy Projects in Cayuse

Step 1: Creating a Modification

1. From your Researcher Dashboard, click on **Studies**.

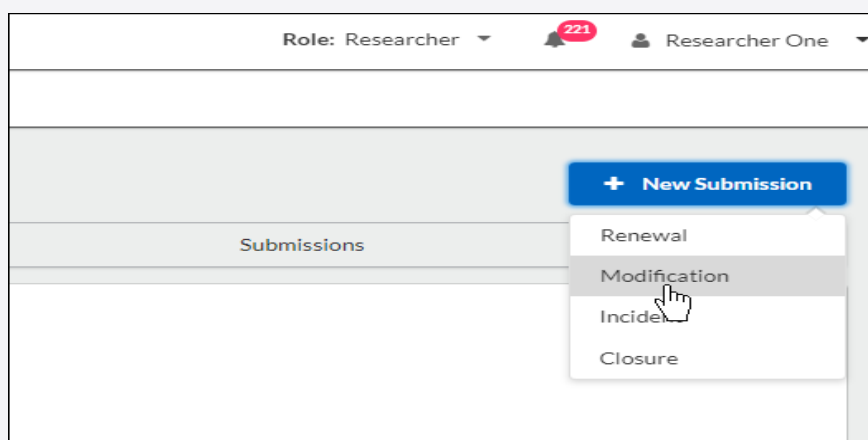


2. Search for the study for which you wish to create a modification and click on the study number. **Please note:** Study must be approved.

The screenshot shows a table of active studies. The 'IRB#' column contains links to study details. A mouse cursor is pointing at the link 'IRB-FY21-26'.

IRB#	Study Title	Status	PI
IRB-FY21-39	Study One	Approved	Researcher One
IRB-FY21-26	Study Two	Approved	Researcher Two
IRB-FY21-18	Study Three	Approved	Researcher Two

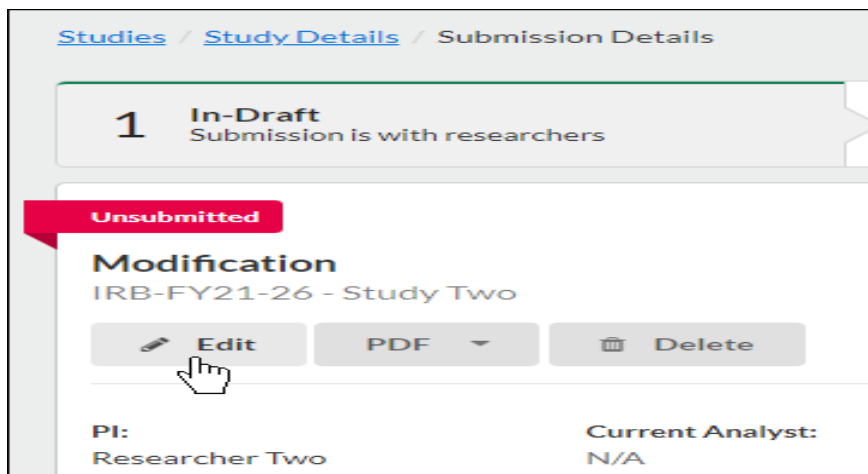
3. In the top right-hand corner of the Study Details page, click on the **New Submission** drop-down menu, and click **Modification**.



Modification Guidance Instructions for Legacy Projects in Cayuse

Submission information will populate beneath the Submission Details tab. The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission.

Click **Edit** to begin your submission.



Step 2: Select the Appropriate Modification Type

When submitting a modification, you must indicate the type of Modification being submitted.

Navigate to **Study Status Legacy** section of Legacy Application and select one of the following:

Research Team: Modification

Select this option for **substantive changes** to an approved study, including:

- Changes to the Principal Investigator (PI)
- Changes to approved research procedures
- Enrollment Increases
- Addition of new study materials
- Changes to recruitment methods
- Changes to consent procedures
- Addition of new participant populations
- Any other significant protocol modification

Modification Guidance Instructions for Legacy Projects in Cayuse

Research Team: Administrative Modification (Limited Submission)

Select this option **only** for the following changes:

1. Minor changes to approved recruitment materials, consent forms, or other study documents. Limited to clarification of consent/recruitment language, correction of minor typographical errors, and updating contact information. The revisions do not alter study procedures, participant population, risks, benefits, confidentiality protections, or the overall study design.
2. Submission of translated materials, site approvals, ancillary approvals, or similar documentation
3. Changes to project personnel **excluding** changes to the Principal Investigator or Faculty Advisor

Important: For all other modifications, select **Research Team: Modification**.

Step 3: Review the Entire Application (Full Modifications Only)

If you are submitting a **full Modification**:

- Carefully review the **entire application**.
- Legacy protocols have sections with missing information for new information requested in Cayuse. It is also important to review the accuracy of details in the application, even though it has been approved.
- Complete any required fields that are blank or incomplete.

Step 4: Review All Attachments (Full Modifications Only)

Before submitting:

- Examine all uploaded study documents.
- Remove outdated or superseded documents.
- Verify that all attachments currently uploaded are actively being used for the study.
- Replace older versions with current documents when appropriate.

Modification Guidance Instructions for Legacy Projects in Cayuse

Examples include:

- Consent forms
 - Recruitment materials
 - Surveys/questionnaires
 - Data collection instruments
 - Study protocols
-

Step 5: Upload Current CITI Certificates (Full Modifications Only)

Under the **Participant Protections** section:

1. Locate the **Other Attachments** question.
2. Upload current **CITI Certificates** for **all key personnel** involved in the study.

This includes:

- Principal Investigator
 - Co-Investigators
 - Faculty Advisors (if applicable)
 - Research Assistants
 - Any other key personnel engaged in human subjects' research activities
-

Modification Guidance Instructions for Legacy Projects in Cayuse

Appendix A: Modification Selection Guide

Type of Change	Select
Change in Principal Investigator	Research Team: Modification
Change in approved research procedures	Research Team: Modification
New recruitment methods/forms	Research Team: Modification
New consent process/forms	Research Team: Modification
New participant population	Research Team: Modification
Enrollment Increase	Research Team: Modification
New study materials	Research Team: Modification
Minor edits to approved recruitment materials	Research Team: Administrative Modification
Minor edits to approved consent forms	Research Team: Administrative Modification
Submission of translated materials	Research Team: Administrative Modification
Submission of site approvals	Research Team: Administrative Modification
Changes to personnel (not PI or Faculty Advisor)	Research Team: Administrative Modification

Modification Guidance Instructions for Legacy Projects in Cayuse

Appendix B: Final Checklist Before Submission

- ☐ Selected the correct Modification type in **Study Status Legacy** section of Cayuse HE Modification Form¹
 - ☐ Reviewed the entire application (full Modifications)
 - ☐ Updated missing or incomplete information (full Modifications)
 - ☐ Reviewed all attachments and removed outdated documents
 - ☐ Uploaded current versions of revised study documents
 - ☐ Uploaded CITI certificates for all key personnel under **Participant Protections** → **Other Attachments** (full Modifications)
 - ☐ Verified all modification details are accurate before submission
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¹ **Note:** Administrative Modifications should be used only for limited, non-substantive updates. Any change affecting study design, procedures, participant involvement, recruitment, consent, or study leadership requires submission as a **Research Team: Modification**.