

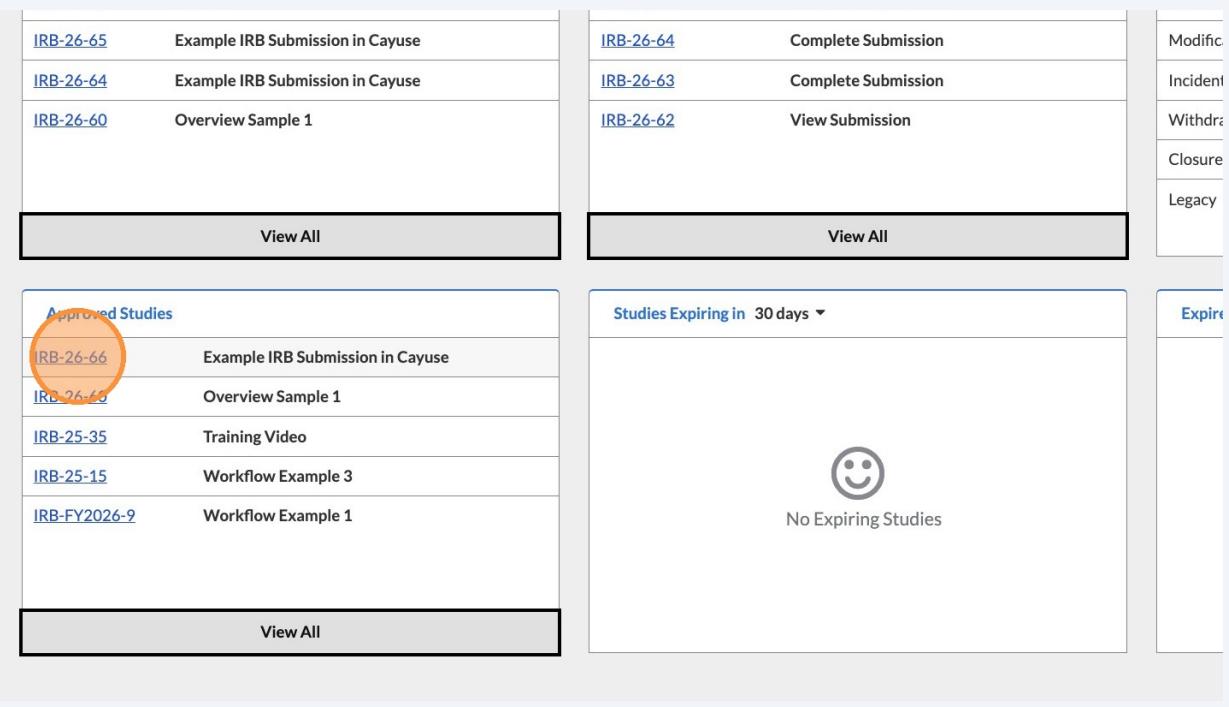
How to Submit a Modification on Cayuse

ScribeTM

This guide provides a step-by-step process for submitting a study modification in Cayuse, ensuring that researchers can efficiently navigate the system. By following these clear instructions, users can avoid common pitfalls and streamline their submission, ultimately saving time and reducing frustration.

1 Navigate to your **Cayuse Dashboard!** <https://usm.app.cayuse.com/>

Locate the protocol you'd like to submit a modification for under "**Approved Studies**".



The screenshot shows the Cayuse Dashboard with a sidebar on the right containing links for Modification, Incident, Withdrawal, Closure, and Legacy. The main content area is divided into sections: Approved Studies, Complete Submission, View All, Studies Expiring in 30 days, and Expiring.

Approved Studies:

IRB-26-65	Example IRB Submission in Cayuse
IRB-26-64	Example IRB Submission in Cayuse
IRB-26-60	Overview Sample 1

Complete Submission:

IRB-26-64	Complete Submission
IRB-26-63	Complete Submission
IRB-26-62	View Submission

View All:

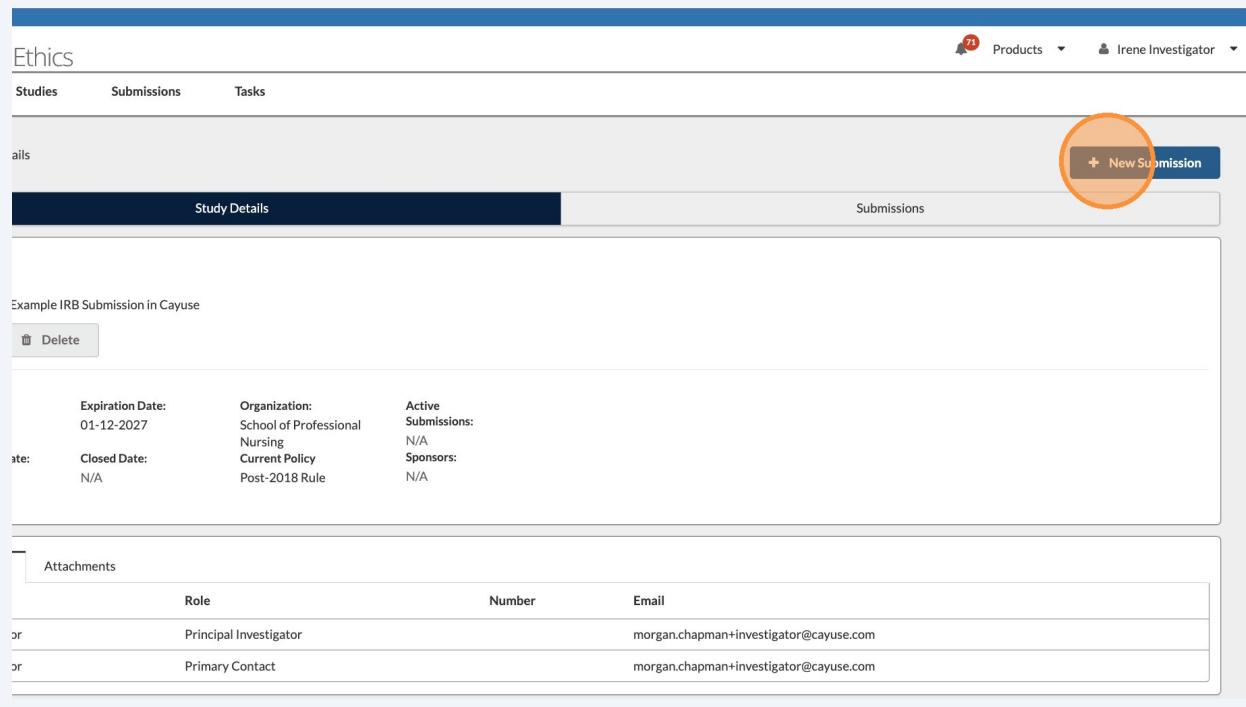
Studies Expiring in 30 days:

Studies Expiring in 30 days ▾

No Expiring Studies

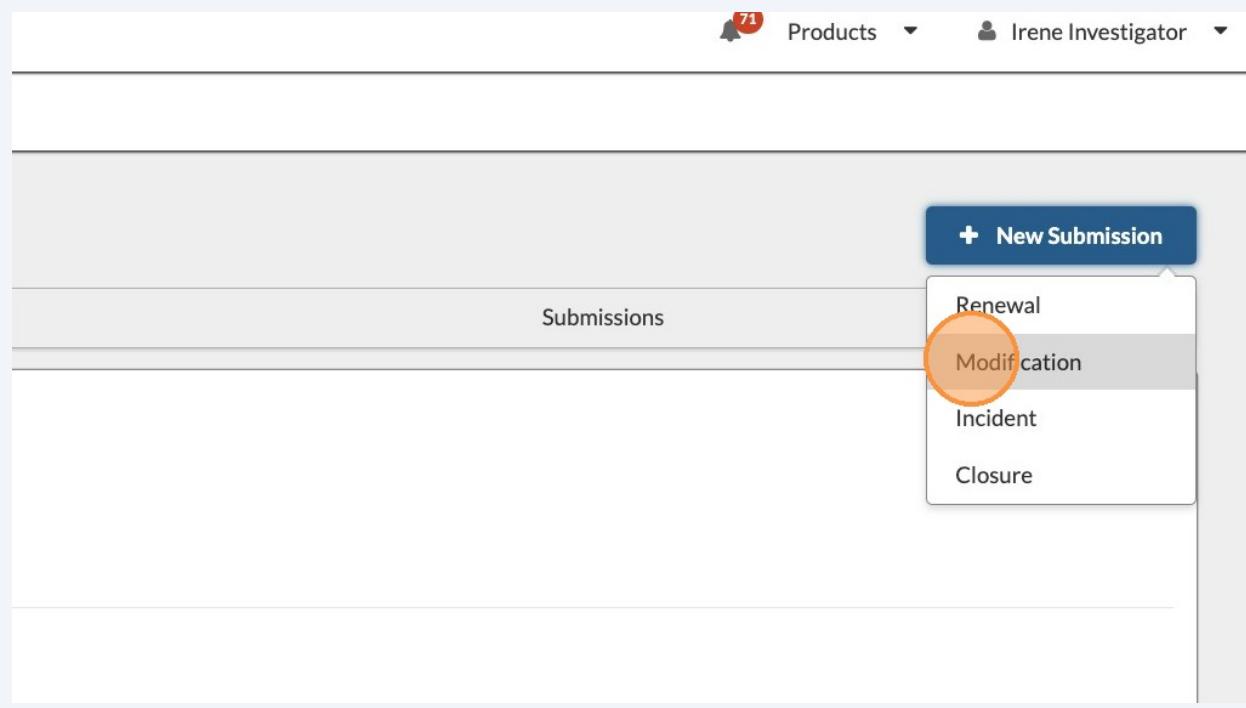
Expiring:

2 Click "New Submission"



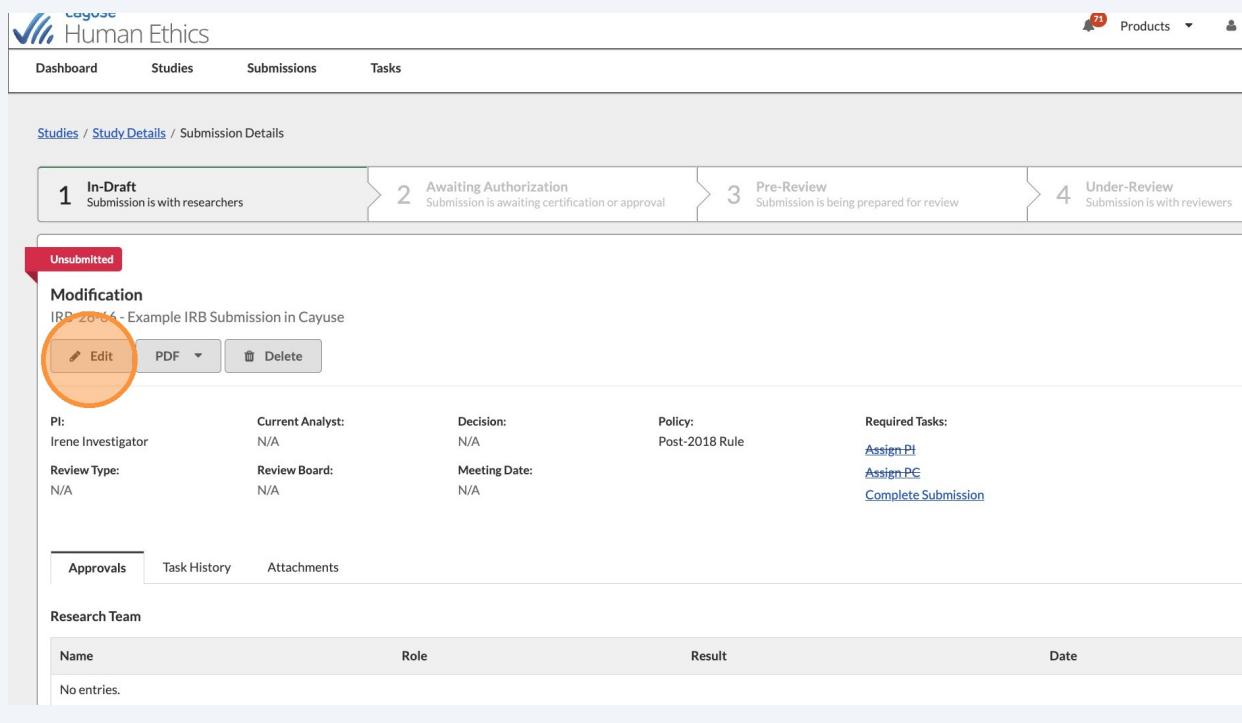
The screenshot shows the Cayuse Ethics interface. At the top, there is a navigation bar with 'Products' (71 notifications) and 'Irene Investigator'. Below the navigation bar, there are tabs for 'Studies', 'Submissions', and 'Tasks'. The 'Submissions' tab is selected. A sub-menu for 'Submissions' is open, showing options: 'New Submission' (highlighted with an orange circle), 'Renewal', 'Modification' (highlighted with an orange circle), 'Incident', and 'Closure'. The main content area shows a study detail card for an example IRB submission. The card includes fields for 'Expiration Date' (01-12-2027), 'Organization' (School of Professional Nursing), 'Active Submissions' (N/A), 'Closed Date' (N/A), 'Current Policy' (Post-2018 Rule), and 'Sponsors' (N/A). Below the card, there is a table for 'Attachments' with two rows: 'Principal Investigator' (Email: morgan.chapman+investigator@cayuse.com) and 'Primary Contact' (Email: morgan.chapman+investigator@cayuse.com).

3 Click "Modification"



The screenshot shows the Cayuse Ethics interface. At the top, there is a navigation bar with 'Products' (71 notifications) and 'Irene Investigator'. Below the navigation bar, there are tabs for 'Studies', 'Submissions', and 'Tasks'. The 'Submissions' tab is selected. A sub-menu for 'Submissions' is open, showing options: 'New Submission' (highlighted with an orange circle), 'Renewal', 'Modification' (highlighted with an orange circle), 'Incident', and 'Closure'. The main content area shows a study detail card for an example IRB submission. The card includes fields for 'Expiration Date' (01-12-2027), 'Organization' (School of Professional Nursing), 'Active Submissions' (N/A), 'Closed Date' (N/A), 'Current Policy' (Post-2018 Rule), and 'Sponsors' (N/A). Below the card, there is a table for 'Attachments' with two rows: 'Principal Investigator' (Email: morgan.chapman+investigator@cayuse.com) and 'Primary Contact' (Email: morgan.chapman+investigator@cayuse.com).

4 Click "Edit"

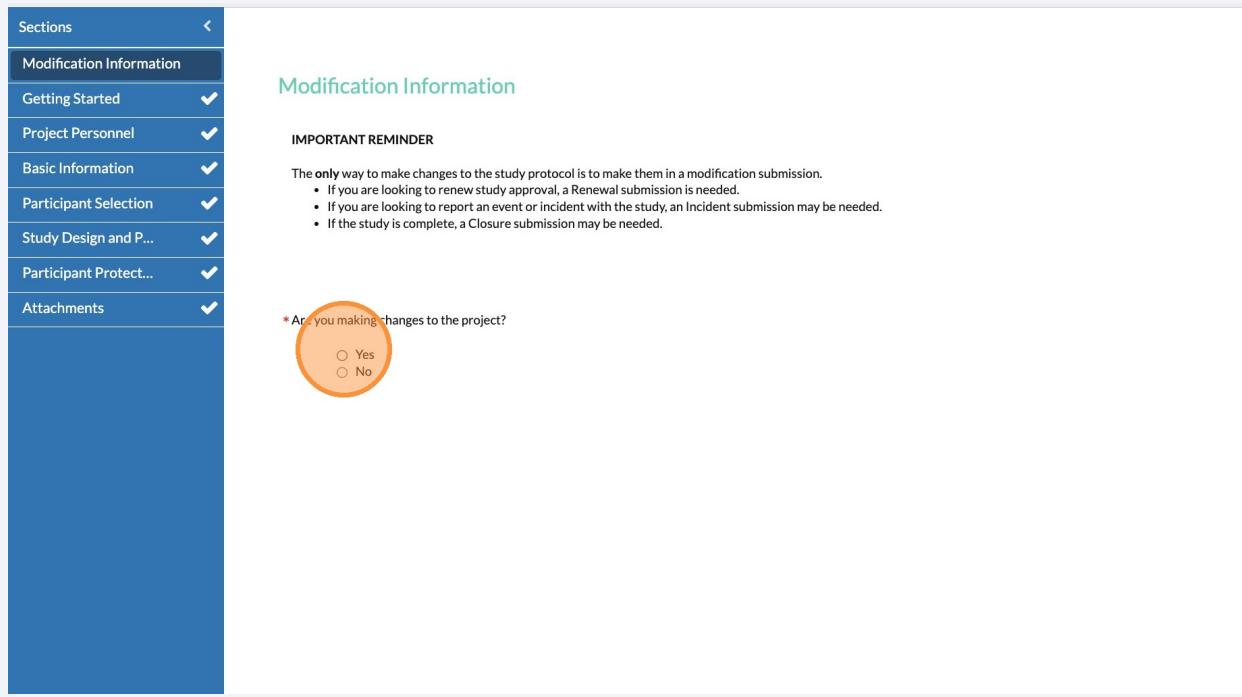


The screenshot shows the Cayuse Human Ethics interface. At the top, there are navigation links: Dashboard, Studies, Submissions, and Tasks. The 'Studies' link is underlined, indicating the current page. Below the navigation, a breadcrumb trail shows: Studies / Study Details / Submission Details. A horizontal bar at the top indicates the status of the submission: 1 In-Draft (Submission is with researchers), 2 Awaiting Authorization (Submission is awaiting certification or approval), 3 Pre-Review (Submission is being prepared for review), and 4 Under-Review (Submission is with reviewers). The main content area is titled 'Modification' and shows a study titled 'IRB 20-36 - Example IRB Submission in Cayuse'. Below the title are buttons for 'Edit' (which is circled in orange), 'PDF', and 'Delete'. The study details table includes fields for PI (Irene Investigator), Current Analyst (N/A), Decision (N/A), Policy (Post-2018 Rule), and Required Tasks (Assign PI, Assign PC, Complete Submission). Below the table are tabs for 'Approvals', 'Task History', and 'Attachments'. The 'Approvals' tab is selected. At the bottom, there is a section titled 'Research Team' with a table that currently has no entries.

5 This is the first page you will land on. At the top of the page, you'll notice some important reminders.

Read the reminders carefully.

Click the "Yes" field if you would like to make changes to your pre-existing project.



The screenshot shows the 'Modification Information' page. On the left, a sidebar titled 'Sections' lists several sections with dropdown arrows: Modification Information (which is expanded), Getting Started, Project Personnel, Basic Information, Participant Selection, Study Design and P..., Participant Protect..., and Attachments. The main content area is titled 'Modification Information' and contains a section titled 'IMPORTANT REMINDER'. It states: 'The only way to make changes to the study protocol is to make them in a modification submission.' followed by a bulleted list: '• If you are looking to renew study approval, a Renewal submission is needed.' '• If you are looking to report an event or incident with the study, an Incident submission may be needed.' '• If the study is complete, a Closure submission may be needed.' Below this is a question: 'Are you making changes to the project?' with two radio button options: 'Yes' and 'No'. The 'Yes' option is circled in orange.

6 When you click "yes", a section labeled "**List and Provide Justification**" will appear.

Please list all changes to your current project and the reasons for the modifications in the text box provided.

Study Design and P ...

Participant Protect... ✓

Attachments ✓

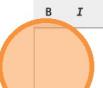
* Are you making changes to the project?

Yes
Please make your changes in the sections to the left.

No

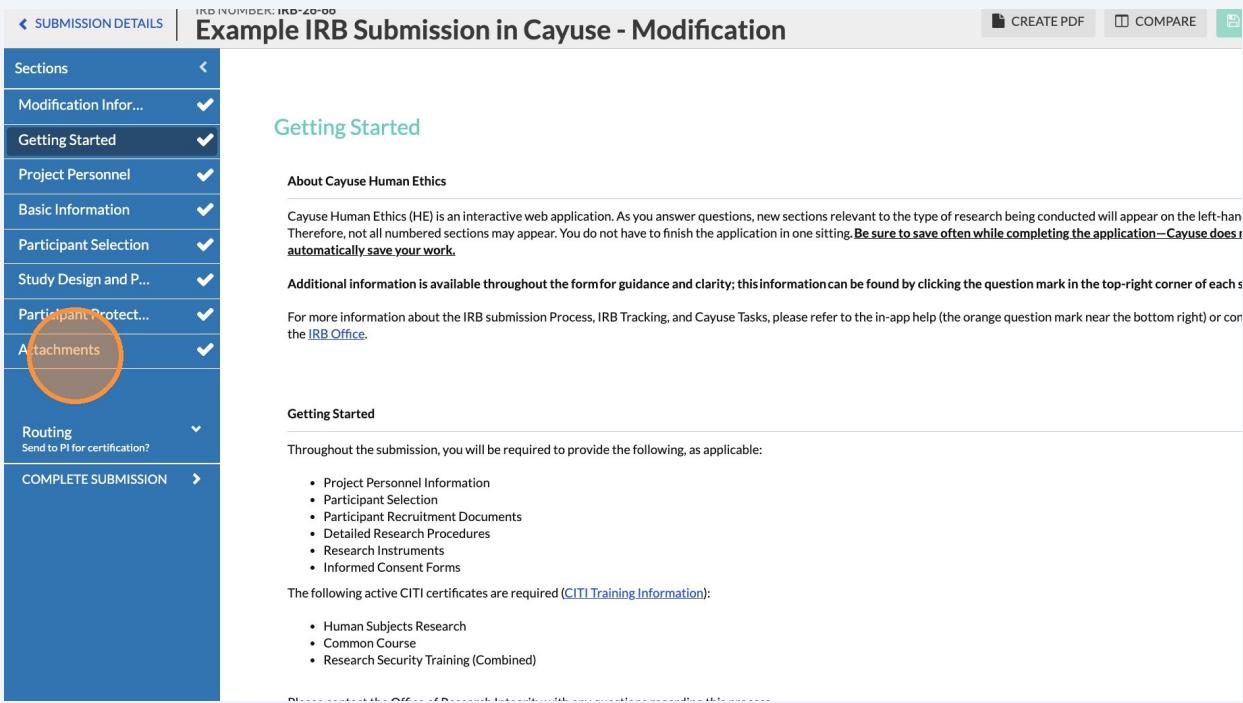
List and Provide Justification

Please list all modifications and provide the reasons for these modifications.



7 Next, select the "**Attachments**" tab.

You will need to attach any **NEW** materials here.



Example IRB Submission in Cayuse - Modification

CREATE PDF | COMPARISON

Sections

Modification Info... ✓

Getting Started ✓

Project Personnel ✓

Basic Information ✓

Participant Selection ✓

Study Design and P... ✓

Participant Protect... ✓

Attachments ✓

Routing

Send to PI for certification?

COMPLETE SUBMISSION

Getting Started

About Cayuse Human Ethics

Cayuse Human Ethics (HE) is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore, not all numbered sections may appear. You do not have to finish the application in one sitting. Be sure to save often while completing the application—Cayuse does not automatically save your work.

Additional information is available throughout the form for guidance and clarity; this information can be found by clicking the question mark in the top-right corner of each section.

For more information about the IRB submission Process, IRB Tracking, and Cayuse Tasks, please refer to the in-app help (the orange question mark near the bottom right) or contact the [IRB Office](#).

Getting Started

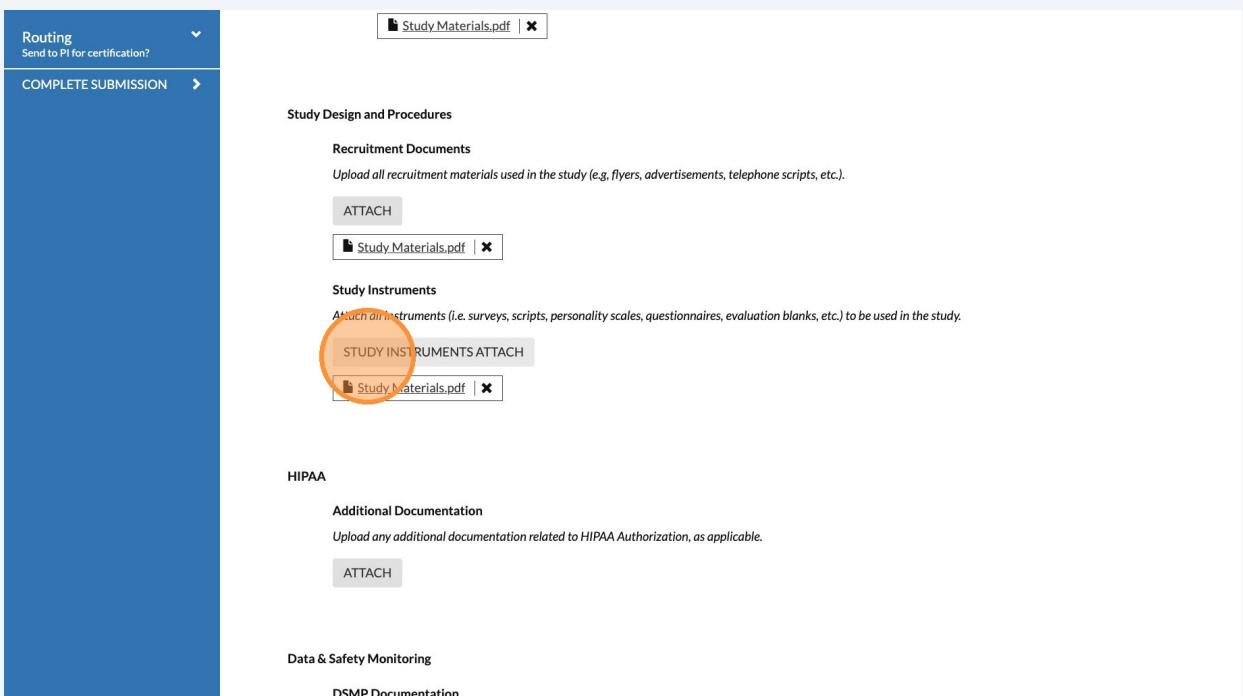
Throughout the submission, you will be required to provide the following, as applicable:

- Project Personnel Information
- Participant Selection
- Participant Recruitment Documents
- Detailed Research Procedures
- Research Instruments
- Informed Consent Forms

The following active CITI certificates are required ([CITI Training Information](#)):

- Human Subjects Research
- Common Course
- Research Security Training (Combined)

8 To attach new materials, click "**Study Instruments Attach**".



Routing

Send to PI for certification?

COMPLETE SUBMISSION

Study Materials.pdf | x

Study Design and Procedures

Recruitment Documents

Upload all recruitment materials used in the study (e.g. flyers, advertisements, telephone scripts, etc.).

ATTACH

Study Materials.pdf | x

Study Instruments

Attach all instruments (i.e. surveys, scripts, personality scales, questionnaires, evaluation blanks, etc.) to be used in the study.

STUDY INSTRUMENTS ATTACH

Study Materials.pdf | x

HIPAA

Additional Documentation

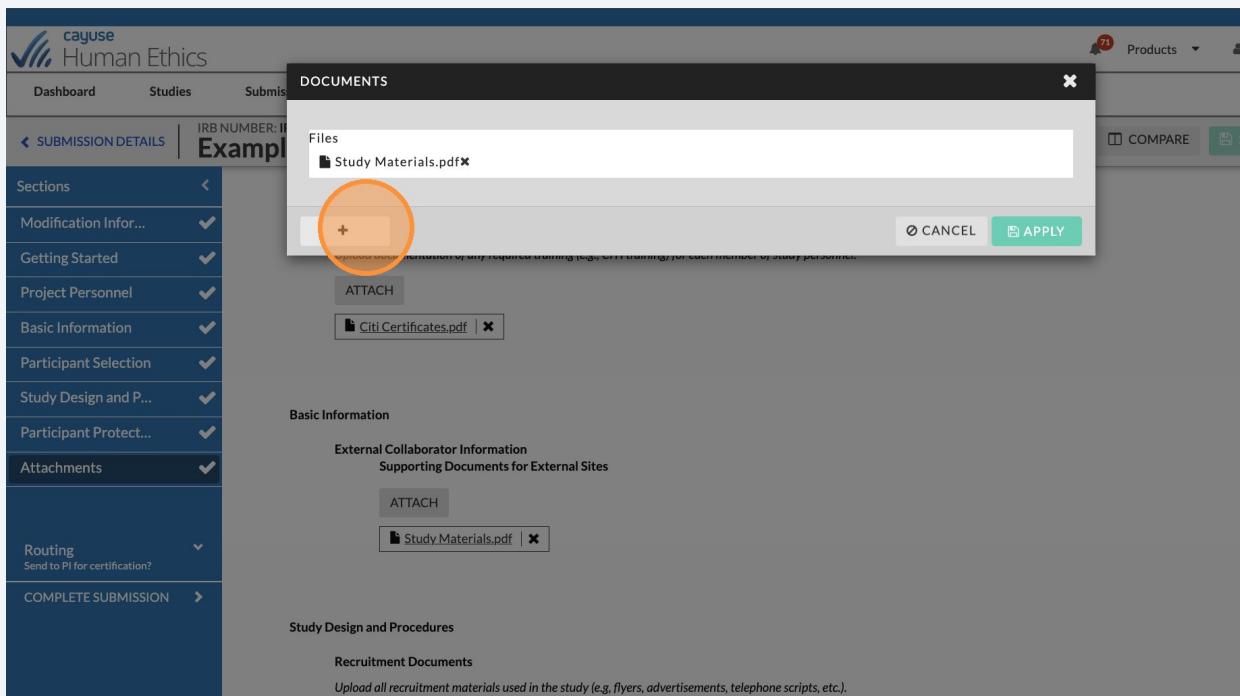
Upload any additional documentation related to HIPAA Authorization, as applicable.

ATTACH

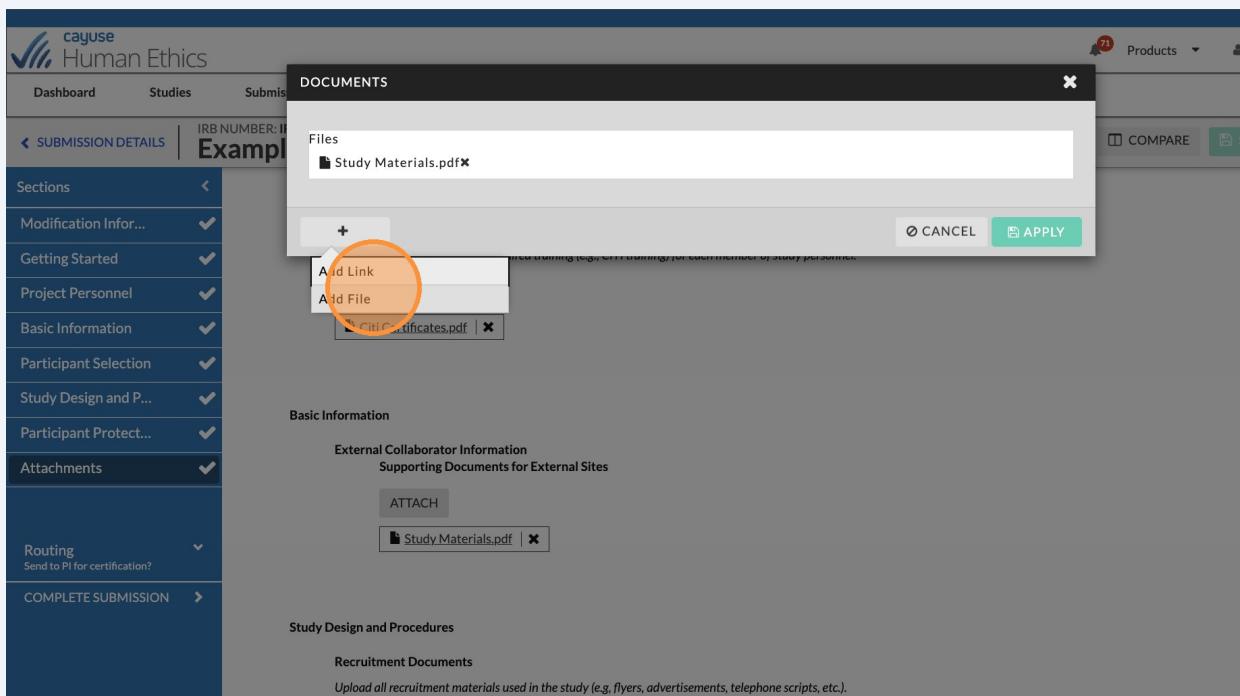
Data & Safety Monitoring

DSMP Documentation

9 Click "+"

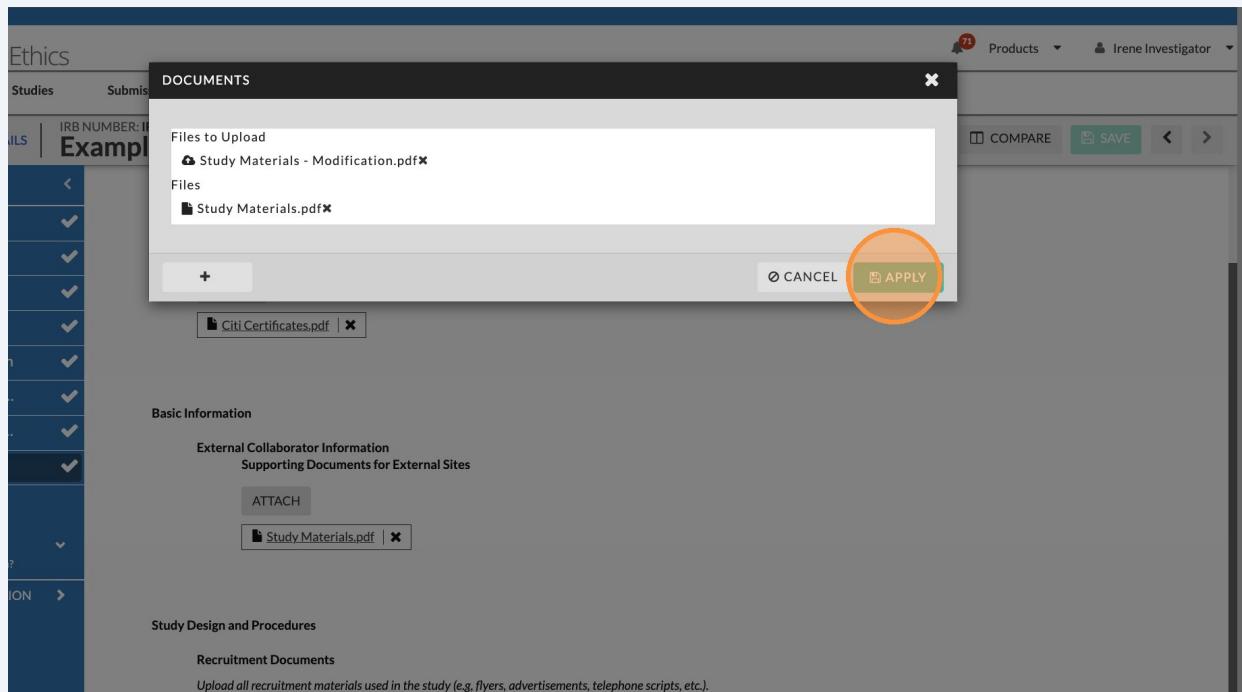


10 Click "Add File"



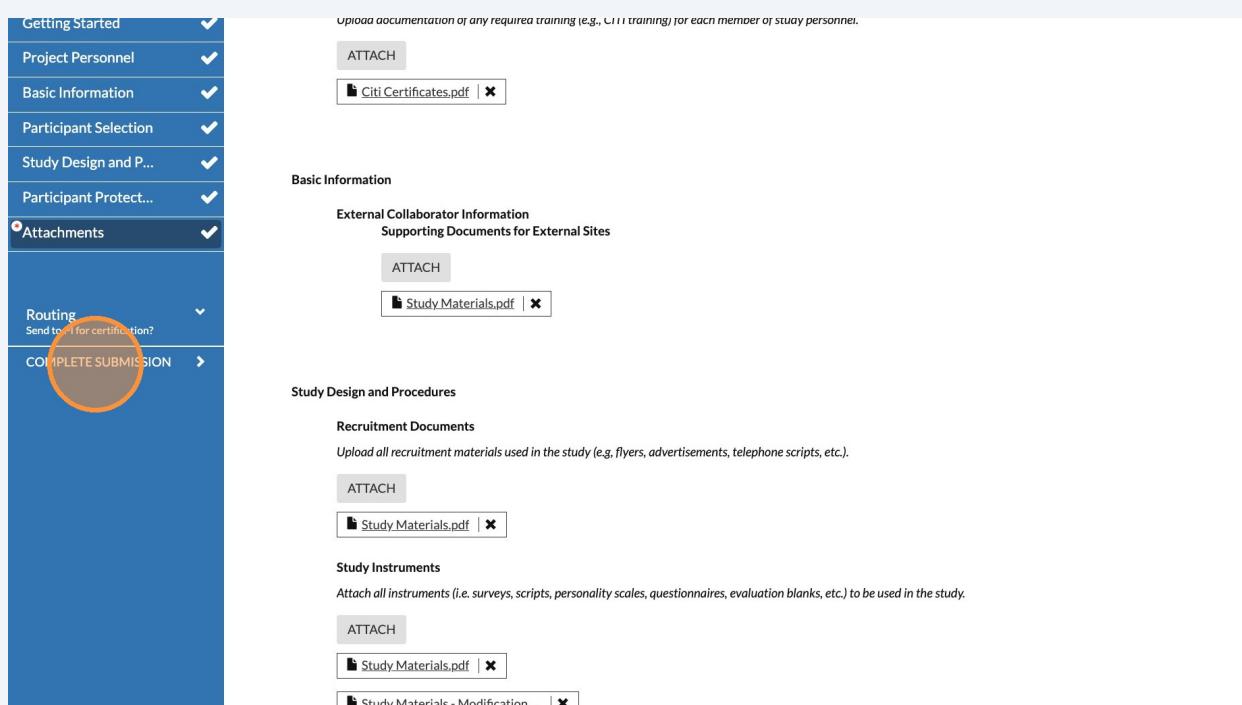
11 Select your desired file and then click "**Apply**".

You should see your new file appear on the attachments page.



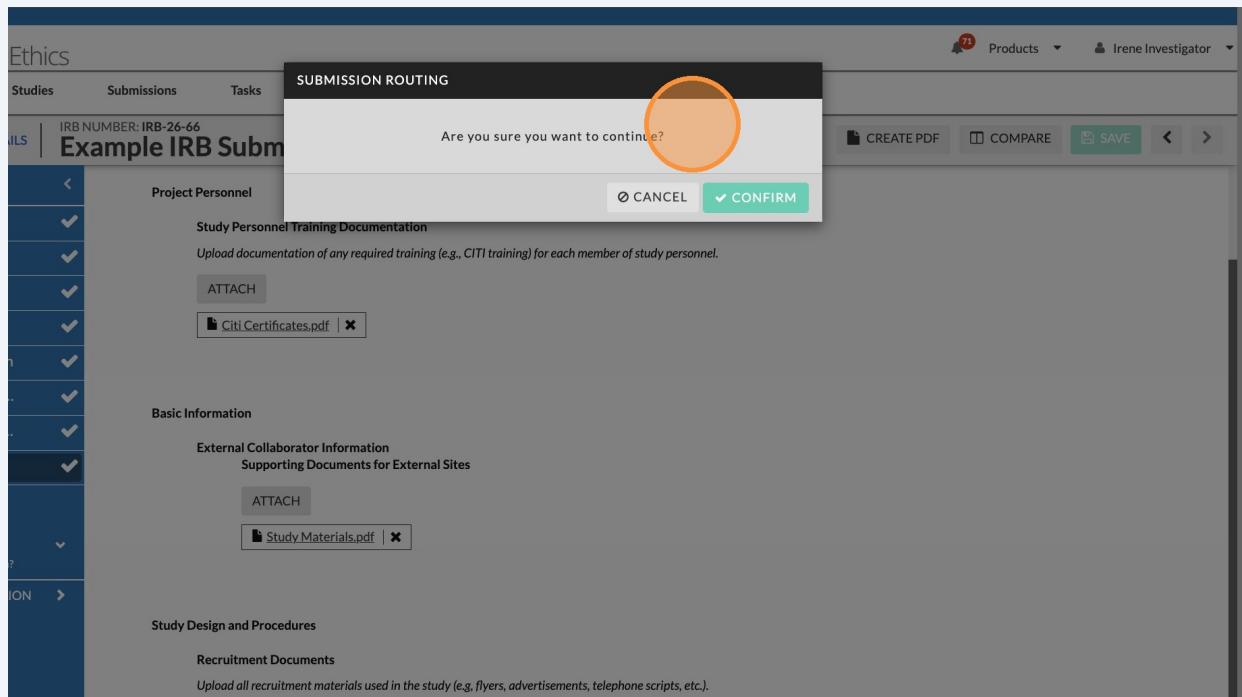
12 When all necessary information is complete and you are ready to submit your proposal, toggle to the bottom left of your screen to find the "**Complete Submission**" tab.

Click "**Complete Submission**"



13 You will be prompted with this message.

Select "**Confirm**".



14 Next, this page will appear.

Click "Certify"

Ethics

Studies Submissions Tasks

alls / Submission Details

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

Simple IRB Submission in Cayuse

PDF Delete

Current Analyst: N/A Decision: N/A Policy: Post-2018 Rule Required Tasks: N/A

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

Task History Attachments

Role	Result	Date
Principal Investigator	Pending Certification	

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

15 If this message is accurate, click "Confirm"

N/A

Certify