

Simmons University Institutional Review Board

Cayuse Human Ethics User Manual



Revised 8/23/2021

Simmons
UNIVERSITY

Table of Contents

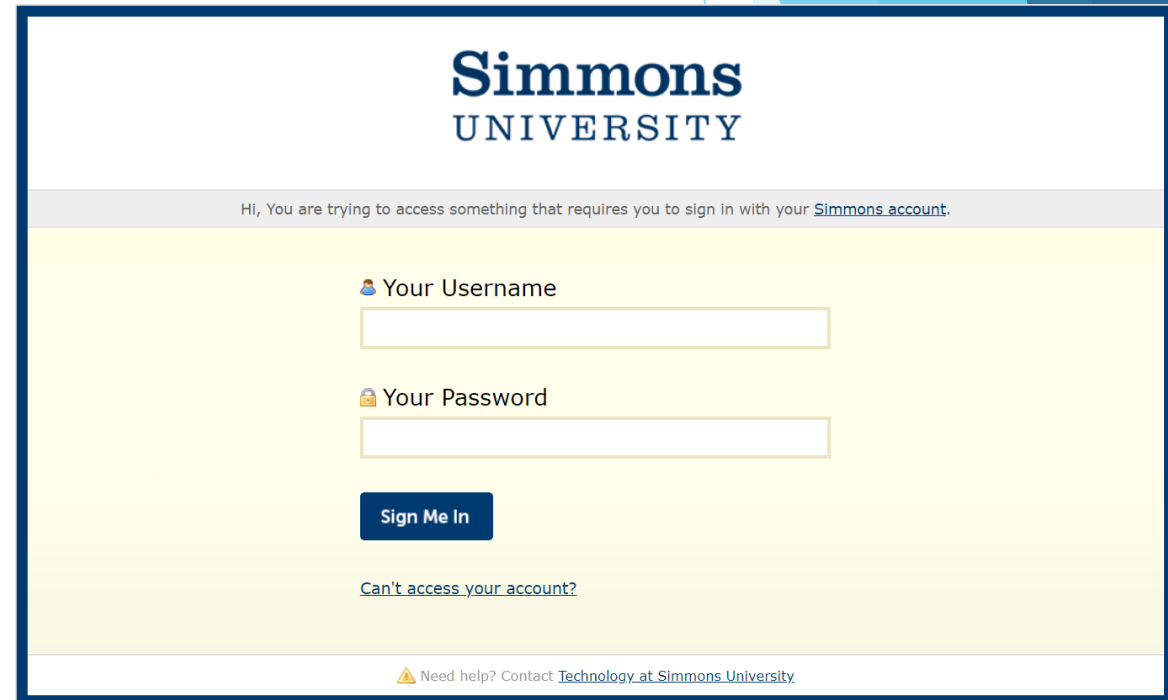
- ▶ What is Cayuse Human Ethics - pg. 3
- ▶ Logging In - pg. 4
- ▶ Creating a new protocol - pg. 5 - 13
- ▶ Checking the status of your protocol - pg. 14
- ▶ Making changes to a submitted protocol - pg. 15
- ▶ Responding to comments and making edits - pg. 16
- ▶ Comparing revisions - pg. 17
- ▶ Creating new submissions - pg. 18
 - ▶ Renewals, Modifications, Incident Reports, Closure
- ▶ Creating and submitting a modification - pg. 19 - 20
- ▶ Review of a modification - pg. 21
- ▶ Modification approval - pg. 22
- ▶ Submitting an incident report - pg. 23
- ▶ Submitting a renewal - pg. 24
- ▶ Submitting a closure - pg. 25
- ▶ Where to find your documents/attachments - pg. 26
- ▶ Still have questions? - pg. 27

What is Cayuse Human Ethics?

- ▶ Cayuse Human Ethics is an interactive web application for the submission and management of Human Subjects Research Projects, Performance Improvement Projects, and Classroom Projects
- ▶ Cayuse allows researchers to create, submit, edit, and amend IRB protocols in a single database while interacting with faculty advisors, co-investigators, IRB administrators, and reviewers

Logging In

- ▶ Only Simmons students, faculty, and staff will be given access to Cayuse Human Ethics
- ▶ When you enter [Cayuse](#) you should see the Simmons single sign on screen and enter your Simmons Username and Password
- ▶ If you are unable to access Cayuse you should fill out the Cayuse Account Request form, available on the simmons.edu/irb webpage



The screenshot shows the Simmons University login interface. At the top, the Simmons University logo is displayed. Below the logo, a message reads: "Hi, You are trying to access something that requires you to sign in with your [Simmons account](#)." The main form area has a light yellow background and contains two input fields: "Your Username" and "Your Password". Below these fields is a dark blue "Sign Me In" button. At the bottom of the form area, there is a link: "[Can't access your account?](#)". At the very bottom of the page, there is a footer with a warning icon and the text: "Need help? Contact [Technology at Simmons University](#)".

Creating a new protocol in Cayuse Human Ethics

- ▶ In Cayuse, you will first create a new “study”
- ▶ Under your “study” there will be “submissions” related to your study
- ▶ Your “initial submission” is your protocol
- ▶ Other submissions include modifications, incident reports, renewals, withdrawals, and closures

Creating a new protocol in Cayuse Human Ethics, step 1

The screenshot shows the Cayuse Human Ethics dashboard for a user with the role of Researcher. The dashboard includes a navigation menu with options like Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The main content area features four summary cards: In-Draft (0), Awaiting Authorization (0), Pre-Review (0), and Under Review (0). A red arrow points to a '+ New Study' button in the top right corner, with a callout box stating 'On your dashboard, select "New Study"'. Below the summary cards are three sections: 'My Studies' (listing 'IRB-FY2022-5 My First Study'), 'My Tasks' (showing 'All Tasks Complete'), and 'Submissions by Type' (a table with counts for Renewal, Initial, Modification, Incident, and Withdrawal).

Role: Researcher | **Products:** | **Kelly Gamache**

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

Summary Cards:

- In-Draft: 0
- Awaiting Authorization: 0
- Pre-Review: 0
- Under Review: 0

Buttons: + New Study

Callout: On your dashboard, select "New Study"

My Studies:

Study ID	Study Name
IRB-FY2022-5	My First Study

My Tasks:

✓ All Tasks Complete

Submissions by Type:

Renewal	1
Initial	1
Modification	0
Incident	
Withdrawal	

Creating a new protocol in Cayuse Human Ethics, step 2

cayuse
Human Ethics

Role: Researcher | Products | Kelly Gamache

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

Studies / Study Details

+ New Submission

Study Details | Submissions

Sample Study 1

Enter your study title, and then select the blue check mark.

PDF | Delete

Approval Date:	Expiration Date:	Organization:	Active Submissions:	Population Flags:	Additional Flags:
N/A	N/A	N/A			
Admin Check-In Date:	Closed Date:	Current Policy	Sponsors:		
N/A	N/A		N/A		

?

Creating a new protocol in Cayuse Human Ethics, step 3

The screenshot displays the Cayuse Human Ethics web application interface. At the top, the logo 'cayuse Human Ethics' is visible on the left, and user information 'Role: Researcher', a notification bell, 'Products', and 'Kelly Gamache' are on the right. A navigation menu includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', and 'Reports'. The main content area shows 'Study Details' for 'IRB-21-14 Sample Study 1' under an 'Unsubmitted' status. A modal dialog box titled 'Begin Initial Submission' is overlaid, containing the text: 'You've created a study! Click here to begin your initial submission to the IRB.' A blue button labeled '+ New Submission' is positioned to the right of the dialog. A red arrow points from the text 'Select "New Submission" and then "Initial"' to the '+ New Submission' button. A red question mark icon is located in the bottom right corner of the interface.

Begin Initial Submission

You've created a study! Click here to begin your initial submission to the IRB.

+ New Submission

Select "New Submission" and then "Initial"

Unsubmitted

IRB-21-14 Sample Study 1

PDF Delete

Approval Date:	Expiration Date:	Organization:	Active Submissions:	Population Flags:	Additional Flags:
N/A	N/A		N/A		
Admin Check-In Date:	Closed Date:	Current Policy	Sponsors:		
N/A	N/A	Post-2018 Rule	N/A		

Creating a new protocol in Cayuse Human Ethics, step 4

The screenshot displays the Cayuse Human Ethics interface. At the top, the logo and navigation menu are visible. The user is logged in as Kelly Gamache, a Researcher. The main navigation bar includes Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The current page is 'Submission Details' for 'StudyDetails'.

The workflow progress bar shows four stages: 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 'In-Draft' stage is currently active.

Below the workflow, a red banner indicates 'Unsubmitted' and instructs the user to 'Select "Edit"'. The submission details for 'IRB-21-14 - Sample Study 1' are shown, including an 'Edit' button, a 'PDF' dropdown, and a 'Delete' button. A red arrow points to the 'Edit' button.

The submission details are organized into a grid:

PI:	Current Analyst: N/A	Decision: N/A	Policy: Post-2018 Rule	Required Tasks: Assign PI Assign PC Complete Submission
Review Type: N/A	Review Board: N/A	Meeting Date: N/A		

A red arrow points to the 'Assign PC' link in the 'Required Tasks' section. A red text box states 'Any remaining tasks will appear here'. A help icon (question mark) is located in the bottom right corner.

Creating a new protocol in Cayuse Human Ethics, step 5 - Complete all sections

- ▶ Be sure that you have satisfied all the CITI training requirements prior to beginning your submission
- ▶ Complete all required sections as applicable to your study
- ▶ Attachments can be any format however, PDF is required for consent forms

The screenshot displays the Cayuse Human Ethics web application interface. At the top, the logo for Cayuse Human Ethics is visible, along with the user's role (Researcher) and name (Kelly Gamache). The navigation menu includes Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The current page is titled 'SUBMISSION DETAILS' for 'Sample Study 1 - Initial' (IRB NUMBER: IRB-21-14). A sidebar on the left lists the sections: Section 1 Getting started, Section 2 Investigator Inf..., Section 3 Project Informa..., and Section 5. The main content area features a red warning message: 'Complete all required sections and submit all study materials.' Below this, the 'Section 1 Getting started' heading is followed by an 'About Cayuse IRB' section, which explains that the application is interactive and that additional information is provided throughout the form. A footer note advises users to read the IRB Manual and complete CITI Training before starting the application.

Complete all required sections and submit all study materials.

Section 1 Getting started

About Cayuse IRB
Cayuse IRB 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. All information can be saved.

Additional information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark in the top-right corner of each section.

Prior to starting your IRB application, please be sure you have read the [IRB Manual: Instructions to Investigators](#) and completed [CITI Training](#).

Creating a new protocol in Cayuse Human Ethics, step 6 - Complete Submission

The screenshot shows the Cayuse Human Ethics interface. At the top, the logo and navigation tabs (Dashboard, Studies, Submissions) are visible. The user's role is 'Researcher' and the name is 'Kelly Gamache'. A modal dialog box titled 'SUBMISSION ROUTING' is centered on the screen, asking 'Are you sure you want to continue?' with 'CANCEL' and 'CONFIRM' buttons. The background shows 'Section 5' of a submission, with a list of sections on the left, all marked as completed. A red arrow points from the 'CONFIRM' button to a text box that says 'Select "Confirm" if you are ready to submit your study submission'. Another red arrow points from a text box that says 'When you have completed all the required sections, select "Complete Submission"' to the 'COMPLETE SUBMISSION' button in the left sidebar.

SUBMISSION ROUTING

Are you sure you want to continue?

Section 5

Thank you for completing your protocol. Once you submit your protocol for review, please allow 5 business days for review.

If you have any questions please contact irbprotocols@simmons.edu.

When you have completed all the required sections, select "Complete Submission"

Select "Confirm" if you are ready to submit your study submission

Routing
Send to PI for certification?

COMPLETE SUBMISSION

Creating a new protocol in Cayuse Human Ethics, step 7 - Certify


- ▶ Submissions that have not been “Certified” will not be reviewed
- ▶ All members of the research team as well as faculty advisors must certify the submission
- ▶ The certification acts as your signature

The screenshot displays the Cayuse Human Ethics interface. At the top, the user is logged in as Kelly Gamache, a Researcher. The navigation menu includes Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The current view is 'Submission Details' for 'IRB-21-14 - Sample Study 1'. A progress bar shows three stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Authorization (Submission is awaiting certification or approval), and 3. Awaiting Certification (Submission is with reviewers). A red text box highlights that the Primary Investigator, Co-Investigator(s), and Faculty Advisors will be required to "Certify" the submission once it has been submitted. A red arrow points to the 'Certify' button in the 'Routing:' section. Below the progress bar, there are buttons for 'View', 'PDF', and 'Delete'. At the bottom, a table lists submission details:

PI:	Current Analyst:	Decision:	Policy:	Required Tasks:
Kelly Gamache	N/A	N/A	Post-2018 Rule	N/A
Review Type:	Review Board:	Meeting Date:		
N/A	N/A	N/A		

Creating a new protocol in Cayuse Human Ethics, step 8 - Certify

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.

After reading the certification agreement, select "Confirm"

Role: Researcher | Products | Kelly Gamache

Dashboard | Studies | Study Detail

In-Draft Submission

Awaiting Certification

Initial IRB-21-14 - Samp

View

PI: Kelly Gamache

Review Type: N/A

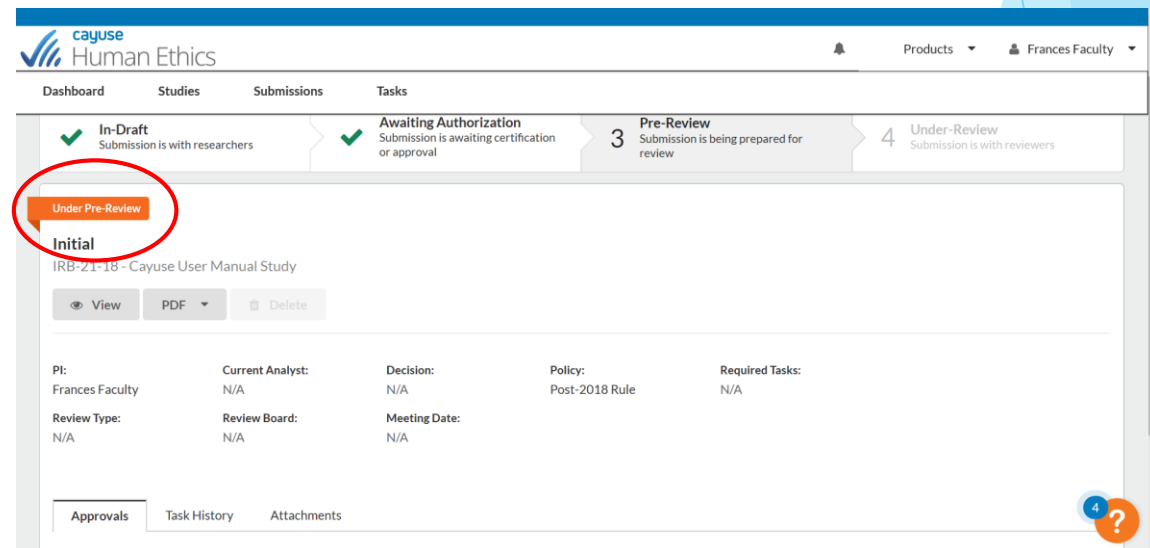
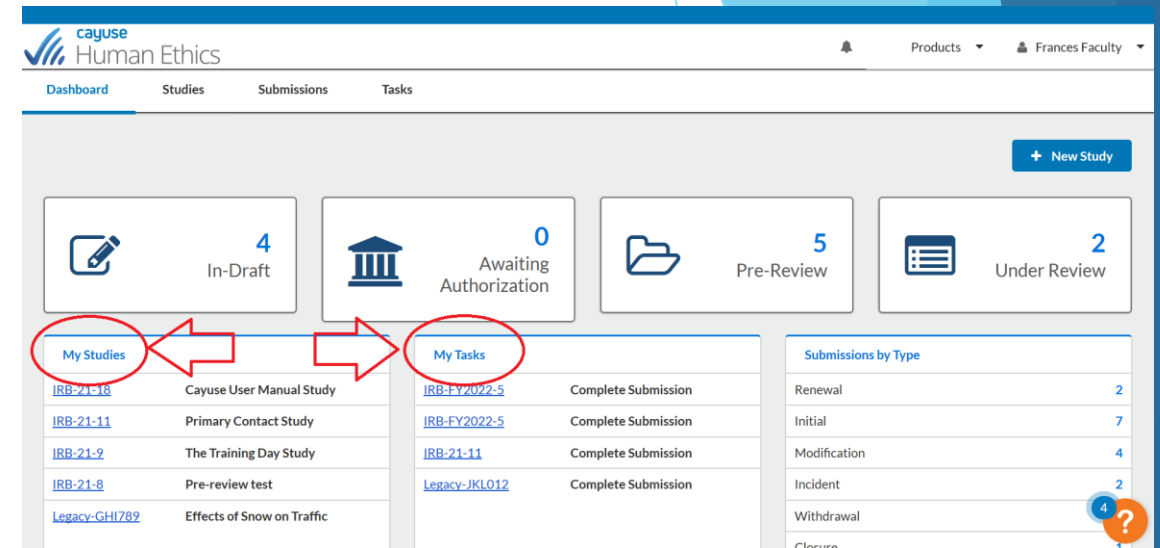
Review Board: N/A

Meeting Date: N/A

?

Checking the status of your protocol

- ▶ On your dashboard you will see “My Studies” and “My Tasks”
- ▶ Selecting a study from “My Studies” will bring you to the Study Details page, where you can select “Submissions” and see the status of a particular submission
 - ▶ The study pictured here has an Initial Submission that is under pre-review, meaning it is with the IRB administrator and not yet with a reviewer
- ▶ If the status of a submission is depending on you, the researcher, you will see what is required of you under “My Tasks”
 - ▶ Tasks may include completing or certifying a submission



Making changes to a submitted protocol

- ▶ The reviewer or the IRB administrator may ask you to make changes to your protocol after it has been submitted
- ▶ When this happens, the submission will be labeled “reopened”
- ▶ The reviewer may include their requested edits under “research notes” in an email and/or add comments throughout your initial submission
- ▶ The submission will be returned to you, as indicated in the email, and you will see the study listed under “My Tasks” on your dashboard
- ▶ When you enter the Initial Submission, you will be able to see where comments were made

The image displays two screenshots of the Cayuse Human Ethics system interface. The top screenshot shows the submission workflow with a 'Reopened' status highlighted. The bottom screenshot shows the 'Cayuse User Manual Study - Initial' submission details with a red circle around 'Section 4 Project Descript...' in the left-hand navigation menu.

Top Screenshot: Submission Workflow

- Navigation: Dashboard, Studies, Submissions, Tasks
- Progress: 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), 4 Under-Review (Submission is with reviewers)
- Status: Reopened (highlighted in a red circle)
- Submission: Initial (IRB-21-18 - Cayuse User Manual Study)
- Actions: Edit, PDF, Delete
- Metadata: PI: Frances Faculty, Current Analyst: Kelly Gamache, Decision: Return to PI, Policy: Post-2018 Rule, Required Tasks: Assign PI
- Review Type: Expedited

Bottom Screenshot: Submission Details

- Navigation: Dashboard, Studies, Submissions, Tasks
- Submission: Cayuse User Manual Study - Initial (IRB NUMBER: IRB-21-18)
- Actions: CREATE PDF, COMPARE, SAVE
- Sections (Left-hand side):
 - Section 1 Getting started ✓
 - Section 2 Investigat... ✓
 - Section 3 Project In... ✓
 - Section 4 Project Descript... 1 (highlighted in a red circle)
 - Section 5 ✓
- Routing: Send to PI for certification? ✓
- COMPLETE SUBMISSION >
- Content: Section 1 Getting started, About Cayuse IRB, Additional information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark in the top-right corner of each section.
- Footer: Prior to starting your IRB application, please be sure you have read the [IRB Manual: Instructions to Investigators](#) and completed [CITI Training](#).

Responding to comments and making edits

- ▶ The reviewer may add comments that request your feedback
- ▶ Click on the comment and select “reply” to respond to the comment
- ▶ You should then make any necessary changes to your protocol, save and complete the submission, and certify your changes to send the protocol back to the reviewer

1 Collapse Comments

IRB Reviewer Today at 9:23 AM
This doesn't seem right, please revise
[Reply](#)

Not Addressed ^

Address

Unaddress

2 Collapse Comments

IRB Reviewer Today at 9:23 AM
This doesn't seem right, please revise
[Reply](#)

B I U ↶ ↷ ☰ ☷ 🔗 🖼

I made the changes

SAVE CANCEL

Addressed v Today at 9:31 AM by you

Human Ethics Products Frances Faculty

Dashboard Studies Submissions Tasks

Studies Study Details Submission Details

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

4 **Under-Review**
Submission is with reviewers

Awaiting Certification

Initial
IRB-21-18 - Cayuse User Manual Study

View PDF Delete

Routing: Return **Certify**

PI: Frances Faculty	Current Analyst: Kelly Gamache	Decision: Return to PI	Policy: Post-2018 Rule	Required Tasks: N/A
Review Type: Expedited	Review Board: Simmons University IRB - Sample	Meeting Date: N/A		

4 ?

Comparing revisions

- ▶ There is no need to tell the reviewer exactly what changes you made
- ▶ The reviewer will be able to compare your first submission to the revised submission

The screenshot displays the Cayuse Human Ethics web application interface. At the top, the logo and name 'cayuse Human Ethics' are visible, along with the user's role 'Analyst' and name 'Kelly Gamache'. The navigation menu includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The main content area is titled 'Comparison: IRB-21-18 (Initial)'. Below this, there is a comparison table with two columns: 'PREVIOUS SUBMISSION' and 'CURRENT SUBMISSION'. The table has a sidebar on the left with a 'Sections' list and a 'PREVIOUS DIFF' / 'NEXT DIFF' navigation bar. The 'Sections' list includes 'Section 1 Getting st...', 'Section 2 Investigat...', 'Section 3 Project In...', 'Section 4 Project D...', and 'Section 5'. The 'PREVIOUS DIFF' / 'NEXT DIFF' bar shows 'PREVIOUS DIFF' and 'NEXT DIFF' with a '1' in a circle. The table content shows two rows of text, each with a red 'no' in the previous submission and a green 'revised.' in the current submission. A question mark icon is visible in the bottom right corner of the screenshot.

	PREVIOUS SUBMISSION	CURRENT SUBMISSION
Sections		← PREVIOUS DIFF NEXT DIFF → 1
Section 1 Getting st...	* 4.1 <i>General Description.</i> Briefly describe the overall goals of the proposed research and the general procedures you plan to use in conducting your research project.	* 4.1 <i>General Description.</i> Briefly describe the overall goals of the proposed research and the general procedures you plan to use in conducting your research project.
Section 2 Investigat...	no	revised.
Section 3 Project In...		
Section 4 Project D...	* 4.2 <i>Significance of the Study.</i> Provide a brief theoretical and empirical rationale for why you believe this study is important. Include a concise review of literature including conceptual framework, and specific hypotheses to be tested and/or research questions to be addressed.	* 4.2 <i>Significance of the Study.</i> Provide a brief theoretical and empirical rationale for why you believe this study is important. Include a concise review of literature including conceptual framework, and specific hypotheses to be tested and/or research questions to be addressed.
Section 5		

Creating new submissions

- ▶ Once an Initial Submission is approved, you will be able to create other submissions such as Renewal, Modification, Incident, and Closure
- ▶ These options are available under “New Submission” within Study Details

The screenshot displays the Cayuse Human Ethics web application. The top navigation bar includes the logo, user name 'Frances Faculty', and a 'Products' dropdown. Below this is a secondary navigation bar with 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area is titled 'Study Details' and shows an 'Approved' status for 'IRB-21-18 Cayuse User Manual Study'. A 'PDF' icon and a 'Delete' button are visible. A dropdown menu is open, showing options: 'New Submission', 'Renewal', 'Modification', 'Incident', and 'Closure'. The 'New Submission' option is circled in red. A small blue circle with the number '4' and an orange question mark icon is located in the bottom right corner of the interface.

Approval Date:	Expiration Date:	Organization:	Active Submissions:
06-16-2021	N/A	Simmons University	N/A
Admin Check-In Date:	Closed Date:	Current Policy:	Sponsors:
06-16-2022	N/A	Post-2018 Rule	N/A

Creating and submitting a modification

- ▶ Select “modification” under “New Submission” in Study Details and then select “Complete Submission”
- ▶ You will be brought to a submission template that contains your initial submission
- ▶ State that you would like to make changes and explain your justification for those changes
- ▶ You should then edit your protocol to reflect the changes you are making to your project
- ▶ Similar to making revisions to your initial submission, there is no need to tell the reviewer where you made changes, they will be able to compare the versions

The top screenshot shows the 'Unsubmitted' modification page for 'IRB-21-18 - Cayuse User Manual Study'. It includes a progress bar with four stages: 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). Below the progress bar, there are buttons for 'Edit', 'PDF', and 'Delete'. The page displays fields for 'PI: Frances Faculty', 'Current Analyst: N/A', 'Decision: N/A', 'Policy: Post-2018 Rule', and 'Review Type: N/A'. Under 'Required Tasks', there are links for 'Assign PI', 'Assign PC', and 'Complete Submission', with a red arrow pointing to the 'Complete Submission' link.

The bottom screenshot shows the 'SUBMISSION DETAILS' page for 'IRB NUMBER: IRB-21-18 Cayuse User Manual Study - Modification'. It features a sidebar with a list of sections: 'Sections', 'Modification', 'Section 1 Getting st...', 'Section 2 Investigat...', 'Section 3 Project In...', 'Section 4 Project D...', and 'Section 5'. The main content area is titled 'Modification' and contains an 'IMPORTANT REMINDER' section. The reminder states: 'Any changes to the study protocol must be included in a modification submission, including but not limited to:'. A bullet point lists: 'Any changes to the target subject population, including but not limited to age, race, disability status, and gender'. Below this, there is a question: '* Are you making changes to the project?' with radio button options for 'Yes' and 'No'.

Creating and submitting a modification

The screenshot shows the 'Cayuse User Manual Study - Modification' page. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The page title is 'Cayuse User Manual Study - Modification' with the IRB number 'IRB-21-18'. A left sidebar lists sections: 'Modification', 'Section 1 Getting st...', 'Section 2 Investigat...', 'Section 3 Project In...', 'Section 4 Project D...', and 'Section 5'. The main content area displays a text editor with the text 'I am changing my participant population|' and a red asterisk followed by the text: '* 4.3 Participant Population. Describe the characteristics of the participant population, highlighting any potential vulnerabilities in this research project. If your participant population includes vulnerable populations, please express rational for including these populations in your study.'

The screenshot shows the submission status and routing page. The top navigation bar is the same as the previous screenshot. The main content area features a progress bar with four stages: 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). Below the progress bar, a 'Routing' section is highlighted with a red circle, containing 'Return' and 'Certify' buttons. The 'Awaiting Certification' section shows the submission title 'Modification' and 'IRB-21-18 - Cayuse User Manual Study'. Below this, there are buttons for 'View', 'PDF', and 'Delete'. At the bottom, a table displays submission details:

PI:	Current Analyst:	Decision:	Policy:	Required Tasks:
Frances Faculty	N/A	N/A	Post-2018 Rule	N/A
Review Type:	Review Board:	Meeting Date:		
N/A	N/A	N/A		

▶ Always remember to Certify every submission once it is completed

Review of a modification

- ▶ The reviewer will be able to see a comparison to the original submission and the modified submission
- ▶ Just like an Initial Submission, the reviewer may send the modification back to you and ask for revisions or have comments and request your feedback

The screenshot displays the Cayuse Human Ethics interface. At the top, the logo and name 'cayuse Human Ethics' are visible, along with the user's role 'Admin', a notification bell with '11' alerts, and the user's name 'Kelly Gamache'. A navigation menu includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The main content area is titled 'Comparison: IRB-21-18 (Modification)'. Below this, there are two columns: 'PREVIOUS SUBMISSION' (Previously Approved Submission) and 'CURRENT SUBMISSION'. A 'Sections' sidebar on the left lists 'Modification' (3), 'Section 1 Getting st...' (0), 'Section 2 Investigat...' (0), 'Section 3 Project In...' (0), 'Section 4 Project D...' (1), and 'Section 5' (0). The 'PREVIOUS SUBMISSION' column shows a 'Yes' radio button selected, with the instruction 'Please make your changes in the sections to the left.' Below this is a 'Justification' section with the prompt 'Please provide the reasons for the modifications.' and an empty text box. The 'CURRENT SUBMISSION' column shows a 'Yes' radio button selected, with the same instruction. Below this is a 'Justification' section with the prompt 'Please provide the reasons for the modifications.' and a text box containing the word 'justification'. A blue circle with the number '2' and an orange circle with a question mark are overlaid on the bottom right of the current submission's justification box.

Modification Approval

- ▶ When your modification, as well with other types of submissions, is approved, you will see it listed as Approved under “submissions” in the Study Details
- ▶ You will also receive an email indicating your submission was approved

The screenshot displays the Cayuse Human Ethics web interface. At the top, the logo for Cayuse Human Ethics is visible, along with navigation links for Dashboard, Studies, Submissions, and Tasks. The user is logged in as Frances Faculty. The main content area shows the 'Study Details' page with a 'Submissions' tab selected. A table lists two submissions, both of which are 'Approved' and 'Review Complete'.

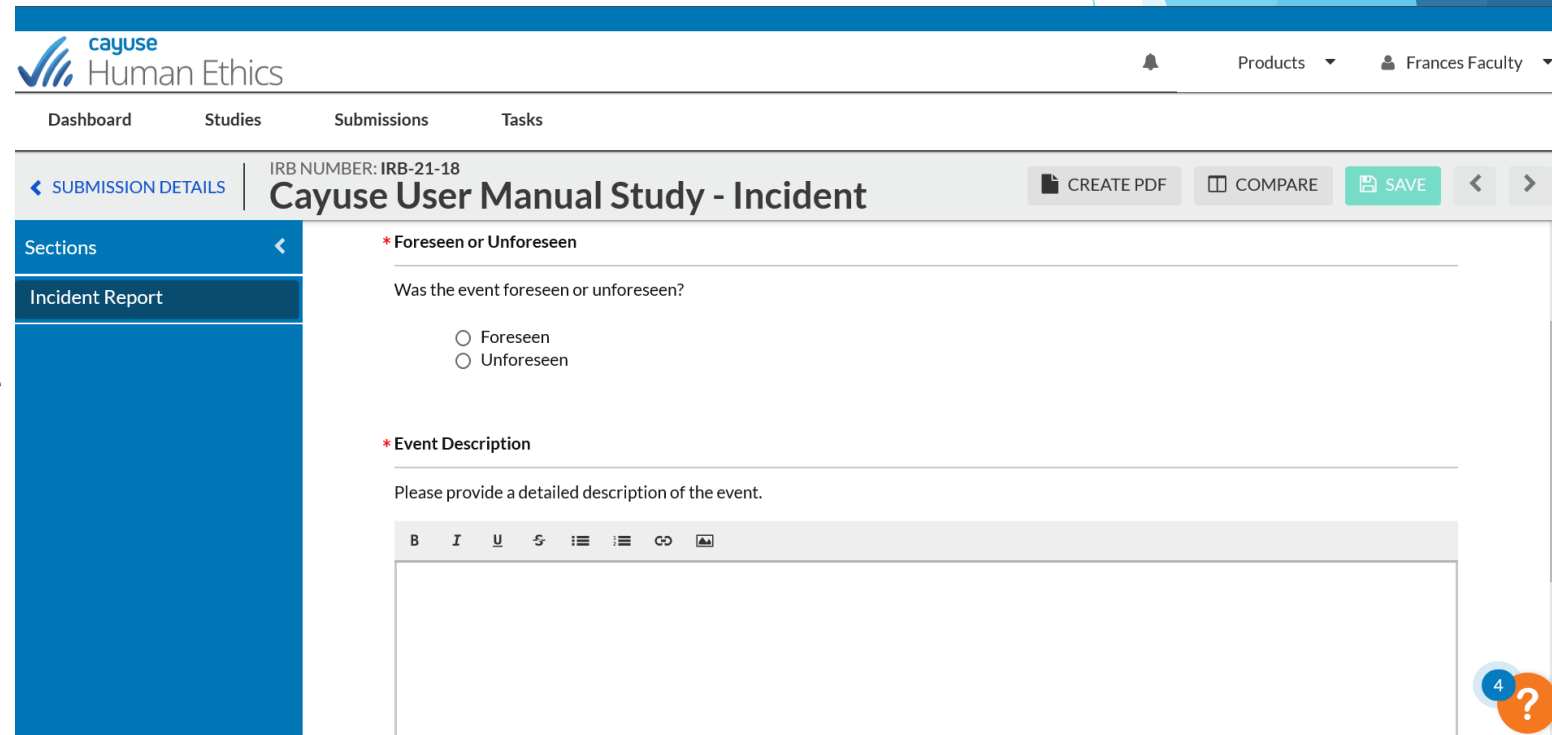
Submission Type	Review Type	Status	Decision
Initial	Expedited	● Review Complete	Approved 06-16-2021
Modification	Expedited	● Review Complete	Approved 06-16-2021

1-2 of 2

25 per page

Submitting an Incident Report

- ▶ Similar to submitting a modification, you will select “Incident” under “New Submission” in Study Details
- ▶ You will select “Complete Submission” under “Required Tasks” and complete the Incident Template
- ▶ As with other submissions, you will be asked to Certify the submission under “submission details”



The screenshot displays the Cayuse Human Ethics web application interface. At the top, the logo for Cayuse Human Ethics is visible, along with navigation links for Dashboard, Studies, Submissions, and Tasks. The user is logged in as Frances Faculty. The main content area shows the submission details for a study titled "Cayuse User Manual Study - Incident" with IRB number IRB-21-18. A sidebar on the left lists "Sections" and "Incident Report". The main form contains two sections: "Foreseen or Unforeseen" with radio buttons for "Foreseen" and "Unforeseen", and "Event Description" with a text area for a detailed description of the event. A toolbar with formatting options (B, I, U, S, L, G, A) is located above the text area. A help icon (question mark) is visible in the bottom right corner.

Submitting a Renewal

- ▶ You will select “Renewal” under “New Submission” in Study Details
- ▶ You will select “Complete Submission” under “Required Tasks” and complete the Renewal template
- ▶ As with other submissions, you will be asked to Certify the submission under “submission details”

The screenshot displays the Cayuse Human Ethics web interface. At the top, the logo for Cayuse Human Ethics is visible, along with a notification bell, a 'Products' dropdown menu, and the user's name 'Frances Faculty'. Below the header, a navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area shows the 'SUBMISSION DETAILS' for 'Cayuse User Manual Study - Renewal' with IRB NUMBER: IRB-21-18. A sidebar on the left lists 'Sections' with 'Request for More Time' selected. The main form area is titled 'Request for More Time' and contains two questions with radio button options:

*** Request for More Time**

Are you requesting more time for the project?

Yes
 No

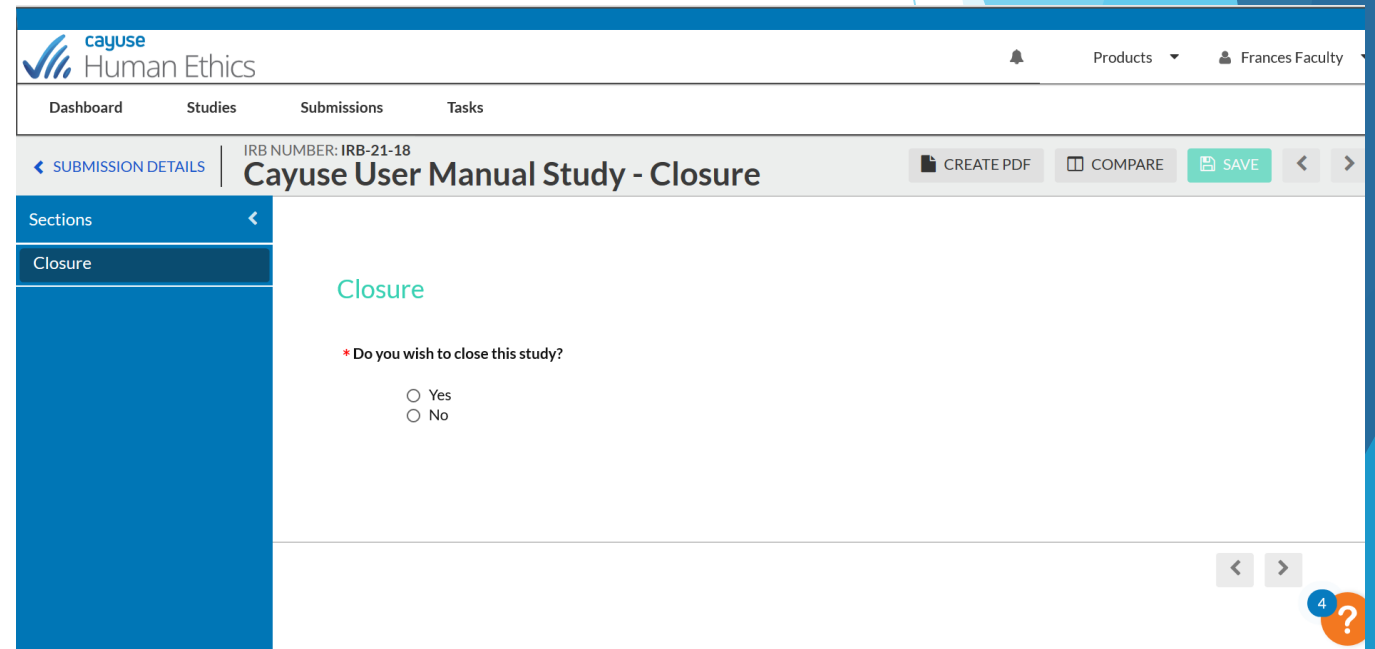
Is there anything that needs to change in the protocol since your last submission?

Yes
 No

In the bottom right corner, there is a blue circle with the number '4' and an orange circle with a white question mark.

Submitting a Closure

- ▶ You will select “Closure” under “New Submission” in Study Details
- ▶ You will select “Complete Submission” under “Required Tasks” and complete the Closure template
- ▶ As with other submissions, you will be asked to Certify the submission under “submission details”
- ▶ You will receive an email confirmation that your study has been closed



The screenshot displays the Cayuse Human Ethics web interface. At the top, the logo for Cayuse Human Ethics is visible, along with navigation links for Dashboard, Studies, Submissions, and Tasks. The user is logged in as Frances Faculty. The main content area shows the 'SUBMISSION DETAILS' for a study titled 'Cayuse User Manual Study - Closure' with IRB NUMBER: IRB-21-18. A sidebar on the left lists 'Sections' and 'Closure'. The main form area is titled 'Closure' and contains a question: '* Do you wish to close this study?' with two radio button options: 'Yes' and 'No'. The interface also includes utility buttons like 'CREATE PDF', 'COMPARE', and 'SAVE'.

Where to find your documents

- ▶ Attachments that have been added as part of any submission such as consent forms, study tools, survey instruments, etc. can be found in your submission details under “attachments”
- ▶ Here, you will be able to download these attachments
- ▶ Faculty Advisors and Co-Investigators will have access to these documents as well
- ▶ Approval letters will be emailed and can also be found in the submission details

The screenshot displays the Cayuse Human Ethics web application. The top navigation bar includes the Cayuse logo, the text 'Human Ethics', a notification bell, a 'Products' dropdown menu, and the user name 'Frances Faculty'. Below this is a secondary navigation bar with 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area shows details for submission 'IRB-21-18 Cayuse User Manual Study'. It includes a 'PDF' icon and a 'Delete' button. A metadata table lists: Approval Date (06-16-2021), Expiration Date (N/A), Organization (Simmons University), Active Submissions (N/A), Admin Check-In Date (06-16-2022), Closed Date (N/A), Current Policy (Post-2018 Rule), and Sponsors (N/A). Below the metadata, there are tabs for 'Key Contacts' and 'Attachments', with the latter circled in red. A search bar and a table header with columns 'Filename', 'Uploaded By', and 'Date Uploaded' are visible. The table currently shows 'No Attachments.' The URL at the bottom is 'https://simmons-t.cayuse.com/rs/irb/#study/list/active' and the page status is '0-0 of 0'. A blue circle with the number '4' and an orange question mark icon is in the bottom right corner.

Still have questions?

- ▶ For questions and problems related to logging in or the content of your protocol please email irbprotocols@simmons.edu
- ▶ For questions and problems related to the Cayuse interface please create an account with the [Cayuse Help Center](#) and submit your question or problem to a Cayuse representative