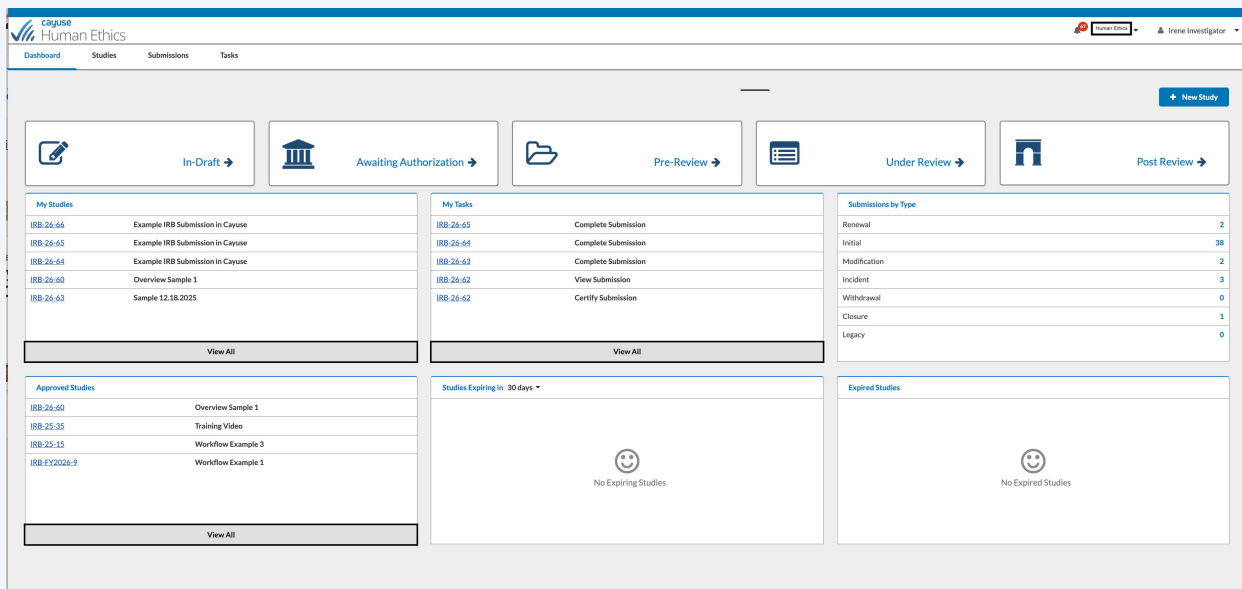


How to Submit an Initial Application on Cayuse

This guide provides a step-by-step process for submitting an initial application in Cayuse, ensuring that users understand each requirement and avoid common pitfalls. By following the outlined steps, researchers can efficiently navigate the application, ensuring all necessary information is included for a successful submission.

1

Navigate to your Cayuse home dashboard using the following link!
<https://usm.app.cayuse.com/>



2 Click "New Study"

The screenshot shows the Cayuse Human Ethics dashboard. At the top right, there are links for 'Products' and 'Irene Investigator'. Below the header, there is a 'Tasks' section. In the center, there are four main workflow buttons: 'Awaiting Authorization', 'Pre-Review', 'Under Review', and 'Post Review'. The 'New Study' button is highlighted with an orange circle. Below these buttons, there are three main sections: 'My Tasks', 'Submissions by Type', and 'Studies Expiring in 30 days'. The 'My Tasks' section lists several IRB submissions with actions like 'Complete Submission', 'View Submission', and 'Certify Submission'. The 'Submissions by Type' section shows a list of submission types and their counts. The 'Studies Expiring in 30 days' section is currently empty.

My Tasks	
IRB-26-65	Complete Submission
IRB-26-64	Complete Submission
IRB-26-63	Complete Submission
IRB-26-62	View Submission
IRB-26-62	Certify Submission

Submissions by Type	
Renewal	2
Initial	37
Modification	2
Incident	3
Withdrawal	0
Closure	1
Legacy	0

3 Enter your study's title in the text box provided.

The screenshot shows the 'Study Details' page in the Cayuse Human Ethics system. The page has a header with the Cayuse logo and 'Human Ethics' text. Below the header, there are tabs for 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The 'Studies' tab is selected. The main content area is titled 'Study Details' and contains a text box for entering the study title. Below the text box, there are buttons for 'PDF' and 'Delete'. At the bottom, there is a table with study details.

Study Details			
Approval Date:	Expiration Date:	Organization:	Active Submissions:
N/A	N/A	N/A	N/A
Admin Check-In Date:	Closed Date:	Current Policy	Sponsors:
N/A	N/A		N/A

4 Click "Confirm"

The screenshot shows a web application interface. At the top, there is a navigation bar with a bell icon, a 'Products' dropdown, and a user profile 'Irene Investigator'. Below the navigation bar is a 'Tasks' section. The main content area has a tabbed interface with 'Study Details' (active) and 'Submissions'. In the 'Study Details' tab, there is a form with several input fields. A confirmation button, represented by a checkmark icon, is highlighted with an orange circle. Below the form, there is a summary section with the following details:

Organization:	Active Submissions:
N/A	
Current Policy	Sponsors:
	N/A

5 Navigate to the top right hand corner and click "New Submission".

The screenshot shows the same web application interface as the previous one. The 'New Submission' button, located in the top right corner of the main content area, is highlighted with an orange circle. Below the 'Study Details' tab, there is a table with the following data:

Organization:	Active Submissions:
N/A	
Current Policy	Sponsors:
Post-2018 Rule	N/A

Role	Number	Email

6 Click "Initial"

The screenshot shows the Cayuse Human Ethics interface. At the top, there is a navigation bar with a bell icon, a 'Products' dropdown, and a user profile 'Irene Investigator'. Below this is a 'Tasks' section. The main content area has a tabbed interface with 'Study Details' selected. A 'New Submission' button is visible in the top right. An orange circle highlights the 'Initial' button in the top right corner of the main content area. Below the tabs, there is a form with fields for 'Organization', 'Current Policy', 'Active Submissions', and 'Sponsors'. At the bottom, there is a table with columns 'Role', 'Number', and 'Email'.

7 Click "Edit" to begin editing your initial application.

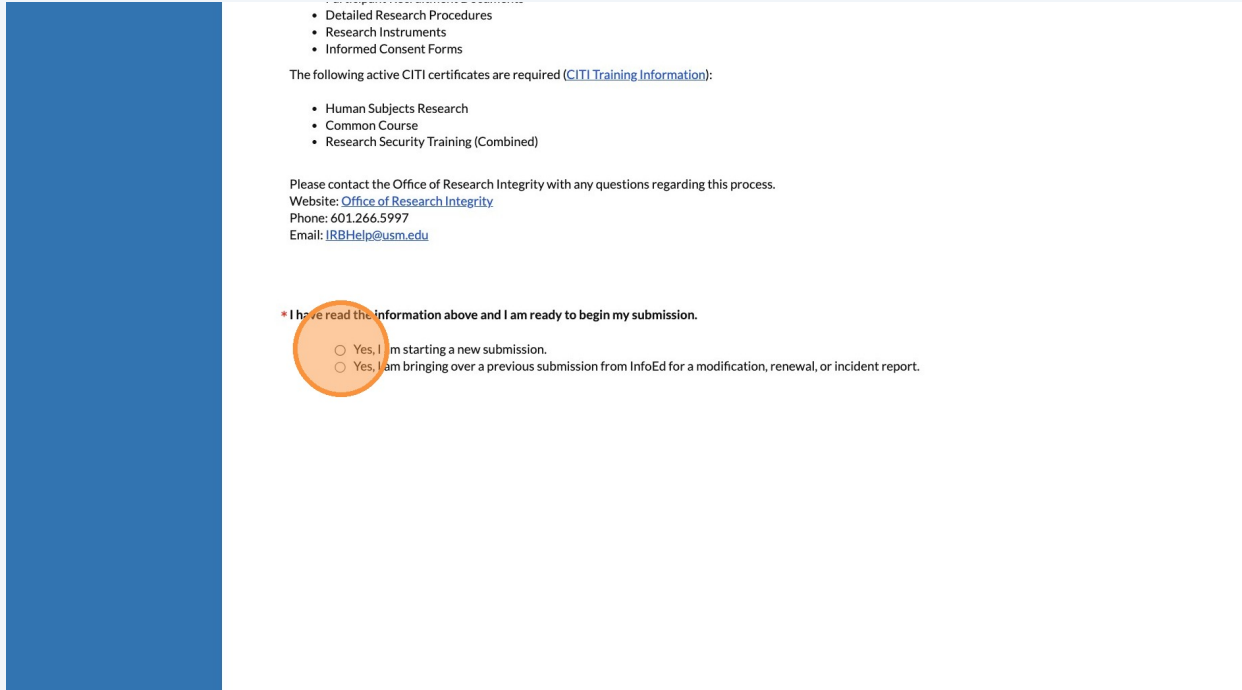
The screenshot shows the Cayuse Human Ethics interface. At the top, there is a navigation bar with the 'cayuse Human Ethics' logo and tabs for 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. Below this is a breadcrumb trail 'Studies / StudyDetails / Submission Details'. The main content area shows a progress bar with four steps: 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. Unsubmitted. Below the progress bar, there is a section for 'Initial' submission. An orange circle highlights the 'Edit' button. To the right of the 'Edit' button are 'PDF' and 'Delete' buttons. Below this, there is a form with fields for 'PI', 'Current Analyst', 'Decision', 'Policy', 'Review Type', 'Review Board', 'Meeting Date', and 'Required Tasks'. At the bottom, there is a table with columns 'Name', 'Role', 'Result', and 'Date'.

8

You have now reached the first page - Getting Started.

Read the information on this page in entirety.

Once finished, select the **"Yes, I am starting a new submission."** field.



• 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)

Please contact the Office of Research Integrity with any questions regarding this process.
Website: [Office of Research Integrity](#)
Phone: 601.266.5997
Email: IRBHelp@usm.edu

* I have read the information above and I am ready to begin my submission.

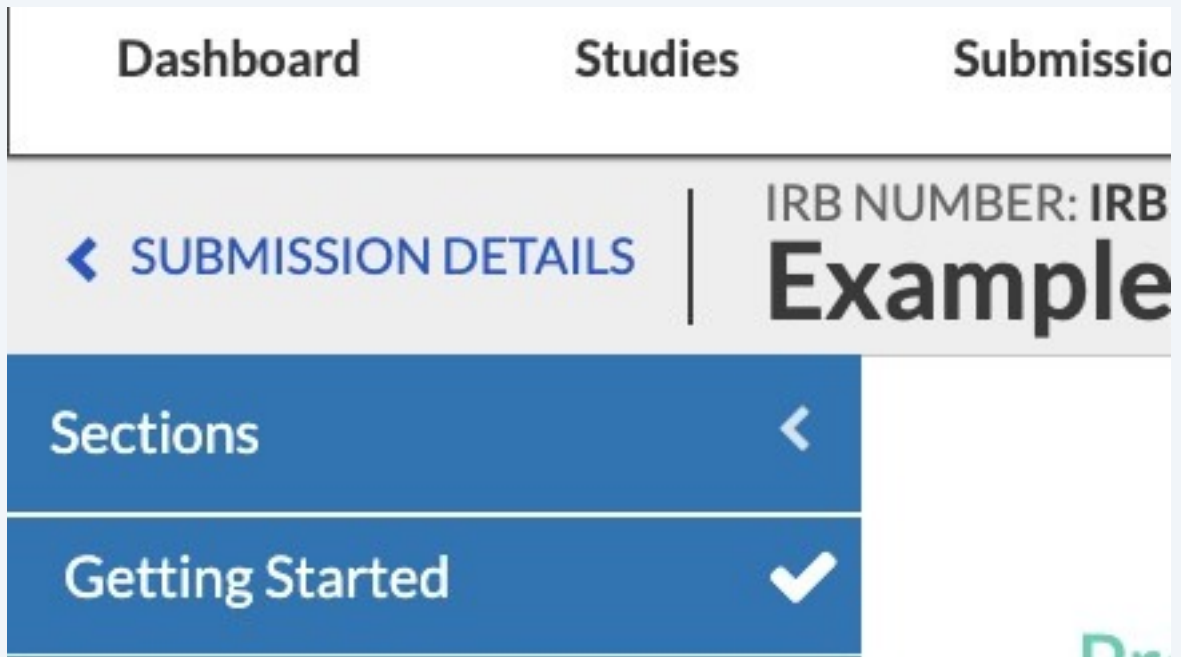
☒ Yes, I am starting a new submission.
☐ Yes, I am bringing over a previous submission from InfoEd for a modification, renewal, or incident report.

9

Once you answer this question, you will notice that the "Getting Started" page now has a checkmark beside it.

Throughout the application, a checkmark will populate beside each page's tab IF you answer each of the required questions on each page,

Note: You can *NOT* officially submit a protocol if there is not a checkmark beside each tab on your application.



10

Click here to continue to the next page.

Office of Research Integrity with any questions regarding this process.
[Research Integrity](#)
 797
[sm.edu](#)

ormation above and I am ready to begin my submission.

m starting a new submission.
 m bringing over a previous submission from InfoEd for a modification, renewal, or incident report.



11 You have now reached the "Project Personnel" page.

In the first question, you will be asked to **indicate** your current relationship with The University of Southern Mississippi.

[← SUBMISSION DETAILS](#)

IRB NUMBER: IRB-26-66

Example IRB Submission in Cayuse - Initial

Sections <

Getting Started ✓

Project Personnel

Basic Information

Participant Selection

Study Design and Proced...

Participant Protection

Attachments

Project Personnel

*What is the applicant's current relationship with The University of Southern Mississippi?

☒ Faculty
☐ Student
☐ Staff
☐ Other

*What is the primary purpose of this human subject research protocol?

☐ Undergraduate Project
☐ Honor's Thesis Project
☐ Graduate Project
☐ Graduate Capstone
☐ Master's Thesis
☐ Doctoral Project

12

Based on the item you select, a dropdown menu may appear to prompt you to continue indicating your specific relationship to the university.

Sections

Getting Started

Project Personnel

Basic Information

Participant Selection

Study Design and Proced...

Participant Protection

Attachments

Project Personnel

*** What is the applicant's current relationship with The University of Southern Mississippi?**

☐ Faculty
☒ Student
** Student researchers cannot serve as PI; your advisor must be listed as PI. Applications that*
☐ Undergraduate Student
☐ Graduate Student
☐ Staff
☐ Other

*** What is the primary purpose of this human subject research protocol?**

☐ Undergraduate Project
☐ Honor's Thesis Project
☐ Graduate Project
☐ Graduate Capstone
☐ Master's Thesis
☐ Doctoral Project

13

Next, **select** the purpose of your protocol.

Participant Selection

Study Design and Proced...

Participant Protection

Attachments

☐ Faculty
☒ Student
** Student researchers cannot serve as PI; your advisor must be listed as PI. Applications that do not follow this requirement*
☐ Undergraduate Student
☒ Graduate Student
☐ Staff
☐ Other

*** What is the primary purpose of this human subject research protocol?**

☐ Undergraduate Project
☐ Honor's Thesis Project
☐ Graduate Project
☐ Graduate Capstone
☐ Master's Thesis
☐ Doctoral Project
☐ Doctoral Dissertation
☐ Faculty Project
☐ Staff Project
☐ McNair Project
☐ Other

Study Personnel

Note: If you cannot locate a person using People Finder, please contact RISGA@usm.edu for assistance.

*** Principal Investigator**

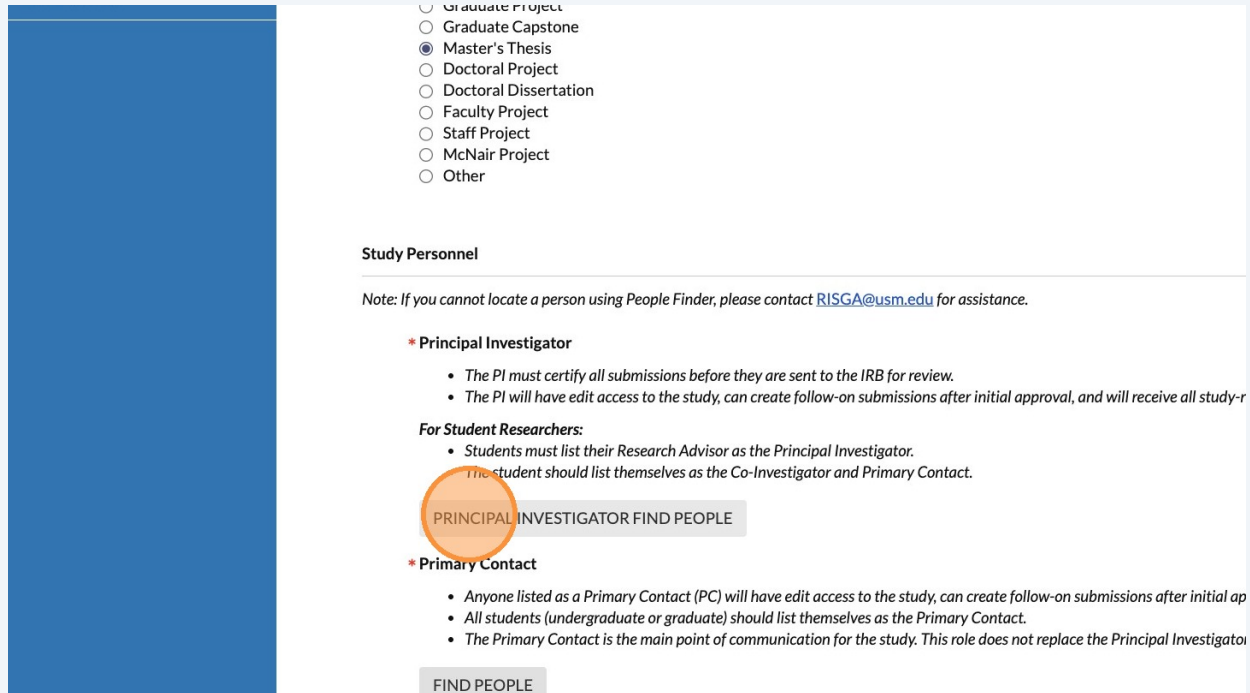
- The PI must certify all submissions before they are sent to the IRB for review.

14 Following this, navigate to the "Study Personnel" section.

In this section, you will be asked to select a PI.

Click "**Principle Investigator Find People**" to select a PI.

Remember: *Student researchers cannot serve as PI; your advisor must be listed as PI*



☐ Graduate Project
☐ Graduate Capstone
☒ Master's Thesis
☐ Doctoral Project
☐ Doctoral Dissertation
☐ Faculty Project
☐ Staff Project
☐ McNair Project
☐ Other

Study Personnel

Note: If you cannot locate a person using People Finder, please contact RISGA@usm.edu for assistance.

*** Principal Investigator**

- The PI must certify all submissions before they are sent to the IRB for review.
- The PI will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-r

For Student Researchers:

- Students must list their Research Advisor as the Principal Investigator.
- The student should list themselves as the Co-Investigator and Primary Contact.

PRINCIPAL INVESTIGATOR FIND PEOPLE

*** Primary Contact**

- Anyone listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial ap
- All students (undergraduate or graduate) should list themselves as the Primary Contact.
- The Primary Contact is the main point of communication for the study. This role does not replace the Principal Investigator

FIND PEOPLE

15 **Locate** your advisor using the search bar.

PRINCIPAL INVESTIGATOR

irene

Name	Organization	Email	Phone
Irene Investigator	School of Professional Nursing	morgan.chapman+investi...	

Selected Records * Select a single record.

Irene Investigator

CANCEL SAVE

16 Once the appropriate party is located, **click their name** on the dropdown menu.

PRINCIPAL INVESTIGATOR

irene

Name	Organization	Email	Phone
Irene Investigator	School of Professional Nursing	morgan.chapman+investi...	

Selected Records * Select a single record.

Irene Investigator

CANCEL SAVE

17 Press "Save".

Note: If a name does NOT appear on your protocol, search for the individual again, SELECT their name and press save until you see the name reflected on your protocol.

	Organization	Email	Phone	
tor	School of Professional Nursing	morgan.chapman+investi...		✓

rds * Select a single record.

or ✕

CANCEL SAVE

Finder, please contact RISGA@usm.edu for assistance.

18 Navigate to the primary contact section below and select "Primary Contact Find People".

- The PI must certify all submissions before they are sent to the IRB for review.
- The PI will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-

For Student Researchers:

- Students must list their Research Advisor as the Principal Investigator.
- The student should list themselves as the Co-Investigator and Primary Contact.

Name	Organization	Address	Pho
Irene Investigator	School of Professional Nursing		

* **Primary Contact**

- Anyone listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial ap
- All students (undergraduate or graduate) should list themselves as the Primary Contact.
- The Primary Contact is the main point of communication for the study. This role does not replace the Principal Investigator

PRIMARY CONTACT FIND PEOPLE

Co-Investigator(s)

- Individuals listed as Co-Investigators will have edit access to the study, can submit follow-on submissions after initial app

FIND PEOPLE

Other Personnel

- Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive st

FIND PEOPLE

19 Utilize the search bar to locate a primary contact.

Important: All students MUST list themselves as the primary contact so they can have access to edit their document(s), and receive all relevant communications.

IRB NUMBER: IRB-26-66

Example IRB Sub

Submissions Tasks

Primary Contact

irene

Name	Organization	Email	Phone
Irene Investigator	School of Professional Nursing	morgan.chapman+investi...	

Selected Records

CANCEL SAVE

Study Personnel

Note: If you cannot find the person you are looking for, please contact the IRB Administrator.

* Principal Investigator

- The Principal Investigator is the person who is responsible for the study.
- The Principal Investigator is the person who is responsible for the study.

For Student

- The student is the person who is responsible for the study.
- The student is the person who is responsible for the study.

Name	Organization	Address	Phone	Email	Trainings
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	View

* Primary Contact

- Anyone listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications.
- All students (undergraduate or graduate) should list themselves as the Primary Contact.

20 Click on the name that appears on the dropdown menu.

PRIMARY CONTACT

irene

Name	Organization	Email	Phone
Irene Investigator	School of Professional Nursing	morgan.chapman+investi...	

Selected Records

CANCEL SAVE

21 Click "Save"

PRIMARY CONTACT

Name	Organization	Email	Phone
Irene Investigator	School of Professional Nursing	morgan.chapman+investi...	

Selected Records

Irene Investigator

CANCEL SAVE

estigator Nursing morgan.chapman+investigator@cayuse.com Training View

contact

e listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications. Students (undergraduate or graduate) should list themselves as the Primary Contact. Primary Contact is the main point of communication for the study. This role does not replace the Principal Investigator's responsibilities.

22 Next, navigate to the **"Study Personnel Training Documentation"** section.

Select **"Study Personnel Training Documentation Attach"** to attach any required training certificates.

Individuals listed as Co-Investigators will have edit access to the study, can submit follow-on submissions after initial approval, and will automatically receive all study-related communications.

FIND PEOPLE

Other Personnel

Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.

FIND PEOPLE

Study Personnel Training Documentation

- Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the study.
- This requirement also applies to external collaborators, if applicable.
- Use CITI Program

STUDY PERSONNEL TRAINING DOCUMENTATION ATTACH

Protocol Related Conflict of Interest

The Principal Investigator (PI) must answer the following questions on behalf of all USM key personnel listed on this protocol. Key personnel include the PI and any named Co-Investigator.

* Have you and all key personnel listed on this protocol completed USM's required Research Security training?

☐ Yes

☐ No

Do you or any key personnel have a Conflict of Interest that could reasonably appear to affect the design, conduct, and/or reporting of the proposed research or scholarship?

☐ Yes

☐ No

23 Select **"+"** to upload any relevant training attachment(s) or certificate(s).

DOCUMENTS

Click the plus button to upload files or add links.

CANCEL APPLY

+

Add Link

Add File

* Principal Investigator

- The PI must complete all submissions before they are sent to the IRB for review.
- The PI will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications.

For Student Researchers:

- Students must list their Research Advisor as the Principal Investigator.
- The student should list themselves as the Co-Investigator and Primary Contact.

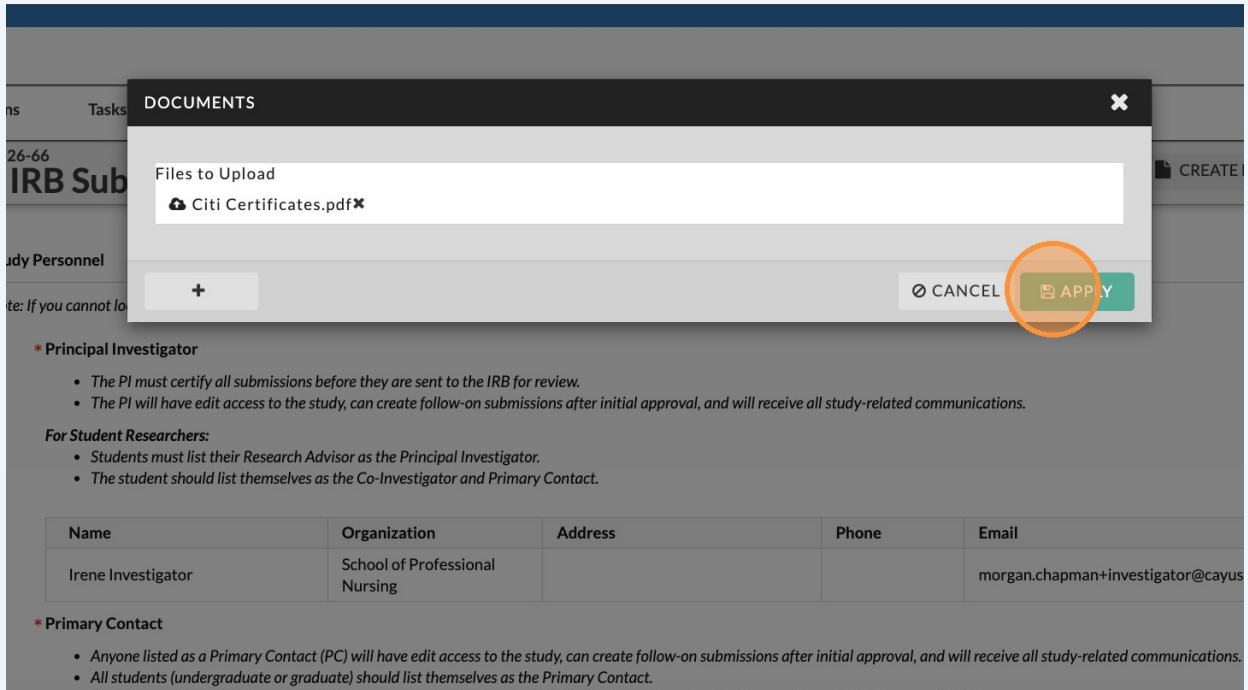
Name	Organization	Address	Phone	Email
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.c

* Primary Contact

- Anyone listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications.
- All students (undergraduate or graduate) should list themselves as the Primary Contact.

24

Once you select those items, press **"Apply"** so each file can populate onto your protocol.



DOCUMENTS

Files to Upload

Citi Certificates.pdf

+ CANCEL APPLY

***Principal Investigator**

- The PI must certify all submissions before they are sent to the IRB for review.
- The PI will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications.

For Student Researchers:

- Students must list their Research Advisor as the Principal Investigator.
- The student should list themselves as the Co-Investigator and Primary Contact.

Name	Organization	Address	Phone	Email
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayus

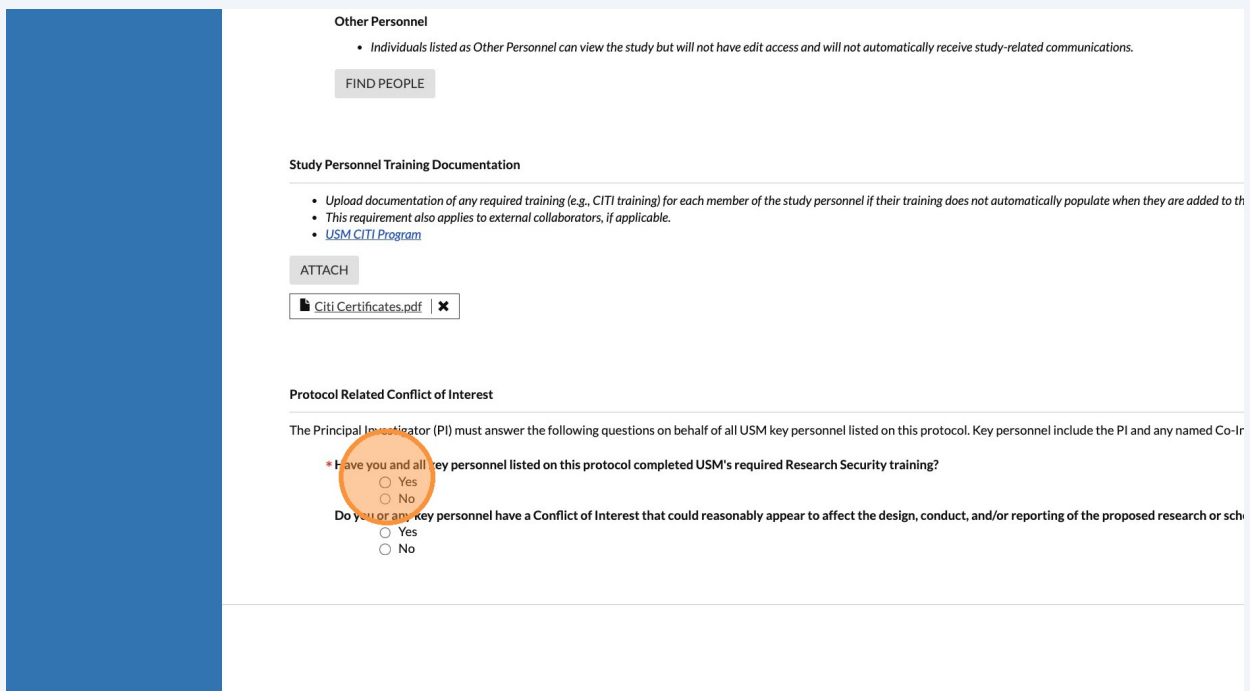
***Primary Contact**

- Anyone listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications.
- All students (undergraduate or graduate) should list themselves as the Primary Contact.

25

Next, navigate to the **"Conflict of Interest"** section.

Answer all relevant questions to the best of your ability.



Other Personnel

- Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.

FIND PEOPLE

Study Personnel Training Documentation

- Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the study.
- This requirement also applies to external collaborators, if applicable.
- USM CITI Program

ATTACH

Citi Certificates.pdf

Protocol Related Conflict of Interest

The Principal Investigator (PI) must answer the following questions on behalf of all USM key personnel listed on this protocol. Key personnel include the PI and any named Co-Investigator.

* Have you and all key personnel listed on this protocol completed USM's required Research Security training?

☐ Yes

☐ No

Do you or any key personnel have a Conflict of Interest that could reasonably appear to affect the design, conduct, and/or reporting of the proposed research or scholarship?

☐ Yes

☐ No

26 When each question is answered, **click here** to continue to the next page.

Personnel

Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.

PEOPLE

Training Documentation

Documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application. Requirement also applies to external collaborators, if applicable.

[Program](#)

cates.pdf x

Conflict of Interest

Investigator (PI) must answer the following questions on behalf of all USM key personnel listed on this protocol. Key personnel include the PI and any named Co-Investigators on this protocol.

You and all key personnel listed on this protocol completed USM's required Research Security training?

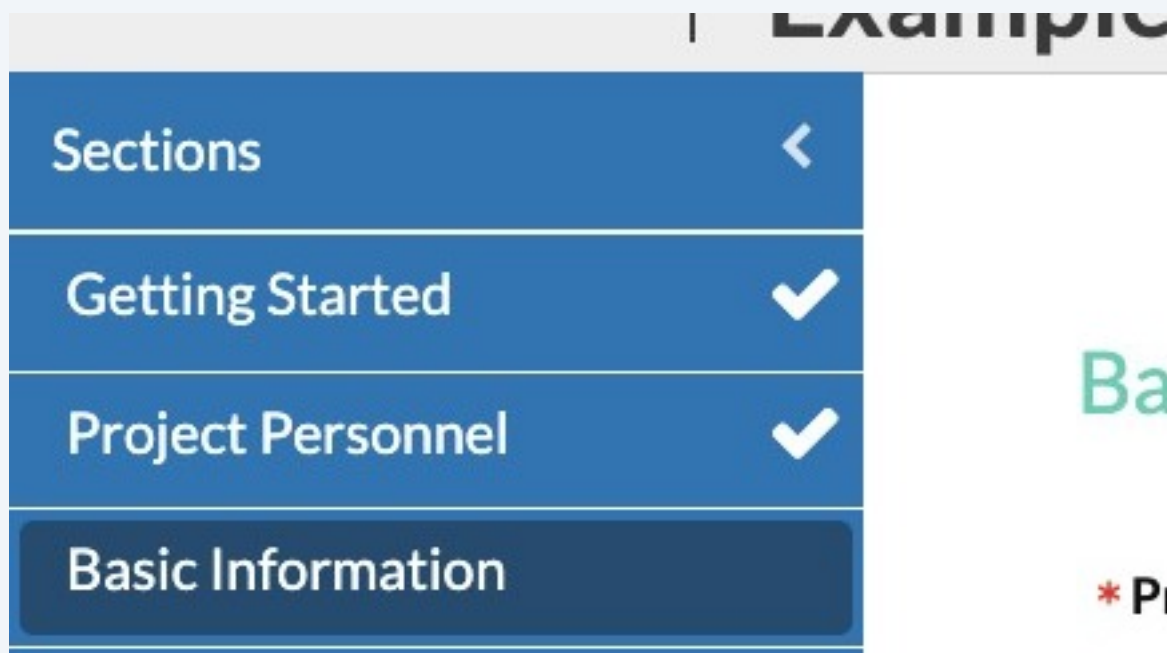
- ☒ Yes
☐ No

Do you or any key personnel have a Conflict of Interest that could reasonably appear to affect the design, conduct, and/or reporting of the proposed research or scholarly activity?

- ☐ Yes
☒ No



27 Note: You should now have a checkmark by the Project Personnel tab, IF you have completed all required questions.



28 You are now on the "Basic Information Page".

The first question asks you to select the type of project that your submission reflects.

The screenshot shows the Cayuse Human Ethics submission interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. Below this, a breadcrumb trail shows 'SUBMISSION DETAILS' and 'Example IRB Submission in Cayuse - Initial'. The left sidebar lists sections: 'Sections', 'Getting Started', 'Project Personnel', 'Basic Information' (highlighted), 'Participant Selection', 'Study Design and Proced...', 'Participant Protection', and 'Attachments'. The main content area is titled 'Basic Information' and contains the following sections:

- * Project Type**
What type of project does this submission represent?
☐ Research Study
☐ Clinical Trial/Intervention
- * Study Sites**
Include all locations where research activities will occur, such as data collection, participant interaction, or storage of research materials.
Primary Site
List the primary site or location involved in this project, including all USM-affiliated sites. Please provide the full physical address for each site.
A text input area with a rich text editor toolbar (B, I, U, S, L, R, O, A) is visible below the instructions.

29 Next, navigate to the "Study Sites" portion below.

List all locations where your research activities will take place.

The screenshot shows the Cayuse Human Ethics submission interface, specifically the 'Study Sites' section. The left sidebar is the same as in the previous screenshot, with 'Basic Information' highlighted. The main content area is titled 'Study Sites' and contains the following sections:

- * Project Type**
What type of project does this submission represent?
☒ Research Study
☐ Clinical Trial/Intervention
- * Study Sites**
Include all locations where research activities will occur, such as data collection, participant interaction, or storage of research materials.
Primary Site
List the primary site or location involved in this project, including all USM-affiliated sites. Please provide the full physical address for each site.
A text input area with a rich text editor toolbar (B, I, U, S, L, R, O, A) is visible below the instructions. An orange circle highlights the text input area.
- Collaboration Information**
 - * External Sites**
Will any research activities occur at external sites within the United States.
☐ No
☐ Yes
 - * International Sites**

30 Navigate to the "Collaboration Information" section.

Answer each of the required questions accordingly.

Study Design and Proced...
Participant Protection
Attachments

Test.

Collaboration Information

* External Sites

Will any research activities occur at external sites within the United States?

☐ No
☐ Yes

* International Sites

Will any research activities occur outside of the United States?

☐ No
☐ Yes

* External Collaborators

Will any non-USM affiliated person conduct research activities for this project?

☐ No
☐ Yes

Study Dates

Please provide the anticipated start date and end date for this study.

Note: All protocols require annual review. Ensure your end date reflects the expected duration of the research activities.

* Anticipated Start Date

31 Next, navigate to the "Study Dates" section to provide the anticipated start and end date(s) of your study.

Will any research activities occur outside of the United States?

☒ No
☐ Yes

* External Collaborators

Will any non-USM affiliated person conduct research activities for this project?

☒ No
☐ Yes

If this institution is relying on an External IRB, the answer to this question should be No.

Study Dates

Please provide the anticipated start date and end date for this study.

Note: All protocols require annual review. Ensure your end date reflects the expected duration of the research activities.

* Anticipated Start Date

MM/DD/YYYY

* End Date

MM/DD/YYYY

* Funding

Does this project have funding or any other type of in-kind support (e.g., provision of drugs or study products, internal support, equipment, or waived lab or service fees)?

☐ No
☐ Yes

Made with Scribe - <https://scribehow.com>

18

32 Please use the dropdown calendar to select the desired dates.

Collaboration Information

* **External Sites**
Will any research activities occur at external sites within the United States?
☒ No
☐ Yes

* **International Sites**
Will any research activities occur outside of the United States?
☒ No
☐ Yes

* **External Collaborators**
Will any non-USM affiliated person conduct research activities for this project?
☒ No
☐ Yes
If this institution is relying on an External IRB, the answer to this question should be No.

Study Dates
Please provide the anticipated start date and end date for this study.
Note: All protocols require annual review. Ensure your end date reflects the expected duration of the research activities.

* **Anticipated Start Date**
01/20/2026

* **End Date**
MM/DD/YYYY

* **Funding**
Does this project have funding or any other type of in-kind support (e.g., provision of drugs or study products, internal support, equipment, or waived lab or service fees)?

33 Finally, navigate to the "Funding" section.

Acknowledge if your project has any funding or any other type of in-kind support.

* **External Collaborators**
Will any non-USM affiliated person conduct research activities for this project?
☒ No
☐ Yes
If this institution is relying on an External IRB, the answer to this question should be No.

Study Dates
Please provide the anticipated start date and end date for this study.
Note: All protocols require annual review. Ensure your end date reflects the expected duration of the research activities.

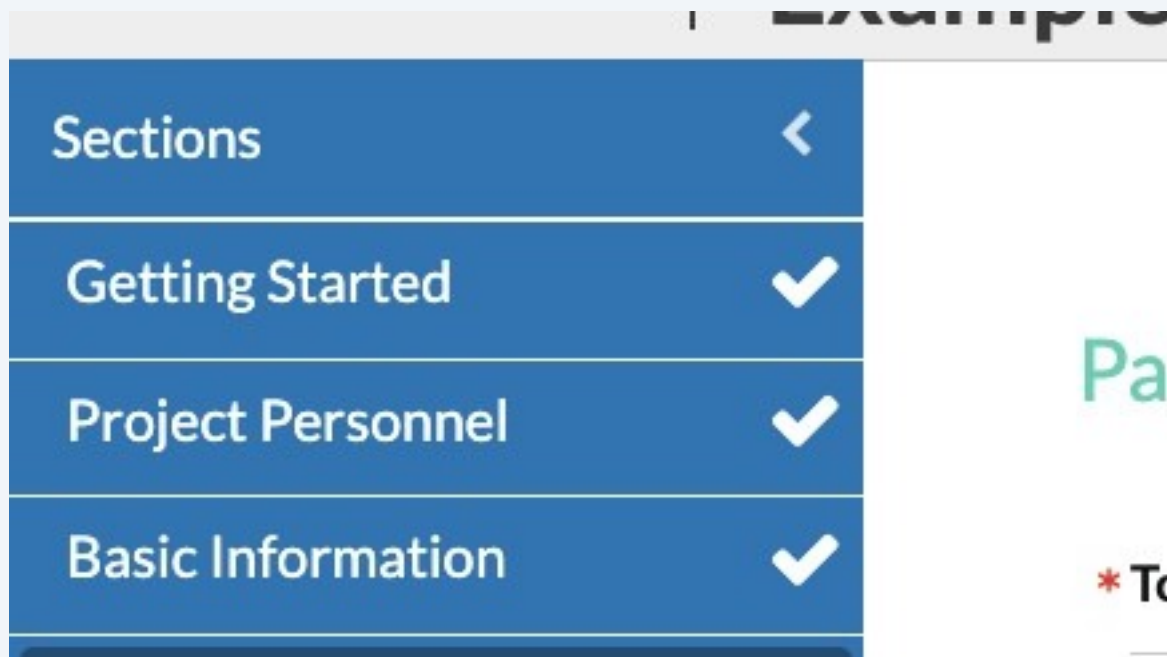
* **Anticipated Start Date**
01/20/2026

* **End Date**
MM/DD/YYYY

* **Funding**
Does this project have funding or any other type of in-kind support (e.g., provision of drugs or study products, internal support, equipment, or waived lab or service fees)?
☐ No
☐ Yes

34

Note: The "**Basic Information**" tab on the left hand side should now have a check mark beside it, if you have completed each of the required questions.



35

Click here to continue to the next page.

☐ Yes
☒ No

al Collaborators
 y non-USM affiliated person conduct research activities for this project?
 If this institution is relying on an External IRB, the answer to this question should be No.

☐ Yes

Provide the anticipated start date and end date for this study.
 protocols require annual review. Ensure your end date reflects the expected duration of the research activities.

ated Start Date
 0/2026

ite
 0/2027

t have funding or any other type of in-kind support (e.g., provision of drugs or study products, internal support, equipment, or waived lab or service fees)?

?

36 You have now reached the "Participant Selection" page.

Human Ethics

Dashboard Studies Submissions Tasks

IRB NUMBER: IRB-24-66

Example IRB Submission in Cayuse - Initial

CREATE PDF COMPARE SAVE

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Participant Selection
- Study Design and Proceed...
- Participant Protection
- Attachments

Participant Selection

*** Total Study Enrollment**

Enter the total number of subjects expected at each study site.
Note: If multiple sites are involved, provide the anticipated enrollment for each site separately.

B I U G L B B O

Test.

*** Ages**

Indicate the age range(s) of participants included in the study. You may specify distinct ranges for different populations (e.g., "Less than 1 month," "12-17 years," "30-89 years").

|

*** Inclusion Criteria**

List and describe the characteristics participants must meet to be eligible for the study.
Examples: Age range, diagnosis, language proficiency, geographic location.
Reminder: Ensure inclusion criteria align with your study objectives and recruitment plan.

B I U G L B B O

37 Locate the "Total Study Enrollment" section

Enter the total number of subjects expected at each study site using the text box.

Human Ethics

Dashboard Studies Submissions Tasks

IRB NUMBER: IRB-24-66

Example IRB Submission in Cayuse - Initial

CREATE PDF COMPARE SAVE

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Participant Selection
- Study Design and Proceed...
- Participant Protection
- Attachments

Participant Selection

*** Total Study Enrollment**

Enter the total number of subjects expected at each study site.
Note: If multiple sites are involved, provide the anticipated enrollment for each site separately.

B I U G L B B O

*** Ages**

Indicate the age range(s) of participants included in the study. You may specify distinct ranges for different populations (e.g., "Less than 1 month," "12-17 years," "30-89 years").

*** Inclusion Criteria**

38

Continue to the "**Ages**" field.

Indicate the desired age range of participants in your study.

* Ages

Indicate the age range(s) of participants included in the study. You may specify distinct ranges for different populations (e.g., "Less than 1 month," "12-17 years," "30-89 years").

* Inclusion Criteria

List and describe the characteristics participants must meet to be eligible for the study.
Examples: Age range, diagnosis, language proficiency, geographic location.
Reminder: Ensure inclusion criteria align with your study objectives and recruitment plan.

B I U ↺ ☰ ☷ ⌂ 🖼️

39

Next, move forward to the **"Inclusion Criteria"** section.

List and describe all eligibility requirements for your study.

Ages

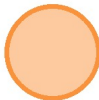
Indicate the age range(s) of participants included in the study. You may specify distinct ranges for different populations (e.g., "Less than 1 month," "12-17 years," "30-89 years").

Test.

Inclusion Criteria

List and describe the characteristics participants must meet to be eligible for the study.
Examples: Age range, diagnosis, language proficiency, geographic location.
Reminder: Ensure inclusion criteria align with your study objectives and recruitment plan.

B I U G L M O A



Exclusion Criteria

List and describe the characteristics that will exclude individuals from participating in the study.
Example: Medical conditions, inability to provide informed consent, prior participation in similar studies.
Note: Exclusion criteria should be scientifically justified and not create unnecessary barriers to participation.

40

List and describe all characteristics that will exclude individuals from participating in your study.

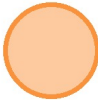
* Exclusion Criteria

List and describe the characteristics that will exclude individuals from participating in the study.

Example: Medical conditions, inability to provide informed consent, prior participation in similar studies.

Note: Exclusion criteria should be scientifically justified and not create unnecessary barriers to participation.

B I U ↺ ☰ ☷ 🔍 🗨



41 Continue to the "Vulnerable Populations" Section.

Answer each of the required questions under "**Included Vulnerable Populations**" and "**Excluded Vulnerable Populations**".

Vulnerable Populations

Including a vulnerable population means:
1. Subjects will belong to the vulnerable population at any time during the intervention, interaction, or collection of identifiable private information for the study; AND
2. You will obtain knowledge that identifies a subject as a member of that vulnerable population.

Important Note:
• You generally are not required to determine a subject's status as a member of a vulnerable population unless doing so is necessary to minimize risks or ensure an appropriate informed consent process.
• However, you must consider the involvement of vulnerable populations even if you are not specifically targeting them for enrollment.

* Included Vulnerable Populations

Please indicate any population(s) that will knowingly be enrolled. Check all that apply.

☐ Fetuses
☐ Pregnant Women
☐ Children
☐ Prisoners
☐ Cognitively Impaired Adult Subjects
☐ Other
☐ None of the Above

* Excluded Vulnerable Populations

Will any vulnerable populations be deliberately excluded from participation?

☐ No
☐ Yes

42 When each of the required questions are answered, Click here.

ulations

erable population means:
will belong to the vulnerable population at any time during the intervention, interaction, or collection of identifiable private information for the study; AND
obtain knowledge that identifies a subject as a member of that vulnerable population.

ally are not required to determine a subject's status as a member of a vulnerable population unless doing so is necessary to minimize risks or ensure an appropriate informed consent process.
you must consider the involvement of vulnerable populations even if you are not specifically targeting them for enrollment.

ed Vulnerable Populations

indicate any population(s) that will knowingly be enrolled. Check all that apply.

☐ Fetuses
☐ Pregnant Women
☐ Children
☐ Prisoners
☐ Cognitively Impaired Adult Subjects
☐ Other
☒ None of the Above

ed Vulnerable Populations

y vulnerable populations be deliberately excluded from participation?

☒ No
☐ Yes

43 You have now reached the **"Study Design and Procedures"** page.

The screenshot shows the Cayuse Human Ethics submission interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main header displays 'IRB NUMBER: IRB-26-66' and 'Example IRB Submission in Cayuse - Initial'. A left sidebar lists sections: 'Sections', 'Getting Started', 'Project Personnel', 'Basic Information', 'Participant Selection', 'Study Design and Procedures' (highlighted with an orange circle), 'Participant Protection', and 'Attachments'. The main content area is titled 'Study Design and Procedures' and contains a section for 'Study Background' (also highlighted with an orange circle). Below this section is a text box with a rich text editor toolbar (bold, italic, underline, link, unlink, list, indent, outdent, image) and a large text area containing the letter 'T'. Below the text box is a section for 'Objectives'.

44 Locate the **"Study Background"** section.

Use the text box to provide the background and rationale of your study.

This screenshot is similar to the previous one but shows the 'Study Background' section more clearly. The 'Study Background' section is highlighted with an orange circle. Below it, a text box with a rich text editor toolbar (bold, italic, underline, link, unlink, list, indent, outdent, image) and a large text area containing the letter 'T' is also highlighted with an orange circle. Below the text box is a section for 'Objectives'.

46 Next, locate the **"Study Design"** section.


Describe the approach of your study in the text box provided.

*** Study Design**

Describe the overall approach of the study. Indicate whether the study is prospective, interventional, retrospective, observational, etc. If your study includes more than one group, arm, or sub-interventional arm and a retrospective chart review arm).

Note: Include details such as randomization, blinding, control groups, and timelines if applicable.

B I U ↺ ↻ ☰ ☷ ☹ 🖨



*** Recruitment Process**

- List and describe all methods of recruitment, including when, where, and how potential participants will be identified and approached.
- Also describe any materials that will be used for recruitment (e.g., flyers, advertisements, social media posts, telephone scripts).

B I U ↺ ↻ ☰ ☷ ☹ 🖨

47 Next you'll see the **"Recruitment Process"** section.

List and describe all methods of recruitment.

Sections

<

Getting Started

✓

Project Personnel

✓

Basic Information

✓

Participant Selection

✓

Study Design and Procedures

●

Participant Protection

Attachments

* Recruitment Process

List and describe all methods of recruitment, including when, where, and how potential participants will be identified and approached.

Also describe any materials that will be used for recruitment (e.g., flyers, advertisements, social media posts, telephone scripts).

B I U ↺ ☰ ☷ ⌂ 🖨

|

* Recruitment Documents

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

All messaging must include the IRB protocol number and a statement that the study has been approved by USM's IRB.

Reminder: Ensure recruitment materials are consistent with the approved protocol and do not include misleading language.

ATTACH

48 Below the text box, there will be a "Recruitment Documents" section.

← SUBMISSION DETAILS | Example IRB Submission in Cayuse - Initial

CREATE PDF COMPARE SAVE

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Participant Selection ✓
- Study Design and Proceed... (selected)
- Participant Protection
- Attachments

* Recruitment Process

- List and describe all methods of recruitment, including when, where, and how potential participants will be identified and approached.
- Also describe any materials that will be used for recruitment (e.g., flyers, advertisements, social media posts, telephone scripts).

Test.

* Recruitment Documents

- Upload all recruitment materials used in the study (e.g., flyers, advertisements, telephone scripts).
- All messaging must include the IRB protocol number and a statement that the study has been approved by USM's IRB.
- Reminder: Ensure recruitment materials are consistent with the approved protocol and do not include misleading language.

RECRUITMENT DOCUMENTS ATTACH

* Incentives

Will subjects receive any compensation or incentives for participation?
Reminder: Ensure incentives are reasonable and do not constitute undue influence or coercion.

☐ No
☐ Yes

49 Select "Recruitment Documents Attach" to upload all recruitment materials.

Test.

* Recruitment Documents

- Upload all recruitment materials used in the study (e.g., flyers, advertisements, telephone scripts).
- All messaging must include the IRB protocol number and a statement that the study has been approved by USM's IRB.
- Reminder: Ensure recruitment materials are consistent with the approved protocol and do not include misleading language.

RECRUITMENT DOCUMENTS ATTACH

* Incentives

Will subjects receive any compensation or incentives for participation?
Reminder: Ensure incentives are reasonable and do not constitute undue influence or coercion.

☐ No
☐ Yes

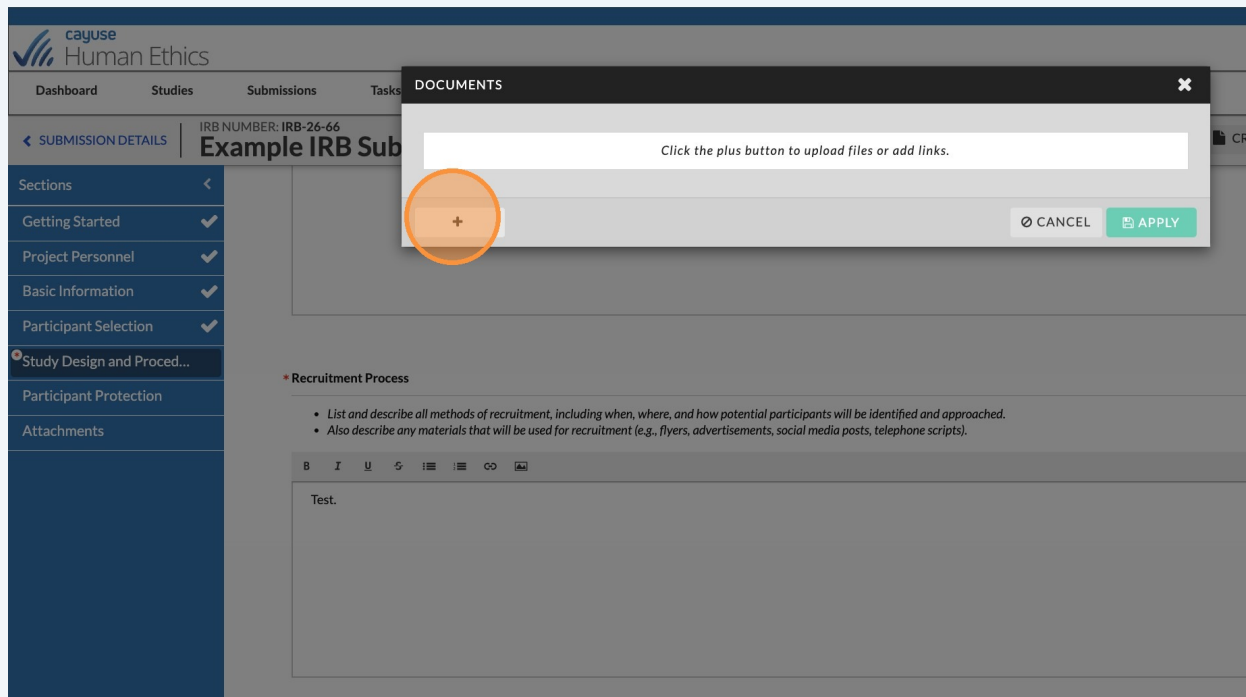
* Study Products

Does your study involve any products that may fall under FDA regulation (e.g., drugs, biologics, food, cosmetics, or devices)?

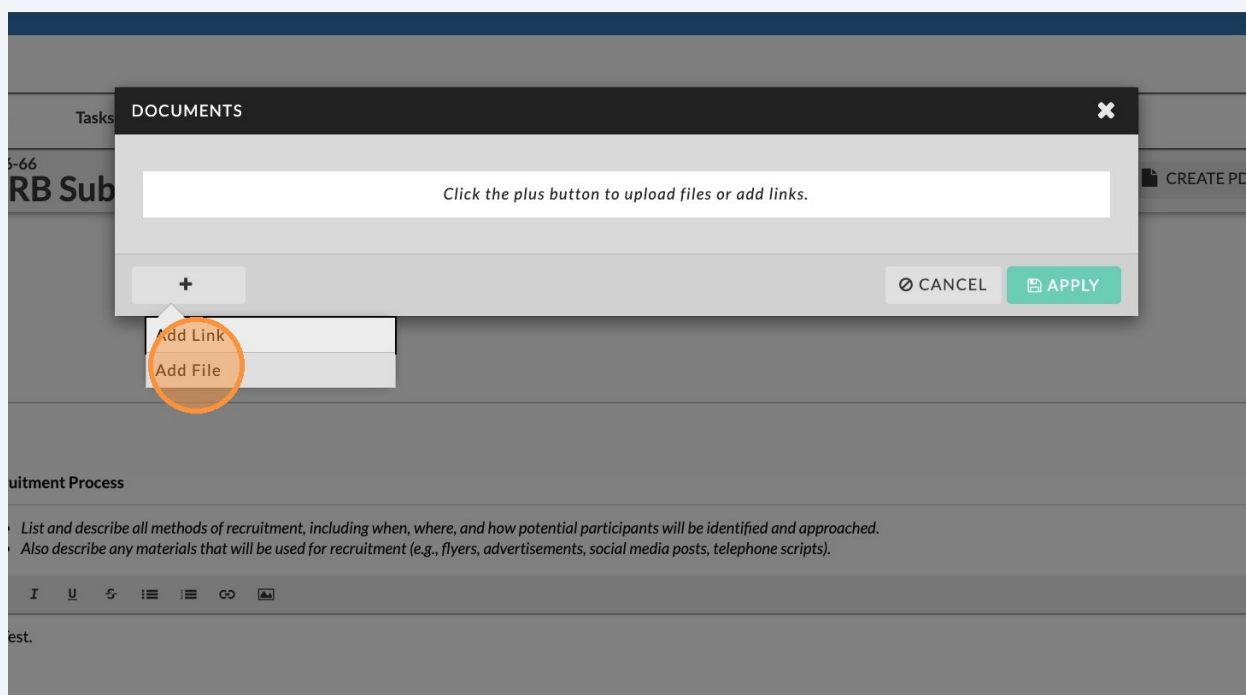
☐ Yes
☐ No

50 After selecting that option, a window will appear for you to attach documents.

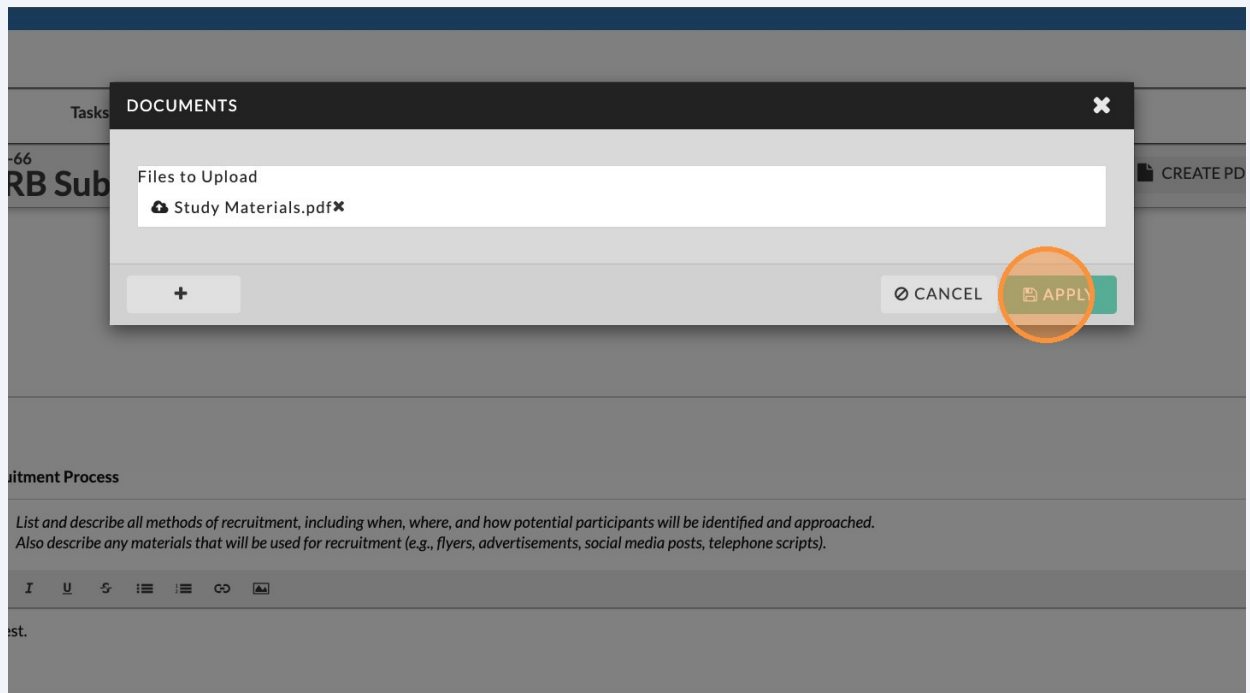
Select the **(+)** button.



51 Click **"Add File"**



52 Click "Apply"



53 Next, is the "Incentives" section.



Acknowledge if subject will receive any **incentives** (course credits, compensation, etc.) in your study.

Attachments

*** Recruitment Documents**

- Upload all recruitment materials used in the study (e.g., flyers, advertisements, telephone scripts).
- All messaging must include the IRB protocol number and a statement that the study has been approved by USM's IRB.
- Reminder: Ensure recruitment materials are consistent with the approved protocol and do not include misleading language.

ATTACH

 Study Materials.pdf 

*** Incentives**

Will subjects receive any compensation or incentives for participation?

Reminder: Ensure incentives are reasonable and do not constitute undue influence or coercion.

☐ No

☐ Yes

*** Study Products**

Does your study involve any products that may fall under FDA regulation (e.g., drugs, biologics, food, cosmetics, or devices)?

☐ Yes

☐ No

*** Genetic Testing**

54 If yes is selected, a text box will appear.

You will be prompted to describe the amount, method, and timing of any payments or incentives.

ATTACH

Study Materials.pdf

*** Incentives**

Will subjects receive any compensation or incentives for participation?
Reminder: Ensure incentives are reasonable and do not constitute undue influence or coercion.

☐ No
☒ Yes

*** Describe the amount, method, and timing of any payments or incentives. Include:**

- How payments will be prorated for participants who partially complete the study
- Circumstances under which participants will no longer be eligible to receive the incentive

*** Study Products**

Does your study involve any products that may fall under FDA regulation (e.g., drugs, biologics, food, cosmetics, or devices)?

55 Next, navigate to the "Study Products" section.

Answer the required question(s).

Study Design and Proced...

Participant Protection

Attachments

*** Study Products**

Does your study involve any products that may fall under FDA regulation (e.g., drugs, biologics, food, cosmetics, or devices)?

☐ Yes
☒ No

*** Genetic Testing**

Will your study include any form of genetic testing or analysis (e.g., sequencing, genotyping, or screening for genetic markers)?

☐ No
☒ Yes

*** Study Procedures**

Provide a detailed description of all study procedures and methods. Include the following information:

56 Scroll down to "Genetic Testing"

Answer the required question(s).

Study Design and Protocol

Participant Protection

Attachments

• Circumstances under which participants will no longer be eligible to receive the incentive

Test.

• Study Products

Does your study involve any products that may fall under FDA regulation (e.g., drugs, biologics, food, cosmetics, or devices)?

☐ Yes

☒ No

• Genetic Testing

Will your study include any form of genetic testing or analysis (e.g., sequencing, genotyping, or screening for genetic markers)?

☐ No

☐ Yes

• Study Procedures

Provide a detailed description of all study procedures and methods. Include the following information:

1. Research procedures and timeline - List all procedures performed for research purposes, when they occur, and the timing/amount of any samples collected.
2. Distinguish research vs. standard of care - Identify which procedures are solely for research and which are part of routine clinical care. *Tip: Consider what would happen if the participant did not join the study.*
3. Drugs and devices - Specify all drugs, biologics, or devices used in the research and their purpose.
4. Data collection tools - Describe instruments, surveys, or software used for data collection.
5. Withdrawal procedures - Explain what happens if a participant withdraws (e.g., stopping interventions, continued data collection).
6. Involuntary withdrawal - Describe any anticipated circumstances under which participants may be withdrawn without consent.

B I U S L B O

57 Next you'll see the **"Study Procedures"** section.

Provide a detailed description of all study procedures and methods.

The screenshot shows a web form for a Cayuse Human Ethics submission. On the left is a blue sidebar. The main content area has a white background. The 'Study Procedures' section is highlighted with an orange circle. It contains a heading, a question about FDA regulation, radio buttons for 'Yes' and 'No' (with 'No' selected), another heading, a question about genetic testing, radio buttons for 'No' and 'Yes' (with 'No' selected), and a detailed text area for study procedures and methods. The text area includes a list of six items to describe: 1. Research procedures and timeline, 2. Distinguish research vs. standard of care, 3. Drugs and devices, 4. Data collection tools, 5. Withdrawal procedures, and 6. Involuntary withdrawal. Below the text area is a rich text editor toolbar.

*** Study Products**

Does your study involve any products that may fall under FDA regulation (e.g., drugs, biologics, food, cosmetics, or devices)?

☐ Yes
☒ No

*** Genetic Testing**

Will your study include any form of genetic testing or analysis (e.g., sequencing, genotyping, or screening for genetic markers)?

☒ No
☐ Yes

*** Study Procedures**

Provide a detailed description of all study procedures and methods. Include the following information:

1. Research procedures and timeline - List all procedures performed for research purposes, when they occur, and the timing/amount of any samples collected.
2. Distinguish research vs. standard of care - Identify which procedures are solely for research and which are part of routine clinical care. *Tip: Consider what would happen if the participant withdraws.*
3. Drugs and devices - Specify all drugs, biologics, or devices used in the research and their purpose.
4. Data collection tools - Describe instruments, surveys, or software used for data collection.
5. Withdrawal procedures - Explain what happens if a participant withdraws (e.g., stopping interventions, continued data collection).
6. Involuntary withdrawal - Describe any anticipated circumstances under which participants may be withdrawn without consent.

B I U S L B B O A

58 Following that, you'll come across a **"Participant Duration"** section.

Describe the duration of participation for each subject.

The screenshot shows the Cayuse Human Ethics submission form. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The 'SUBMISSION DETAILS' section is active, showing the IRB number 'IRB-26-66' and the title 'Example IRB Submission in Cayuse - Initial'. The left sidebar lists sections: 'Sections', 'Getting Started', 'Project Personnel', 'Basic Information', 'Participant Selection', 'Study Design and Proce...', 'Participant Protection', and 'Attachments'. The 'Study Design and Proce...' section is highlighted with an orange circle. It contains a heading, a question about participant duration, and a list of three items to describe: 1. Total time commitment, 2. Number and length of study visits, and 3. Overall study timeline. Below the list is a rich text editor toolbar.

*** Participant Duration**

Describe the expected duration of participation for each subject. Include:

1. Total time commitment - How long will each participant be involved in the study (e.g., days, weeks, months)?
2. Number and length of study visits - Specify how many visits are required and the approximate duration of each visit.
3. Overall study timeline - Provide the anticipated timetable for study completion, including enrollment and follow-up periods.

B I U S L B B O A

*** Study Instruments**

59 Scroll down to the **"Study Instruments"** section.

This section asks you to attach all study instruments.

Select **"Study Instruments Attach"** to attach all study instruments.

The screenshot shows a web form with a left sidebar containing a list of sections: 'Sections', 'Getting Started', 'Project Personnel', 'Basic Information', 'Participant Selection', 'Study Design and Procedures' (highlighted with an orange circle), 'Participant Protection', and 'Attachments'. The main content area is titled 'Study Design and Procedures' and includes three numbered instructions: 1. Total time commitment, 2. Number and length of study visits, and 3. Overall study timeline. Below these instructions is a large text area with a toolbar and the word 'Test.' inside. The 'Study Instruments' subsection is highlighted with an orange circle and contains the text: '* Study Instruments', 'Attach all study instruments that will be used for data collection or participant interaction. If instruments will be translated, describe the translation process.', 'Examples include:', a bulleted list of examples (Surveys or questionnaires, Interview or focus group scripts, Personality or psychological scales, Evaluation forms or scoring sheets), 'If instruments are not yet finalized, provide drafts or describe the planned content and format.', an 'ATTACH' button, and a question '* Will you use any previously collected data in this study?'.

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Participant Selection ✓
- Study Design and Procedures**
- Participant Protection
- Attachments

1. Total time commitment - How long will each participant be involved in the study (e.g., days, weeks, months)?

2. Number and length of study visits - Specify how many visits are required and the approximate duration of each visit.

3. Overall study timeline - Provide the anticipated timetable for study completion, including enrollment and follow-up periods.

B I U S L B B O A

Test.

*** Study Instruments**

Attach all study instruments that will be used for data collection or participant interaction. If instruments will be translated, describe the translation process.

Examples include:

- Surveys or questionnaires
- Interview or focus group scripts
- Personality or psychological scales
- Evaluation forms or scoring sheets

If instruments are not yet finalized, provide drafts or describe the planned content and format.

ATTACH

* Will you use any previously collected data in this study?

60 The next question asks if you plan to use previously collected data.

Select an item.

Attach all study instruments that will be used for data collection or participant interaction. If instruments will be translated, describe the translation process.

Examples include:

- Surveys or questionnaires
- Interview or focus group scripts
- Personality or psychological scales
- Evaluation forms or scoring sheets

If instruments are not yet finalized, provide drafts or describe the planned content and format.

ATTACH

Study Materials.pdf x

* Will you use any previously collected data in this study?

☐ No
☐ Yes

Data Handling (including specimens if applicable)

* Identifiable Data/Specimens

Will this study involve collecting or using data or specimens that could identify participants, either directly or through linked identifiers (e.g., coded data with access to the key)?

☐ Yes
☐ No

* Data Collection

Select all methods you will use to collect data (check all that apply):

☐ Personal Interview
☐ Focus Group
☐ Audio Recording
☐ Video Recording
☐ Questionnaire or Survey

61 Next, navigate to the "Data Handling" section.

Select all methods that you will use to collect data.

* Will you use any previously collected data in this study?

☒ No
☐ Yes

Data Handling (including specimens if applicable)

* Identifiable Data/Specimens

Will this study involve collecting or using data or specimens that could identify participants, either directly or through linked identifiers (e.g., coded data with access to the key)?

☐ Yes
☒ No

* Data Collection

Select all methods you will use to collect data (check all that apply):

☐ Personal Interview
☐ Focus Group
☐ Audio Recording
☐ Video Recording
☐ Questionnaire or Survey
☐ Behavioral Observation
☐ Secondary Data (e.g., existing datasets)
☐ Chart Review
☐ Other

* Collection & Handling of Data

Describe how data and/or specimens will be collected, recorded, stored, and managed. Address the following points:

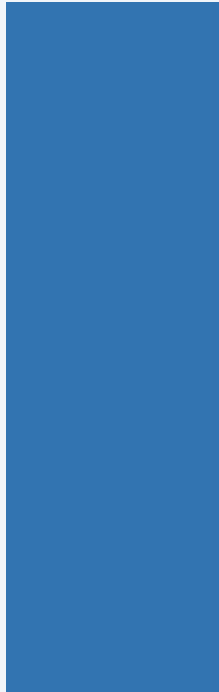
1. Information to be gathered – What data or specimen details will you collect?
2. Collection and recording methods – How will data be collected (e.g., electronic forms, paper records) and documented?
3. Storage location and security – Where will data or specimens be stored (physical or electronic), and what security measures will be used?
4. Associated information – What identifiers or metadata will be linked to the data or specimens?
5. Retention period – How long will data or specimens be stored before destruction or archiving?
6. Responsible personnel – Who will handle receipt, transmission, and storage?
7. Transport procedures – How will data or specimens be transported (e.g., encrypted files, courier, chain of custody)?
8. Previously collected data – If applicable, describe both the original purpose and the proposed new use of these data.

B I U S : ||| ||| ||| |||

62

Next, continue to the **"Collection & Handling of Data"**

Describe how data will be collected in the text box provided.



Data Handling (including specimens if applicable)

* Identifiable Data/Specimens

Will this study involve collecting or using data or specimens that could identify participants, either directly or through linked identifiers (e.g., coded data with access to the key)?

- ☐ Yes
☒ No

* Data Collection

Select all methods you will use to collect data (check all that apply):

- ☐ Personal Interview
☐ Focus Group
☐ Audio Recording
☐ Video Recording
☒ Questionnaire or Survey
☐ Behavioral Observation
☐ Secondary Data (e.g., existing datasets)
☐ Chart Review
☐ Other

* Collection & Handling of Data

Describe how data and/or specimens will be collected, recorded, stored, and managed. Address the following points:

1. Information to be gathered - What data or specimen details will you collect?
2. Collection and recording methods - How will data be collected (e.g., electronic forms, paper records) and documented?
3. Storage location and security - Where will data or specimens be stored (physical or electronic), and what security measures will be used?
4. Associated information - What identifiers or metadata will be linked to the data or specimens?
5. Retention period - How long will data or specimens be stored before destruction or archiving?
6. Responsible personnel - Who will handle receipt, transmission, and storage?
7. Transport procedures - How will data or specimens be transported (e.g., encrypted files, courier, chain of custody)?
8. Previously collected data - If applicable, describe both the original purpose and the proposed new use of these data.

B I U

63 Click "Data and Specimen Confidentiality and Security".

Describe the measures you will take to protect confidentiality of various items in the text box provided.

Attachments

4. Associated information – What identifiers or metadata will be linked to the data or specimens?
5. Retention period – How long will data or specimens be stored before destruction or archiving?
6. Responsible personnel – Who will handle receipt, transmission, and storage?
7. Transport procedures – How will data or specimens be transported (e.g., encrypted files, courier, chain of custody)?
8. Previously collected data – If applicable, describe both the original purpose and the proposed new use of these data.

B I U S L I I O A

Test.

* Data and Specimen Confidentiality and Security

Describe the measures you will take to protect the confidentiality and security of data and/or specimens during storage, use, and transfer. Include details on:

1. Access controls – Who will have access and how will access be restricted?
2. Electronic security – Password protection, encryption, secure servers, or other safeguards.
3. Physical security – Locked cabinets, restricted areas, or other measures for specimen storage.
4. Separation of identifiers – How identifiers will be stored separately from research data/specimens.
5. Transfer procedures – How data/specimens will be securely transmitted or transported.
6. Additional protections – Certificates of Confidentiality or other regulatory protections, if applicable.

B I U S L I I O A

64 Navigate to "Sharing Results with Subjects"

Answer the required question.

Describe the measures you will take to protect the confidentiality and security of data and/or specimens during storage, use, and transfer. Include details on:

1. Access controls – Who will have access and how will access be restricted?
2. Electronic security – Password protection, encryption, secure servers, or other safeguards.
3. Physical security – Locked cabinets, restricted areas, or other measures for specimen storage.
4. Separation of identifiers – How identifiers will be stored separately from research data/specimens.
5. Transfer procedures – How data/specimens will be securely transmitted or transported.
6. Additional protections – Certificates of Confidentiality or other regulatory protections, if applicable.

B I U S L I I O A

Test.

* Sharing Results with Subjects

Will you share study findings or individual participant results with subjects or their healthcare providers (e.g., incidental findings, lab test results, genetic test results)?
☐ Yes
☐ No

* Data or Specimen Banking & Future Research

Will any data and/or specimens from this project be stored for future research use?
☐ Yes
☐ No

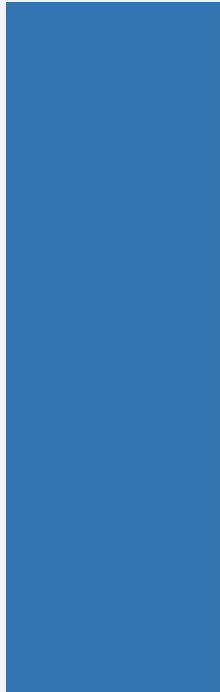
Made with Scribe - <https://scribehow.com>

38

65

Finally, locate the next question under **"Data or Specimen Banking & Future Research"**

Answer the required question.



Describe the measures you will take to protect the confidentiality and security of data and/or specimens during storage, use, and transfer. Include details on:

1. Access controls – Who will have access and how will access be restricted?
2. Electronic security – Password protection, encryption, secure servers, or other safeguards.
3. Physical security – Locked cabinets, restricted areas, or other measures for specimen storage.
4. Separation of identifiers – How identifiers will be stored separately from research data/specimens.
5. Transfer procedures – How data/specimens will be securely transmitted or transported.
6. Additional protections – Certificates of Confidentiality or other regulatory protections, if applicable.

B I U

Test.

*** Sharing Results with Subjects**

Will you share study findings or individual participant results with subjects or their healthcare providers (e.g., incidental findings, lab test results, genetic test results)?

☐ Yes

☒ No

*** Data or Specimen Banking & Future Research**

Will any data and/or specimens from this project be stored for future research use?

☐ Yes

☐ No

66

Click here to advance to the next page.

Describe the measures you will take to protect the confidentiality and security of data and/or specimens during storage, use, and transfer. Include details on:

Access controls – Who will have access and how will access be restricted?

Electronic security – Password protection, encryption, secure servers, or other safeguards.

Physical security – Locked cabinets, restricted areas, or other measures for specimen storage.

Separation of identifiers – How identifiers will be stored separately from research data/specimens.

Transfer procedures – How data/specimens will be securely transmitted or transported.

Additional protections – Certificates of Confidentiality or other regulatory protections, if applicable.

I U

t.

*** Sharing Results with Subjects**

Will you share study findings or individual participant results with subjects or their healthcare providers (e.g., incidental findings, lab test results, genetic test results)?

☐ Yes

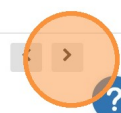
☒ No

*** Data or Specimen Banking & Future Research**

Will any data and/or specimens from this project be stored for future research use?

☐ Yes

☒ No



67

Reminder: The "**Study Design and Procedures**" section should now have a checkmark beside the tab if each of the required questions have been completed.



68

You have now reached the "**Participant Protection**" page.

← SUBMISSION DETAILS | Example IRB Submission in Cayuse - Initial

CREATE PDF | COMPARE | SAVE

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Participant Selection ✓
- Study Design and P... ✓
- Participant Protection**
- Attachments

Participant Protection

Potential Risks and Mitigation

Describe all reasonably foreseeable risks, discomforts, hazards, or inconveniences to participants related to their involvement in the study. Address the following points:

1. Types of Risks - Physical; Psychological; Social; Legal; Economic (e.g., extra costs or time burden); Risk of breach of confidentiality (common to most studies)
2. Risk Characteristics - Probability (likelihood of occurrence); Magnitude (severity); Duration (how long effects may last); Reversibility (can effects be undone or treated?)
3. Unforeseeable Risks - Identify any procedures that may involve risks currently unforeseeable.
4. Risks to Non-Participants - If applicable, describe risks to individuals who are not study subjects.
5. Risk Management Strategies - Explain how risks will be minimized or managed (e.g., psychological support, option to skip sensitive questions, safety monitoring).

Test.

Potential Benefits

Describe any potential benefits to participants from taking part in this study. Address the following:

1. Direct benefits - Will participants gain any health, educational, or personal benefit?
2. Indirect benefits - Will the study contribute to generalizable knowledge or future improvements in care or services?
3. Benefit characteristics - For each potential benefit, describe:
 - Probability (likelihood of occurrence)
 - Magnitude (extent of benefit)
 - Duration (how long the benefit may last)

Note: Incentives such as payments or gifts are not considered benefits.

69

Under the **"Potential Risks and Mitigation"** section, describe all foreseeable risk, discomforts, hazards, etc. in the text box provided.

Project Personnel	✓
Basic Information	✓
Participant Selection	✓
Study Design and P...	✓
Participant Protection	
Attachments	

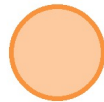
Participant Protection

* Potential Risks and Mitigation

Describe all reasonably foreseeable risks, discomforts, hazards, or inconveniences to participants related to their involvement in the study. Address the following points:

1. Types of Risks - Physical; Psychological; Social; Legal; Economic (e.g., extra costs or time burden); Risk of breach of confidentiality (common to most studies)
2. Risk Characteristics - Probability (likelihood of occurrence); Magnitude (severity); Duration (how long effects may last); Reversibility (can effects be undone or treated?)
3. Unforeseeable Risks - Identify any procedures that may involve risks currently unforeseeable.
4. Risks to Non-Participants - If applicable, describe risks to individuals who are not study subjects.
5. Risk Management Strategies - Explain how risks will be minimized or managed (e.g., psychological support, option to skip sensitive questions, safety monitoring).

B I U ↺ ↻ ☰ ☷ ☹ ☲



* Potential Benefits

Describe any potential benefits to participants from taking part in this study. Address the following:

1. Direct benefits - Will participants gain any health, educational, or personal benefit?
2. Indirect benefits - Will the study contribute to generalizable knowledge or future improvements in care or services?
3. Benefit characteristics - For each potential benefit, describe:
 - Probability (likelihood of occurrence)
 - Magnitude (extent of benefit)
 - Duration (how long the benefit may last)

70

Scroll down to **"Potential Benefits"**.

Describe any potential benefits that participants may receive.

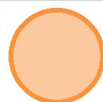
* Potential Benefits

Describe any potential benefits to participants from taking part in this study. Address the following:

1. Direct benefits - Will participants gain any health, educational, or personal benefit?
2. Indirect benefits - Will the study contribute to generalizable knowledge or future improvements in care or services?
3. Benefit characteristics - For each potential benefit, describe:
 - Probability (likelihood of occurrence)
 - Magnitude (extent of benefit)
 - Duration (how long the benefit may last)

Note: Incentives such as payments or gifts are not considered benefits.

B I U ↺ ↻ ☰ ☷ ☹ ☲



* Artificial Intelligence (AI) Data & Safety Monitoring

Will any study procedures involve the use of artificial intelligence (AI), such as interacting with participants, accessing identifiable data, or analyzing data?

[Responsible Use of AI](#)

- ☐ No
☐ Yes

71

Next, complete the required questions under **"AI Data and Safety Monitoring"** and **"Deception"**.

Example IRB Submission in Cayuse - Initial

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Participant Selection ✓
- Study Design and P... ✓
- Participant Protection**
- Attachments

*** Artificial Intelligence (AI) Data & Safety Monitoring**

Will any study procedures involve the use of artificial intelligence (AI), such as interacting with participants, accessing identifiable data, or analyzing data?
[Responsible Use of AI](#)

☒ No
☐ Yes

Deception

*** Will this study use deception as a method of data collection?**

☐ No
☐ Yes

Informed Consent Process

[USM Consent Templates](#)

*** Waivers or Alterations**

Will this project involve any waivers or alterations of the informed consent process (in part or in full)?

☐ No
☐ Yes

*** Consent Process**

Describe the procedures for obtaining informed consent. Include:

72

Next, navigate to the **"Informed Consent Process"** section.

Answer the required questions under **"Waivers or Alterations"** and **"Consent Process"**.

☐ Yes

Deception

*** Will this study use deception as a method of data collection?**

☒ No
☐ Yes

Informed Consent Process

[USM Consent Templates](#)

*** Waivers or Alterations**

Will this project involve any waivers or alterations of the informed consent process (in part or in full)?

☒ No
☐ Yes

*** Consent Process**

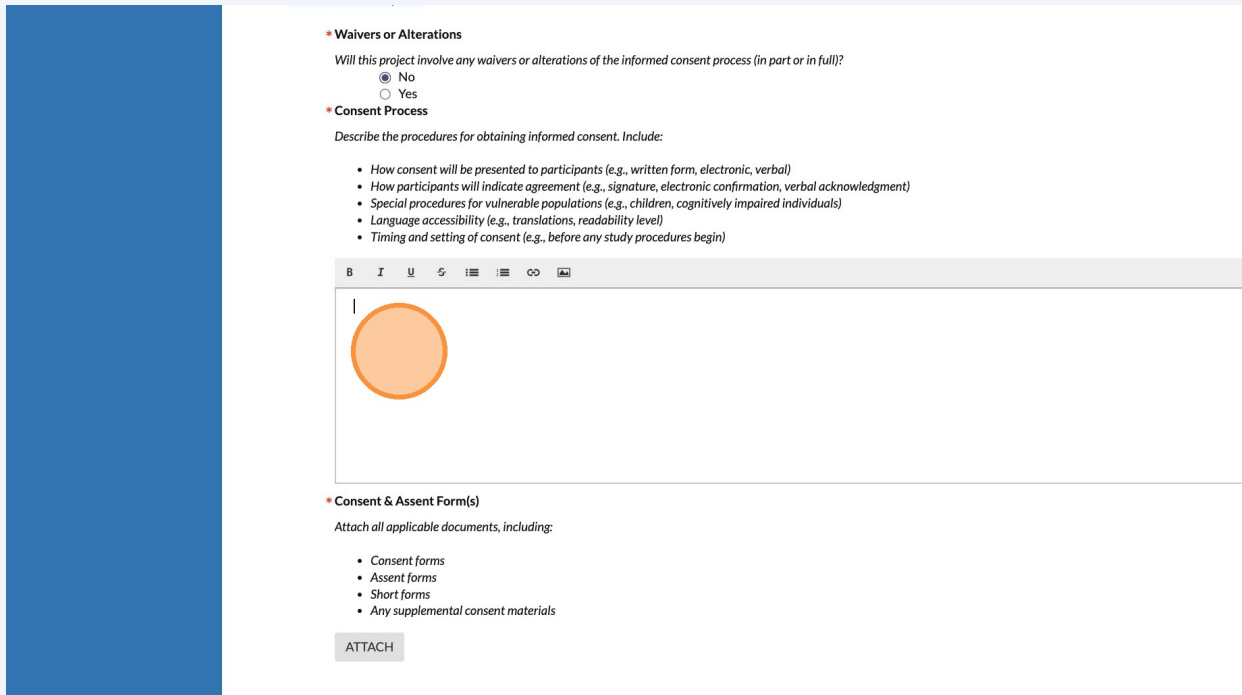
Describe the procedures for obtaining informed consent. Include:

- How consent will be presented to participants (e.g., written form, electronic, verbal)
- How participants will indicate agreement (e.g., signature, electronic confirmation, verbal acknowledgment)
- Special procedures for vulnerable populations (e.g., children, cognitively impaired individuals)
- Language accessibility (e.g., translations, readability level)
- Timing and setting of consent (e.g., before any study procedures begin)

73

Next, navigate to the **"Consent and Assent Form(s)"** section.

Attach all applicable documents.



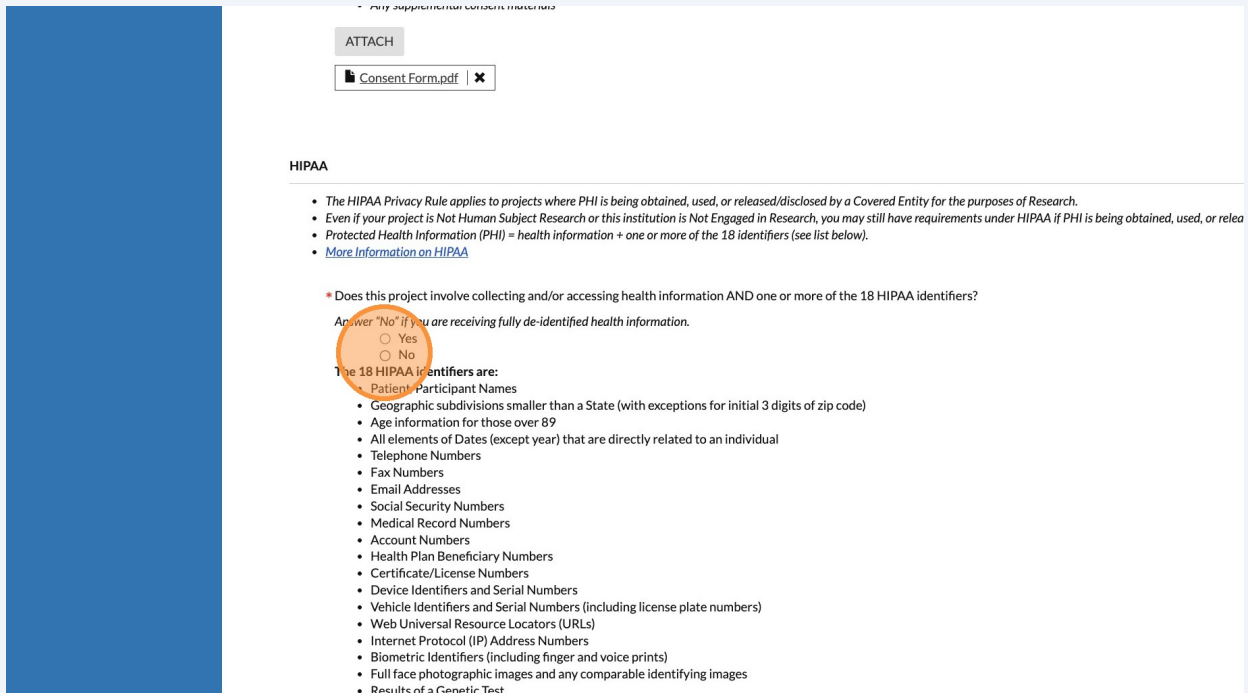
The screenshot displays a research ethics form with the following sections:

- * Waivers or Alterations**
Will this project involve any waivers or alterations of the informed consent process (in part or in full)?
☒ No
☐ Yes
- * Consent Process**
Describe the procedures for obtaining informed consent. Include:
 - How consent will be presented to participants (e.g., written form, electronic, verbal)
 - How participants will indicate agreement (e.g., signature, electronic confirmation, verbal acknowledgment)
 - Special procedures for vulnerable populations (e.g., children, cognitively impaired individuals)
 - Language accessibility (e.g., translations, readability level)
 - Timing and setting of consent (e.g., before any study procedures begin)
- * Consent & Assent Form(s)**
Attach all applicable documents, including:
 - Consent forms
 - Assent forms
 - Short forms
 - Any supplemental consent materials

Below the 'Consent Process' section is a text area with a rich text editor toolbar (B, I, U, S, list, link, unlink, image) and a large orange circle placeholder. Below the 'Consent & Assent Form(s)' section is an 'ATTACH' button.

74 Finally, refer to the "HIPAA" section.

Complete the required inquiry.



ATTACH

Consent Form.pdf | X

HIPAA

- The HIPAA Privacy Rule applies to projects where PHI is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research.
- Even if your project is Not Human Subject Research or this institution is Not Engaged in Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a Covered Entity.
- Protected Health Information (PHI) = health information + one or more of the 18 identifiers (see list below).
- [More Information on HIPAA](#)

• Does this project involve collecting and/or accessing health information AND one or more of the 18 HIPAA identifiers?

Answer "No" if you are receiving fully de-identified health information.

☐ Yes

☒ No

The 18 HIPAA identifiers are:

- Patient/Participant Names
- Geographic subdivisions smaller than a State (with exceptions for initial 3 digits of zip code)
- Age information for those over 89
- All elements of Dates (except year) that are directly related to an individual
- Telephone Numbers
- Fax Numbers
- Email Addresses
- Social Security Numbers
- Medical Record Numbers
- Account Numbers
- Health Plan Beneficiary Numbers
- Certificate/License Numbers
- Device Identifiers and Serial Numbers
- Vehicle Identifiers and Serial Numbers (including license plate numbers)
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) Address Numbers
- Biometric Identifiers (including finger and voice prints)
- Full face photographic images and any comparable identifying images
- Results of a Genetic Test

75 When you are ready to proceed to the next page, **click here.**

The HIPAA Privacy Rule applies to projects where PHI is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research.

Even if your project is Not Human Subject Research or this institution is Not Engaged in Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a Covered Entity.

Protected Health Information (PHI) = health information + one or more of the 18 identifiers (see list below).

[More Information on HIPAA](#)

Does this project involve collecting and/or accessing health information AND one or more of the 18 HIPAA identifiers?

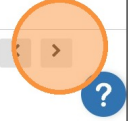
Answer "No" if you are receiving fully de-identified health information.

☐ Yes

☒ No

The 18 HIPAA identifiers are:

- Patient/Participant Names
- Geographic subdivisions smaller than a State (with exceptions for initial 3 digits of zip code)
- Age information for those over 89
- All elements of Dates (except year) that are directly related to an individual
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- Fax Numbers
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- Account Numbers
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- Certificate/License Numbers
- Device Identifiers and Serial Numbers
- Vehicle Identifiers and Serial Numbers (including license plate numbers)
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) Address Numbers
- Biometric Identifiers (including finger and voice prints)
- Full face photographic images and any comparable identifying images
- Results of a Genetic Test
- Any other unique identifying number, characteristic, or code



76 You have now reached the "Attachments" page.

The screenshot shows the Cayuse Human Ethics interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main header displays 'SUBMISSION DETAILS' and 'Example IRB Submission in Cayuse - Initial'. The left sidebar lists sections: 'Getting Started', 'Project Personnel', 'Basic Information', 'Participant Selection', 'Study Design and P...', 'Participant Protect...', 'Attachments' (highlighted with a red circle), 'Routing', and 'COMPLETE SUBMISSION'. The main content area is titled 'Attachments' and shows sections for 'Project Personnel' (Study Personnel Training Documentation), 'Basic Information' (External Collaborator Information), and 'Study Design and Procedures' (Recruitment Documents). An 'ATTACH' button is visible next to the 'Study Personnel Training Documentation' section, and a file named 'Citi Certificates.pdf' is listed below it.

77 On this page, you will see a copy of each file that you have attached to your application.

If you would like to add any more files, select **"attach"**.

Each file that you add should populate on this page.

This screenshot is similar to the previous one, showing the 'Attachments' page. The 'Attachments' section in the left sidebar is highlighted with a red circle. In the main content area, the 'ATTACH' button next to the 'Study Personnel Training Documentation' section is also highlighted with a red circle. The file 'Citi Certificates.pdf' is still listed below the button.

78

Note: Upon completion, The "**Attachments**" tab should have a checkmark it.



79

Direct your attention to the left hand side of this page.

When the entire protocol has checkmarks by each tab, you'll notice that a **"Complete Submission"** button will appear at the bottom left.

To submit the protocol, select the "Complete Submission".

Getting Started

Project Personnel ✓

Basic Information ✓

Participant Selection ✓

Study Design and P... ✓

Participant Protect... ✓

Attachments ✓

Routing Send to PI for certification? ✓

COMPLETE SUBMISSION >

Study Personnel Training Documentation

Upload documentation of any required training (e.g., CITI training) for each member of study personnel.

ATTACH

Citi Certificates.pdf ✕

Basic Information

External Collaborator Information

Supporting Documents for External Sites

ATTACH

Study Materials.pdf ✕

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 ✕

Study Instruments

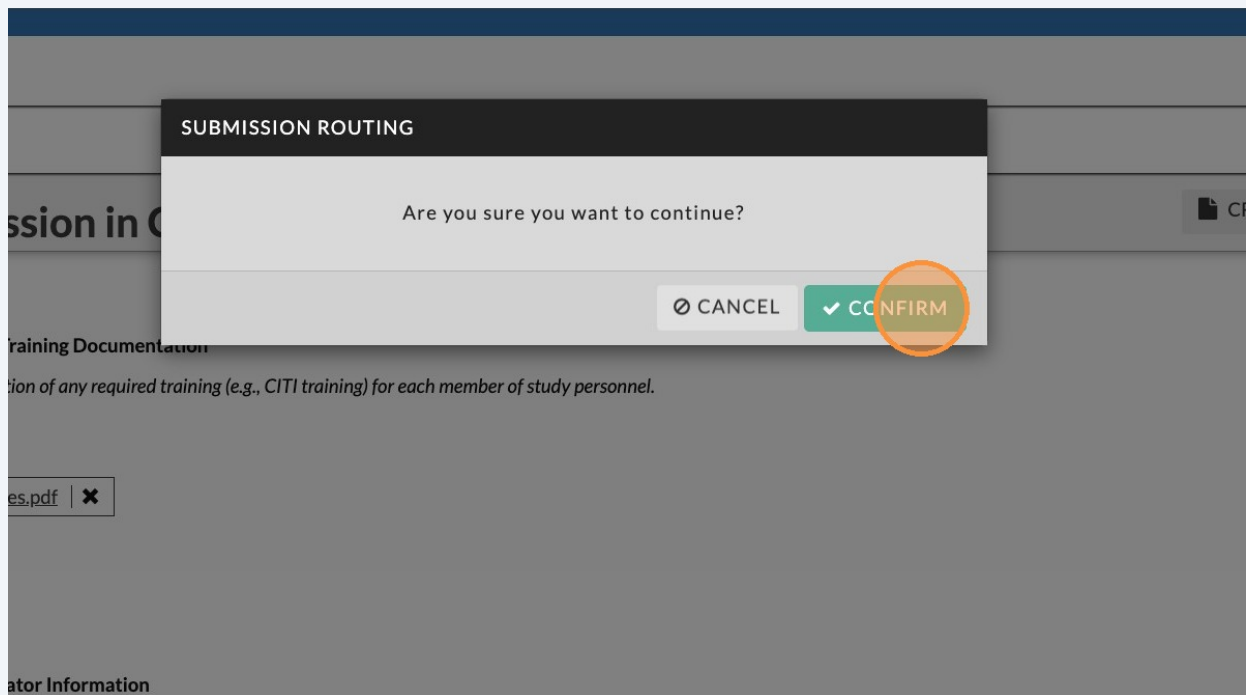
Attach all instruments (i.e. surveys, scripts, personality scales, questionnaires, evaluation blanks, etc.) to be used in the study.

ATTACH

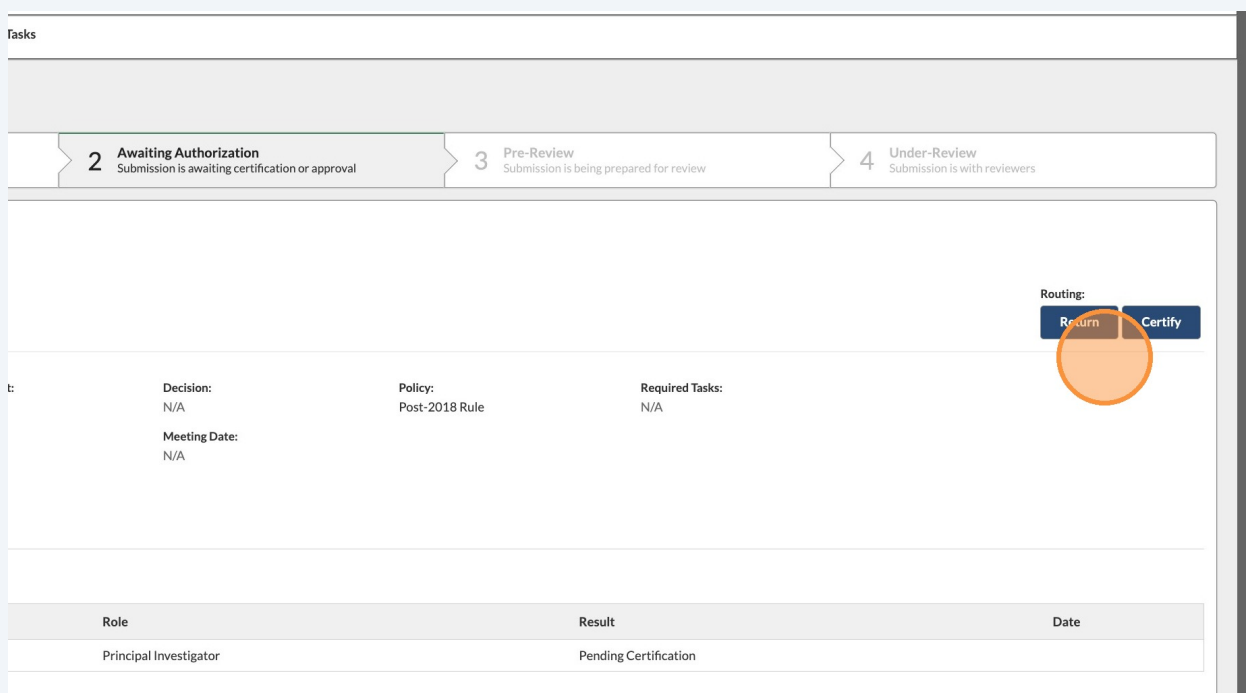
Study Materials.pdf ✕

80 You will be prompted with a confirmation message.

Click **"Confirm"**



81 After you press confirm, you'll be prompted to a page where you can **"Return"** or **"Certify"** the protocol.



82 If you need to make further changes, select **"Return"**

If you are ready to submit the proposal for review, Click "Certify"

Products Irene Investigator

Tasks

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

Routing: Return Certify

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

Meeting Date: N/A

Role	Result	Date
Principal Investigator	Pending Certification	

83 If you press **"Certify"** a message will populate.

Read the message.

If you can confirm that all statements are true, Click "Confirm".

The screenshot shows a 'Certify' modal window with a paper plane icon. The text inside reads: '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.' At the bottom right, there are 'Cancel' and 'Confirm' buttons. The 'Confirm' button is highlighted with an orange circle.

84 You'll immediately notice that your document will be labeled as "Under Pre-Review"

The screenshot shows the Cayuse Human Ethics dashboard. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area shows a progress bar with four stages: 'In-Draft' (Submission is with researchers), 'Awaiting Authorization' (Submission is awaiting certification or approval), '3 Pre-Review' (Submission is being prepared for review), and '4'. The 'Pre-Review' stage is highlighted with an orange circle. Below the progress bar, there is a section titled 'Under Pre-Review' with a sub-header 'Initial' and a sub-text 'IRB-26-66 - Example IRB Submission in Cayuse'. This section includes buttons for 'View', 'PDF', and 'Delete'. Below these buttons, there is a table with the following data:

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

Below the table, there are tabs for 'Approvals', 'Task History', and 'Attachments'. The 'Approvals' tab is selected. Below the tabs, there is a section titled 'Research Team' with a table that has the following headers: 'Name', 'Role', 'Result', and 'Date'.

85

Your document will also advance in the workflow to the **"Awaiting Authorization"** phase, meaning you have completed your part.

You will receive further communication from Cayuse if more action is needed from you.

cayuse
Human Ethics

Dashboard Studies Submissions Tasks

Studies / Study Details / Submission Details

✓ **In-Draft**
Submission is with researchers

✓ **Awaiting Authorization**
Submission is awaiting certification or approval

3 **Pre-Review**
Submission is being prepared for review

4

Under Pre-Review

Initial
IRB-26-66 - Example IRB Submission in Cayuse

View PDF Delete

PI: Irene Investigator 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

Approvals Task History Attachments

Research Team

Name	Role	Result	Date
------	------	--------	------