

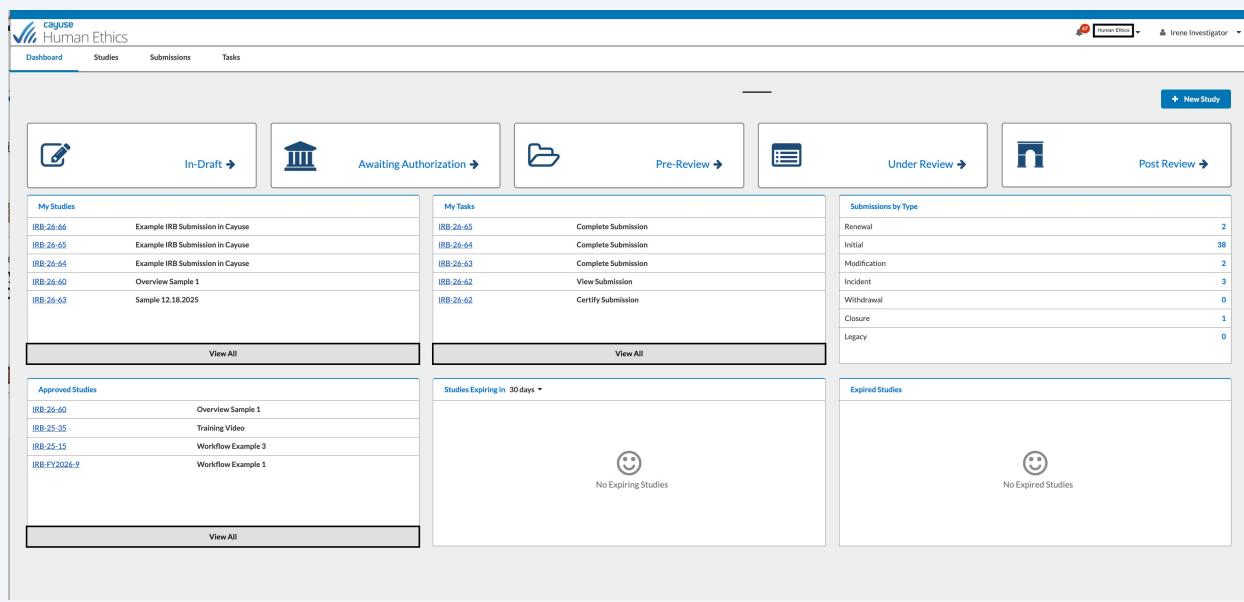
# How to Submit an Initial Application on Cayuse

Scribe<sup>®</sup>

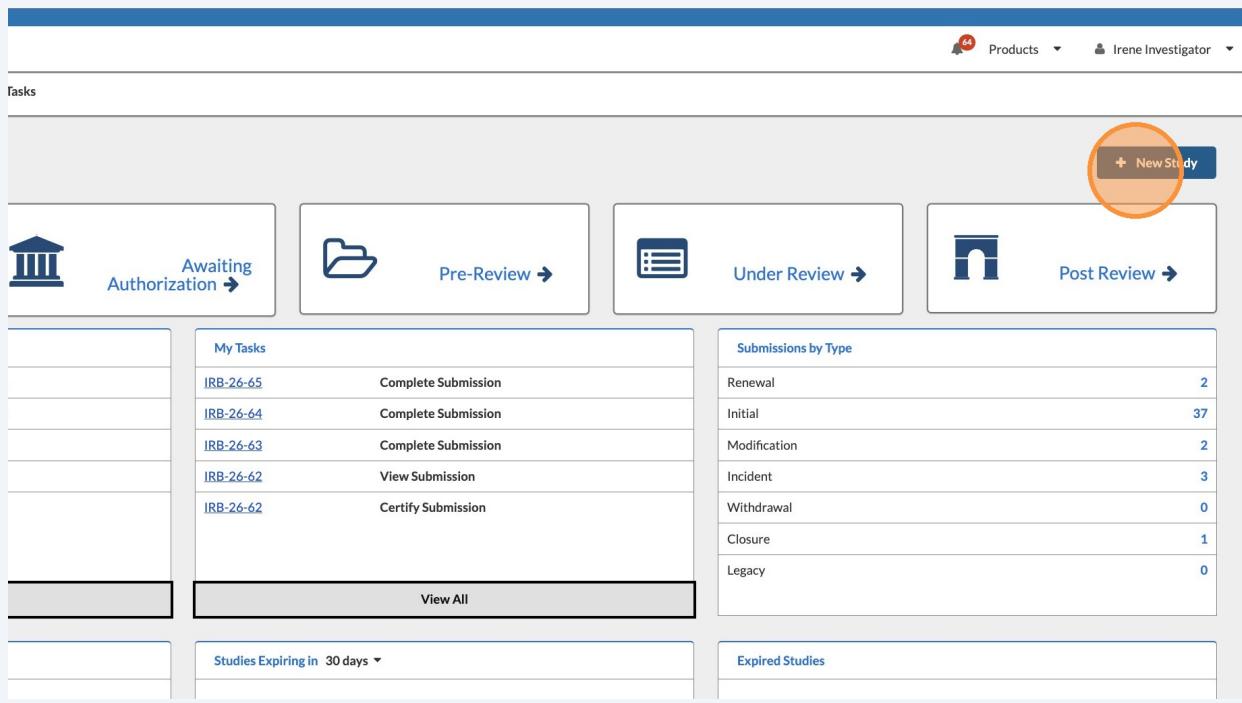
This guide provides a step-by-step process for submitting an initial application in Cayuse, ensuring that users understand each requirement and avoid common pitfalls. By following the outlined steps, researchers can efficiently navigate the application, ensuring all necessary information is included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

1

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

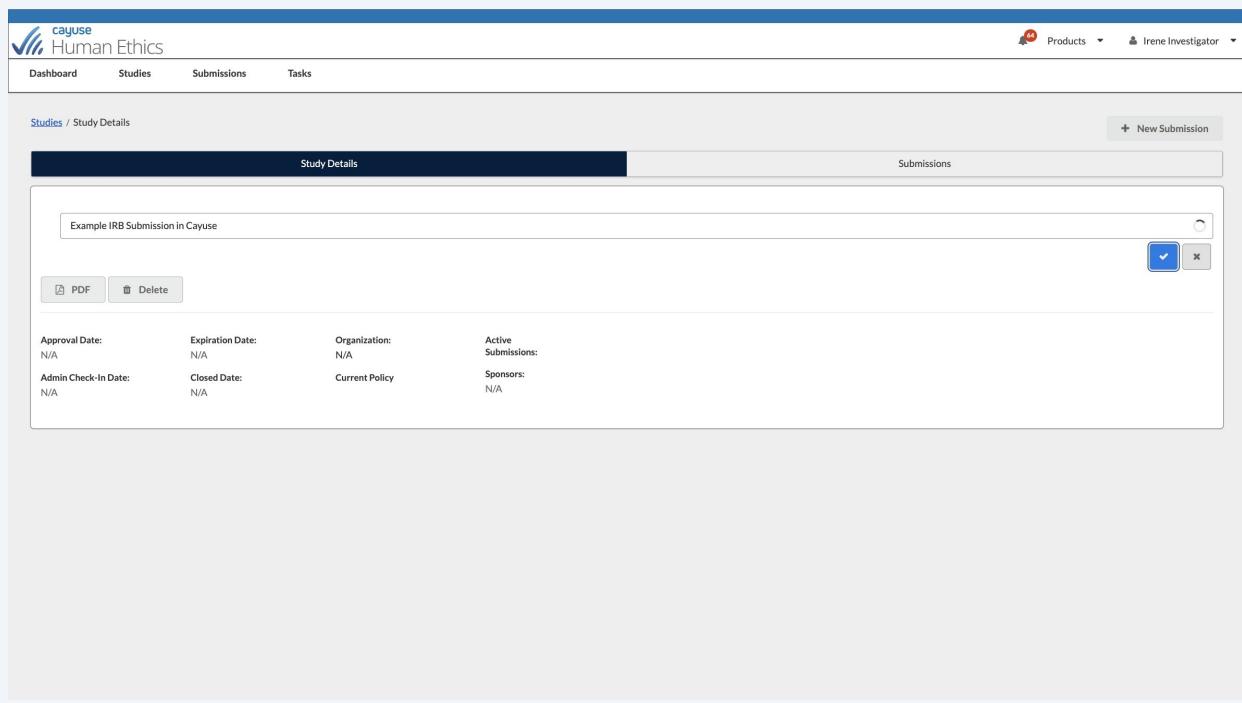


## 2 Click "New Study"



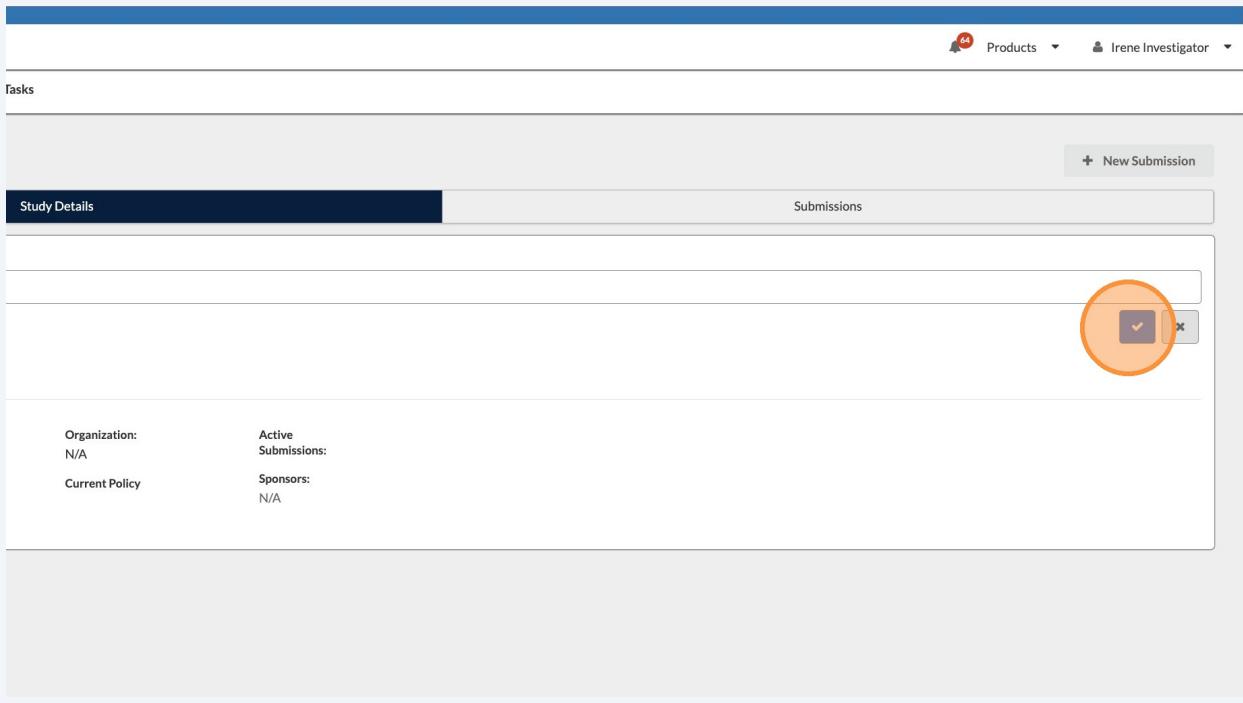
The screenshot shows the Cayuse Human Ethics dashboard. At the top right, there are notifications for 64 products and a user profile for Irene Investigator. Below the header, there is a section titled 'Tasks' with four status boxes: 'Awaiting Authorization' (with a building icon), 'Pre-Review' (with a folder icon), 'Under Review' (with a document icon), and 'Post Review' (with a document icon). A large orange circle highlights the 'New Study' button in the top right corner of the dashboard area. The main content area includes sections for 'My Tasks' (listing submissions like IRB-26-65, IRB-26-64, etc.) and 'Submissions by Type' (listing Renewal, Initial, Modification, Incident, Withdrawal, Closure, and Legacy). There are also sections for 'Studies Expiring in 30 days' and 'Expired Studies'.

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



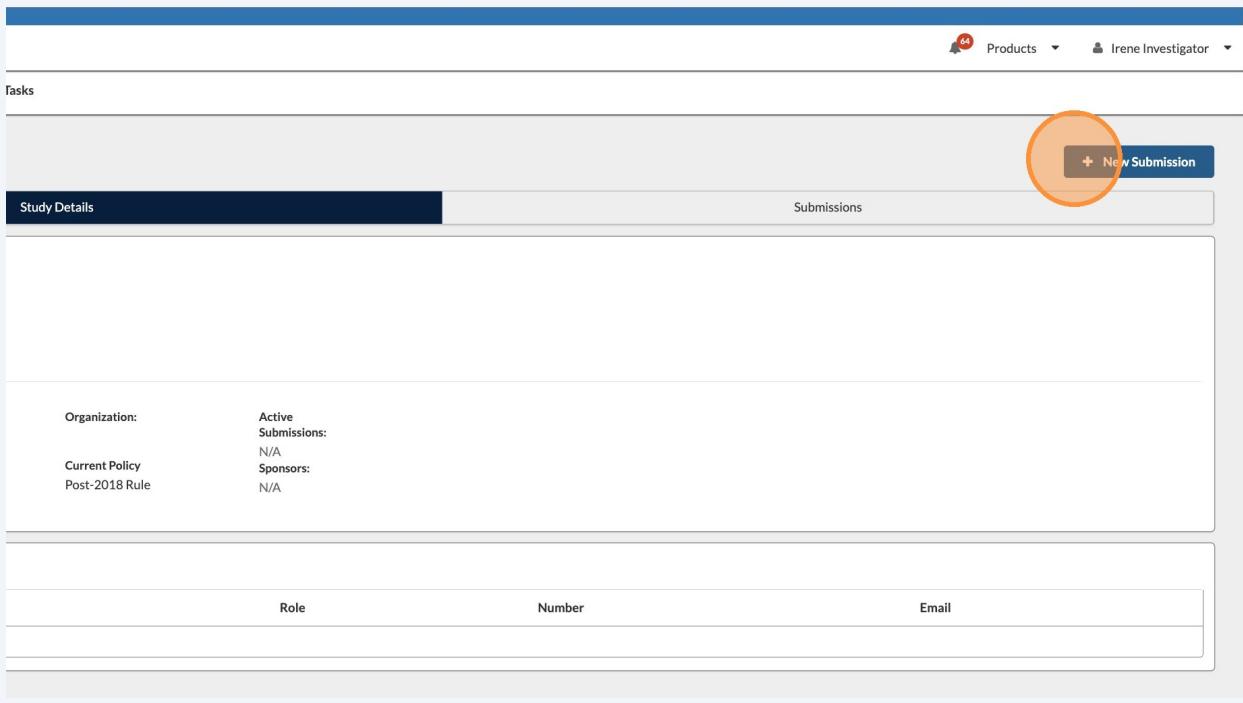
The screenshot shows the 'Study Details' page. At the top, there is a navigation bar with 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The 'Studies' tab is active. Below the navigation, the page title is 'Studies / Study Details'. A 'New Submission' button is located in the top right corner. The main content area is titled 'Study Details' and contains a text box with the placeholder 'Example IRB Submission in Cayuse'. Below the text box are two buttons: 'PDF' and 'Delete'. A table provides detailed information: Approval Date (N/A), Expiration Date (N/A), Organization (N/A), Active Submissions (N/A); Admin Check-In Date (N/A), Closed Date (N/A), Current Policy (N/A), Sponsors (N/A). A large orange circle highlights the 'New Submission' button.

4 Click "Confirm"



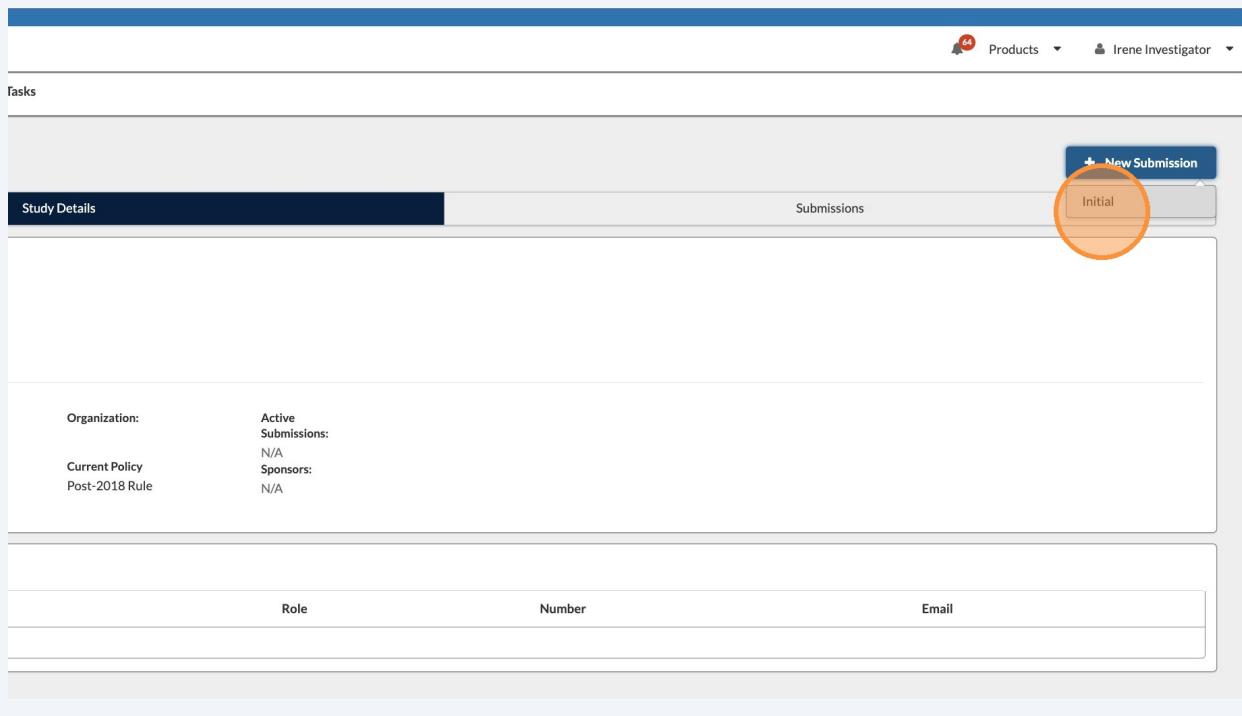
The screenshot shows a software interface with a dark blue header bar. On the right side of the header are icons for 'Products' (with a red notification badge) and 'Irene Investigator'. Below the header is a 'Tasks' section. The main content area has a dark blue header bar with 'Study Details' on the left and 'Submissions' on the right. A large orange circle highlights the 'New Submission' button, which is a dark blue button with a white plus sign and the text 'New Submission'.

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

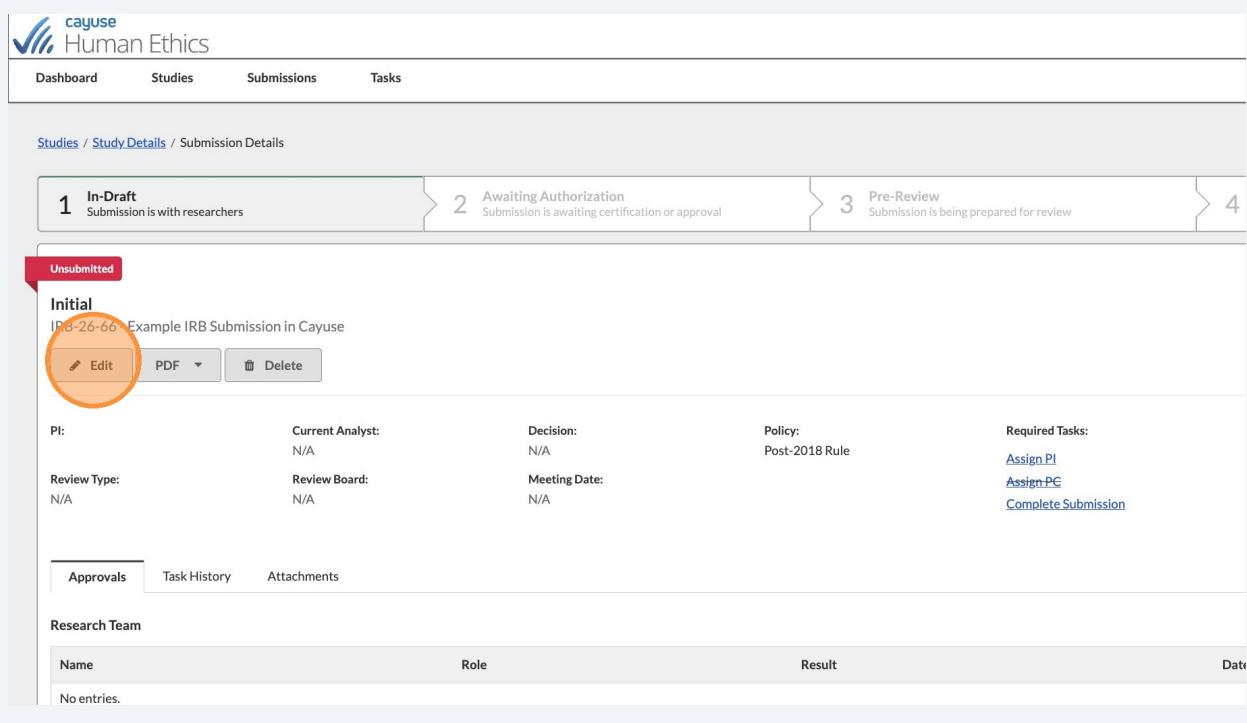


The screenshot shows the same software interface as the previous step, but with a table visible below the main content area. The table has three columns: 'Role', 'Number', and 'Email'. A large orange circle highlights the 'New Submission' button in the top right corner of the main content area.

## 6 Click "Initial"



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



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](mailto:IRBHelp@usm.edu)

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

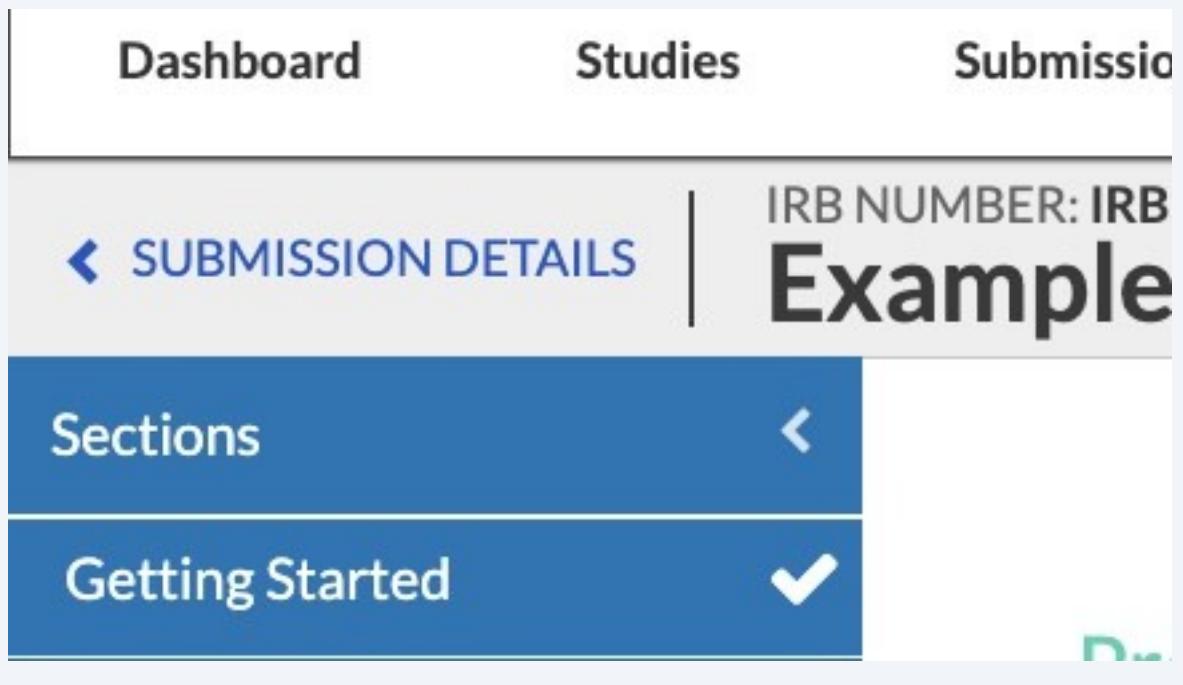
Yes, I am starting a new submission.  
 Yes, I am bringing over a previous submission from InfoEd for a modification, renewal, or incident report.

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.

Slections

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 do not follow this requirement will be rejected.

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

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

Faculty  
 Student  
\* Student researchers cannot serve as PI; your advisor must be listed as PI. Applications that do not follow this requirement will be rejected.

Undergraduate Student  
 Graduate Student

Staff  
 Other

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](mailto:RISGA@usm.edu) for assistance.

\* Principal Investigator

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

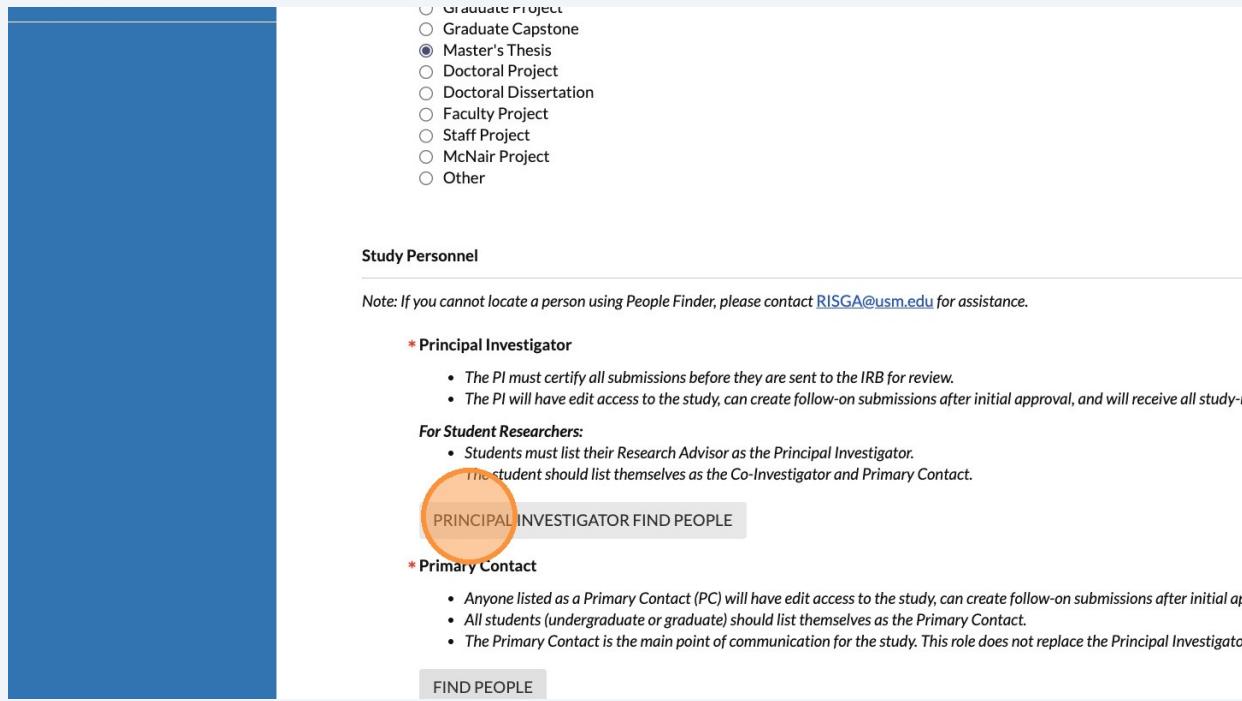
14

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*



The screenshot shows a user interface for selecting study personnel. On the left, a vertical blue sidebar is visible. On the right, a list of project types is shown with 'Master's Thesis' selected. Below this is a 'Study Personnel' section with a note about using People Finder. It includes sections for 'Principal Investigator' and 'Primary Contact', each with a bulleted list of responsibilities. A large orange circle highlights the 'PRINCIPAL INVESTIGATOR FIND PEOPLE' button, which is also highlighted with a yellow background. A 'FIND PEOPLE' button is located at the bottom of the section.

- 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](mailto: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-related notifications.

**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.

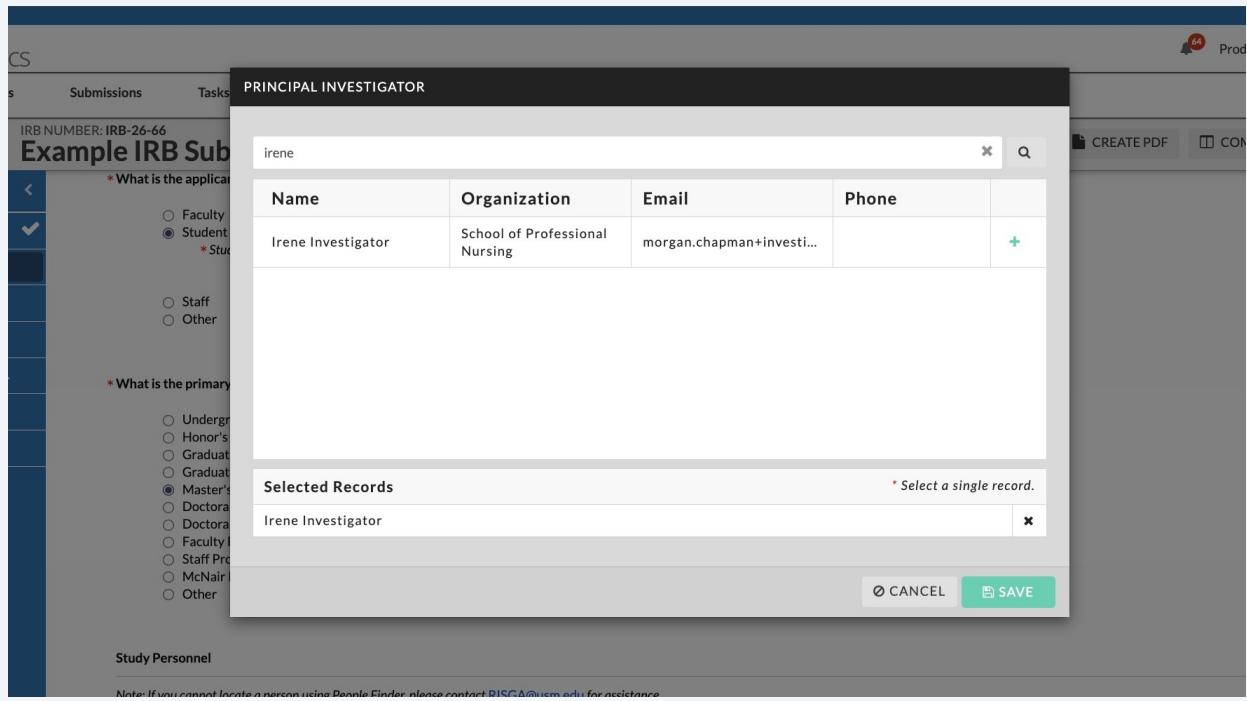
**PRINCIPAL INVESTIGATOR FIND PEOPLE**

**\*Primary Contact**

- Anyone listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related notifications.
- 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.

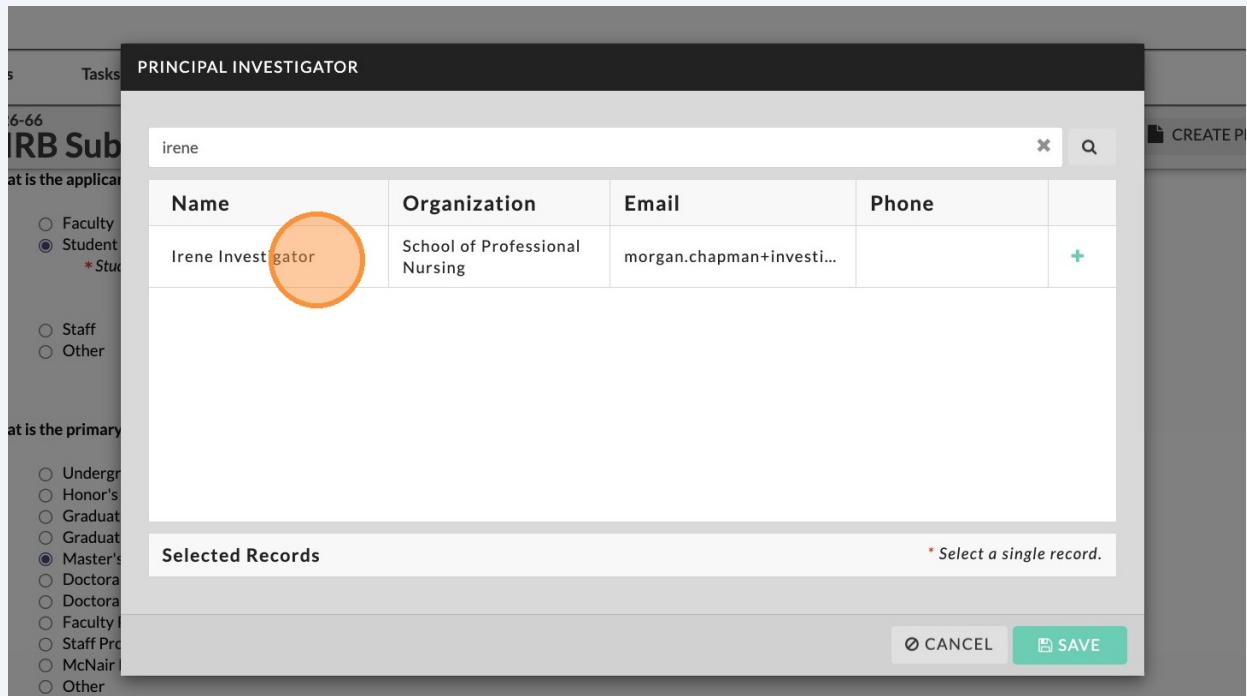


The screenshot shows a search interface for a Principal Investigator. The search term 'irene' is entered in the search bar. A single result is displayed in the table:

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

Below the table, a dropdown menu titled 'Selected Records' shows the same result: 'Irene Investigator'. The 'SAVE' button is visible at the bottom right of the modal.

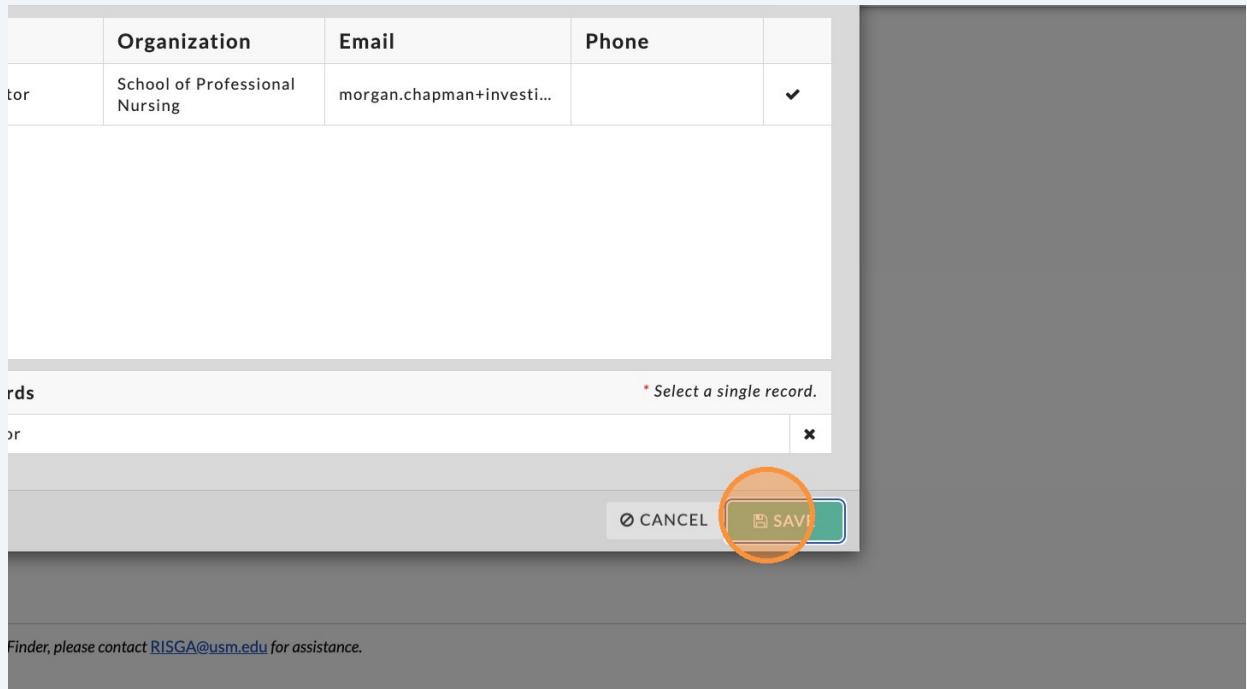
**16** Once the appropriate party is located, click their name on the dropdown menu.



The screenshot shows the same search interface as the previous one, but with a large orange circle highlighting the name 'Irene Investigator' in the 'Selected Records' dropdown menu. The 'SAVE' button is visible at the bottom right of the modal.

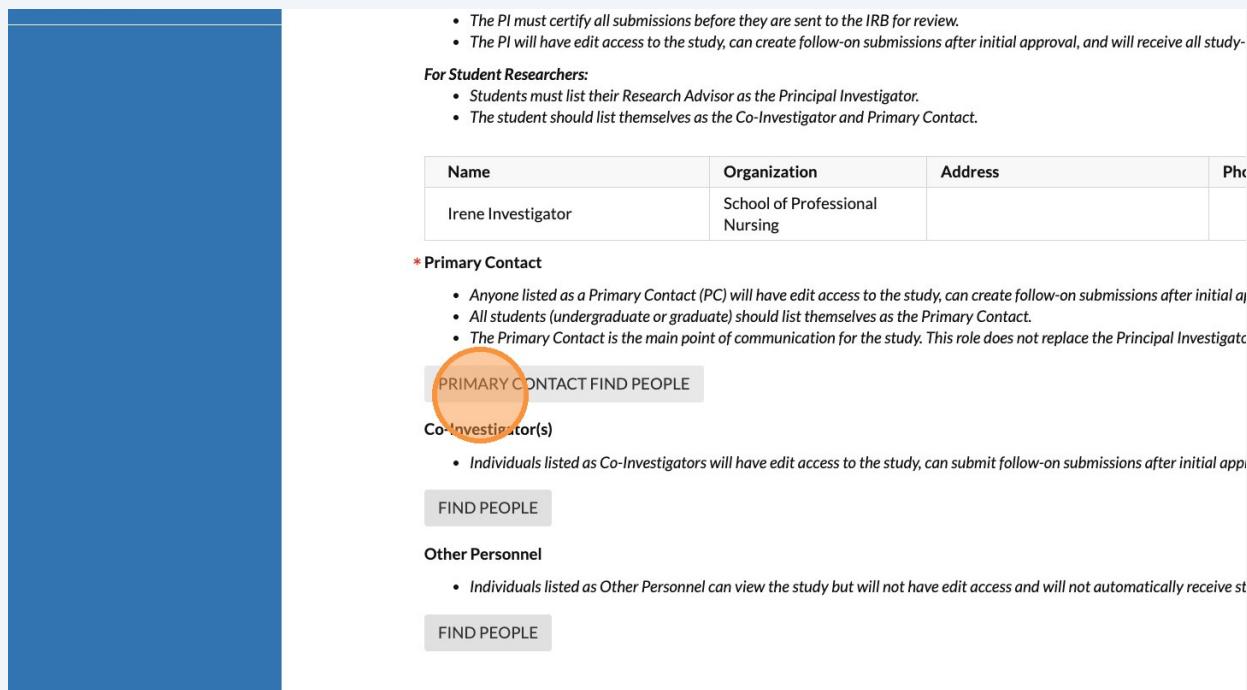
17 Press "Save".

**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.**



A screenshot of a software interface. At the top, there is a table with three columns: 'Organization', 'Email', and 'Phone'. The 'Organization' column contains 'School of Professional Nursing', the 'Email' column contains 'morgan.chapman+investi...', and the 'Phone' column has a dropdown menu with a checkmark. Below the table, there is a search bar with the placeholder 'Search' and a note 'Select a single record.' To the right of the search bar is a button with an 'X'. At the bottom right of the interface is a button labeled 'SAVE' with a circled orange border around it. The bottom of the screen has a footer with the text 'Finder, please contact [RISGA@usm.edu](mailto:RISGA@usm.edu) for assistance.'

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



A screenshot of a software interface. At the top, there is a list of instructions for the PI and for student researchers. Below this, there is a table with columns for 'Name', 'Organization', 'Address', and 'Phone'. The table has one row with 'Irene Investigator' in the 'Name' column and 'School of Professional Nursing' in the 'Organization' column. Below the table, there is a section titled '\* Primary Contact' with a list of instructions. At the bottom, there are three buttons: 'PRIMARY CONTACT FIND PEOPLE' (circled in orange), 'Co-Investigator(s)', and 'Other Personnel'. Each button has a 'FIND PEOPLE' button below it.

- 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
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 approval, and will receive all study-related communications.
- 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)**

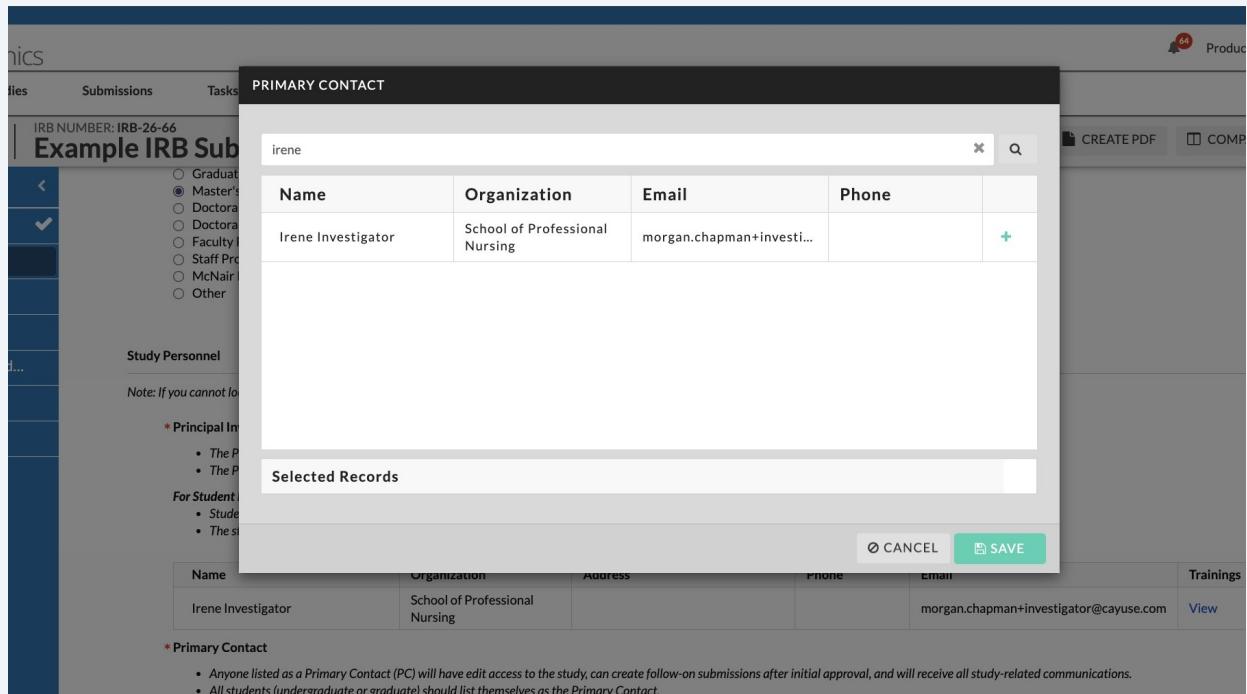
- Individuals listed as Co-Investigators will have edit access to the study, can submit follow-on submissions after initial approval, and will receive all study-related communications.

**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.

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.**

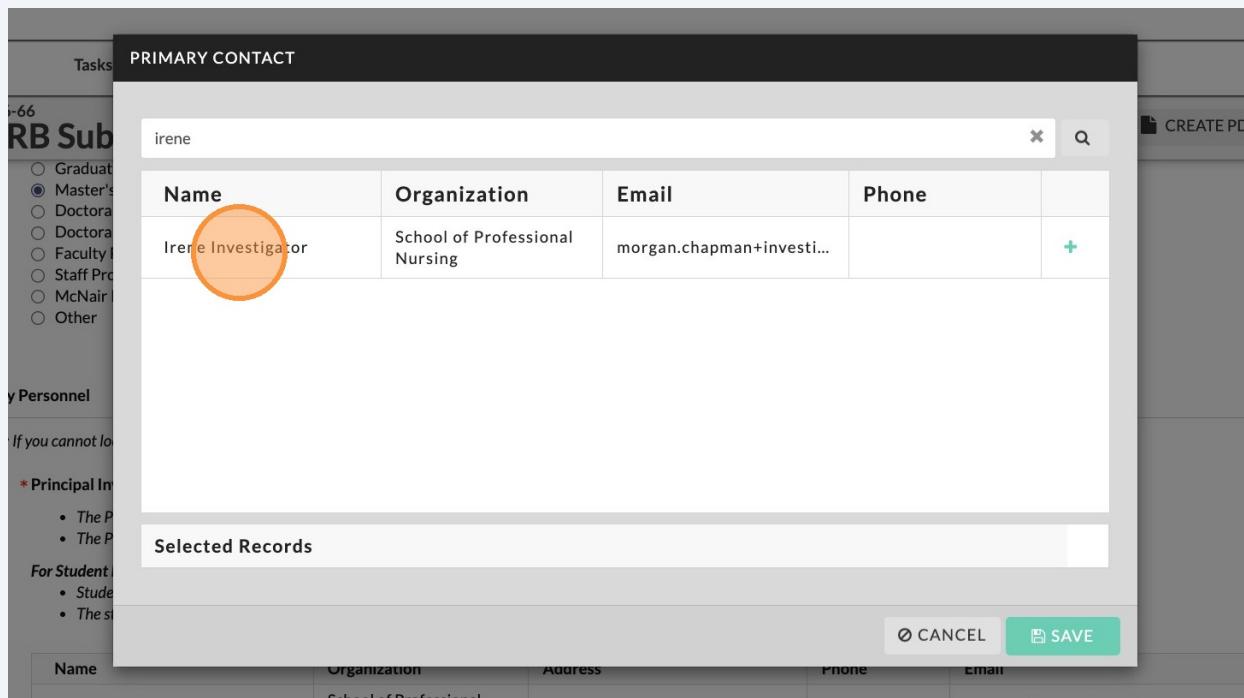


The screenshot shows the 'PRIMARY CONTACT' search results for 'irene'. The search bar at the top contains 'irene'. The results table has columns: Name, Organization, Email, and Phone. One record is listed: Irene Investigator, School of Professional Nursing, morgan.chapman+investi..., and a plus sign for adding more. Below the table, there is a note: 'Note: If you cannot locate the Primary Contact, please contact the Study Personnel Manager.' There is also a section for 'Selected Records' with a table showing the same information for Irene Investigator. At the bottom, there is a note about 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.'

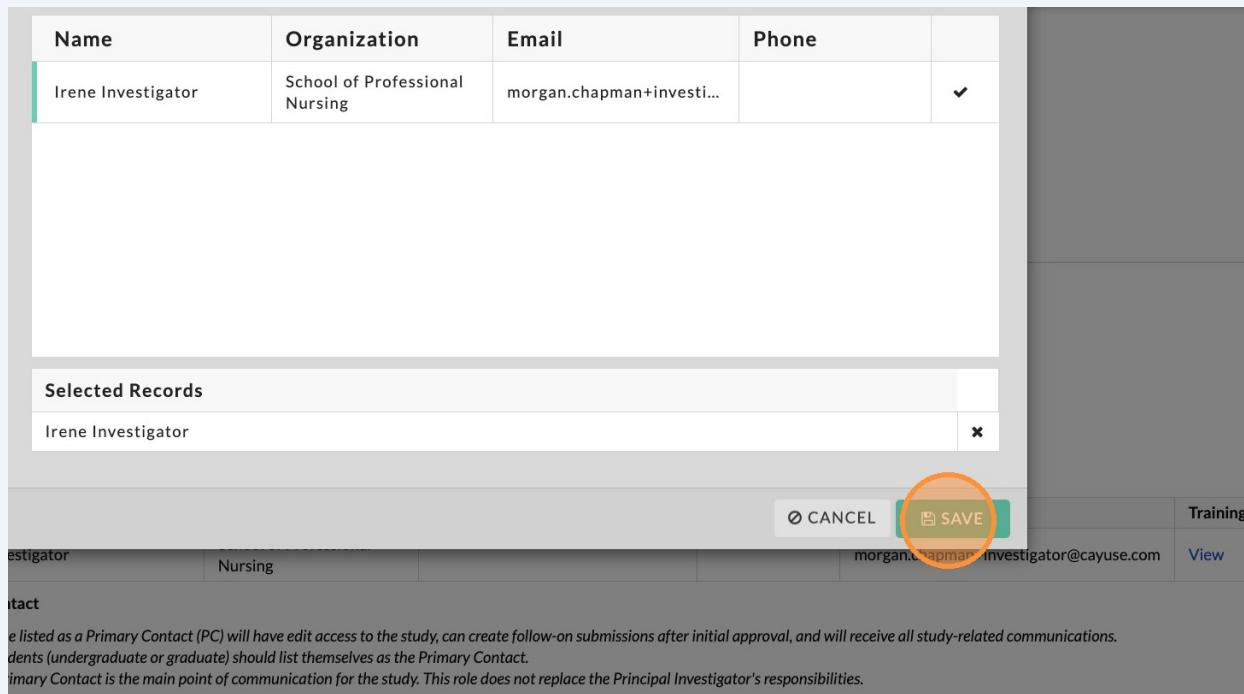
Name	Organization	Email	Phone
Irene Investigator	School of Professional Nursing	morgan.chapman+investi...	<a href="#">+</a>

Name	Organization	Address	Phone	Email	Trainings
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	<a href="#">View</a>

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

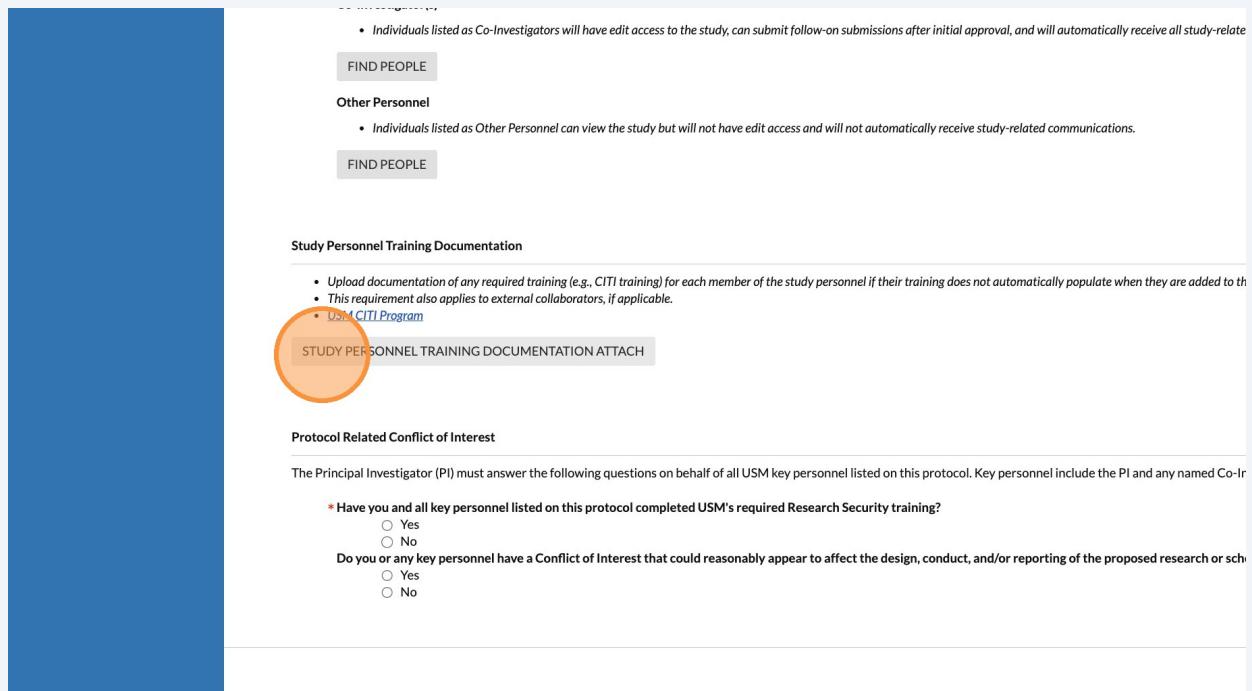


21 Click "Save"

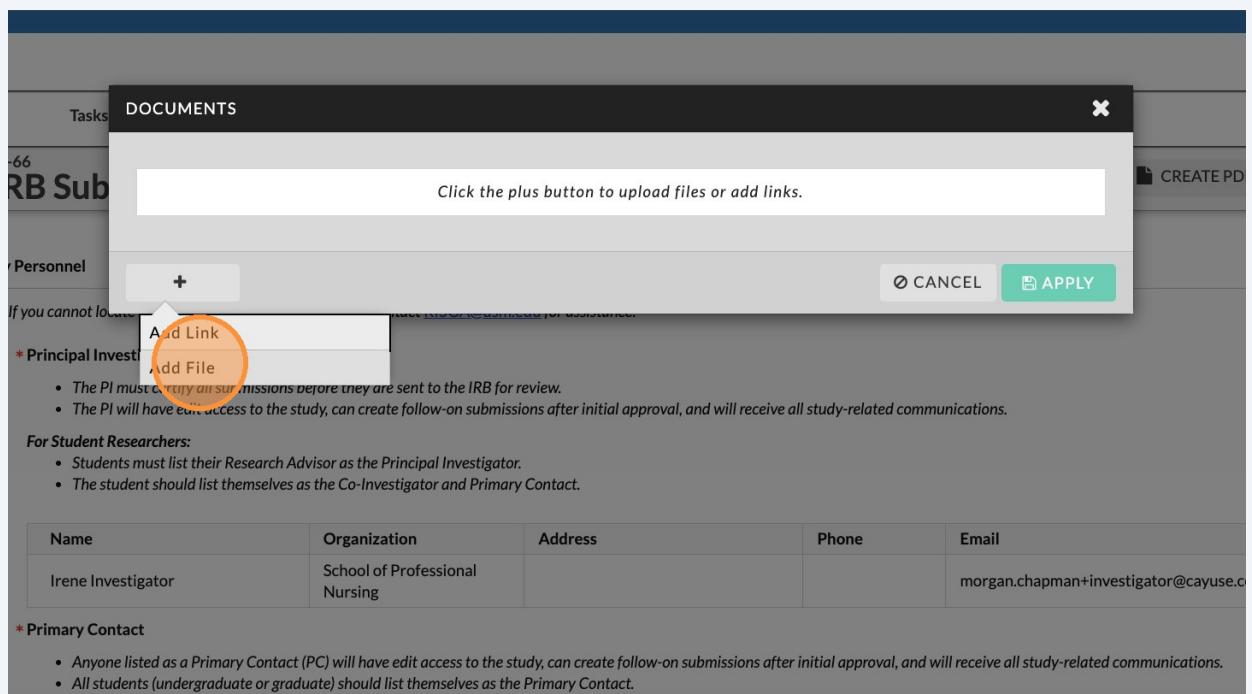


22 Next, navigate to the "**Study Personnel Training Documentation**" section.

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

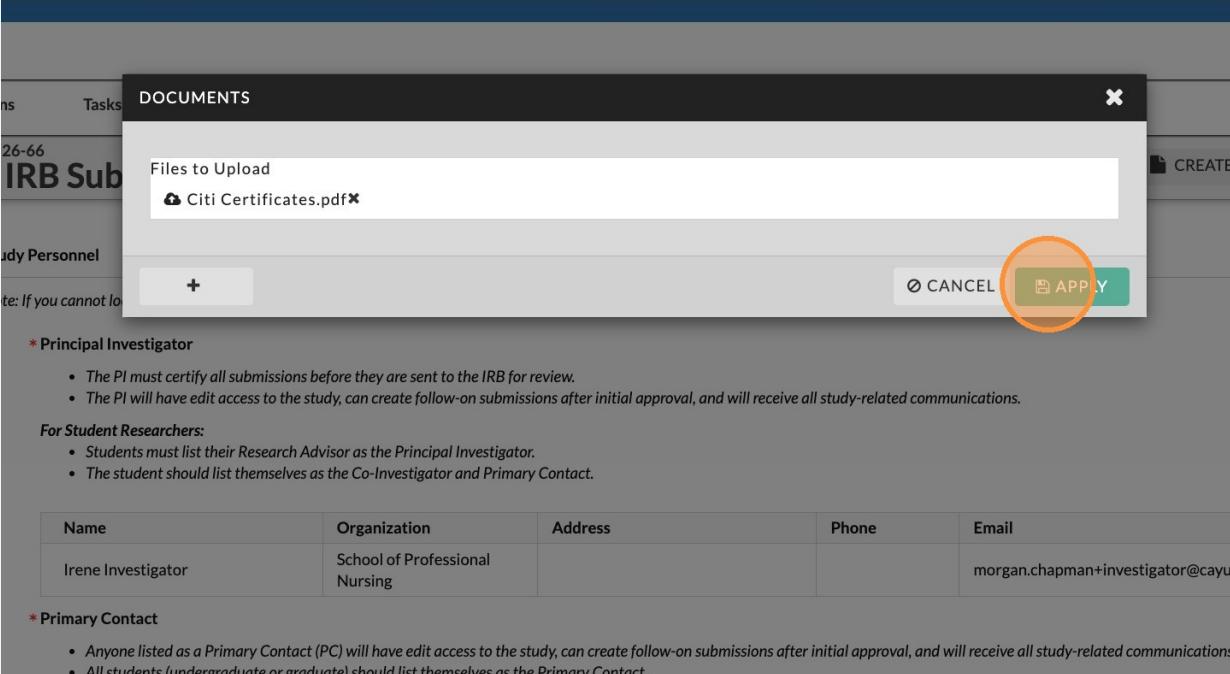


23 Select "+" to upload any relevant training attachment(s) or certificate(s).



24

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

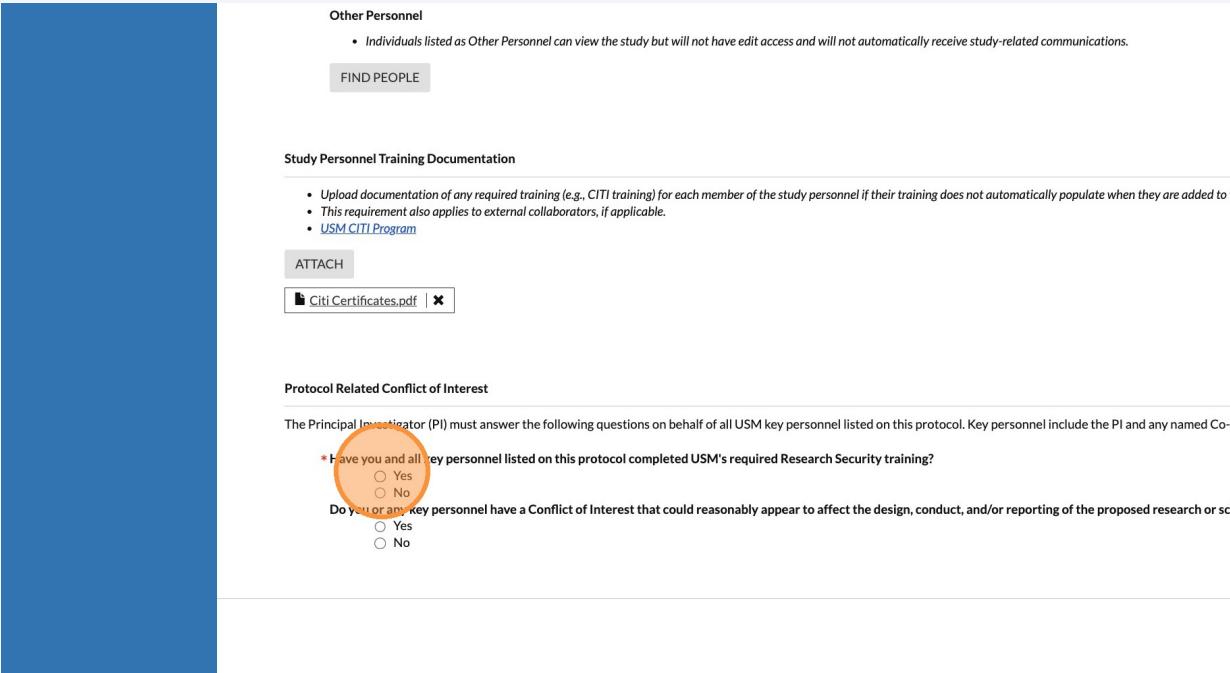


The screenshot shows a 'DOCUMENTS' modal window. At the top, it says 'Files to Upload' and shows a file named 'Citi Certificates.pdf'. Below this is a '+' button for adding more files. At the bottom right are 'CANCEL' and 'APPLY' buttons, with 'APPLY' being circled in orange. The background of the modal shows study personnel information, including a table for 'Name', 'Organization', 'Address', 'Phone', and 'Email', and sections for 'Principal Investigator' and 'Primary Contact' with their respective requirements.

25

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

Answer all relevant questions to the best of your ability.



The screenshot shows the 'Conflict of Interest' section. It includes a 'Study Personnel Training Documentation' section with a 'Citi Certificates.pdf' file attached, and a 'Protocol Related Conflict of Interest' section. In the 'Protocol Related Conflict of Interest' section, the first question, 'Have you and all key personnel listed on this protocol completed USM's required Research Security training?', has a radio button for 'Yes' circled in orange. The second question, '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?', also has a radio button for 'Yes' circled in orange.

**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.

[View 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. This requirement also applies to external collaborators, if applicable.

[View Program](#)

[View Documentation](#) | [X](#)

**Conflict of Interest**

The 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.

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

Yes  
 No

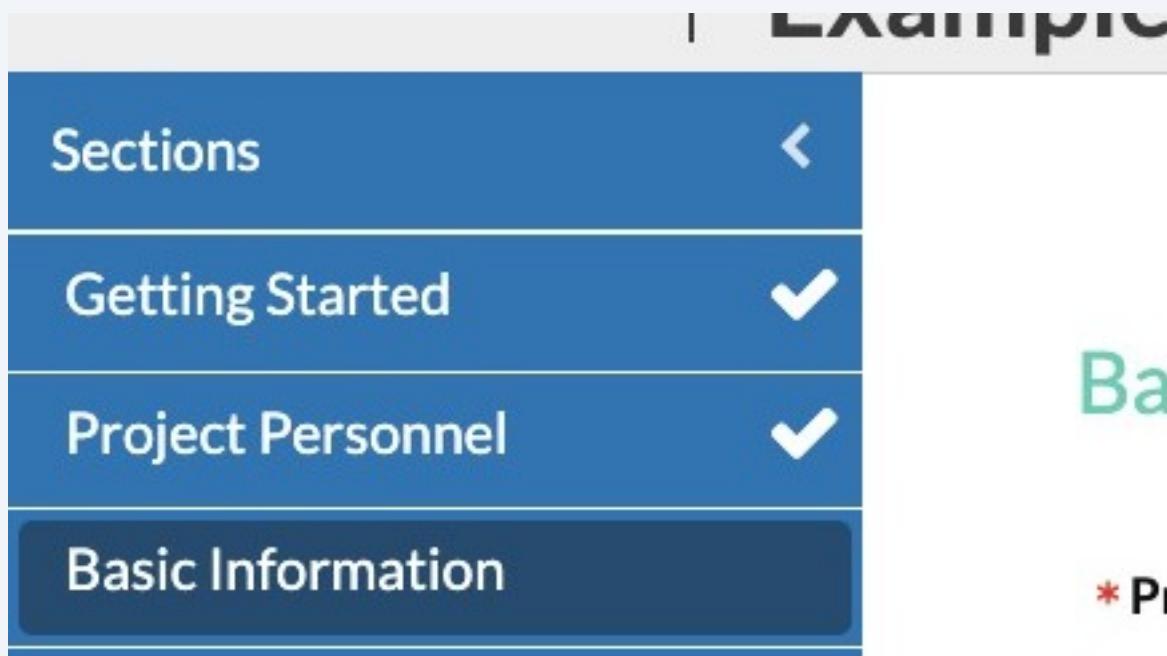
Do any key personnel have a Conflict of Interest that could reasonably appear to affect the design, conduct, and/or reporting of the proposed research or scholarly activity?

Yes  
 No



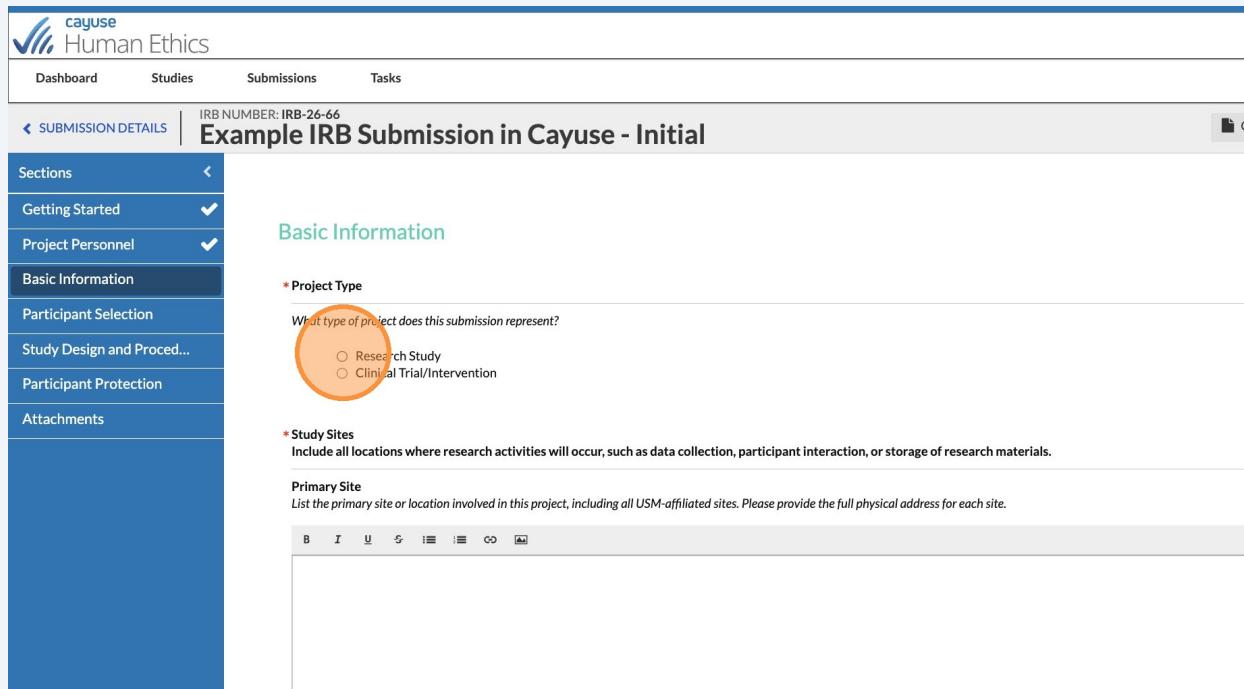
**27**

**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.



IRB NUMBER: IRB-26-66

### Example IRB Submission in Cayuse - Initial

**Basic Information**

**\*Project Type**  
What type of project does this submission represent?

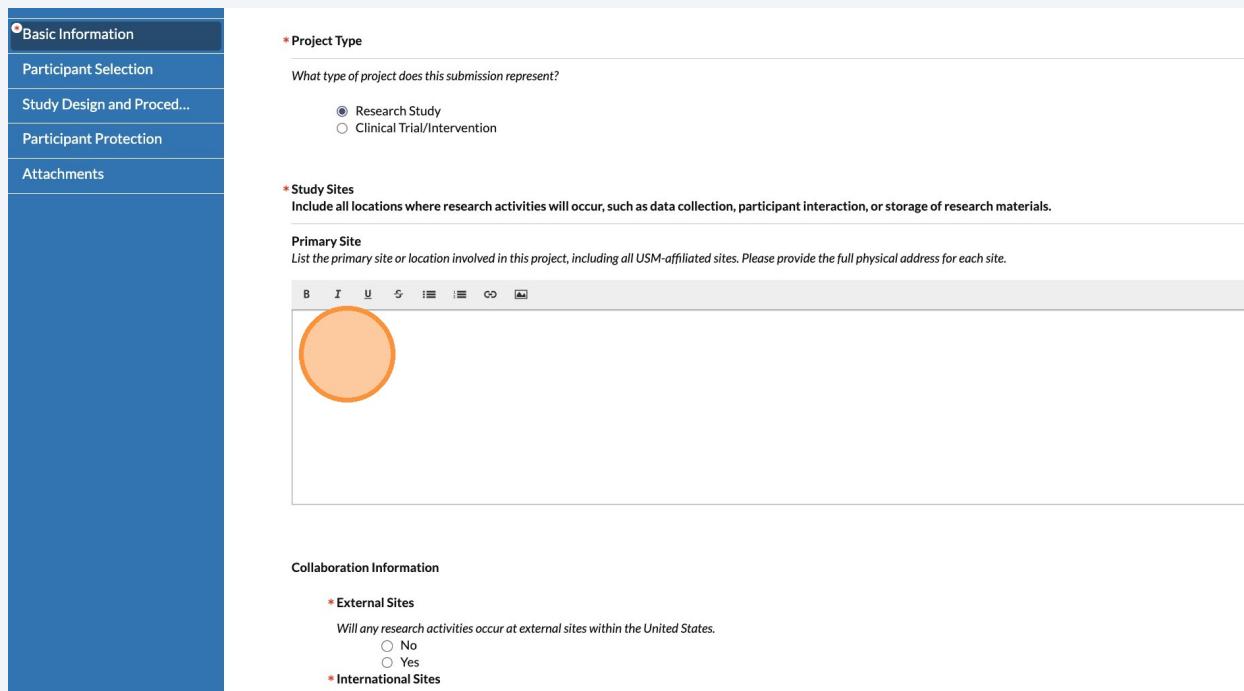
Research Study  
 Clinical Trial/Intervention

**\*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.

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

List all locations where your research activities will take place.



**\*Basic Information**

**\*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.

**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  
If this institution is relying on an External IRB, the answer to this question should be 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**  
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

**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

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.

Start Date:  

End Date:  

**\* 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

If this institution is relying on an External IRB, the answer to this question should be 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:  

End Date:  

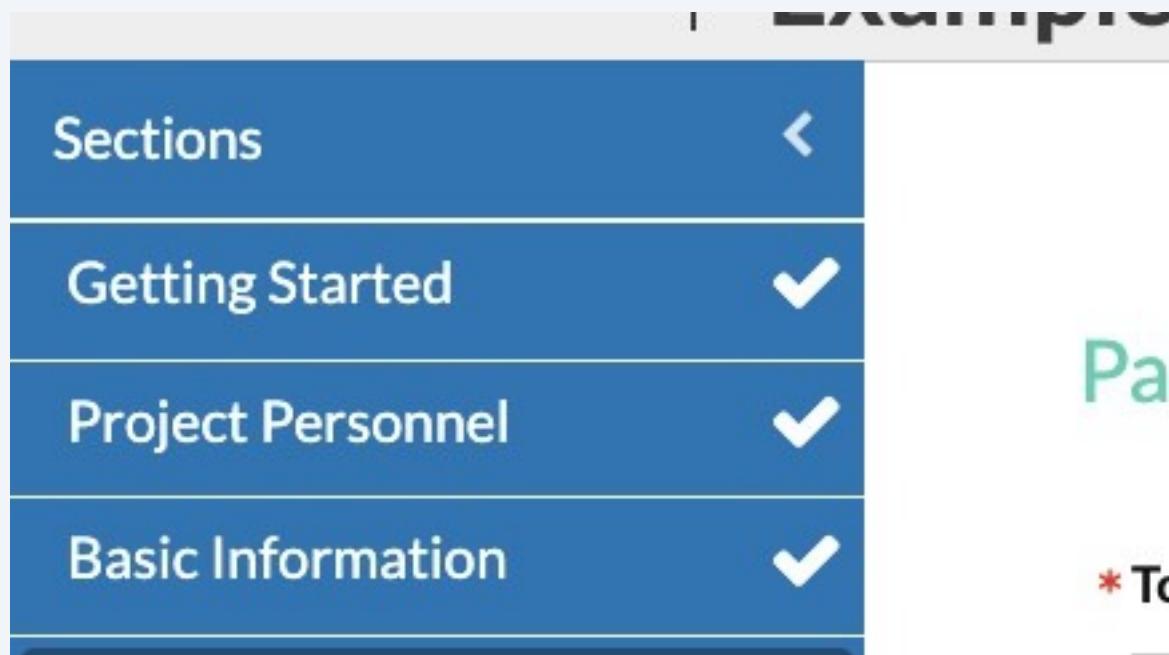
**\* Funding**

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

Do you have any non-USM affiliated person conduct research activities for this project?

Yes  
 No

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. These dates will be used for annual review. Ensure your end date reflects the expected duration of the research activities.

Anticipated Start Date: 0/2026

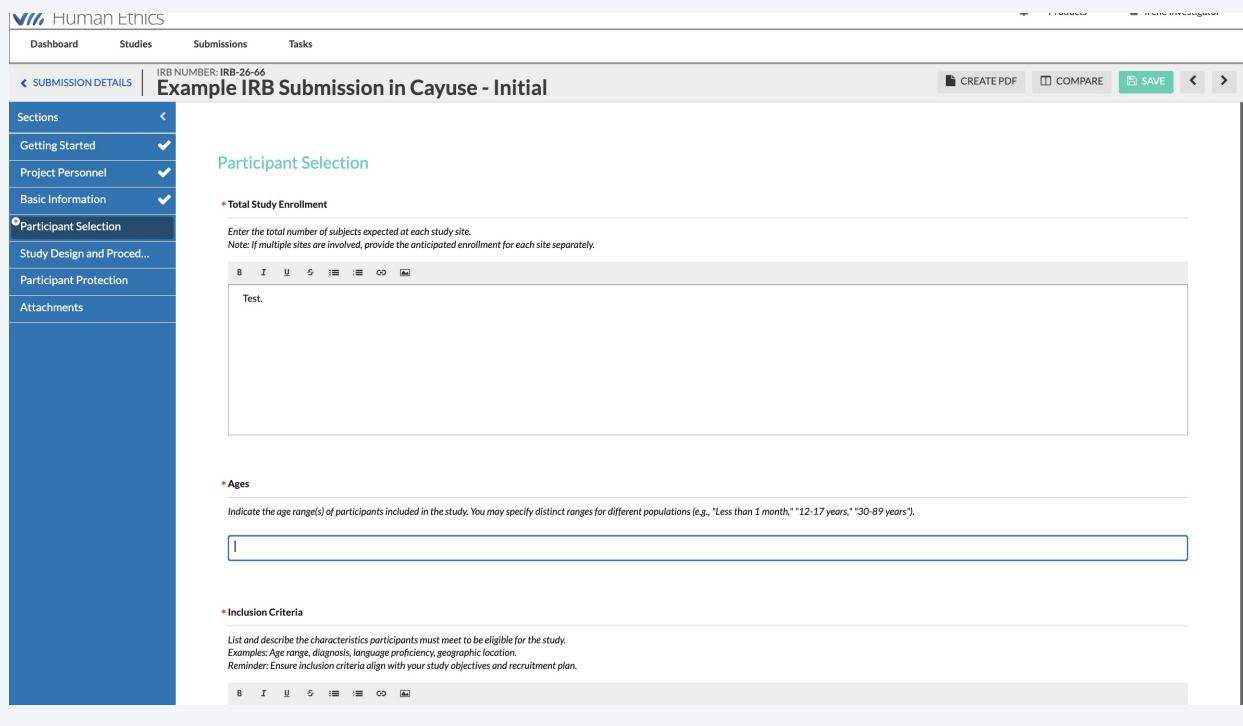
Anticipated End Date: 0/2027

Does your institution 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)?

Yes  
 No



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



Human Ethics

Dashboard Studies Submissions Tasks

◀ SUBMISSION DETAILS | IRB NUMBER: IRB-26-66 Example IRB Submission in Cayuse - Initial

CREATE PDF COMPARE SAVE

Sections

Getting Started ✓

Project Personnel ✓

Basic Information ✓

Participant Selection

Study Design and Proced...

Participant Protection

Attachments

**Participant Selection**

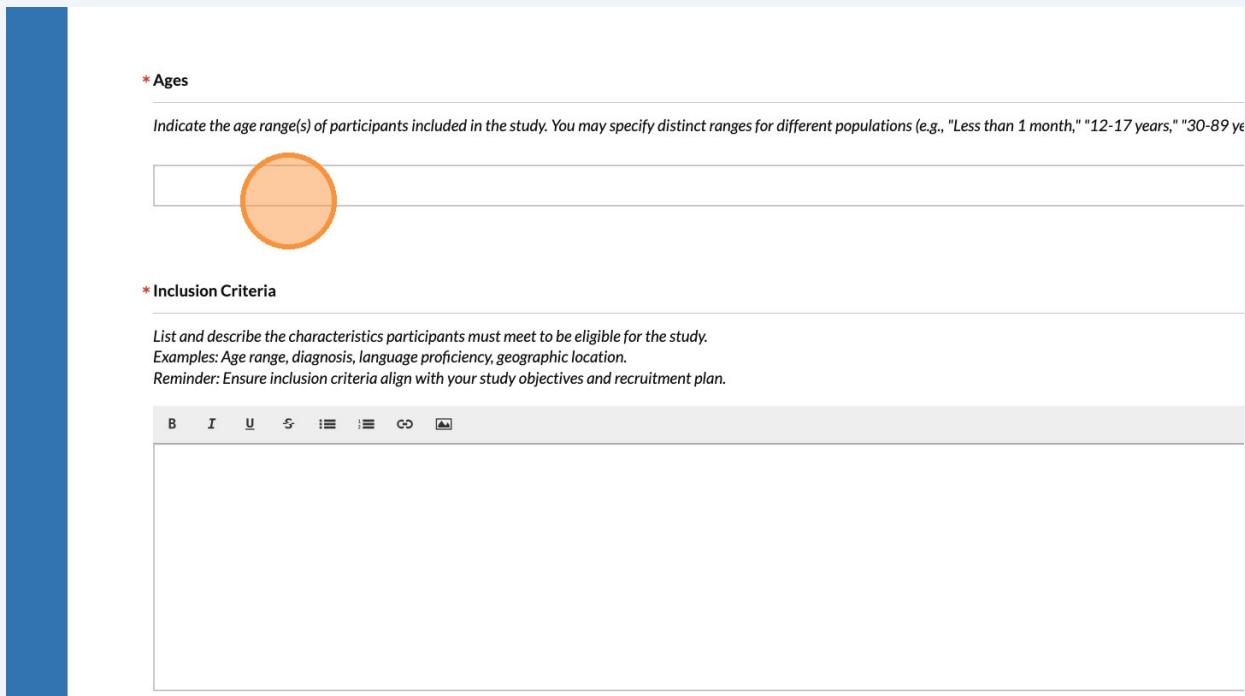
\* Total Study Enrollment

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 S                                  <img alt="Text editor icons" data-bbox="7628 238 7645

## 38 Continue to the "Ages" field.

Indicate the desired age range of participants in your study.



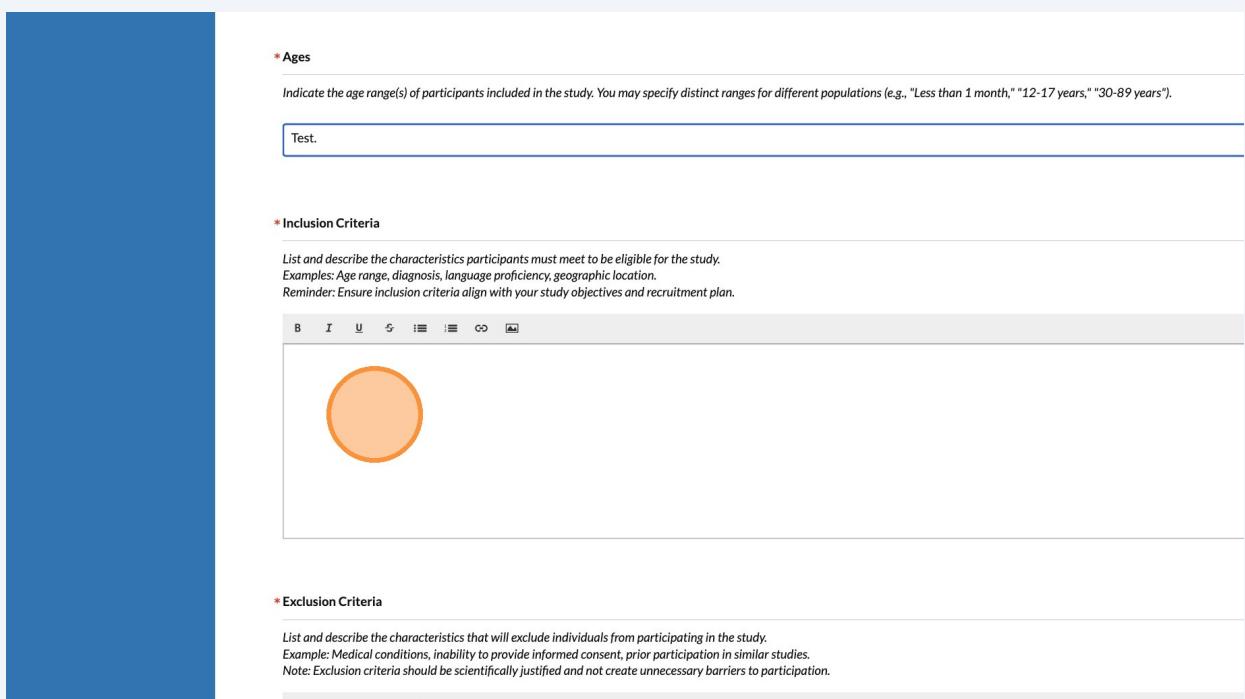
**\* Ages**

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").

Test.

## 39 Next, move forward to the "Inclusion Criteria" section.

List and describe all eligibility requirements for your study.



**\* 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.

Test.

40

Next is the "**Exclusion Criteria**" section.

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 S** 



**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
- However, you must consider the involvement of vulnerable populations even if you are not specifically targeting them for enrollment.

**\* Included Vulnerable Populations**

**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**.

**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

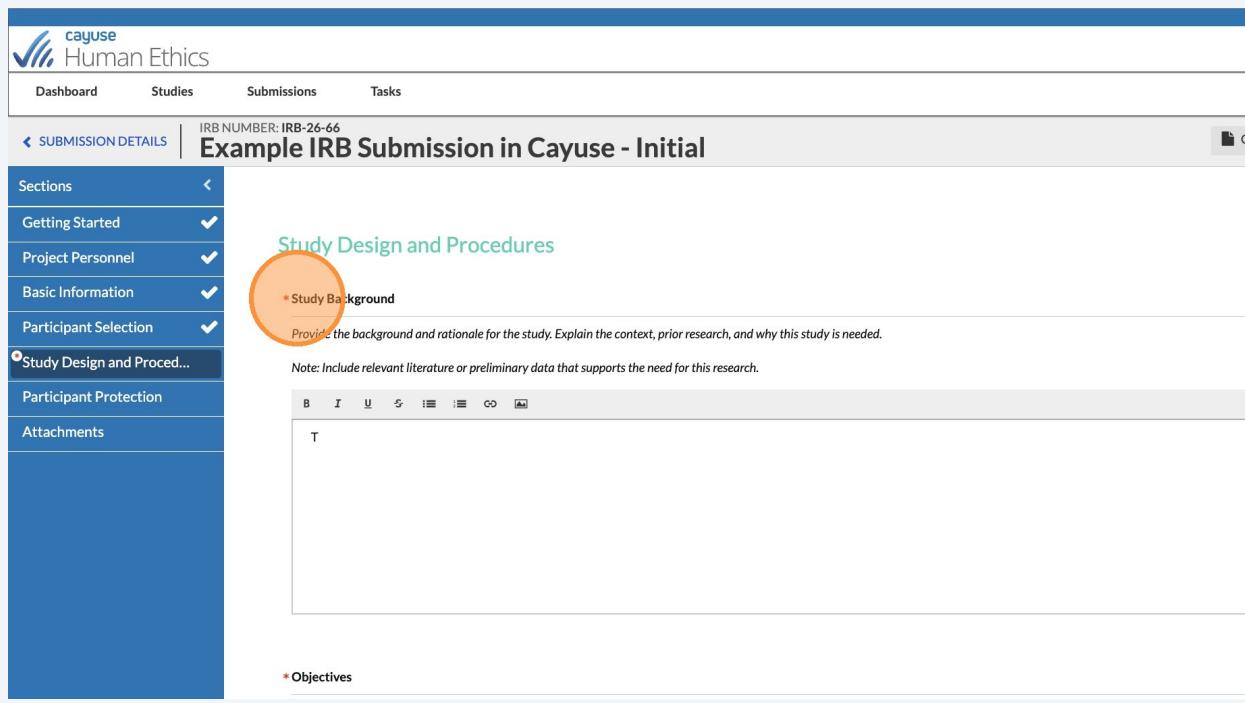
**\* Excluded Vulnerable Populations**

*Will any vulnerable populations be deliberately excluded from participation?*

No  
 Yes



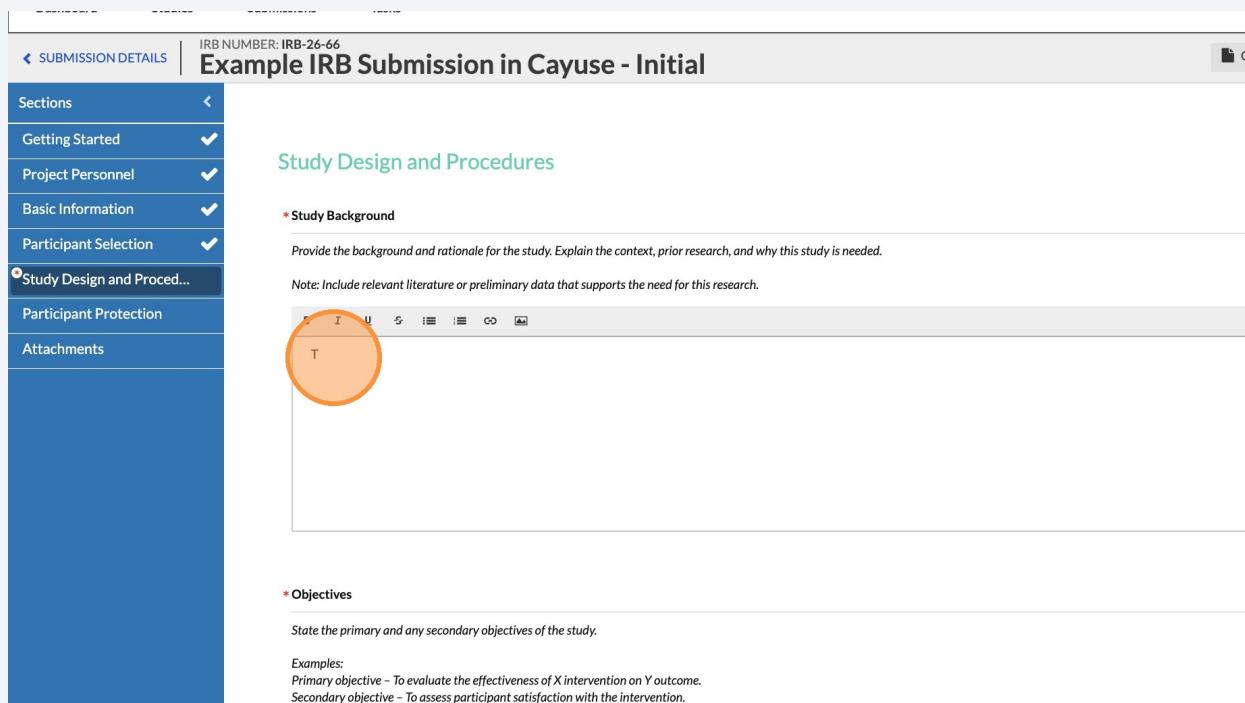
43 You have now reached the "Study Design and Procedures" page.



The screenshot shows the Cayuse Human Ethics interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main title is 'Example IRB Submission in Cayuse - Initial' with an IRB number 'IRB-26-66'. On the left, a sidebar lists 'Sections' such as 'Getting Started', 'Project Personnel', 'Basic Information', 'Participant Selection', 'Study Design and Proced...', 'Participant Protection', and 'Attachments'. The 'Study Design and Proced...' section is currently selected. The main content area is titled 'Study Design and Procedures'. It contains a field labeled 'Study Background' with the instruction: 'Provide the background and rationale for the study. Explain the context, prior research, and why this study is needed.' Below this is a note: 'Note: Include relevant literature or preliminary data that supports the need for this research.' A text editor toolbar is above a text area containing the letter 'T'. At the bottom, there is a field for 'Objectives'.

44 Locate the "Study Background" section.

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



This screenshot is identical to the one above, showing the 'Study Design and Procedures' section in the Cayuse platform. The 'Study Background' field is again highlighted with an orange circle. The text area contains the letter 'T'.

45

Move forward to the "**Objectives**" section.

State the objective(s) of your study in the text box provided.

**\* Objectives**

State the primary and any secondary objectives of the study.

Examples:

Primary objective - To evaluate the effectiveness of X intervention on Y outcome.  
Secondary objective - To assess participant satisfaction with the intervention.

B I U S 



**\* Study Design**

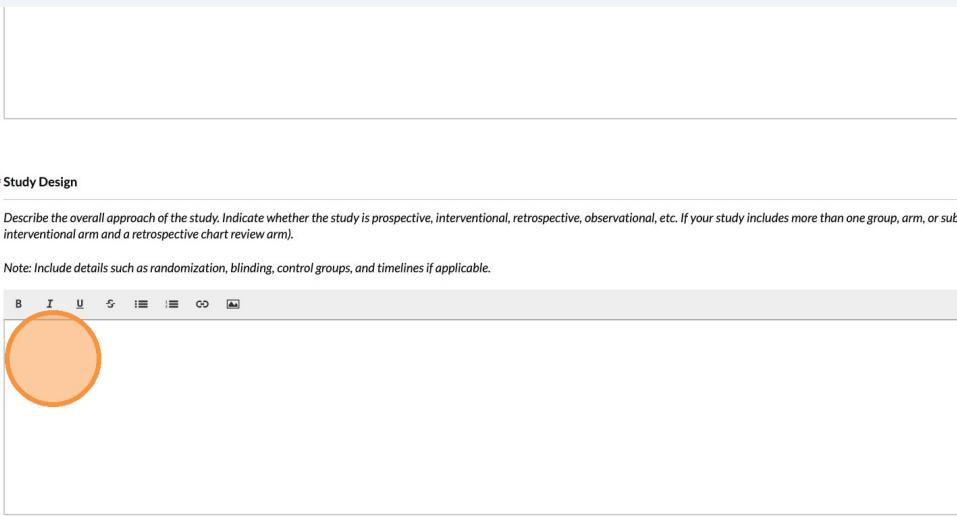
Describe the overall approach of the study. Indicate whether the study is prospective, interventional, retrospective, observational, etc. If your study includes more than one group, arm, or sub-interventional arm and a retrospective chart review arm).

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

B I U S 

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

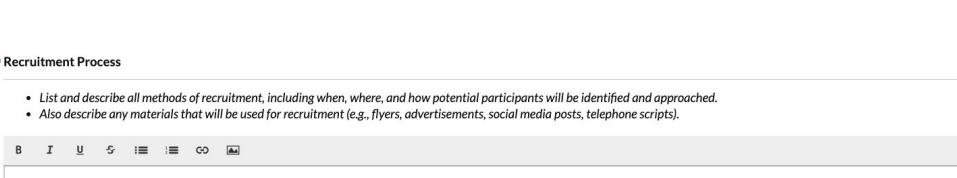
Describe the approach of your study in the text box provided.



**\* 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.



**\* 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).

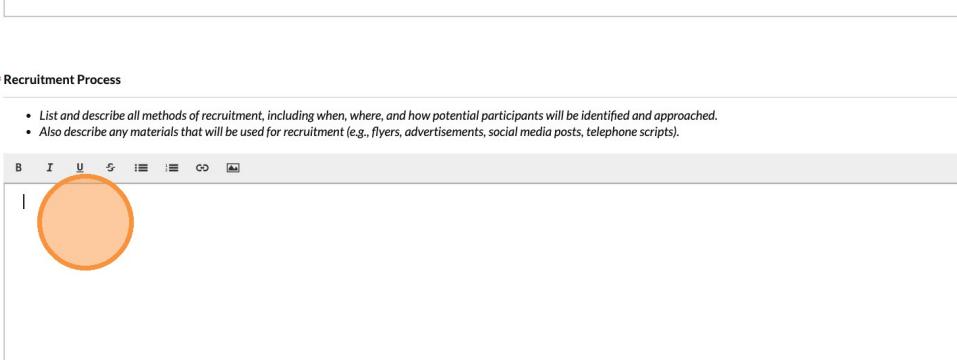
**47** Next you'll see the "**Recruitment Process**" section.

List and describe all methods of recruitment.



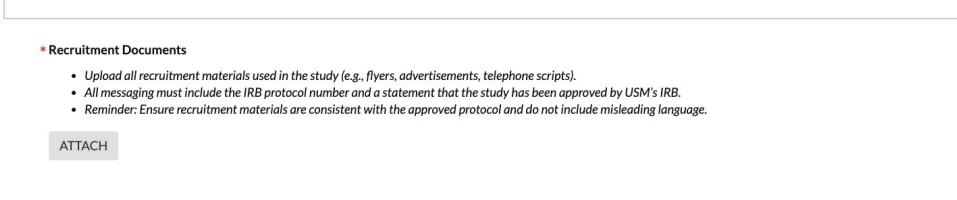
**Sections**

- Getting Started
- Project Personnel
- Basic Information
- Participant Selection
- Study Design and Proced...**
- 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).



**\* 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.

Example IRB Submission in Cayuse - Initial

**Sections**

- Getting Started
- Project Personnel
- Basic Information
- Participant Selection
- Study Design and Procedure
- 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**

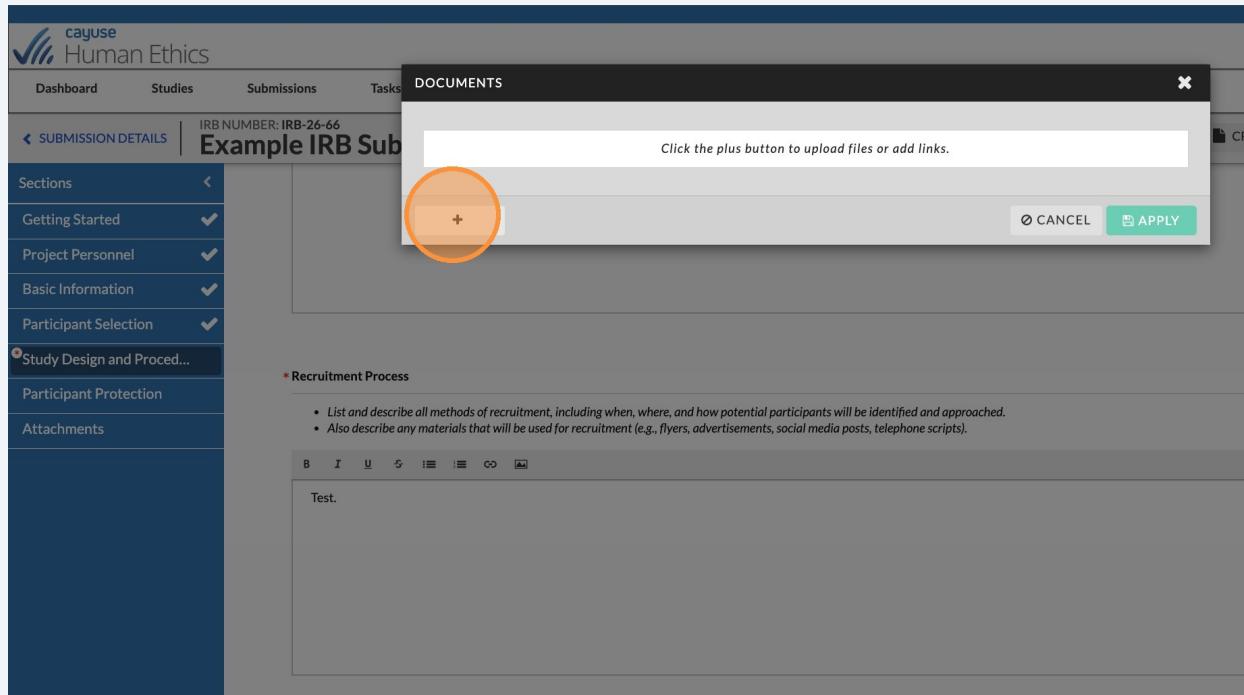
*Does your study involve any products that may fall under FDA regulation (e.g., drugs, biologics, food, cosmetics, or devices)?*

Yes

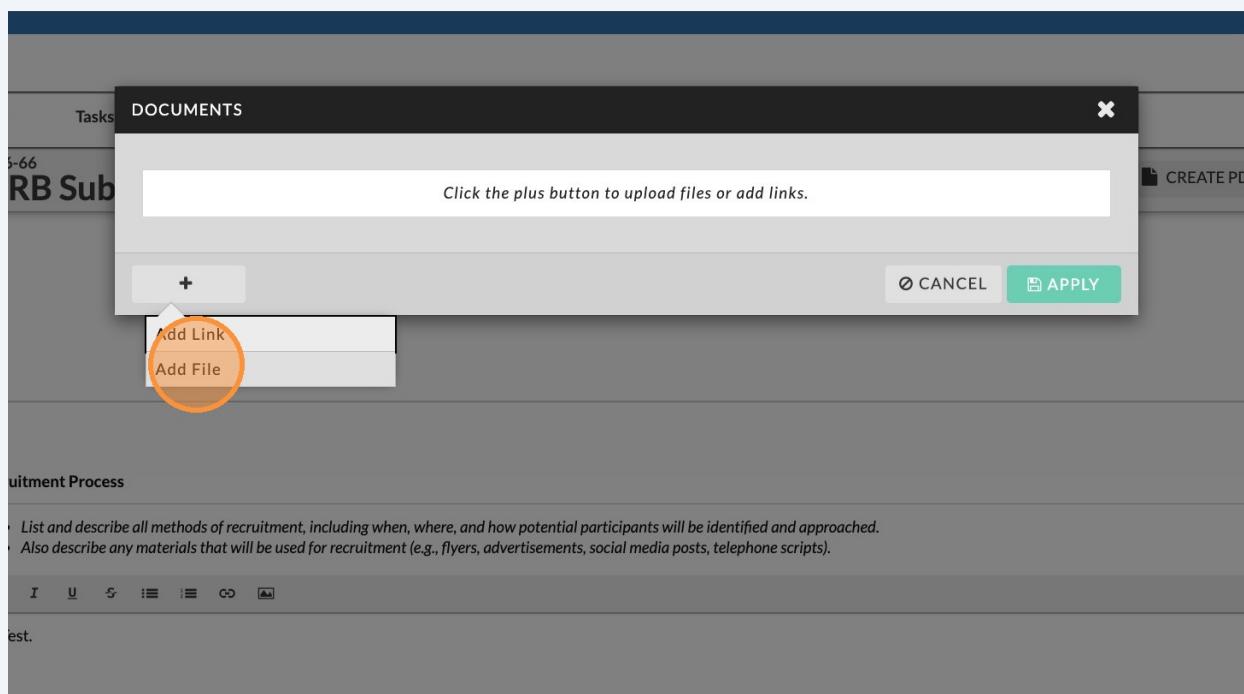
No

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

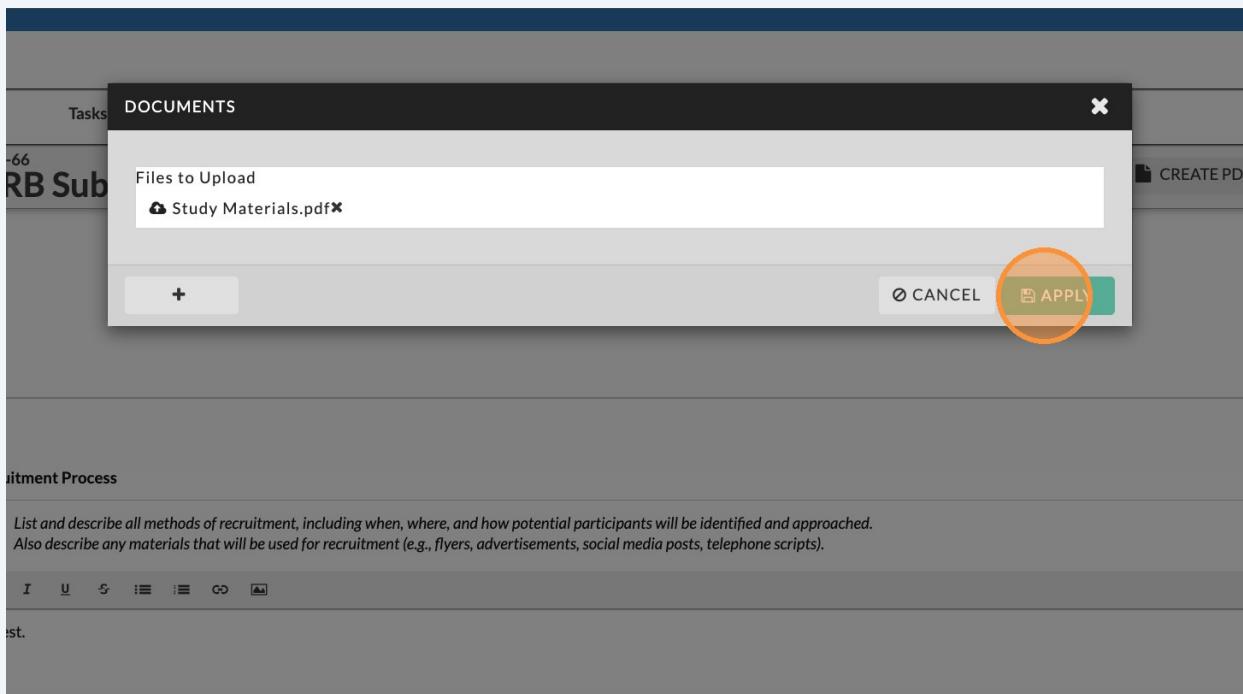
Select the (+) button.



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.

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

ATTACH

 Study Materials.pdf | x

**\* 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).

Participant Protection

Attachments

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

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

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 | | | | | | | |

57

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

Provide a detailed description of all study procedures and methods.

**\* 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.

58

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

Describe the duration of participation for each subject.

**\* 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.

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 software interface for managing study designs. On the left, a sidebar lists sections: Getting Started, Project Personnel, Basic Information, Participant Selection, Study Design and Proced..., Participant Protection, and Attachments. The 'Study Design and Proced...' section is currently selected and highlighted in blue. The main content area has a grey header with instructions: 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. Below this is a rich text editor toolbar with buttons for bold, italic, underline, etc. A text area contains the word 'Test.' A large orange circle highlights the 'Study Instruments' section, which is described as: 'Attach all study instruments that will be used for data collection or participant interaction. If instruments will be translated, describe the translation process.' Below this, a list of examples includes: Surveys or questionnaires, Interview or focus group scripts, Personality or psychological scales, and Evaluation forms or scoring sheets. A note states: 'If instruments are not yet finalized, provide drafts or describe the planned content and format.' A grey 'ATTACH' button is visible. At the bottom, a question asks: 'Will you use any previously collected data in this study?' with a red asterisk indicating it is required.

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 | 

\* 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.

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 S = = = C ☰

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 | | | | | | | | | | | |

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 | | | | | | | | | | | |

Test.

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 | | | | | | | | | | | |

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

Test.

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.

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.

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.

Getting Started	✓
Project Personnel	✓
Basic Information	✓
Participant Selection	✓
Study Design and P...	✓

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 unforeseen.
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 S | ☰

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.

B I U S | ☰

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 S ━ ━ ━ ━ ━ ━



**\* 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 S ━ ━ ━ ━ ━ ━



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

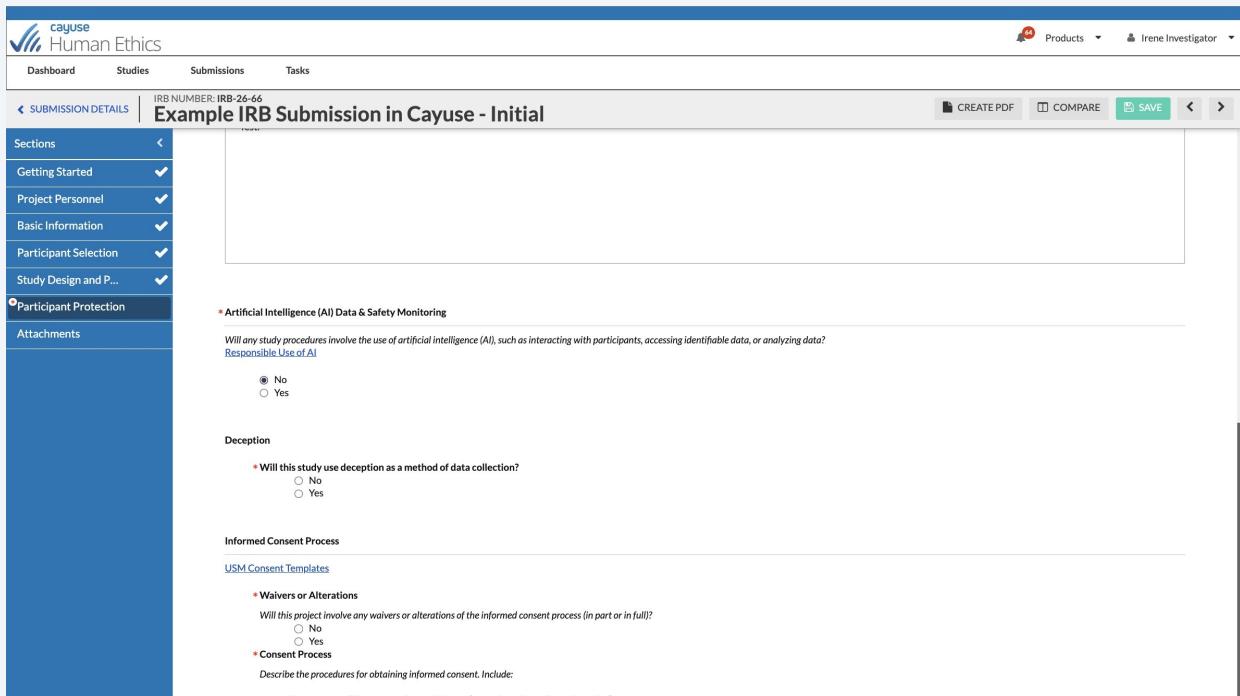
Will any study procedures involve the use of artificial intelligence (AI), such as interacting with participants, accessing identifiable data, or analyzing data?

[Responsible Use of AI](#)

No  
 Yes

71

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



IBR NUMBER: IRB-26-64 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

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?

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

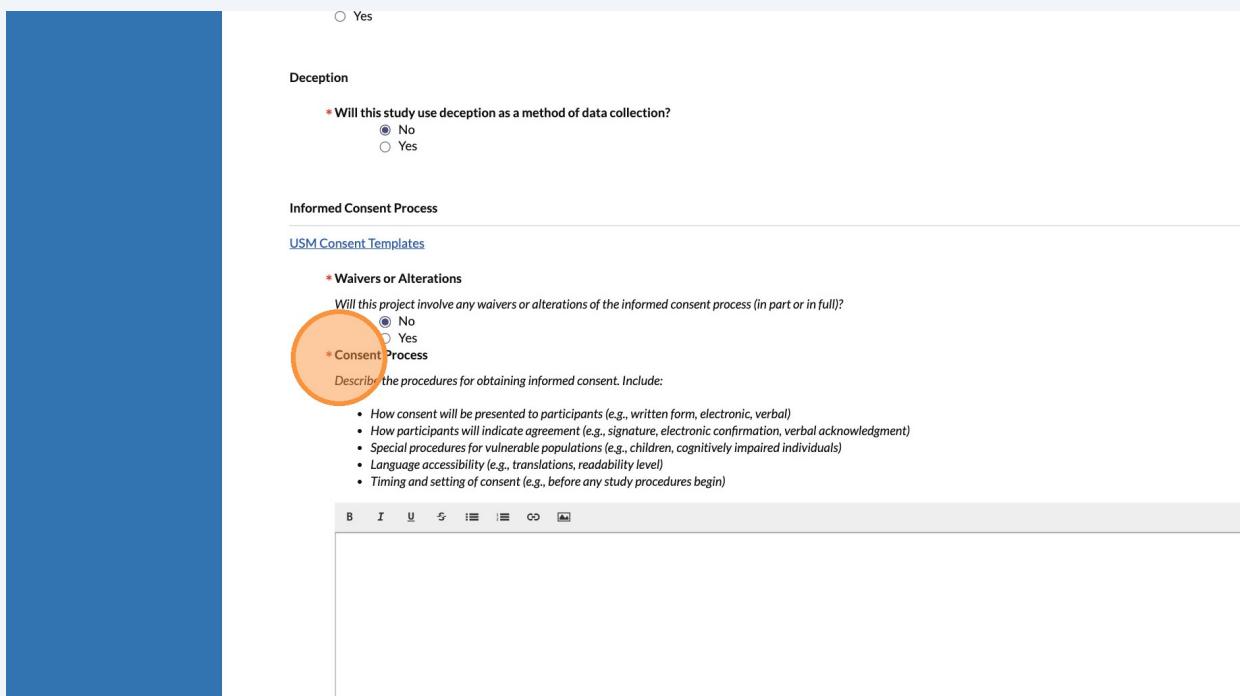
Consent Process

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.

**\* 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

ATTACH



74

Finally, refer to the "**HIPAA**" section.

Complete the required inquiry.

ATTACH

Consent Form.pdf | x

**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**.

VA Privacy Rule applies to projects where PHI is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research. Our 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. Health Information (PHI) = health information + one or more of the 18 identifiers (see list below). More Information on HIPAA

his 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

**3 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)

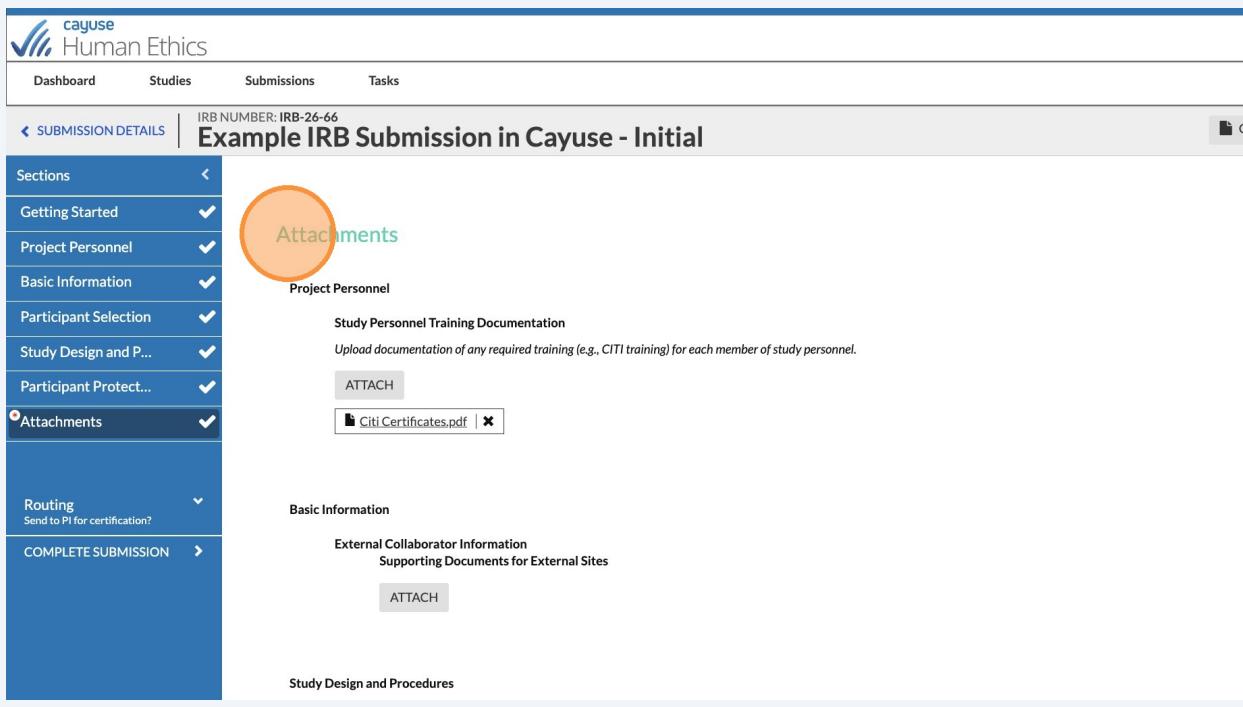
Full face photographic images and any comparable identifying images

Results of a Genetic Test

Any other unique identifying number, characteristic, or code



76 You have now reached the "Attachments" page.

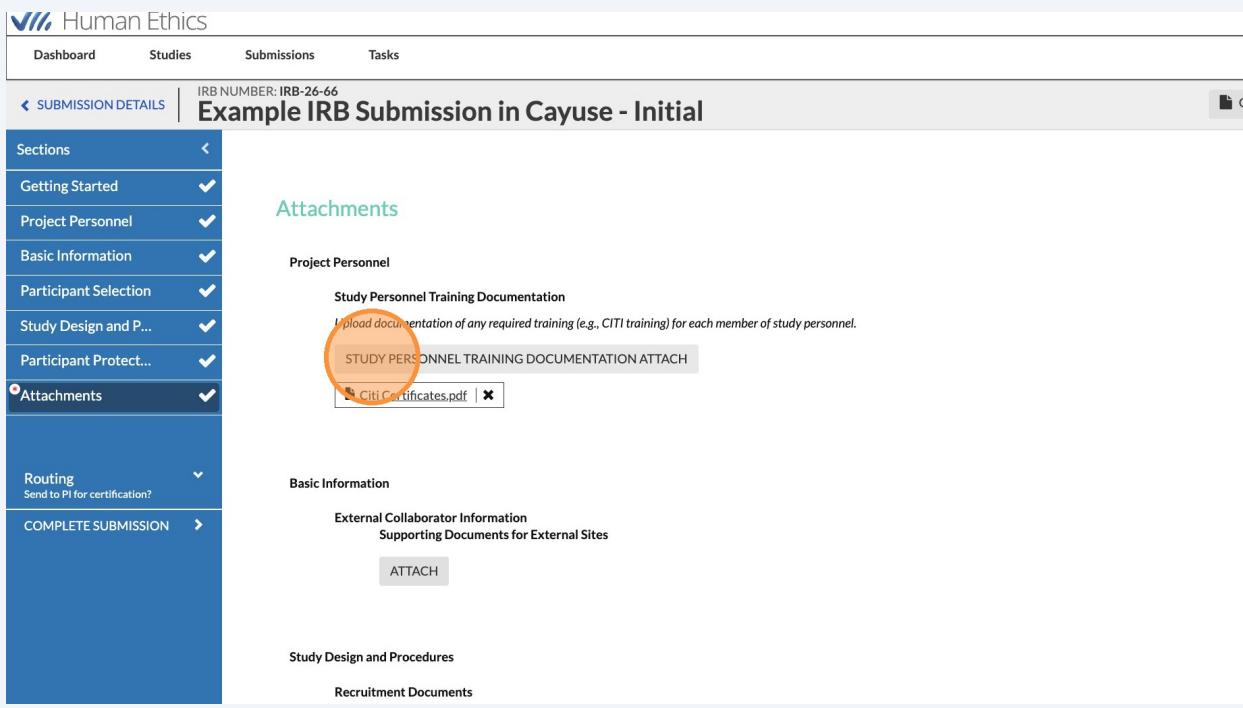


The screenshot shows the Cayuse Human Ethics interface for an IRB submission. The top navigation bar includes links for Dashboard, Studies, Submissions, and Tasks. The main content area is titled "Example IRB Submission in Cayuse - Initial" with an IRB number: IRB-26-66. On the left, a sidebar lists "Sections" with "Attachments" selected, indicated by a blue background. The main content area shows the "Attachments" section, which includes "Project Personnel" and "Basic Information" sections. Under "Project Personnel", there is a "Study Personnel Training Documentation" section with an "ATTACH" button and a file preview for "Citi Certificates.pdf". Under "Basic Information", there is an "External Collaborator Information" section with an "ATTACH" button and a file preview for "Supporting Documents for External Sites". The bottom of the page shows "Study Design and Procedures" and "Recruitment Documents" sections.

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.



The screenshot shows the Cayuse Human Ethics interface for an IRB submission, similar to the previous one but with a file attached. The "Attachments" section under "Project Personnel" now has a "STUDY PERSONNEL TRAINING DOCUMENTATION ATTACH" button highlighted with an orange circle. A file preview for "Citi Certificates.pdf" is shown below it. The rest of the interface is identical to the previous screenshot, including the "Basic Information" section and the "Study Design and Procedures" section.

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 [redacted] 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 | x

Basic Information

External Collaborator Information  
Supporting Documents for External Sites

ATTACH

Study.Materials.pdf | x

Study Design and Procedures

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

ATTACH

Study.Materials.pdf | x

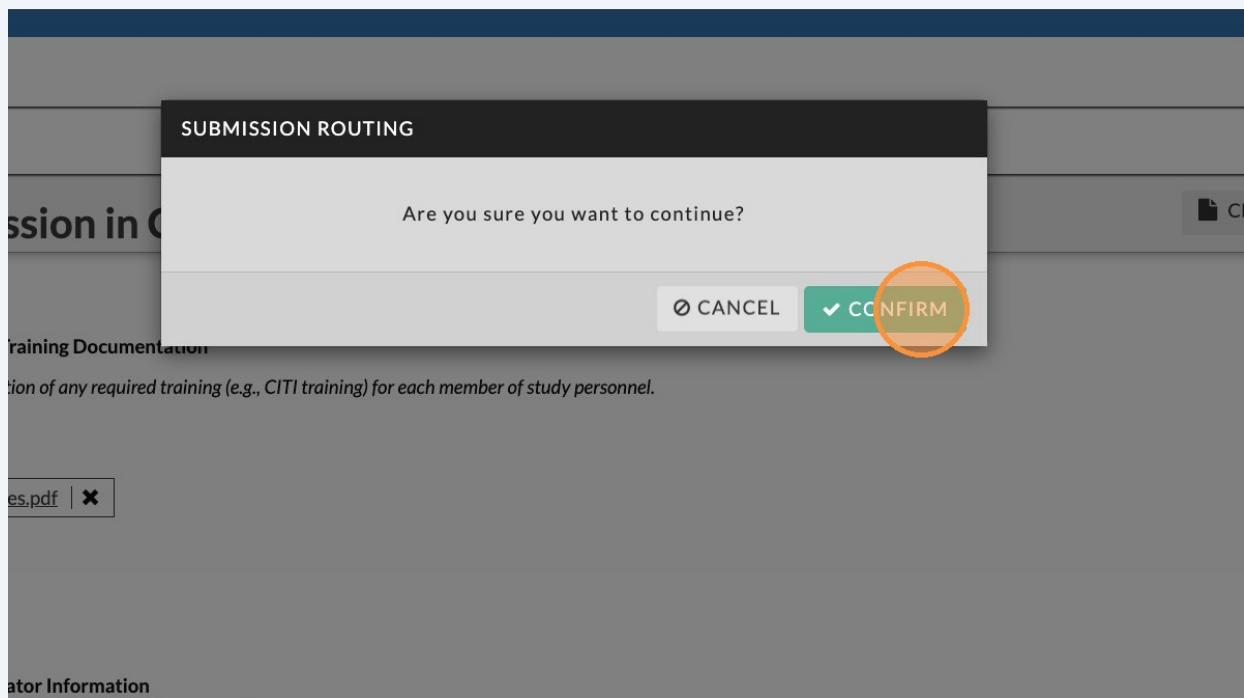
Study Instruments  
Attach all instruments (i.e. surveys, scripts, personality scales, questionnaires, evaluation blanks, etc.) to be used in the study.

ATTACH

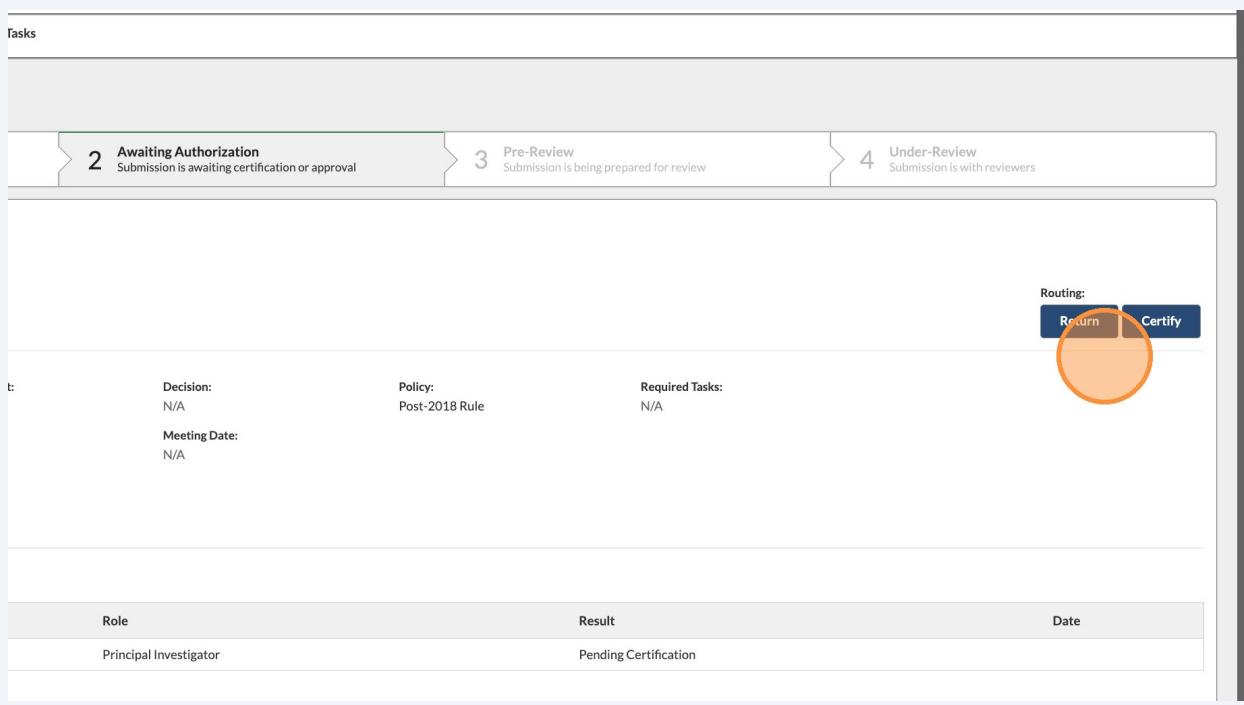
Study.Materials.pdf | x

80 You will be prompted with a confirmation message.

Click "Confirm"



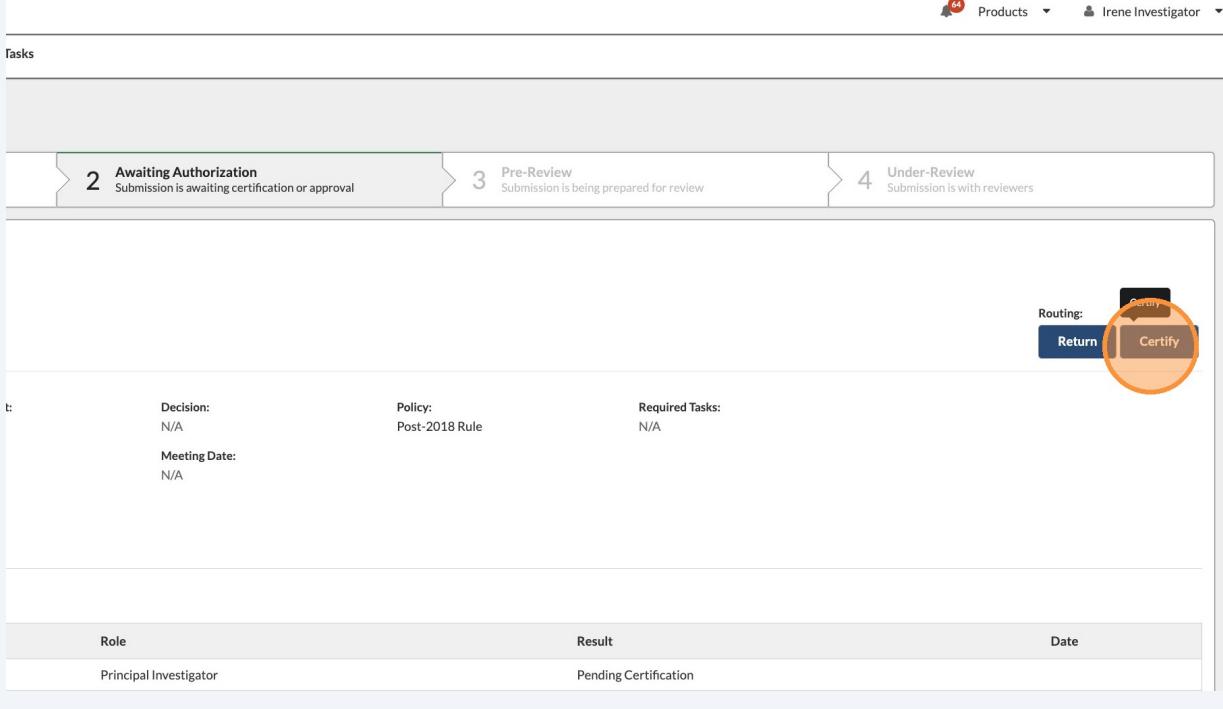
81 After you press confirm, you'll be prompted to a page where you can "**Return**" or "**Certify**" the protocol.



82

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

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



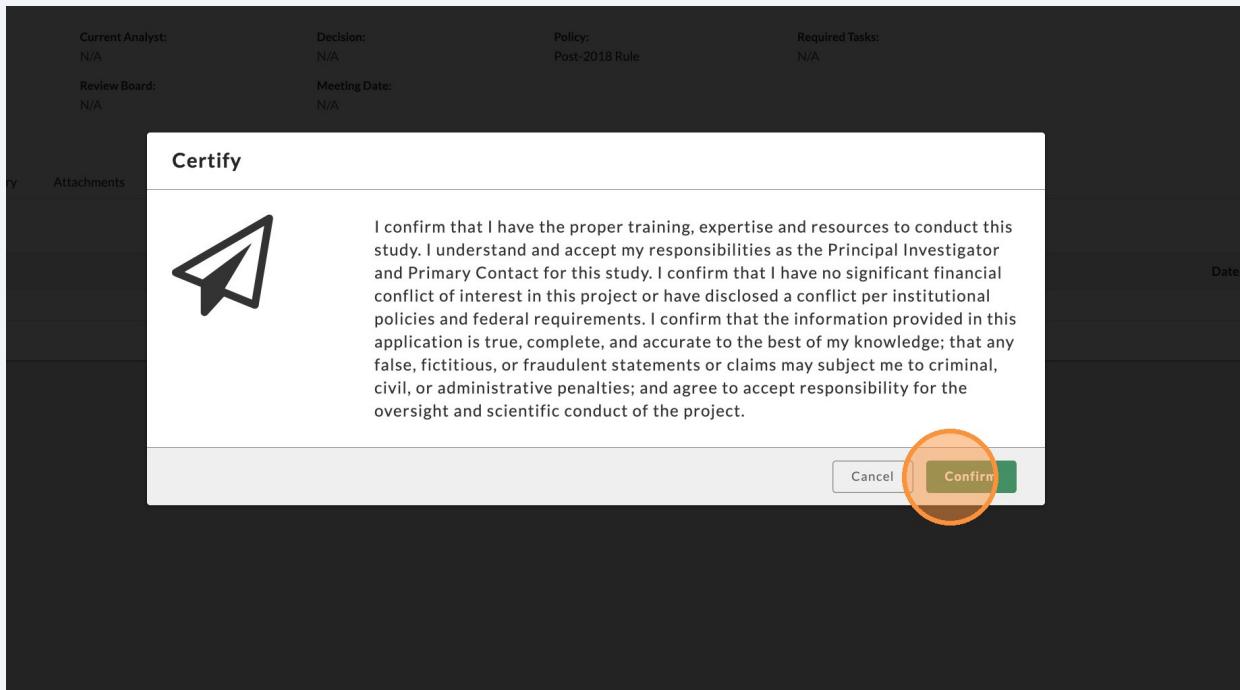
The screenshot shows a software interface for managing proposals. At the top, there are user icons for 'Products' and 'Irene Investigator'. Below this is a 'Tasks' section. A horizontal timeline shows three stages: 2 Awaiting Authorization (Submission is awaiting certification or approval), 3 Pre-Review (Submission is being prepared for review), and 4 Under-Review (Submission is with reviewers). The 'Certify' button, located in the 'Under-Review' stage, is highlighted with a large orange circle. The 'Certify' button is part of a 'Certify' icon, which also includes a 'Return' button. Below the timeline, there are sections for 'Decision' (N/A), 'Policy' (Post-2018 Rule), 'Required Tasks' (N/A), 'Meeting Date' (N/A), and a table showing the status of tasks assigned to 'Principal Investigator' (Pending Certification).

Role	Result	Date
Principal Investigator	Pending Certification	

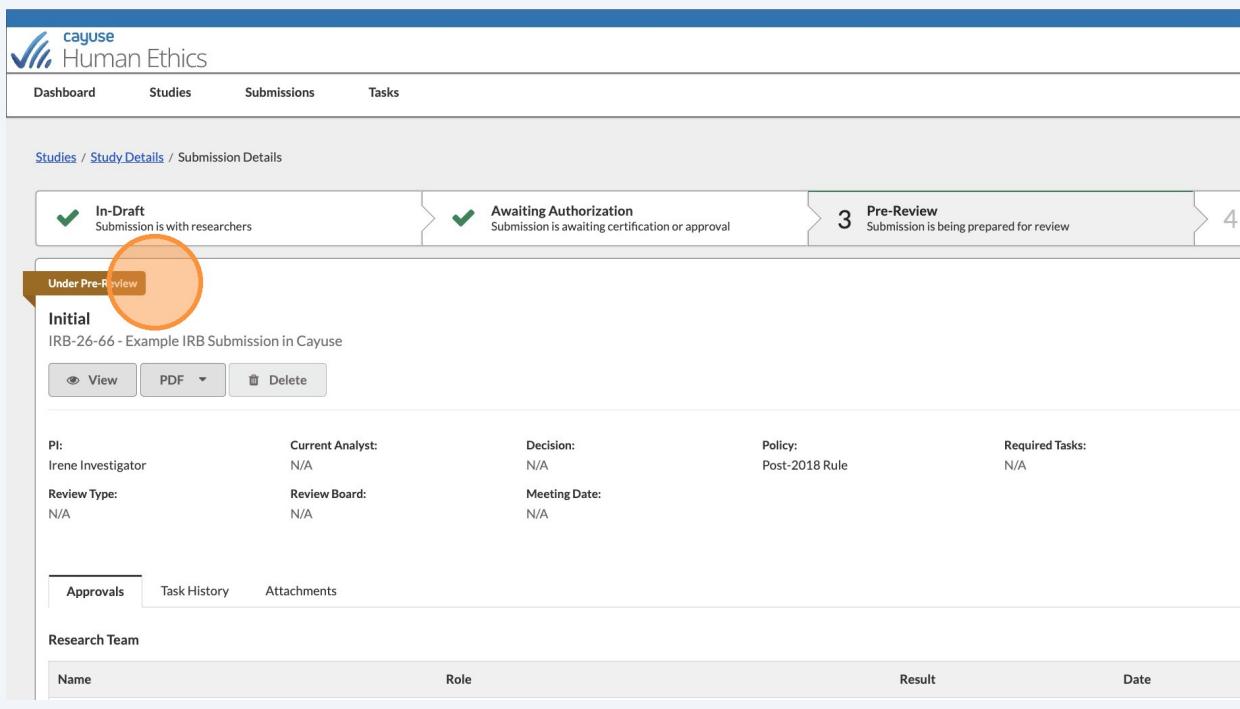
83 If you press "**Certify**" a message will populate.

**Read the message.**

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



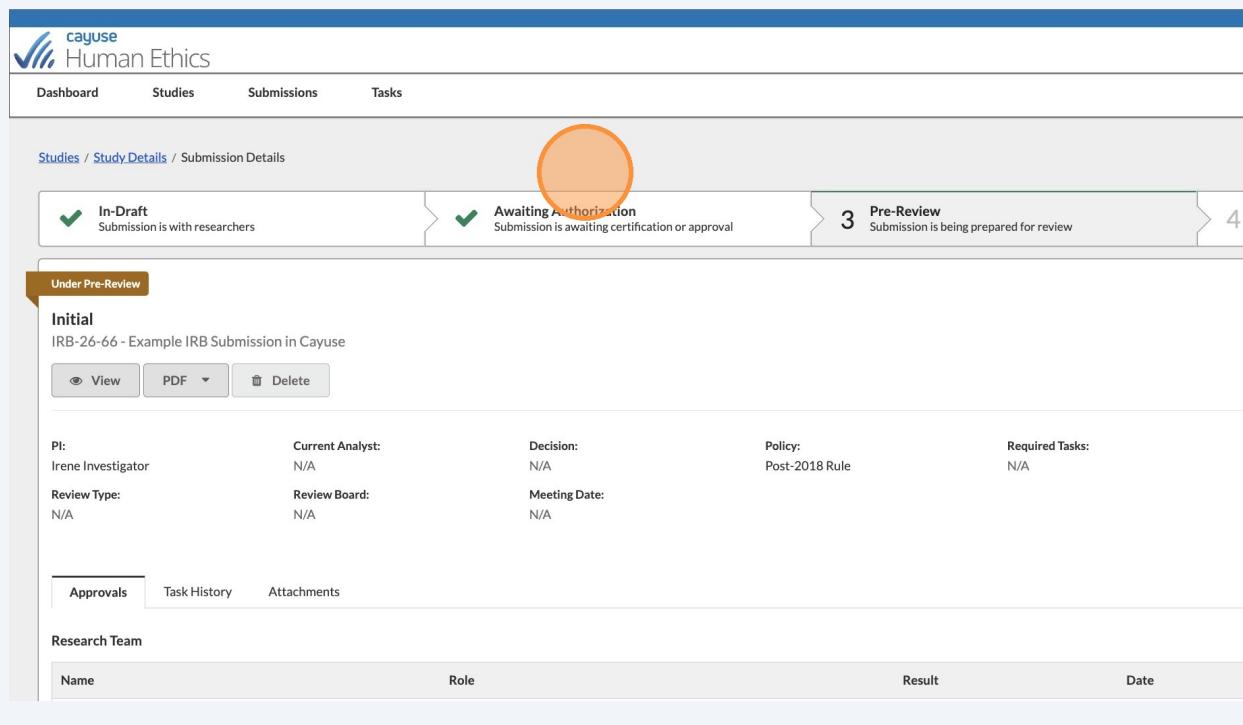
84 You'll immediately notice that your document will be labeled as "Under Pre-Review"



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.**



The screenshot shows the Cayuse Human Ethics interface. At the top, there is a navigation bar with links for Dashboard, Studies, Submissions, and Tasks. Below this, a breadcrumb navigation shows 'Studies / Study Details / Submission Details'. The main content area displays a workflow diagram with four stages: 'In-Draft' (Submission is with researchers), 'Awaiting Authorization' (Submission is awaiting certification or approval, highlighted with an orange circle), 'Pre-Review' (Submission is being prepared for review), and '4' (the next stage in the process). Below the diagram, a section titled 'Under Pre-Review' shows a study titled 'IRB-26-66 - Example IRB Submission in Cayuse'. It includes buttons for 'View', 'PDF', and 'Delete'. Below this, detailed information is provided for the study, including PI, Current Analyst, Decision, Policy, and Required Tasks. At the bottom, there are tabs for 'Approvals', 'Task History', and 'Attachments', and a 'Research Team' table with columns for Name, Role, Result, and Date.