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Cayuse IRB

Submitting a Proposal

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University Information Technology Services

Cayuse IRB - Submitting a Proposal

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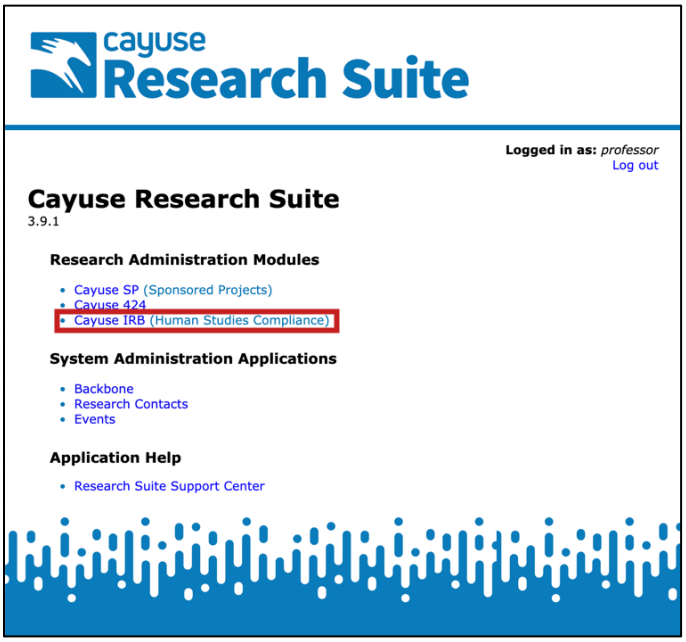
Accessing Cayuse IRB

The following section describes how to access and log into Cayuse.

1. In your browser, navigate to **https://kennesaw.cayuse424.com/**.
2. Log in using your KSU credentials and authenticate with Duo.
3. You will be directed to the Cayuse Research Suite. Click **Cayuse IRB (Human Studies Compliance).**



Click Cayuse IRB

4. You have successfully logged into your Cayuse IRB account.

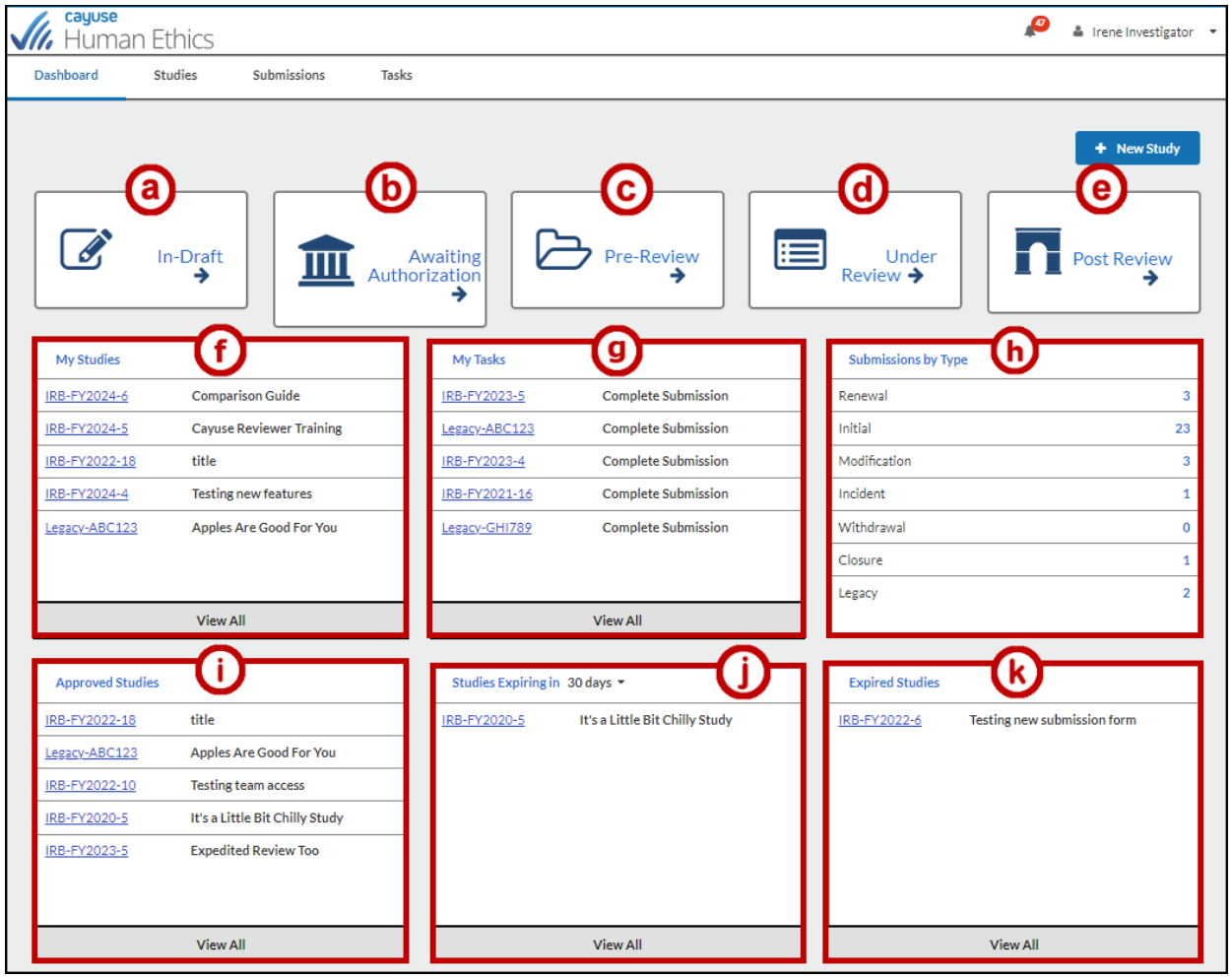
Note: For information on creating or accessing your Cayuse account, please navigate to **https://research.kennesaw.edu/irb/cayuse-human-subjects.php**.

Interface Orientation

Once logged into Cayuse IRB, you will see the main dashboard menu, composed of four tabs: *Dashboard, Studies, Submissions,* and *Tasks*.

Dashboard Tab

The *Dashboard* Tab will appear by default. From here, you have quick access to an overview of your account. Use these sections to quickly identify pertinent information about studies you are involved in:



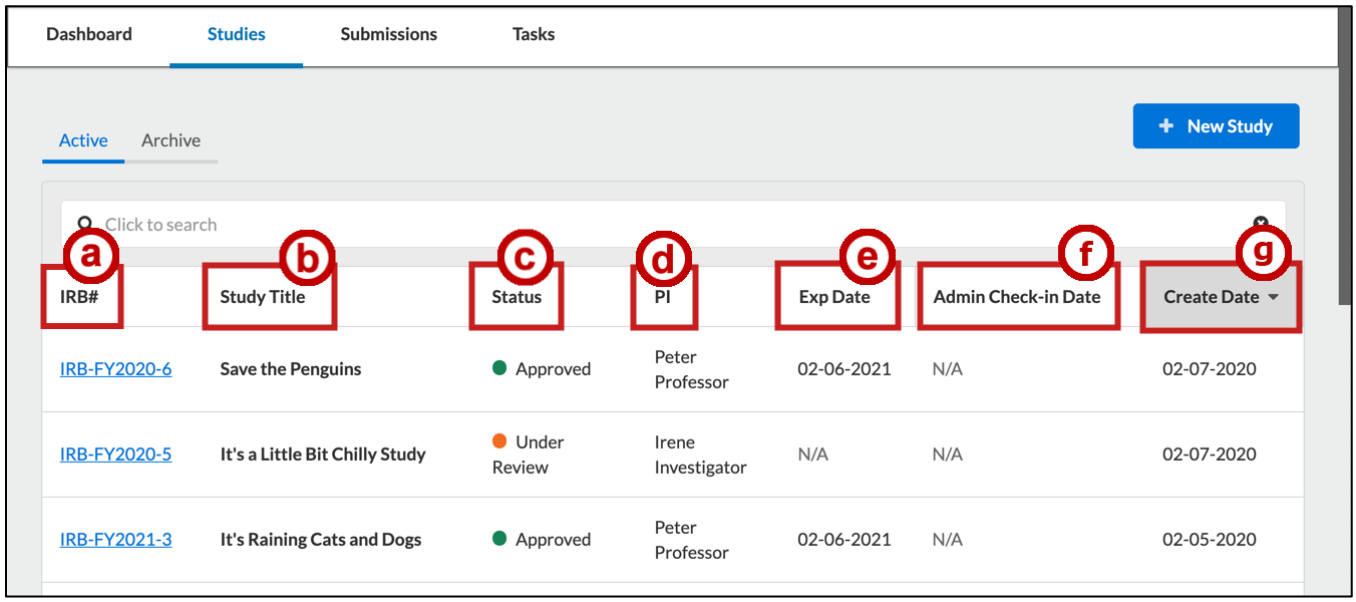
Dashboard Tab Interface

a. **In-Draft:** Submissions currently being completed by your research team.
b. **Awaiting Authorization:** Submissions waiting for approval or certification by the Principal Investigator(s).
c. **Pre-Review:** Submissions sent to the IRB Office.
d. **Under Review**: Submissions awaiting a decision from a committee or reviewers.
e. **Post Review**: Submissions awaiting final approval.
f. **My Studies:** Submissions you have authored or in which you are included as personnel.
g. **My Tasks:** Any specific tasks you are responsible for.
h. **Submissions by Type:** Separated by the type of submissions.
i. **Approved Studies:** Studies that have been approved.
j. **Studies Expiring in (Length of Time**): Studies close to expiration.
k. **Expired Studies**: Studies that are expired.

Note: No research activity is allowed under expired studies.

Studies Tab

This tab displays all studies that you are involved with and additional information about each one. By default, the *Active* tab will be displayed. To see studies that have been closed or expired, select the *Archive* tab.

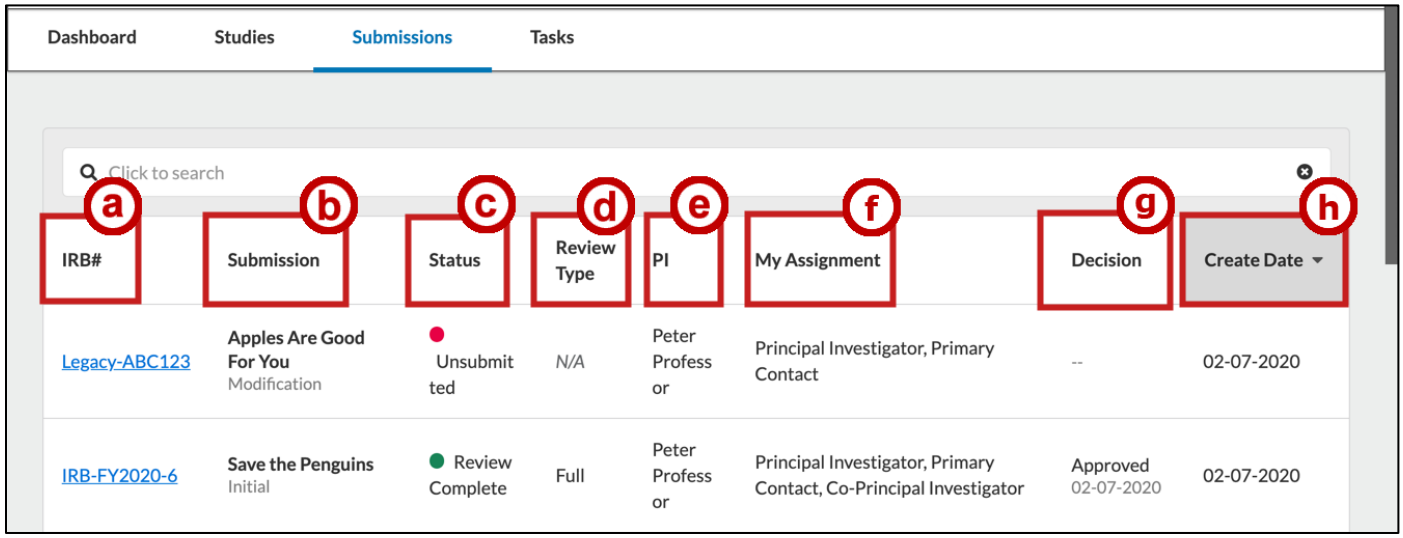


Studies Tab Interface

a. **IRB#:** Reference number for submission.
b. **Study Title:** Title given to the submission.
c. **Status:** Displays the current status of the study.
d. **PI:** User listed as the Principal Investigator.
e. **Expiration Date:** Date the study is set to expire.
f. **Admin Check-in Date:** Date the protocol requires check-in with the IRB office.
g. **Create Date:** Date study was created.

Submissions Tab

This tab displays additional information about the individual submissions.

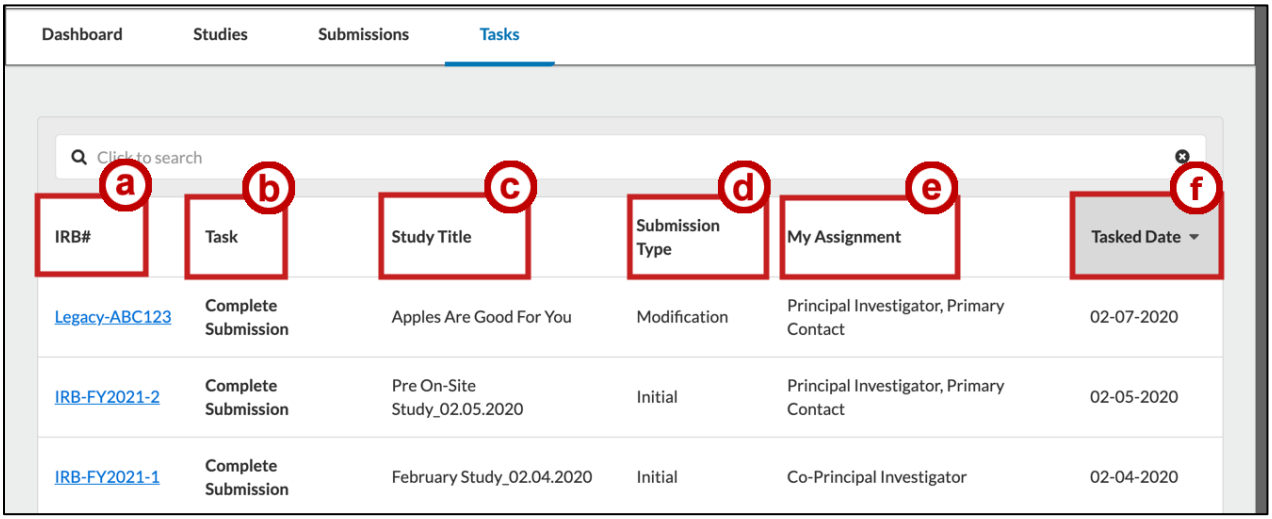


Submissions Tab Interface

a. **IRB#:** Reference number for submission.
b. **Submission:** Displays the title of the study and submission type.
c. **Status:** Displays the current status of the submission.
d. **Review Type**: Displays the type of review for the submission.
e. **PI:** User listed as the Principal Investigator.
f. **My Assignment:** Your role as listed in the application.
g. **Decision:** Displays any decision by the reviewer or committee.
h. **Create Date:** Date submission was created.

Tasks Tab

This tab specifically displays tasks that need to be completed for individual studies.



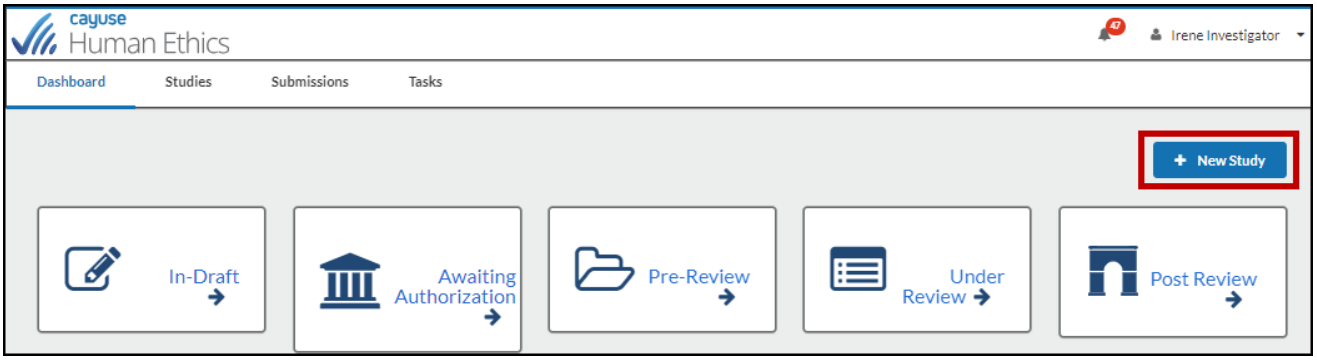
Tasks Tab Interface

a. **IRB#:** Reference number for submission.
b. **Task:** Lists the next task to complete.
c. **Study Title:** Displays the title of the study.
d. **Submission Type:** Displays the type of form.
e. **My Assignment:** Your role as listed in the application.
f. **Tasked Date:** Displays date task was assigned.

Submitting a New Study

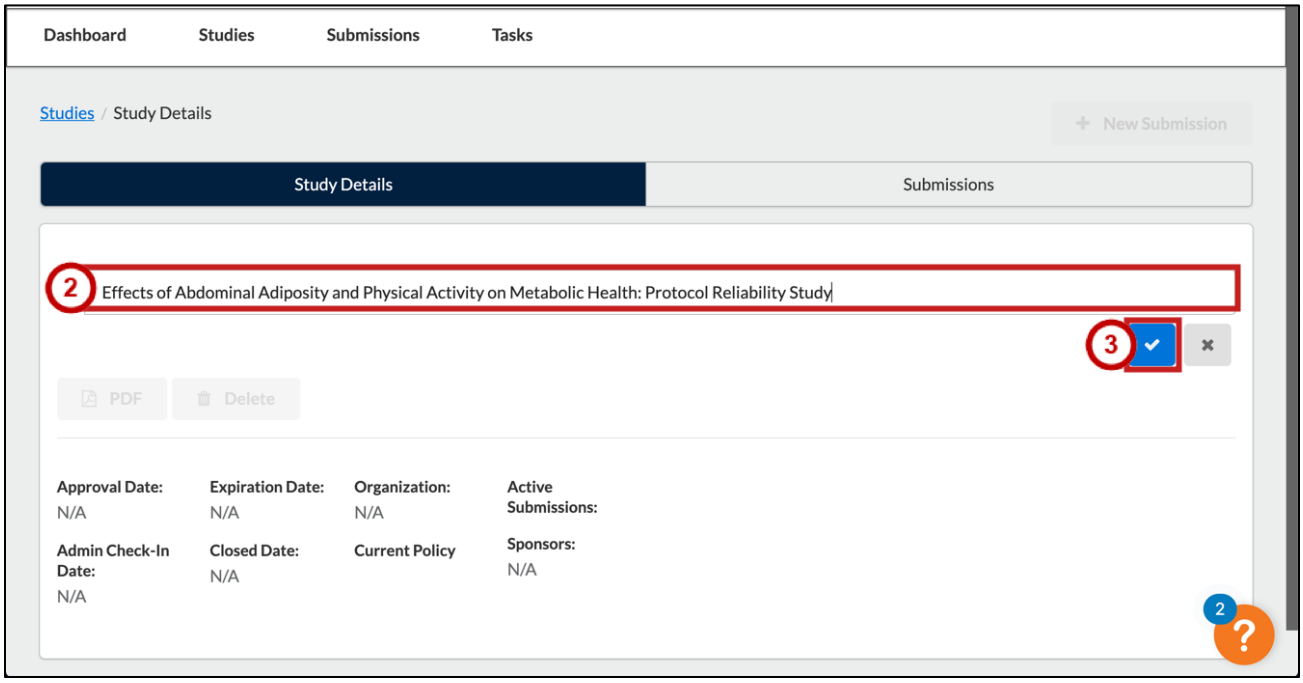
The following section explains how to create an initial submission.

1. From the *Dashboard* tab, click the blue **New Study** button.



Click the New Study Button

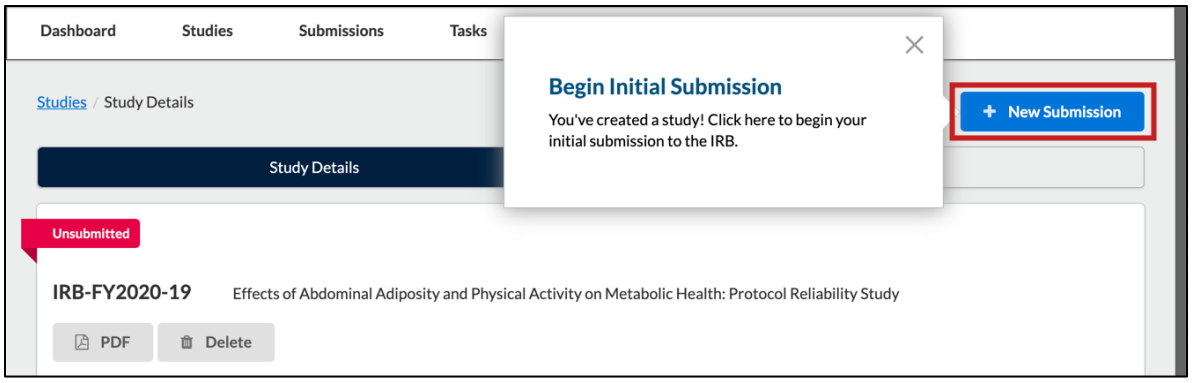
2. The *Study Details* page will open. Enter the **title of your study** in the text box.
3. Click the **blue checkmark** button to begin the submission process.



Enter Study Title and Click Blue Checkmark

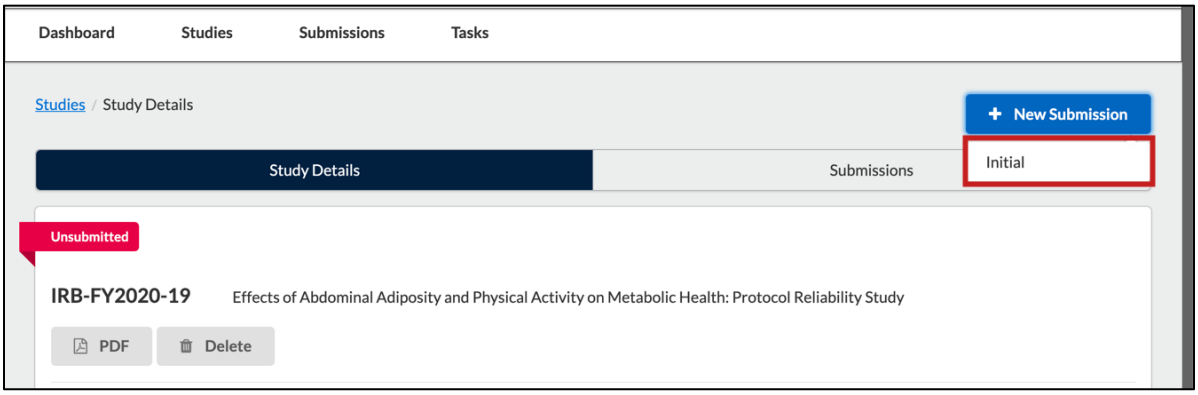
Note: The title of your study should offer specific details about your study. Avoid generic terms.

4. Your study will be assigned a number, and you will be prompted to begin your initial submission. Click the **New Submission** button to proceed.



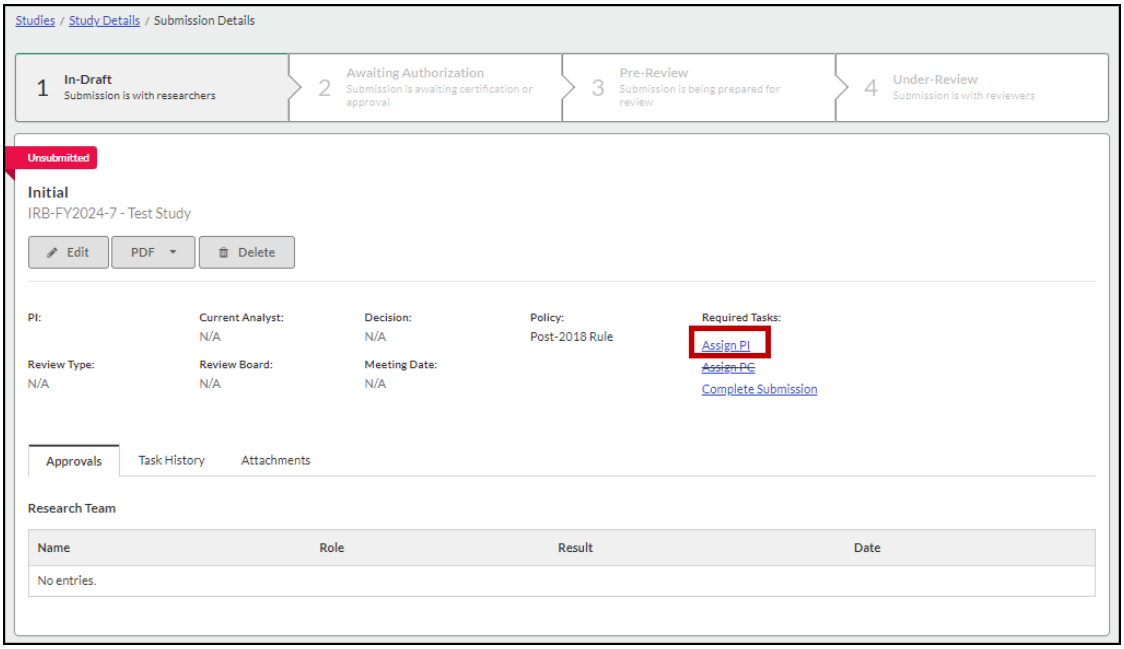
Click the New Submission Button

5. In the resulting dropdown menu, click **Initial**.



Click Initial

6. The study is now in the draft stage. A list of the required tasks will be displayed. Click **Assign PI**.



Click Assign PI

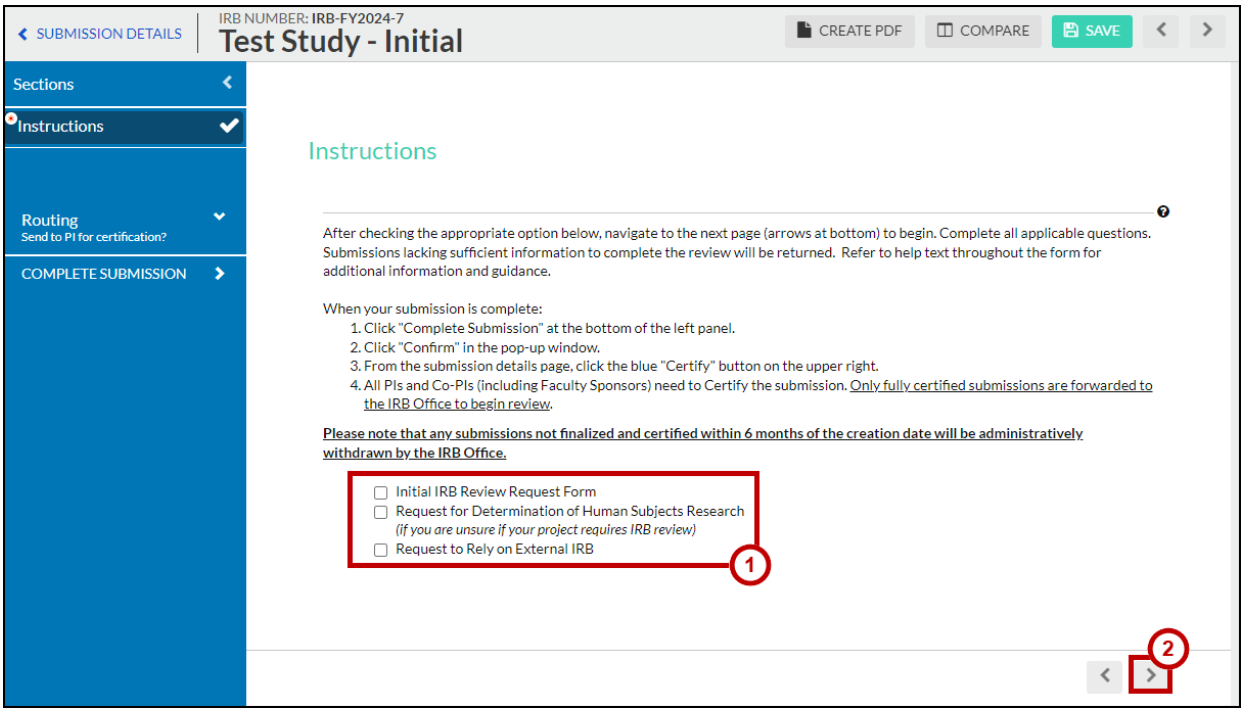
7. You will be directed to the *Instructions* section.

Instructions

This section will provide instructions and ask you to select the type of review that is needed.

1. Read through the information on the screen and select the **checkbox** next to the applicable review type.
2. Click the **forward arrow** to move to the next section.

Note: Click the **Save** button at any time to save your progress and return to the application later.



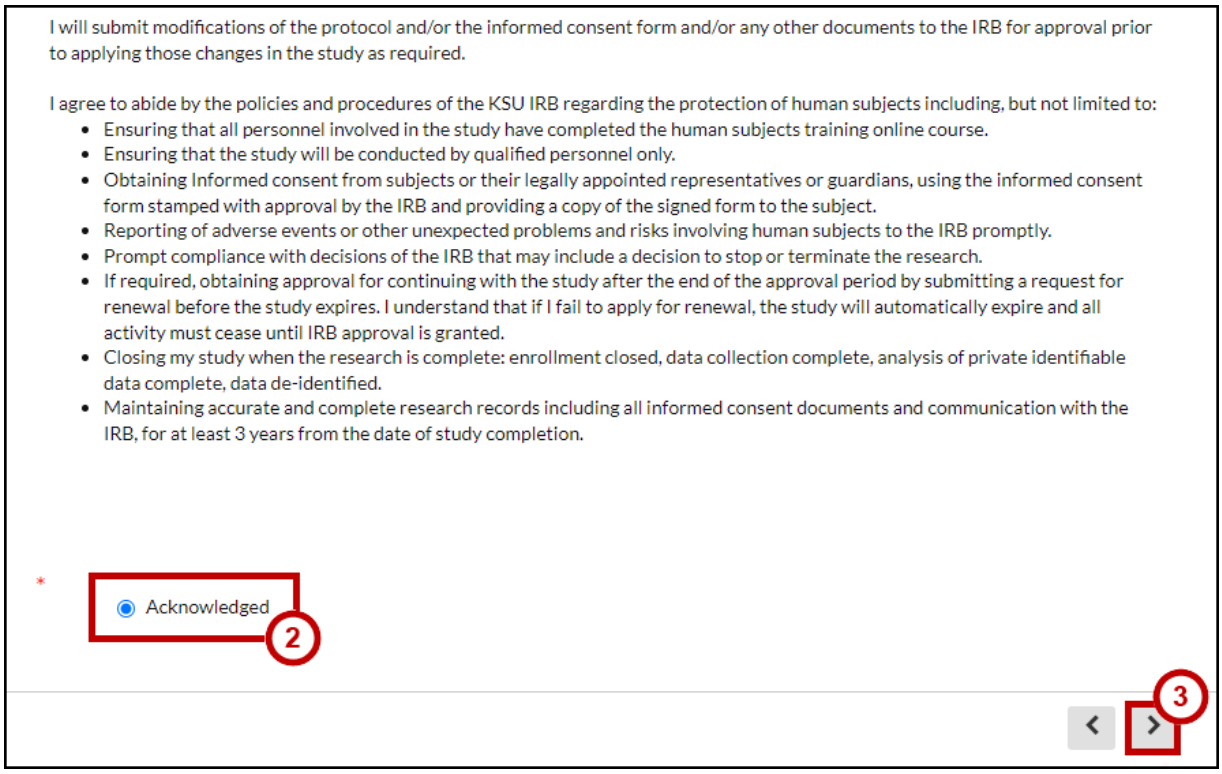
Select Review Type

Note: As you move through the application process, the menu bar to the left will populate with sections. You can move to another section anytime by clicking it, or navigate through the application using the arrows.

PI Assurance

This section will ask you to confirm that you agree to all KSU IRB policies.

1. Read the contents of the page and scroll to the bottom.
2. Select the radio button next to **Acknowledged** to confirm that you have read and agreed to all policies.
3. Click the **forward arrow** to move to the next section.

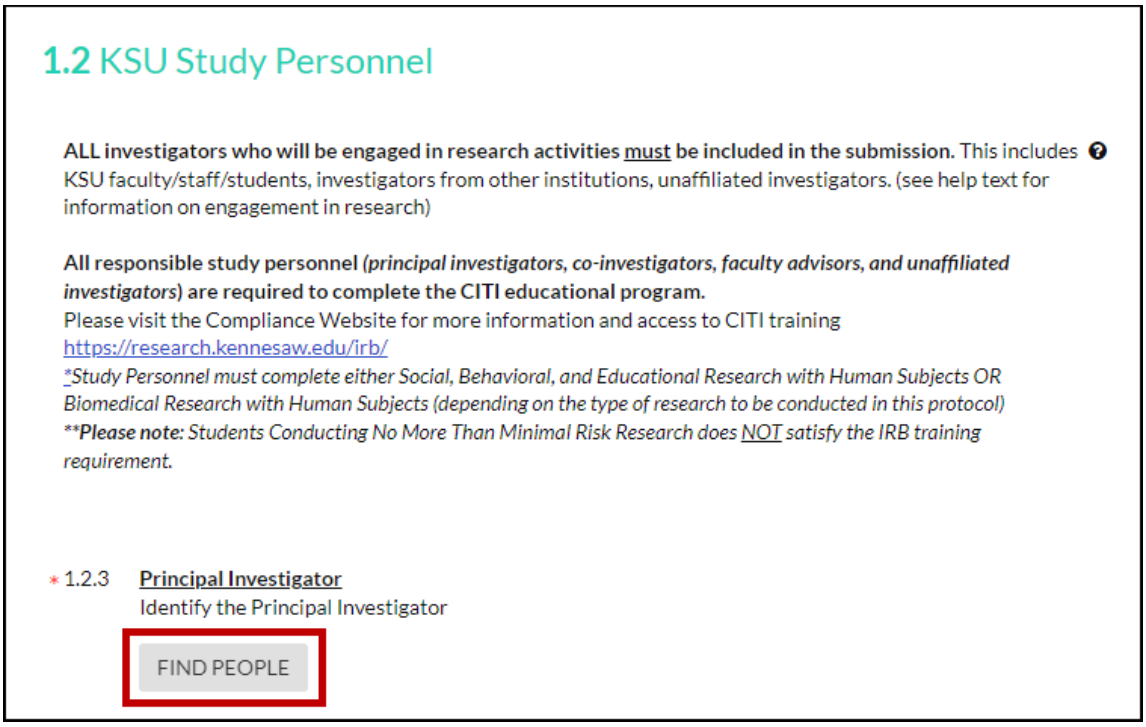


Agree to project policies

KSU Study Personnel

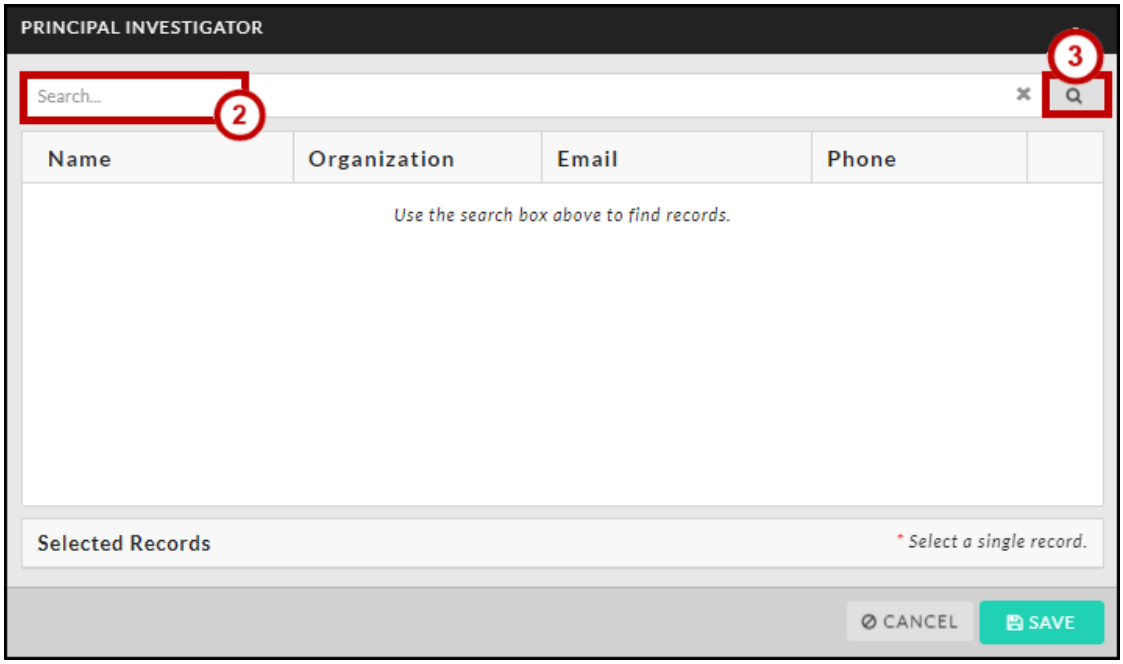
In this section, you will be prompted to provide information about the investigators participating in the study.

1. You will be asked to provide information about the principal investigator. To search for a user, click the **Find People** button.



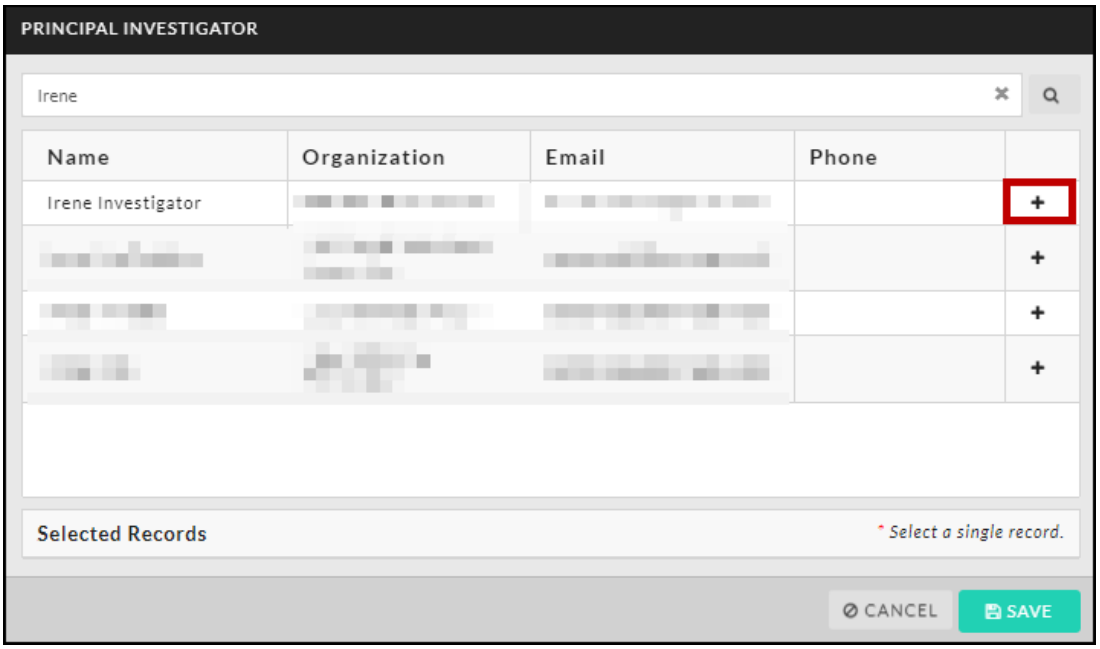
Click Find People

2. A new window will open. Enter the **Principal Investigator's name** in the search bar.
3. Click the **search** button to conduct a search.



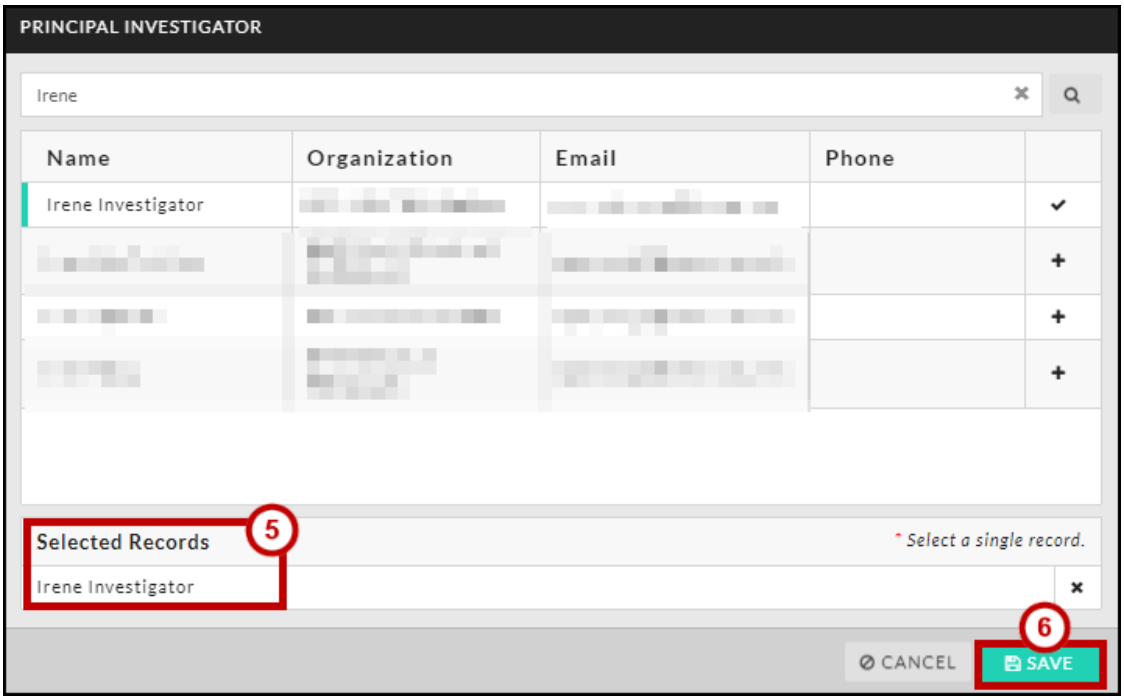
Enter PI Name and Click Search Button

4. A list of potential options will appear. To add a user, click the **plus sign** to the right of their name.



Click Plus Sign

5. The user's name will populate in the *Selected Records* box below the search results.
6. When you are finished, click **Save** to finish adding the selected user(s).

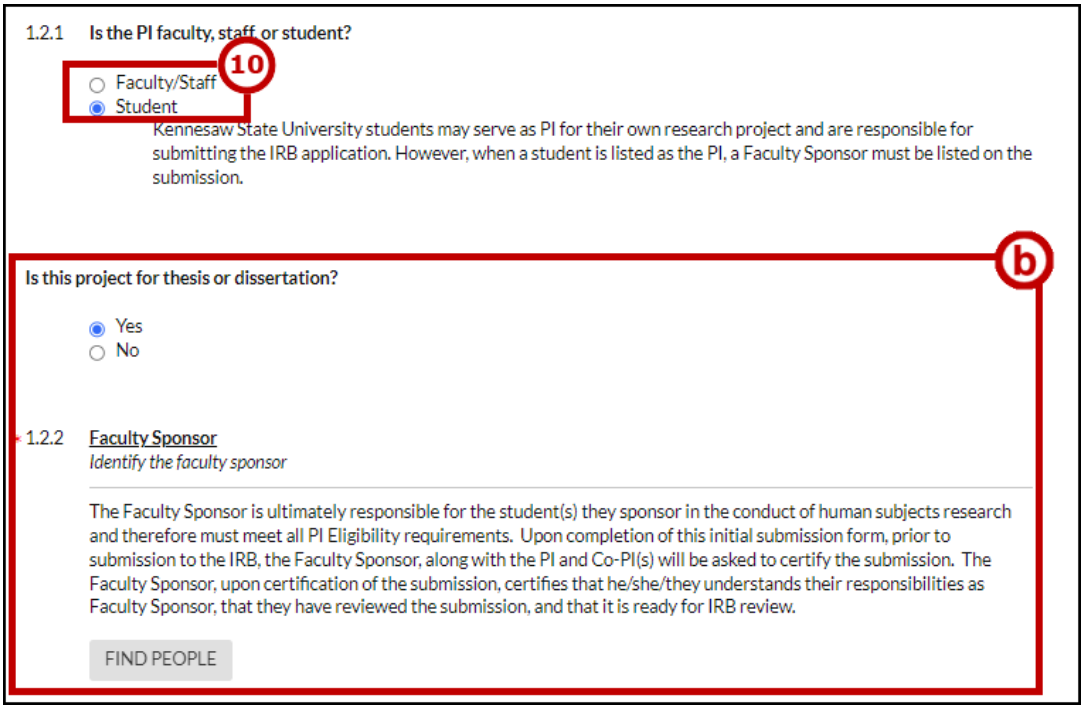


Review User(s) and Click Save

7. The user's information will now be populated under the appropriate field.
8. Once the user's information populates, click **View** to verify that the user has a current *CITI Training* associated with their account.

View CITI Training Status

9. A new window will open, displaying the training history. If the window is blank, the user will need to complete CITI training or ensure their CITI account is synced with Cayuse before the study can be approved. For information on CITI training, direct the user to https://research.kennesaw.edu/irb/citi-training.php.
10. Select one of the available options to indicate the PI's primary status at KSU.
    a. **Faculty/Staff:** Move on to the next question.
    b. **Student**: Answer the two additional questions before proceeding.



PI Status

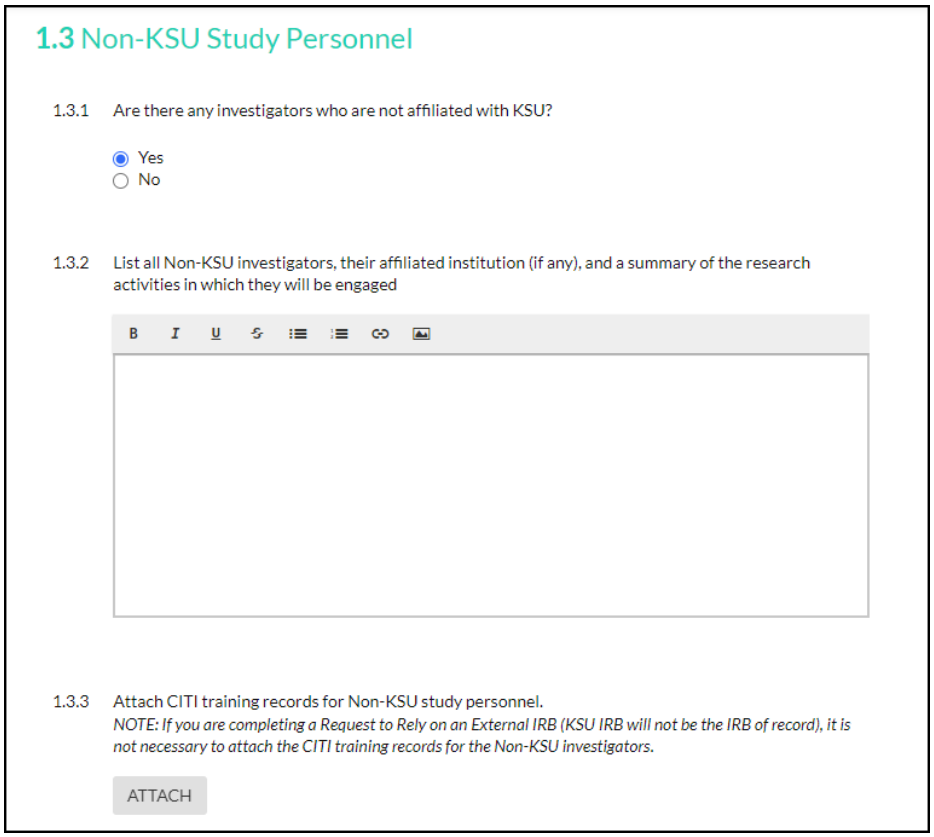
11. Repeat steps 1 through 6 to populate the fields for the *Co-Principal Investigator(s), Primary Contact,* and/or *Other KSU Personnel*, if applicable.

Note: Only questions with an asterisk (*) are required. If a question does not apply to your study, you may leave it blank. The *Principal Investigator* and *Primary Contact* must be listed to continue the submission process. Students must include a faculty sponsor who will be listed as a Co-PI. If you cannot find a user, it is likely they do not have an active Cayuse profile. You should direct the person to Cayuse - Human Subjects - Institutional Review Board to request an account.

Non-KSU Study Personnel

In this section, you will be prompted to provide information about any investigators who are not affiliated with KSU.

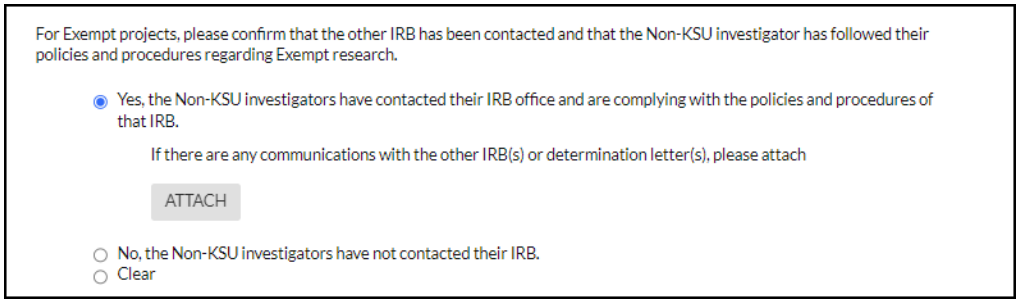
1. Select one of the available options to indicate whether there are any non-KSU personnel involved in the study.
    a. **No:** Continue to the next section.
    b. **Yes:** Enter the **names** and **details** of non-KSU investigators into the text field and attach **CITI Certificates** for each additional non-KSU user.



Enter personnel information

Note: Non-KSU personnel can affiliate with KSU in CITI and complete training.

2. Confirm that the non-KSU investigator has contacted their IRB office and attach any relevant documentation.



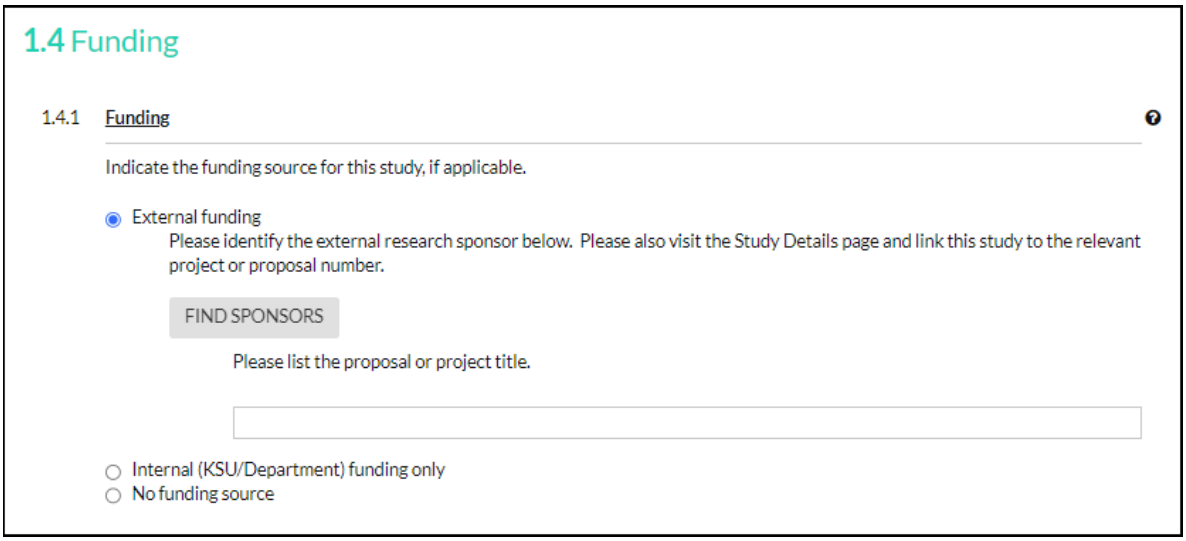
Non-KSU IRB Confirmation

Note: Please see the *Attach a File* section at the bottom of this document for more information on adding attachments.

Funding

This section will prompt you to select the funding source for the study.

1. Select the **radio button** next to the applicable funding source.
    a. If *External Funding* is selected, you will be asked to identify a Sponsor and list the proposal title.



External Funding

    b. If *Internal Funding* is selected, you will be asked to list the department and proposal title.

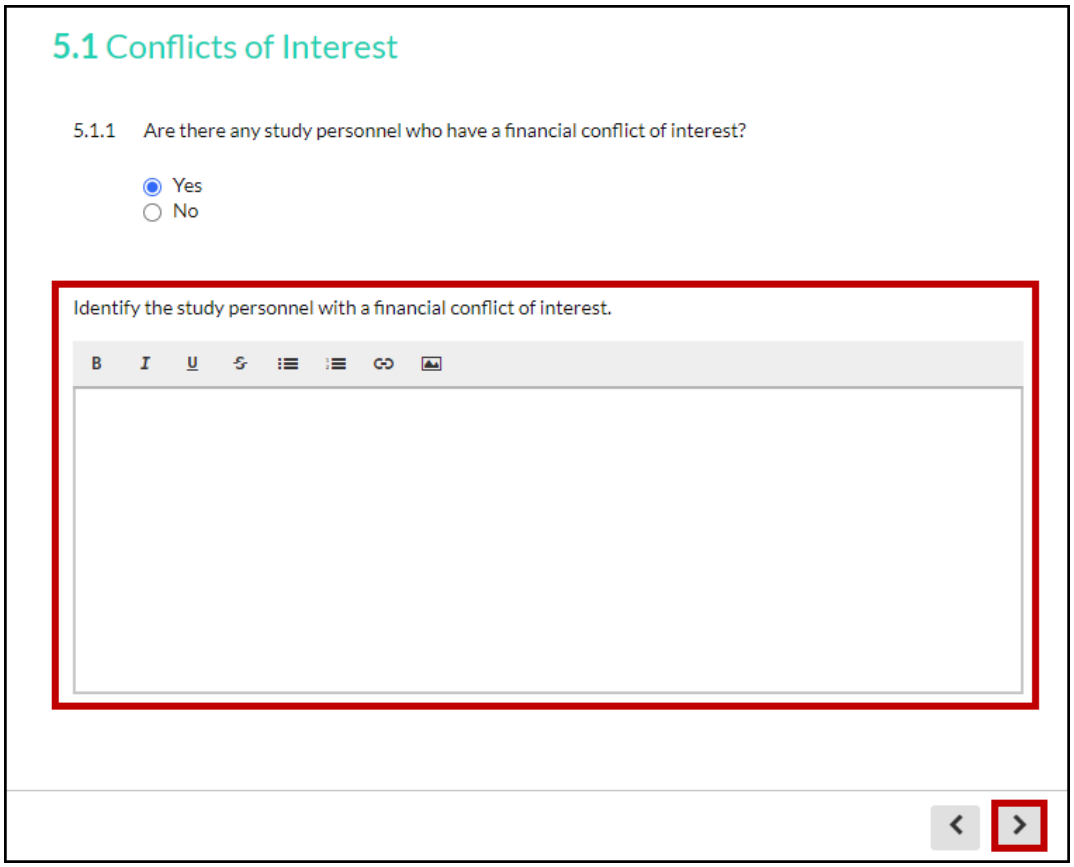
Internal Funding

    c. If *No funding source* is selected, there will be no additional questions.
2. Click the **forward arrow** to move on.

Conflicts of Interest

In this section, you will be asked to disclose any conflicts of interest.

1. Select the radio button next to the applicable option regarding potential conflicts of interest.
    a. **No**: Click the **forward arrow** to move on to the next section.
    b. **Yes**: Enter the name(s) of study personnel into the text box, then click the **forward arrow** to move on.



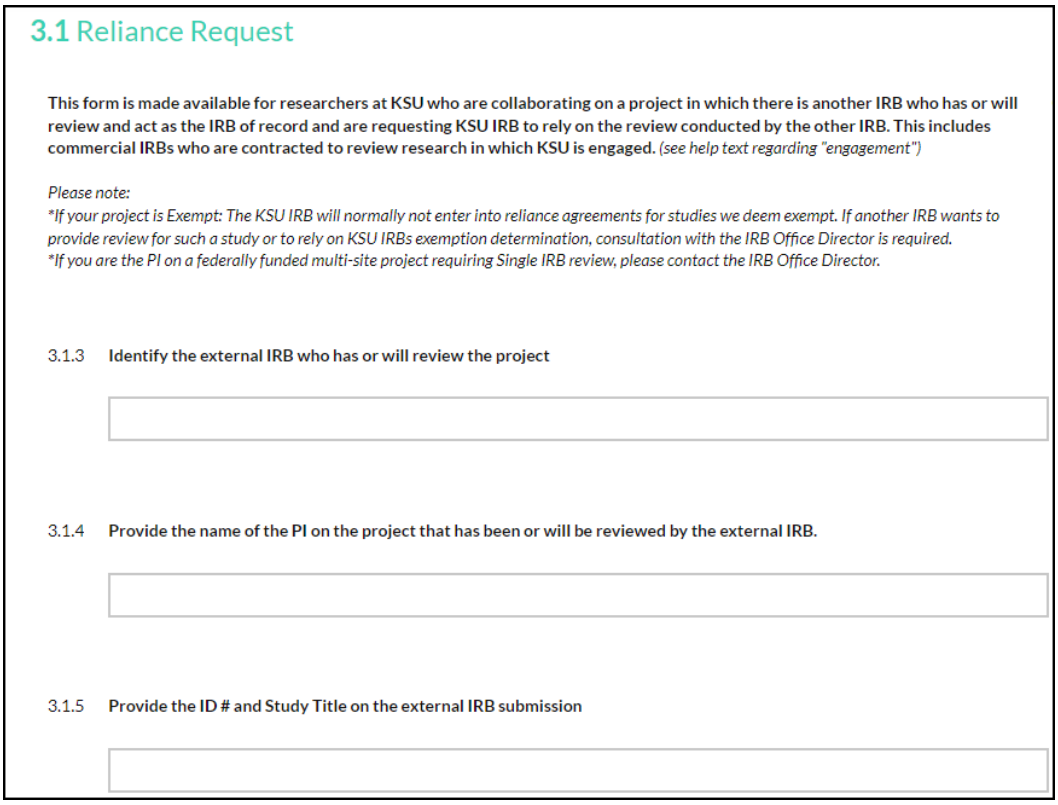
Identify study personnel

Note: Please also ensure that KSU personnel complete an FCOI disclosure.

Reliance Request

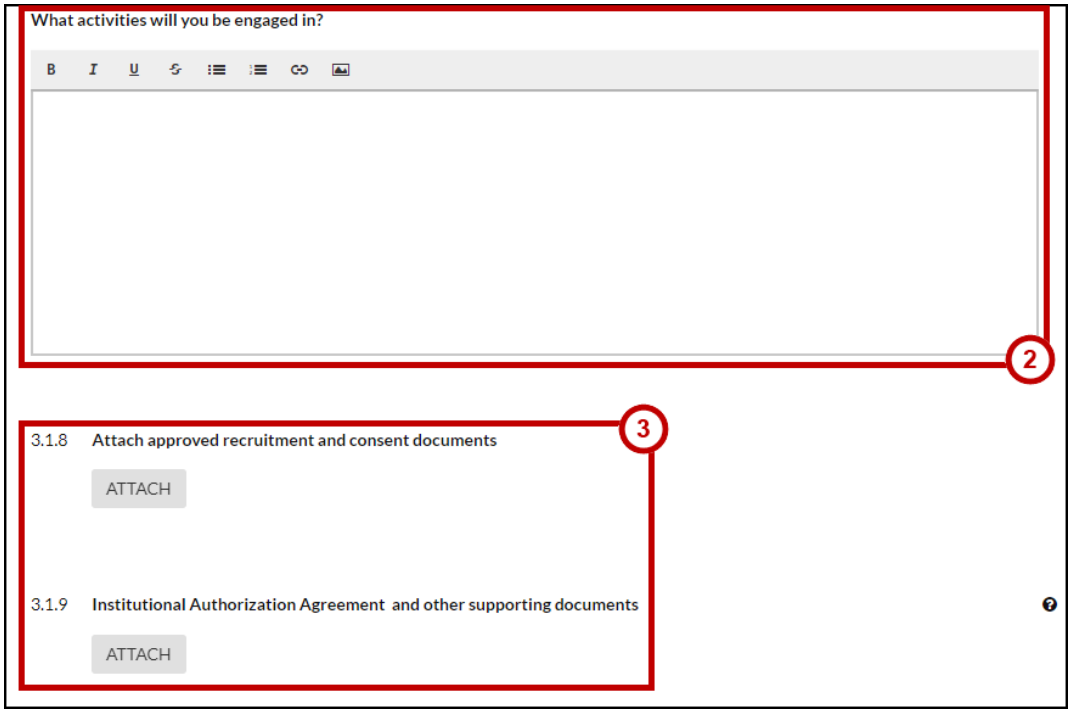
If you requested to rely on an external IRB (see the *Instructions* section), this section will prompt you to provide information on the external IRB.

1. Provide information about the external IRB.



External IRB Information

2. Provide a detailed response to the stated question regarding the activities being engaged in.
3. Attach any applicable documentation regarding the consent and protocols for the external IRB.



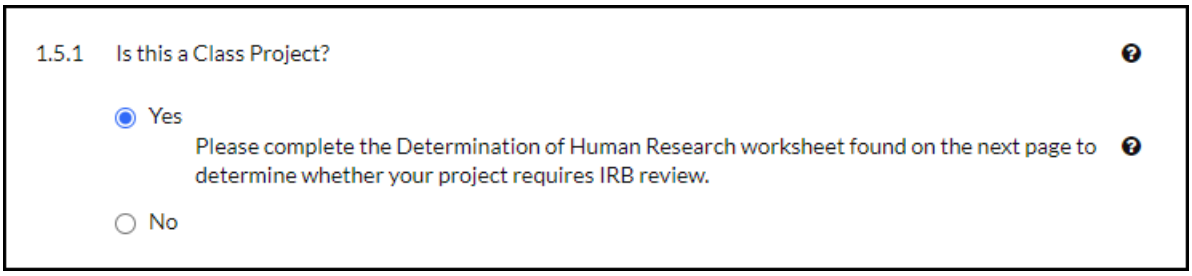
Attach documents

4. Click the **forward arrow** to proceed to the next section.

Class Projects

This section prompts you to say whether or not this is for a class project.

1. Select the radio button next to the option that best fits your study.
    a. **No**: Click the **forward arrow** to move on to the next section.
    b. **Yes:** An additional section entitled *Determination of Human Subjects Research* will appear after the current section. Click the **forward arrow** to complete the next section.

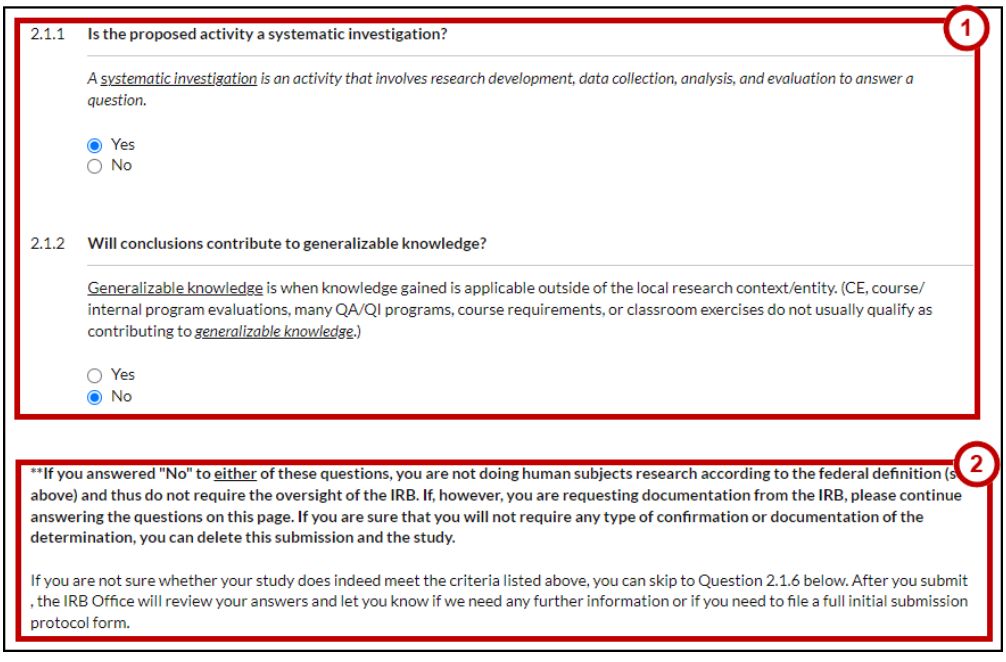


Select class project option

Determination of Human Subjects Research

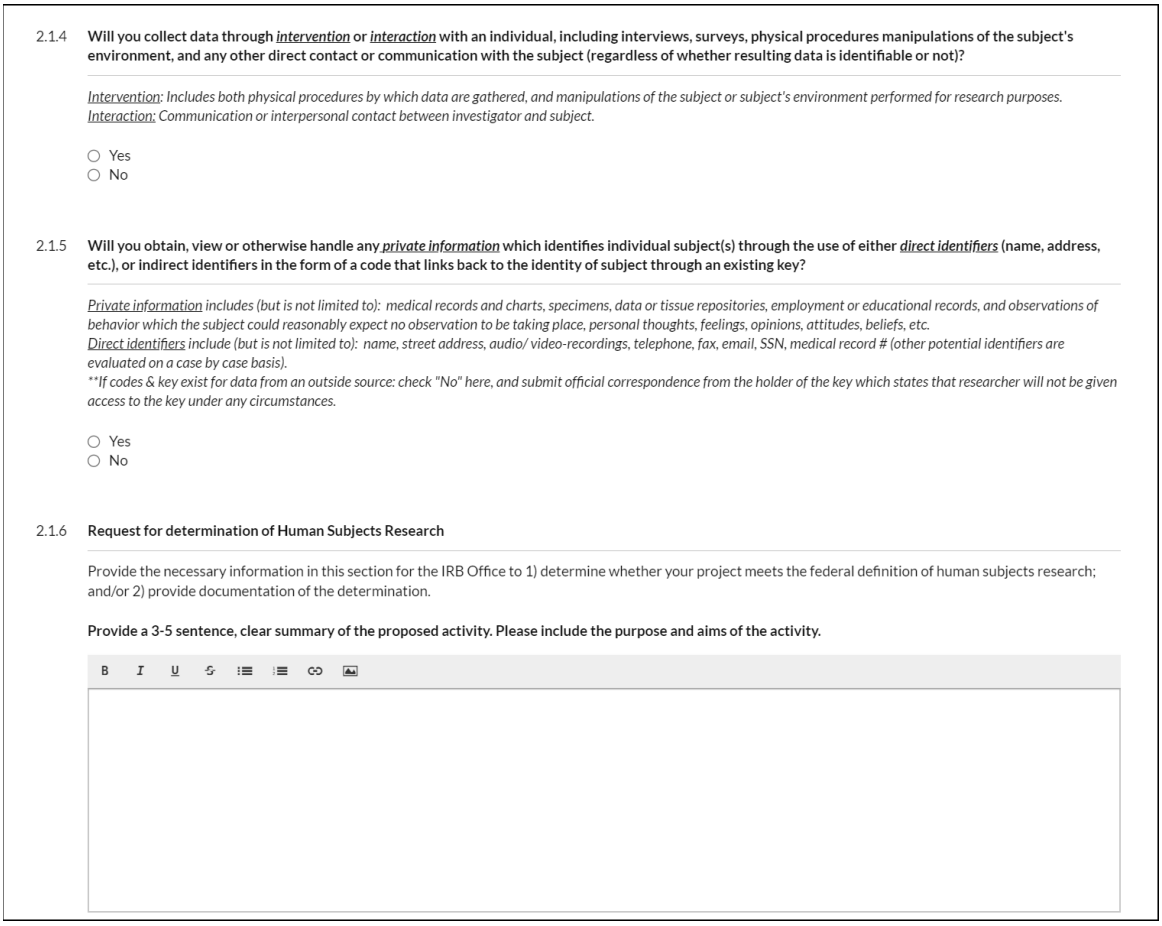
If you selected that you are unsure if your study requires review (see the *Instructions* section), or if this is a class project, this section will prompt you to provide information to determine whether or not this study is considered human subjects research.

1. For each multiple-choice question, select the radio button next to the option that best fits your study.
2. Read the information below each question carefully to determine whether or not you should continue this section.



Determination questions

3. If you determine that your study includes human subjects research *or* if you are still unsure, provide detailed answers to each additional question in this section.



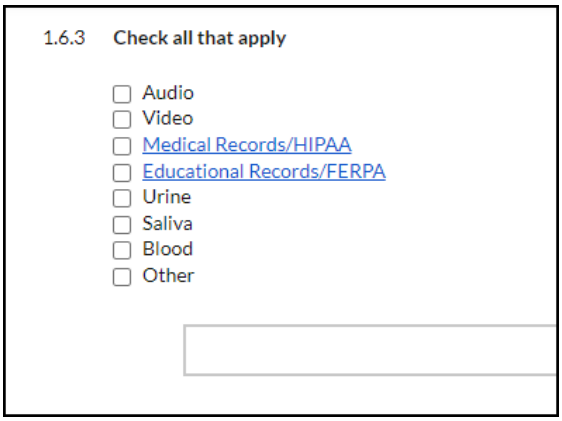
Complete additional questions

4. Click the **forward arrow** to continue to the next section.

Research Design

This section allows you to provide additional details about how the study is designed.

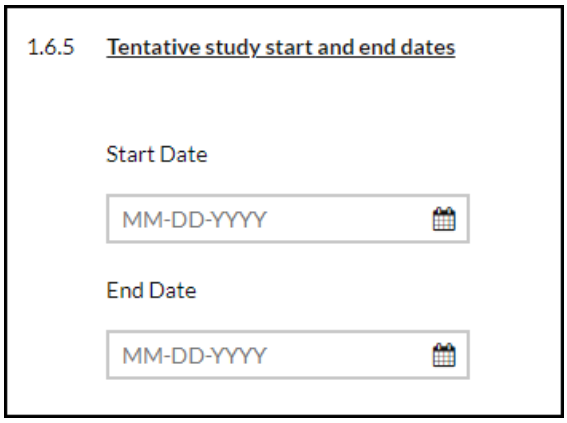
1. Enter detailed answers into each text box on the page.
2. Select the checkbox next to each option that applies to the study.
   Note: If *urine*, *saliva*, or *blood* is selected, you will be prompted to answer additional questions about specimen use.



Select options

Note: Urine, saliva, blood, or other biological specimens require IBC review and approval. https://research.kennesaw.edu/ibc/index.php

3. Click within the field to browse for a **Start Date** and **End Date** for your study.



Select a start and end date

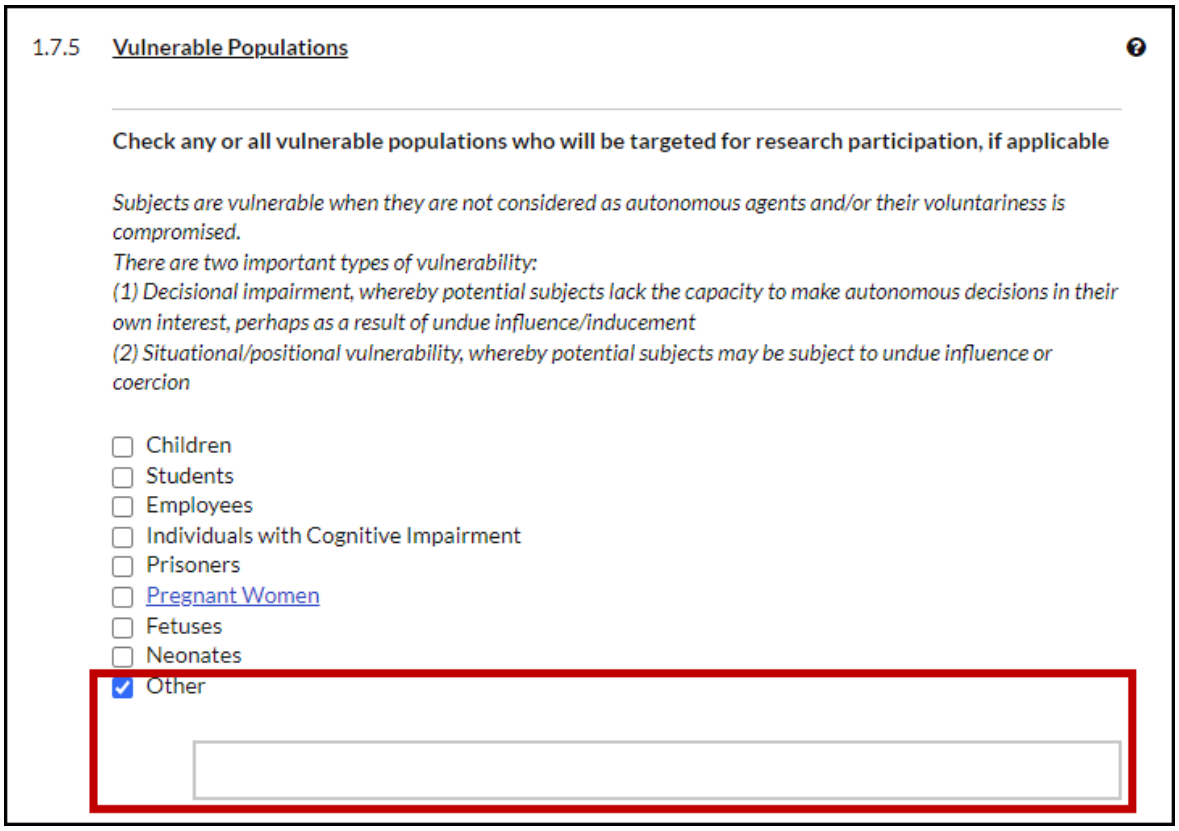
Note: The Start Date must be after the submission date of the study.

4. Ensure that you scroll to the bottom of the page and answer any applicable questions, then click the **forward arrow** to move on.

Subject Selection

In this section, you will be prompted to provide details about the participants in the study.

1. Enter detailed answers into each text box on the page.
2. Select one or more of the available options to indicate any vulnerable populations that will participate in the study.
    a. If none of the answers apply, move on to the next section.
    b. If **Other** is selected, you will be prompted to provide additional information about the participants. Enter a **description** in the text field.



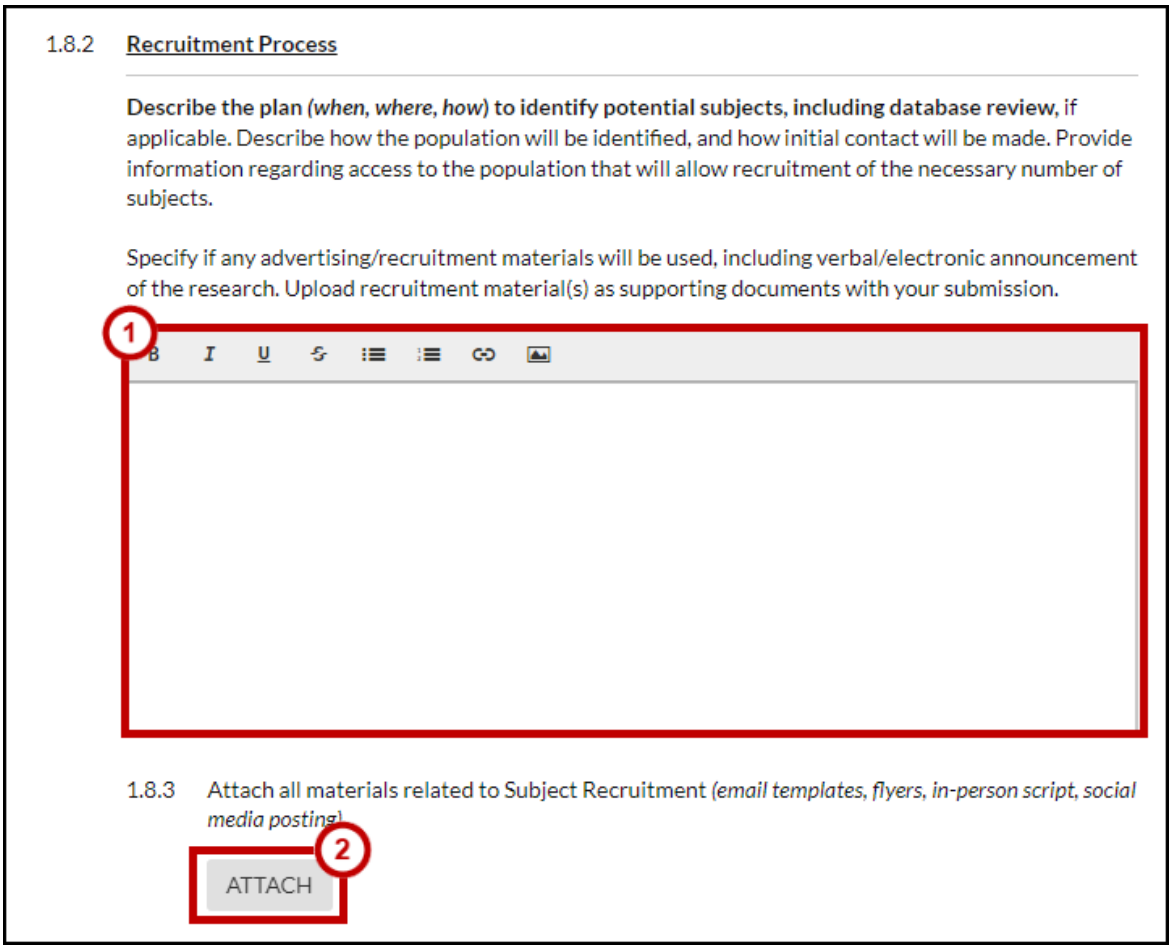
Describe Vulnerable Population

3. When you have answered all applicable questions, click the **forward arrow** to move on.

Subject Recruitment

In this section, you will be asked to describe the relevant processes for recruiting subjects.

1. Enter details into each applicable text box. If your study does not require compensation or screening, leave those boxes blank.
2. If you have any additional materials related to subject recruitment, click the **Attach** button to attach them to the appropriate question.



Describe subject recruitment

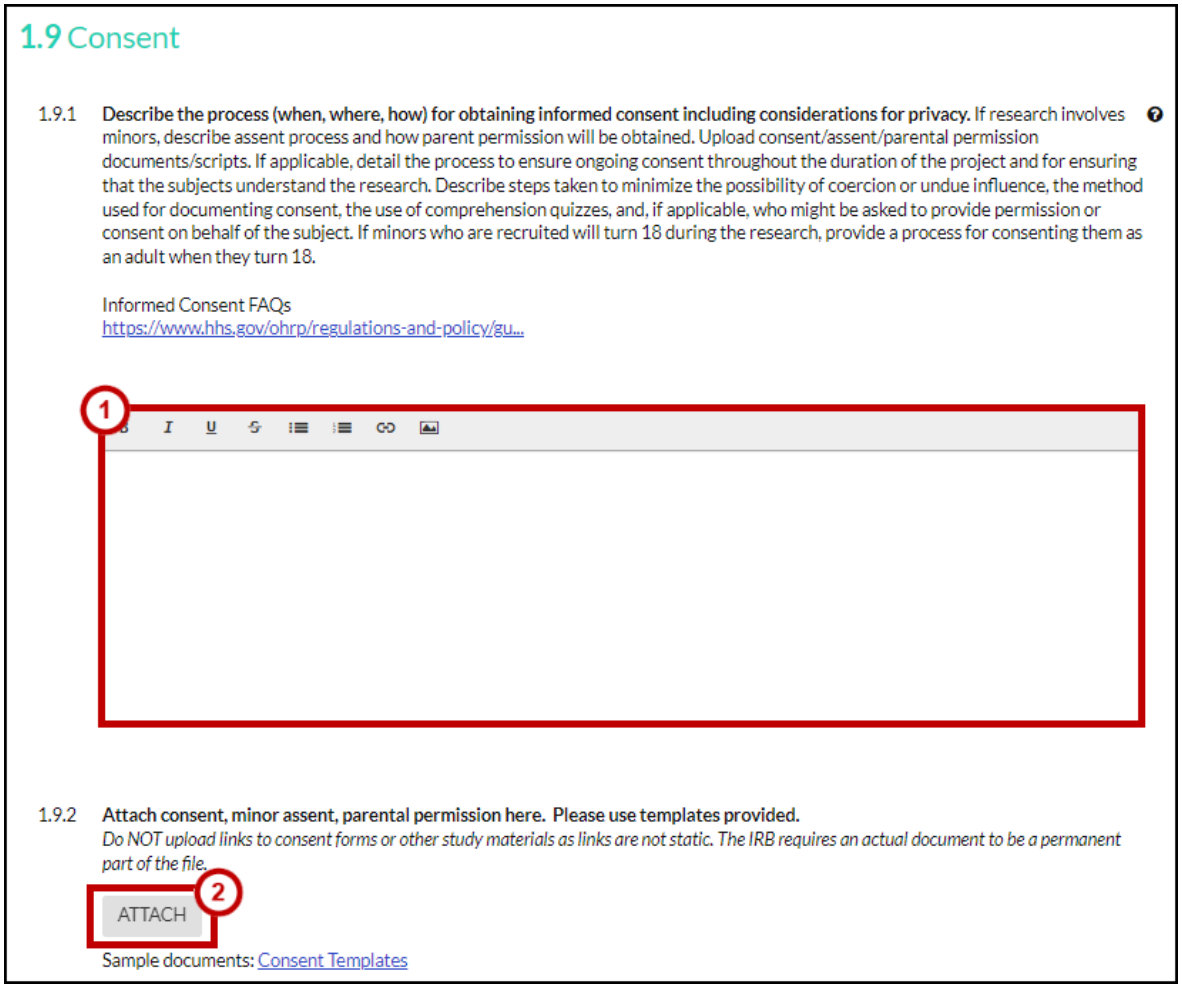
Note: Please see the *Attach a File* section of this document for more information.

3. After completing all applicable questions, click the **forward arrow** to proceed to the next section.

Consent

In this section, you will be asked to describe the processes in place for obtaining consent from study participants.

1. Enter detailed answers regarding the consent procedures for each group involved in your study.
2. Click the **Attach** button to attach consent forms for each question.



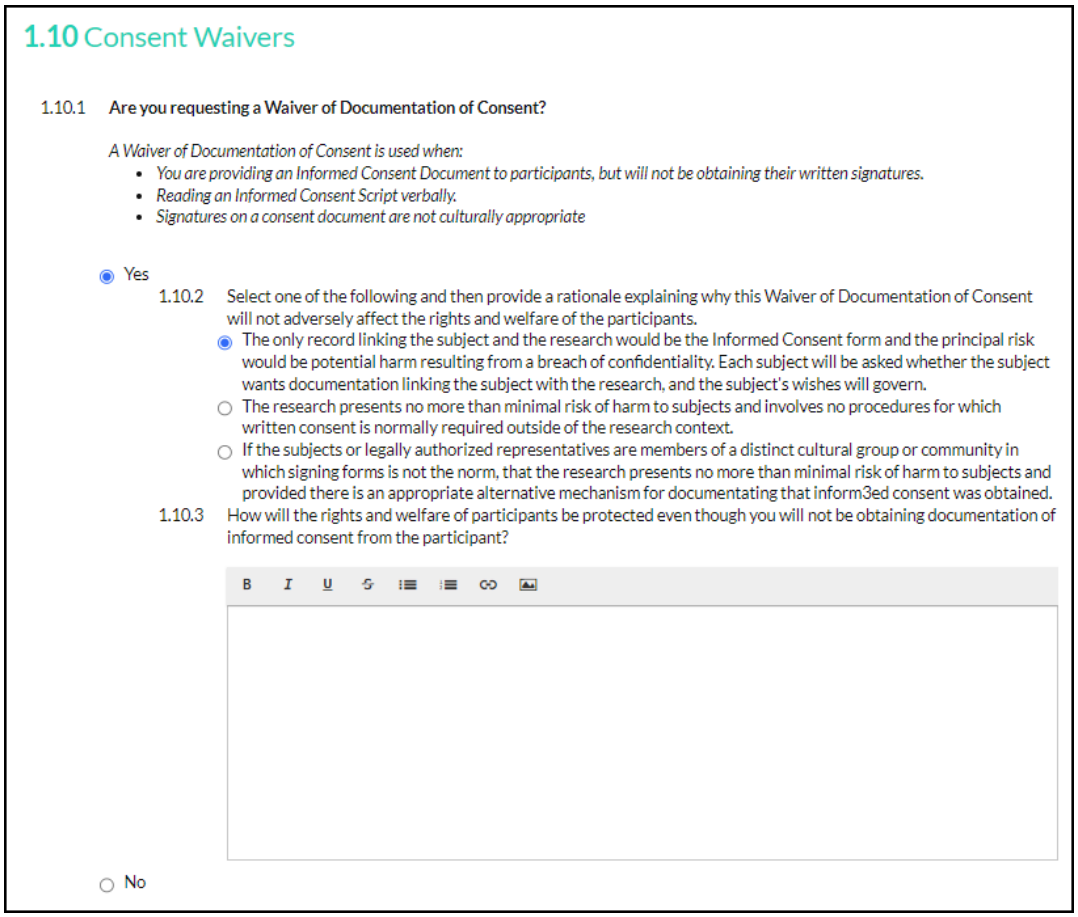
Describe consent details

3. After completing all applicable questions, click the **forward arrow** to proceed to the next section.

Consent Waivers

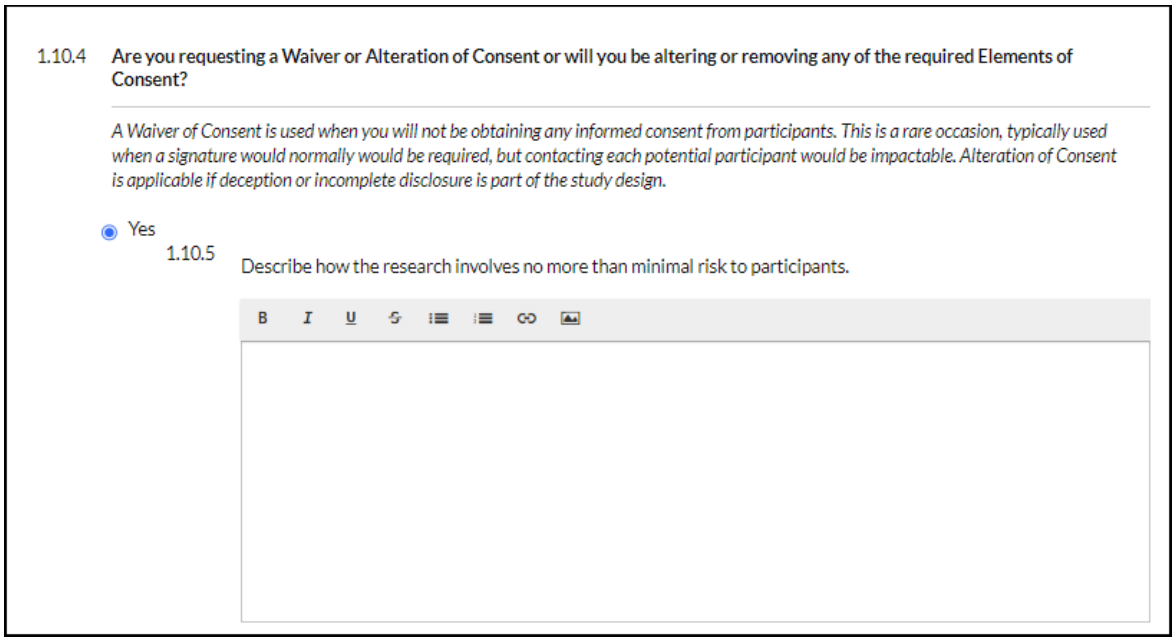
This section will prompt you to explain the reasoning for any consent waiver requests.

1. Select the radio button next to the option that best fits your study for *Documentation of Consent*.
    a. **No**: Continue to the next question.
    b. **Yes:** Additional questions will appear asking you to provide details about your consent waiver documentation.



Waiver of Documentation of Consent

2. Select the radio button next to the option that best fits your study for *Alteration of Consent*.
    a. **No**: Click the **forward arrow** to move on to the next section.
    b. **Yes:** Additional questions will appear. After responding to these questions, click the **forward arrow** to move on to the next section.



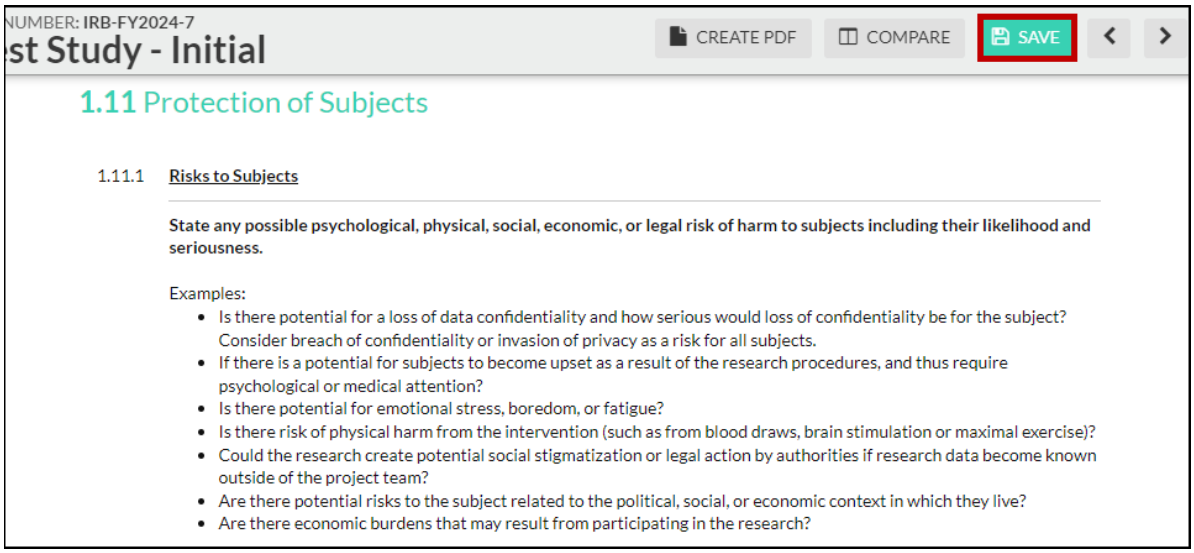
Waiver or Alteration of Consent

Protection of Subjects

In this section, you will be asked about the procedures for protecting the participants in the study.

1. Enter **detailed answers** to each question in this section.
2. Click the **forward arrow** to proceed to the next section.

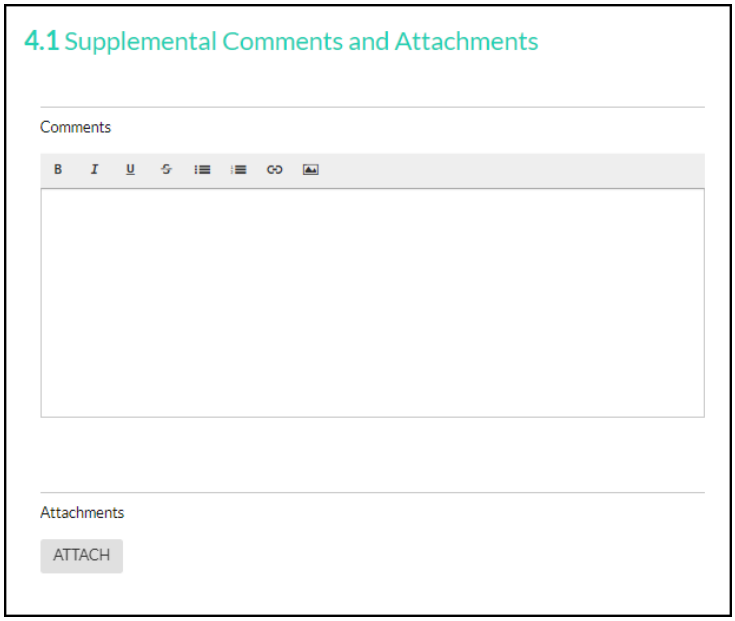
Note: Be sure to click the **Save** button after answering each question to avoid losing your progress.



Save progress

Supplemental Comments and Attachments

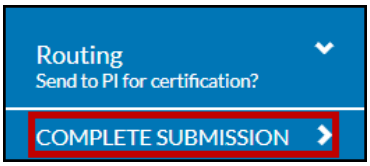
In this final section, you will have the opportunity to include any additional information and attach relevant documents.



Add final comments and attachments

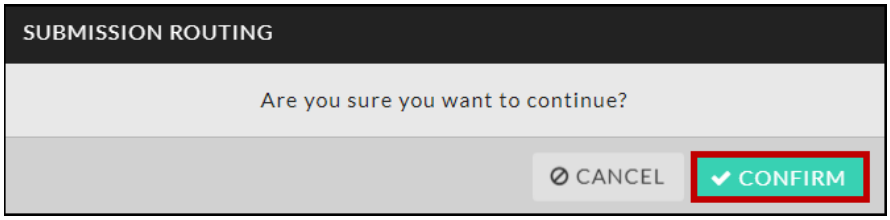
Completing the Submission

1. Click **Complete Submission** in the bottom left corner of the screen.



Complete submission

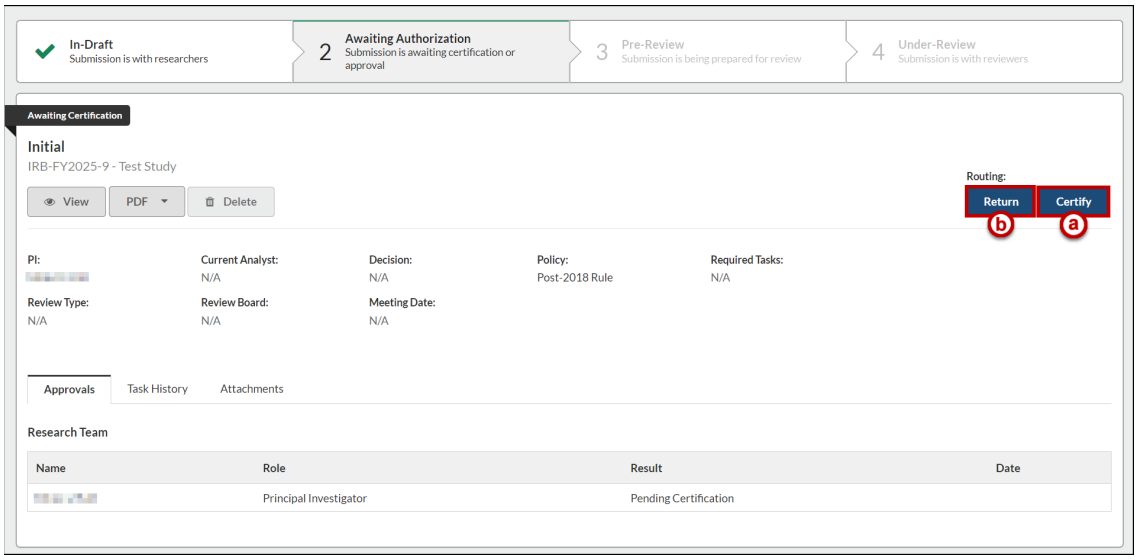
2. A new window will open asking you to confirm your submission. Click **Confirm.**



Confirm

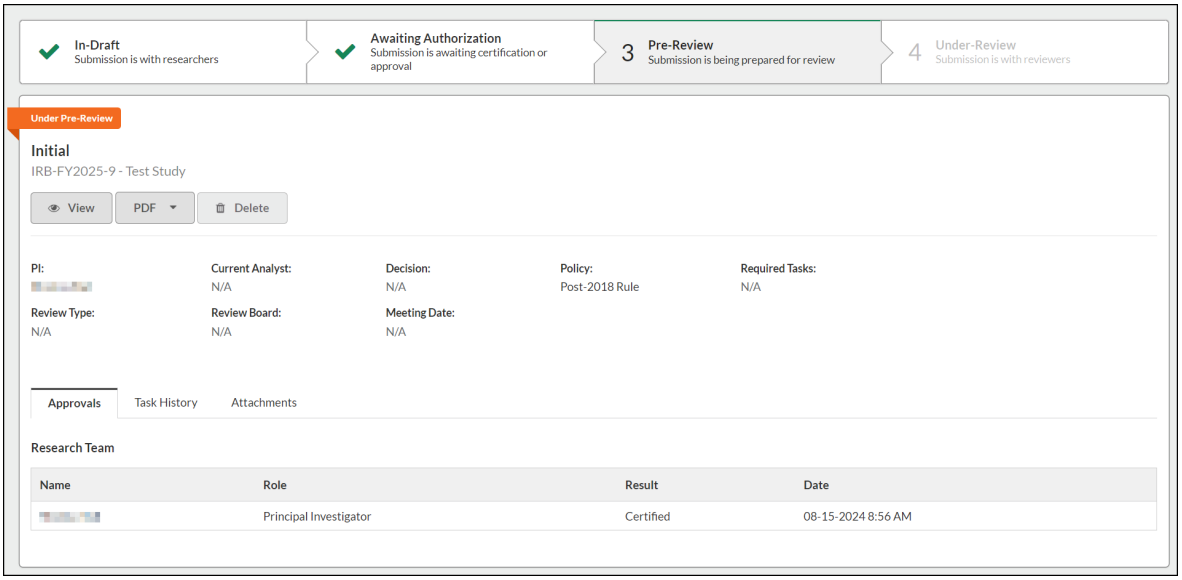
Note: The Complete Submission tab will only appear when all required fields in the document have been completed. If you do not see this tab, review all previous tabs and ensure that all required fields have been completed and all sections have been viewed. This can be confirmed by the checkmarks next to each section in the menu.

3. You will be redirected to the application screen.
    a. The PI and Co-PI(s) must click **Certify** to send the submission to the IRB.
    b. If changes are needed, the PI may click **Return** to make edits to the submission.



Certify submission

Note: The PI and Co-PI(s) will receive an email notification when the submission is ready for certification. If the PI is a student, the faculty sponsor (Co-PI) must review the submission before certifying.



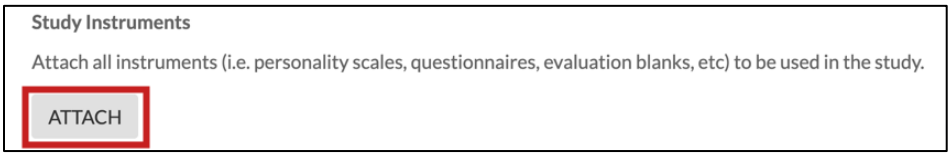
Study under review

4. Your application has been submitted, and you will be notified via email by Cayuse with further instructions.

Attach a File

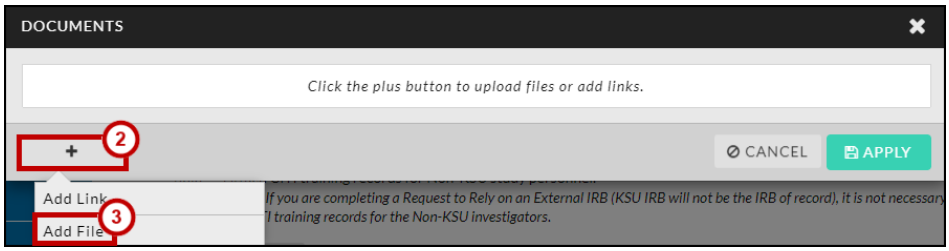
This section will outline the steps to attach a file or link to your submission.

1. Click the **Attach** button.



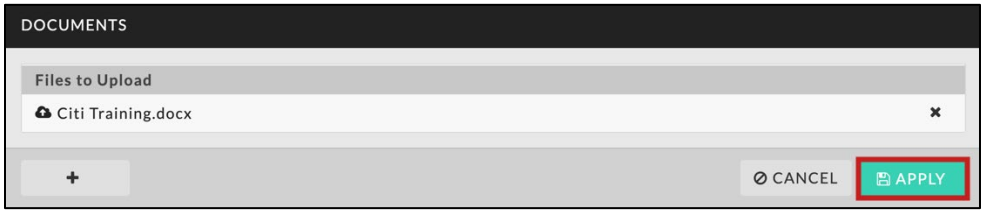
Click Attach

2. A new window will open. Click the **plus sign**.
3. In the drop-down menu that appears, click **Add File**.



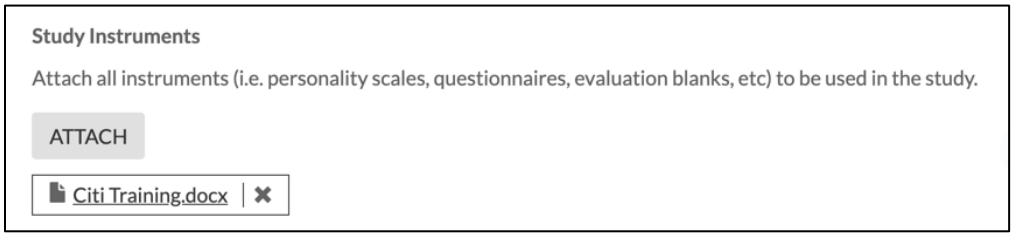
Add File

4. Find and click on the name of the **file** you want to upload, then click **Open.**
5. The file name will populate the window. Click **Apply** to finish attaching the file.



Click Apply

6. The file has been attached.



File is Attached

Additional Help

For technical support, email service@kennesaw.edu
For protocol development and submission questions, email irb@kennesaw.edu