



KENNESAW STATE
UNIVERSITY

OFFICE OF RESEARCH
Research Integrity

Cayuse IRB

Submitting a Proposal

Cayuse IRB - Submitting a Proposal

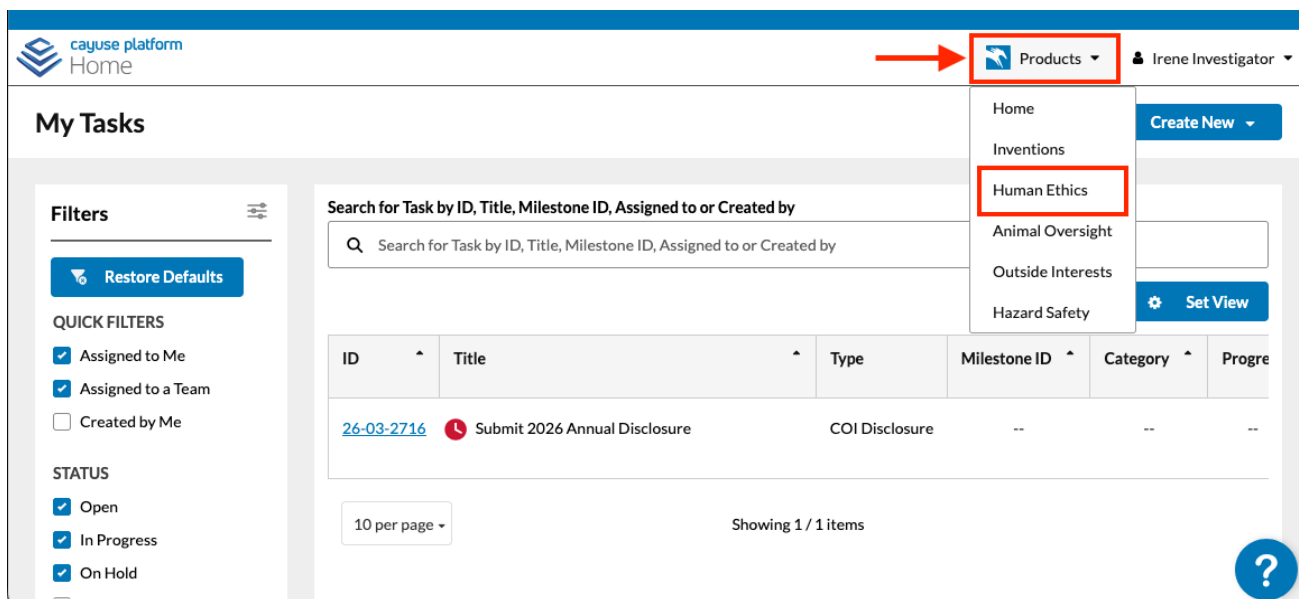
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Accessing Cayuse IRB

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.
4. You will use the Product switcher at the top right of the screen. Click on “Human Ethics” to open Cayuse IRB. Please see the screenshot below.



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

Note: For information on creating or accessing your Cayuse account, please navigate to <https://campus.kennesaw.edu/offices-services/research/resources/research-integrity/compliance-committees/institutional-review-board/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:

The screenshot displays the Cayuse Human Ethics Dashboard. At the top, there are navigation tabs for 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. A user profile for 'Irene Investigator' is visible in the top right corner. Below the navigation is a '+ New Study' button. The dashboard is organized into several sections:

- Status Cards (a-e):** Five cards representing submission stages: 'In-Draft', 'Awaiting Authorization', 'Pre-Review', 'Under Review', and 'Post Review'.
- My Studies (f):** A table listing studies authored or involving the user, including IRB-FY2024-6 (Comparison Guide), IRB-FY2024-5 (Cayuse Reviewer Training), IRB-FY2022-18 (title), IRB-FY2024-4 (Testing new features), and Legacy-ABC123 (Apples Are Good For You).
- My Tasks (g):** A table listing tasks assigned to the user, such as IRB-FY2023-5 (Complete Submission), Legacy-ABC123 (Complete Submission), IRB-FY2023-4 (Complete Submission), IRB-FY2021-16 (Complete Submission), and Legacy-GHI789 (Complete Submission).
- Submissions by Type (h):** A table showing the count of submissions for various types: Renewal (3), Initial (23), Modification (3), Incident (1), Withdrawal (0), Closure (1), and Legacy (2).
- Approved Studies (i):** A table listing approved studies, including IRB-FY2022-18 (title), Legacy-ABC123 (Apples Are Good For You), IRB-FY2022-10 (Testing team access), IRB-FY2020-5 (It's a Little Bit Chilly Study), and IRB-FY2023-5 (Expedited Review Too).
- Studies Expiring in 30 days (j):** A table listing studies nearing expiration, such as IRB-FY2020-5 (It's a Little Bit Chilly Study).
- Expired Studies (k):** A table listing expired studies, such as IRB-FY2022-6 (Testing new submission form).

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.

The screenshot shows the 'Studies' tab interface. At the top, there are navigation tabs: 'Dashboard', 'Studies' (selected), 'Submissions', and 'Tasks'. Below these, there are sub-tabs: 'Active' (selected) and 'Archive'. A '+ New Study' button is in the top right. A search bar with the text 'Click to search' is at the top left. The main content is a table with the following columns: IRB#, Study Title, Status, PI, Exp Date, Admin Check-in Date, and Create Date. Three rows of study data are visible. Red boxes with letters a-g are placed over the column headers to identify them.

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2020-6	Save the Penguins	Approved	Peter Professor	02-06-2021	N/A	02-07-2020
IRB-FY2020-5	It's a Little Bit Chilly Study	Under Review	Irene Investigator	N/A	N/A	02-07-2020
IRB-FY2021-3	It's Raining Cats and Dogs	Approved	Peter Professor	02-06-2021	N/A	02-05-2020

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.

The screenshot shows a web application interface with a navigation bar at the top containing 'Dashboard', 'Studies', 'Submissions' (highlighted), and 'Tasks'. Below the navigation bar is a search bar with the placeholder text 'Click to search'. The main content area is a table with the following columns: IRB#, Submission, Status, Review Type, PI, My Assignment, Decision, and Create Date. The table contains two rows of data. Red boxes and letters (a-h) are overlaid on the table to highlight specific columns: 'a' on IRB#, 'b' on Submission, 'c' on Status, 'd' on Review Type, 'e' on PI, 'f' on My Assignment, 'g' on Decision, and 'h' on Create Date.

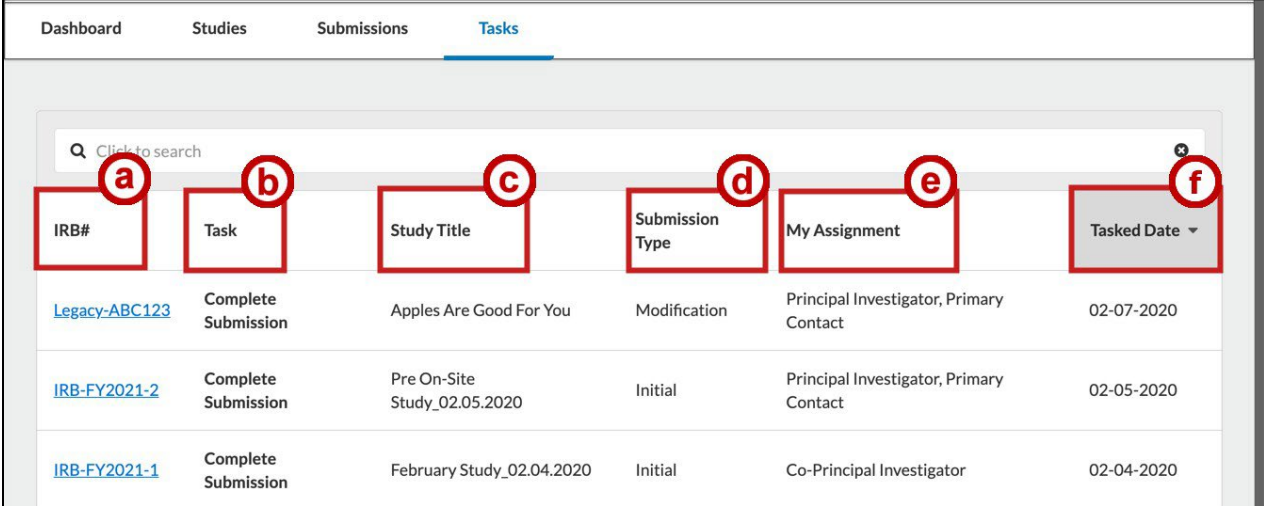
IRB#	Submission	Status	Review Type	PI	My Assignment	Decision	Create Date
Legacy-ABC123	Apples Are Good For You Modification	Unsubmitted	N/A	Peter Professor	Principal Investigator, Primary Contact	--	02-07-2020
IRB-FY2020-6	Save the Penguins Initial	Review Complete	Full	Peter Professor	Principal Investigator, Primary Contact, Co-Principal Investigator	Approved 02-07-2020	02-07-2020

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.



The screenshot shows the 'Tasks' tab interface. At the top, there are navigation tabs: 'Dashboard', 'Studies', 'Submissions', and 'Tasks' (which is selected). Below the navigation is a search bar with the text 'Click to search'. The main content is a table with six columns: 'IRB#' (labeled 'a'), 'Task' (labeled 'b'), 'Study Title' (labeled 'c'), 'Submission Type' (labeled 'd'), 'My Assignment' (labeled 'e'), and 'Tasked Date' (labeled 'f'). The table contains three rows of data.

IRB#	Task	Study Title	Submission Type	My Assignment	Tasked Date
Legacy-ABC123	Complete Submission	Apples Are Good For You	Modification	Principal Investigator, Primary Contact	02-07-2020
IRB-FY2021-2	Complete Submission	Pre On-Site Study_02.05.2020	Initial	Principal Investigator, Primary Contact	02-05-2020
IRB-FY2021-1	Complete Submission	February Study_02.04.2020	Initial	Co-Principal Investigator	02-04-2020

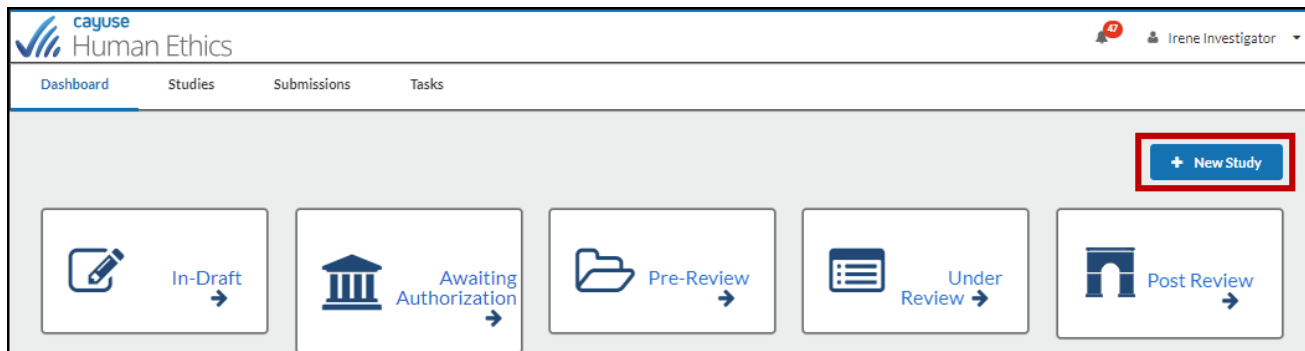
Tasks Tab Interface

- 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

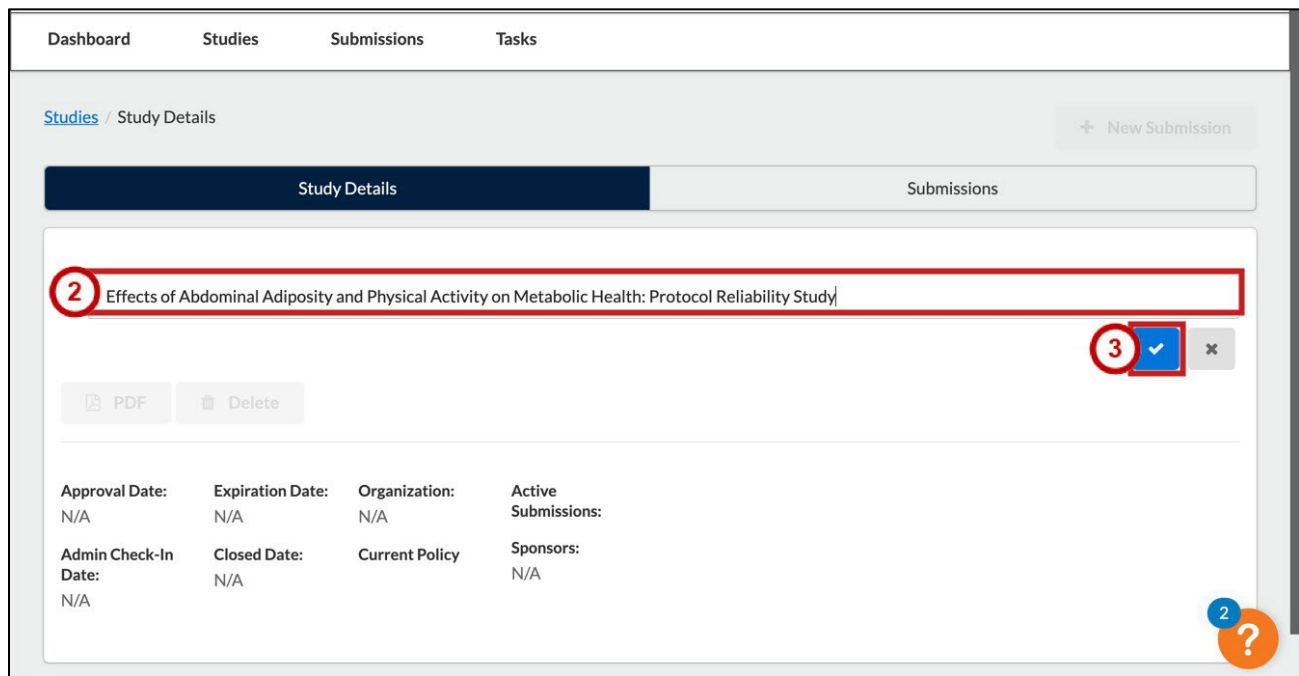
The following section explains how to create an initial submission.

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



Click the New Study Button

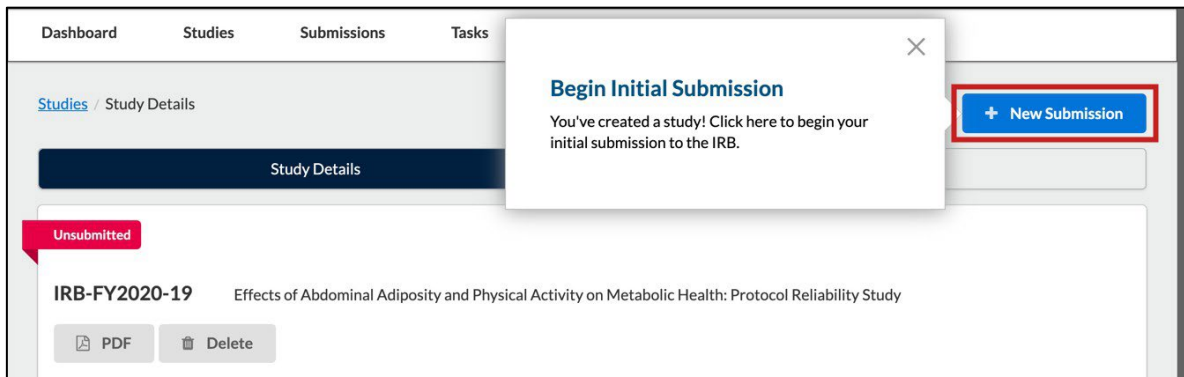
2. The *Study Details* page will open. Enter the **title of your study** in the text box.
3. Click the **blue checkmark** button to begin the submission process.



Enter Study Title and Click Blue Checkmark

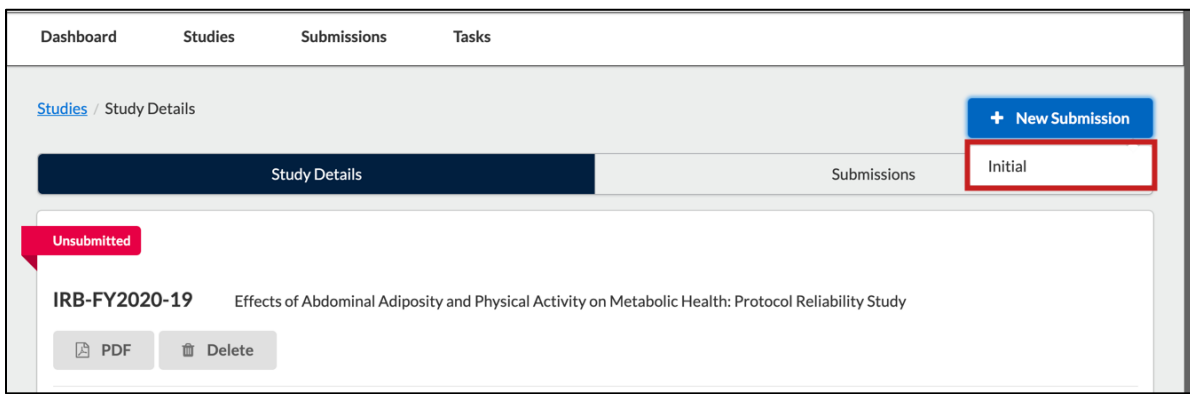
Note: The title of your study should offer specific details about your study. Avoid generic terms.

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.



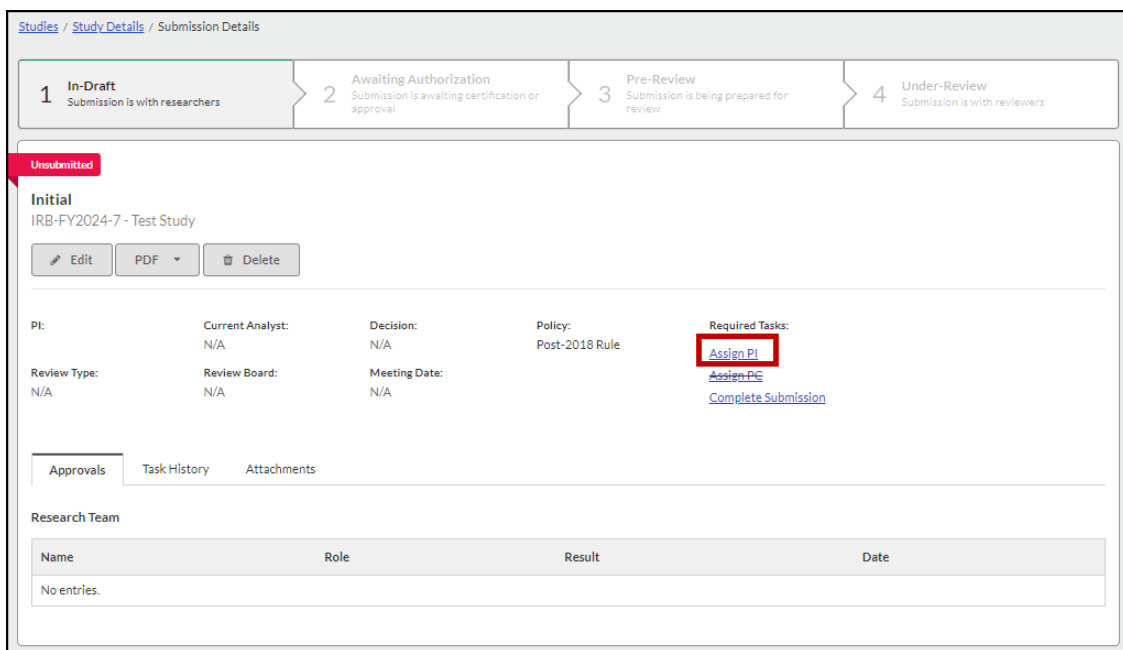
Click the New Submission Button

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.

IRB NUMBER: IRB-FY2024-7

Test Study - Initial

CREATE PDF COMPARE SAVE

Sections

- Instructions ✓
- Routing Send to PI for certification?
- COMPLETE SUBMISSION

Instructions

After checking the appropriate option below, navigate to the next page (arrows at bottom) to begin. Complete all applicable questions. Submissions lacking sufficient information to complete the review will be returned. Refer to help text throughout the form for additional information and guidance.

When your submission is complete:

1. Click "Complete Submission" at the bottom of the left panel.
2. Click "Confirm" in the pop-up window.
3. From the submission details page, click the blue "Certify" button on the upper right.
4. All PIs and Co-PIs (including Faculty Sponsors) need to Certify the submission. Only fully certified submissions are forwarded to the IRB Office to begin review.

Please note that any submissions not finalized and certified within 6 months of the creation date will be administratively withdrawn by the IRB Office.

- Initial IRB Review Request Form
- Request for Determination of Human Subjects Research (if you are unsure if your project requires IRB review)
- Request to Rely on External IRB

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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.

I will submit modifications of the protocol and/or the informed consent form and/or any other documents to the IRB for approval prior to applying those changes in the study as required.

I agree to abide by the policies and procedures of the KSU IRB regarding the protection of human subjects including, but not limited to:

- Ensuring that all personnel involved in the study have completed the human subjects training online course.
- Ensuring that the study will be conducted by qualified personnel only.
- Obtaining Informed consent from subjects or their legally appointed representatives or guardians, using the informed consent form stamped with approval by the IRB and providing a copy of the signed form to the subject.
- Reporting of adverse events or other unexpected problems and risks involving human subjects to the IRB promptly.
- Prompt compliance with decisions of the IRB that may include a decision to stop or terminate the research.
- If required, obtaining approval for continuing with the study after the end of the approval period by submitting a request for renewal before the study expires. I understand that if I fail to apply for renewal, the study will automatically expire and all activity must cease until IRB approval is granted.
- Closing my study when the research is complete: enrollment closed, data collection complete, analysis of private identifiable data complete, data de-identified.
- Maintaining accurate and complete research records including all informed consent documents and communication with the IRB, for at least 3 years from the date of study completion.

* Acknowledged

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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.

1.2 KSU Study Personnel

ALL investigators who will be engaged in research activities must be included in the submission. This includes  KSU faculty/staff/students, investigators from other institutions, unaffiliated investigators. (see help text for information on engagement in research)

All responsible study personnel (*principal investigators, co-investigators, faculty advisors, and unaffiliated investigators*) are required to complete the CITI educational program.

Please visit the Compliance Website for more information and access to CITI training

<https://research.kennesaw.edu/irb/>

**Study Personnel must complete either Social, Behavioral, and Educational Research with Human Subjects OR Biomedical Research with Human Subjects (depending on the type of research to be conducted in this protocol)*

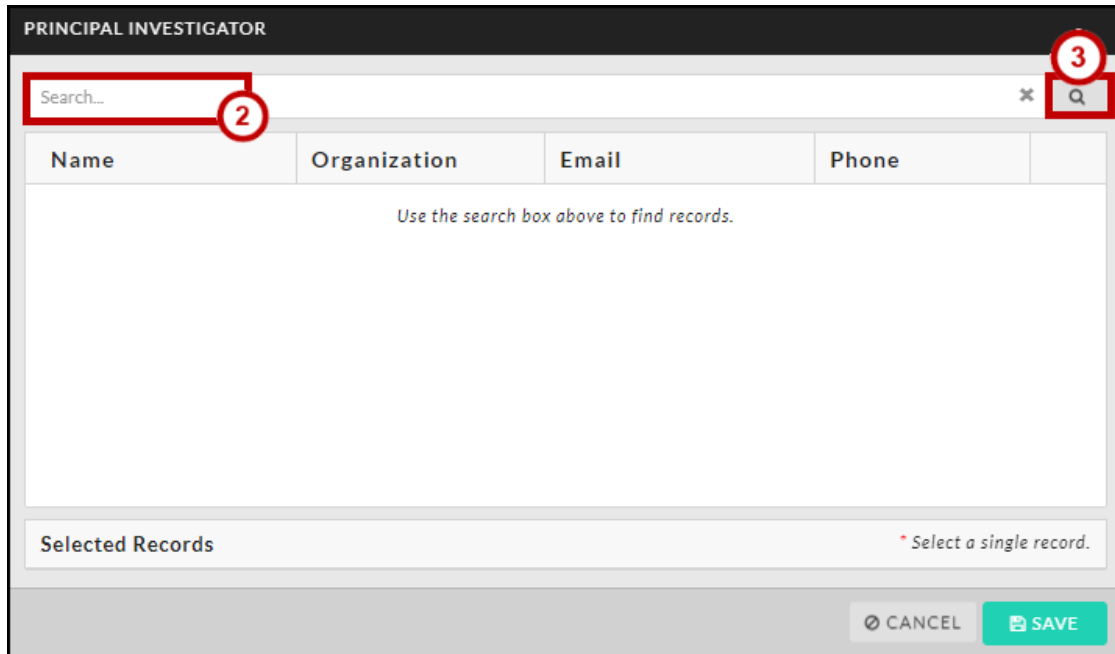
****Please note: Students Conducting No More Than Minimal Risk Research does NOT satisfy the IRB training requirement.**

- * 1.2.3 **Principal Investigator**
Identify the Principal Investigator

FIND PEOPLE

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.



PRINCIPAL INVESTIGATOR

Search...

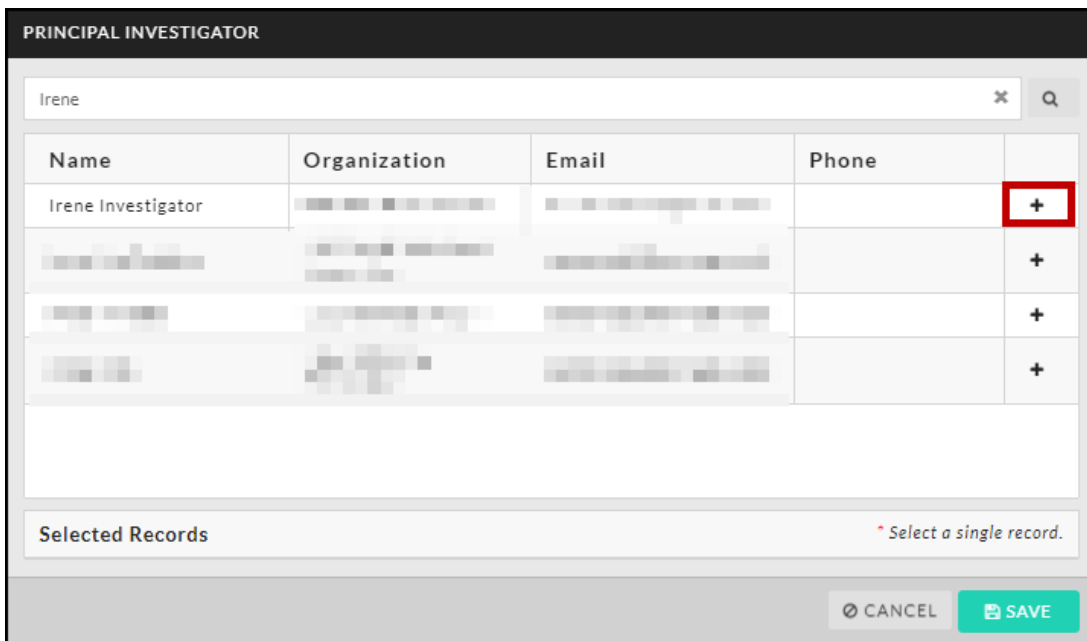
Name	Organization	Email	Phone
Use the search box above to find records.			

Selected Records * Select a single record.

CANCEL SAVE

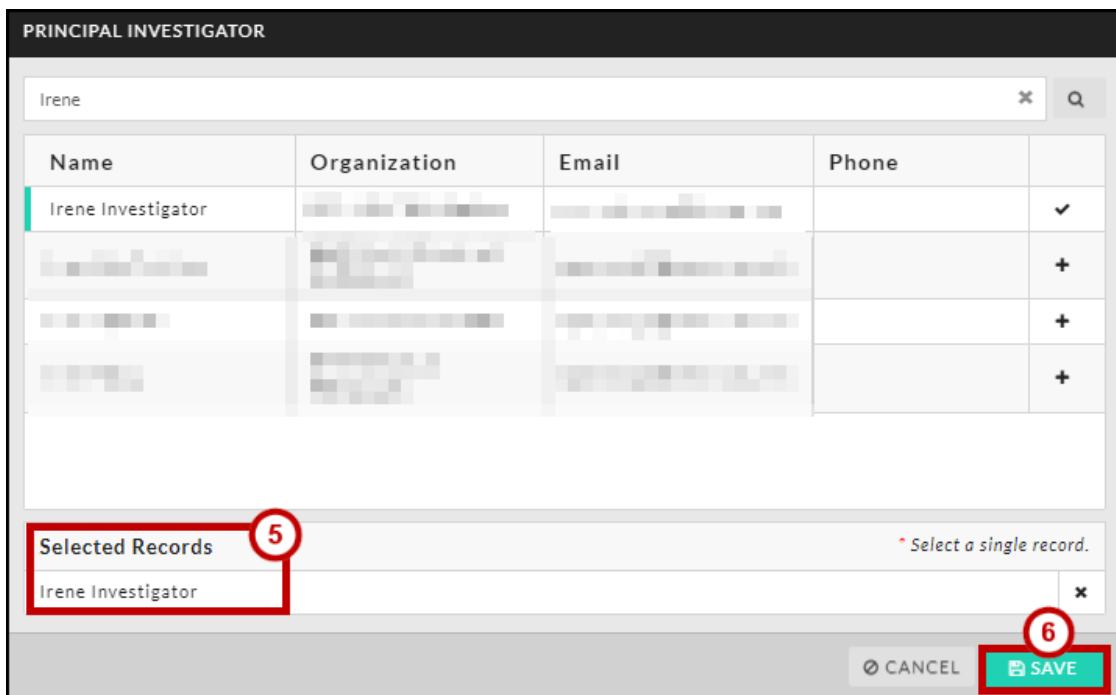
Enter PI Name and Click Search Button

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.

* 1.2.3 **Principal Investigator**
Identify the Principal Investigator

Name	Organization	Address	Phone	Email	Trainings	
Irene Investigator					View	✕

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.

1.2.1 Is the PI faculty, staff, or student?

Faculty/Staff

Student

Kennesaw State University students may serve as PI for their own research project and are responsible for submitting the IRB application. However, when a student is listed as the PI, a Faculty Sponsor must be listed on the submission.

Is this project for thesis or dissertation?

Yes

No

1.2.2 **Faculty Sponsor**
Identify the faculty sponsor

The Faculty Sponsor is ultimately responsible for the student(s) they sponsor in the conduct of human subjects research and therefore must meet all PI Eligibility requirements. Upon completion of this initial submission form, prior to submission to the IRB, the Faculty Sponsor, along with the PI and Co-PI(s) will be asked to certify the submission. The Faculty Sponsor, upon certification of the submission, certifies that he/she/they understands their responsibilities as Faculty Sponsor, that they have reviewed the submission, and that it is ready for IRB review.

FIND PEOPLE

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.

1.3 Non-KSU Study Personnel

1.3.1 Are there any investigators who are not affiliated with KSU?

Yes
 No

1.3.2 List all Non-KSU investigators, their affiliated institution (if any), and a summary of the research activities in which they will be engaged

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1.3.3 Attach CITI training records for Non-KSU study personnel.
NOTE: If you are completing a Request to Rely on an External IRB (KSU IRB will not be the IRB of record), it is not necessary to attach the CITI training records for the Non-KSU investigators.

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.

For Exempt projects, please confirm that the other IRB has been contacted and that the Non-KSU investigator has followed their policies and procedures regarding Exempt research.

Yes, the Non-KSU investigators have contacted their IRB office and are complying with the policies and procedures of that IRB.

If there are any communications with the other IRB(s) or determination letter(s), please attach

No, the Non-KSU investigators have not contacted their IRB.
 Clear

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.

1.4 Funding

1.4.1 **Funding** ?

Indicate the funding source for this study, if applicable.

External funding
Please identify the external research sponsor below. Please also visit the Study Details page and link this study to the relevant project or proposal number.

Please list the proposal or project title.

Internal (KSU/Department) funding only
 No funding source

External Funding

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

External funding
 Internal (KSU/Department) funding only

Department or Unit name

If the source is at the University level and required a project submission, please indicate the project or proposal title.

No funding source

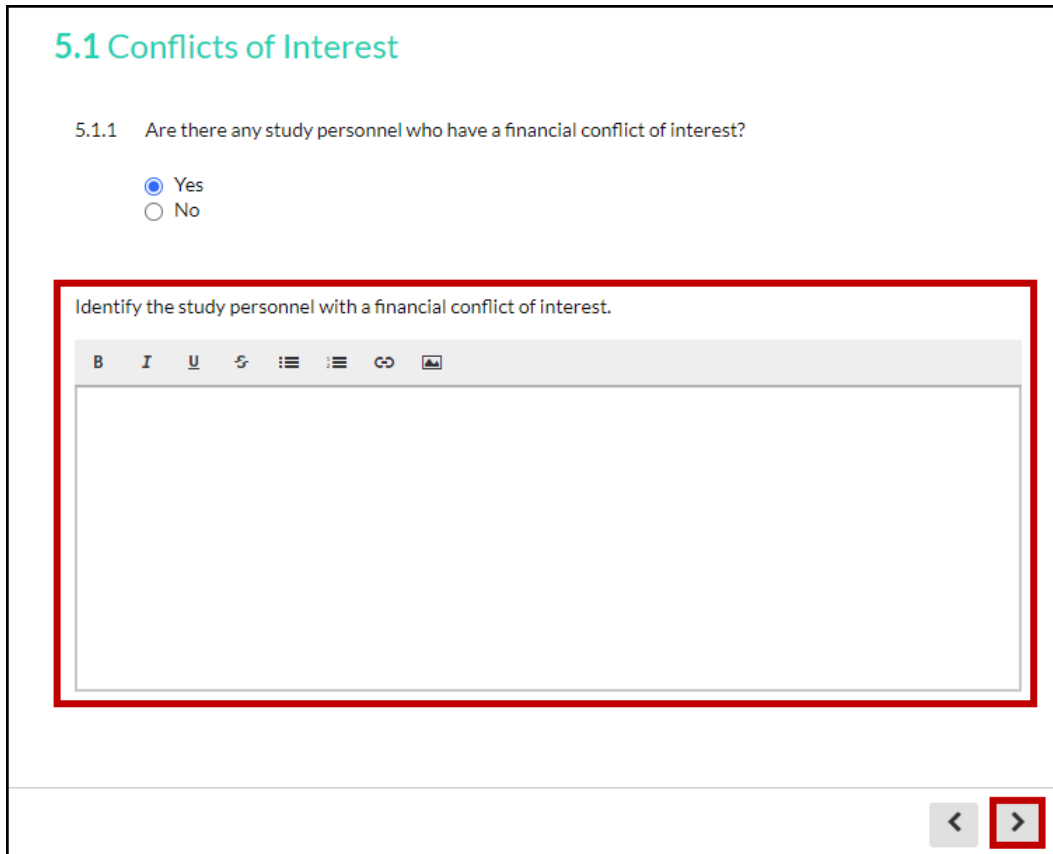
Internal Funding

- 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.



The screenshot shows a survey question titled "5.1 Conflicts of Interest". The question is "5.1.1 Are there any study personnel who have a financial conflict of interest?". There are two radio button options: "Yes" (selected) and "No". Below the options is a text box with the prompt "Identify the study personnel with a financial conflict of interest." The text box has a rich text editor toolbar with icons for Bold (B), Italic (I), Underline (U), Strikethrough (ABC), Bulleted List, Numbered List, Link, and Image. At the bottom right of the form, there are two navigation arrows: a left arrow and a right arrow. The right arrow is highlighted with a red box.

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.

3.1 Reliance Request

This form is made available for researchers at KSU who are collaborating on a project in which there is another IRB who has or will review and act as the IRB of record and are requesting KSU IRB to rely on the review conducted by the other IRB. This includes commercial IRBs who are contracted to review research in which KSU is engaged. (see help text regarding "engagement")

Please note:

**If your project is Exempt: The KSU IRB will normally not enter into reliance agreements for studies we deem exempt. If another IRB wants to provide review for such a study or to rely on KSU IRBs exemption determination, consultation with the IRB Office Director is required.*

**If you are the PI on a federally funded multi-site project requiring Single IRB review, please contact the IRB Office Director.*

3.1.3 Identify the external IRB who has or will review the project

3.1.4 Provide the name of the PI on the project that has been or will be reviewed by the external IRB.

3.1.5 Provide the ID # and Study Title on the external IRB submission

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.

What activities will you be engaged in?

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3.1.8 Attach approved recruitment and consent documents 3

ATTACH

3.1.9 Institutional Authorization Agreement and other supporting documents ⓘ

ATTACH

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.

1.5.1 Is this a Class Project? ?

Yes

Please complete the Determination of Human Research worksheet found on the next page to determine whether your project requires IRB review. ?

No

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.

2.1.1 Is the proposed activity a systematic investigation? 1

A systematic investigation is an activity that involves research development, data collection, analysis, and evaluation to answer a question.

Yes
 No

2.1.2 Will conclusions contribute to generalizable knowledge?

Generalizable knowledge is when knowledge gained is applicable outside of the local research context/entity. (CE, course/internal program evaluations, many QA/QI programs, course requirements, or classroom exercises do not usually qualify as contributing to generalizable knowledge.)

Yes
 No

****If you answered "No" to either of these questions, you are not doing human subjects research according to the federal definition (see above) and thus do not require the oversight of the IRB. If, however, you are requesting documentation from the IRB, please continue answering the questions on this page. If you are sure that you will not require any type of confirmation or documentation of the determination, you can delete this submission and the study.** 2

If you are not sure whether your study does indeed meet the criteria listed above, you can skip to Question 2.1.6 below. After you submit, the IRB Office will review your answers and let you know if we need any further information or if you need to file a full initial submission protocol form.

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.

2.1.4 Will you collect data through intervention or interaction with an individual, including interviews, surveys, physical procedures manipulations of the subject's environment, and any other direct contact or communication with the subject (regardless of whether resulting data is identifiable or not)?

Intervention: Includes both physical procedures by which data are gathered, and manipulations of the subject or subject's environment performed for research purposes.
Interaction: Communication or interpersonal contact between investigator and subject.

Yes
 No

2.1.5 Will you obtain, view or otherwise handle any private information which identifies individual subject(s) through the use of either direct identifiers (name, address, etc.), or indirect identifiers in the form of a code that links back to the identity of subject through an existing key?

Private information includes (but is not limited to): medical records and charts, specimens, data or tissue repositories, employment or educational records, and observations of behavior which the subject could reasonably expect no observation to be taking place, personal thoughts, feelings, opinions, attitudes, beliefs, etc.
Direct identifiers include (but is not limited to): name, street address, audio/ video-recordings, telephone, fax, email, SSN, medical record # (other potential identifiers are evaluated on a case by case basis).
**If codes & key exist for data from an outside source: check "No" here, and submit official correspondence from the holder of the key which states that researcher will not be given access to the key under any circumstances.

Yes
 No

2.1.6 Request for determination of Human Subjects Research

Provide the necessary information in this section for the IRB Office to 1) determine whether your project meets the federal definition of human subjects research; and/or 2) provide documentation of the determination.

Provide a 3-5 sentence, clear summary of the proposed activity. Please include the purpose and aims of the activity.

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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.

1.6.3 Check all that apply

- Audio
- Video
- [Medical Records/HIPAA](#)
- [Educational Records/FERPA](#)
- Urine
- Saliva
- Blood
- Other

Below the list is a large empty text input box.

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.

1.6.5 Tentative study start and end dates

Start Date

MM-DD-YYYY 

End Date

MM-DD-YYYY 

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.

1.7.5 Vulnerable Populations ?

Check any or all vulnerable populations who will be targeted for research participation, if applicable

Subjects are vulnerable when they are not considered as autonomous agents and/or their voluntariness is compromised.

There are two important types of vulnerability:

(1) Decisional impairment, whereby potential subjects lack the capacity to make autonomous decisions in their own interest, perhaps as a result of undue influence/inducement

(2) Situational/positional vulnerability, whereby potential subjects may be subject to undue influence or coercion

Children

Students

Employees

Individuals with Cognitive Impairment

Prisoners

[Pregnant Women](#)

Fetuses

Neonates

Other

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.

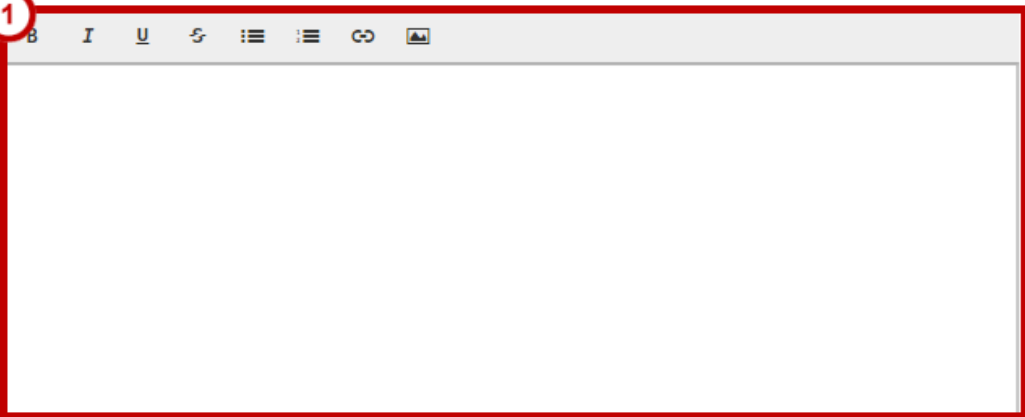
1. Enter details into each applicable text box. If your study does not require compensation or screening, leave those boxes blank.
2. If you have any additional materials related to subject recruitment, click the **Attach** button to attach them to the appropriate question.

1.8.2 Recruitment Process

Describe the plan (*when, where, how*) to identify potential subjects, including database review, if applicable. Describe how the population will be identified, and how initial contact will be made. Provide information regarding access to the population that will allow recruitment of the necessary number of subjects.


Specify if any advertising/recruitment materials will be used, including verbal/electronic announcement of the research. Upload recruitment material(s) as supporting documents with your submission.

1



1.8.3 Attach all materials related to Subject Recruitment (*email templates, flyers, in-person script, social media postings*)

2



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.

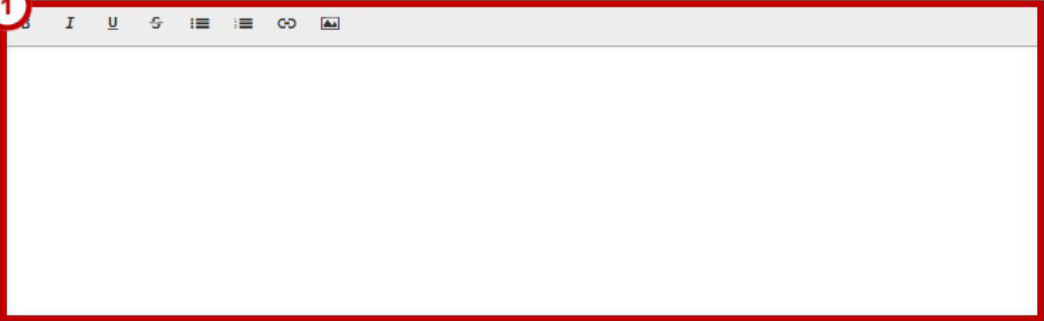
1. Enter detailed answers regarding the consent procedures for each group involved in your study.
2. Click the **Attach** button to attach consent forms for each question.

1.9 Consent

1.9.1 Describe the process (when, where, how) for obtaining informed consent including considerations for privacy. If research involves minors, describe assent process and how parent permission will be obtained. Upload consent/assent/parental permission documents/scripts. If applicable, detail the process to ensure ongoing consent throughout the duration of the project and for ensuring that the subjects understand the research. Describe steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, the use of comprehension quizzes, and, if applicable, who might be asked to provide permission or consent on behalf of the subject. If minors who are recruited will turn 18 during the research, provide a process for consenting them as an adult when they turn 18.

Informed Consent FAQs
<https://www.hhs.gov/ohrp/regulations-and-policy/gu...>

1



1.9.2 Attach consent, minor assent, parental permission here. Please use templates provided. Do NOT upload links to consent forms or other study materials as links are not static. The IRB requires an actual document to be a permanent part of the file.

2

ATTACH

Sample documents: [Consent Templates](#)

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.

1.10 Consent Waivers

1.10.1 Are you requesting a Waiver of Documentation of Consent?

A Waiver of Documentation of Consent is used when:

- You are providing an Informed Consent Document to participants, but will not be obtaining their written signatures.
- Reading an Informed Consent Script verbally.
- Signatures on a consent document are not culturally appropriate

Yes

1.10.2 Select one of the following and then provide a rationale explaining why this Waiver of Documentation of Consent will not adversely affect the rights and welfare of the participants.

- The only record linking the subject and the research would be the Informed Consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

1.10.3 How will the rights and welfare of participants be protected even though you will not be obtaining documentation of informed consent from the participant?

B I U S | | | |

No

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.

1.10.4 Are you requesting a Waiver or Alteration of Consent or will you be altering or removing any of the required Elements of Consent?

A Waiver of Consent is used when you will not be obtaining any informed consent from participants. This is a rare occasion, typically used when a signature would normally be required, but contacting each potential participant would be impactful. Alteration of Consent is applicable if deception or incomplete disclosure is part of the study design.

Yes

1.10.5 Describe how the research involves no more than minimal risk to participants.

B I U G [List Icon] [List Icon] [Link Icon] [Image Icon]

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.

NUMBER: IRB-FY2024-7

CREATE PDF
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1.11 Protection of Subjects

1.11.1 Risks to Subjects

State any possible psychological, physical, social, economic, or legal risk of harm to subjects including their likelihood and seriousness.

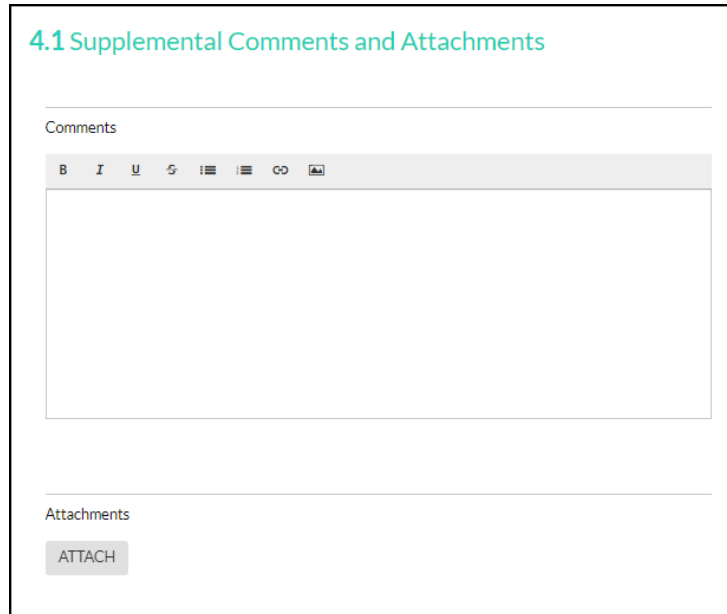
Examples:

- Is there potential for a loss of data confidentiality and how serious would loss of confidentiality be for the subject? Consider breach of confidentiality or invasion of privacy as a risk for all subjects.
- If there is a potential for subjects to become upset as a result of the research procedures, and thus require psychological or medical attention?
- Is there potential for emotional stress, boredom, or fatigue?
- Is there risk of physical harm from the intervention (such as from blood draws, brain stimulation or maximal exercise)?
- Could the research create potential social stigmatization or legal action by authorities if research data become known outside of the project team?
- Are there potential risks to the subject related to the political, social, or economic context in which they live?
- Are there economic burdens that may result from participating in the research?

Save progress

Supplemental Comments and Attachments

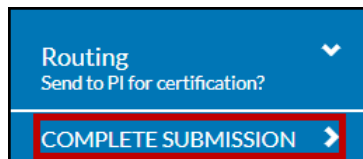
In this final section, you will have the opportunity to include any additional information and attach relevant documents.



Add final comments and attachments

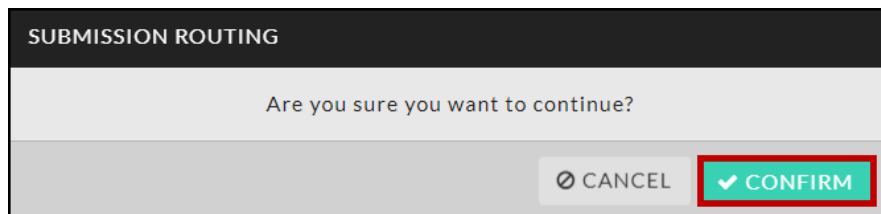
Completing the Submission

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



Complete submission

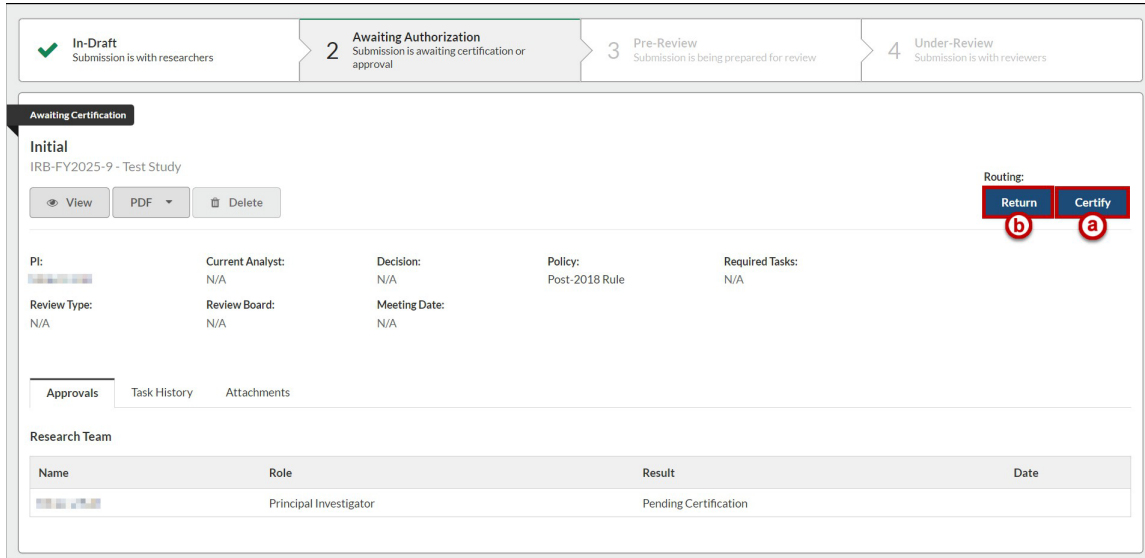
2. A new window will open asking you to confirm your submission. Click **Confirm**.



Confirm

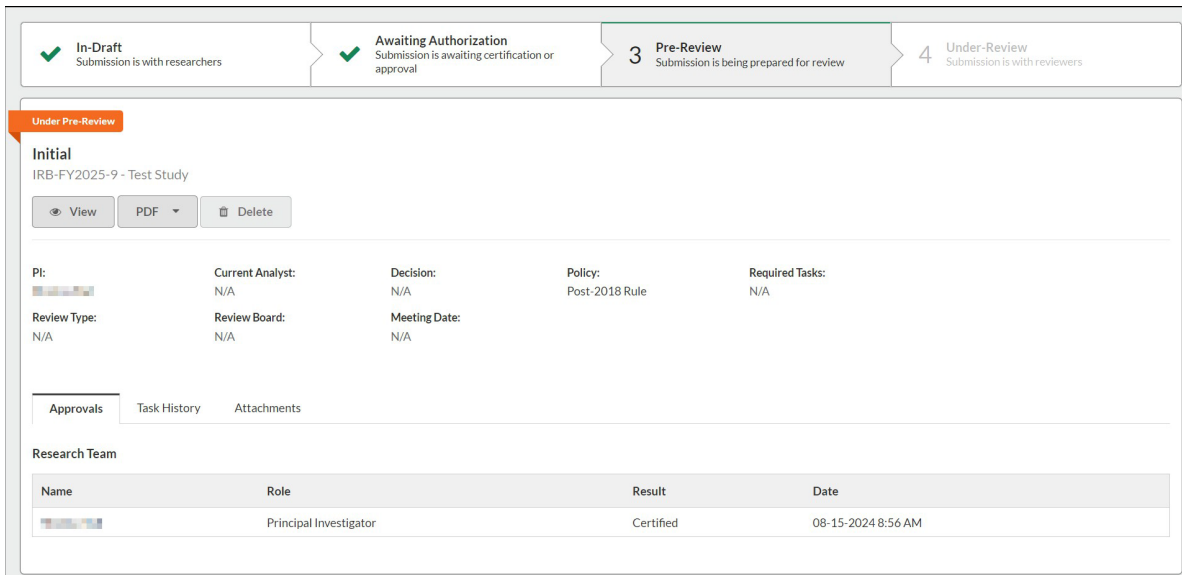
Note: The Complete Submission tab will only appear when all required fields in the document have been completed. If you do not see this tab, review all previous tabs and ensure that all required fields have been completed and all sections have been viewed. This can be confirmed by the checkmarks next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



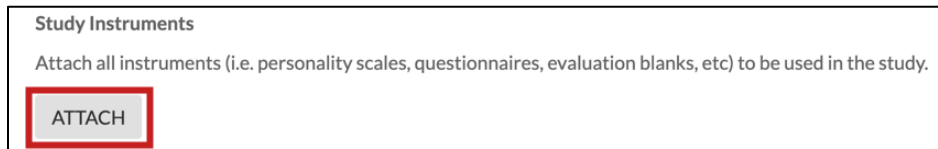
Study under review

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

Attach a File

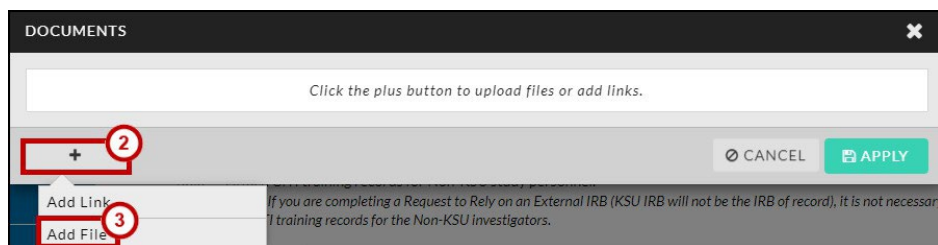
This section will outline the steps to attach a file or link to your submission.

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**.



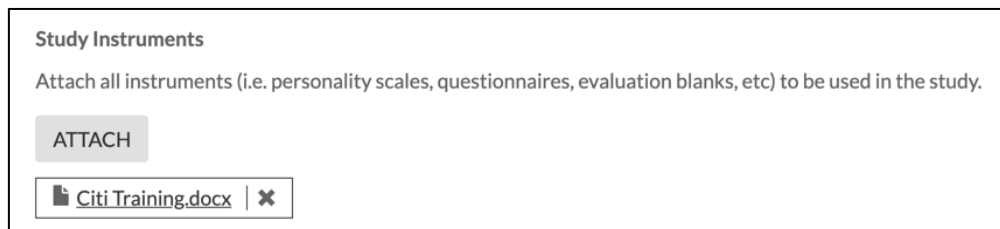
Add File

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