Cayuse IRB

Submitting a Proposal
University Information Technology Services

Cayuse IRB
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Table of Contents
Introduction ........................................................................................................................................... 4
Learning Objectives ........................................................................................................................ 4
Accessing Cayuse IRB ..................................................................................................................... 5
Logging In ......................................................................................................................................... 5
Interface Orientation ...................................................................................................................... 8
Dashboard Tab .................................................................................................................................. 8
Studies Tab ....................................................................................................................................... 9
Submissions Tab .............................................................................................................................. 10
Tasks Tab ......................................................................................................................................... 11
Submitting a New Study .................................................................................................................. 12
Getting Started ............................................................................................................................. 15
Submission Information .................................................................................................................. 16
Attach a File ...................................................................................................................................... 22
Study Information ............................................................................................................................ 23
Study Selection ............................................................................................................................... 30
Study Design .................................................................................................................................... 33
Study Procedures ............................................................................................................................. 36
Participant Protection ...................................................................................................................... 40
Conflict of Interest .......................................................................................................................... 43
Attachments ...................................................................................................................................... 44
Completing the Submission ............................................................................................................. 45
Additional Help ............................................................................................................................... 46
**Introduction**

Cayuse is a useful tool that allows you to submit requests for IRB approval electronically. The process is secure, streamlined, and designed to identify and address the components of the application.

The booklet demonstrates how to navigate and submit a proposal.

**Learning Objectives**

After completing the instructions in this booklet, you will be able to:

- Access and log into Cayuse
- Navigate the application process
- Submit a proposal
Accessing Cayuse IRB

Logging In

The following section will describe how to access and log into Cayuse.


![Figure 1 – Navigate to IRB Website](image)

2. Click the [https://kennesaw.cayuse424.com/](https://kennesaw.cayuse424.com/) link under the Access Cayuse heading.

![Figure 2 - Click the link under Access Cayuse](image)
3. You will be prompted to log in using your KSU login credentials. Enter:
   a. KSU NetID (See Figure 3)
   b. NetID Password (See Figure 3)
4. Click **Sign in** (See Figure 3).

![Figure 3 - Log In Using NetID and Password and Click Sign In](image)

5. Use your preferred method to authenticate your account through DUO.

![Figure 4 - Authenticate through DUO](image)

6. You will be directed to a log in screen. Enter:
   a. KSU NetID (See Figure 5)
   b. NetID Password (See Figure 5)
7. Click **Sign in** (See Figure 5).
8. You will be directed to the *Cayuse Research Suite*. Click *Cayuse IRB (Human Studies Compliance)*.

9. You have successfully logged into your *Cayuse IRB* account.
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:

![Figure 7 – Dashboard Tab Interface](image)

a. **In-Draft**: Number of studies currently being completed by your research team (See Figure 7).

b. **Awaiting Authorization**: Number of studies waiting for approval or certification by the Primary Investigator (See Figure 7).

c. **Pre-Review**: Number of studies sent to the IRB Office (See Figure 7).
d. **Under Review**: Number of studies awaiting a decision from a committee or reviewers (See Figure 7).

e. **My Studies**: Studies you have authored (See Figure 7).

f. **My Tasks**: Any specific tasks you are responsible for (See Figure 7).

g. **Submissions by Type**: Separated by the type of submissions (See Figure 7).

h. **Approved Studies**: Studies that have been approved (See Figure 7).

i. **Studies Expiring in (Length of Time)**: Studies close to expiration (See Figure 7).

j. **Expired Studies**: Studies that are expired (See Figure 7).

**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 archived, toggle to the *Archive* tab.

![Figure 8 - Studies Tab Interface](image)

- **IRB#**: Reference number for submission (See Figure 8).
- **Study Title**: Title given to the submission (See Figure 8).
- **Status**: Displays the current status of the application (See Figure 8).
- **PI – Primary Investigator**: User listed as the Primary Investigator (See Figure 8).
- **Expiration Date**: Date the study is set to expire (See Figure 8).
- **Admin Check-in Date**: Date that proposal was accessed after it was submitted (See Figure 8).
- **Create Date**: Date proposal was created (See Figure 8).
Submissions Tab
This tab displays additional information about the individual submissions.

![Figure 9 - Submissions Tab Interface](image)

a. **IRB#:** Reference number for submission (See Figure 9).
b. **Submission:** Displays the current step in the review process (See Figure 9).
c. **Status:** Displays the current status of the application (See Figure 9).
d. **Review Type:** Displays the type of review selected in the application (See Figure 9).
e. **Primary Investigator (PI):** User listed as the Primary Investigator (See Figure 9).
f. **My Assignment:** Your role as listed in the application (See Figure 9).
g. **Decision:** Displays any decision by the reviewer or committee (See Figure 9).
h. **Create Date:** Date application was created (See Figure 9).
Tasks Tab

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

![Tasks Tab Interface](image)

- **IRB#**: Reference number for submission (See Figure 10).
- **Task**: Lists the next task to complete (See Figure 10).
- **Study Title**: Displays the title of the study (See Figure 10).
- **Submission Type**: Displays the current step in the review process (See Figure 10).
- **My Assignment**: Your role as listed in the application (See Figure 10).
- **Tasked Date**: Displays date task was assigned (See Figure 10).
Submitting a New Study

The following section will outline how to create an initial submission.

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

![Click the New Study Button](image1)

Figure 11 - Click the New Study Button

2. The Study Details page will open. Enter the **title of your study** in the text box (See Figure 12).
3. Click the blue checkmark button to begin the submission process (See Figure 12).

![Enter Study Title and Click Blue Checkmark](image2)

Figure 12 - 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 by a new window to begin your initial submission. Click the **New Submission** button to proceed.

![Figure 13 - Click the New Submission Button](image_url)

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

![Figure 14 - Click Initial](image_url)
6. The study is now in the draft stage. A list of the required tasks will be displayed. Click **Assign PI**.

![Figure 15 - Click Assign PI](image)

7. You will be redirected to the *Getting Started* section.
Getting Started

This section will ask you to confirm your understanding of the IRB process at Kennesaw State University.

1. Read through the information on the screen and scroll to the bottom of the page.

2. Click inside the radio button next to Yes to confirm that you have read through the information (See Figure 17).

3. Once you select Yes, the forward arrow at the bottom will change to a dark gray color, indicating that you can move forward in the submission process. Click the forward arrow to move to the next section (See Figure 17).

Note: Use these arrows to move forward and backwards through the application.
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. The section you are currently in will display in green.

Submission Information

In this section, you will be prompted to provide basic information about your submission.

1. Select one of the available options regarding the type of submission.

Figure 17 - Click Yes and Click Arrow

Figure 18 – Select the Type of Submission
2. The next question will display. Select one of the available options:
   a. **No**: Click the **forward arrow** to move directly to the next page.

   ![Figure 19 – No is Selected. Click the Forward Arrow](image)

   b. **Yes**: You will be asked for additional information.

   ![Figure 20 - Yes is Selected. Move to Next Question.](image)
3. The next question will display. Select one of the available options.
   a. **Yes**: You will be asked for additional information in step four. Step five is not required for this answer.

   ![Figure 21 - Yes is Selected. Move to Next Question.]

   b. **No**: Provide additional information in step five. Step four is not required for this answer.

   ![Figure 22 - No is Selected. Move to Next Question.]
4. The next question will display. Select one of the available options.
   a. **Yes**: Additional information will be provided. Click the **forward arrow** to continue to the next section.

   ![Figure 23 - Yes is Selected. Click Forward Arrow.](image)

   b. **No**: Click **forward arrow** to continue to the next section.

   ![Figure 24 - No is Selected. Click Forward Arrow.](image)
5. The next question will display. Select one of the available options.
   a. **No**: Click the *forward arrow* to move to the next section.

![Figure 25 - No is Selected. Click Forward Arrow.](image)
b. **Yes**: Enter a text response and attach relevant documents.

c. Click forward arrow to proceed to the next section.

Figure 26 - Enter Information in Text Box and Attach Documents
Attach a File

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

1. Click the **Attach** button.

![Figure 27 - Click Attach](image)

2. A new window will open. Click the **plus sign**.

![Figure 28 - Click the Plus Sign](image)

3. A drop-down menu will appear. Click **Add File**.

![Figure 29 - Click Add File](image)

4. A new window will open, and you will be prompted to select a file. Click **the file** you wish to attach (See Figure 30).

5. Click **Open** (See Figure 30).

![Figure 30 - Click File and Click Open](image)
6. The file name will populate the window. Click **Apply** to finish attaching the file.

   ![Figure 31 - Click Apply](image)

7. The file has been attached.

   ![Figure 32 - File is Attached](image)

**Study Information**

In this section, you will be prompted to provide more detailed information about your study.

1. Select one of the available options to indicate your primary status at KSU (i.e., Faculty, Student, or Staff).

   ![Figure 33 - Select Primary Status at KSU](image)

**Note:** If you select **Student**, you will be asked to clarify whether your status is **Undergraduate** or **Graduate**.
2. You will be asked to provide additional information about the primary investigator and contact. To conduct a search for a user, click the **Find People** button.

![Figure 34 - Click Find People Button](image)

3. A new window will open. Enter the **Principal Investigator’s name** (See Figure 35).

4. Click the **search** button to conduct a search (See Figure 35).

![Figure 35 - Enter PI Name and Click Search Button](image)
5. A list of potential options will display. To add a user, click the **plus sign** to the right of their name.

![Figure 36 - Click Plus Sign](image)

**Note:** The plus sign will change color from gray to green when you hover over it.

6. The user’s name will populate in the **Selected Records** box below the search results (See Figure 37).

![Figure 37 - Review User(s) and Click Save](image)

**Note:** You may add additional users by repeating steps 2 through 7.
8. The user’s information will now be populated under the appropriate field.

![Image](image_url)

**Figure 38 - User's Information is Populated**

9. Once the user’s information is populated, click **View** to verify that the user has a current CITI Certificate attached to their account.

10. A new window will open displaying the certificate. If the window is blank, the user will need to complete CITI training before the study can be approved. To complete CITI training, direct user to [https://research.kennesaw.edu/irb/index.php](https://research.kennesaw.edu/irb/index.php)
   a. Scroll down to the Human Subjects Ethics heading
   b. Click the More info/directions link and follow all instructions on the page.

11. Repeat steps 2 through 7 to populate the fields for the Principal and Co-Principal Investigator(s) and/or Other Personnel, if applicable.

![Image](image_url)

**Figure 39 - Repeat Steps to add Users as Necessary**
Note: The Principal Investigator and Primary Contact must be listed to continue the submission process.

12. Select one of the available options to indicate whether there are any non-KSU personnel involved in the study.
   a. **No**: Move to the next question.

   ![Figure 40 - No is Selected. Move to Next Question.](image)

   b. **Yes**: Enter the names into the text field and attach CITI Certificates for each additional non-KSU user.

   ![Figure 41 - Yes is Selected. Enter User Names and Attach Citi Certificates](image)
13. Select one of the available options regarding the location of the study.
   a. If Kennesaw State University is selected, enter the name of the campus in the text box.

   ![Figure 42 - Kennesaw State University is Selected. Enter Campus Name in Text Box.](image1)

   b. If External Site (Non Kennesaw State University location) is selected, enter the name of the external location and attach a document confirming your permission to study at the external site.

   ![Figure 43 - External Site is Selected. List External Locations in Text Box and Attach Permission Document.](image2)
14. Click within the field to browse for a **Start Date** and **End Date** for your study (See Figure 44).

15. Click the **forward arrow** to proceed to the next section (See Figure 44).

![Figure 44 - Select Start Date and End Date. Click Forward Arrow.](image)

**Note:** Your **Start Date** must be a minimum of 14 days after the submission date of the application.
Study Selection

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

1. Enter the **number of subjects** enrolled at Kennesaw State University (See Figure 45).
2. Enter the total **number of subjects** to be enrolled at all study sites (See Figure 45).

![Figure 45 - Enter Number of Subjects in Text Boxes](image)

**Note:** In this example, all participants in the study are enrolled at Kennesaw State University, so the numbers are identical.

3. Select one or more of the available options to indicate the age group(s) of participants.
   a. If *only* the final option (i.e., 18 years and older) is selected, move to the next question.
   
   ![Figure 46 - Only Final Option is Selected. Move to Next Question.](image)

   b. If *any* of the first four options is selected, an additional question will populate.
c. Select one of the available options to clarify level of risk.

4. Select one or more of the available options to indicate whether any of the participants fall into one or more of the vulnerable population groups.
   a. If the final option (i.e., None of the Above) is selected, click forward arrow to move to the next section.

   b. If any of the four middle options is selected, additional instructions will populate.
c. If Other Vulnerable Populations is selected, you will be prompted to provide additional information about the participants. Enter a description in the text field.

5. Click the forward arrow to proceed to the next section.
Study Design

In this section, you will be asked to provide additional details about how the study is designed.

1. Select one of the available options to indicate the type of study.
   a. **Exempt**: Select one of the available options to indicate the category.

   ![Figure 51 - Select a Category for Exempt](image1)

   b. **Expedited**: Select one of the available options to indicate a category.

   ![Figure 52 - Select a Category for Expedited](image2)
c. **Full:** Enter **additional details** about the study background and rationale in the text box.

![Figure 53 - Enter Detailed Answer in Text Area](image)

2. Enter a **detailed answer** to the stated question regarding the objectives of the study.

![Figure 54 - Enter Detailed Answer in Text Area](image)
3. Enter a **detailed answer** to the stated question regarding the outcome measures.

![Figure 55 - Enter Detailed Answer in Text Area](image)

4. Select **one of the available options** (i.e., No or Yes) to indicate level of risk to the PI/Research Team (See Figure 56).

5. Click the **forward arrow** to proceed to the next section (See Figure 56).

![Figure 56 - Select an Option and Click Forward Arrow](image)
Study Procedures

In this section, you will be asked to provide information about the procedures for the study.

1. Enter a **detailed answer** to the stated question regarding the procedures for the study.

   ![Figure 57 - Enter a Detailed Answer in Text Area](image)

2. Enter a **detailed answer** to the stated question regarding the recruitment materials and material inducements for participation (See Figure 58).

3. Attach any **relevant documents** (See Figure 58).

   ![Figure 58 - Enter a Detailed Answer in Text Area and Attach Relevant Documents](image)
4. Enter a **detailed answer** to the stated question regarding the duration of the study, the length and number of study visits, and the timetable for study completion.

![Figure 59 - Enter a Detailed Answer in Text Area](image)

5. Enter a **detailed answer** to the stated question regarding the means for collecting and recording data.

![Figure 60 - Enter a Detailed Answer in Text Area](image)

6. Attach **copies of all study instruments**.

![Figure 61 - Attach Copies of Study Instruments](image)
7. Select one of the available options (i.e., Yes or No) regarding the use of questionnaires or surveys.

Note: If Yes is selected, you will be prompted to attach a copy of the instrument.

8. Select one of the available options regarding drugs, devices, and biologics.
   a. If the final option is selected, you will be prompted to move to the next question.
   b. If any of the first three options is selected, enter additional details in the text area.
9. Select one of the available options regarding participant data, specimens, and records (See Figure 65).

10. Click the forward arrow to proceed to the next section (See Figure 65).
Participant Protection

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

1. Select one of the available options regarding whether participants will experience more than minimal risk.
   a. No: Move to the next question.

   Figure 66 - No is Selected. Move to Next Question.

   b. Yes: Enter detailed answers to two additional questions regarding potential risks in the corresponding text areas.

   Figure 67 - Enter Detailed Answer in Text Area
2. Enter a **detailed answer** regarding the expected benefits in the text box.

![Figure 68 - Enter Detailed Answer in Text Area](image)

3. Select one of the available options regarding whether the study will involve deception.
   a. **No**: Move to the next question.
      
      ![Figure 69 - No is Selected. Move to Next Question.](image)
   
   b. **Yes**: Enter a **detailed answer** regarding the cause and nature of the deception in the text area.
      
      ![Figure 70 - Enter Detailed Answer in Text Area](image)
4. **Enter detailed answers** regarding the safeguarding of subjects’ identities in the corresponding text area.

![Figure 71 - Enter Detailed Answers in Text Areas](image)

5. **Enter a detailed answer** regarding the procedure for consent (See Figure 72).
6. Click **Attach** to attach a copy of the consent form (See Figure 72).

![Figure 72 - Enter Detailed Answer in Text Area and Attach File](image)

7. Click the **forward arrow** to proceed to the next section.
Conflict of Interest

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

1. Select one of the available options regarding potential conflicts of interest:
   a. **No**: Click the forward arrow to move to the next section.

   ![Figure 73 - No is Selected. Move to Next Section.](image)

   b. **Yes**: Click **Find People** to add user(s).

   ![Figure 74 - Click Find People and Add Users](image)

   **Note**: If you cannot find the user, contact the IRB Office at irb@kennesaw.edu

   2. Click the forward arrow to proceed to the next section.
Attachments

In this final section, you will have the opportunity to review all documents attached to the submission and attach any additional relevant documents.

Figure 75 - Review and Attach Additional Files
Completing the Submission

Follow the directions in this section to submit your completed application:

1. Click **Complete Submission** in the bottom left corner of the screen (See Figure 76).
2. A new window will open asking you to confirm your submission. Click **Confirm** (See Figure 76).

![Figure 76 - Click Complete Submission and Click Confirm](image)

**Note:** The Complete Submission tab will only appear when all required fields in the document have been completed. If you do not see the tab, review all previous tabs and ensure that all required fields have been completed.

3. You will be redirected to the application screen. Your application has been submitted, and you will be contacted by the IRB office by email with further instructions.

![Figure 77 - Verification of Submission Screen](image)
Additional Help

For technical support, email service@kennesaw.edu

For proposal development and submission questions, email irb@kennesaw.edu