Cayuse Human Ethics User Guide

Stockton University's Office of Research and Sponsored Programs

irb@stockton.edu

(609) 626-4844

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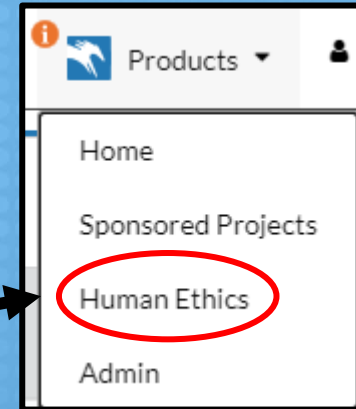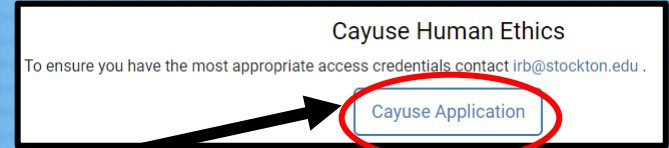
How do I…

Important Deadline Information
Monthly deadlines for the submission of protocols that will undergo Full Board review are available on the IRB Website.

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HOW DO I LOG ON TO CAYUSE HUMAN ETHICS?

1. Email irb@stockton.edu to gain access to Cayuse.

   • Stockton affiliates must provide email, GoPortal user, and Z-Number.

   • External researchers must provide their full name, email, and institutional affiliation.

2. Go to the IRB Webpage.

3. Select the "Cayuse Application" link.

4. Sign into Cayuse.

   • Stockton affiliates will sign on using SSO credentials.

   • External researchers will use their email and self-created password and must access Cayuse using the unique URL provided via email.

5. Use the product selector in the top right of the page and select "Human Ethics" from the drop-down menu.

Cayuse Human Ethics

To ensure you have the most appropriate access credentials contact irb@stockton.edu .

Cayuse Application

Products ▾

Home

Sponsored Projects

Human Ethics

Admin

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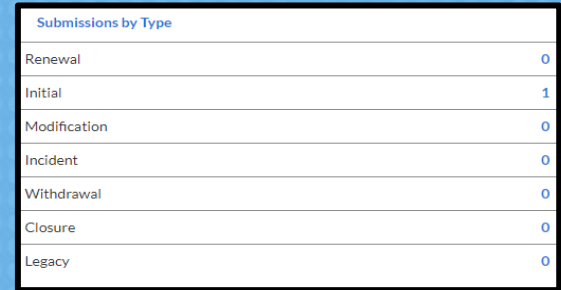
HOW DO I NAVIGATE THE DASHBOARD?

1. **In Draft** includes studies PIs have not yet submitted and studies returned to PI with comments

2. **Awaiting Authorization** includes studies that are awaiting certification from research team members.

3. **Pre-Review** includes studies that IRB staff are currently pre-reviewing before assigning to a reviewer.

4. **Under Review** includes the studies that are currently with a reviewer.

   • Note: When a study application is moved to the "under review" bucket, this means it is in the queue for review – it does not mean the study application is being reviewed at that moment.

5. **Post Review** includes the studies that have been reviewed by the IRB but are preparing correspondence of the final decision for a protocol.

In-Draft ➔

Awaiting Authorization ➔

Pre-Review ➔

Under Review ➔

Post Review ➔

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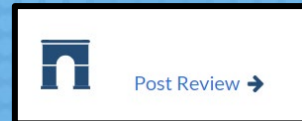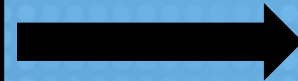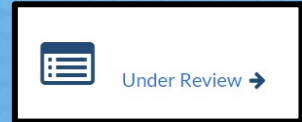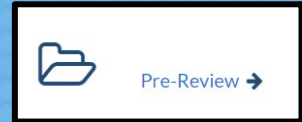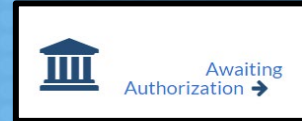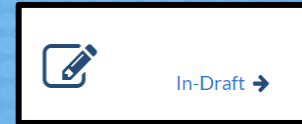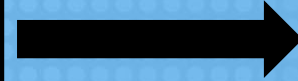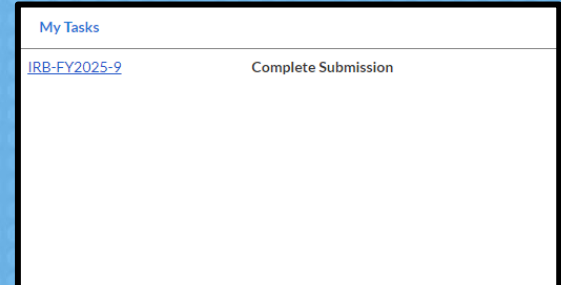
HOW DO I NAVIGATE THE DASHBOARD?

5. **Submissions by Type** provides a quick summary of the types of submissions associated with a researcher.

6. **My Tasks** lists all outstanding tasks regarding active studies.

7. **My Studies** summarizes all protocols associated with you, including their protocol number and title with hyperlinks to ease access for subsequent submissions.

Submissions by Type

Renewal	0
Initial	1
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0

My Tasks

IRB-FY2025-9	Complete Submission

My Studies

IRB-FY2025-9	xxx

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HOW DO I NAVIGATE THE DASHBOARD?

8. **Approved Studies** – Current list of the investigator's approved studies

9. **Studies Expiring** – Current list of the investigator's studies that are pending expiration – can view in 30, 60, 90-day increments

10. **Expired Studies** – list of studies that have expired – no recruitment or data collection can occur until a renewal has been submitted and approved by the IRB

Approved Studies

No Approved Studies

Studies Expiring in 30 days ▼

No Expiring Studies

Expired Studies

IRB-FY2023-5   SAMPLE STUDY - Faculty - 5.16.23

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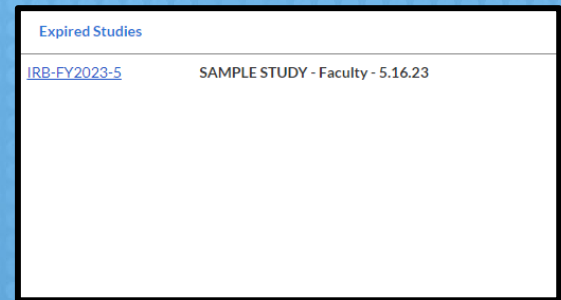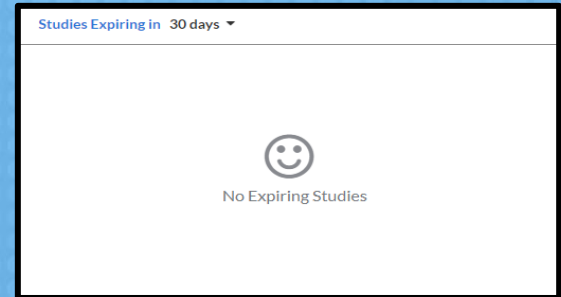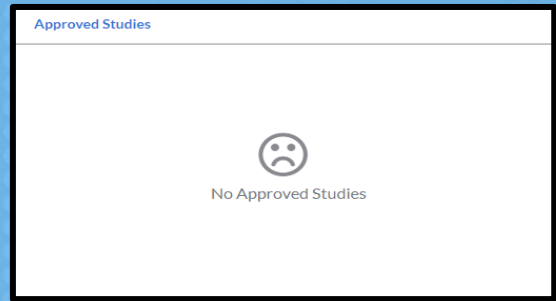
HOW DO I CHECK THE STATUS OF MY APPLICATION?

Submission Status Flags can be found on the top left of the study details page for any protocol. Below are the various submission status flags you may see when using Cayuse Human Ethics:

1. **Unsubmitted:** An in-draft submission that is open for editing and has not yet been routed to the IRB. Likely some required items still need to be completed before the submission can be declared complete and certified.

2. **Awaiting Certification:** Once a submission is declared complete, it informs the certifying researchers that they need to sign off on it. A submission cannot be edited once it reaches this point unless a certifier rejects it.

3. **Reopened:** This status is applied if a Certifier, Approver, Analyst, or Reviewer returns the submission at any point. It is functionally the same as the Unsubmitted status.

4. **Under Pre-Review:** Once all certifications and approvals are in, the submission routes to the IRB Office where an IRB Analyst will be assigned, determine the review level for the protocol, and begin a preliminary review. The Analyst may return a submission if they need additional information or clarification before sending the protocol to review.

5. **Under Review:** Regardless of the level of review or number of board members reviewing, this status indicates that the IRB review process is underway for a submission. For Full Board reviews, this can be expected to go through the Board's next meeting date, unless the submission has already been through a Full Board Review and needs only minor edits.

6. **Under Post Review:** This status is applied once the Reviewer's assessment of a submission is completed and they have come to a decision to either approve the protocol or ask for revisions. After a decision is made, the submission routes back to the assigned IRB Analyst for a final check before declaring the review complete, returning it, sending it to additional Reviewers (if needed).

7. **Review Complete:** Once an approval or exemption decision has been reached for a protocol and the IRB Office has signed off on it, this status becomes permanent for the submission and the Study Status may change to reflect it, as when an Initial Submission is first declared "**Approved**" or when an **expired** protocol finishes the continuing review process.

Submission Status Flag Icons

- **Unsubmitted**
- **Awaiting Certification**
- **Reopened**
- **Under Pre-Review**
- **Under Review**
- **Under Post Review**
- **Approved**
- **Expired**

Routing: **Return** **Certify**

If you see "Awaiting Certification," this means the IRB is not aware of your protocol. Make sure all research team members hit the Certify button to ensure the IRB and IRB staff are notified to review your submission

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HOW DO I CHECK THE STATUS OF MY APPLICATION?

Submission Progress Tracker

The Submission Progress Tracker provides a visual representation of the stages your submission will undergo. This is found at the top of your submission details page.

This bar highlights the current step and outlines the sequence of steps involved in the review process:

1. **Draft** - Your submission is in the draft stage and can be edited.

2. **Awaiting Authorization** - The submission is awaiting necessary authorizations.

3. **Pre-Review** - The submission is being reviewed for completeness and compliance before the formal review.

4. **Under Review** - The submission is actively being reviewed by the IRB.

Use this tracker to monitor the status of your submission and understand where it is in the review process.

✓ **In-Draft** Submission is with researchers	2 **Awaiting Authorization** Submission is awaiting certification or approval	3 Pre-Review Submission is being prepared for review	4 Under-Review Submission is with reviewers

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HOW DO I CREATE A STUDY?

1. Click the blue "+ New Study" button in the upper right-hand corner. This will create a study repository, essentially a folder for all your submissions for a singular project.

2. Enter the title in the text box then click on the blue check box.

3. Click the blue "+ New Submission" button in the top right-hand corner then select "Initial". This will begin a new study submission.

Products

Your Name

+ New Study

+ New Submission

Initial

Study Details	Submissions

Enter study title here

PDF   Delete

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HOW DO I CREATE A STUDY?

4. The individual filling out the submission will automatically be assigned as the PC or Primary Contact, which is why the Assign PC button is crossed off. To access the full submission, click the "Assign PI" button or the "Edit" button on the study details page.

5. The first page is the Getting Started page. Read for information on key contacts for assistance, a general summary of information that may be requested of you throughout the form, and access to CITI Training. At the bottom of the Getting Started page, you will attest that you are ready to begin your submission. Red asterisks next to a question indicate that it is a required question.

Required Tasks:

Assign PI

~~Assign PC~~

Complete Submission

‹ SUBMISSION DETAILS | IRB NUMBER: **IRB-FY2025-6**
cc - Initial

Sections ‹

Getting Started

Getting Started

Stockton University IRB

Welcome to the Stockton University IRB submission platform. Please note:
- Decisions made by the IRB are intended to ensure ethical human subject
- No study activities may begin unless IRB approval or an exempt determin

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HOW DO I CREATE A STUDY?

6. Cayuse is an interactive form, meaning new questions will appear based on which answers are selected.

    • Note: If you need to determine whether your project is considered Human Subjects Research, go to the Basic Information section and use the "Non-Human Subjects Research OR Activities Without a Plan to Conduct Research" option in the Submission Type field. The IRB can provide a formal determination for you with this option.

7. When adding a Principal Investigator select the "Find People" button. PIs need to save the principal investigator entry before the IRB can receive the submission.

✱ Principal Investigator

The person listed as the PI will be required certify submissions before they are sent to the IRB for review. They will also have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications.

FIND PEOPLE

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HOW DO I CREATE A STUDY?

8. Enter a last name into the search box and click the magnifying glass button.

9. Select the name and click the green save button at the bottom of the box.

10. In the Sections tab, a red star indicates an unfinished page. A check mark indicates a finished page.

11. Continue to fill out the application and answer to the best of your abilities. Refer to help text using the black circled question mark icons to assist you in your responses.

PRINCIPAL INVESTIGATOR

dileo

Name	Organization	Email	Phone
Britny Dileo	Off of Research & Sponsored Program - Org 210010	britny.dileo@stockton.edu	+

Selected Records   *Select a single record.*

Britny Dileo   ✕

⊘ CANCEL   💾 SAVE

Sections   ‹

Getting Started   ✓

Project Personnel
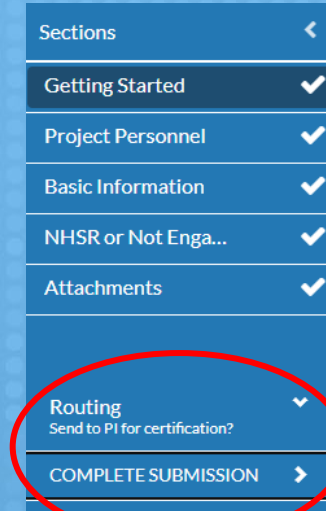
Basic Information

Attachments

TIP: USE MANUAL SAVE FEATURE.
Although Cayuse has auto-save features as you go from section to section. ORSP recommends using the manual save button on the top right and bottom of the form on each page. ORSP also recommends drafting the main portions of the submission in a separate document so your materials are saved twice in the event of a system failure
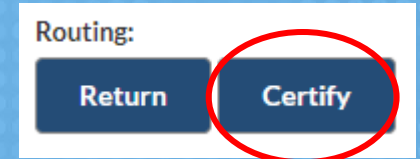
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HOW DO I SUBMIT AN INITIAL APPLICATION?

1. Once the form is complete, a Routing and Complete submission button will appear. Select "Complete Submission", then confirm.

2. Once the completed submission is confirmed, the user will be redirected to the Submission Details Page. The user and all research team members must click the "certify" button on the study details page to route the submission to IRB review.

NOTE: If research personnel are having issues certifying the submission, contact the IRB Administrator to administratively certify on their behalf to prevent review delays. In cases of student research, administration certification requests will not be accepted by students and must be disclosed by the faculty advisor associated with the project.

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HOW DO I CHECK CITI TRAINING CREDENTIALS?

Name	Organization	Address	Phone	Email	Trainings	
Britny Dileo	Office of the Provost - SAMPLE			britny.dileo@stockton.edu	View	✖

Once research team members are saved into the application through the "Find People" buttons in the Project Personnel tab, PIs can check if those individuals' CITI trainings are up to date.

Select "View" under Trainings in the personnel table. This will bring up a list of all CITI trainings associated with the individual along with completion and expiration dates.

NOTE: If a research team member's CITI profile is not the same as their Stockton affiliated email, their training credentials may not sync. In this case, there is a field to manually upload CITI training certificates.

TRAININGS

Course Name	Group	Stage	Status	Completion Date	Expiration Date
IRB Members - Basic/Refresher	IRB Members - Basic/Refresher	Basic Course	Current	12/6/2022	12/6/2025
CITI Health Information Privacy and Security (HIPS)	CITI Health Information Privacy and Security (HIPS) for IRB members	Basic Course		12/1/2022	
CITI Conflicts of Interest	Conflicts of Interest	Stage 1	Current	11/23/2022	11/23/2025
Essentials of Research Administration	Essentials of Research Administration	Basic Course	Current	11/29/2022	11/29/2025

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HOW DO I ADDRESS REVISION REQUESTS AND COMMENTS?

1. Comments from a reviewer or the IRB administrator will appear as a bubble next to the sections the comments are located.

2. Type "Ctrl + F" and search for "expand" to locate all comments on the page. Click the "Expand Comments" button.

3. To address comments, reply to the comment, and fix the issue in the actual submission.

4. After replying to the comment, click the "Not Addressed" button then select "Addressed." After all comments have been addressed, resubmit your submission.
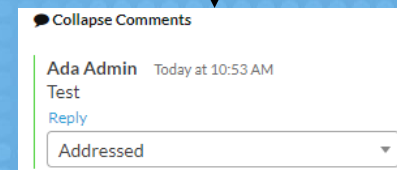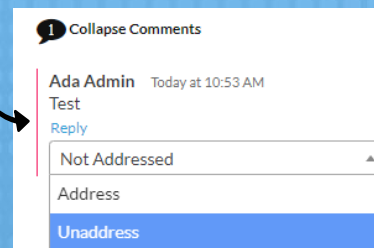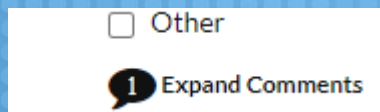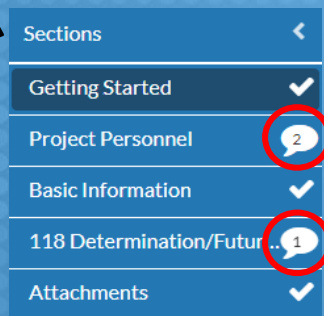
HOW DO I SUBMIT A MODIFICATION?

1. Select the study to modify under the "My Studies," box.

   If you do not see the study on your main dashboard, make sure to use the "View All" option at the bottom of the "My Studies" section.

2. Click the blue "New Submission" button and select Modification.

My Studies

IRB-FY2023-6   Insert Study Title Here

Studies / Study Details

+ New Submission

Study Details   Submissions

Renewal
Modification
Incident
Closure

Approved

IRB-FY2023-6   Full Study Title Here

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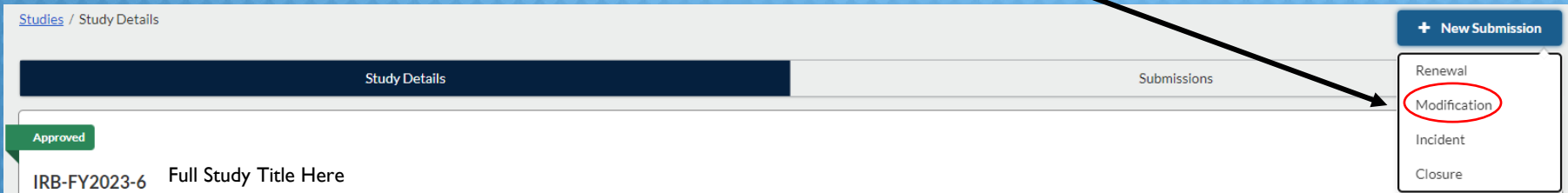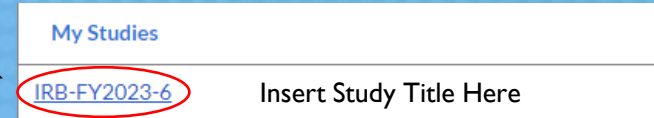
HOW DO I SUBMIT A MODIFICATION?

3. Complete the modification information page and change the appropriate sections in the initial submission.

4. When the modifications are finished, submit the modification form. Select "Complete Submission" and ensure all research team members "Certify" after.

Sections ‹

Modification Infor... ✔

Getting Started ✔

Project Personnel ✔

Basic Information ✔

NHSR or Not Enga... ✔

Attachments ✔

Modification Information

IMPORTANT REMINDER

The **only** way to make changes to the study protocol is to make them in a modification submission.

- If you are looking to renew study approval, a Renewal submission is needed.
- If you are looking to report an event or incident with the study, an Incident submission may be needed.
- If the study is complete, a Closure submission may be needed.

Sections ‹

Modification Infor... ✔

Getting Started ✔

Project Personnel ✔

Basic Information ✔

NHSR or Not Enga... ✔

Routing ⌄
Send to PI for certification?

COMPLETE SUBMISSION ›

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HOW DO I RENEW MY INITIAL APPLICATION?

1. Select the study to renew under the "My Studies" box.

2. Click the blue "New Submission" button and select "Renewal" from the list.

3. Complete the renewal or status update form, depending on the study's review level. Once the form is complete, select "Complete Submission" and ensure all research team members "Certify" after.

My Studies

IRB-FY2023-6   Insert Study Title Here

Studies / Study Details

+ New Submission

Study Details	Submissions

Renewal
Modification
Incident
Closure

Approved

IRB-FY2023-6   Full Study Title Here

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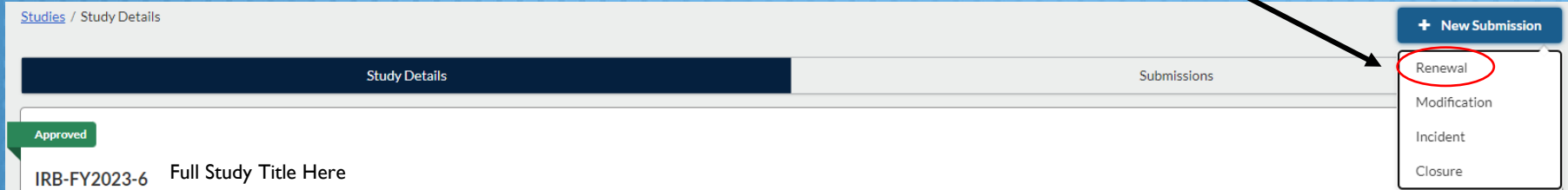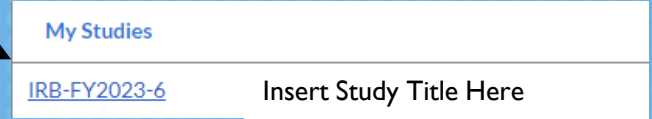
HOW DO I SUBMIT AN INCIDENT REPORT?

1. Select the study to renew under the "My Studies" box.

2. Click the blue "New Submission" button and select "Incident" from the list.

3. Complete the one-page incident report. Once the form is complete, select "Complete Submission" and ensure all research team members "Certify" after.

My Studies

IRB-FY2023-6   Insert Study Title Here

Studies / Study Details

+ New Submission

Study Details	Submissions

Renewal

Modification

Incident

Closure

Approved

IRB-FY2023-6   Full Study Title Here

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HOW DO I CLOSE MY APPLICATION?

1. Select the study to renew under the "My Studies" box.

2. Click the blue "New Submission" button and select "Closure" from the list.

3. The closure report is one page. Complete the required questions. Once the form is complete, select "Complete Submission" and ensure all research team members "Certify" after.

My Studies

| IRB-FY2023-6 | Insert Study Title Here |

IMPORTANT NOTE: Please do NOT submit this form unless the study is ready to be closed. Once the closure is submitted it cannot be undone. To continue with the research, a brand-new submission would be required.

Studies / Study Details

+ New Submission

| Study Details | Submissions |

Approved

IRB-FY2023-6   Full Study Title Here

Renewal
Modification
Incident
Closure

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HOW DO I FIND PRIOR APPROVAL LETTERS?

1. Select the study you are trying to locate approval letters for under the "My Studies" box.

2. Toggle the screen to view individual submissions associated with a protocol.

3. Select the submission you need an approval letter for (e.g.: Initial, modification, incident)

My Studies

IRB-FY2023-6   Insert Study Title Here
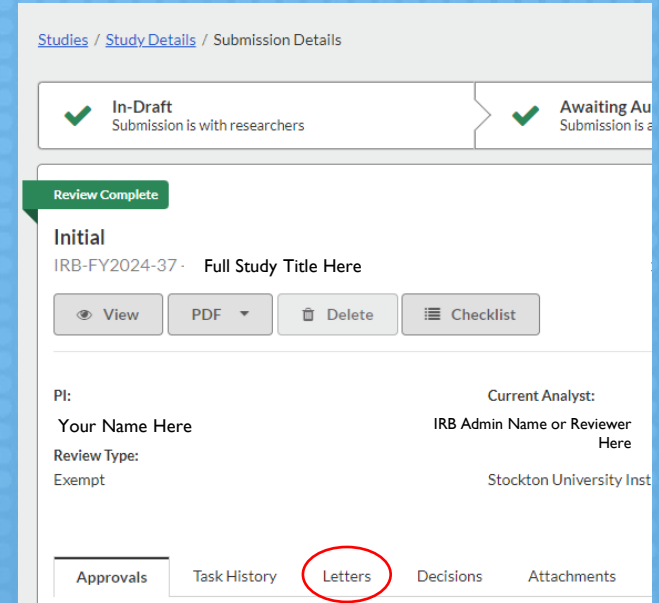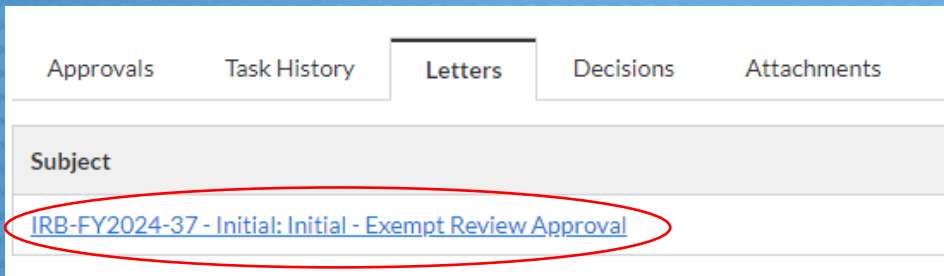
Studies / Study Details

+ New Submission

Study Details   Submissions

Submission Type	Review Type	Status
Initial	Exempt	● Review Complete

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HOW DO I FIND PRIOR APPROVAL LETTERS?

4. Select the letters tab.

5. Select the approval letter correspondence that you need a copy of. The file will automatically open as a downloadable PDF.

NOTE: Approval letters are automatically sent via email. However, with funded research or research involving external collaborations, entities may request copies of approval decisions and other IRB determinations

Studies / Study Details / Submission Details

In-Draft
Submission is with researchers

Awaiting Au
Submission is a

Review Complete

Initial
IRB-FY2024-37 · Full Study Title Here

View   PDF ▾   Delete   Checklist

PI: Current Analyst:
Your Name Here   IRB Admin Name or Reviewer
                                              Here
Review Type:
Exempt   Stockton University Inst

Approvals   Task History   Letters   Decisions   Attachments

Approvals   Task History   **Letters**   Decisions   Attachments

Subject

IRB-FY2024-37 - Initial: Initial - Exempt Review Approval

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HOW DO I SUBMIT A TECHNICAL SUPPORT TICKET?

- If you are experiencing technical issues with the Cayuse Human Ethics system, please email Cayuse Tech support at support@cayuse.com.

- Please be sure to include your name, contact information, study number, a screenshot of the error (if applicable), and a description of the issue.

TIP: TROUBLESHOOT FIRST.
If you have confirmed your access to Cayuse Human Ethics with the **IRB** administrator but are met with a blank page or cannot load Cayuse, try troubleshooting. **ORSP** recommends clearing your cache and browsing history and reloading the page.
If the issue persists, contact support@cayuse.com.

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CONTACT US

Office of Research and Sponsored Programs

609.626.3567

irb@stockton.edu

https://stockton.edu/research-sponsored-programs/irb.html

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