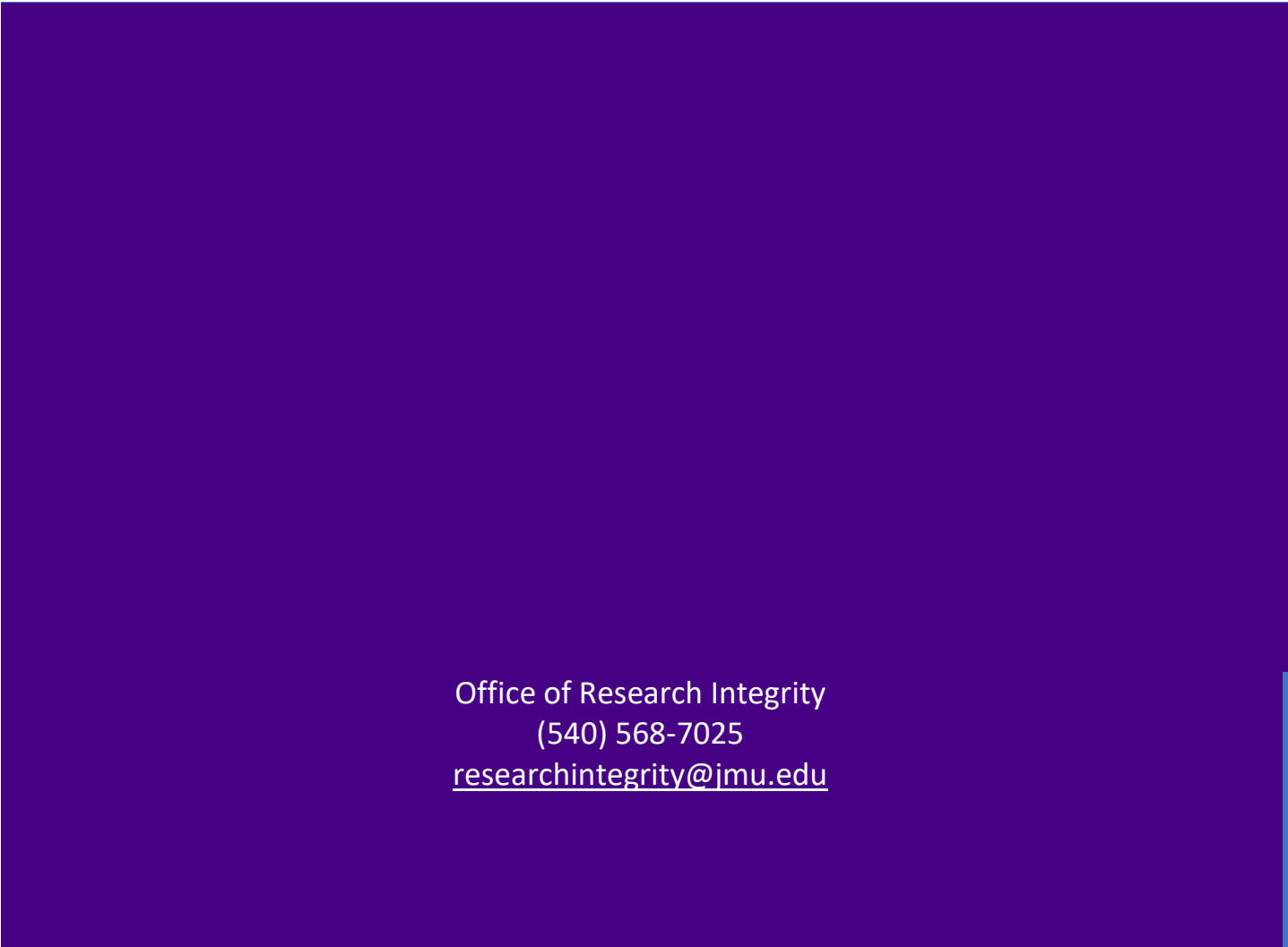




Human Ethics

Manual for Researchers



Office of Research Integrity
(540) 568-7025
researchintegrity@jmu.edu

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Accessing Cayuse

To access Cayuse Human Ethics, go to <https://jmu.app.cayuse.com/> and login with your JMU eID and password via Duo.

JAMES MADISON UNIVERSITY

Log in to Cayuse Research Suite
- Live

ATTENTION:

- **Duo two-factor authentication is now required** for this and many other JMU systems. See [here](#) for a complete list.
- **If you have not yet enrolled with Duo**, find instructions [here](#). For assistance, contact the IT Help Desk at 540-568-3555, or email helpdesk@jmu.edu

JMU eID

Password

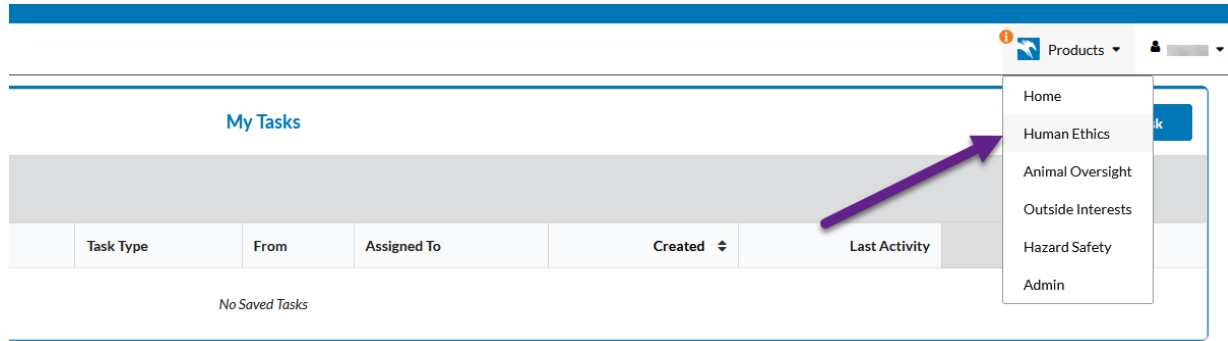
Log in

Protect Your Privacy!

Be sure to log out of this system by completely closing your web browser when finished. If you do not, someone else could use your web browser to login as you.

- **Windows users:** Close all web browser windows.
- **Mac users:** Quit your web browser

Under Products, click on **Human Ethics**:



Creating a New Study in Human Ethics

A **Study** is a container for all of your submissions, actions, and changes on a particular research activity. You must create a study before creating your initial submission.

Click on **+ New Study** in the upper right-hand corner of your Dashboard **or** the Studies page.

The screenshot shows the Cayuse Human Ethics Dashboard. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The 'Dashboard' tab is selected. Below the navigation bar, there are five main sections: 'In-Draft', 'Awaiting Authorization', 'Pre-Review', 'Under Review', and 'Post Review'. A purple arrow points to the '+ New Study' button in the top right corner.

The screenshot shows the Cayuse Human Ethics Studies page. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The 'Studies' tab is selected. Below the navigation bar, there are two sub-tabs: 'Active' and 'Archive'. A purple arrow points to the '+ New Study' button in the top right corner.

Enter the title of your study. The title can be up to 600 characters long.

The screenshot shows the Cayuse Human Ethics Study Details page. The top navigation bar includes 'Studies / Study Details' and '+ New Submission'. Below the navigation bar, there are two tabs: 'Study Details' and 'Submissions'. The 'Study Details' tab is selected. Below the tabs, there is a large text input field for the study title, with a placeholder 'Enter study title here'. To the right of the input field are a checkmark icon and a close icon. Below the input field, there are two buttons: 'PDF' and 'Delete'. Below the buttons, there is a table of metadata fields:

Approval Date: N/A	Expiration Date: N/A	Organization: N/A	Active Submissions:	Population Flags:	Additional Flags:
Admin Check-In Date: N/A	Closed Date: N/A	Current Policy	Sponsors: N/A		

After creating your study, you will be taken to the Study Details page. Here, you will see where important study information will populate once you begin your submission.

Studies / Study Details

Study Details

Unsubmitted

IRB-FY2024-46 TEST Protocol

PDF Delete

Approval Date: N/A	Expiration Date: N/A	Organization:	Active Submissions: N/A	Population Flags:	Additional Flags:
Admin Check-In Date: N/A	Closed Date: N/A	Current Policy Post-2018 Rule	Sponsors: N/A		

Key Contacts (1) Attachments Flags

Team Member	Role	Number	Email
No Key Study Contacts.			

Begin Initial Submission
You've created a study! Click here to begin your initial submission to the IRB.

+ New Submission


The person who creates the study is added as the primary contact by default. You can change this when editing the submission.

You can rename your study up until the completion of a withdrawal or admin closure submission. From the Study Details screen, hover over the study title and click within the field to edit.

Studies / Study Details

Study Details

Unsubmitted

IRB-FY2024-46 TEST Protocol 

PDF Delete

Approval Date: N/A	Expiration Date: N/A	Organization:	Active Submissions: N/A
Admin Check-In Date: N/A	Closed Date: N/A	Current Policy Post-2018 Rule	Sponsors: N/A

Key Contacts (1) Attachments Flags

Team Member	Role
No Key Study Contacts.	

Once you create your study, you can begin your initial submission. **Initial** is the first submission that you create when you enter a new study in the system. The initial submission describes the research you intend to do and the methodology you intend to use. The initial submission must be approved before any research can be begin. Click on **New Submission** in the upper right-hand corner then **Initial** to start completing your protocol.

The screenshot shows the 'Study Details' page for a study with ID 'IRB-FY2024-46' and protocol 'TEST Protocol'. The status is 'Unsubmitted'. A tooltip titled 'Begin Initial Submission' is displayed, stating 'You've created a study! Click here to begin your initial submission to the IRB.' and pointing to the 'Initial' button in the submission dropdown menu. The page includes a 'PDF' icon and a 'Delete' button. A table for 'Key Contacts' is shown at the bottom, which is currently empty.

Approval Date:	Expiration Date:	Organization:	Active Submissions:	Population Flags:	Additional Flags:
N/A	N/A		N/A		
Admin Check-In Date:	Closed Date:	Current Policy	Sponsors:		
N/A	N/A	Post-2018 Rule	N/A		

Team Member	Role	Number	Email
No Key Study Contacts.			

Project Personnel

Principal Investigator (PI): The person listed as the PI will be required to 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.

Primary Contact: The person that starts the application is automatically assigned as Primary Contact (PC). This can be changed. You can have as many PC's as you need. Any people listed as a Primary Contact will have edit access to this study, can create amendments after Initial approval, and will be included in study communications.

Co-Principal Investigator(s): Any people listed as Co-Principal Investigators will be required to certify the submission, have edit access to this study, can create amendments after Initial approval, and will be included in study communications. If you prefer the Co-Principal Investigator(s) **NOT** be required to certify, please instead list them as a Co-Investigator.

***Note to faculty with multiple Student Co-PIs:** To avoid delays in the system with regard to study communications, it is recommended to list your Student Co-PIs as Co-Investigators.

Co-Investigator(s): This could include Co-Principal Investigators as well. Any people listed as Co-Investigators will be able to view the study, but will **NOT** have edit access to the study nor be included in study communications automatically.

Collaborators

If you have a collaborator that will need access to the protocol, please contact the Office of Research at researchintegrity@jmu.edu for a Guest User account to be created.

The following information will be needed:

- First and Last Name
- Email Address

Once an account has been created they will receive an activation email that will include the following information:

- Username
- Temporary password (they will be prompted to change at first login)
- Unique Guest Account URL

Completing a Submission in Human Ethics

The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission. Make sure to not remove yourself from all roles and Save, or you will not be able to access your submission once you leave. The Principal Investigator and Primary Contact may be the same. You must designate one Principal Investigator.

IRB NUMBER: IRB-FY2024-46
TEST Protocol - Initial

Sections

- Getting Started
- Project Personnel
- Basic Information
- Attachments

Project Personnel

Study Personnel

Note: If you cannot find a person in the people finder, please contact the IRB Office immediately.

Principal Investigator

The person listed as the PI will be required to 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

What kind of affiliation does the PI have with this institution?

- Faculty
- Student
- Staff
- Other

Primary Contact

Any people listed as a Primary Contact will have edit access to this study, can create amendments after Initial approval, and will be included in study communications.

Note that the Primary Contact and the Principal Investigator may be the same.

FIND PEOPLE

Name	Organization	Address	Phone	Email	Trainings
					View

What kind of affiliation does the Primary Contact have with this institution?

- Faculty
- Student
- Staff
- Other

Co-Principal Investigator(s)

Any people listed as Co-Principal Investigators will be required to certify the submission, have edit access to this study, can create amendments after Initial approval, and will be included in study communications. If you prefer the Co-Principal Investigator(s)

The Human Ethics module uses skip logic, a feature that changes what question or page a respondent sees next based on the answer to the current question.

* Funding

Does this project have any funding?

- Yes
 No

VS.

* Funding

Does this project have any funding?

- Yes
 No
- Internally
 Externally

The **Complete Submission** button will only appear when you have check marks next to all of your sections. If one of your sections doesn't have a check mark and you aren't sure why, click on the section to search for any required questions you may have missed.

The screenshot displays the Cayuse Human Ethics interface. At the top, there is a navigation bar with 'Dashboard', 'Studies', and 'Submission' tabs. Below this, a breadcrumb trail shows 'SUBMISSION DETAILS' with a back arrow, and the IRB number 'TEST P'. A vertical list of sections is shown on the left, each with a checkmark indicating completion. A purple arrow points to the 'Basic Information' section. The 'Participant Protection' section has a red asterisk icon next to its checkmark. At the bottom of the list is an 'Attachments' section.

Adding Attachments to Submissions

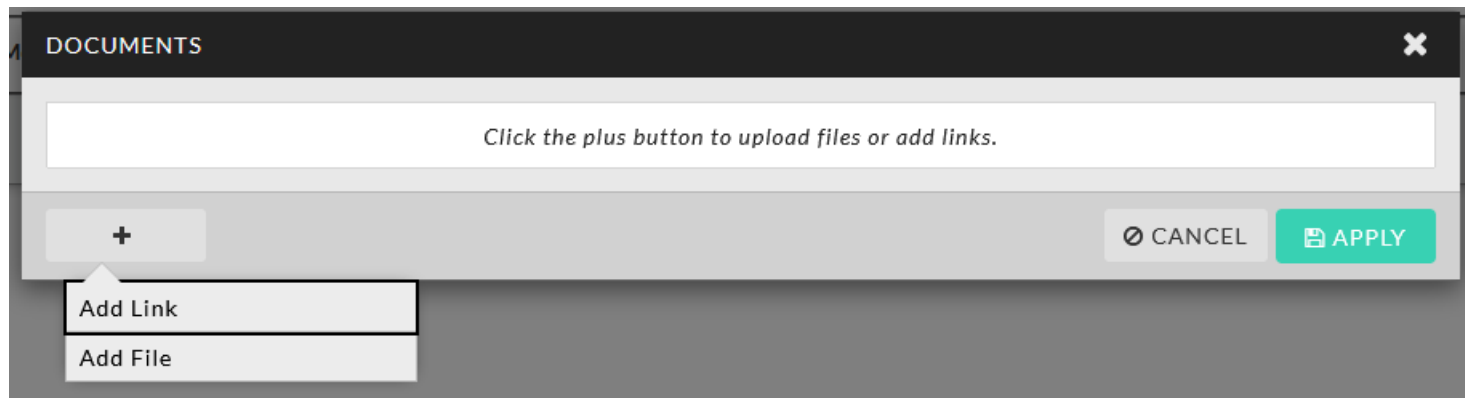
Throughout the protocol there are opportunities to upload Attachments. Click on the **Attach** button.

Study Personnel Training Documentation

Upload documentation of any required training (e.g., CITI training) if not automatically populated, completed at another institution within the past three years, or for personnel outside of JMU.


ATTACH

Click the plus sign to upload a link or a file. You can upload one or more files.



Human Ethics supports the following file types:

File Type	Extension
Text	txt
Adobe	pdf
Raster image formats	png, bmp, gif, tif, tiff, jpg, jpeg, jp2, jpx
Vector image formats	wmf, emf, svg
Microsoft Word	doc, docx, docm
Microsoft Excel	xls,xlsx, xlsxm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm

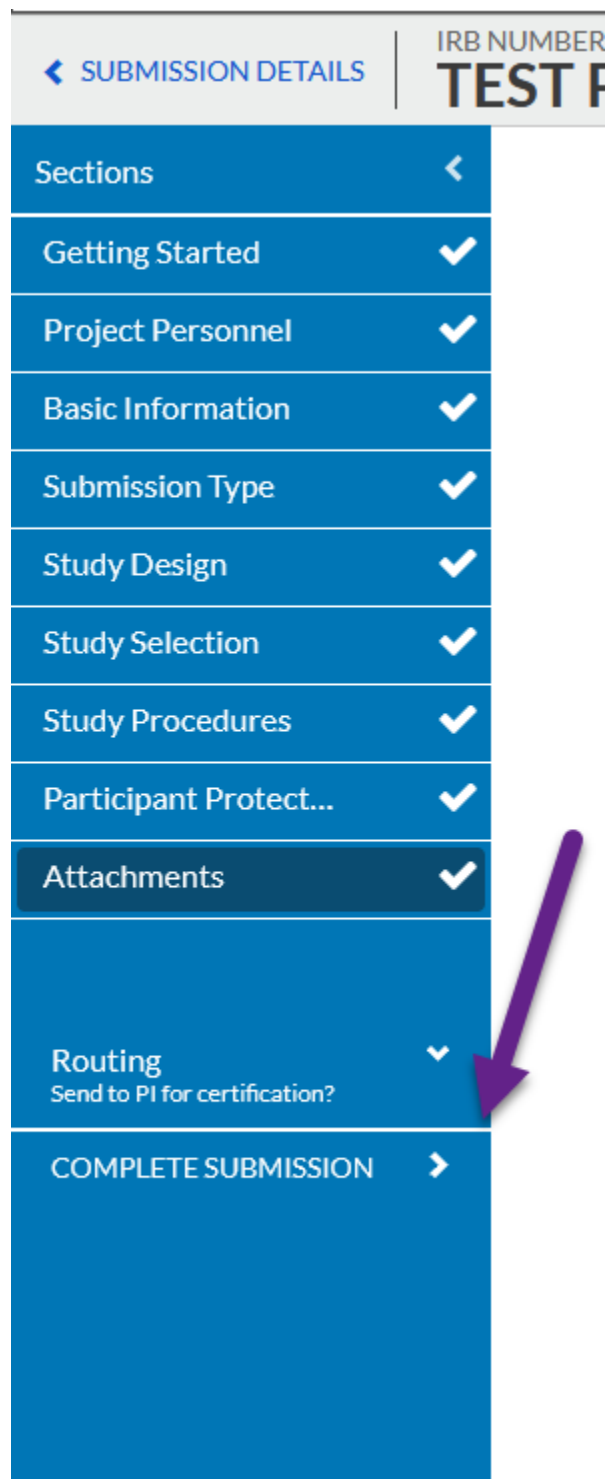
To delete an attachment, click the  icon next to the attachment.

Simultaneous Users

More than one member of the research team (PI, Co-PI, Primary Contact, or another authorized Investigator) can be working on different sections of a submission at the same time. When another user is currently working on a section, that section will have a red lock icon in the section menu and you will not be able to make edits to that section. You can still work on other sections that are not locked. To see who is currently editing a locked section, hover over the lock icon in the section menu.

Note: A submission cannot be completed while another user is still editing it.

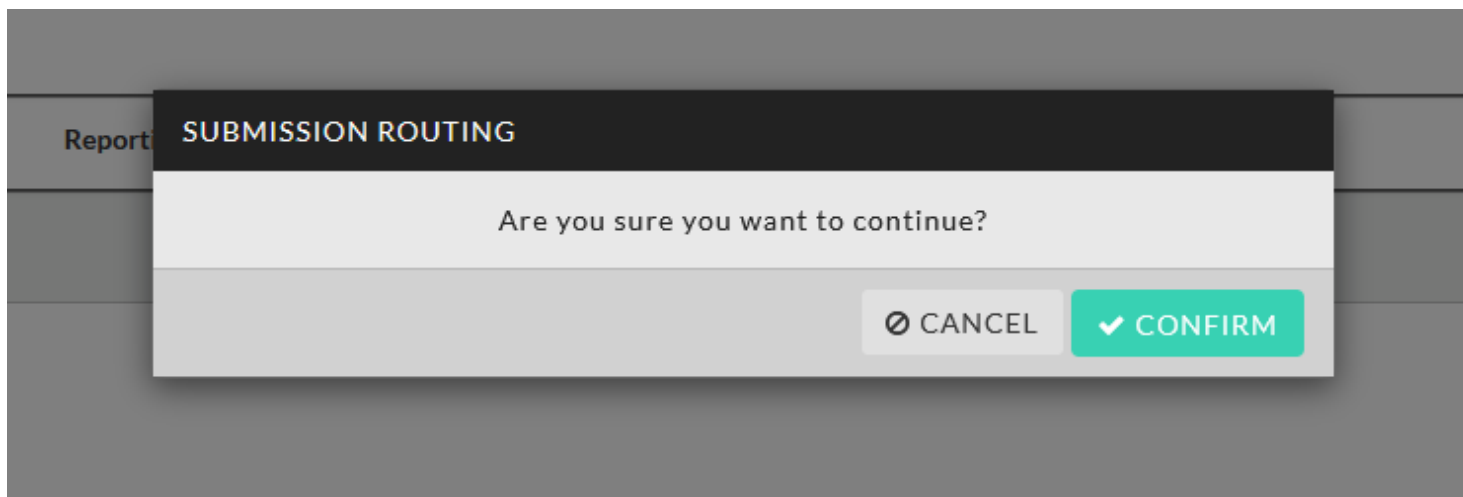
Once you have filled out every section of your submission and have added all required attachments, a **Complete Submission** option appears beneath **Routing** within the menu.



The screenshot shows a vertical menu for submission details. At the top, there is a header with a back arrow and the text 'SUBMISSION DETAILS' on the left, and 'IRB NUMBER TEST F' on the right. Below the header is a list of menu items, each with a checkmark icon on the right. The items are: Sections, Getting Started, Project Personnel, Basic Information, Submission Type, Study Design, Study Selection, Study Procedures, Participant Protect..., Attachments, Routing (with a dropdown arrow and the text 'Send to PI for certification?'), and COMPLETE SUBMISSION (with a right-pointing arrow). A purple arrow points to the 'COMPLETE SUBMISSION' option.

Section	Status
Sections	<
Getting Started	✓
Project Personnel	✓
Basic Information	✓
Submission Type	✓
Study Design	✓
Study Selection	✓
Study Procedures	✓
Participant Protect...	✓
Attachments	✓
Routing Send to PI for certification?	∨
COMPLETE SUBMISSION	>

After clicking Complete Submission, you will be prompted to **Confirm** or **Cancel**.



Upon confirmation, you will see the status of your submission change on the Submission Details page.

Studies / Study Details / Submission Details

1 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

Awaiting Certification

Initial
IRB-FY2024-46 - TEST Protocol

View PDF Delete

Routing: Return Certify

PI: [Redacted] Current Analyst: N/A Decision: N/A Policy: Post-2018 Rule Required Tasks: N/A

Review Type: N/A Review Board: N/A Meeting Date: N/A

Approvals Task History Attachments

Research Team

Name	Role	Result	Date
Carrie Tillman	Principal Investigator	Pending Certification	

Certification

Your completed submission is sent to the PI for certification. The PI will receive an email letting them know that the submission needs to be certified. When the PI certifies the submission, they are asserting the submission is complete and accurate and are accepting their PI responsibilities.

If the PI decides that changes need to be made, they will send the submission back. All research team members will receive an email notifying them of the change in status so they can make the necessary edits and complete the submission once more.

Once the PI has certified the submission, the submission will be routed to the Analyst. The submission may be returned at any point for edits or clarification.

Completing Submission as a PI: If you are a PI completing your submission, you will be able to certify the submission right away.

Co-PIs: Any Co-PIs listed on the study must also certify the submission. These individuals also have the ability to return to the submission to the research team.

Other personnel will not have to certify the protocol.

Recertification: If the submission does get returned to the research team, all previous certifications are cleared. All individuals who were required to certify the submission in previous rounds of routing must recertify every time the submission is returned before it can move forward.

Studies / Study Details / Submission Details

✓ 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

Awaiting Certification

Initial
IRB-FY2024-46 - TEST Protocol

[View](#)
[PDF](#)
[Delete](#)

Routing: [Return](#) [Certify](#)

PI: [REDACTED]
 Current Analyst: N/A
 Decision: N/A
 Policy: Post-2018 Rule
 Required Tasks: N/A

Review Type: N/A
 Review Board: N/A
 Meeting Date: N/A


[Approvals](#)
[Task History](#)
[Attachments](#)

Research Team

Name	Role	Result	Date
Carrie Tillman	Principal Investigator	Pending Certification	

2 Awaiting Authorization

Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Cancel Confirm

Once a Study has been certified, the status will change to **Under Pre-Review** and you will receive an email confirmation.

[Studies](#) / [Study Details](#) / Submission Details

✓ **In-Draft**
Submission is with researchers

✓ **Awaiting Authorization**
Submission is awaiting certification or approval

3 **Pre-Review**
Submission is being pre

Under Pre-Review

Initial

IRB-FY2024-46 - TEST Protocol

Review PDF Delete

PI:	Current Analyst:	Decision:	Policy:
	N/A	N/A	Post-2018 Rule
Review Type:	Review Board:	Meeting Date:	
N/A	N/A	N/A	

Approvals Task History Attachments

Research Team

Name	Role	Result
Carrie Tillman	Principal Investigator	Certified

Reopening Your Submission

To reopen the submission and make edits, click on the **Edit** button within Submission Details.

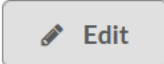

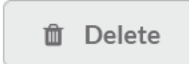
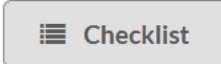
[Studies](#) / [Study Details](#) / Submission Details

1 In-Draft
Submission is with researchers

2 Awaiting Authorization
Submission is awaiting certification approval

Reopened

Initial
IRB-FY2024-28 - Study for Full Board Review

 **Edit**  **PDF**  **Delete**  **Checklist**

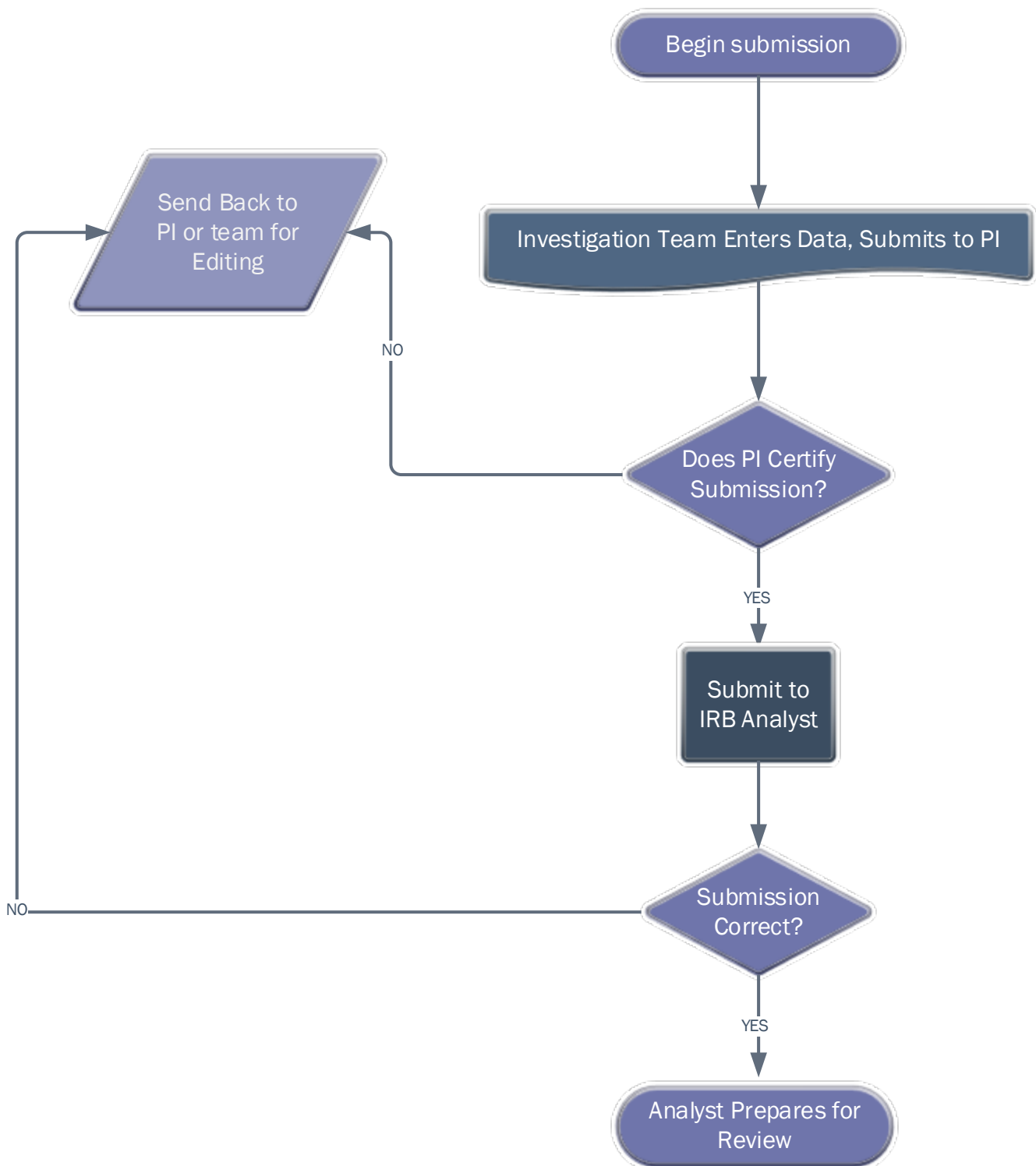
IRB NUMBER: **Study**

← SUBMISSION DETAILS

Sections <

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Submission Type ✓
- Study Design 1
- Study Selection ✓
- Study Procedures 1
- International Resea... ✓
- Participant Protect... ✓
- Attachments ✓

Submission Routing



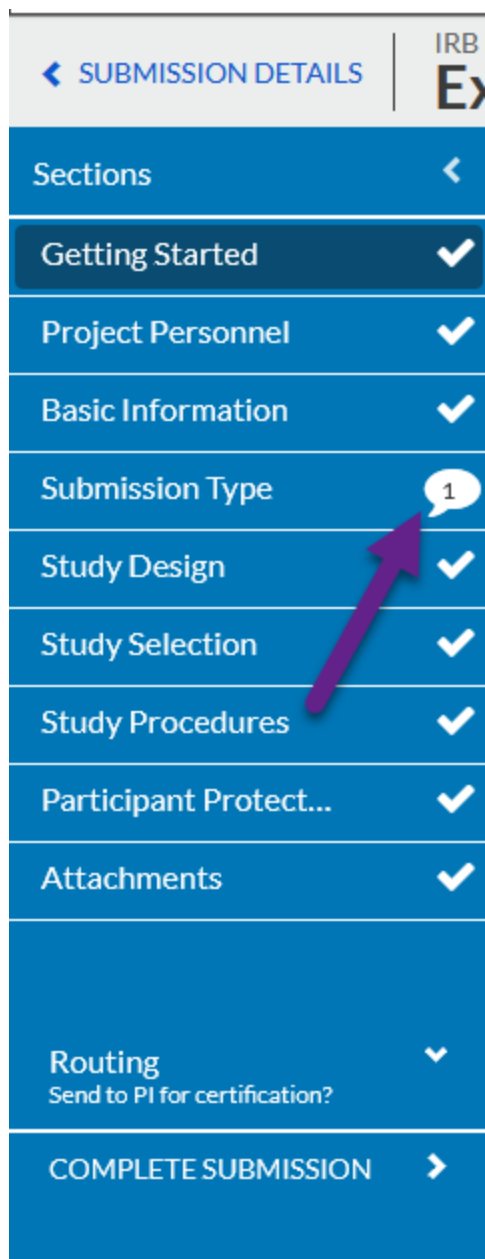
Addressing Comments in Human Ethics

When a submission has been certified by a PI and sent to the Analyst, the Analyst or other individuals reviewing the submission may comment on various questions within the submission forms. The Analyst will return the submission to the investigators, and the investigators will need to address any of the comments.

Sections with unresolved comments have a comment bubble icon indicating the total number of unresolved comments in that section. Click on the section to see which questions have a comment attached.

Addressing Comments

1. Click on the numbered comment bubble to view the unaddressed comments associated with each question.



Click on the numbered comment bubble to view the unaddressed comments associated with each question:

* Select the Admin Contact

Name	Organizati...
Mr. Burns	Comparative Medicine

1 Expand Comments

1 Collapse Comments

IRB Reviewer 05-13-2024 11:56 AM

Please also check # 7 as you plan to conduct focus groups.

[Reply](#)






Not Addressed

2. **Reply is Optional.** If you choose to include a reply, enter one and click **Save**.

IRB Reviewer 05-13-2024 11:56 AM

Please also check # 7 as you plan to conduct focus groups.

[Reply](#)

B I U     

|

 SAVE  CANCEL

3. Once you have resolved an issue, change the status drop-down from **Not Addressed** to **Addressed**.

1 Collapse Comments

IRB Reviewer 05-13-2024 11:56 AM

Please also check # 7 as you plan to conduct focus groups.

[Reply](#)

Addressed

Today at 3:05 PM by you

Note: You must mark all comments as addressed before the submission can be completed.

Once all comments on the submission have been addressed and the submission has been completed, the PI will need to re-certify the submission to return it to the Analyst.

Available Submission Types

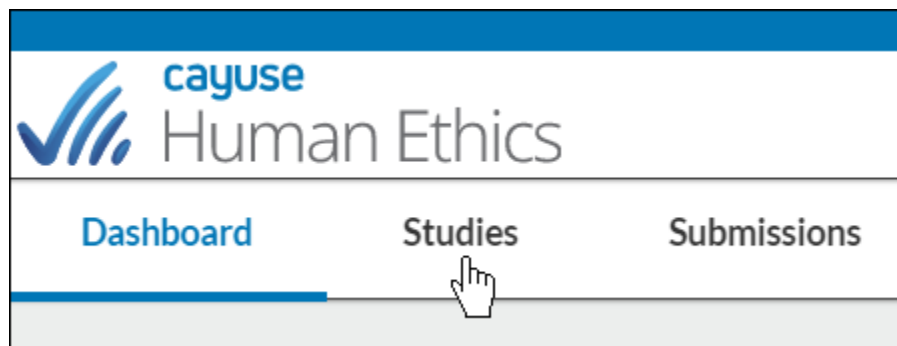
- **Initial:** This is the first submission that you create when you enter a new study in the system. The initial submission describes the research you intend to do and the methodology you intend to use. The initial submission must be approved before any research can begin.
- **Modification:** If you wish to change any of the details of the study after it has been approved, you must submit a modification which must be approved before you can proceed with the changes.
- **Renewal:** When a study is nearing its expiration date, you must submit a renewal request in order to continue with the research. The renewal will need to be approved before you can continue with the study.
- **Incident:** You must submit an incident report to inform the Office of Research Integrity of any adverse incidents, protocol violations, and deviations as required by JMU. Incident reports may be submitted at any time after a study has been approved, including after it has been closed. More than one incident report may be created for a given study, as needed.
- **Withdrawal:** A withdrawal submission notifies the Office of Research Integrity that you no longer wish to submit your initial submission and want to withdraw the study. Withdrawn studies are marked as finalized and can no longer be modified. You may create a withdrawal submission at any point once an initial submission has been created, until it has been approved. If the initial submission has been approved, you must create a closure submission in order to close the study if you no longer wish to conduct the research.
- **Closure:** A closure submission indicates that the research is complete and will not be continuing. Closed studies are marked as finalized and can no longer be modified.
- **Legacy:** Used for studies imported from previous systems. The legacy submission replaces the initial submission for imported studies. Once the legacy submission is finalized, you can create additional submissions such as modifications, renewals, etc. An Analyst must create and publish a legacy template before users can create legacy submissions or work with studies that have been imported from other systems.

Submission Types Available to Analysts and Admins

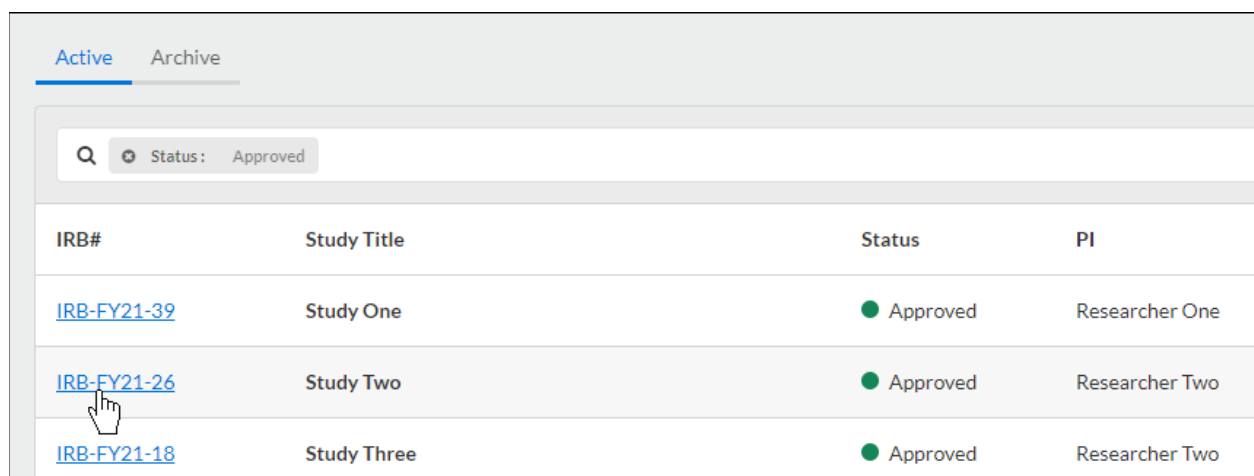
- **Admin Closure:** Allows a study to be administratively closed when needed, for example when the PI leaves the institution or chooses to let a study expire.
- **Admin Withdrawal:** Allows a study to be administratively withdrawn when needed, for example when the PI leaves the institution.

Creating a Modification

1. From your Researcher Dashboard, click on **Studies**.



2. Search for the study for which you wish to create a modification, and click on the study number. **Please note:** Study must be approved.

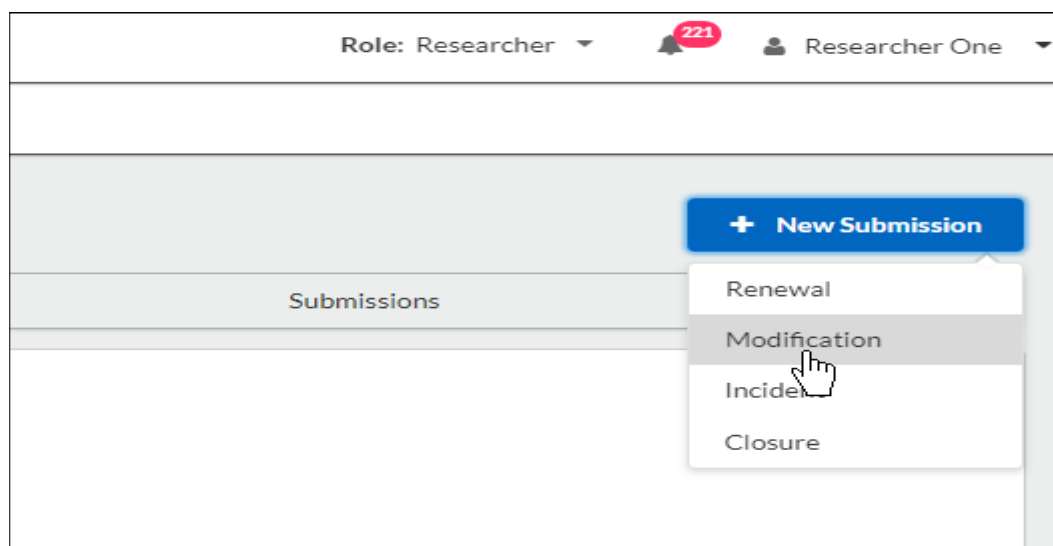


The screenshot shows the 'Active' tab of the Studies list page. A search bar contains the text 'Status: Approved'. Below the search bar is a table with the following data:

IRB#	Study Title	Status	PI
IRB-FY21-39	Study One	● Approved	Researcher One
IRB-FY21-26	Study Two	● Approved	Researcher Two
IRB-FY21-18	Study Three	● Approved	Researcher Two

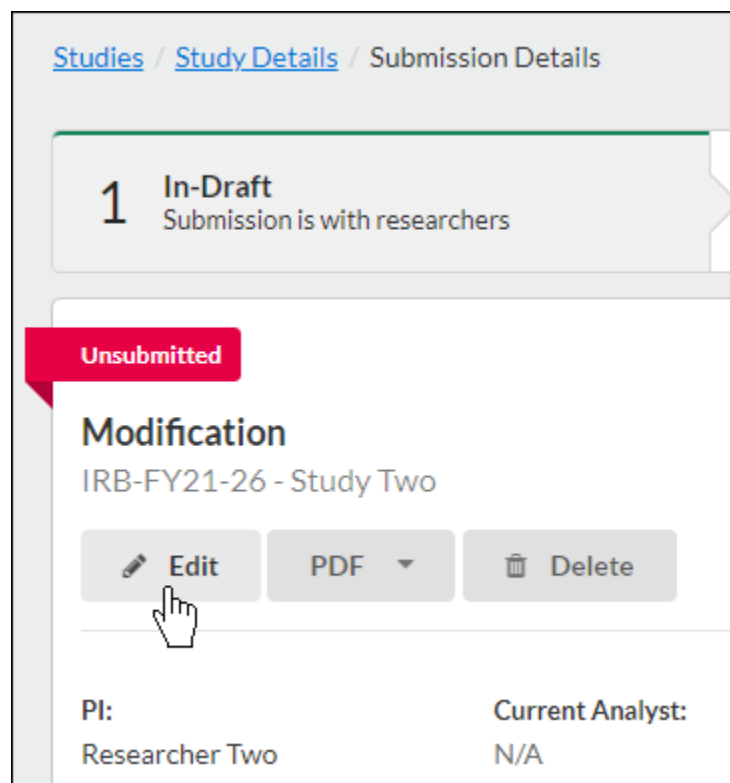
A mouse cursor is pointing at the link 'IRB-FY21-26' in the second row.

3. In the top right-hand corner of the Study Details page, click on the **New Submission** drop-down menu, and click **Modification**.



Submission information will populate beneath the Submission Details tab. The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission.

Click **Edit** to begin your submission.



Filling Out Your Submission

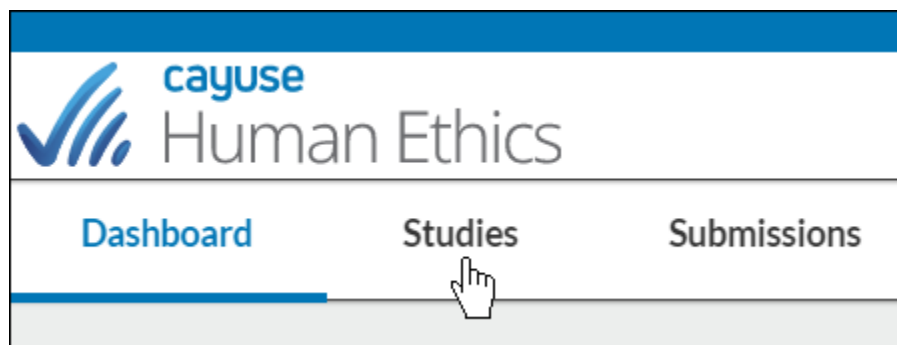
Filling out your Modification is a lot like filling out your Initial Submission with some key differences:

- Some sections may be modification specific, and are meant to show reviewers what changes have been made within the other sections.
- The other sections are from the approved Initial Submission, and where the modifications are made. Since a Modification is a request for changes, changes do not go into effect until a Modification has been approved.

When you're finished, click **Complete Submission**.

Creating a Renewal Submission in Human Ethics

1. From your Researcher Dashboard, click on **Studies**.



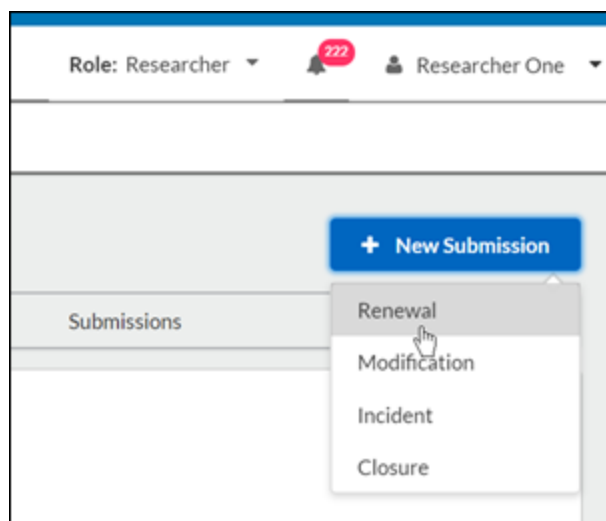
2. Search for the study for which you wish to create a Renewal Submission, and click on the study number. **Please note:** Study must be approved.

The screenshot shows the 'Active' tab in the Studies section. There is a search bar with a magnifying glass icon and a filter dropdown set to 'Status: Approved'. Below the search bar is a table with the following data:

IRB#	Study Title	Status	PI
IRB-FY21-39	Study One	● Approved	Researcher One
IRB-FY21-26	Study Two	● Approved	Researcher Two
IRB-FY21-18	Study Three	● Approved	Researcher Two

A mouse cursor is pointing at the 'IRB-FY21-26' link in the first column.

3. In the top right-hand corner of the Study Details page, click on the **New Submission** drop-down menu, and click **Renewal**.



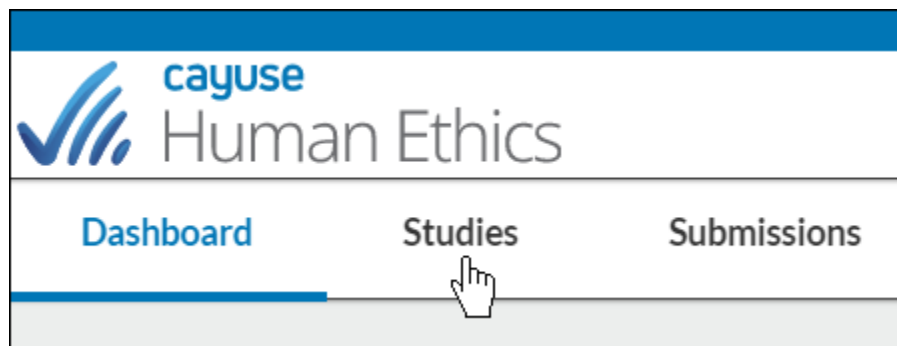
Submission information will populate beneath the Submission Details tab. The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission.

Click **Edit** to begin your submission.

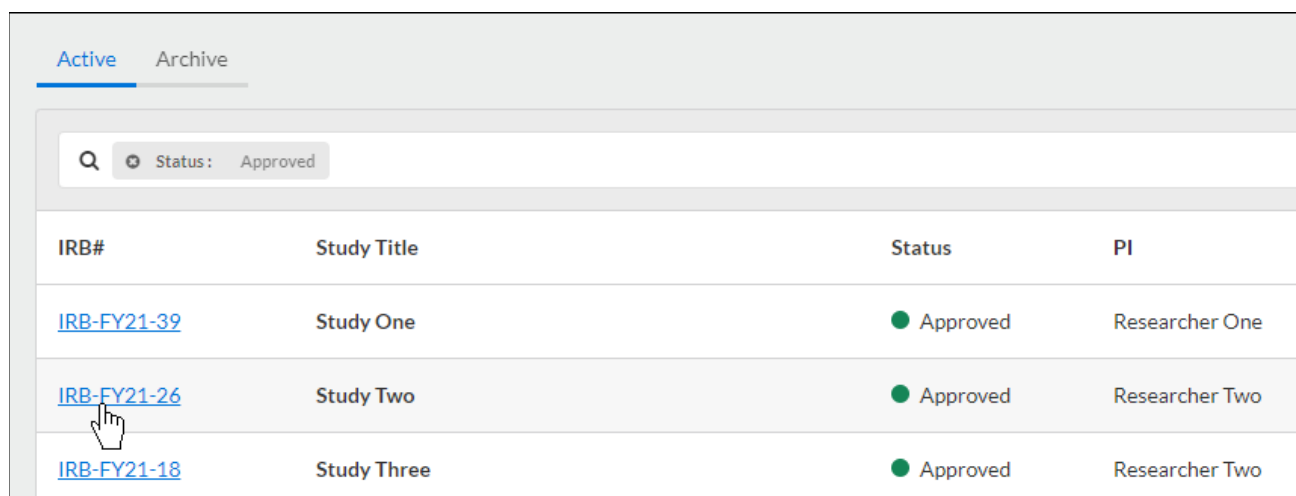
Fill out your submission form, and when you're finished, click **Complete Submission** to begin the routing process.

Creating an Incident Report

1. From your Researcher Dashboard, click on **Studies**.



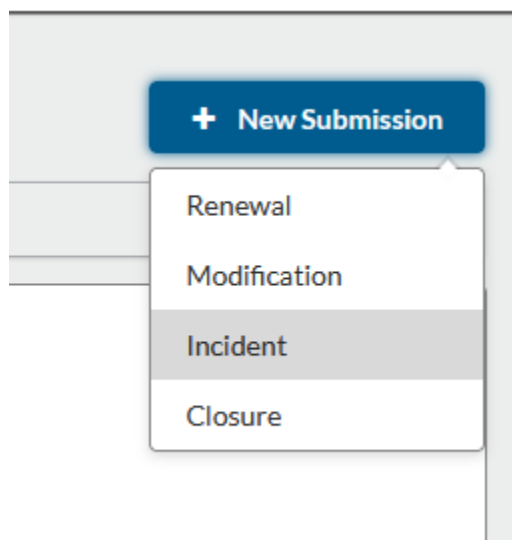
2. Search for the study for which you wish to create a Renewal Submission, and click on the study number. **Please note:** Study must be approved.



The screenshot shows a table of active studies. At the top, there are tabs for 'Active' and 'Archive'. Below the tabs is a search bar with a magnifying glass icon and a filter dropdown set to 'Status: Approved'. The table has four columns: 'IRB#' (with a link icon), 'Study Title', 'Status', and 'PI'. Three rows of data are visible, each with a green dot indicating 'Approved' status.

IRB#	Study Title	Status	PI
IRB-FY21-39	Study One	● Approved	Researcher One
IRB-FY21-26	Study Two	● Approved	Researcher Two
IRB-FY21-18	Study Three	● Approved	Researcher Two

3. In the top right-hand corner of the Study Details page, click on the **New Submission** drop-down menu, and click **Incident**.



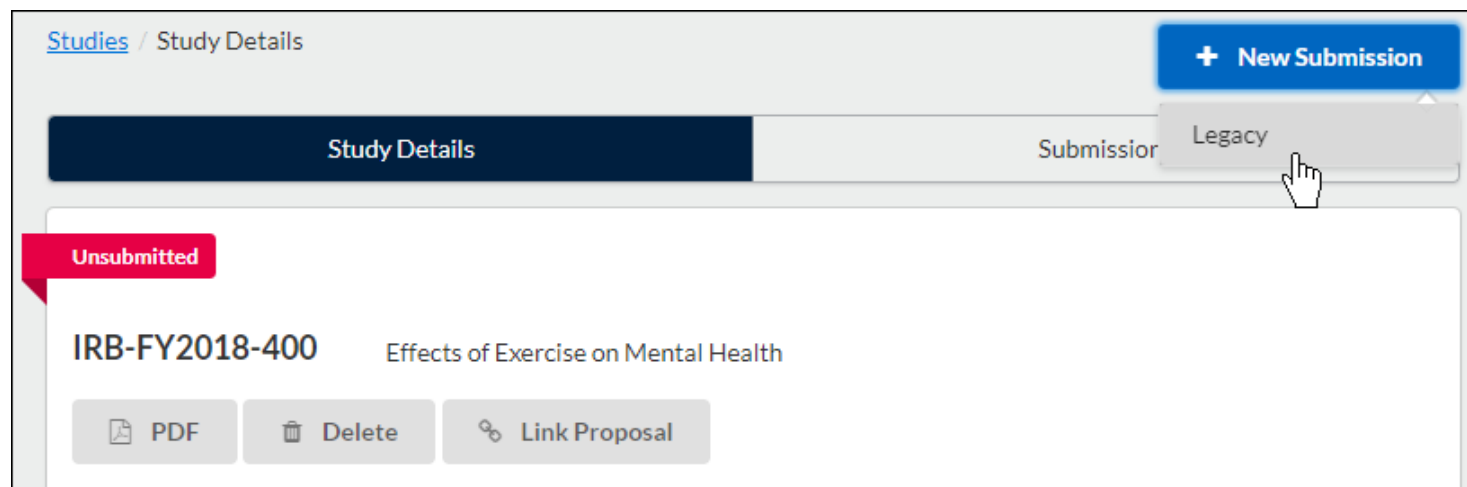
Submission information will populate beneath the Submission Details tab. The person who creates the study is added as the Primary Contact by default, but this can be changed when editing the submission.

Click **Edit** to begin your submission.

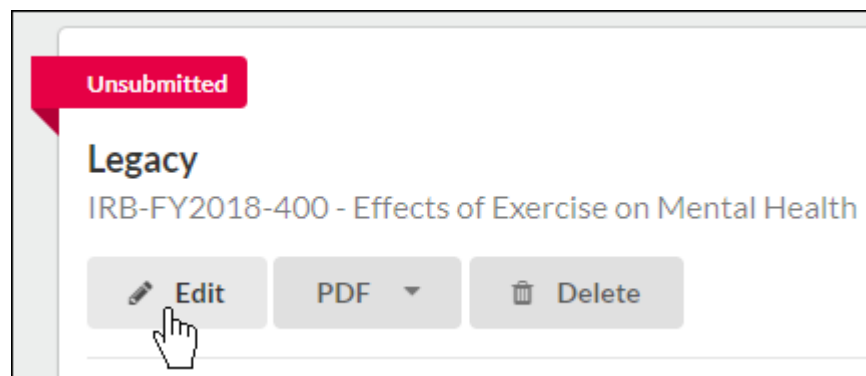
Fill out your submission form, and when you're finished, click **Complete Submission** to begin the routing process.

Creating a Legacy Submission

When you first open an imported study, the only available submission type will be Legacy submission. Click **Legacy** beneath **New Submission** to proceed.



The Legacy submission is created similarly to the Initial submission, but will use a Legacy template instead of an Initial template. To access the Legacy forms, click **Edit**.



Note: You may see that some of the data, such as the Principal Investigator, is pre-populated within the submission form. You must save the form in order for these changes to be remembered.

Make any changes to personnel as necessary:

The screenshot shows a sidebar on the left with a blue background. The top bar is labeled "Sections" with a left-pointing chevron. Below it, "Legacy Form" is listed with a white checkmark. The main content area is titled "Legacy Form" in teal. It contains three sections:

- * Principal Investigator**: A grey button labeled "FIND PEOPLE".
- * Primary Contact**: A grey button labeled "FIND PEOPLE".
- Faculty Advisor**: A horizontal line, followed by the text "This is required if the PI is a student." and a grey button labeled "FIND PEOPLE".

Upload your approved documents, include:

- IRB protocol
- Information consent form(s)
- Data collection tools

The screenshot shows the same sidebar as above, with "Legacy Form" selected. The main content area is titled "Legacy Form" in teal. It contains two sections:

- Other Research Team Members**: A grey button labeled "FIND PEOPLE".
- Study Documents**: A grey button labeled "ATTACH".

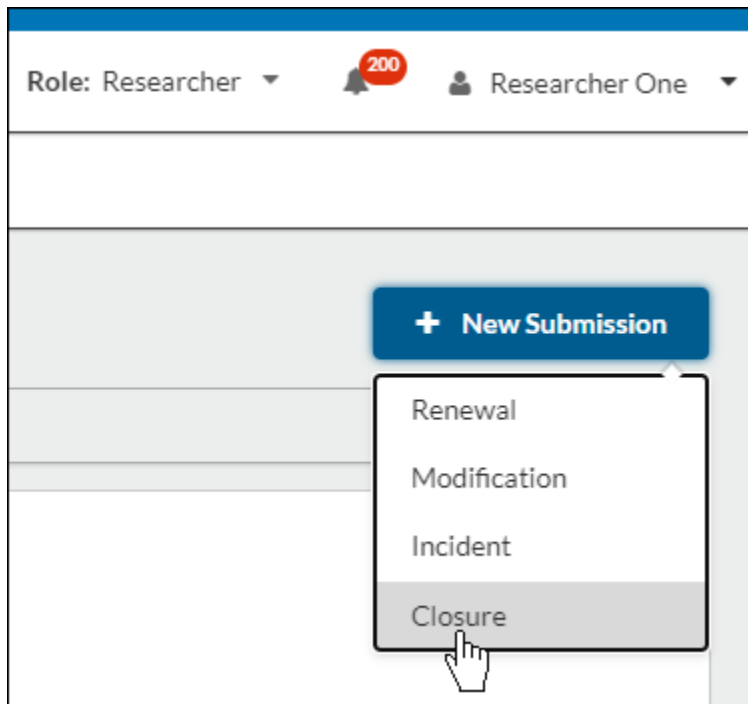
When you are finished editing the forms and every section has a green check mark next to it, click **Complete** to finalize the Legacy submission.

You will arrive back to your **Submission Details** page. Click **Study Details** and in the top right corner, select New Submission to begin a new renewal, modification, incident, or closure submission.

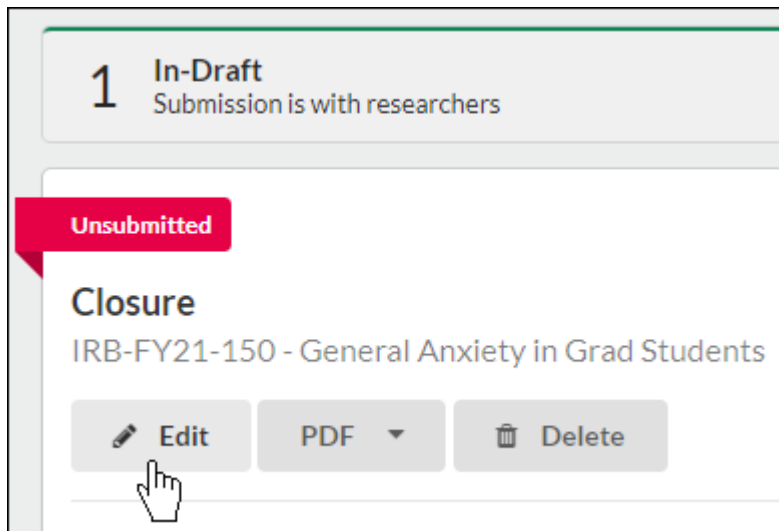
Note: after the Legacy submission has been activated via the steps above, the Analyst only has the option to create an Admin Closure submission. Only the PI can create renewal, modification, incident, or closure submissions.

Closing a Study

1. On the Study Details page of your study, click on **New Submission** in the top right-hand corner. In the drop-down menu, click **Closure**.



2. On the new Submission Details page, click **Edit**.

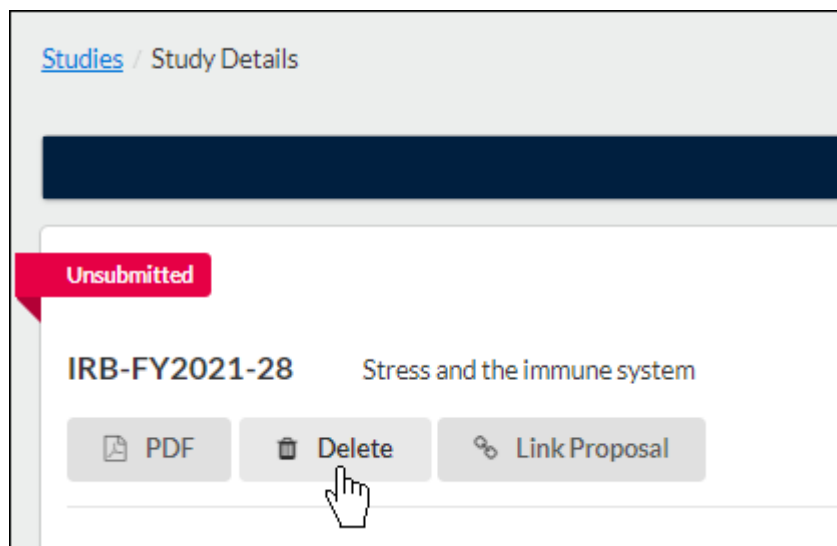


3. Fill out the submission form, including all required fields, and click **Complete Submission**.

The Analyst will now need to approve the closure before your study will be marked as closed.

Deleting a Study or Submission

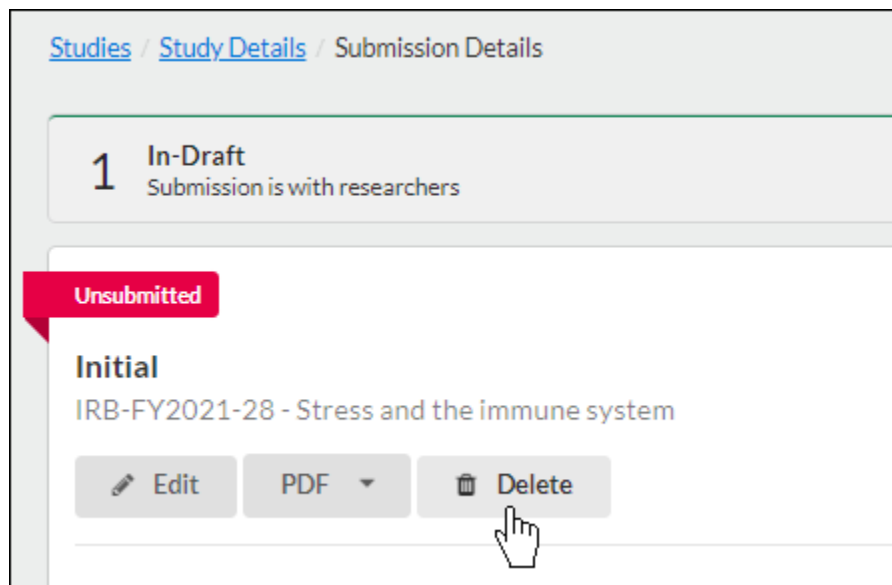
You can only delete a study if it has no submissions attached. To delete a study, click on **Delete** on the **Study Details** page.



On the confirmation page, click **Delete**.

You can only delete a submission prior to the initial completion (when Complete Submission is clicked). If a submission can't be deleted, it can be withdrawn instead.

To delete a submission, click on **Delete** on the **Submission Details** page.



On the confirmation page, click **Delete**.



Delete Item



Decision:

Posting Date:

Are you sure you want to delete *"Initial Submission"* ?

Policy:

POST-2010 Rule

Required Tasks:

- [Assign PI](#)
- ✓ [Assign PC](#)
- [Complete Submission](#)

Cancel

✕ Delete



Viewing Submission Details and History

You can access all details and history for a submission within the **Submissions** tab on the **Study Details** page, or from the menu on your Dashboard.

From Study Details

From the **Study Details** page, click on the **Submissions** tab.



The Submissions tab shows the list of submissions associated with the study, including the submission type, review type and status, decision, and last modified date. Click on the submission you wish to view.

The screenshot shows the 'Submissions' tab selected. It displays a table with the following columns: Submission Type, Review Type, Status, and Decision. A hand cursor is pointing to the 'Initial' link in the first row.


Submission Type	Review Type	Status	Decision
Initial	Exempt	● Review Complete	Exempt 10-01-2018
Modification	Unassigned	● Unsubmitted	--

At the bottom of the Submission Details screen, you'll see tabs that vary depending on the submission stage. Tabs may include **Approvals**, **Task History**, **Letters**, **Meetings**, **Decisions**, and **Linked Proposals**.

Reopened

Initial
IRB-FY2018-22 - Fame

[View](#) [PDF](#) [Delete](#)

PI: Zillow Zillowson **Current Analyst:** Marge Simpson  **Decision:** Return to PI **Policy:** Pre-2018 Rule **Required Tasks:** N/A

Review Type: Expedited **Review Board:** Duff Review Board **Meeting Date:** N/A


Approvals | **Task History** | Letters | Meetings | Decisions


Name	Role	Routing Action	Completion Date
Marge Simpson	Analyst	Post Review Completed	12-14-2018 5:48 PM
Ned Flanders	Reviewer	Review Completed	01-12-2018 6:23 PM
Barney Gumble	Analyst	Reviewers Assigned	01-12-2018 6:21 PM

Click on the desired tab to locate the required information.

From Your Dashboard

Click on **Submissions** in the menu.



Dashboard **Studies** **Submissions** 

Search for the submission you wish to view, and then click on the submission.

My Role: Admin ▾

Q All: 2019-18


IRB#	Submission
IRB-FY2019-18	The Effects of Blue Light on Sleeping Patterns Initial

This will bring you to the Submission Details page.

Viewing and Downloading Letters

During the submission process, the compliance office may send communication to the PI in the form of letters notifying the PI of status changes, approvals, and needed information. Letters are sent via email and are available to download directly from Submission Details in Human Ethics.

[Studies](#) / Study Details

Study Details		Submissions	
Submission Type	Review Type	Status	Decision
Initial 	Exempt	● Review Complete	Exempt 04-22-2024

The Letters tab appears for a submission when there is at least one letter associated with that submission. To view a letter, click on the letter tab.

Review Complete

Initial
IRB-FY2024-46 - TEST Protocol

View
PDF
Delete
Checklist

PI: [Redacted]
Current Analyst: [Redacted]
Decision: Exempt
Policy: Post-2018 Rule

Review Type: Exempt
Review Board: Institutional Review Board

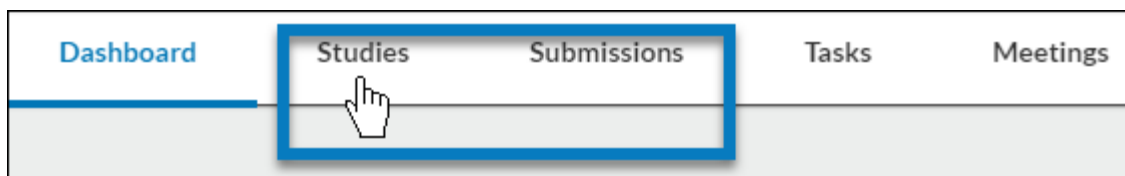
Approvals
Task History
Letters
Decisions
Attachments

Subject	Recipients	Sent Date
IRB-FY2024-46 - Initial: Initial - Exempt Review Approval	[Redacted]	04-22-2024

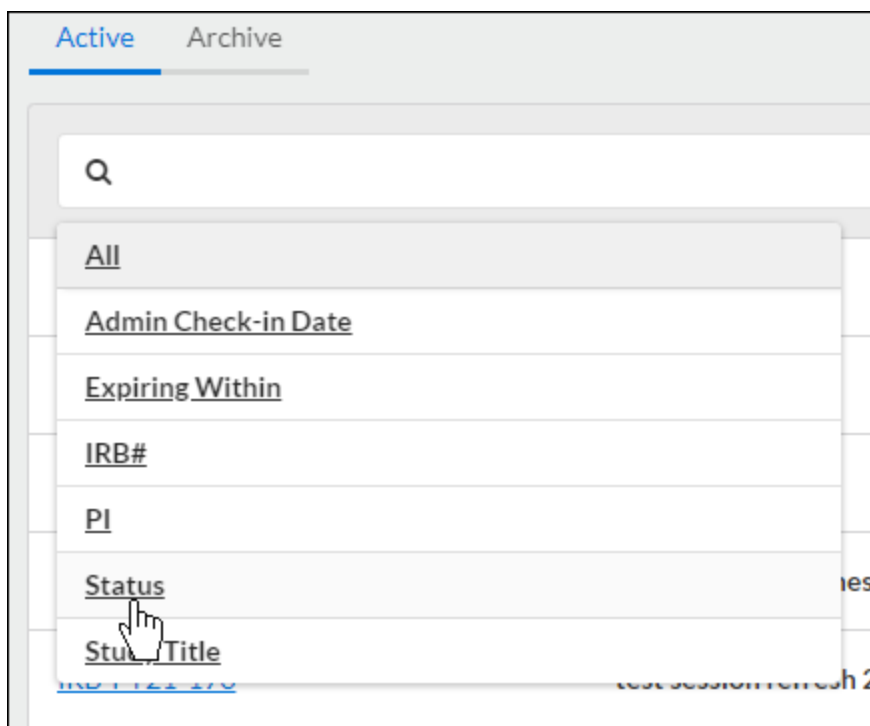
You will be able to view the subject, send date, and recipient(s) for each letter. You can click anywhere on the line to open a PDF of the letter in a new window.

Searching for Studies and Submissions

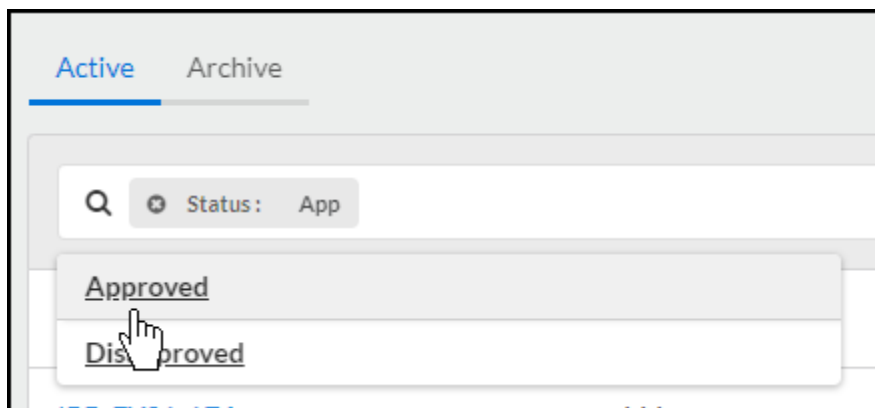
To search for a specific study or submission you have worked on in Human Ethics, click on either the **Studies** or **Submissions** tab.



Click into the search box, and select a filter from the drop-down list.



In the filter's gray area, type in your search criteria until you see it in the drop-down menu, then click on the item.



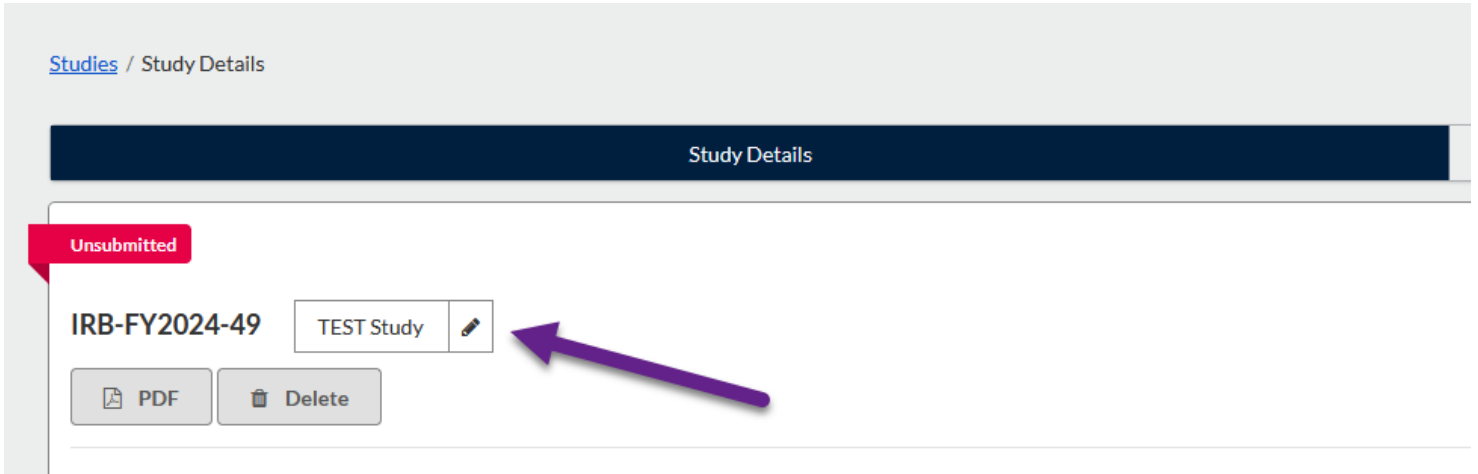
In the results, click on your study or submission to be brought to the Study Details or Submission Details page.

Missing Studies or Submissions

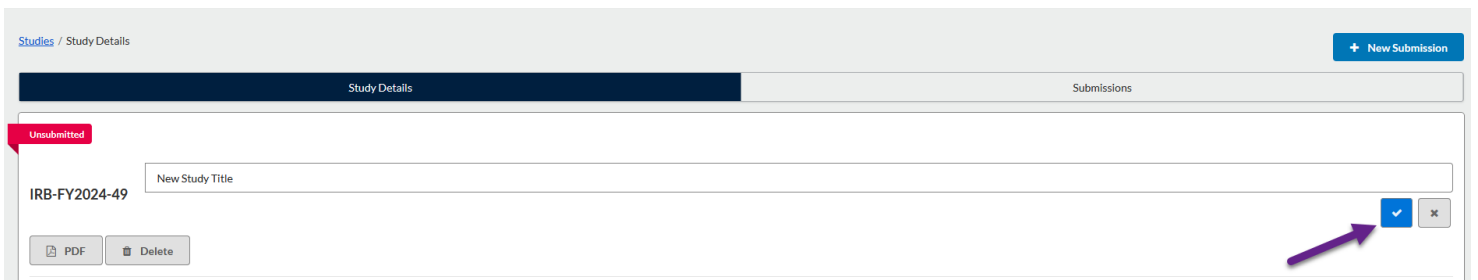
If you can't find a study or submission, it may mean that you've been removed from the research team. The primary contact must re-add you in order for you to regain access. They can do this by creating an Initial or Modification submission.

Changing a Study Title

To change a study title, go to the Study Details page and hover over your study title. Click the title and type the new name.

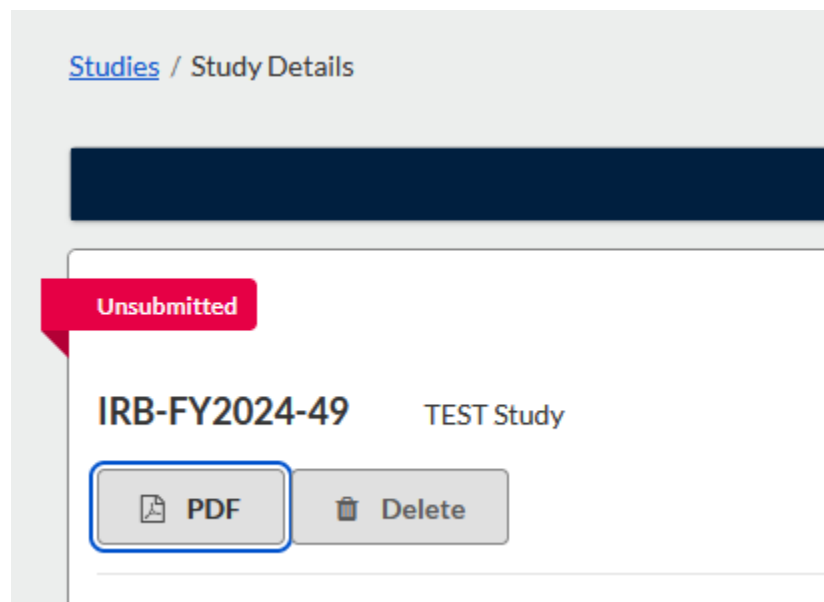


Click on the blue check mark to save.



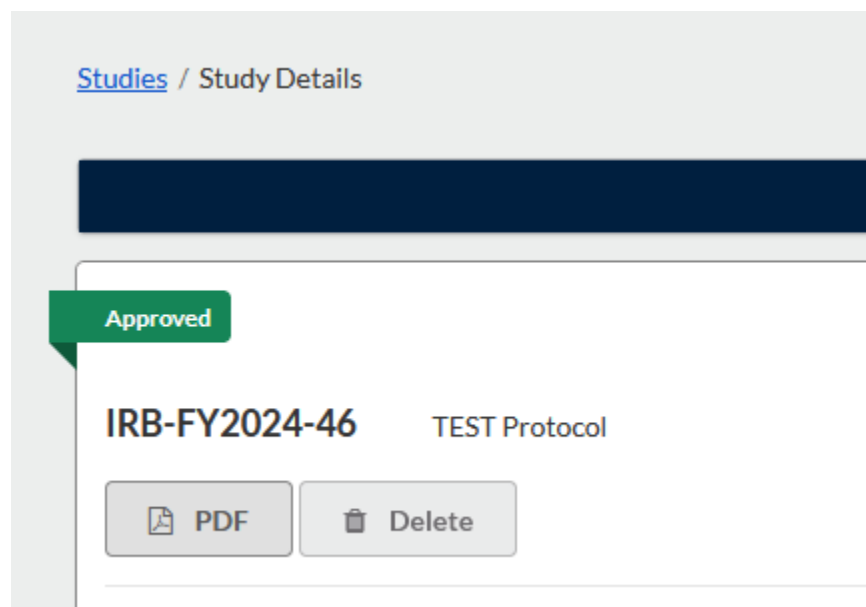
Downloading a PDF copy of your Submission

To download a copy of your protocol, go to the Study Details page.



The screenshot shows the 'Study Details' page for an 'Unsubmitted' study. At the top, there is a breadcrumb trail: [Studies](#) / Study Details. Below this is a dark blue header bar. A red callout box on the left contains the text 'Unsubmitted'. The study ID is 'IRB-FY2024-49' and the study name is 'TEST Study'. Below the study information are two buttons: 'PDF' (with a document icon) and 'Delete' (with a trash can icon). The 'PDF' button is highlighted with a blue border.

You can download the protocol at any stage of the process.



The screenshot shows the 'Study Details' page for an 'Approved' study. At the top, there is a breadcrumb trail: [Studies](#) / Study Details. Below this is a dark blue header bar. A green callout box on the left contains the text 'Approved'. The study ID is 'IRB-FY2024-46' and the study name is 'TEST Protocol'. Below the study information are two buttons: 'PDF' (with a document icon) and 'Delete' (with a trash can icon).