

Cayuse Investigator Training

metrocare.acer

Office of Research

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1/15/2023

ACER Research Office

Requirements for External Investigators

Before you can begin a submission, you need to complete the Metrocare Reliance Agreement (MRA)

You must send a signed copy to us for Metrocare CEO and IRB Chair signatures; this process usually takes two weeks unless your university has modified the document. Any modifications will lengthen the process.

- Submit a copy of the MRA signed by both the institution and Metrocare

All external researchers must have Institutional IRB Approval

- Submit a copy of the current approval from your institution
- If there is another IRB your university relies on– submit that as well
- Metrocare ACER interns are also considered external researchers as they are conducting research on behalf of the University

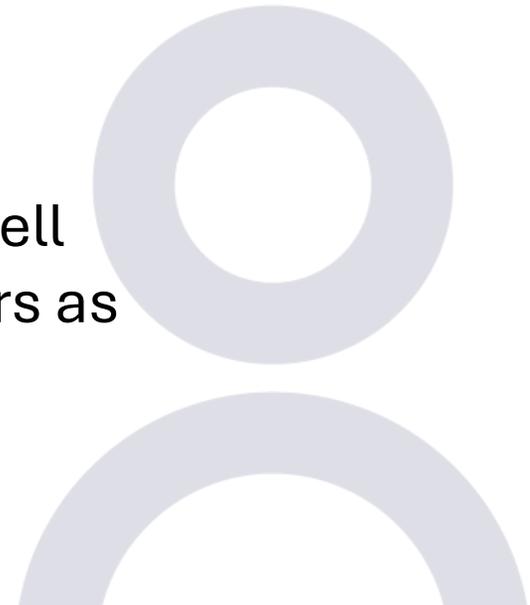


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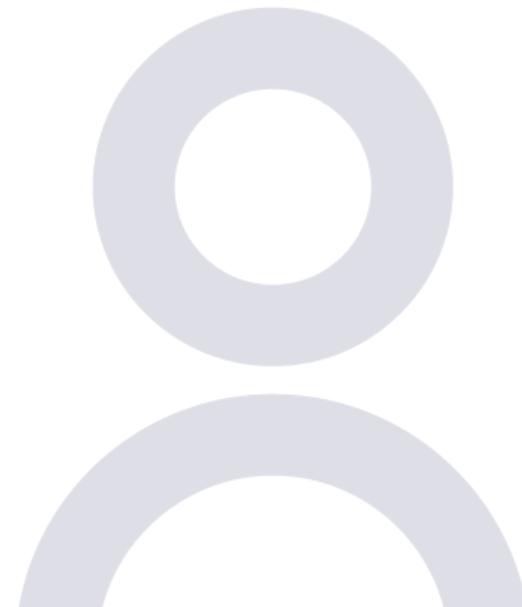
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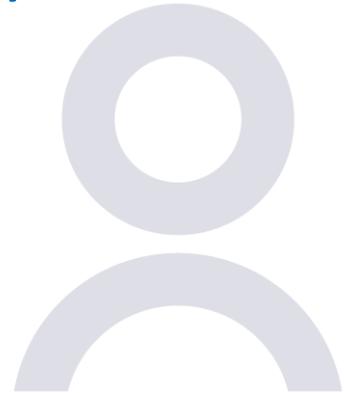
Accessing Cayuse

Production/Live Site Date: February 1, 2024

Researchers who have worked with ACER Research Office (RO) in the past, [contact us](#) to activate your password.

New to Research with ACER, complete the Access Request Form or email us at link above.

Once you have an account set up, go to: <https://metrocare.app.cayuse.com/> and login using your Username/Password.



Home Screen

After you log-in, the Home screen will appear.

SKIP My Tasks, click “Products” and Select **Human Ethics**

Click Product & Select Human Ethics



The screenshot shows the Home screen interface. At the top left is the logo for 'cayuse platform Home'. The main content area is titled 'My Tasks' and contains a filter bar with buttons for 'Assigned to Me', 'Created by Me', 'Open', and 'All'. Below this is a table with columns: Task, Task Type, From, Assigned To, and Created. The table is currently empty, displaying 'No Saved Tasks'. On the right side, there is a 'Products' dropdown menu with a plus sign. A purple callout box with an arrow points to the 'Products' dropdown, containing the text 'Click Product & Select Human Ethics'. A secondary callout box with an orange border highlights the 'Human Ethics' option in the dropdown menu. Other options in the dropdown are 'Home' and 'Admin'. To the right of the dropdown is a 'New Task' button and a 'Status' section.

- Any tasks added here will not connect with HE product. It will ONLY show up on here on the home task page.

The Researcher Dashboard

cayuse Human Ethics Role: Researcher Products Your Name

Dashboard Studies Submissions Tasks Meetings Reporting More **Notifications**

Review Process Status [+ New Study](#)

- PI Studies not yet submitted**
In-Draft →
- PI needs to certify study**
Awaiting Authorization →
- Research Office Analyst reviewing study**
Pre-Review →
- IRB Reviewing**
Under Review →
- Sending Letter to PI; Complete**
Post Review →

My Studies
All Assigned to you
You Have No Studies

My Tasks
All Tasks Assigned to you
All Tasks Complete

Submissions by Type

Renewal
Initial
Modification
Incident
Withdrawal
Closure
Legacy

Approved Studies
Once the study is approved, it will be displayed here until it has been closed by the researcher OR administratively closed by ACER RO.

Studies Expiring in 30 days
Studies that need renewal in 90-60-30 days are listed here.
Please start a renewal submission. External researchers note: we will request a copy of your institutional IRB renewal approval letter

Expired Studies
Any study that has expired must halt using MC clients
If you are still engaging with MC clients, you must submit a renewal
If you are no longer collecting data/engaging with MC clients, you must close the study –

[Interactive Help](#)

Notification

The screenshot displays the Cayuse Human Ethics dashboard. At the top left is the logo and name. The top right shows the user's role as 'Researcher', a notification bell icon (highlighted with an orange box), and the user's name. Below this is a navigation bar with tabs for Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The main content area features a '+ New Study' button and five status cards: In-Draft, Awaiting Authorization, Pre-Review, Under Review, and Post Review. Below these are three panels: 'My Studies' (empty), 'My Tasks' (highlighted with an orange box and containing 'All Tasks Complete'), and 'Submissions by' (a list of submission types). An email notification overlay is shown on the right, detailing a submission receipt.

- Located in Cayuse dashboard: Click on “My Tasks”  icon
- Sent from Cayuse via Email

Submissions by Notice of Receipt of Initial Submission on Jan 11, 2024 1:09:51 PM CST

Renewal

Initial

Modification

Incident

Withdrawal

Closure

TO: irb-uat@cayuse.com
To: ACER Research; ACER Research

FROM: metrocare.acer

TO: PI Name Here

FROM: ACER Research Office

DATE: Jan 11, 2024 1:09:51 PM CST

RE: Notice of Receipt of Initial Submission on Jan 11, 2024 1:09:51 PM CST

STUDY #: IRB-FY2024-53

STUDY TITLE: Sample 1

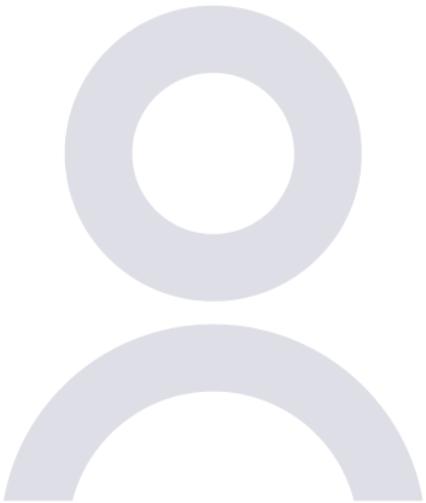
Your IRB submission for the above-referenced study has been received by the ACER Research Office via Cayuse IRB. You will be notified if further information is needed and when this has been reviewed and approved.

Best regards,

The ACER Research Office Team

The Altshuler Center for Education & Research
214.743.1202
ACERResearch@metrocareservices.org

DEFINING SUBMISSION TYPES & STATUSES



Submission Types

When researchers create a study, they also create the initial submission outlining the purpose of that study. In addition to this initial, there are **3 other types of submissions** that IRB Users may submit over the course of their research. *The available submission types include:*

- **Initial** – First submission PI creates to enter a new study in the system. The initial submission describes the study's research purpose, activities, and methodology. The initial submission must be approved before any research can begin.
- **Modification** - If PI wants to change any details of the study after its approval, a modification submission must be submitted and approved before PI can proceed with the changes.
- **Renewal** - When a study is nearing its expiration date, a renewal request must be submitted and approved before continuing with the study.
- **Incident** - Incident reports inform the Compliance Office of any adverse incidents that occur with MC clients. Incident reports may be submitted at any time after a study has been approved, including after it has been closed. There are no limits on the number of submissions.
- **Withdrawal** - A withdrawal submission notifies the RO that the PI no longer wishes to submit your initial submission and wants to withdraw the study. They are marked as finalized and can no longer be modified. A withdrawal submission can be created for initial submission up until it has been approved. If it has been approved, create a closure submission to close the study if the PI no longer wishes to conduct the research.
- **Closure** - Closure submissions indicate that research is complete & will not be continuing. CS are marked as finalized and cannot be modified.

There are two additional submission types. that are only available to IRB Analysts and Admins:

- **Admin Closure** - Allows a study to be administratively closed when needed, for example, when the PI leaves MC or lets a study expire.
- **Admin Withdrawal** – Allows a study to be administratively withdrawn when needed, for example, when the PI leaves MC.

Submission Statuses

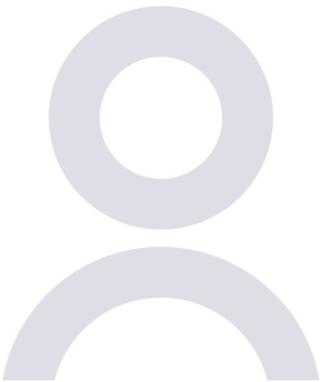
There are two types of statuses in Cayuse Human Ethics to help you keep track of project progress:

- **Study Status:** Represents the overarching place of a project in the lifecycle
- **Submission Status:** Shows where the current IRB request regarding your protocol is at

Submission Statuses

- **Unsubmitted:** An in-draft submission that is open for editing and has not yet been routed to the Research Office (RO). Likely some required items still need to be completed before the submission can be declared complete and certified.
- **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.
- **Reopened:** This status is applied if a Certifier, the RO, or IRB returns the submission at any point. It is functionally the same as the Unsubmitted status.
- **Under Pre-Review:** Once all certifications and approvals are in, the submission routes to the RO where an Analyst will be assigned, determine the review level for the protocol, and begin a preliminary review. The Analyst may return a submission to the Researcher if they need additional information or clarification before sending the protocol for review.
- **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.
- **Under Post Review:** This status is applied once the IRB's assessment of 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 RO Analyst for a final check before declaring the review complete, returning it, and sending it to additional Reviewers (if needed).
- **Review Complete:** Once an approval or exemption decision has been reached for a protocol and the RO 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.

creating YOUR STUDY



Create your Study

Creating the study is like building a file folder or container where all your submissions may be created and stored.

Study Details

Sample IRB Study

Enter your title here.

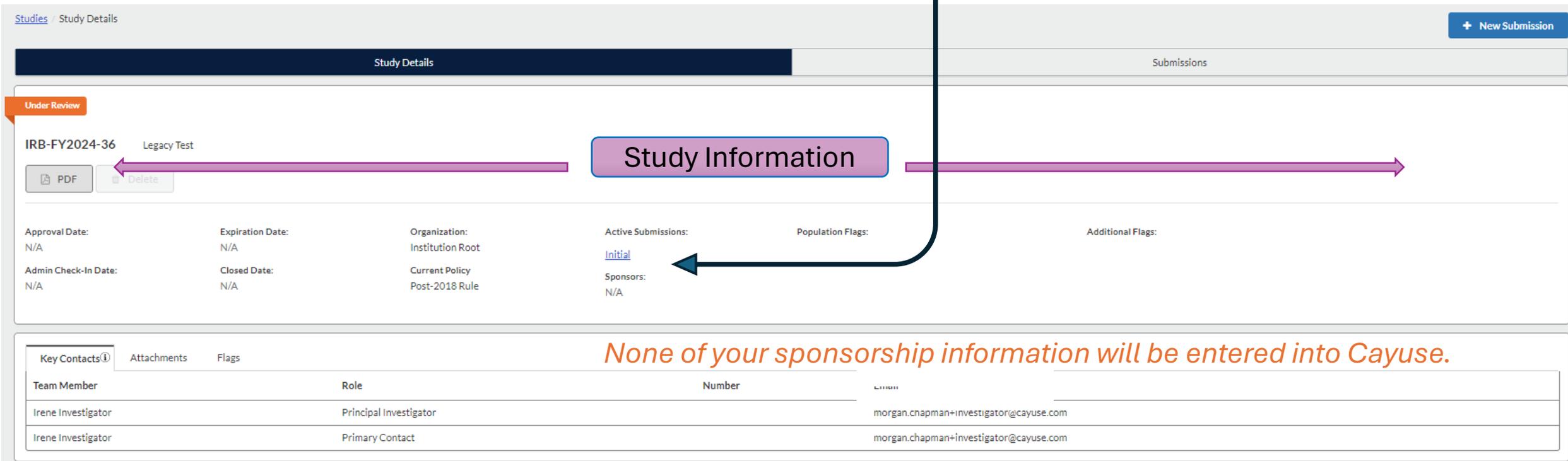
Click on the check mark to save.

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		N/A		

Study Details

The study details page is where you can see all submissions related to this study.

Hyperlinks to your active submission will be available on this page. Important dates like *approval, expiration, and check-ins* are visible here as well.



Studies / Study Details + New Submission

Study Details Submissions

Under Review

IRB-FY2024-36 Legacy Test

PDF Delete

Approval Date: N/A Expiration Date: N/A Organization: Institution Root Active Submissions: [Initial](#) Population Flags: Additional Flags:

Admin Check-In Date: N/A Closed Date: N/A Current Policy: Post-2018 Rule Sponsors: N/A

Key Contacts	Attachments	Flags
Team Member	Role	Number
Irene Investigator	Principal Investigator	morgan.chapman+investigator@cayuse.com
Irene Investigator	Primary Contact	morgan.chapman+investigator@cayuse.com

None of your sponsorship information will be entered into Cayuse.

CREATING YOUR INITIAL SUBMISSION

DOCUMENTS YOU'LL NEED FOR SUBMISSION TO MC IRB

STARTING AND EDITING THE INITIAL SUBMISSION

MOVING THROUGH THE DOCUMENT

ASSIGNING PRINCIPAL INVESTIGATOR (AND OTHERS)

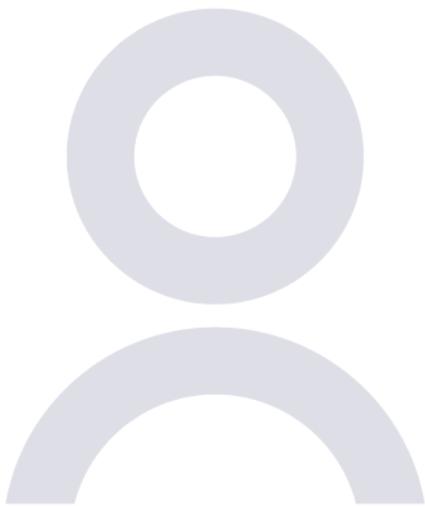
FIND PEOPLE FUNCTION

TYPES OF QUESTIONS AND ATTACHING DOCUMENTS

COMPLETING SUBMISSION & CERTIFYING

WHAT IS ACER DOING WITH YOUR SUBMISSION

HOW TO CHECK STUDY STATUS



DOCUMENTS NEEDED TO COMPLETE A SUBMISSION TO METROcare IRB

- IRB of Record / Institutional Approval Letter (copy)
- Reliance Agreement signed by both parties
- Protocol, Recruitment, Consents, Study procedures, instruments
- Information about what access is needed to the center locations (including which locations and when)
once approved, a RO staff member will coordinate with you to arrange access to the center locations
- Students completing study for their program will need a faculty supervisor/advisor (both student and supervisor will need reliance agreements)

Start a New Submission

The screenshot shows the Cayuse Human Ethics interface. At the top, the logo and 'Human Ethics' text are on the left, and 'Role: Researcher' with a dropdown, a notification bell, and 'Your Name' are on the right. A navigation bar contains 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The main content area is titled 'Studies / Study Details' and features a dark blue header for 'Study Details'. A red 'Unsubmitted' badge is visible. The study ID 'IRB-FY2023-36' and title 'Sample IRB Study' are shown, along with 'PDF' and 'Delete' buttons. A table below lists various fields: 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), and Sponsors (N/A). A modal window titled 'Begin Initial Submission' is open, containing the text 'You've created a study! Click here to begin your initial submission to the IRB.' and a blue '+ New Submission' button. A red arrow points from a text box 'Click here, then click on "Initial."' to this button. Another '+ New Submission' button is shown in a separate callout box with an 'Initial' dropdown menu.

Begin Initial Submission

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

+ New Submission

+ New Submission

Initial

Click here, then click on "Initial."

Unsubmitted

IRB-FY2023-36 Sample IRB Study

PDF Delete

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		

Edit to Start the Initial Submission

The screenshot displays the Cayuse Human Ethics interface. At the top, the logo and name 'cayuse Human Ethics' are visible, along with the user's role 'Role: Researcher'. A navigation menu includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The breadcrumb trail shows 'Studies / Study Details / Submission Details'. A progress bar indicates four stages: 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), and 4. Under Submission. Below the progress bar, a red 'Unsubmitted' badge is present. The submission title is 'Initial' with the ID 'IRB-FY2023-36 - Sample IRB Study'. Action buttons for 'Edit', 'PDF', and 'Delete' are shown, with the 'Edit' button circled in yellow. A red callout box points to the 'Edit' button with the text 'Click on any of these to start your application.' Below the submission details, a table lists various fields: PI, Current Analyst, Decision, Policy, Review Type, Review Board, Meeting Date, and Required Tasks. The 'Required Tasks' section includes 'Assign PI', 'Assign PC', and 'Complete Submission', all of which are circled in yellow. Red arrows point from the 'Edit' button to these three tasks.

Unsubmitted

Initial
IRB-FY2023-36 - Sample IRB Study

[Edit](#) [PDF](#) [Delete](#)

PI:	Current Analyst:	Decision:	Policy:	Required Tasks:
	N/A	N/A	Post-2018 Rule	Assign PI
Review Type:	Review Board:	Meeting Date:		Assign PC
N/A	N/A	N/A		Complete Submission

Moving through Initial Applications

cayuse Human Ethics Products 121 Irene Investigator

Dashboard Studies Submissions Tasks

Be sure to click **SAVE** throughout the process.

IRB NUMBER: IRB-FY2024-57

Insert Study Title Here - Initial

CREATE PDF COMPARE SAVE

Sections

- Introduction ✓
- Getting Started ✓
- Project Personnel ✓
- Basic Information (...)
- Section 2 Project D...
- Section 3 Approval...
- Section 4 Supporting Doc...
- Attachments

Project Personnel

** Any question with a red * must be completed. You will not be able to proceed in the document or submit to IRB without a response.*

* What kind of affiliation does the PI have with Metrocare?

- Faculty from affiliated research institution
- Student from affiliated research institution
- Metrocare Staff
(Note: all Metrocare Staff must have an ACER representative as a part of their research team)
- Corporation partnered with research institution
- Other

Each section will have a check mark once it's completed

What is the name of your Research Institution?

Assigning PI

Cayuse will automatically assign the individual completing the submission as the **Primary Contact**, which can be changed if necessary.

You may have multiple PCs.

You will have to assign the **Principal Investigator (PI), Co-investigator(s) & Other personnel** by using the “Find People” button.

You can only have one PI, but multiple Co-Investigators and Personnel.

You can only “Find People” who have an Activated Cayuse Account. Any of these people added will have Assess your submission. If you wish to add Personnel who don’t need access in Cayuse can do that in upcoming questions.

Access Rights:

PI, Co-PI, PC: Edit Rights

Personnel: View Only Rights

If you change the PC, add the new PC first. If you delete the existing PC before adding a new one, access can be lost. **Change in PC after approval would be a modification.**

Study Personnel

Note: If you cannot find a person in the people finder, please

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

Primary Contact

Any people listed as a PC will have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications.

FIND PEOPLE

Name	Organization	Address	Phone	Email	Trainings	
Ian Investigator	Users loaded with unmatched Organization affiliation.			ACERresearch+investigator@metrocareservices.org	View	✕

Co-Investigator(s)

Any people listed as Co-Investigators will have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications.

FIND PEOPLE

Other Personnel

Any people listed as Investigators will be able to view the study, but will NOT have edit access to the study nor be included in study communications automatically.

FIND PEOPLE

Find People

When you click on “Find People”, **type their name here** & press ENTER
You may need to include last name.

PRINCIPAL INVESTIGATOR

Irene|

Name	Organization	Email	Phone
Irene Investigator	Metrocare Services	morgan.chapman+investi...	+

Selected Records * Select a single record.

CANCEL SAVE

Once you find the right person, click the **+ sign** and **SAVE**.

Adding Additional People not in Cayuse

We request the names of all individuals involved in the consenting process and those who could access PHI. If there are individuals who do NOT need Cayuse access because they are not considered researchers or research personnel, their names can be added in the text box.

Informed Consent

* Will the PI be a direct part of the consenting process?

- Yes
 No

Will other researcher personnel be a part of the consenting process as well?

- Yes
 No

Provide the name(s) of any other person(s) involved in the Consenting Process.

FIND PEOPLE

Please list the individuals involved in consenting who are not personnel noted in Cayuse.

Constance Consenter

In this example, the PI is the researcher who is consenting participants, but an office admin who is not a researcher but may be responding to inquiries about the consenting document

Protected Health Information (PHI) Access

* Will PHI be involved in this study?

- Yes
 No

Provide the name(s) of any person(s) who will have access to PHI.

FIND PEOPLE

Name	Organization	Address
Irene Investigator	Metrocare Services	
Ian Investigator	Users loaded with unmatched Organization affiliation.	

Please list the individuals not noted as personnel in Cayuse who will have access to PHI.

Constance Consenter

In this example, the PI and PC (who have access to Cayuse) and an office admin who is not a researcher but has access to files so not listed as personnel

Types of Questions

Radio Buttons

Select one of the available options.

* 1.0 What type of submission is this? 

- Research Study Involving Human Subjects (Exempt, Expedited, Full Board Review) oversight by the Cayuse University IRB
- Research Study involving an Outside IRB of Record or NCI PCIRB
- Emergency Use of Investigational Agent
- Request for Determination of the Need for IRB Review

Check Boxes

Select one or more of the available options.

* 3.0 In which locations will the research take place? (Check all that apply.)

- Inpatient Location
- Outpatient Location
- Community Settings
- Subject's Home
- N/A (limited to review of records, data and analysis)

Text Box

A text box provides space for a short answer that does not require a lot of explanation. You can enter multiple lines of text here if needed; the box will expand to fit the text.

* 3.0 Create a SHORT title for your research protocol. (Five words maximum.)

Text Area

The multi-line text editor allows you to apply simple text formatting such as bold, italics, underline, strikethrough, bulleted lists, numbered lists, and hyperlinks.

* 2.0 What is the FULL title of the research protocol?

B **I** **U**     

Types of Questions: Attachments

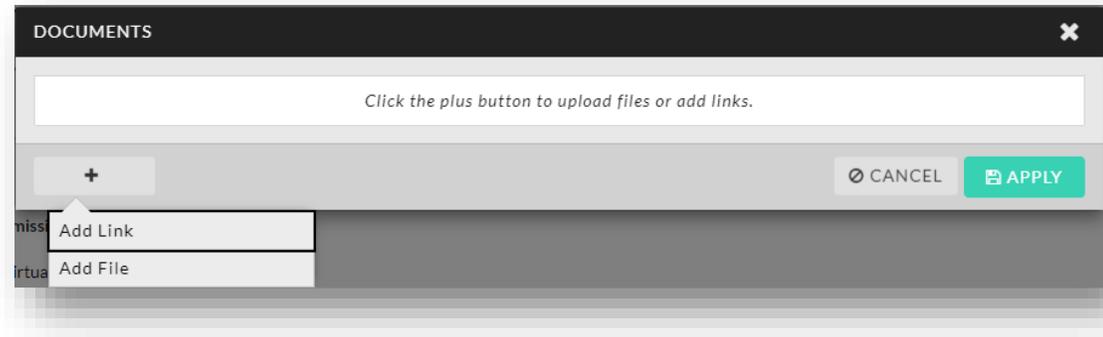
* **Reviewing IRB**

Please indicate the name of the Reviewing IRB Institution.

Attach Reviewing and/or Institutional IRB approvals here

ATTACH

When you click **ATTACH**, click **+** to find file to attach, then click **APPLY**



Once attached, it should look like this



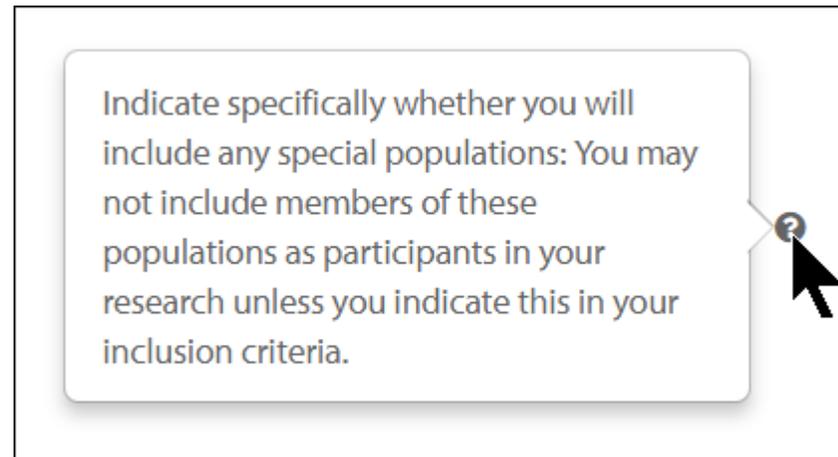
Should you need to delete a file, just click the **X**

Acceptable 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, xlsm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm

Help with Questions

If there is help text for a question, you can click on the  button to view the additional information for that question.



Completing your Submission

IRB NUMBER: IRB-FY2024-57

← SUBMISSION DETAILS | **Insert Study Title Here - Initial**

Sections <

- Introduction ✓
- Getting Started ✓
- Project Personnel ✓
- Basic Information (...) ✓
- Section 2 Project D... ✓
- Section 3 Approval... ✓
- Section 4 Supporti... ✓
- Attachments ✓

Routing
Send to PI for certification? ▾

COMPLETE SUBMISSION >

Project Personnel

* What kind of affiliation does the PI have with Metrocare?

- Faculty from affiliated research institution
- Student from affiliated research institution
- Metrocare Staff

(Note: all Metrocare Staff must have an ACER representative as a part of their research team)

- Corporation partnered with research institution
- Other

What is the name of your Research Institution?

UTSW

What department and/or program are you affiliated with?

Once you have a checkmark for each section, the “Complete Submission” option will appear at the bottom of the bar.

We recommend having your PI or Co-PI review before clicking “complete submission”; once you click it, it locks editing.

After you select, “Complete Submission”, this box will appear. Click **CONFIRM**.

SUBMISSION ROUTING

Are you sure you want to continue?

Certify

Once confirmed, you'll return to the submission details page.

Awaiting Certification

Initial
IRB-FY2024-57 - Insert Study Title Here

View PDF Delete

PI: Irene Investigator	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		

Routing: Return Certify

If you need to make edits you can click on "Return" to reopen the submission.

If all looks good, click on "Certify."

After you click certify, a notification is sent to the PI and Co-In to review and certify.

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

The PI (and Co-In) MUST certify the submission for it to be submitted to the IRB.

Your status bar will have a green check mark here once they have completed that task. 1/15/2023

“Return to Investigator” during certification

If the PI/Co-In decides that changes must be made, they can return the submission to *the research team* by clicking . The *research team* will receive an e-mail notification of the change in status so that they can make necessary edits before marking it complete again.

Once the PI/Co-In has certified this submission, it goes to the ACER RO. At any point, the submission can be returned to the investigation team to answer questions or make changes.

Once your PI / Co-Inv has certified the study, it's been submitted. Great Job!

Your study status bar should look like this

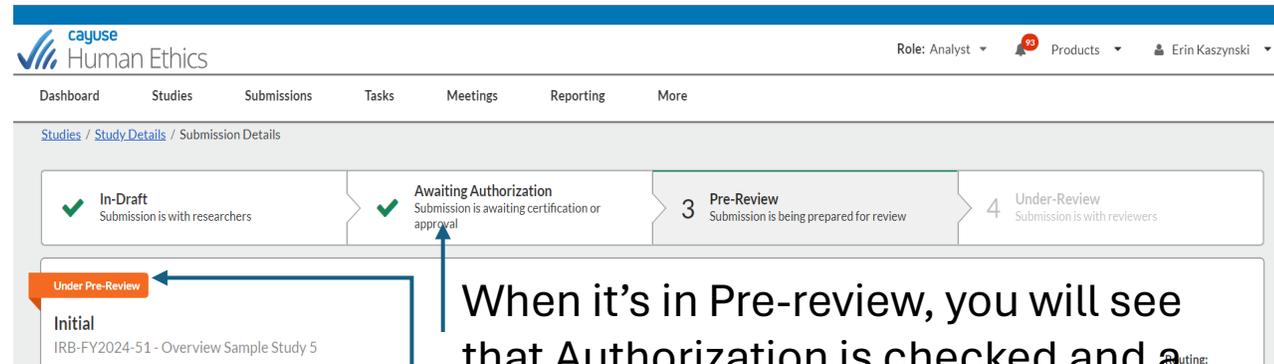


WHAT IS THE AC&R RESEARCH OFFICE DOING WITH YOUR STUDY?

PRE-REVIEW:

Quick Overview Occurs

- Correct Application Type Completed, Content is detailed and clear
- Quick confirmation of the review path
- Required Documents Attached and signed as necessary
- If everything looks good, it's sent to the IRB Committee Reviewers



When it's in Pre-review, you will see that Authorization is checked and a green line over pre-review in the status bar and the orange flag tells you it's **Under Review**.

If the RO finds a problem, the study will be returned to the investigator.
(See "editing and resubmitting a reopened submission")

How to check the Status of your Study

The image shows two screenshots of the Cayuse Human Ethics dashboard. The left screenshot displays the main dashboard with a navigation menu and several summary cards for study statuses: In-Draft (8), Awaiting Authorization (0), Pre-Review (0), and Under Review (2). Below these are sections for 'My Studies', 'My Tasks', and 'Submissions by Type'. A blue callout box points to the 'View All' link under 'My Studies' with the text: "Click View All under 'My Studies' for a list of all your protocols." The right screenshot shows the 'Studies' page with a search bar and a table of study protocols. A blue callout box points to the 'IRB#' column header with the text: "Click the IRB number of the protocol you are interested in." The table contains the following data:

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2021-		Unsubmitted		N/A	N/A	02-16-2021
IRB-FY2020-		Unsubmitted		N/A	N/A	10-16-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	04-18-2019
IRB-FY2019-		Under Review		N/A	N/A	04-03-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	03-01-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	12-21-2018
IRB-FY2019-		Expired				12-11-2018
IRB-FY2019-		Requires Changes				12-11-2018
IRB-FY2018-		Unsubmitted				08-22-2018

Role: Researcher

Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / Study Details

Study Details Submissions

Under Review

IRB-FY2019-

PDF Delete

Approval Date: N/A Expiration Date: N/A Organization: PROVOST - Vice Provost for Research (VPR) Active Submissions: Population Flags: Additional Flags:

Admin Check-In Date: N/A Closed Date: N/A

Key Contacts: Attachm

Team Member Number Email

Principal Investigator

Primary Contact

Click "Submissions" on the Study Details page for a list of submissions related to the protocol

Role: Researcher

Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / Study Details

Study Details Submissions

Submission Type	Review Type	Status	Decision
Initial	Full	Under Review	--
Withdrawal	Unassigned	Under Review	--

1-2 of 2

25 per page

Click the link for the submission you are interested in

Study Statuses:

There are 10 types of status your study can be in.

Study Status is indicated by the flag on the study details page.

- **Approved** - Study has been approved by the Compliance Office and/or Review Board.
- **Closed** - Study is no longer in progress.
- **Disapproved** - After being reviewed, the study was not approved by the Compliance Office/review board.
- **Expired** - The study has passed its expiration date without being renewed.
- **Requires Changes** - The Compliance Office has requested modifications to the study in order for it to be approved.
- **Submitted** - The PI has sent a submission to the Compliance Office and it is awaiting review.
- **Suspended** - Used when an incident has occurred to place the study on hold until further notice. The research team must submit a modification in order to remove the suspension.
- **Under Review** - The Compliance Office and/or Review Board is currently reviewing the study.
- **Unsubmitted** - The study has not yet been sent to the Compliance Office for review.
- **Withdrawn** - The research team has submitted a withdrawal for this study and no longer wishes to pursue it.

EDITING AND RE-SUBMITTING A REOPENED SUBMISSION

How to address changes requested by the IRB

cayuse Human Ethics Role: Researcher

Dashboard Studies Submissions Tasks Meetings Reporting More

[+ New Study](#)



8

In-Draft



Awaiting
Authorization



0

Pre-Review



2

Under Review

My Studies

IRB-FY2019-	
IRB-FY2021-	
IRB-FY2020-	
IRB-FY2019-	
IRB-FY2019-	

[View All](#)

My Tasks

IRB-FY2021-	Complete Submission
IRB-FY2020-	Complete Submission
IRB-FY2019-	Complete Submission
IRB-FY2019-	Complete Submission
IRB-FY2019-	Complete Submission

[View All](#)

Submissions by Type

Renewal	0
Initial	11
Modification	0
Incident	0
Withdrawal	1
Closure	0
Legacy	0

Approved Studies

IRB-FY2018-	Test Study
-----------------------------	------------

Studies Expiring in 30 days

Expired Studies

IRB-FY2019-	
-----------------------------	--

6 

On the Dashboard, click here to view your studies



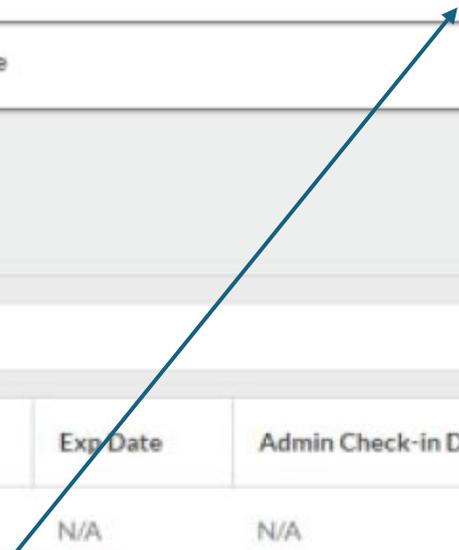
Active Archive

[+ New Study](#)

Click to search

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2021-		● Unsubmitted		N/A	N/A	02-16-2021
IRB-FY2020-					N/A	10-16-2019
IRB-FY2019-					N/A	04-18-2019
IRB-FY2019-					N/A	04-03-2019
IRB-FY2019-		● Unsubmitted		N/A	N/A	03-01-2019
IRB-FY2019-		● Unsubmitted		N/A	N/A	12-21-2018
IRB-FY2019-		● Expired		12-11-2019	N/A	12-11-2018
IRB-FY2019-		● Requires Changes		N/A	N/A	12-11-2018
IRB-FY2018-		● Unsubmitted		N/A	N/A	08-22-2018

Look through your active studies to identify the submission that has the status “requires changes”
You may find it in your notifications as well



When IRB has Requires Changes

Click on the Active Submission Type

- Initial
- Modification
- Renewal
- Incident
- Closure

In this example, change requests were made on a submitted modification.....

The screenshot shows the Cayuse Human Ethics web application. The user is logged in as IRBResearcher. The navigation menu includes Dashboard, Studies, Submissions, and Tasks. The current view is 'Study Details' for 'IRB-FY17-6 Sample Study'. A green 'Approved' badge is visible. The study details include:

- Approval Date: 05-16-2018
- Expiration Date: N/A
- Organization: External Researcher
- Active Submissions: [Modification](#)
- Sponsors: N/A
- Admin Check-In Date: 05-30-2018
- Closed Date: N/A
- Current Policy: Post-2018 Rule

Below the details is a 'Key Contacts' table:

Team Member	Role	Number	Email
IRBResearcher	Principal Investigator		
IRBResearcher	Primary Contact		

A blue callout box with the text 'Click on the appropriate Submission' points to the 'Modification' link in the 'Active Submissions' section.

cayuse Human Ethics IRBResearcher

Dashboard Studies Submissions Tasks

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

Reopened

Modification
IRB-FY17-6 - Sample Study

Edit PDF Delete

PI: IRBResearcher Current Analyst: IRBAnalyst Policy: Required Tasks:
 Review Type: Expedited Review Board: Testing Board Meeting Date: N/A

Approvals Task History Letters Attachments

Research Team

Name	Role	Result	Date

Click here to edit the Submission

cayuse Human Ethics IRBResearcher

Dashboard Studies Submissions Tasks

IRB NUMBER: IRB-FY17-6

Sample Study - Modification CREATE PDF COMPARE SAVE

Sections

- Amendment Details **1**
- Screening Questions ✓
- Research Personnel ✓
- Project Information ✓
- Project Informatio... ✓
- Use of Deception in... ✓
- Participants ✓
- Consent & Privacy ✓
- Data Confidentiality ✓
- Exempt Supplement ✓
- Attachments ✓

Please provide a brief description of changes being made and include a clear rationale for the changes:

test

Expand Comments

A bubble with the number of comments will display in each section needing changes

Clicking on Expand Comments will allow you to read and address the Reviewer's comments

Please provide a brief description of changes being made and include a clear rationale for the changes:

test

Collapse Comments

IRB Reviewer Yesterday at 4:44 PM
Please provide a more thorough description of the changes being made.
Reply

Not Addressed
Address
Unaddress

Is your study funded by the NIH (National Institutes of Health)?

Yes

Changes/information must be added to the questions and/or text boxes themselves, not just in a reply to a comment

Click here once you have made the requested changes and select "Address"

Managing Comments

When ACER RO is reviewing a submission, the analyst or reviewer may have questions regarding some of your answers.

If the submission gets returned to, there will be a comment icon in the sidebar next to each question that contains comments, and a similar icon underneath the questions that have comments on them click on the link to see and respond to the comments

PC Primary Contact

FIND PEOPLE

Name	Organization	Address	Phone	Email
Bob Rawley	School of Medicine	440 Exchange, Irvine, CA	714 265 7498	brawley@evisions.com

Collapse Comments

IRB Analyst Today at 2:05 PM

Are there any additional contacts for this study?

Reply

IRB User Today at 5:39 PM

No, there are no additional contacts.

Addressed Today at 5:39 PM by you

IRB Reviewer Today at 6:01 PM

I think there should be more contacts. What if the first one is out of the office?

Reply

Not Addressed

When you have responded to a comment, **change the dropdown** from **Not Addressed** to **Addressed**.

You can toggle comments between addressed and unaddressed as needed.

Sections <

Introduction ✓

Getting Started ✓

Project Personnel ✓

Basic Information (...) ✓

Section 2 Project D... ✓

Section 3 Approval... ✓

Section 4 Supporti... ✓

Attachments ✓

Routing

Send to PI for certification?

COMPLETE SUBMISSION >

Project Personnel

* Wh

W

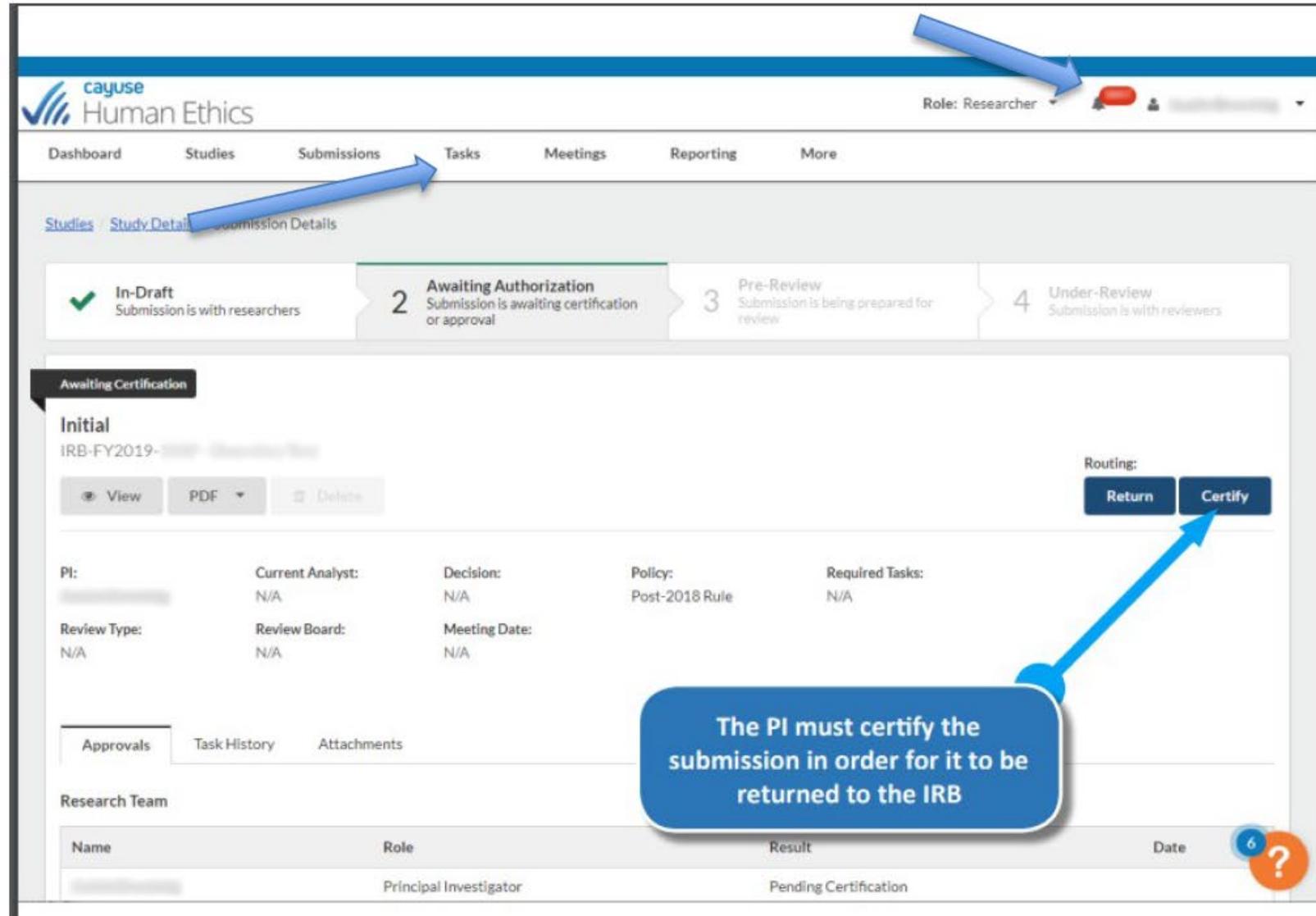
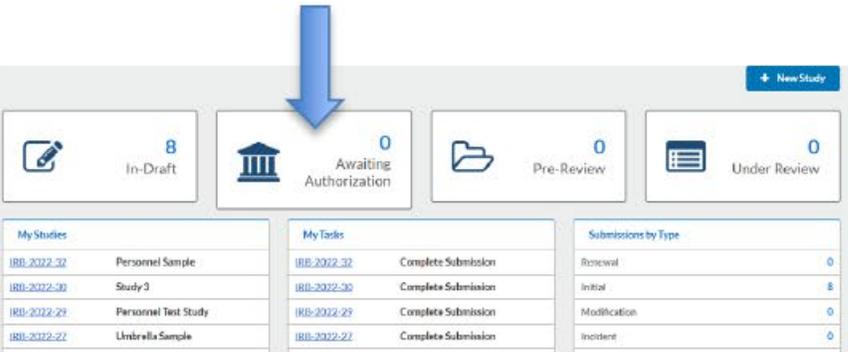
UTSW

What department and/or program are you affiliated with?

Once you've addressed all the comments, make sure to **SAVE**, then select **"COMPLETE SUBMISSION"** to send the submission to the PI / Co-Inv to certify

The PI, Co-PI, and PC will receive:

- E-mail Message
- Notification Bubble
- Task
- Added to Awaiting Authorization Display Button



WHERE TO FIND YOUR APPROVAL DOCUMENTS

Documents
Letters

Finding Documents

Unsubmitted

Initial
IRB-FY2019-3107 - Overview Test

Edit PDF Delete

PI: Current Analyst: N/A Decision: N/A Policy: Required Tasks:
Review Type: N/A Review Board: N/A Meeting Date: N/A

Approvals Task History **Attachments**

Q Click to search

Filename	Uploaded By	Date Uploaded
test doc.pdf		05-02-2019 12:54 PM

For stamped documents, look under Submission Details and click the Attachments tab

Click the ellipsis next to the document you wish to view and select "Download"

Finding Letters

The screenshot shows the Cayuse Human Ethics interface. At the top, there's a navigation bar with 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. Below that, a breadcrumb trail reads 'Studies / Study Details / Submission Details'. A progress bar shows four stages: 'In-Draft' (Submission is with researchers), 'Awaiting Authorization' (Submission is awaiting certification or approval), 'Pre-Review' (Submission is being prepared for review), and 'Under-Review' (Submission is with reviewers). A green banner indicates 'Review Complete'. The main content area shows 'Initial' for 'IRB-FY16-23 - Test - 8/12/16'. Below this are buttons for 'View', 'PDF', and 'Delete'. Further down, key information is displayed: PI: IRBResearcher, Current Analyst: IRBAnalyst, Decision: Exempt, and Policy: (blank). Review Type: Exempt, Review Board: NYU Test Board. At the bottom, there are tabs for 'Approvals', 'Task History', 'Letters', and 'Attachments'. A blue callout box with an arrow points to the 'Letters' tab, containing the text: 'Click the "Letters" tab under the Submission Details to view and/or print your letters'. Below the tabs is a table of sent letters.

Subject	Recipients	Sent Date
IRB-FY16-23 - Initial: Exempt Approval	@nyu.edu	08-16-2016
IRB-FY16-23 - Initial: Request for Modification(s) and/or Information	@nyu.edu	08-16-2016

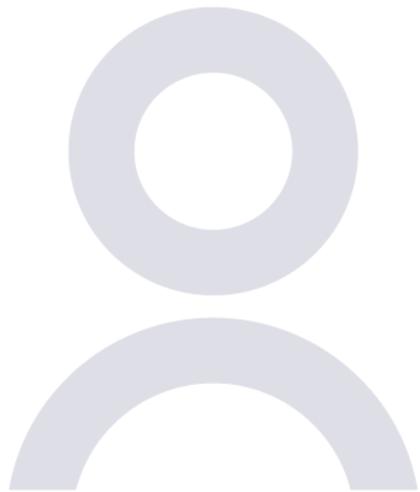
The PI, Co-Inv, and PC will also receive an approval letter via email, but the copy is always available in Cayuse

MODIFICATIONS

Create & Submit a **Modification**

Revising the application

Using the Comparison Tool



CREATING & SUBMITTING a MODIFICATION

The screenshot shows the Cayuse Human Ethics dashboard for a user with the role of 'Researcher'. The dashboard includes a navigation menu with 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. A '+ New Study' button is located in the top right. The main content area features four summary cards: 'In-Draft' (8), 'Awaiting Authorization' (0), 'Pre-Review' (0), and 'Under Review' (2). Below these are three tables: 'My Studies' (listing IRB-FY2019- and IRB-FY2021-), 'My Tasks' (listing 'Complete Submission' tasks for IRB-FY2021-, IRB-FY2020-, and IRB-FY2019-), and 'Submissions by Type' (listing Renewal, Initial, Modification, Incident, Withdrawal, Closure, and Legacy). At the bottom, there are sections for 'Approved Studies' (listing IRB-FY2018- Test Study), 'Studies Expiring in 30 days', and 'Expired Studies' (listing IRB-FY2019-). A blue callout box with the text 'On the Dashboard, click here to view your studies' has an arrow pointing to the 'View All' link at the bottom of the 'My Studies' table.

You may only have one modification **in process** at a time.

You can make multiple modifications in one submission, YET once you have submitted one – you must wait to submit another.

In most cases, Modification submissions are reviewed in an expedited process.

cayuse Human Ethics

Dashboard Studies Submissions Tasks Meetings

Active Archive

Click to search

Click on the Study you wish to submit a Modification (Amendment) for

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2021		Unsubmitted		N/A	N/A	02-16-2021
IRB-FY2020		Unsubmitted		N/A	N/A	10-16-2019
IRB-FY2019		Unsubmitted		N/A	N/A	04-18-2019
IRB-FY2019		Under Review		N/A	N/A	04-03-2019
IRB-FY2019		Unsubmitted		N/A	N/A	03-01-2019
IRB-FY2019		Unsubmitted		N/A	N/A	12-21-2018
IRB-FY2019		Expired		1-2019	N/A	12-11-2018
IRB-FY2019		Required			N/A	12-11-2018
IRB-FY2018		Unsubmitted			N/A	08-22-2018

Only the PI, PC, and co-PI can view or edit the Study.

+ New Study

When the study details page opens, click on **Modification**

+ New Submission

Studies / Study Details

Study Details Submissions

+ New Submission

- Renewal
- Modification**
- Incident
- Closure

Approved

IRB-FY2024-48 Overview Sample Study 2

PDF Delete

cayuse Human Ethics

173 Products Irene Investigator

Dashboard Studies Submissions Tasks

Studies / Study Details / Submission Details

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

Unsubmitted

Modification

IRB-FY2024-48 Overview Sample Study 2

Edit PDF Delete

Click on *Edit* or *complete the submission*

PI: Irene Investigator
Current Analyst: N/A
Decision: N/A
Policy: Post-2018 Rule
Required Tasks:
[Assign PI](#)
[Assign PC](#)
[Complete Submission](#)

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

Your submission will open, and you will document the justification for your changes – then, you can make the necessary changes in all the sections and add additional attachments.

Make sure you SAVE everything.

A copy is made of your original submission- you can compare them side-by-side using the

compare tool.

Sections

- Modification Information
- Introduction
- Getting Started
- Project Personnel
- Basic Information (...)
- Section 2 Project D...
- Section 3 Approval...
- Section 4 Supporti...
- Attachments

Routing
Send to PI for certification?

COMPLETE SUBMISSION

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.

*Are you making changes to the study? ★

Yes
Please make your changes in the sections to the left.

No

Justification ★

Please provide the reasons for the modifications.

Insert justification info

Products Irene Investigator

CREATE PDF COMPARE SAVE

- **Select Compare**
- Shows the changes made between this application version and the previous one
- Can be used for uploaded documents
- Number indicators for the number of differences
- Green for additions
- Red for deletions

***DO NOT DELETE ANY DOCUMENTS THAT ARE STILL BEING USED*
Only upload documents that have changes. Please include the date in the file name.**

When information has been updated. Click **“COMPLETE SUBMISSION”** and **CONFIRM** to send to PI/Co-in for certification.

Submission will remain at Awaiting Approvals status and will not go to the IRB until the PI/Co-In has sent the certified Modification

PC – Point of Contact person cannot certify

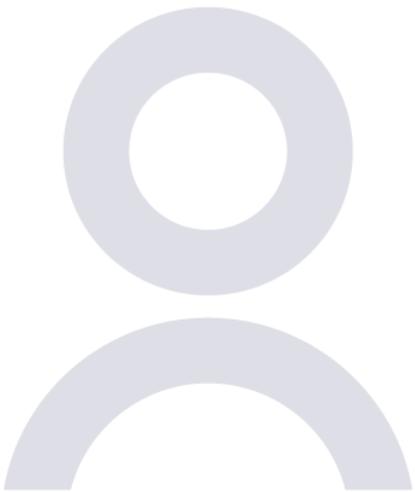
The PI will receive:

- E-mail Message
- Notification Bubble
- Task
- Added to Awaiting Authorization Display Button

PI /Co-In can certify Modification by clicking CERTIFY (and CONFIRM)

RENEWAL SUBMISSIONS & ADMINISTRATIVE CHECK-IN

STARTING a SUBMISSION
SUBMISSION requirements
procedure change



CREATING AND SUBMITTING a RENEWAL

The dashboard shows the following study status counts:

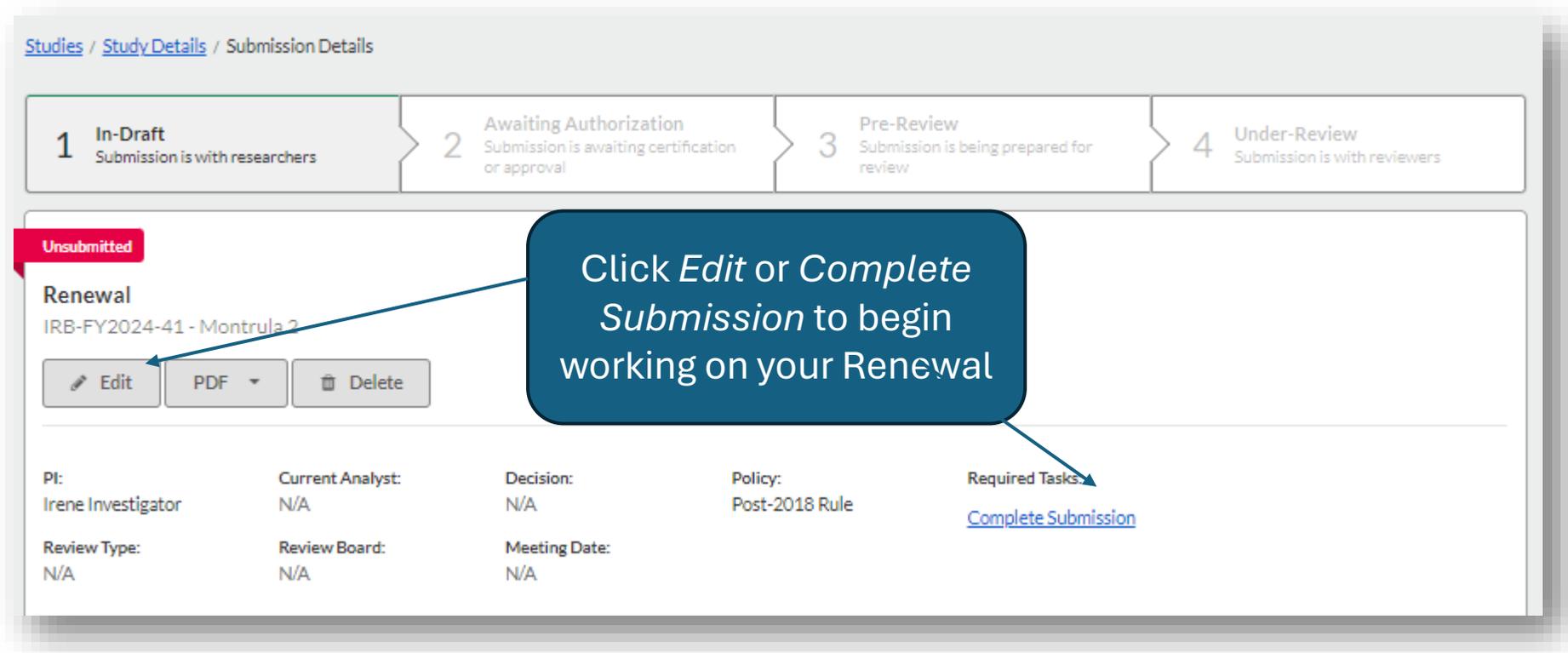
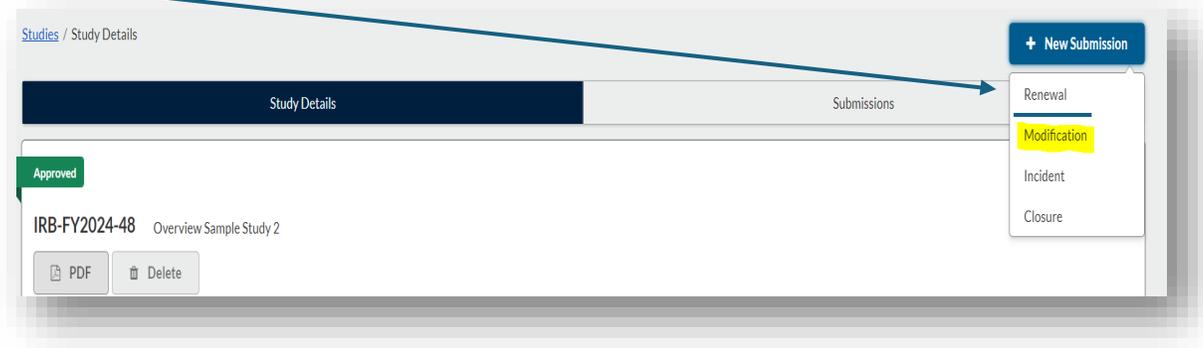
- In-Draft: 8
- Awaiting Authorization: 0
- Pre-Review: 0
- Under Review: 2

A blue callout box points to the 'View All' link under the 'My Studies' section with the text: "On the Dashboard, click here to view your studies".

The 'Studies' page displays a table of study records. A blue callout box points to the 'IRB-FY2021-' link in the first row with the text: "Click on the Study you wish to submit a Renewal for".

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2021-		Unsubmitted		N/A	N/A	02-16-2021
IRB-FY2020-		Unsubmitted			N/A	10-16-2019
IRB-FY2019-		Unsubmitted			N/A	04-18-2019
IRB-FY2019-		Under Review			N/A	04-03-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	03-01-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	12-21-2018
IRB-FY2019-		Expired		12-11-2019	N/A	12-11-2018
IRB-FY2019-		Requires Changes		N/A	N/A	12-11-2018
IRB-FY2018-		Unsubmitted		N/A	N/A	08-22-2018

When the study details page opens, click on and select **Renewal**



Answer all questions and attach all documents in the Renewal Form. Click **SAVE**. Once finished, click **“COMPLETE SUBMISSION”** to send to the PI and Co-Inv for certification.

The screenshot displays the Cayuse Human Ethics interface for a submission titled "Montrula 2 - Renewal" (IRB NUMBER: IRB-FY2024-41). The user is logged in as Irene Investigator. The left sidebar shows navigation options: Sections, Check-in & Continuation (checked), Routing (Send to PI for certification?), and COMPLETE SUBMISSION (highlighted in blue). The main content area is titled "Check-in & Continuing Review" and includes the following sections:

- * Request for More Time**: A question "Are you requesting more time for the project?" with radio buttons for "Yes" (selected) and "No".
- * What type of affiliation does the principal investigator have with Metrocare?**: Radio buttons for "External Researcher: The Principal Investigator is conducting research on behalf of their Institution or organization, and the Institution or its affiliate serves as the IRB of Record." (selected) and "Metrocare Researcher: The Principal Investigator is conducting research on behalf of Metrocare."
- * Reviewing IRB Approvals**: A text input field with the instruction "Please upload the Reviewing IRBs renewal/continuing review approval letter." and an "ATTACH" button. A file named "ABC University IRB Approval 2..." is attached.
- * Metrocare Reliance Agreement**: A text input field with the instruction "Please upload the Metrocare Reliance Agreement that has been signed by both parties." and an "ATTACH" button. A file named "Metrocare Reliance Agreemen..." is attached.

At the top right, there are buttons for "CREATE PDF", "COMPARE", and "SAVE" (circled in green). The date "11/13/2023" is visible at the bottom center.

Answer all questions and attach all documents in the Renewal Form. Click **SAVE**. Once finished, click **“COMPLETE SUBMISSION”** to send to the PI and Co-Inv for certification.

The screenshot displays the Cayuse Human Ethics interface for a renewal submission. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main header shows 'SUBMISSION DETAILS' for 'Montrula 2 - Renewal' with IRB number 'IRB-FY2024-41'. Action buttons for 'CREATE PDF', 'COMPARE', and 'SAVE' are visible. The left sidebar contains 'Sections' with 'Check-in & Continu...' selected, and 'COMPLETE SUBMISSION' highlighted. The main content area is titled 'Check-in & Continuing Review' and contains the following sections:

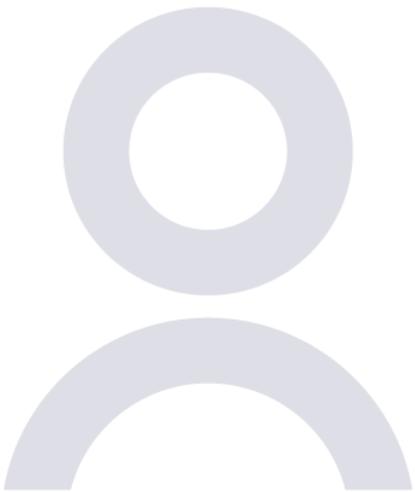
- * Request for More Time**
Are you requesting more time for the project?
 Yes
 No
- * What type of affiliation does the principal investigator have with Metrocare?**
 External Researcher: The Principal Investigator is conducting research on behalf of their Institution or organization, and the Institution or its affiliate serves as the IRB of Record.
 Metrocare Researcher: The Principal Investigator is conducting research on behalf of Metrocare.
- * Reviewing IRB Approvals**
Please upload the Reviewing IRBs renewal/continuing review approval letter.
ATTACH
ABC University IRB Approval 2... | ✕
- * Metrocare Reliance Agreement**
Please upload the Metrocare Reliance Agreement that has been signed by both parties.
ATTACH
Metrocare Reliance Agreemen... | ✕

Submitted Renewals are scheduled to be approved as close to the expiration date as possible

INCIDENTS and REPORTABLE events

WHAT SHOULD BE REPORTED

HOW TO CREATE AND SUBMIT AN INCIDENT



WHAT SHOULD BE REPORTED

- Incidents should always be reported to your IRB or record following their policies and procedures
- Any incident involving Metrocare participants should be reported to Metrocare IRB via Cayuse immediately, within 48 hours of the occurrence
 - Include incident reports submitted to your IRB of Record as well

HOW TO CREATE AND SUBMIT AN INCIDENT

The dashboard displays the following study counts:

- In-Draft: 8
- Awaiting Authorization: 0
- Pre-Review: 0
- Under Review: 2

Below these are sections for My Studies, My Tasks, and Submissions by Type. A blue callout box points to the 'View All' button at the bottom of the My Studies section.

On the Dashboard, click here to view your studies

The 'Studies' page displays a table with the following columns: IRB#, Study Title, Status, PI, Exp Date, Admin Check-in Date, and Create Date. A blue callout box points to the IRB# 'IRB-FY2020-' in the second row.

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2021-		Unsubmitted		N/A	N/A	02-16-2021
IRB-FY2020-		Unsubmitted		N/A	N/A	10-16-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	04-18-2019
IRB-FY2019-		Under Review		N/A	N/A	04-03-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	03-01-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	12-21-2018
IRB-FY2019-		Expired		12-11-2019	N/A	12-11-2018
IRB-FY2019-		Requires Changes		N/A	N/A	12-11-2018
IRB-FY2018-		Unsubmitted		N/A	N/A	08-22-2018

Click on the Study for which an Incident will be entered

- Modification
- Incident
- Closure

Approved

Select [New Submission](#) > **Incident**

IRB-FY2024-41 Montrula 2

PDF

Delete

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

Unsubmitted

Incident

IRB-FY2024-41 - Montrula 2

Edit

PDF

Delete

Click "edit" or "Complete Submission" to begin editing the Incident Report

PI:
Irene Investigator

Current Analyst:
N/A

Decision:
N/A

Policy:
Post-2018 Rule

Required Tasks:

[Complete Submission](#)

Review Type:
N/A

Review Board:
N/A

Meeting Date:
N/A

Approved

Select [New Submission](#) > **Incident**

IRB-FY2024-41 Montrula 2

PDF

Delete

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

Unsubmitted

Incident

IRB-FY2024-41 - Montrula 2

Edit

PDF

Delete

Click "edit" or "Complete Submission" to begin editing the Incident Report

PI:
Irene Investigator

Current Analyst:
N/A

Decision:
N/A

Policy:
Post-2018 Rule

Required Tasks:

[Complete Submission](#)

Review Type:
N/A

Review Board:
N/A

Meeting Date:
N/A

- Sections <
- Incident Report
- Routing Send to PI for certification? v
- COMPLETE SUBMISSION >

Incident Report

* What type of affiliation does the principal investigator have with Metrocare?

- External Researcher: The Principal Investigator is researching on behalf of their Institution or organization, and the Institution or its affiliate serves as the IRB of Record. Only incidents involving Metrocare clients are required to be submitted.
- Metrocare Researcher: The Principal Investigator is conducting research on behalf of Metrocare.

* Incident Type

An incident/event (or series of related events) may fit into more than one category, so check all that apply. Distinct or events unrelated to another should generally have separate Incident submissions.

- New or Increased Risk
 For example:
 - Unanticipated Problems
 - Adverse events
 - Serious adverse events (SAE)
 Certain information may indicate new risks or that subjects may be at higher risk than previously recognized:
 - Investigator's Brochure (IB) updates identifying new or increased risks
 - New FDA Black Box Warning
 - DSMB/C report identifying new risks
 - Publications identifying new risks
 - Unauthorized disclosures of subject information
 - Unanticipated Adverse Device Effect
- Protocol Deviation and/or Noncompliance
 This is deviation/noncompliance in relation to federal regulations governing human subject research, with the protocol, or requirements/determinations by the IRB. For example:
 - Events that harmed a subject.
 - Events that increased risk of harm.
 - Serious Noncompliance: where events may adversely affect subjects rights or welfare.
 - Continuing Noncompliance: where a pattern of noncompliance is likely to continue

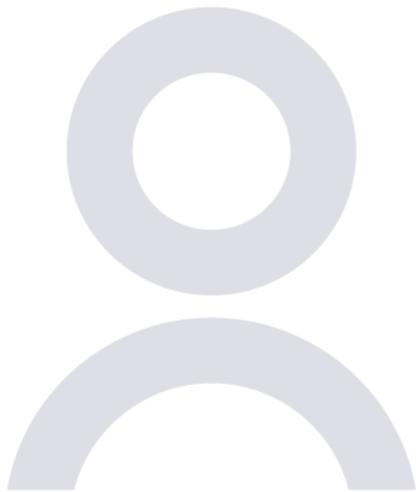
- Complete all questions
- When finished, click **COMPLETE SUBMISSION**
- Recommend submitting all minor study deviations once per year for Exempt/Expedited studies

Your PI/Co-inv will have to CERTIFY before it is sent to IRB like other submission types, so please collaborate to ensure it's completed timely.

CLOSURE REQUESTS

WHEN TO SUBMIT a CLOSURE REQUEST

HOW TO CREATE & SUBMIT a CLOSURE REQUEST





WHEN TO SUBMIT A CLOSURE

Study closure should occur when:

- the study was not and will not be initiated;
- the study was discontinued before its completion;
- or **the study has been completed.**

*Note: once a study is closed in the system,
there is no way to re-open it*

CREATING AND SUBMITTING a CLOSURE

On dashboard, click here to view studies

The dashboard shows the following study status counts:

- In-Draft: 8
- Awaiting Authorization: 0
- Pre-Review: 0
- Under Review: 2

Below the counts are sections for 'My Studies', 'My Tasks', and 'Submissions by Type'. The 'View All' button for the 'My Studies' section is highlighted with a blue arrow pointing to the callout box.

Click on the study you wish to close

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2021-		Unsubmitted		N/A	N/A	02-16-2021
IRB-FY2020-		Unsubmitted			N/A	10-16-2019
IRB-FY2019-		Unsubmitted			N/A	04-18-2019
IRB-FY2019-		Under Rev			N/A	04-03-2019
IRB-FY2019-		Unsubmitted			N/A	03-01-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	12-21-2018
IRB-FY2019-		Expired		12-11-2019	N/A	12-11-2018
IRB-FY2019-		Requires Changes		N/A	N/A	12-11-2018
IRB-FY2018-		Unsubmitted		N/A	N/A	08-22-2018

A blue arrow points from the callout box to the first row of the table (IRB-FY2021-).

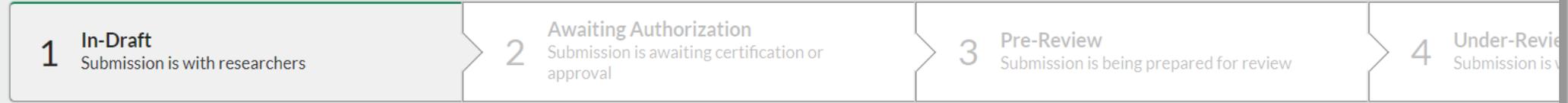
Approved

Select [New Submission](#) > **Closure**

IRB-FY2024-41 Montrula 2

PDF Delete

- Modification
- Incident
- Closure



Unsubmitted

Closure

IRB-FY2024-41 - Montrula 2

Edit PDF Delete

Click "edit" or "Complete Submission" to begin editing the Closure

PI: Irene Investigator

Current Analyst: N/A

Decision: N/A

Policy: Post-2018 Rule

Required Tasks:

[Complete Submission](#)

Review Type: N/A

Review Board: N/A

Meeting Date: N/A

1/15/2023

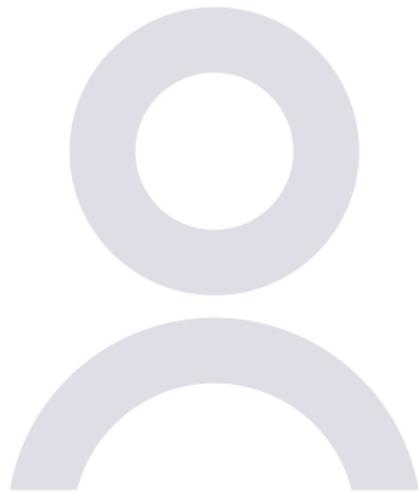
TO COMPLETE THE CLOSURE SUBMISSION...

The screenshot displays the Cayuse Human Ethics interface. At the top, the logo and name 'cayuse Human Ethics' are visible, along with a notification bell showing 182 alerts, a 'Products' dropdown, and the user name 'Irene Investigator'. Below this is a navigation bar with 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area is titled 'SUBMISSION DETAILS' and shows the IRB number 'IRB-FY2024-41' and the study name 'Montrula 2 - Closure'. Action buttons for 'CREATE PDF', 'COMPARE', and 'SAVE' are present. A left-hand menu lists 'Sections' (with a left arrow), 'Project Closure' (with a checkmark), 'Routing' (with a dropdown arrow and the text 'Send to PI for certification?'), and 'COMPLETE SUBMISSION' (with a right arrow). The main content area is titled 'Project Closure' and contains a section '* Closing Study' with the question 'Do you wish to close this study?'. Below this, the 'Yes' radio button is selected. A text field labeled '* Reason for study Closure:' contains the text 'vabba zabbahgvkglvlvlg l' and 'lksnv'lsdkngvds'lg' with red wavy lines underneath. A rich text editor toolbar is visible above the text field.

- Complete all sections on the left menu
- Make sure to **SAVE** as you move through the document
- Submit when complete
- Will follow the same process as modifications, renewals, and incidents by being routed to the PI / Co-Inv for certification before review by the IRB.
- Once closed, the study cannot be reopened.

SUBMITTING a WITHDRAWAL

WHEN TO SUBMIT a WITHDRAWAL



WHEN CAN I SUBMIT a WITHDRAWAL?

- Withdrawals may be completed until the time it is approved
- You may withdraw any type of submission
- **In Draft** – you may withdraw your submission at any point while the document is in draft
- **In Pre-Review or Review status**, contact the ACER RO as soon as possible, and the submission can be returned to the researchers so that they may withdraw the submission
- **If it has been approved**, create a closure submission to close the study if the PI no longer wishes to conduct the research.

Creating a withdrawal

On dashboard, click here to view studies

The dashboard displays the following metrics:

- In-Draft: 8
- Awaiting Authorization: 1
- Pre-Review: 1
- Under Review: 2

My Studies

IRB#	Status
IRB-FY2019-	Complete Submission
IRB-FY2021-	Complete Submission
IRB-FY2020-	Complete Submission
IRB-FY2019-	Complete Submission
IRB-FY2019-	Complete Submission
IRB-FY2019-	Complete Submission

Submissions by Type

Type	Count
Renewal	0
Initial	11
Modification	0
Incident	0
Withdrawal	1
Closure	0
Legacy	0

View All (under My Studies)

Click on Study you wish to withdraw

IRB#	Study Title	Status	PI	Exp Date	Admin Check-in Date	Create Date
IRB-FY2021-		Unsubmitted		N/A	N/A	02-16-2021
IRB-FY2020-		Unsubmitted			N/A	10-16-2019
IRB-FY2019-		Unsubmitted			N/A	04-18-2019
IRB-FY2019-		Under Review			N/A	04-03-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	03-01-2019
IRB-FY2019-		Unsubmitted		N/A	N/A	12-21-2018
IRB-FY2012-		Expired		12-11-2019	N/A	12-11-2018
IRB-FY2012-		Requires Changes		N/A	N/A	12-11-2018
IRB-FY2018-		Unsubmitted		N/A	N/A	08-22-2018

Under Review

IRB-FY2024-40 Sample 1 - Assign to Meeting Late

PDF Delete

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

- 1. Click withdrawal
- 2. Select Withdrawal

Withdrawal

By creating this withdrawal submission, you will be withdrawing the entire study from review. If you still wish to submit this submission, you will have to restart your application from the beginning. Are you sure you would like to proceed?

Cancel Withdraw

Unsubmitted

Withdrawal

IRB-FY2024-40 - Sample 1 - Assign to Meeting Late

Edit PDF Delete

PI: Irene Investigator	Current Analyst: N/A	Decision: N/A	Policy: Post-2018 Rule	Required Tasks: Complete Submission
Review Type: N/A	Review Board: N/A	Meeting Date: N/A		

- 3. Then click EDIT

IRB NUMBER: IRB-FY2024-40
Sample 1 - Assign to Meeting Late - Withdrawal
CREATE PDF COMPARE SAVE

Sections
Withdrawal Request ✓
Routing Send to PI for certification?
COMPLETE SUBMISSION >

Withdrawal Request

* Do you want to withdraw your Initial submission?

This will withdrawal not only your Initial submission, but also archive this Study. You will **NOT** be able to reopen this study or Initial submission after this, and would have to start over and create a New Study (if needed).

Yes
 No

Justification

Please provide the reason(s) for withdrawal.

Rich text editor with text: "Because...."

1. Complete request
2. Click SAVE button
3. Click Complete Submission
4. CONFIRM
5. PI / Co-In need to CERTIFY & CONFIRM

SUBMISSION ROUTING

Are you sure you want to continue?

CANCEL CONFIRM

Routing:

Return Certify

CONDITIONS FOR ADMINISTRATIVE CLOSURE AND WITHDRAWAL

Administrative Closure – Researchers should receive an automatic 90-60-30-day reminder about their study expiration or check-in. Studies whose expiration or check-in has passed must halt all research with MC clients and data and must have a renewal approved within 30 days, or their study will be administratively closed. Once closed, you will not be able to re-open.

Administrative Withdrawal – Studies left open for more than 60 days without being submitted to the IRB will be administratively withdrawn. You will not have the ability to reopen.

ACER RESEARCH OFFICE IS HERE TO SUPPORT YOU

Cayuse Consultation is available by appointment via Teams

- Cayuse user walk-through, navigation
- Trouble-shooting

Include a brief explanation of the problem and your day/time availability
–we will try to support you in resolving the problem within 24 business hours....unless it's a Cayuse problem

Contact us if you have **ACER Research Office or IRB questions** OR
to discuss opportunities to collaborate on research projects

ACER RO Hours of operation: Monday-Friday 8:00am-2:00pm

Contact acerresearch@metrocareservices.org

