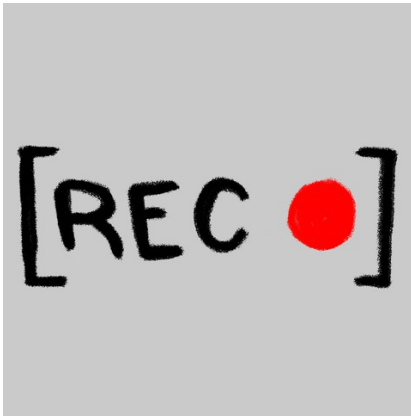


Cayuse Human Ethics Training

University of Montana Institutional
Review Board

FYI:

- This session will be recorded
- This PowerPoint will be made available on our website
- I will pause for questions periodically



Resources

- **UM IRB Cayuse Human Ethics page**
- **Cayuse Help Center – lots of helpful videos and articles**

RESEARCH COMPLIANCE

- Animal Research (IACUC and LAR)
- Biosafety (IBC)
- Export Control
- Human Subjects Research**
- Cayuse Human Ethics
- Research Misconduct
- Important Links
- UM Legal Counsel
- Directory

INSTITUTIONAL REVIEW BOARD (IRB) FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Starting January 1, 2024, The University of Montana will begin to use the web system Cayuse Human Ethics for human subject research, replacing the paper-and-email submission system. [Click here](#) for more information and guidelines for the new Cayuse platform.

- [A Guide to Getting Started](#)
- [Board Members](#)
- [Contact the IRB](#)
- [Deadline for Submission](#)
- [External Review](#)
- [Forms, Templates, Examples](#)
- [Guidelines](#)
- [Human Subjects Protection Course](#)

IRB Forms:
Always download the most recent version from the website
[Go to the Forms page](#)

RESEARCH COMPLIANCE

- Animal Research (IACUC and LAR)
- Biosafety (IBC)
- Export Control
- Human Subjects Research
- Cayuse Human Ethics**
- Cayuse Application Guide
- Cayuse FAQ
- Research Misconduct
- Important Links
- UM Legal Counsel
- Directory

CAYUSE HUMAN ETHICS PLATFORM

[CAYUSE HE LOGIN](#) [REQUEST ACCESS TO CAYUSE](#)

Starting January 1, 2024, the University of Montana IRB will begin to use the web-based Cayuse Human Ethics for managing human subject research studies. Cayuse Human Ethics is an electronic protocol management platform that is cloud-based, user-friendly, and secure. Cayuse Human Ethics will be used to prepare and submit all initial human subjects research studies, as well as make modifications, request renewals, and report incidents.

The UM IRB office will still accept paper/email applications until February 1, 2024.

Log in to Cayuse Human Ethics

[Links will be live January 1, 2024]

- Click to access Cayuse Human Ethics. If you cannot access it, you may need to request an account using the Cayuse Account Request Form.
- From the Product drop-down menu, select Human Ethics to view your Dashboard.

Each investigator will need to have a Cayuse account before they can be added to a study submission. If you try to log in and get an error message, or if you know that you do not have a Cayuse account, fill out the Request Access to Cayuse form (link above). All UM Main Campus faculty and staff accounts have already been created and you will be able to login starting on January 1st. Faculty and staff at UM-affiliate campuses (UM-Western, MT Tech, and Helena College) will need to submit a Cayuse Account Request Form. All UM students, regardless of campus, will also need to submit a Cayuse Account Request Form for right now. We are hoping to load student accounts into Cayuse in the near future.

What is Cayuse Human Ethics (HE)?

- Cayuse Human Ethics is UM's new electronic IRB protocol submission and review platform
- Paperless electronic approvals and management of IRB protocols from initial submission to closure
- Go Live Date: January 1, 2024
- Last day for paper/email submissions for new projects: February 1, 2024

Logging into Cayuse IRB

- Link is on the IRB website
- SSO – use your NetID and password to log in
- Non-UM (main campus) PIs/collaborators and students need to request access
- Choose Human Ethics module from drop down menu

CAYUSE HUMAN ETHICS PLATFORM

CAYUSE HE LOGIN

REQUEST ACCESS TO CAYUSE



Beginning January 1, 2024, the University of Montana IRB will begin to use the web-based system Cayuse Human Ethics for managing human subject research studies. Cayuse Human Ethics is an electronic protocol management platform that is cloud-based, user-friendly, and secure. Cayuse Human Ethics will be used to prepare and submit all initial human subjects research studies, as well as make modifications, request renewals, and report incidents.

The UM IRB office will still accept paper/email applications until February 1, 2024.

Log in to Cayuse Human Ethics

[Links will be live January 1, 2024]

A screenshot of the Cayuse Human Ethics platform interface. At the top right, there is a user profile for Michaela Shifley (790766251) and a 'Products' dropdown menu. Below this, a navigation menu is open, showing options: Home, Sponsored Projects, Human Ethics (highlighted with a red arrow), and Admin. To the right of the navigation menu, there is a '+ New Task' button and an 'Open' button. Below the navigation menu, there is a table with columns: Created, Last Activity, Due, and Status. The 'Assigned to Me' button is visible above the table.

Cayuse HE Dashboard

Notifications appear here! Click bell to view



cayuse
Human Ethics

Role: Researcher | Products | Michaela Shifley (790766251)

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Shows status of your submission

- In-Draft →
- Awaiting Authorization →
- Pre-Review →
- Under Review →
- Post Review →

My Studies
Shows all your studies
You Have No Studies

My Tasks
Shows all tasks you need to complete
All Tasks Complete

Submissions by Type
Shows your submissions

Renewal
Initial
Modification
Incident
Withdrawal
Closure
Legacy

Approved Studies
Shows your approved studies
No Approved Studies

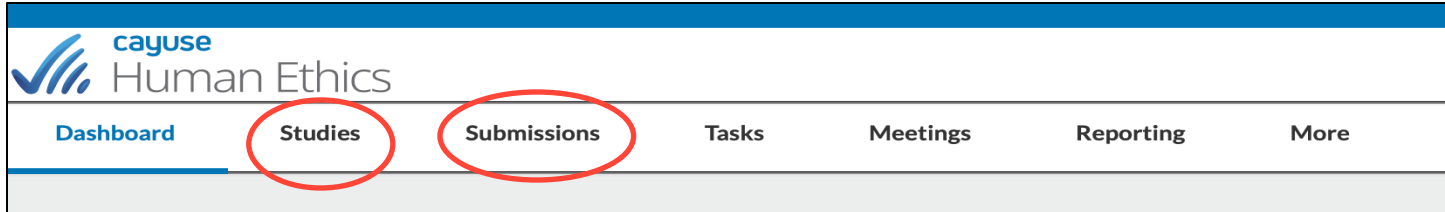
Studies Expiring in 30 days
Shows your expiring studies
No Expiring Studies

Expired Studies
Shows your expired studies
No Expired Studies

1 ?

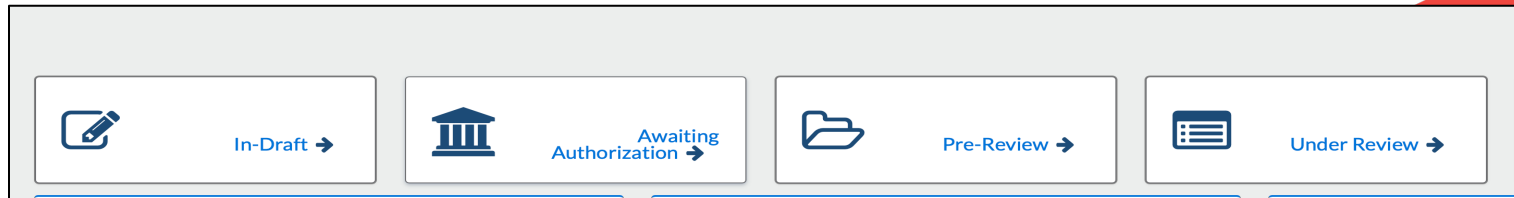
Studies vs. Submissions

- **STUDY** refers to your entire research project
- **SUBMISSION** refers to specific applications within a study – e.g., initial submission, modification, renewal, closure, etc.



Submission Statuses

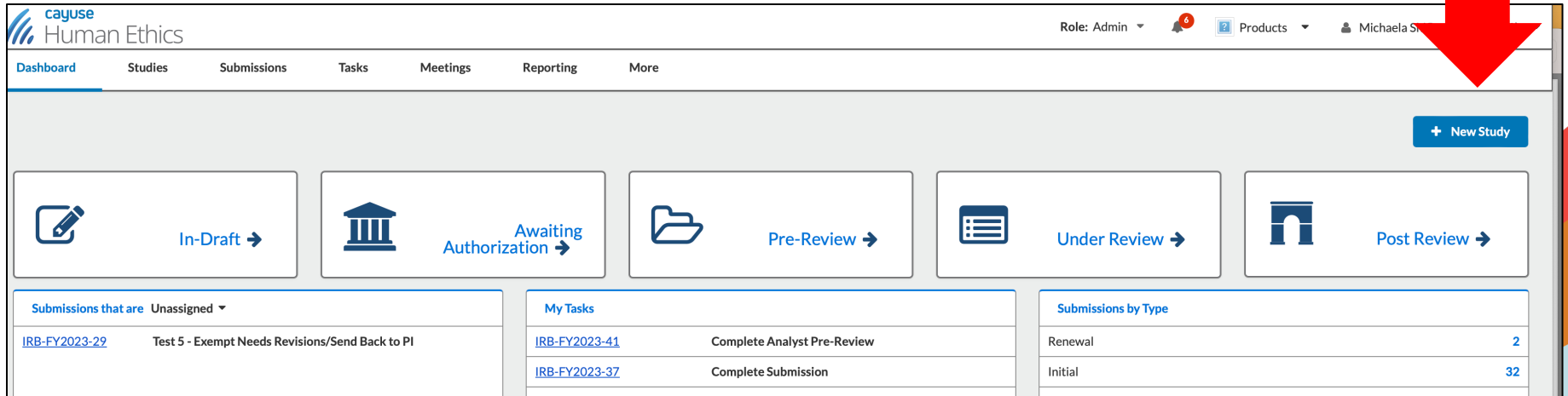
- **In-Draft** = submission is still being worked on by the study team
- **Awaiting Authorization** = submission needs to be certified by PI, Co-PI, and/or Faculty Sponsor
- **Pre-Review** = submission is being reviewed by the IRB Analyst
- **Under Review** = submission is under review by a designated IRB reviewer, IRB Chair, or IRB Committee.



Creating a New Study and Initial Submission

Creating a New Study

To create a new study, click the **New Study** button in the top right corner of your dashboard



The screenshot shows the cayuse Human Ethics dashboard. The top navigation bar includes the logo, user role (Admin), notification bell, and user name (Michaela S.). The main navigation menu contains Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The dashboard content area features a '+ New Study' button in the top right corner, highlighted by a large red arrow. Below this are five status cards: In-Draft, Awaiting Authorization, Pre-Review, Under Review, and Post Review, each with a right-pointing arrow. At the bottom, there are three summary tables: 'Submissions that are Unassigned', 'My Tasks', and 'Submissions by Type'.

Submissions that are Unassigned	
IRB-FY2023-29	Test 5 - Exempt Needs Revisions/Send Back to PI

My Tasks	
IRB-FY2023-41	Complete Analyst Pre-Review
IRB-FY2023-37	Complete Submission


Submissions by Type	
Renewal	2
Initial	32





Study Title

Enter a title for your study (up to 600 characters), then click the **Blue Checkmark/Save** button

Studies / Study Details + New Submission

Study Details Submissions

Test Study | 

 PDF  Delete  

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		

Begin Your Application

To begin working on your study, click **New Submission** to add the **Initial** submission for your study

Studies / Study Details

Study Details Submissions Initial

Unsubmitted

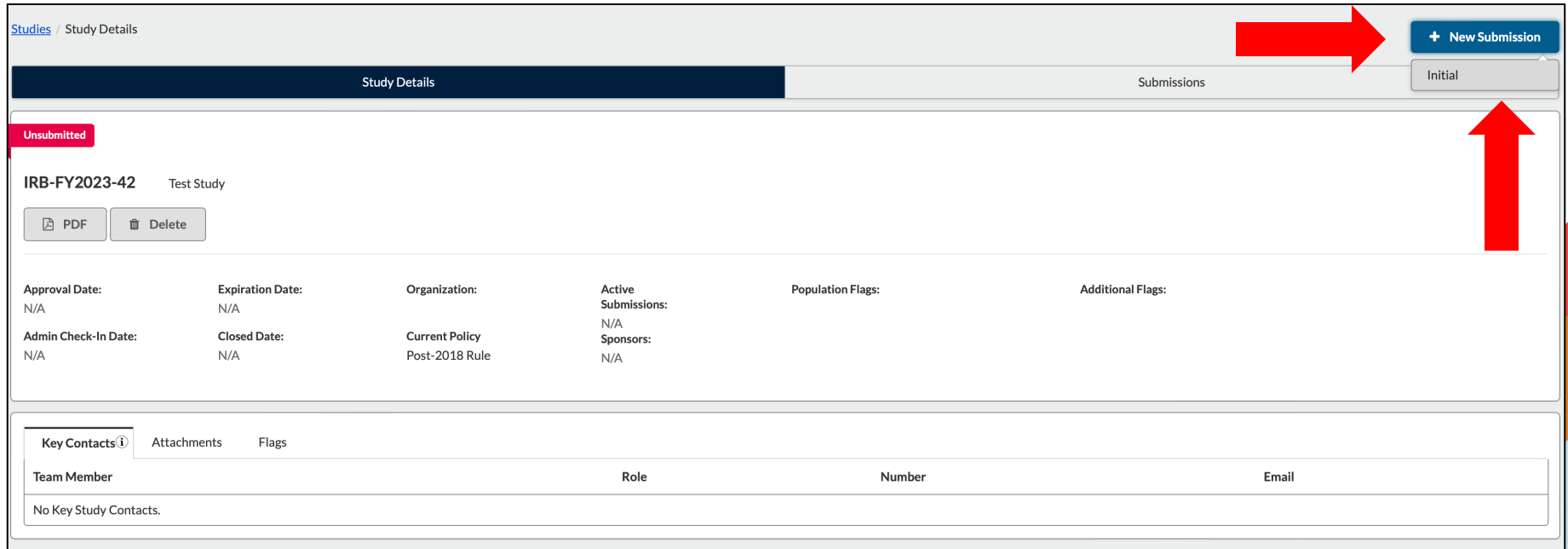
IRB-FY2023-42 Test Study

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		

Key Contacts ⓘ Attachments Flags

Team Member	Role	Number	Email
No Key Study Contacts.			



Editing an Initial Submission

The screenshot displays the IRB application interface. At the top, there is a navigation bar with tabs for Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. Below this, the breadcrumb trail reads 'Studies / Study Details / Submission Details'. The main content area shows two steps: '1 In-Draft Submission is with researchers' and '2 Awaiting Authorization Submission is awaiting certification or approval'. A red 'Unsubmitted' badge is visible. The submission title is 'Initial IRB-FY2023-42 - Test Study'. Below the title, there are three buttons: 'Edit' (with a pencil icon), 'PDF' (with a dropdown arrow), and 'Delete' (with a trash icon). A large red arrow points to the 'Edit' button. Below the buttons, there is a table with three columns: 'PI:', 'Current Analyst:', and 'Decision:'. The 'PI:' and 'Review Board:' rows show 'N/A'. Below the table, there are tabs for 'Approvals', 'Task History', and 'Attachments'. At the bottom, there is a 'Research Team' section with a table header for 'Name' and 'Role', and a message 'No entries.'

Click the **Edit** button – this will take you into the IRB application

The person who creates the study is added as the Primary Contact by default (different than PI). You can change this when you edit the application if needed

Before starting an application:

- Have all study documents ready to upload, including but not limited to informed consents and advertising materials (flyers, emails, etc.)
- Be prepared to upload all Ethics training documentation!

Completing Your Protocol

Don't forget to **Save**
your work!

IRB NUMBER: IRB-FY2023-42

Test Study - Initial

CREATE PDF COMPARE **SAVE**

Sections

- Getting Started ✓
- Project Personnel**
- Basic Information
- Attachments

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	
Michaela Shifley (790766251)	34100A - ELCS	University of Montana 32 Campus Dr, Missoula, MT 59812-0004	406-243-2175	michaela.shifley@mso.umt.edu	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 NOT be able to view the study, will not have edit access to the study, and will not be included in study communications automatically.

*** Study Personnel Training Documentation**

Upload documentation of any required training (e.g., CITI training) for each member of study personnel.

ATTACH

*** Conflict of Interest**

Do any of the study personnel have a financial conflict of interest related to this project?

Yes
 No

Navigate sections here

Questions marked with a red star are **required**

Navigate sections here

< >

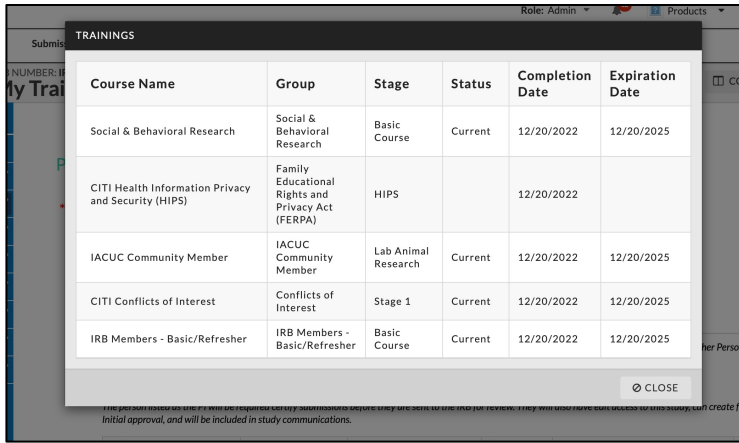
TIP!

- **Cayuse does not automatically save your work!**
- **Remember to click the green save button in the top right or bottom right of the form**
- **The UM IRB office recommends drafting the main portions of the application in a Word document as well, so the submission is saved twice**



Adding Personnel

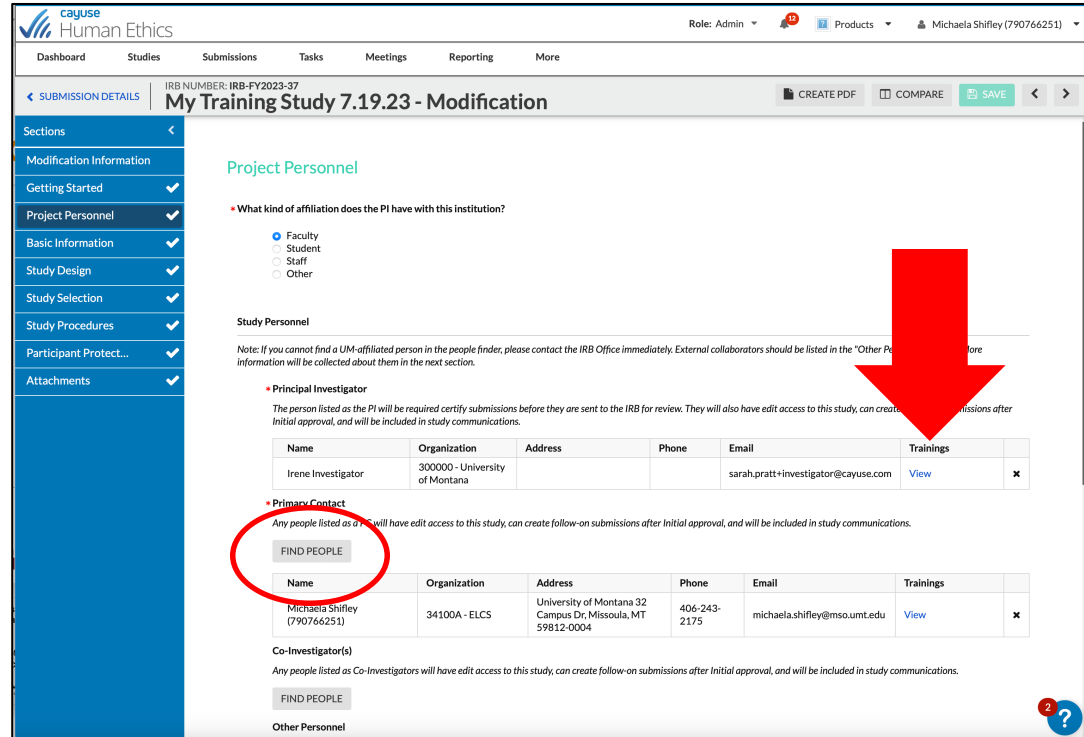
- Find People button – searches the UM Cayuse system only
- Other Personnel – free form text box to add additional or non-UM team members
- PIs, Co-PIs, and Faculty Supervisors will be required to certify submissions



TRAININGS

Course Name	Group	Stage	Status	Completion Date	Expiration Date
Social & Behavioral Research	Social & Behavioral Research	Basic Course	Current	12/20/2022	12/20/2025
CITI Health Information Privacy and Security (HIPS)	Family Educational Rights and Privacy Act (FERPA)	HIPS		12/20/2022	
IACUC Community Member	IACUC Community Member	Lab Animal Research	Current	12/20/2022	12/20/2025
CITI Conflicts of Interest	Conflicts of Interest	Stage 1	Current	12/20/2022	12/20/2025
IRB Members - Basic/Refresher	IRB Members - Basic/Refresher	Basic Course	Current	12/20/2022	12/20/2025

Role: Admin



My Training Study 7.19.23 - Modification

Project Personnel

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

Faculty
 Student
 Staff
 Other

Study Personnel

Note: If you cannot find a UM-affiliated person in the people finder, please contact the IRB Office immediately. External collaborators should be listed in the "Other Personnel" section.

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.

Name	Organization	Address	Phone	Email	Trainings
Irene Investigator	300000 - University of Montana			sarah.pratt+investigator@cayuse.com	View ✕

Primary Contact

Any people listed as a PI 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
Michaela Shifley (790766251)	34100A - ELC5	University of Montana 32 Campus Dr, Missoula, MT 59812-0004	406-243-2175	michaela.shifley@mso.umt.edu	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

Role: Admin

Research on Indian Reservation and/or with Native Americans

Research on Indian Reservations and/or with Native American Populations

Any research conducted with indigenous people or on sovereign tribal land comes under the indigenous people's individual governing authority. This includes, but is not limited to, the Tribal Council, Tribal Cultural Committee, and Tribal IRB. UM involvement must comply with all applicable tribal, federal, state, and University regulations, policies, and procedures.

The UM IRB may conduct a review at the tribe's request, or it may enter into a reliance agreement with the tribal IRB, such that the tribal IRB assumes oversight. When the UM IRB conducts the review, separate written permission must be obtained from the collective tribal governing body to conduct research on the reservation. UM IRB approval or an approved reliance agreement and tribal IRB approval must be finalized before any research is conducted.

When planning projects, UM researchers should allow adequate time to obtain the proper approvals. Depending on the nature of the project and type of review, this may take from one to ten months.

All UM projects involving indigenous people should be performed in a culturally appropriate manner and consistent with tribal customs and traditions, as determined by the involved Tribe(s). Thus, there may be occasions where food or gifts are given to tribal participants during gatherings, as well as when collecting materials, information, data, and samples.

Any proposed research at an Indian Health Service (IHS) facility, whether on or off a reservation, will require additional review by the IHS IRB or its designee.

The University of Montana and the Confederated Salish and Kootenai Tribes (CSKT) IRBs have a standing IAA for all research with human subjects covered by the respective entities' Federal Wide Assurance. Notification via a copy of the approval memo to the PI from the IRB is sent to the non-reviewing IRB. This relieves a PI from having a proposal reviewed by both the UM IRB and CSKT IRB.

* I have read UM's Indigenous Peoples' Policy and Procedures document (found here: <https://www.umt.edu/research/compliance/irb/indigenous.php>) and agree to abide by these guidelines throughout the course of my research. I understand that I am responsible for ensuring that any study team members under my supervision, including Co-PIs, students, research assistants, and others, have read and agreed to abide by these guidelines throughout the study's duration as well.

Yes

* Are you conducting research at an Indian Health Service (IHS) facility?

Please note that any proposed research at an Indian Health Service (IHS) facility, whether on or off a reservation, will require additional review by the IHS IRB or its designee.

Yes
 No

Please read all
instructions
first before
completing
this section

Reliance Agreements

For Expedited and Full Board studies only – if you are not sure what your study is/will be, contact the IRB office.

IRB Oversight and Collaboration Information

Investigators engaged* in human subjects research must be overseen by an IRB. Typically, this is the IRB of his or her own institution.

However, when multiple IRBs are involved in a protocol, an IRB Authorization Agreement (IAA), or Reliance Agreement may be needed. A Reliance Agreement is a formal, written agreement that provides a mechanism by which one institution or individual engaged in research delegate IRB oversight to an independent IRB, or an IRB of another institution.

The University of Montana will not enter into a Reliance Agreement when UM or the Reviewing IRB has determined the protocol to be Exempt. All investigators must submit an IRB application to their own IRB in this case.

The University of Montana and Montana State University have a standing IAA for all research with human subjects covered by the respective university's Federal Wide Assurance. Notification via a copy of the approval memo to the PI from the IRB is sent to the non-reviewing IRB. This relieves a PI from having a proposal reviewed by both the UM IRB and Montana State University IRB.

****Engaged* means: the UM investigator receives funding from a federal department or agency for the research; the UM investigator is obtaining informed consent; the UM investigator is obtaining data about subject through intervention or interaction for research purposes; and/or the UM investigator is obtaining identifiable private information about subjects for research purposes.*

* IRB Oversight Arrangements

Indicate how IRB oversight is organized for this study.

- Study involving more than 1 site where each site will conduct their own IRB review
- Study involving more than 1 site where the University of Montana is the Reviewing IRB (IRB of Record) for other sites
- Study involving more than 1 site where the University of Montana is Relying on an External IRB
- Multi-site study (multiple US sites participating in a research study using the same protocol) where the University of Montana is the Reviewing IRB (IRB of Record) for all sites (ex. clinical trials)
- Multi-site study (multiple US sites participating in a research study using the same protocol) where the University of Montana is Relying on an External IRB

* Clinical Trials

Is this study a clinical trial?

- Yes
- No

Reliance Agreements

Relying on an External IRB

• **Name of Reviewing IRB**
Identify the IRB of Record for this study.

• **Reviewing IRB Point of Contact (POC)**
List the name, email, and phone number of the POC.

• **Name of Lead Site**
Identify the lead site for this study.

• **Lead Site PI Name**
Name the PI at the Lead Site

Consent/Assent Forms
Upload all documents used in the Consent/Assent process, including the templates provided by the Reviewing IRB or Lead Site and any forms that will be used at this site.

ATTACH

Study Documents
Upload study documents provided by the Reviewing IRB or Lead Site, such as the Protocol documents, recruitment templates, study instruments, etc.

ATTACH

Reviewing IRB Approvals
Upload approval documentation from the Reviewing IRB, such as the overall study approval and the approval adding this site to the study.

ATTACH

1 ?

- Name of Reviewing IRB
- Reviewing IRB point of contact
- Name of Lead Site
- Lead Site PI Name
- Consent/Assent forms
- Study documents (recruitment, study instruments, etc.)
- Reviewing IRB approvals

Human Subjects Research Determinations

NHSR or Not Engaged in Research

Does the project meet definition of "Research"?

As defined by 45 CFR 46, **research** is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

*** Is the activity a systematic investigation?**

For example a project that is a careful examination or inquiry, which has a system, method, or plan, with the intention of ascertaining facts. Consider that randomizing individuals/groups/organizations or designating them to receive different interventions for comparison tends to indicate systematic investigation.

- Yes
 No

*** Is the project intended to develop or contribute to generalizable knowledge?**

Consider if the knowledge gained in this project could be generalizable, or universally applied/accepted, to other contexts or situations.

Case studies of more than a couple patients/subjects are generally considered research.

- Yes
 No

*** Based on the 2 answers above, does this project meet the definition of "Research"?**

- Yes (both answers above were Yes)
 No (at least one answer above was No)

HIPAA

- The HIPAA Privacy Rule applies to projects where PHI is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research.
- Even if your project is Not Human Subject Research or this institution is Not Engaged in Research, you may still have requirements under HIPAA if PHI is being obtained, used, or released/disclosed by a Covered Entity.
- Protected Health Information (PHI) = health information + one or more of the 18 identifiers (see help text).

*** Does this project involve collecting and/or accessing health information AND one or more of the 18 identifiers?**

- Yes
 No

*** Does this project involve obtaining, using, or releasing/disclosing PHI by a Covered Entity?**

- Yes
 No

- Submit one of these if you are unsure if your project requires IRB oversight
- Fill out Basic Information page like normal; you will choose this option at the end of that section
- If your project is determined to be Human Subjects Research, you will be asked to complete an IRB application

Section 118 Determinations

118 Determination/Future Human Research

* Human Subject Plans

Does your research project currently contain a definite plan for involvement of human subjects?

- Yes
 No

* Project Description

Provide a non-technical description of the research project as is currently known, such as the Purpose, Study Population information Procedures, etc.

B I U

* Protocol Development

Describe what must be done before human subjects would be involved in the research project (e.g., development of measures, recruitment materials, assays, etc.).

B I U

- Submit one of these if your project will/may involve human subjects in the future BUT:
 - Future protocol development must take place first, AND
 - You need documentation of IRB review in order to release grant funds
- Fill out Basic Information page like normal; you will choose this option at the end of that section
- A formal IRB application **must** be submitted and approved before any work with human subjects begin



Completing the Submission

- When all questions are answered and documents are uploaded, click the **Complete Submission** button

The screenshot displays the IRB submission system interface for a submission titled "Test Study - Initial" with IRB number "IRB-FY2023-42". The left sidebar shows a list of sections: "Getting Started", "Project Personnel", "Basic Information", "NHRSR or Not Enga...", "Attachments", "Routing", and "COMPLETE SUBMISSION". The "COMPLETE SUBMISSION" button is highlighted with a red circle. The main content area shows the "Attachments" section with three sub-sections: "Project Personnel" (Study Personnel Training Documentation), "Basic Information" (Site Permission Documentation), and "IRB Oversight and Collaboration Information" (External Collaborator Information and Training Documentation for External Collaborators). Each sub-section has an "ATTACH" button and a description of the required documentation.

IRB NUMBER: IRB-FY2023-42
Test Study - Initial

CREATE PDF COMPARE SAVE

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- NHRSR or Not Enga... ✓
- Attachments ✓
- Routing Send to PI for certification? ✓
- COMPLETE SUBMISSION >

Attachments

Project Personnel

Study Personnel Training Documentation
Upload documentation of any required training (e.g., CITI training) for each member of study personnel.

ATTACH

Screenshot 2023-08-30 at 11:1...

Basic Information

Site Permission Documentation
Upload all site permission documentation here.

ATTACH

IRB Oversight and Collaboration Information

External Collaborator Information
UM IRB Individual Investigator Agreement (IIA)
Upload IIAs here for collaborators from institutions that DO NOT have their own IRB.


ATTACH

Training Documentation for External Collaborators
Upload any required training documentation for External Collaborators.

Certifying the Submission

- All PIs and Co-PIs must certify a submission
- All Faculty Sponsors must certify their students' submissions

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

 **In-Draft**
Submission is with researchers

1 Awaiting Authorization
Submission is awaiting certification or approval

2 Pre-Review
Submission is being prepared for review

3 Under-Review
Submission is with reviewers

Awaiting Certification

Initial
IRB-FY2023-42 - Test Study

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

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

PI: Michaela Shifley (790766251)	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
Michaela Shifley (790766251)	Principal Investigator	Pending Certification	

After Certification: Now What?

- **Pre-Review** = the submission is being reviewed by the IRB office for completeness
- **Under Review** = the submission is being formally reviewed by the IRB office/IRB Chair/IRB Committee

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

In-Draft
Submission is with researchers

Awaiting Authorization
Submission is awaiting certification or approval

1 Pre-Review
Submission is being prepared for review

2 Under-Review
Submission is with reviewers

Under Pre-Review

Initial
IRB-FY2023-42 - Test Study

[Review](#) [PDF](#) [Delete](#) Routing: [Proceed](#)

PI: Michaela Shifley (790766251)	Current Analyst: N/A	Decision: N/A	Policy: Post-2018 Rule ✎	Required Tasks: Assign Analyst
Review Type: N/A	Review Board: N/A	Meeting Date: N/A		

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

Research Team

Name	Role	Result	Date
Michaela Shifley (790766251)	Principal Investigator	Certified	08-30-2023 1:28 PM

Addressing IRB Comments

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

1 In-Draft
Submission is with researchers

2 Awaiting Authorization
Submission is awaiting certification or approval

Reopened

Initial
IRB: P12023-42 - Test Study

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

PI:
Michaela Shifley (790766251)

Current Analyst:
Alice Administrator [Edit](#)

Decision:
N/A

Review Type:
N/A

Review Board:
N/A

Meeting Date:
N/A

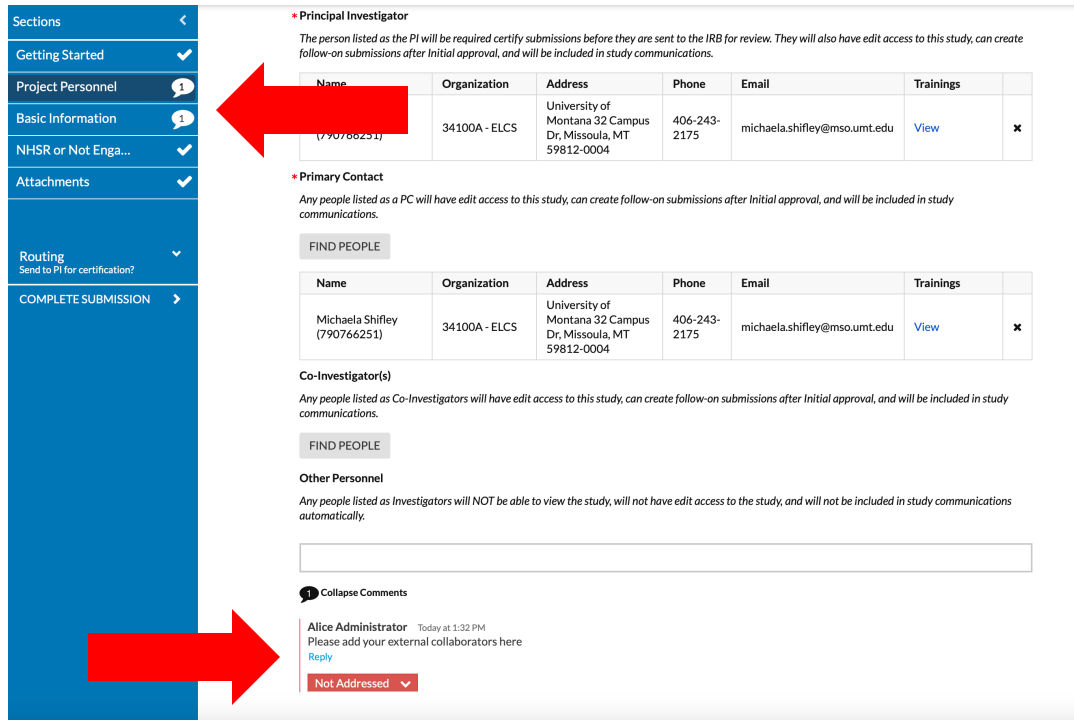
[Approvals](#) [Task History](#) [Attachments](#)

Research Team

Name	Role
No entries.	

- Comments can come during either the pre-review or review
- You will receive a notification that your study has been reopened

Addressing IRB Comments



The screenshot shows a sidebar on the left with a list of sections. A red arrow points from the 'Project Personnel' section (which has a '1' bubble) to the 'Principal Investigator' section in the main content area. Another red arrow points from the 'Collapse Comments' section (which has a '1' bubble) to a comment in the 'Collapse Comments' section.

Sections

- Getting Started ✓
- Project Personnel 1
- Basic Information 1
- NHSR or Not Enga... ✓
- Attachments ✓
- Routing Send to PI for certification? ✓
- COMPLETE SUBMISSION >

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

Name	Organization	Address	Phone	Email	Trainings	
[Redacted]	34100A - ELCS	University of Montana 32 Campus Dr, Missoula, MT 59812-0004	406-243-2175	michaela.shifley@mso.umt.edu	View	✕

***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	
Michaela Shifley (790766251)	34100A - ELCS	University of Montana 32 Campus Dr, Missoula, MT 59812-0004	406-243-2175	michaela.shifley@mso.umt.edu	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 NOT be able to view the study, will not have edit access to the study, and will not be included in study communications automatically.

[Empty text box]

1 Collapse Comments

Alice Administrator Today at 1:32 PM
Please add your external collaborators here
[Reply](#)

Not Addressed ▾

Accessing Comments

- Look for little bubbles next to each section of the application
- Bubbles indicate which sections have comments, and the number indicates *how many* comments are in that section
- Scroll through the application and you will see areas where the pre-reviewer or reviewer have made their comments

Addressing IRB Comments

Sections <

Getting Started ✓

Project Personnel ✓

Basic Information

NHSR or Not Enga... ✓

Attachments ✓

Routing Send to PI for certification? ✓

COMPLETE SUBMISSION >

*** Principal Investigator**

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

Name	Organization	Address	Phone	Email	Trainings	
Michaela Shifley (790766251)	34100A - ELCS	University of Montana 32 Campus Dr, Missoula, MT 59812-0004	406-243-2175	michaela.shifley@mso.umt.edu	View	✕

*** 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	
Michaela Shifley (790766251)	34100A - ELCS	University of Montana 32 Campus Dr, Missoula, MT 59812-0004	406-243-2175	michaela.shifley@mso.umt.edu	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 NOT be able to view the study, will not have edit access to the study, and will not be included in study communications automatically.

Collapse Comments

Alice Administrator Today at 1:32 PM
Please add your external collaborators here
[Reply](#)

Addressed ✓ Today at 1:34 PM by you

Addressing Comments

- Make the requested changes to the application and/or study materials
- You can reply to reviewer comments if needed
- Upload new versions of any study materials, if needed, and remove old versions
- Each comment **must** be marked as “addressed” in order to complete the resubmission process
- You will have to recertify your study before resubmitting for review
- Don’t forget to click **Save!!**

Review Complete

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

Review Complete

Initial

IRB# 12023-37 - My Training Study 7.19.23

View PDF Delete Checklist

PI: Irene Investigator Current Analyst: Sarah Pratt Decision: Approved Policy: Post-2018 Rule

Review Type: Full Board Review Board: Training Board

Approvals Task History Letters Meetings Decisions Attachments

Research Team

Name	Role	Result	Date
Irene Investigator	Principal Investigator	Certified	07-19-2023 11:59 AM

You can access approval letters, decisions, and task history in the tabs here

Possible IRB Decisions

- Approved
- Requires Changes
- Disapproved
- Suspended
- Withdrawn
- Closed
- Expired

Studies / Study Details

Study Details

Approved

IRB-FY2023-37 My Training Study 7.19.23

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

Approval Date:	Expiration Date:	Organization:
07-19-2023	07-17-2024	300000 - Unive Montana Current Policy Post-2018 Rule
Admin Check-In Date:	Closed Date:	
N/A	N/A	

Key Contacts ⓘ Attachments Flags

Team Member	Role	Number
Irene Investigator	Principal Investigator	
Michaela Shifley (790766251)	Primary Contact	406-243-2175

Re: Initial - IRB-FY2023-37

My Training Study 7.19.23

On Jul 19, 2023 12:15:00 PM MDT, the Training Board reviewed the above-referenced submission and rendered the decision below. All approval letters and study documents are located in the tabs on the Submission Details page.

Decision: Approved

Decision Date: July 19, 2023

Study Expiration Date: July 17, 2024

Findings: These are the findings

Key Principal Investigator Responsibilities:

- All **consent/permission/assent forms** for this project must bear the IRB stamp. Use the copy uploaded to the tabs on the Submission Details page as a "master" to make copies.
- All **study recruitment materials** must be reviewed and approved the IRB prior to being used. Flyers and posters must bear the IRB stamp. Use the copy uploaded to the tabs on the Submission Details page as a

Final Tips for Completing Initial Submissions:

- Answer all questions thoroughly and completely
- Attach all of the required documents
- Don't forget to Save!
- You will receive email notifications throughout the pre-review/review processes
- Email or call the IRB office with questions

Submitting Modifications, Renewals, Closures, and Incidents

Modifications

- You will be asked to describe the Modification
- You can make changes to the original application details, which will be reviewed by the IRB office

The screenshot displays the Cayuse Human Ethics system interface. The top navigation bar includes the Cayuse logo, user role (Researcher), notification count (10), and user name (Michaela Shifley). The main navigation menu contains Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The current page is 'Study Details' for 'IRB-FY2024-11', an Experiment Study. A red arrow points to the 'Submissions' tab, which has a dropdown menu open with options: 'Renewal', 'Modification', 'Incident', and 'Closure'. The study details section includes a green 'Approved' badge, a PDF icon, and a 'Delete' button. Below this is a table of key information:

Approval Date: 06-27-2023	Expiration Date: N/A	Organization: 300000 - University of Montana	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		

At the bottom, there is a 'Key Contacts' section with a table of team members:

Team Member	Role	Number	Email
Irene Investigator	Principal Investigator		sarah.pratt+investigator@cayuse.com
Michaela Shifley (790766251)	Primary Contact	406-243-2175	michaela.shifley@mso.umt.edu

Modifications

IRB NUMBER: IRB-FY2024-11

Experiment Study - Modification

← SUBMISSION DETAILS

Sections <

Modification Information

Getting Started ✓

Project Personnel ✓

Basic Information ✓

NHSR or Not Enga... ✓

Attachments ✓

Modification Information

IMPORTANT REMINDER

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

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

* Are you making changes to the project?

Yes

No

Make changes to the sections on the left-hand side

Incident Reports

Incident Report

• 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 without intervention, or failure to work with the IRB to resolve noncompliance
 - Deviations from the research plan made to avoid apparent and immediate hazard to a subject.
- Written Reports
Any of the following when conducted by a federal agency, funding agency, the IRB, monitor, state agency, or other oversight agency:
 - Audits
 - Inspections
 - Inquiries
- Suspension or early Termination of the Study
This unplanned suspension or termination could be required by the sponsor, investigator, or institution.
- Other
For example:
 - Unexpected incarceration of a subject when the study is not approved to include prisoners
 - Data/security breach
 - Significant or unresolved subject complaint
- None of the above

- Incident Reports = reporting unanticipated problems, adverse events, and non-compliance
- Must be submitted within 5 working days of the event
- Process is very similar to submitting a Modification

Renewals and Closures

- Only required if your project has an expiration or administrative check-in date issued by the IRB

Check-in & Continuing Review

* Request for More Time

Are you requesting more time for the project?

- Yes
 No

* IRB Oversight Arrangements

Indicate how IRB oversight is organized for this study. This should match what is in the latest approved version of this study (latest approved Modification or Initial approval).

- UM is the only IRB involved
 Study involving more than 1 site where each site will conduct their own IRB review
 Study involving more than 1 site where this site is the Reviewing IRB (IRB of Record) for other sites
 Study involving more than 1 site where this site is Relying on an External IRB
 Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is the Reviewing IRB (IRB of Record) for all sites
 Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is Relying on an External IRB

* Study & Subject Status

Check all that apply.

- Study has not started or is on hold
 Study enrollment is open; NO enrollment to date
 Study enrollment is open and ongoing
 Study enrollment is closed
 Treatment and/or active follow-up continues
 Long-term follow-up only (no intervention/interaction)
 Remaining activities limited to data analysis

Project Closure

* Closing Study

Do you wish to close this study?

- Yes

* Reason for study Closure:

B I U G [Rich text editor toolbar]

- No

* IRB Oversight Arrangements

Indicate how IRB oversight is organized for this study. This should match what is in the latest approved version of this study (latest approved Modification or Initial approval).

- Study involving more than 1 site where each site will conduct their own IRB review
 Study involving more than 1 site where this site is the Reviewing IRB (IRB of Record) for other sites
 Study involving more than 1 site where this site is Relying on an External IRB
 Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is the Reviewing IRB (IRB of Record) for all sites
 Multi-site study (multiple US sites participating in a research study using the same protocol) where this site is Relying on an External IRB

* Study & Subject Status

Check all that apply.

Frequently Asked Questions

FAQs

- **What about my study that is already in progress?**
 - Current in-progress studies will continue to utilize the paper/email application system for amendments, renewals, and closures. These studies will not be migrated to Cayuse HE.
- **Will my Cayuse HE application link to my grant information from Sponsored Projects?**
 - No, at this time Cayuse HE will not link to any Sponsored Projects information. However, this is a feature that we are hoping to implement in the near future, so stay tuned!
- **What if I have already started an IRB application using the old system?**
 - No worries! We are accepting paper/email applications until February 1, 2024 just in case you have already started an application.

FAQs

- **Do I still need to complete Human Ethics Training?**
 - YES. All research team members must have up-to-date CITI or UM Ethics training (within the past three years) and you will be asked to upload these certificates into the initial submission form.
- **Do I still need to use UM IRB's templates for consent forms?**
 - HIGHLY RECOMMENDED. These templates will continue to be available on the IRB website and you can upload these to your Cayuse submission.

Questions? Contact:

UM IRB Office

irb@umt.edu

406-243-6672

ISB 104 – 8am – 5pm or by appointment