Cayuse Human Ethics Training

University of Montana Institutional Review Board

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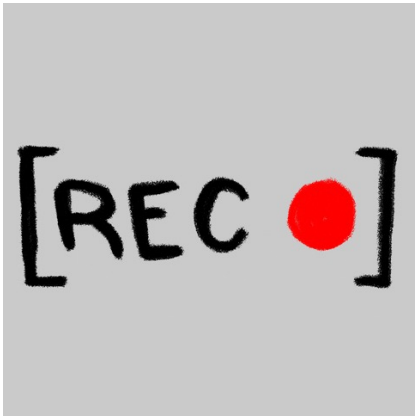
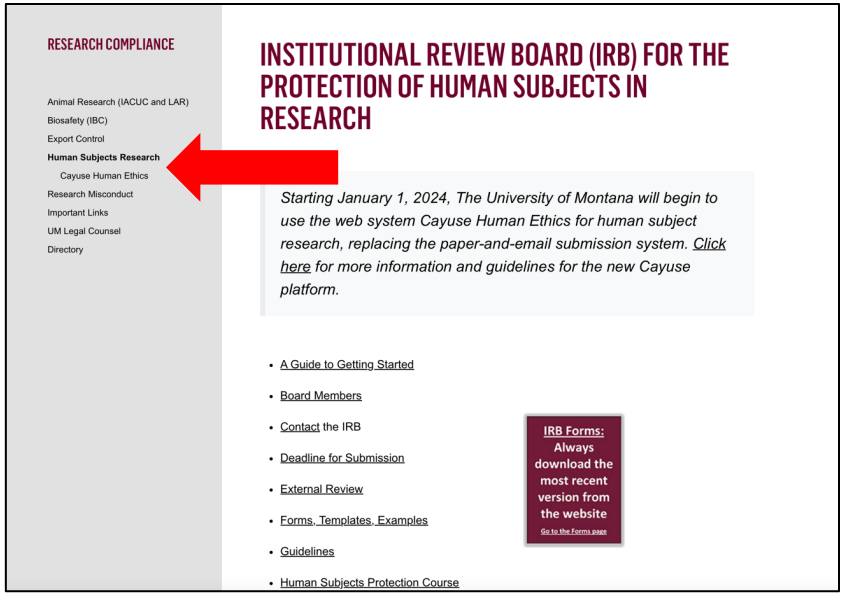
FYI:

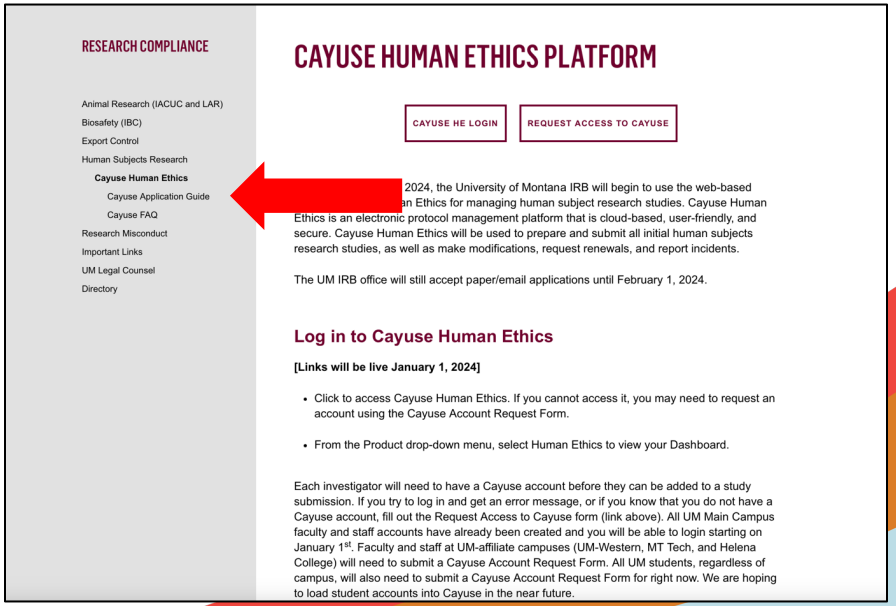
- This session will be recorded
- This PowerPoint will be made available on our website
- I will pause for questions periodically



Resources

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





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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

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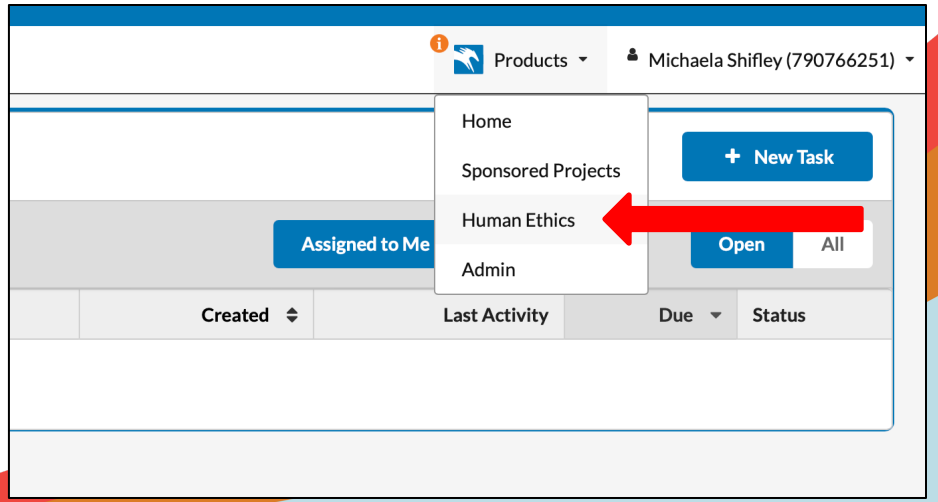
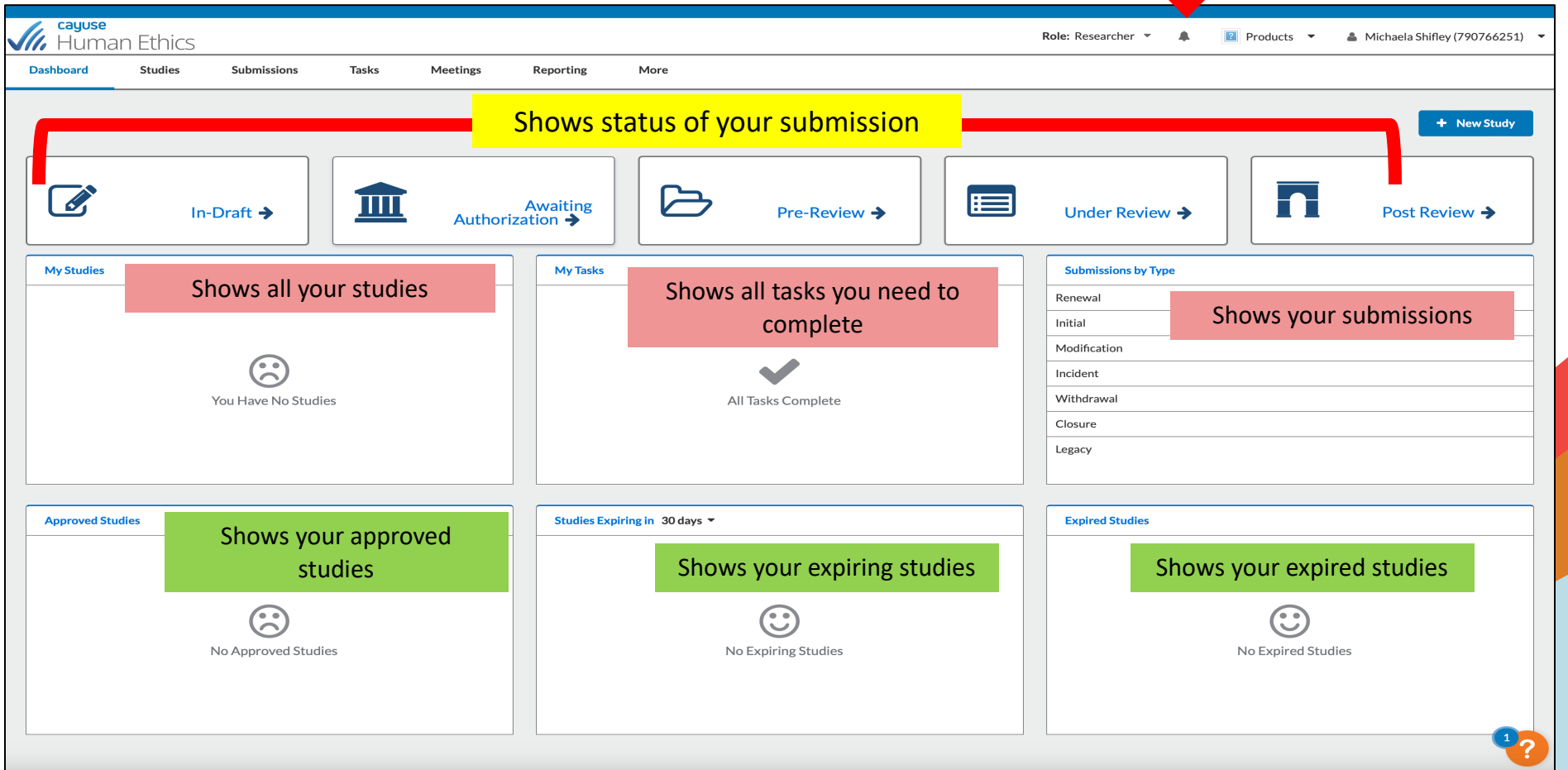
Logging into Cayuse IRB

- 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 HE Dashboard

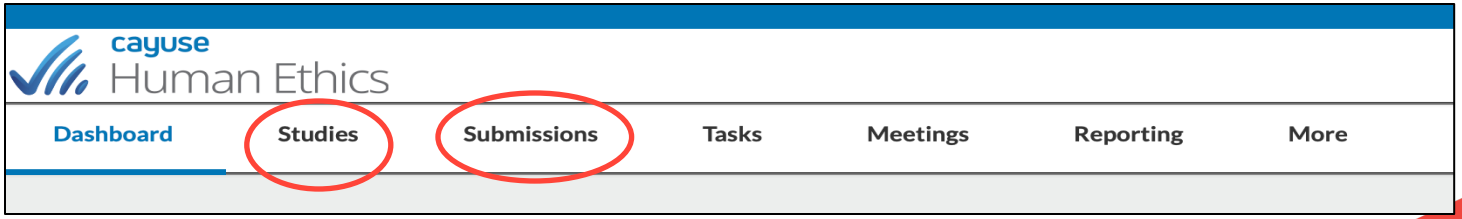
Notifications appear here! Click bell to view



Studies vs. Submissions

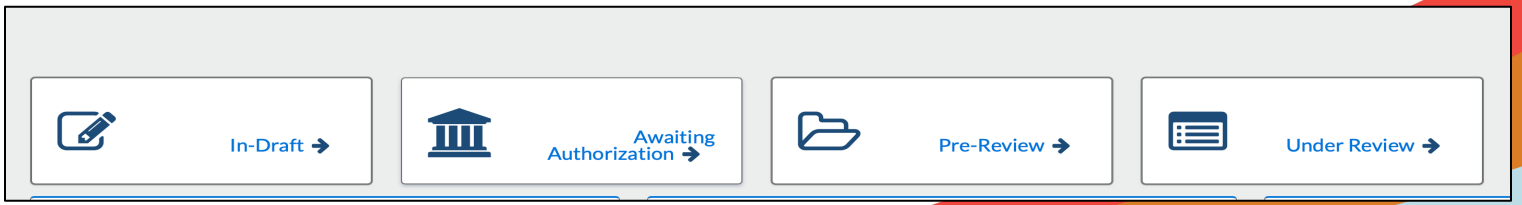
- **STUDY refers to your entire research project**

- **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

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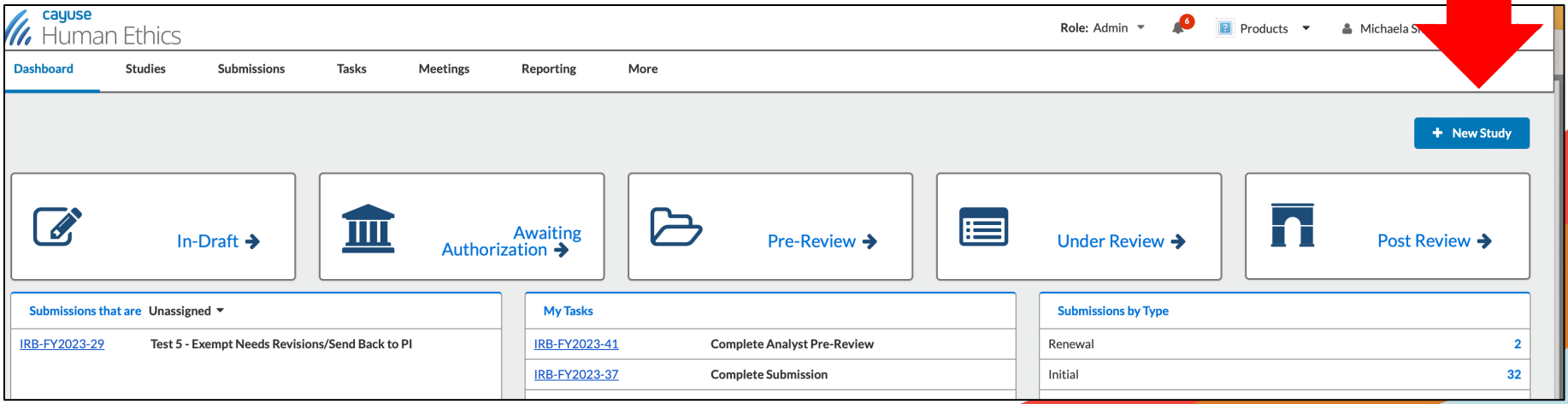
Creating a New Study

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



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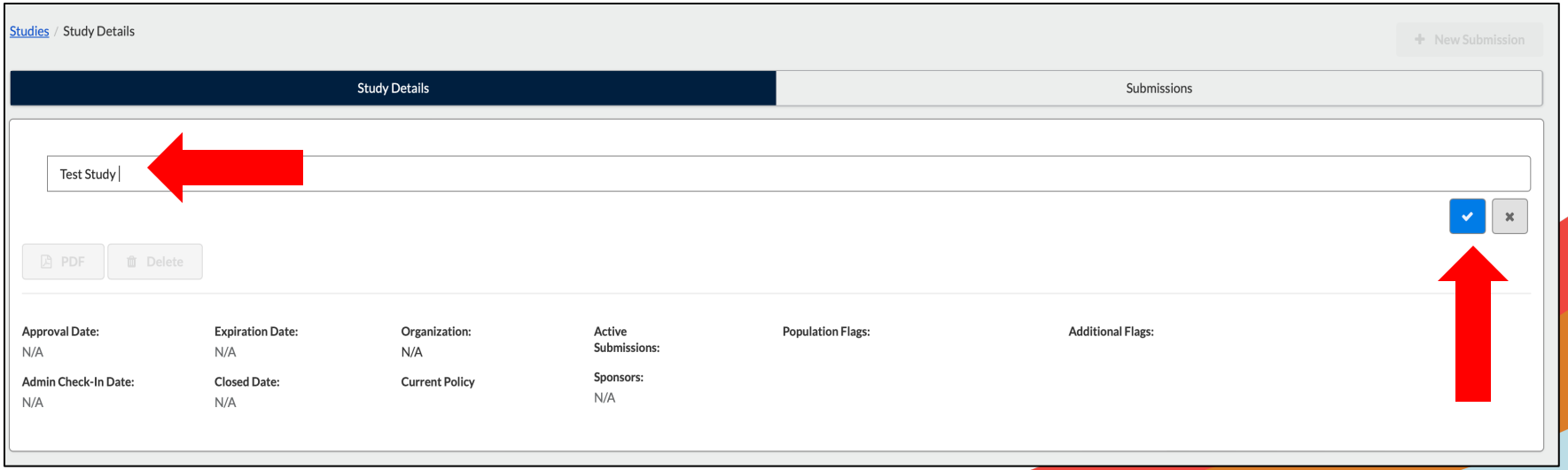
Study Title

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



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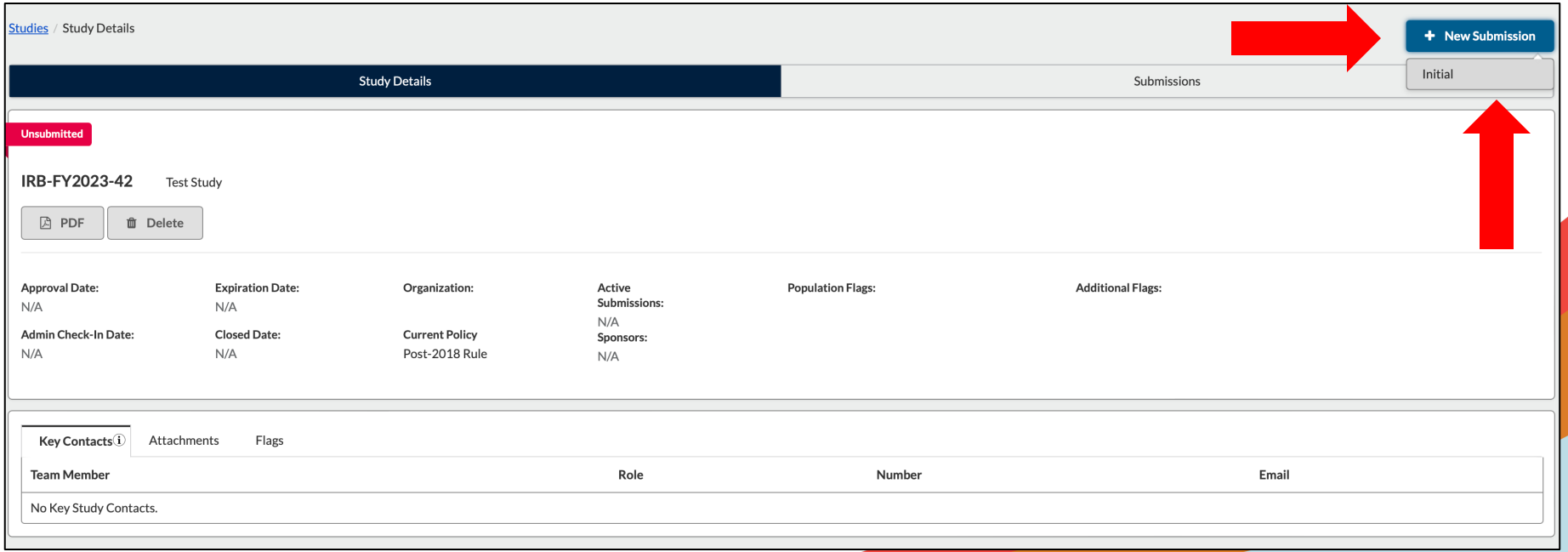
Begin Your Application

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



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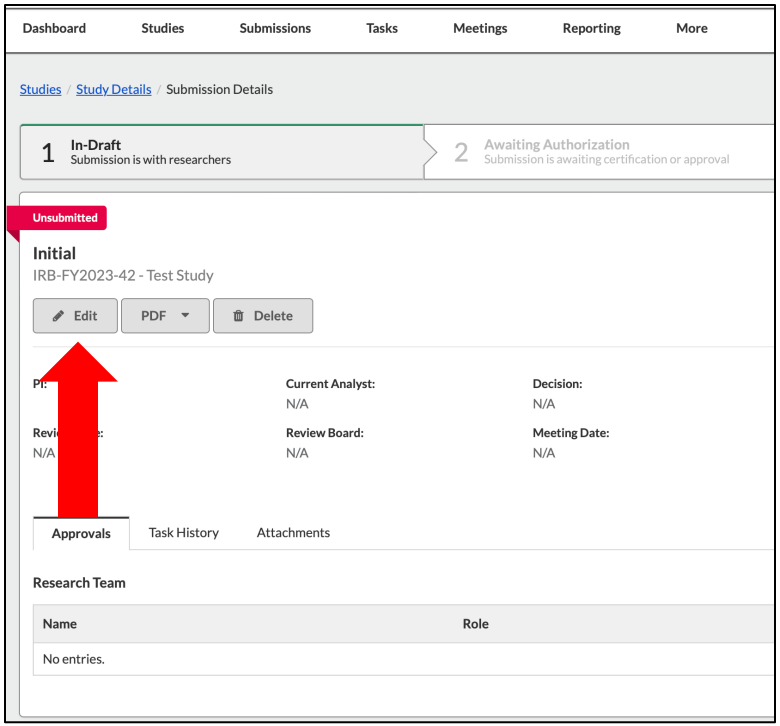
Editing an Initial Submission



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!

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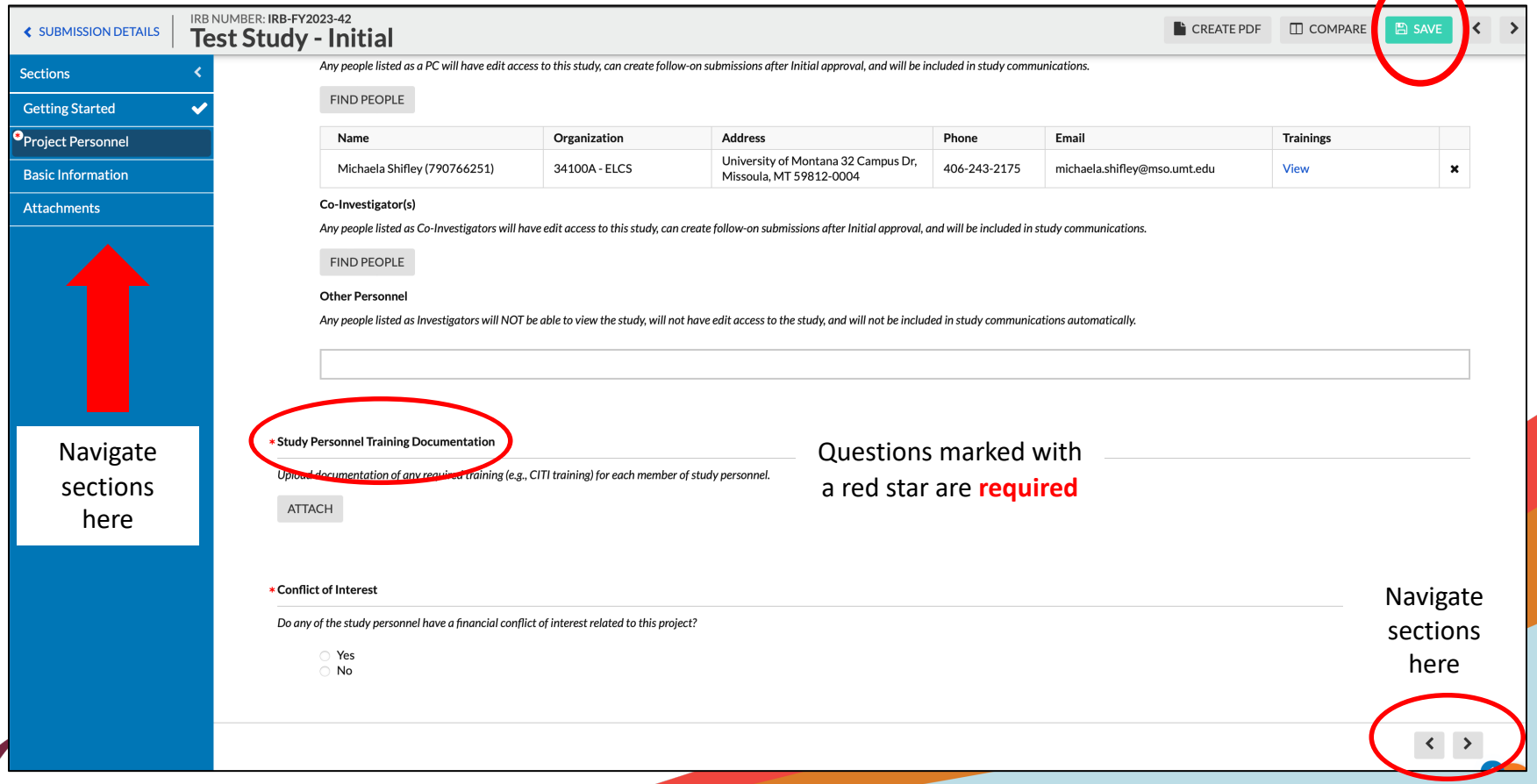
Completing Your Protocol

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



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

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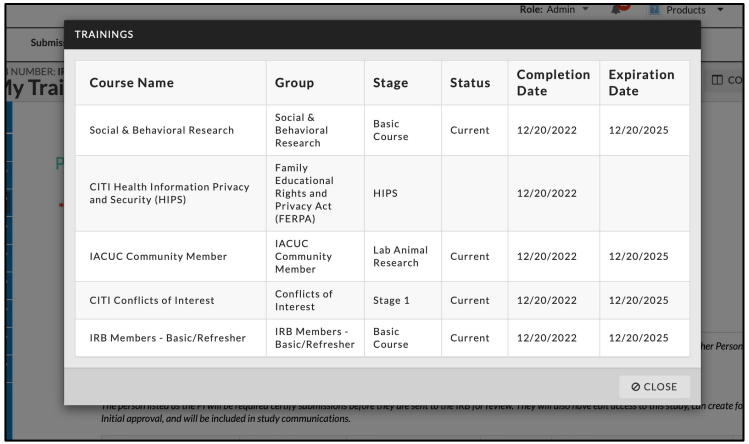
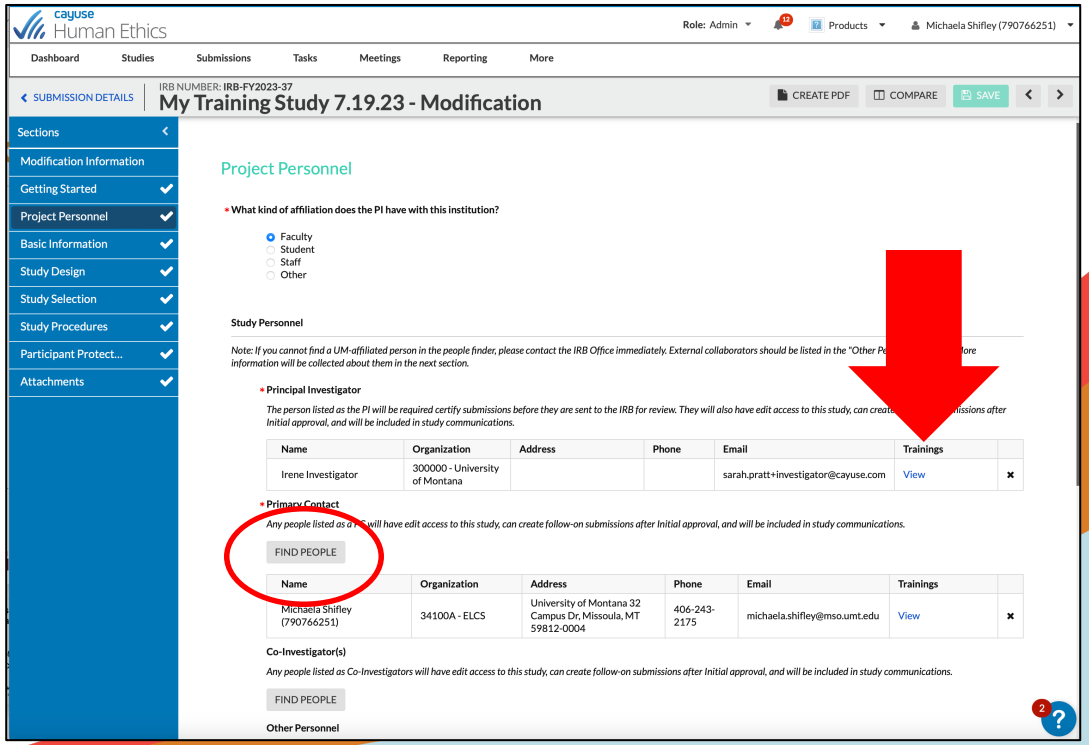
Adding Personnel

- 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





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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'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 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 <u>all</u> instructions first before completing this section

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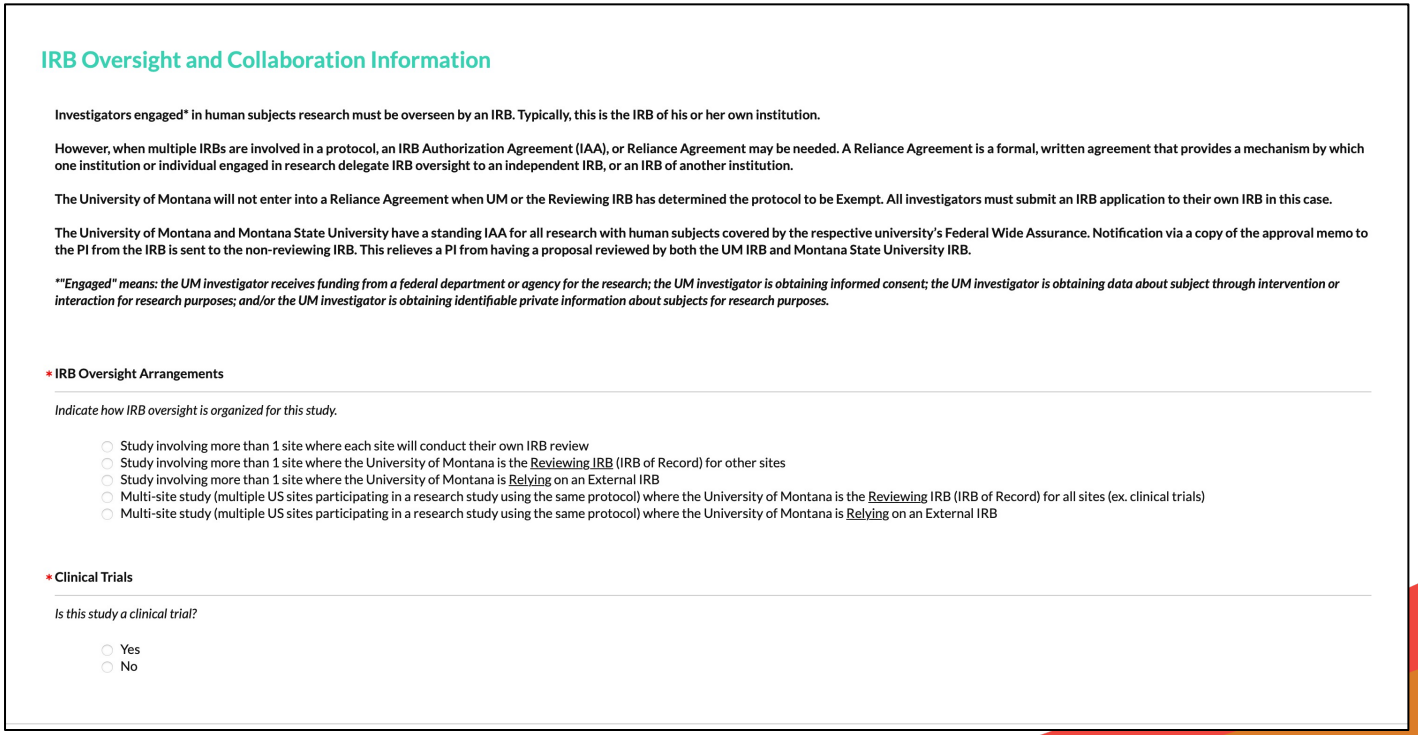
Reliance Agreements



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

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

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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

- 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

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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

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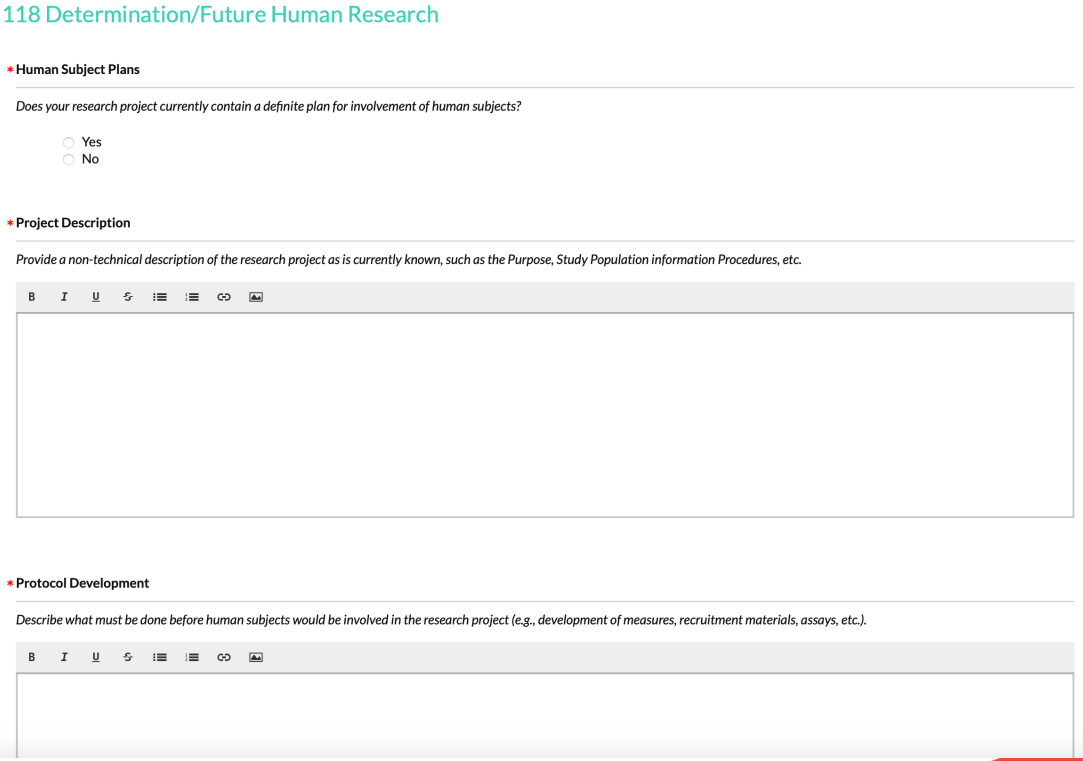
Section 118 Determinations



- 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

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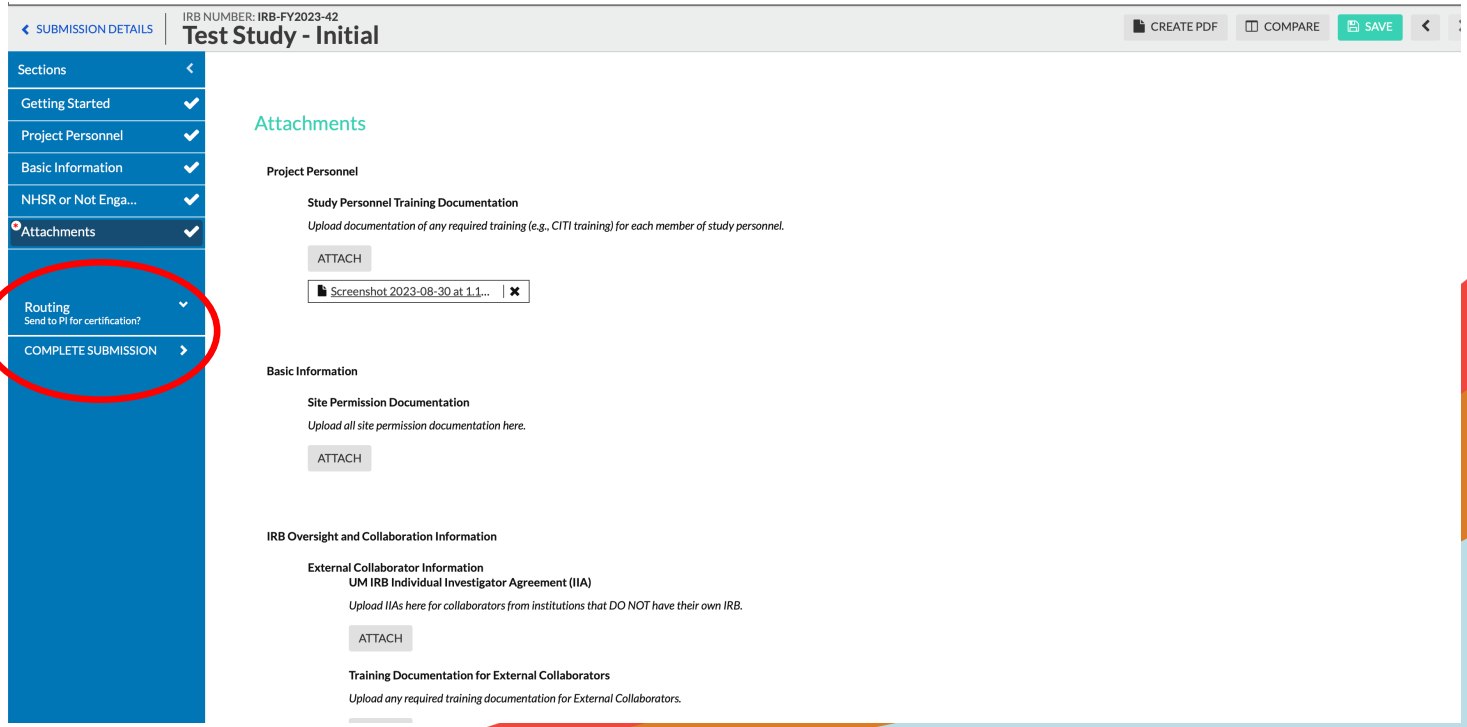
Completing the Submission

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



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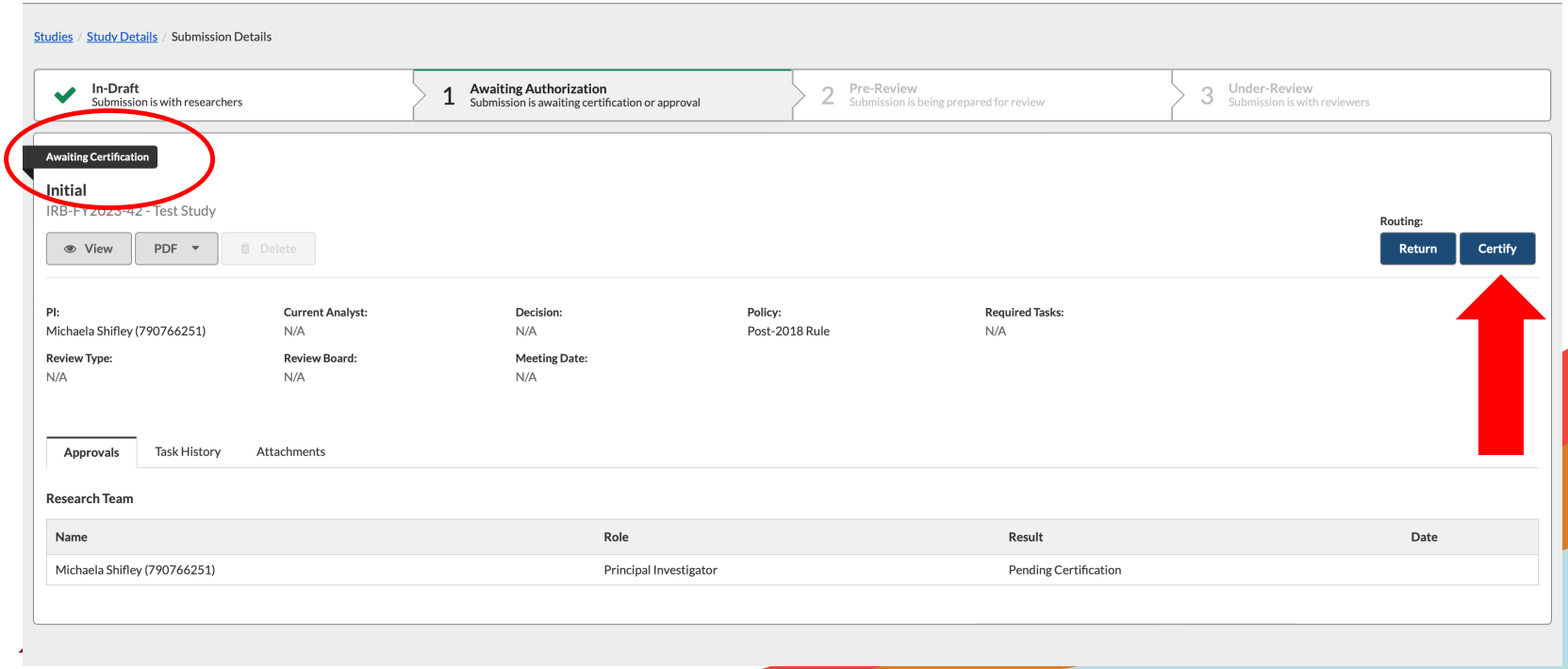
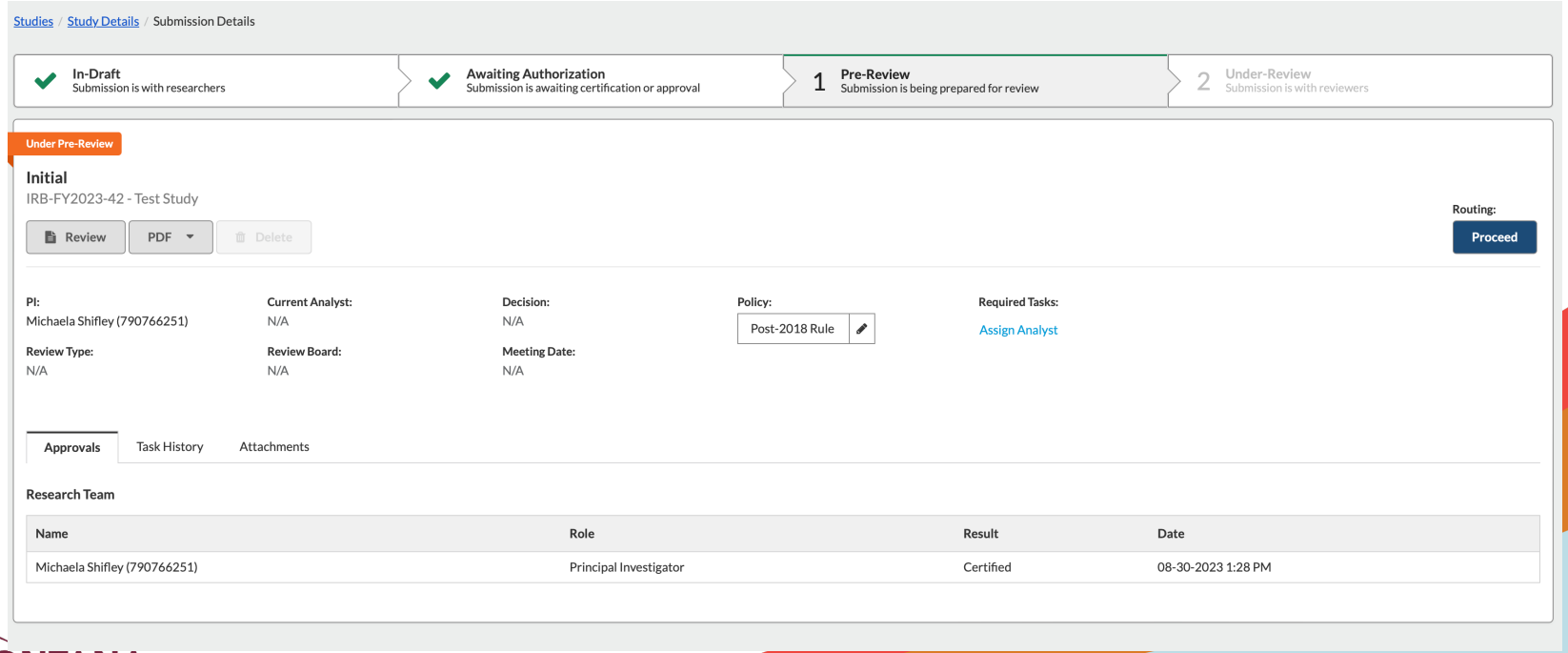
Certifying the Submission

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



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



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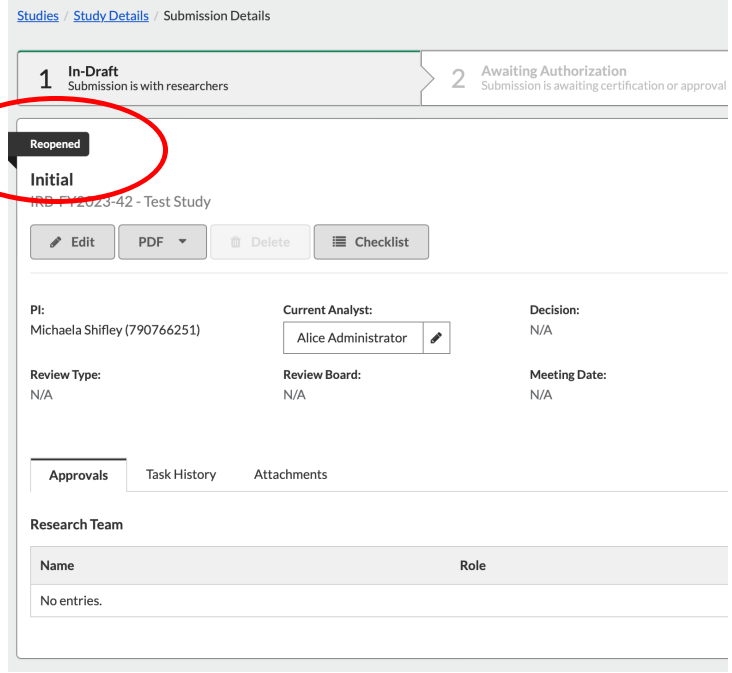
Addressing IRB Comments



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

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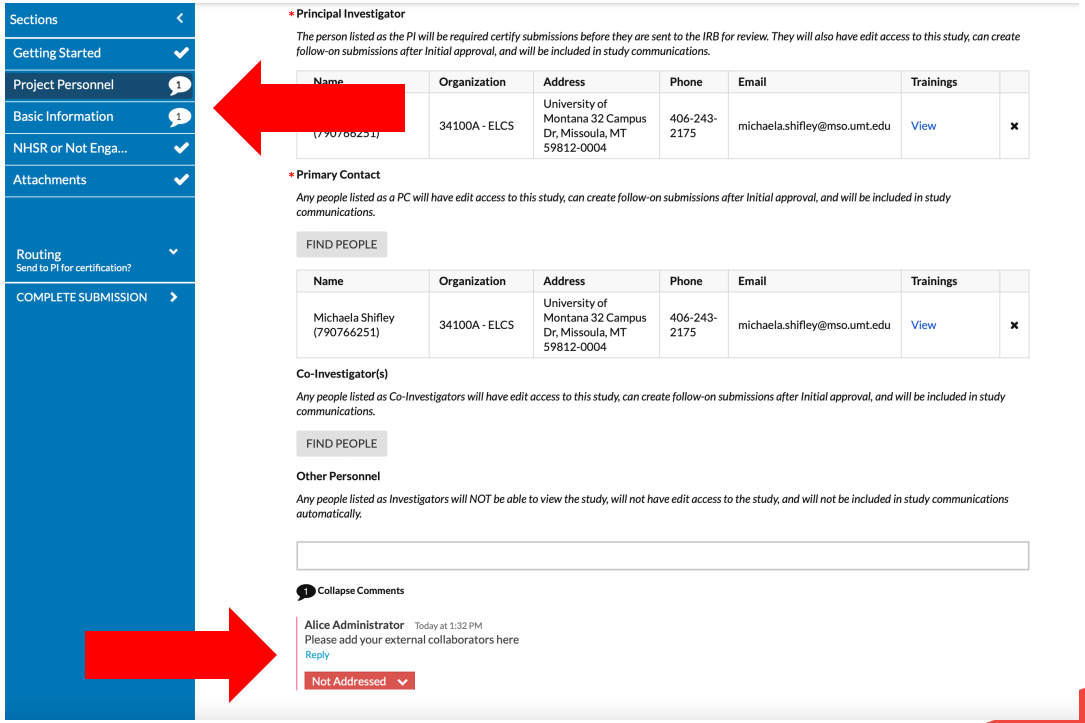
Addressing IRB Comments



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

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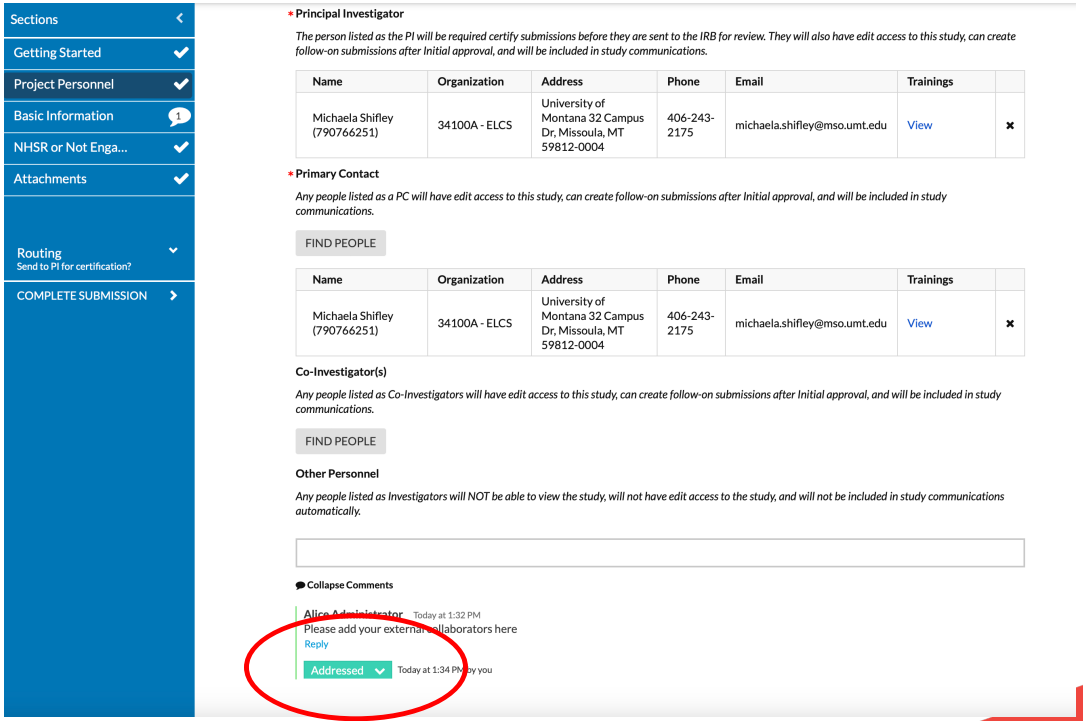
Addressing IRB Comments



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!!**

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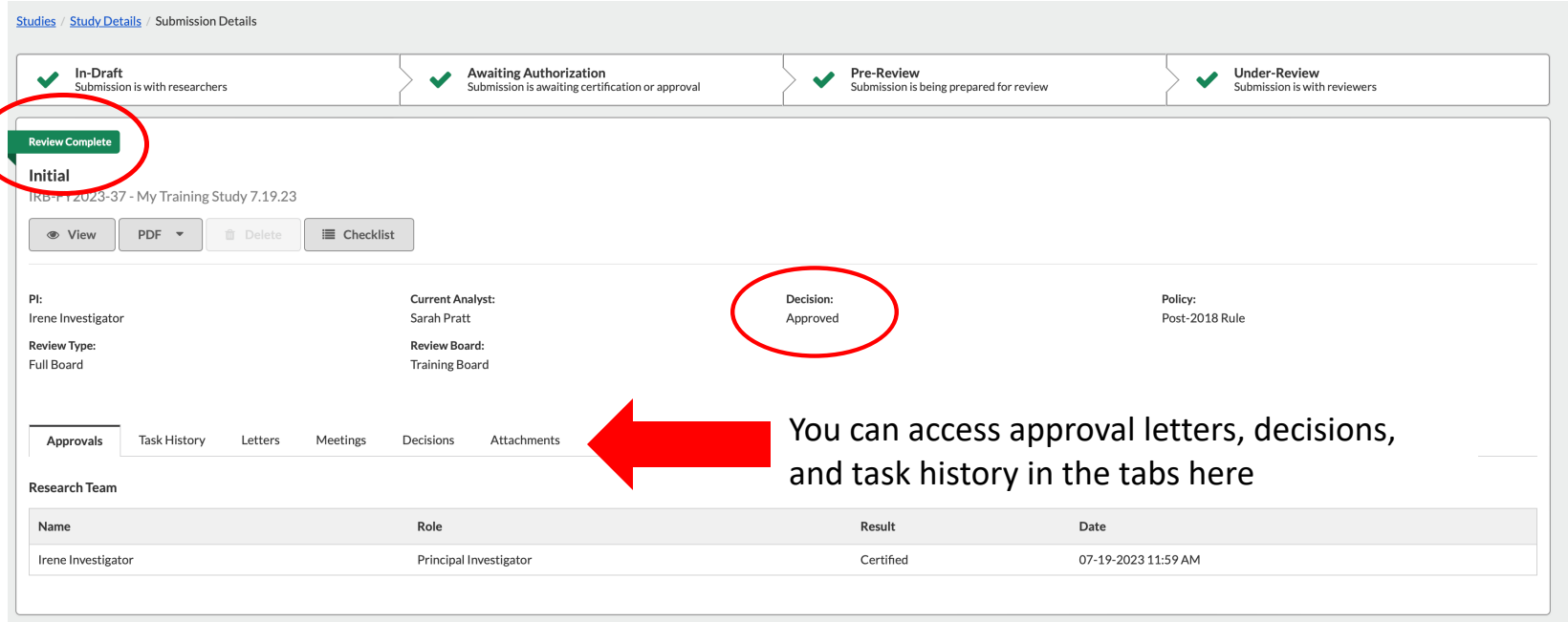
Review Complete



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

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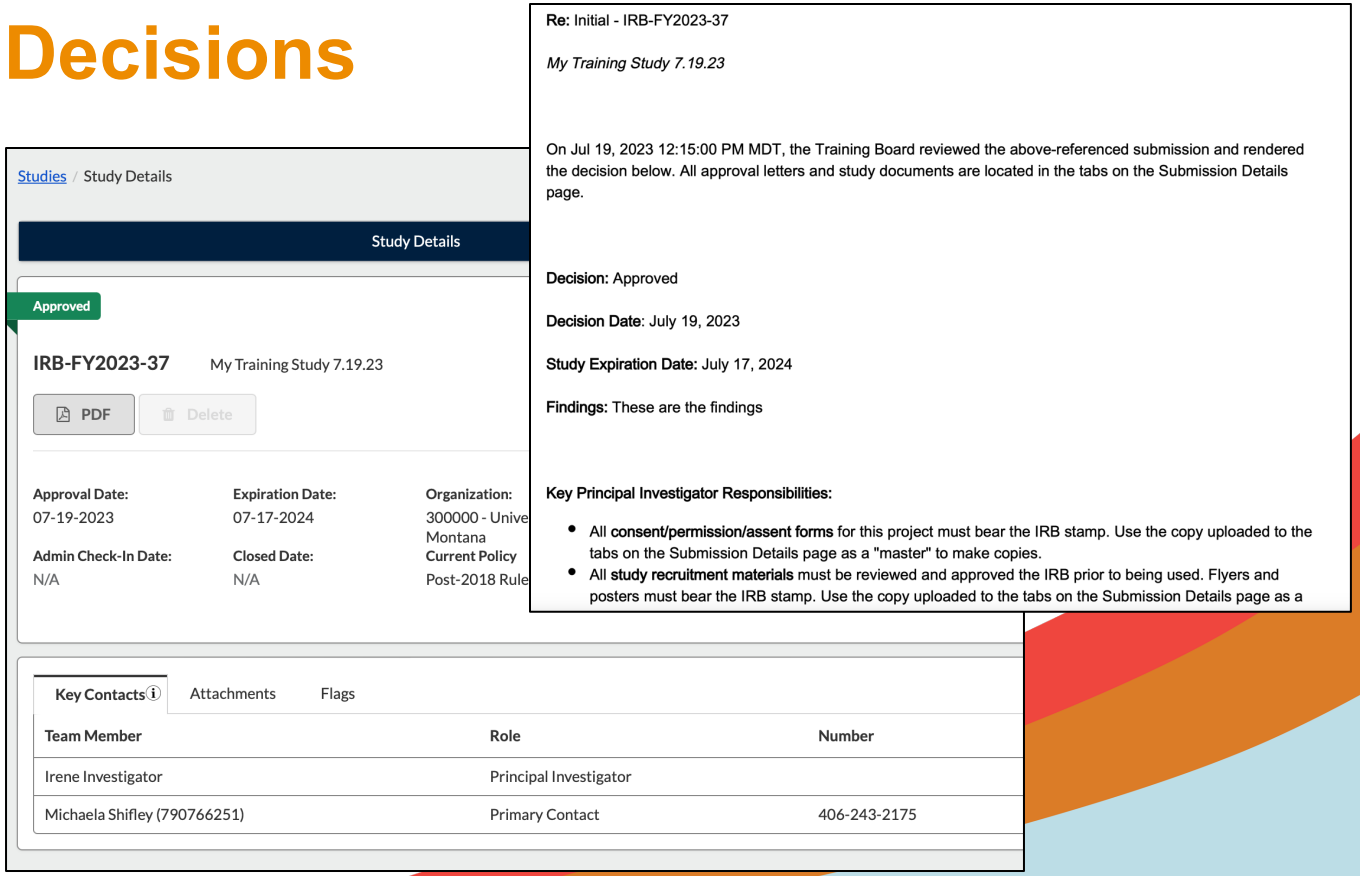
Possible IRB Decisions

- **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: 07-19-2023

Expiration Date: 07-17-2024

Organization: 300000 - Unive Montana

Admin Check-In Date: N/A

Closed Date: N/A

Current Policy Post-2018 Rule

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

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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

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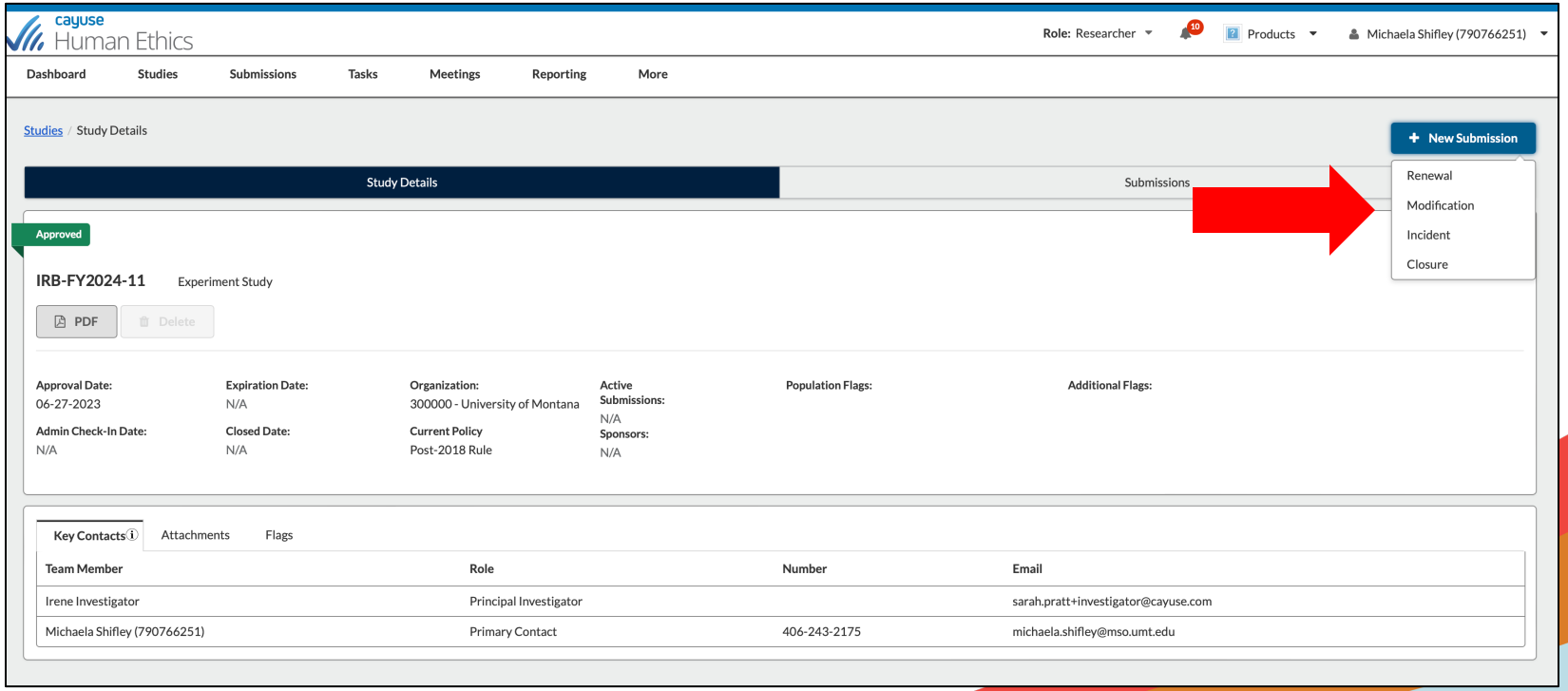
Modifications

- 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



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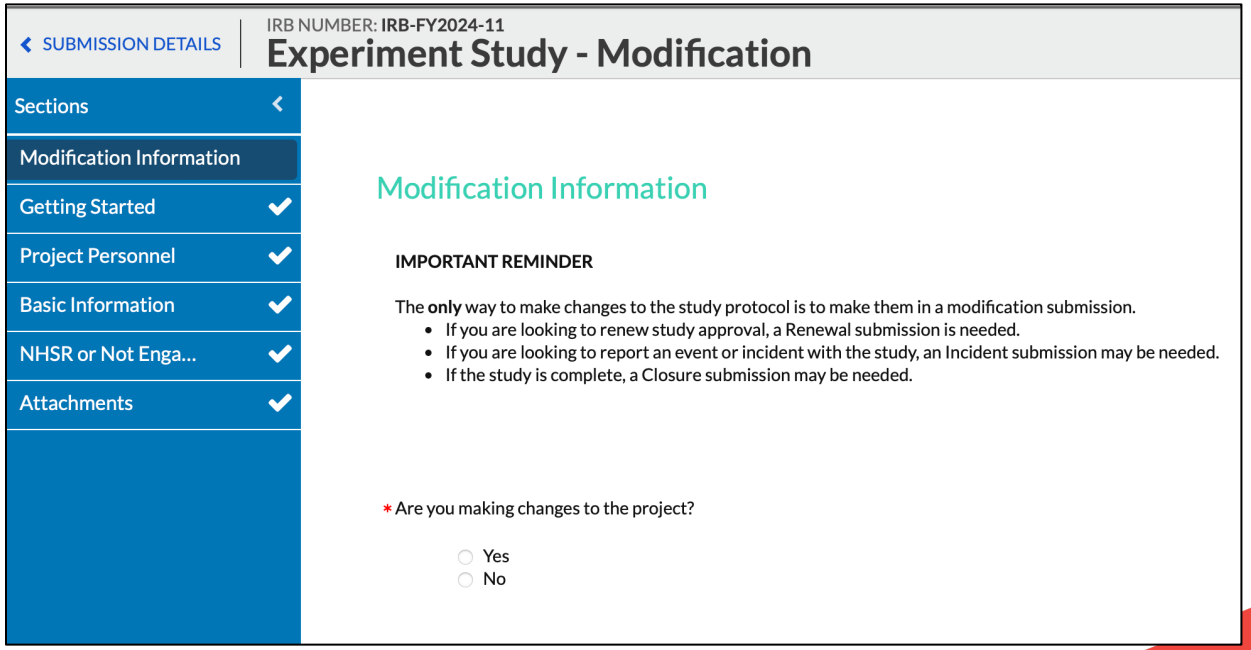
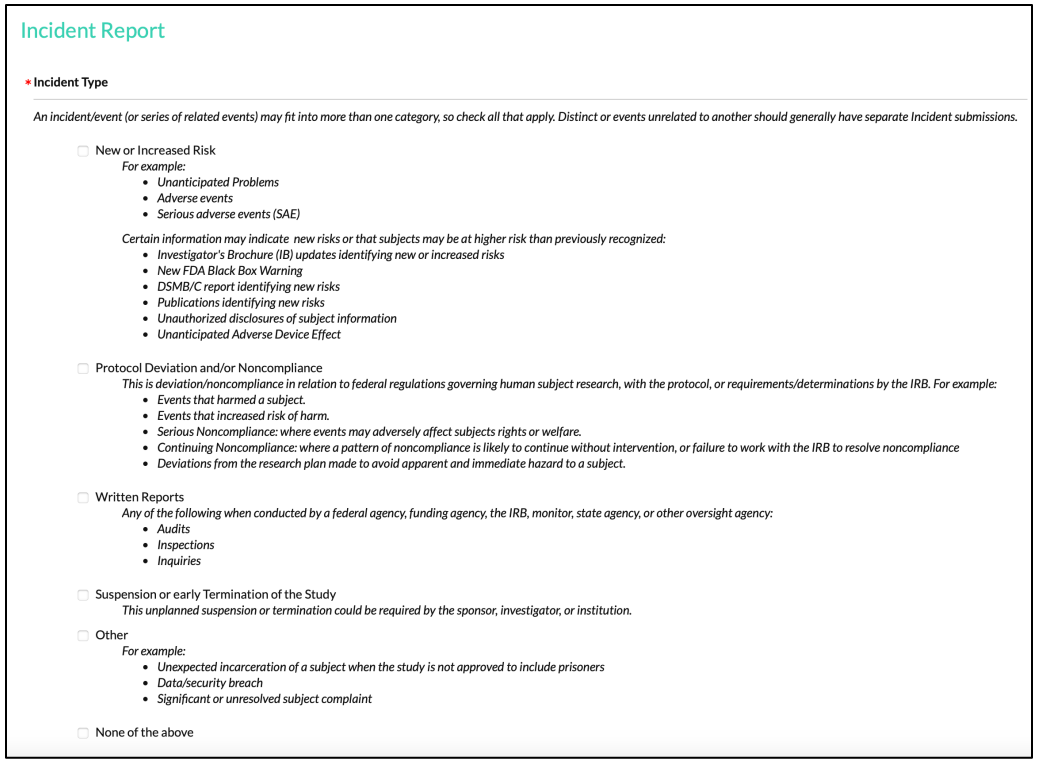
Modifications



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

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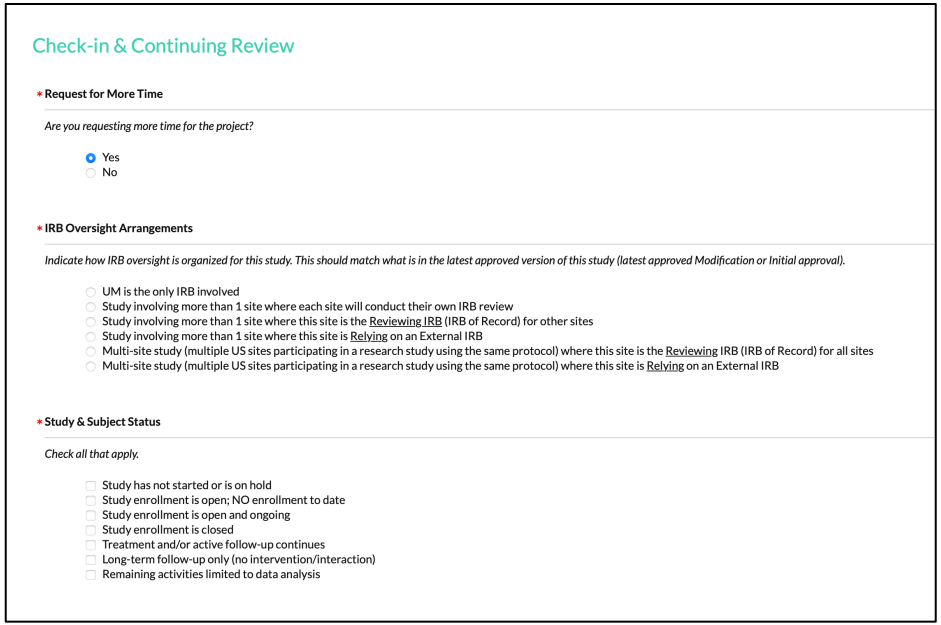
Renewals and Closures

- 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**

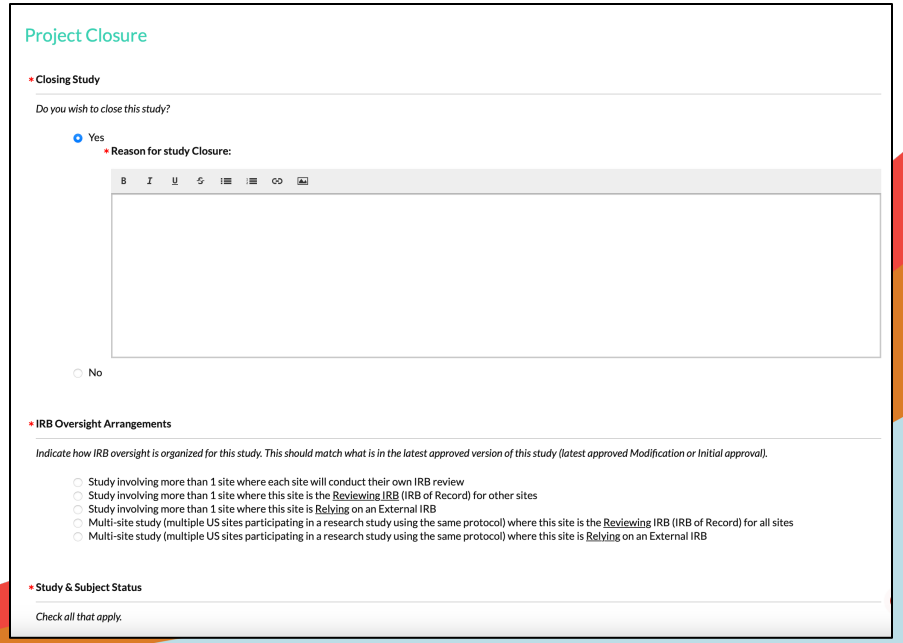
Indicate how IRB oversight is organized for this study. This should match what is in the latest approved version of this study (latest approved Modification or Initial approval).

- ( ) 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:**
- ( ) 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.

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Frequently Asked Questions

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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

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