

For IRB Researchers: How to Create a Protocol in Cayuse

Presentation Overview

In this presentation, we will cover:

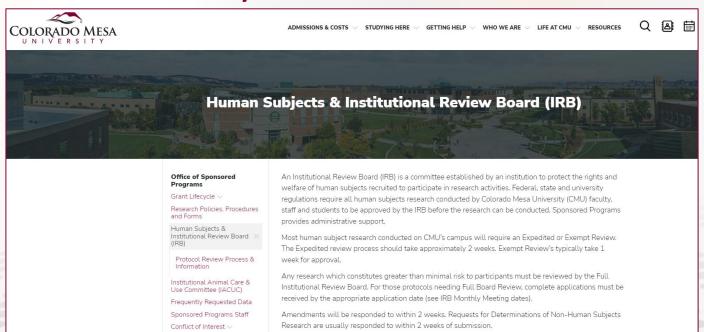
- Accessing Cayuse
- Building a protocol
- Submitting your protocol to the IRB Office (Office of Sponsored Programs)
- Who to contact with Cayuse-related inquiries



Accessing Cayuse: Finding the Site

You can access Cayuse for IRB Protocols through the CMU IRB website, or with a direct link

- www.coloradomesa.edu/sponsored-programs/irb
- https://coloradomesa.app.cayuse.com/
- Bookmark the site for easy future access!



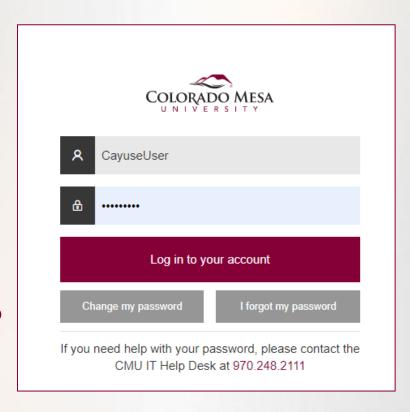
Accessing Cayuse: Creating a Cayuse Account

You will likely need to contact the IRB Administrator to request a new account

- Many <u>faculty</u> members will already have accounts, so try logging in first
- <u>Students</u> will need to request a new account for their first protocol

To request a new account:

- Complete the Account Request Form on the CMU IRB website (allow up to 2 business days for processing)
- www.coloradomesa.edu/sponsored-programs/irb

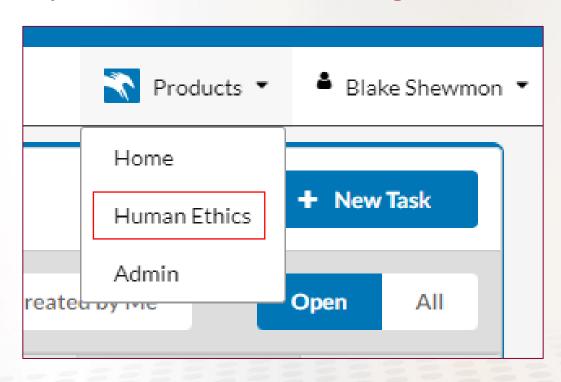


Once you have an account, you will use your MavZone credentials to login

Please ensure all research team members have accounts before starting!

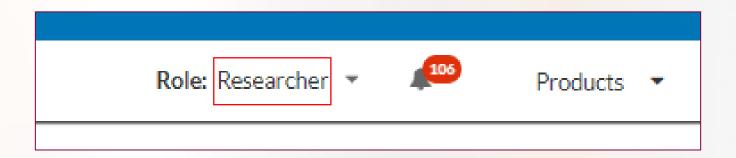
Once logged in, click **Products** \rightarrow **Human Ethics**

- Human Ethics and Home will likely be your only options
- Admin will not show up, as it does in the image below



Once logged in, click **Products** \rightarrow **Human Ethics**

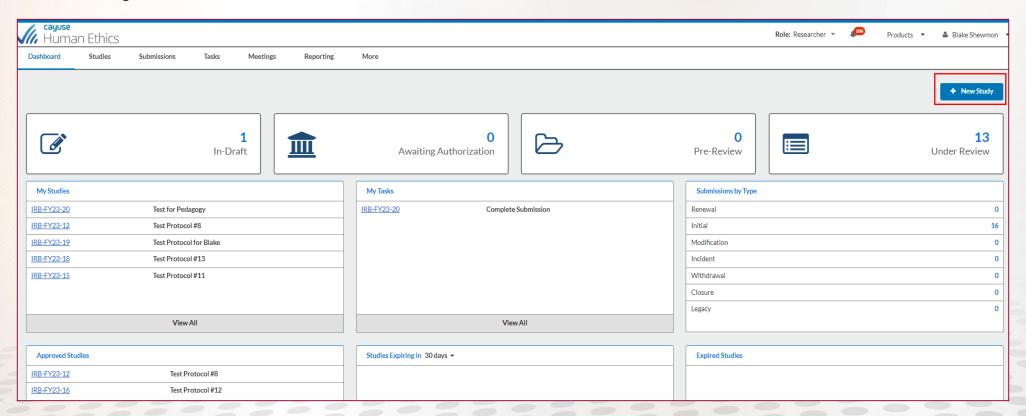
Ensure that the Researcher role is selected



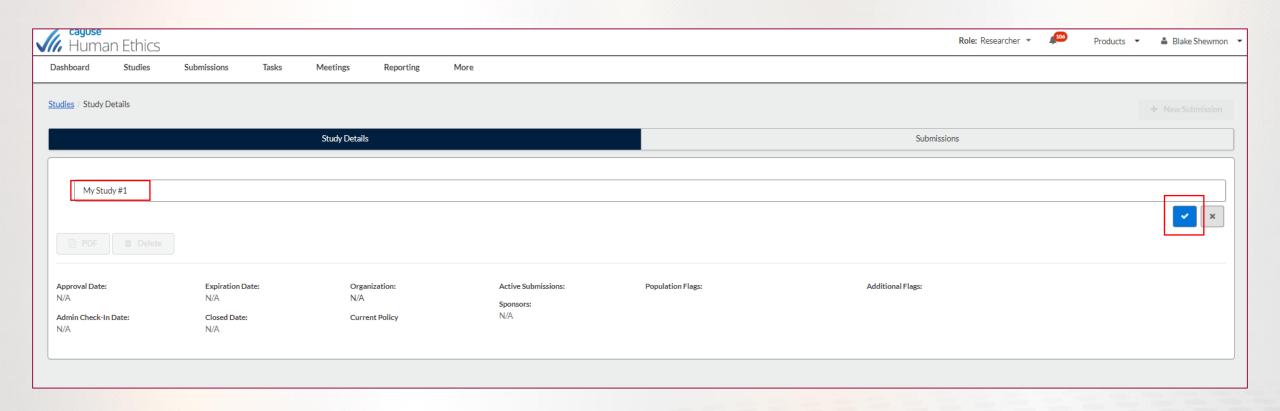
Once logged in, click **Products** \rightarrow **Human Ethics**

Ensure that the Researcher role is selected

Click New Study

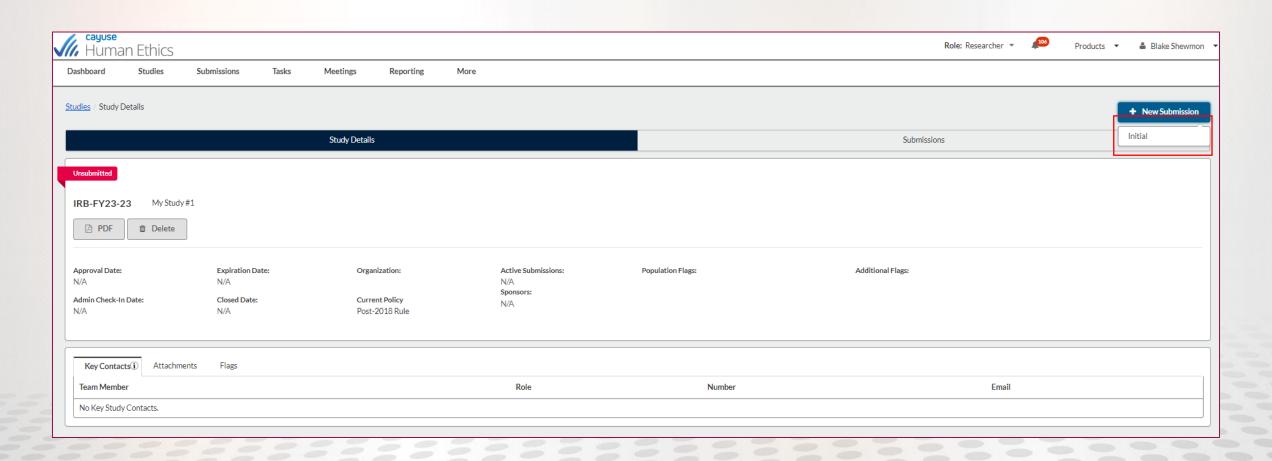


Enter a name for your study, then click the blue check mark



Enter a name for your study, then click the blue check mark

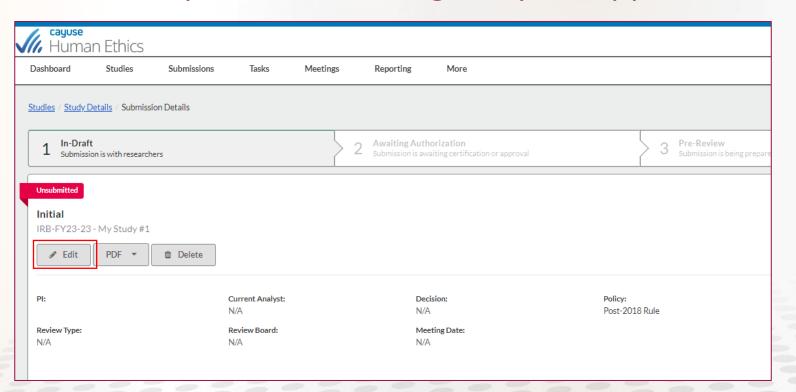
Click New Submission > Initial



Enter a name for your study, then click the blue check mark

Click New Submission → Initial

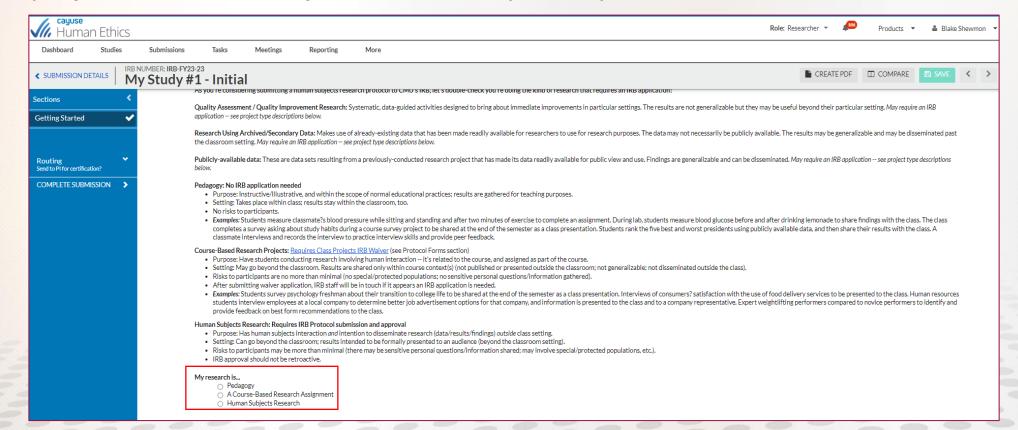
Click Edit -> This will allow you to start filling out your application



Building a Protocol: Introductory Questions

Please read all provided information and answer the question at the bottom

- If you believe—based on the info provided—that your study is Pedagogy or a Course Based Research Assignment, your protocol will end here
 - Use the hyperlink for Course Based Research and complete the Request for Waiver Form
- If your project is Human Subjects Research, please proceed

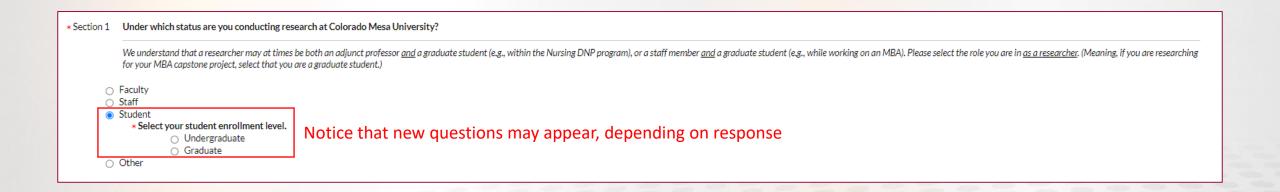


Building a Protocol: Answering Questions

You are now in the Human Subjects Research protocol application

Work your way through and answer questions

- Red asterisks indicate required questions
- Carefully read the instructions/descriptions for each question
- Depending on your responses, new questions may generate



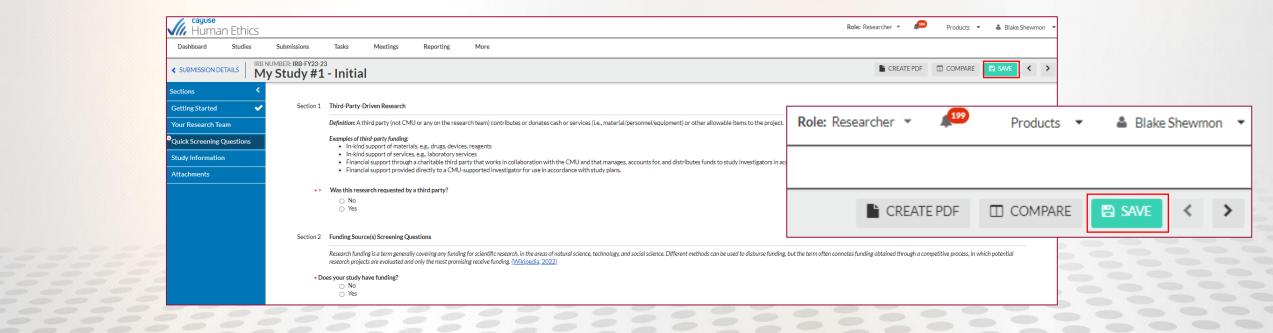
Building a Protocol: Answering Questions

It may be easier to utilize the Word version IRB application and copy-and-paste responses into Cayuse as you work through the questions

- The Word form is found on the CMU IRB website
- This may also allow you to work offline on your protocol

MAKE SURE TO SAVE OFTEN!

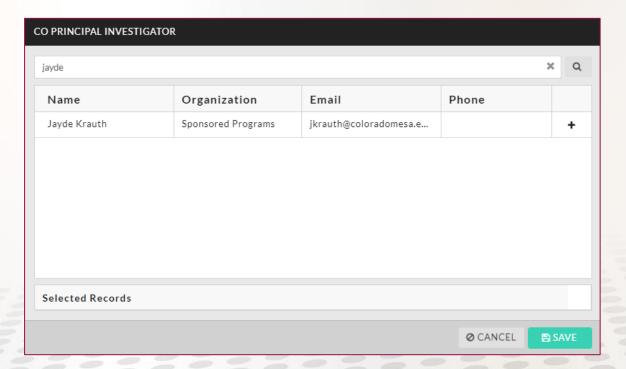
Cayuse does not auto-save any work for you



Building a Protocol: Adding Investigators

Please ensure that all members of your research team have active Cayuse accounts before you begin work on your protocol application

- When adding co-investigators and faculty advisors, Cayuse will draw users from the system for you to add
- You cannot manually enter the name, email, etc. for any study personnel



Building a Protocol: Adding Attachments

Some questions in the protocol request attachments; some are required

Red asterisks indicate a requirement

To add an attachment to these types of questions, click Attach

You will also get to review your attachments at the end, prior to submission

* 7.1 Attach your informed consent form(s) below.

Please attach copies of informed consent/assent forms, emails, and/or letters.

NOTE: If participants are under 18 you must attach parental/guardian consent forms and participant assent forms.

ATTACH

Sample documents: See Informed Consent Template docs here!

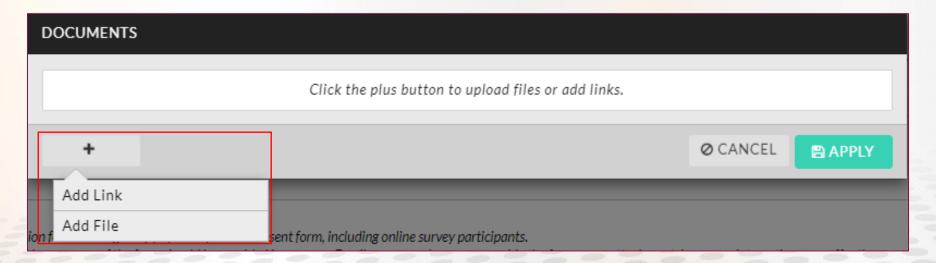
Building a Protocol: Adding Attachments

After clicking Attach, you will need to add either a link or file

- We ask that you submit files whenever possible, preferably PDFs
- Links may not always have sufficient sharing permissions (i.e. a link to a document in OneDrive might not be accessible by the IRB reviewer)

Click the + symbol, then select Add Link or Add File

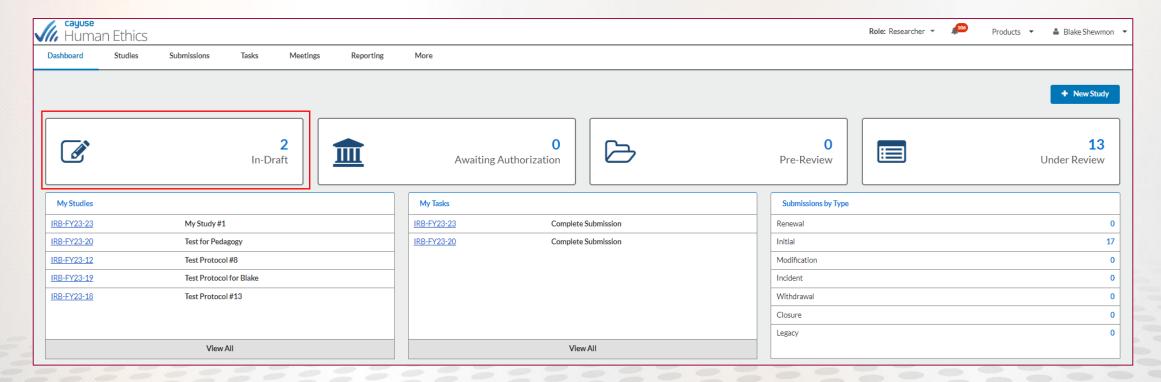
You can add multiple links/files



Building a Protocol: Resuming Editing

If you need to pause your editing and resume at a later date:

- Make sure to save your work first!
- Once the work is saved, you can exit out of Cayuse
- When you log in again, click In-Draft to view your protocol draft(s)

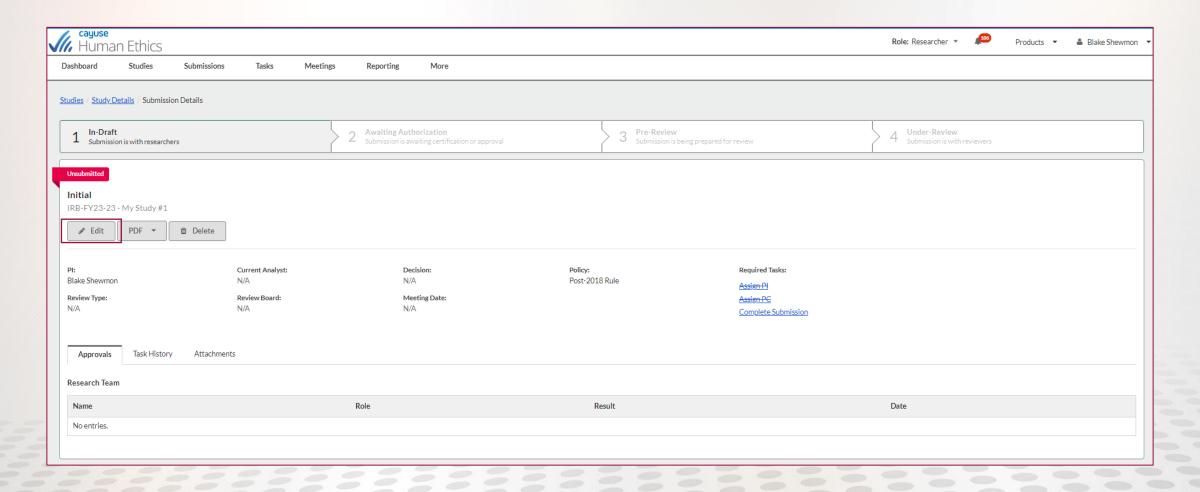




Building a Protocol: Resuming Editing

After selecting the protocol you want to work on, click Edit and make your changes

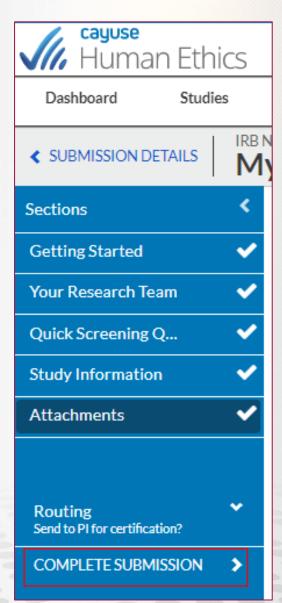
Again, make sure to save throughout!



Building a Protocol: Ready to Submit

The left-hand sidebar will show checkmarks next to each section once all required questions have been answered

- A checkmark will not appear if any required questions remain unanswered in a section
- Once you have completed all sections, the option to Complete Submission will appear

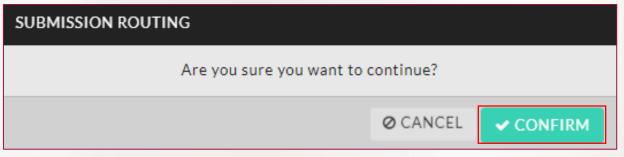


Building a Protocol: Ready to Submit

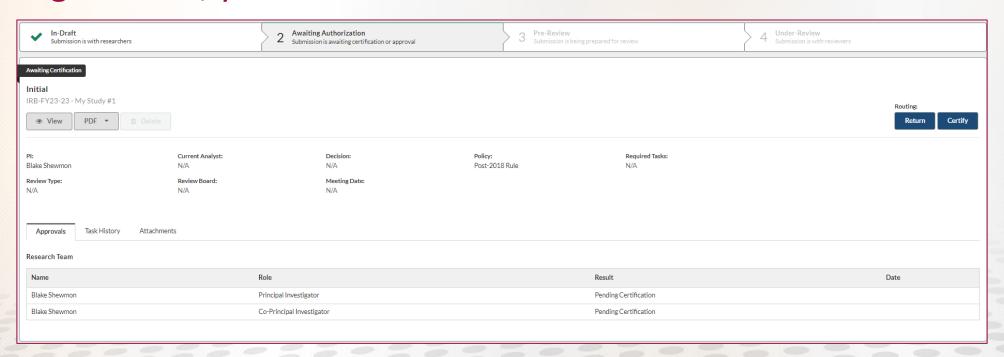
Once you have reviewed your protocol and are ready to

submit, click Complete Submission

Then click Confirm



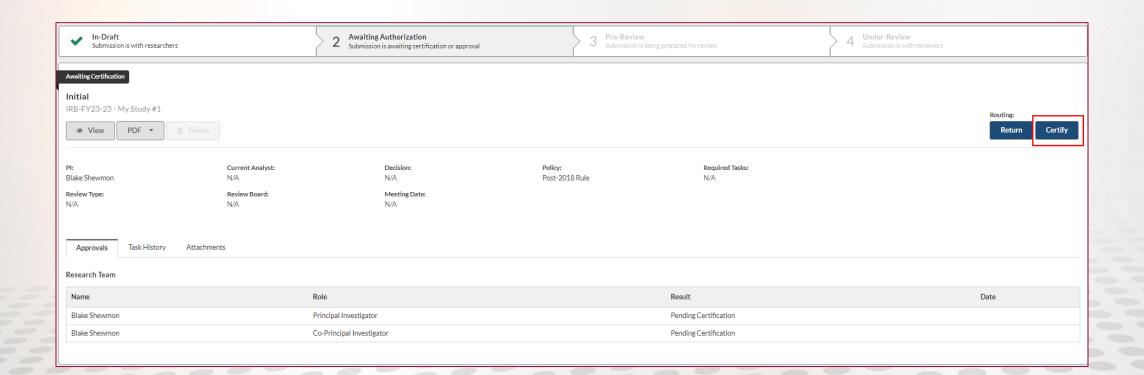
After clicking Confirm, you are taken to the screen below



Building a Protocol: Ready to Submit

By clicking **Certify**, the study is sent to the IRB Office (Sponsored Programs) for review by the IRB Administrator

 Only the PI can certify the study, but all members of the research team will receive a confirmation email



Building a Protocol: Once Submitted

After the PI certifies and submits the protocol to the IRB Office for review, all research team members will receive the following email:



Institutional Review Board

1100 North Avenue • Grand Junction, CO 81501-3122 irb@coloradomesa.edu

TO: Blake Shewmon, Blake Shewmon, Blake Shewmon

FROM: IRB Administrator

DATE: Oct 28, 2022 9:35:55 AM MDT

RE: Notice of Receipt of Initial Submission on Oct 28, 2022 9:35:55 AM MDT

STUDY #: IRB-FY23-23

STUDY TITLE: My Study #1

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

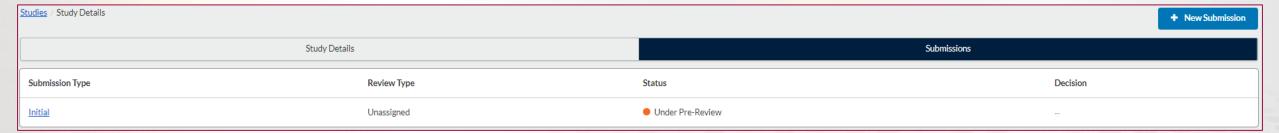
Thank you,

CMU IRB Administrator

Building a Protocol: Once Submitted

While the study is under pre-review by the IRB Administrator, members of the research team will see the following on the **Studies** page in Cayuse

udies / Study Details						+ New Submiss	
Study Details					Submissions		
Submitted							
IRB-FY23-23 My Stud	dy#1						
☐ PDF ☐ Delete							
Approval Date:	Expiration Date:	Organization:	Active Submissions:	Population Flags:	Additional Flags:		
N/A	N/A	Sponsored Programs	<u>Initial</u>				
Admin Check-In Date: N/A	Closed Date: N/A	Current Policy Post-2018 Rule	Sponsors: N/A				

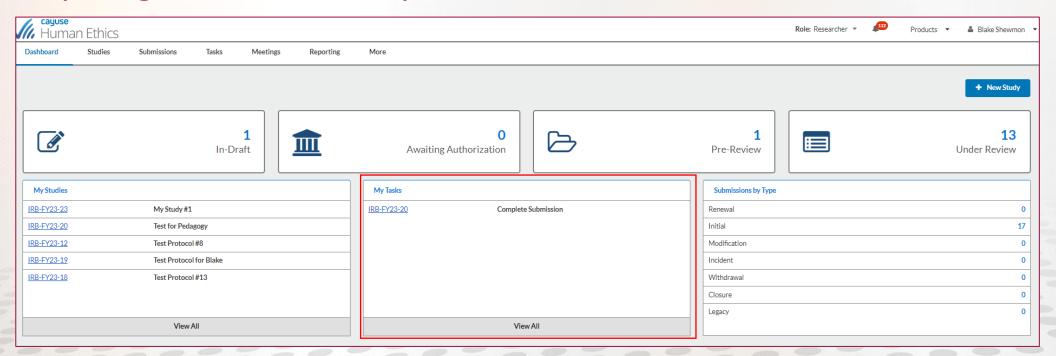


Building a Protocol: Once Submitted

After submitting the study for review, you will be notified of updates in the review process (approval, requested modifications, etc.) via email

 Please ensure that emails from do-not-reply@cayuse.com are not directed to your spam folder

Please also use the My Tasks tab in Cayuse to see the status of your protocol and if anything is needed from you



Reviewing Your Protocol

General information about the review process:

- Your study first goes to the IRB Administrator (Office of Sponsored Programs)
- The IRB Administrator pre-reviews the document for completeness
- The IRB Administrator sends the protocol to an IRB Member for review
- IRB Members have 10 business days to complete their review
- The IRB Administrator will relay the reviewer's feedback or a decision letter to the researcher(s)
- The study may need to be revised and resubmitted if the IRB Member requests modifications
- IRB Members will also be given 10 business days for each additional review period for revised protocols
- No work on your study (including recruiting efforts) can begin until you receive a formal approval letter from the CMU IRB

Who to Contact With Cayuse Questions

Any questions during the process can be directed to the IRB Administrator

- irb@coloradomesa.edu
- 970-248-1493
- Or stop by the Office of Sponsored Programs (LHH 209)

