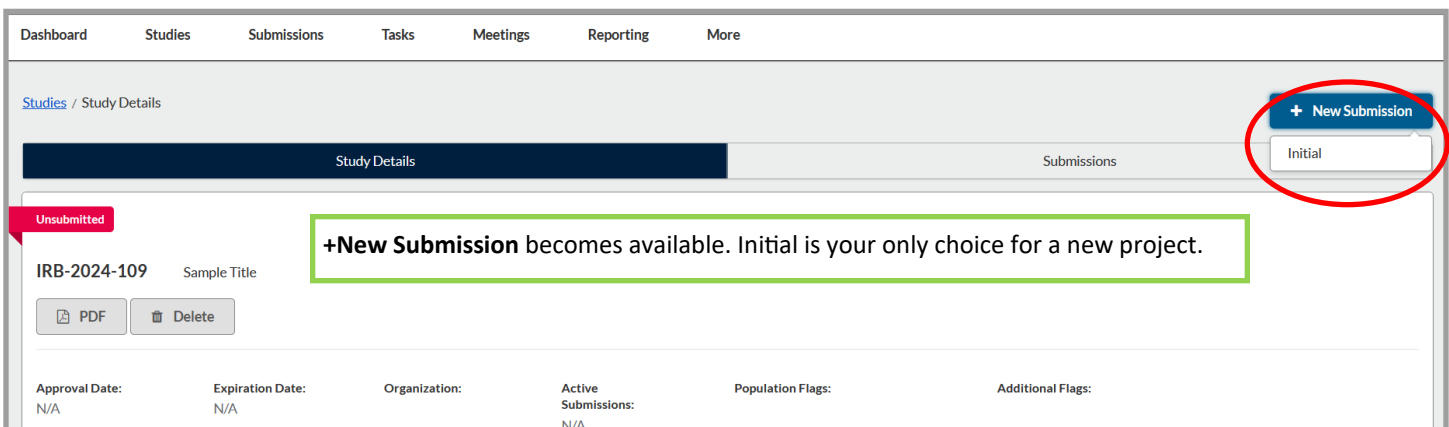
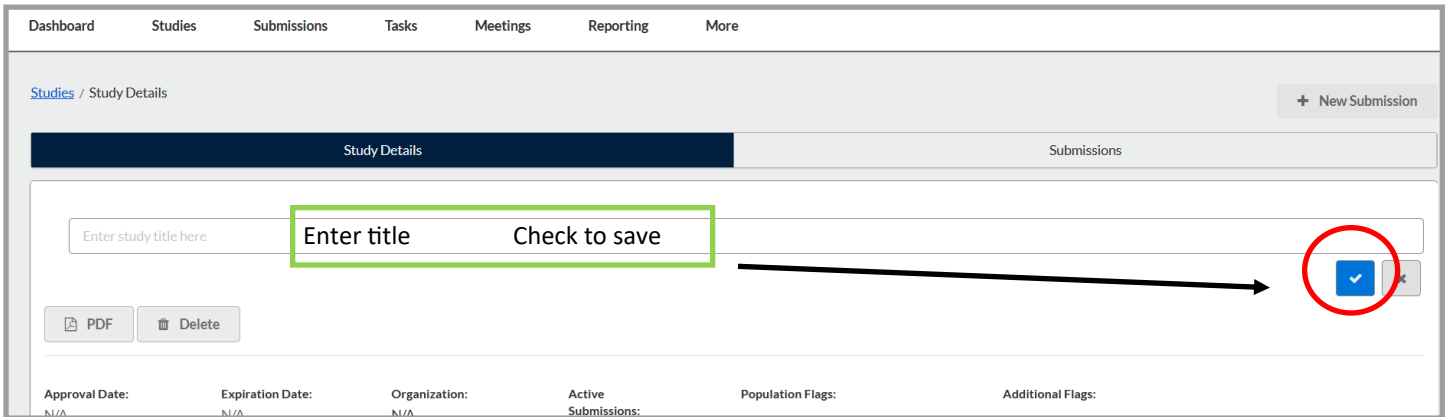
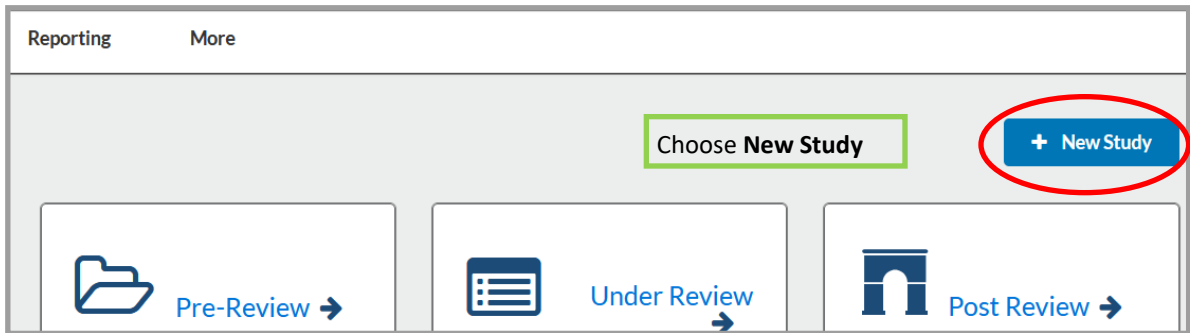
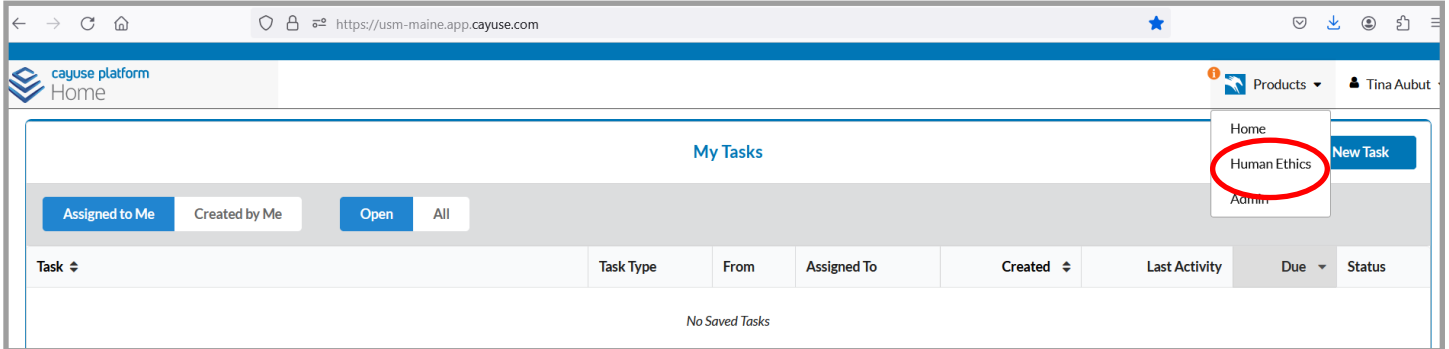


Starting a New Human Subject Research Study

After logging in, select **Human Ethics** from the Products drop-down.



Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / Study Details / Submission Details

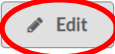
1 **In-Draft**
Submission is with researchers

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

3 **Pre-Review**
Submission is being prepared for review

Unsubmitted

Initial
IRB-2024-109 - Sample Title

 PDF Delete

The person creating the submission is automatically the Primary Contact (PC).
Click on **Assign PI (Principal Investigator)** (or Edit button).

PI:	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		

Approvals Task History Attachments

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-2024-109

Sample Title - Initial

CREATE PDF COMPARE SAVE

Sections <

Getting Started

Read through **Getting Started**
Then click **Yes** that you have read the information.
The other sections will begin to appear based on your responses.

About Cayuse Human Ethics

Cayuse Human Ethics (HE) is an interactive web application. As you answer questions, more sections will appear. Therefore not all numbered sections may appear. You do not have to finish the sections to proceed to the next section.

Additional information has been added throughout the form for guidance and assistance. Please read through each section.

For more information about the IRB submission Process, IRB Tracking, and Cayuse HE Tasks, please refer to the in-app help (the orange question mark near the bottom right) or contact the IRB Office: Office of Research Integrity and Outreach (ORIO) at: usmorio@maine.edu or 207-780-4517

Submit protocol for review at least thirty (30) days prior to starting data collection.

[EMI Collaborative Boards](#)

IORG#: IORG 1507
Federalwide Assurance
IRB 1953, U of S
IRB 11534, U of S

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-2024-109

Sample Title - Initial

Sections <

Getting Started ✓

Project Personnel

Basic Information

Attachments

Throughout the submission, you will be required to provide the following, as applicable:

- CV or Resume for all research staff
- Human Subject Research training for all research staff
- Interview/Focus Group Questions
- Questionnaires/Surveys
- Recruitment Materials (e.g., flyers, email text, verbal scripts)
- Letters of Agreement/Cooperation from organizations
- Consent Forms
- Assent Forms/Parental Permission
- Methods section of your thesis or dissertation proposal
- Grants/Sub-contract
- Other files associated with the project

I have read the information above and I am ready to begin my submission.

Yes

In the scenario below, checking off Student triggers adding a Faculty Sponsor for this project. Which behind the scene is a Co-Principal Investigator (PI). Use the arrows instead of the browser navigation and SAVE your work.

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-2024-109
Sample Title - Initial

CREATE PDF COMPARE SAVE

Sections
Getting Started ✓
Project Personnel
Basic Information
Attachments

Project Personnel

* What kind of affiliation does the Principal Investigator have with USM?

Student
* Undergraduate Student
 Graduate Student
 Staff
 Faculty
 External to USM

* Name of USM Department or External Organization

Muskie School of Public Service

Click "Find People" to add the **Principal Investigator**. POP-UP: type in part of a name, click find icon.

If you are not finding someone, they may not have had a profile set up.

Cayuse User ID Request: <https://forms.gle/SUUNKEmL2EE3AKEW7>

IRB NUMBER: IRB-2024-109
Sample Title - Initial

CREATE PDF COMPARE SAVE

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

* Principal Investigator
The person listed as the PI will be required 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. The PI will be required certify submissions before they are sent to the IRB for review

FIND PEOPLE

* Primary Contact
Any people listed as the Primary Contact 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. The PI will be required certify submissions before they are sent to the IRB for review

FIND PEOPLE

Name
Tina Aubert

* Faculty Sponsor
If the PI is a Student, the Faculty Sponsor 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. The PI will be required certify submissions before they are sent to the IRB for review

FIND PEOPLE

Co-Investigator
Any people listed as Co-Investigator 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. The PI will be required certify submissions before they are sent to the IRB for review

FIND PEOPLE

PRINCIPAL INVESTIGATOR

Aubert

Name	Organization	Email	Phone
Tina Aubert	Research Integrity	tina.aubert@maine.edu	

Type in part of the name, click the magnifying glass symbol, then the plus sign next to the name you want. Then Save.

Selected Records
* Select a single record.

CANCEL SAVE

You may add more than one Co-PI. However, all the Co-PI(s) and Faculty Advisor are also **required to certify submissions before they are sent to the IRB for review**. As the protocol goes through a review, it may be sent back with questions. Each PI will need to certify each time it is returned to the IRB. Other Personnel do not need to Certify the submission.

This guide shows the process for **human subject research** projects. By checking YES you will be required to upload Human Subject Research CITI training report (or equivalent) and Resume/CV for EACH person.

IRB NUMBER: IRB-2024-109

Sample Title - Initial

← SUBMISSION DETAILS

Sections <

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

* Is this Human Subject Research?

If no, only the Determination for Human Subject Research form will display.
If yes, attach resume and training will display.

Yes
 No

Sections <

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

* Study Personnel Training Documentation

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

ATTACH

* Study Personnel CV/Resume

Upload CV or Resume for each member of study personnel.
-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

ATTACH

DOCUMENTS

Click the plus button to upload files or add links.

+ CANCEL APPLY

- Add Link
- Add File

You may add multiple documents within attachments. A pop-up will appear. Note: **we do not accept links to Google docs or SharePoint**. Some of our reviewers are not able to access them. Word or PDF documents work best.

Please make sure anyone can access links to online surveys, etc.

Conflict of Interest. If any are marked as Yes it will ask to explain and to pick a name of the person with the conflict.

*** Conflict of Interest**

NOTE: If you answer Yes to any of the questions below and are faculty or staff for USM, you may be required to file a Conflict of Interest disclosure statement and complete Conflict of Interest CITI training. View the FCOI information on the USM website [here](#).

- * Do any of the involved Investigators or their immediate family have consulting arrangements, management responsibilities or equity holdings in the sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
 Yes
 No
- * Do any Investigators or their immediate family have any financial relationship with the sponsoring company, including the receipt of honoraria, income, or stock/stock options as payment?
 Yes
 No
- * Is any Investigator(s) a member of an advisory board with the Sponsoring company?
 Yes
 No
- * Do any investigators receive gift funds from the Sponsoring company?
 Yes
 No
- * Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?
 Yes
 No

If any of the above are yes, please explain.

* Provide the name(s) of the person(s) with financial interests to disclose.

If you cannot find the person you are looking for in the person finder above, please list them here.

Students and Faculty Advisors (FA) and/or Co-PIs

It is recommended that the student notify their Faculty Advisor when a draft is complete **BEFORE** Complete Submission and Certify the submission. Once certified, the Faculty Advisor cannot review and make any edits. ORIO staff can send it back; however, that is an extra step and takes time.

Faculty Advisor reviews first before either Complete and Certify the submission at the end.

IRB NUMBER: IRB-2024-109

← SUBMISSION DETAILS | **Sample Title - Initial**

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

Basic Information

* Study Site(s)

List all sites/locations involved with this project.

B I U

Initial - USM Preview Only

Sections <

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

Collaboration Information

* External Sites
 Will any research activities occur at any External Sites in the United States? This would include locations other than where you are employed as long as they are within the United States.
 Yes
 No

* External Collaborators
 Will any External Collaborators be conducting research activities?
 Yes
 No

* International Sites
 Will any research activities occur at non-US sites?
 Yes
 No

Depending on your answers to Collaborative Information, additional questions may appear. Example on next image.

Sections <

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓
- Study Products ✓
- International Resea... ✓
- Participant Protect... ✓
- HIPAA ✓
- Data & Safety Moni... ✓
- Attachments ✓

Collaboration Information

* External Sites
 Will any research activities occur at any External Sites in the United States? This would include sites not affiliated with this institution or that have their own IRB.
 Yes
 No

* 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 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

* External Collaborators
 Will any External Collaborators be conducting research activities?
 Yes
 No
 If any External Collaborators are engaged in research activities on behalf of an Institution, the answer to External Sites above should probably be Yes as well.

External Collaborator Information

* Name and Affiliation of all External Collaborators
 List all External Collaborators, the institution they are affiliated with (if any), and their duties in the study.

Collaborators

Sections <

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓
- Study Products ✓
- International Resea... ✓
- Participant Protect... ✓
- HIPAA ✓

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

ATTACH

sample attachment.docx | ✕

Reliance Agreements
 Upload all applicable reliance agreements for any External Collaborators or US External Sites (Individual Investigator Agreements (IIA), IRB Authorization Agreements (IAA), MOUs, etc.).

ATTACH

* International Sites
 Will any research activities occur at non-US sites?
 Yes
 No

International Research has an additional section.

Once a Yes/No is chosen above, the type of project will appear. For this example, Research Study.

IRB NUMBER: IRB-2024-107

← SUBMISSION DETAILS **Sample Title - Initial** CREATE PDF COMPARE SAVE

Sections <

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓
- Study Products ✓
- International Resea... ✓
- Participant Protect... ✓

* Project Type
 What type of project is this submission for?

Research Study
 Request for Determination of Human Subject Research: Activities Without a Plan to Conduct Research (Case Report, Quality Improvement project, Public Health project, Pilot Project) OR Research in which this Institution is Not Engaged
 Select this option if **either** are true:
 • You are not sure if your project requires IRB oversight.
 • You need a formal determination from the IRB on if the project requires IRB oversight.

118 Determination/Future Human Research
 Select this option if **BOTH** are true:
 • This research project will involve or may involve human subjects in the future, but future protocol development must take place first.
 • You need documentation of IRB review in order to release your grant funds.

Clinical Trial
 Single Patient, Treatment Use, Continued Access Drug/Device Study
 Emergency (or Compassionate) Use of Investigational Drug or Device

Choose the most appropriate board for your project. Then Exempt or Expedited.

Exempt Categories: <https://usm.maine.edu/orio/wp-content/uploads/sites/361/2022/08/IRB-Exempt-categories.pdf>

Expedited Categories: <https://usm.maine.edu/orio/wp-content/uploads/sites/361/2022/08/IRB-Expedited-categories-1.pdf>

Categories for that type of review will appear. Choose all that apply to the best of your knowledge.

IRB NUMBER: IRB-2024-109

← SUBMISSION DETAILS **Sample Title - Initial** CREATE PDF COMPARE SAVE

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓
- Study Products ✓
- International Resea... ✓

*** Institutional Review Board**

Note: In addition to, other submissions maybe necessary, such as Institutional Bio-safety Committee (IBC) and Institutional Animal Care and Use Committee (IACUC)

Social/Behavioral IRB
 Biomedical IRB

*** The IRB will make the final determination if your protocol is eligible for Exempt or Expedited/Full review.**

- Exempt categories here do not apply to research involving prisoners.
- Expedited/Full: all aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve one or more of the specific categories listed below.
- Check one

Exempt
 Expedited/Full Board

IRB NUMBER: IRB-2024-109

← SUBMISSION DETAILS **Sample Title - Initial** CREATE PDF COMPARE SAVE

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓
- Study Products ✓

*** Expedited/Full**

- All aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve one or more of the specific categories listed below.
- Check all that apply

Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 2 ml per 100 lbs in an 8 week period and collection may not occur more frequently than 2 times per week.

Sections

- Getting Started ✓
- Project Personnel ✓
- Basic Information ✓
- Study Design ✓
- Study Selection ✓
- Study Procedures ✓

Study Dates

Please provide the intended study start and end dates.
Consider: start date should be about 30 days after submission to the IRB.

*** Start Date**

10-01-2024

*** End Date**

10-31-2025

Sections

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

None/In Kind/Internal funding from the principal investigator's organization
 Other External Funding: Private non-profit, Foundations, State Funding, etc
 US Government: Federally funded
 Industry Sponsored: funding from a company, usually for-profit, specific to the advancement of your type of research
 International/Non US

*** Funding**

*** Name the Funder(s):**

FIND SPONSORS

If your funding entity is not in the list, please name them here.

Sections <	<ul style="list-style-type: none">* Title of Grant (if different from protocol title): <input type="text"/>* Period of funding: <input type="text"/>* Amount of funding: <input type="text"/>* Attach grant materials, contracts, or agreements with the funding source. -Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers. <input type="button" value="ATTACH"/>
Getting Started ✓	
Project Personnel	
Basic Information	
Attachments ✓	

Attachments ✓	<p>If applicable, USM Research Service Center Award Notification Number(s):</p> <input type="text"/> <p>National Science Foundation (NSF) proposals and National Institutes of Health (NIH) with direct costs greater than \$500,000 must attach a Data Management Plan in the Attachment section</p> <p>-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.</p> <input type="button" value="ATTACH"/>
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End of Basic Information Section