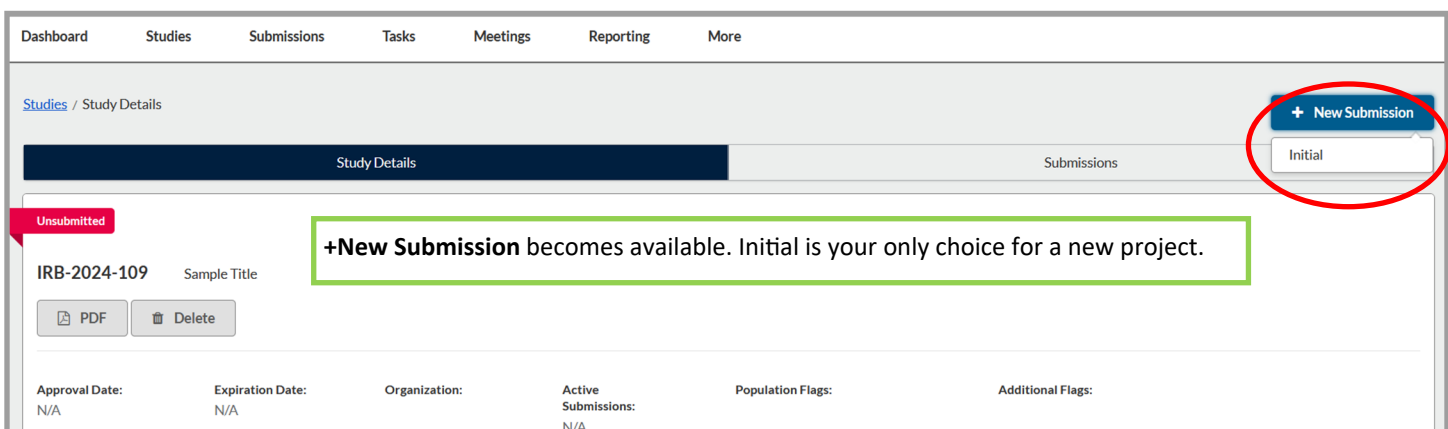
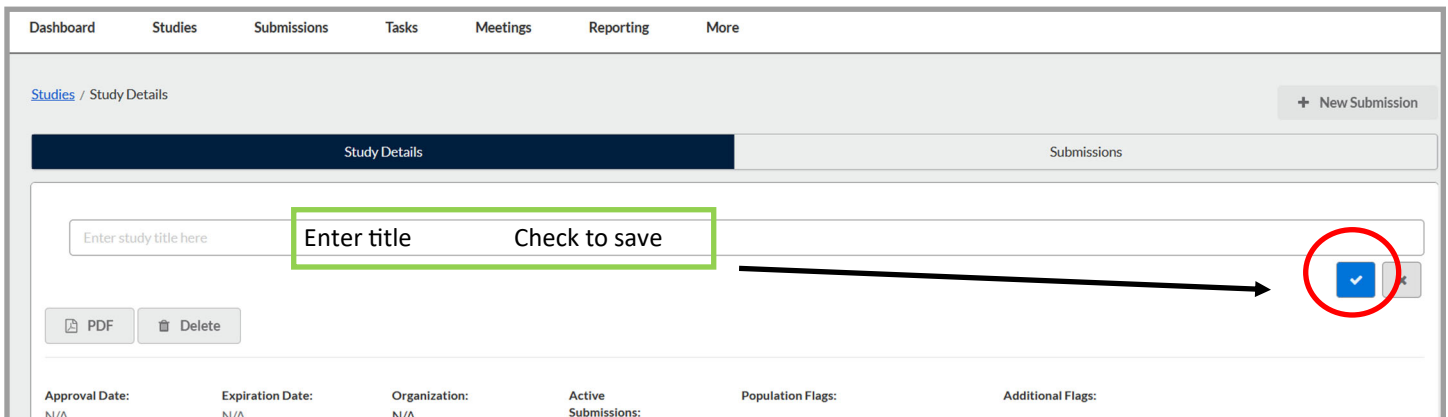
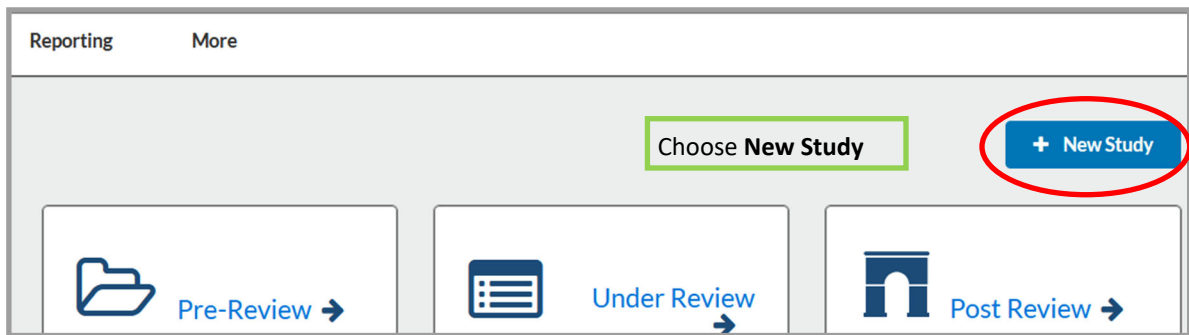
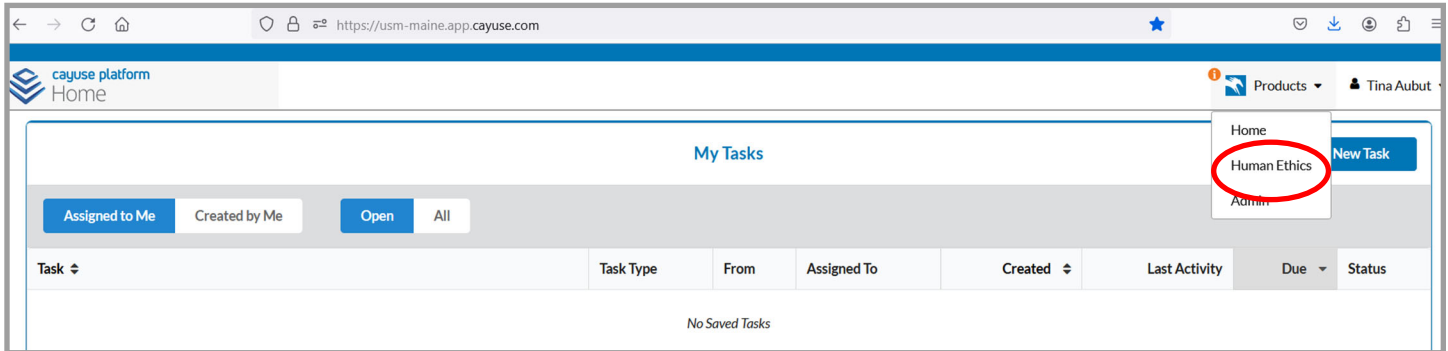


Starting a New Human Subject Research Study

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



DashboardStudiesSubmissionsTasksMeetingsReportingMore

Studies / StudyDetails / Submission Details

1 In-Draft
Submission is with researchers

2 Awaiting Authorization
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4

Unsubmitted

Initial

IRB-2024-109 - Sample Title

Edit

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:

Decision:

Policy:

Required Tasks:

Review Type:

Review Board:

Meeting Date:

Post-2018 Rule

Assign PI

Assign Reviewer

Complete Submission

Approvals

Task History

Attachments

DashboardStudiesSubmissionsTasksMeetingsReportingMore

SUBMISSION DETAILS

IRB NUMBER: IRB-2024-109

Sample Title - Initial

CREATE PDF

COMPARE

SAVE

Sections

Getting Started

Getting Started

About Cayuse Human Ethics

Cayuse Human Ethics (HE) is an interactive web application. As you answer questions, the system will dynamically generate sections for you. Therefore not all numbered sections may appear. You do not have to finish the sections in order.

Additional information has been added throughout the form for guidance and assistance. Please read through the information and respond to the questions as you go.

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.

[FMI Collaborative Boards](#)

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

DashboardStudiesSubmissionsTasksMeetingsReportingMore

SUBMISSION DETAILS

IRB NUMBER: IRB-2024-109

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Sections

Getting Started

Project Personnel

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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

< SUBMISSION DETAILS 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>

Study Personnel

- If you cannot find a person in the people finder, please contact ORIO at usmorio@maine.edu or User ID Request: <https://forms.gle/SUUNKEmL2EE3AKEW7>.
- Any external collaborators must ensure their institution will accept USM's review of this study.

* Principal Investigator

The Principal Investigator procedures and federal, state, and local regulations can create follow-on submissions required to certify submissions.

FIND PEOPLE

Co-Principal Investigator

Any person listed as Co-Principal Investigator after Initial approval, and before they are sent to the IRB for review.

FIND PEOPLE

PRINCIPAL INVESTIGATOR

Aubut

Name	Organization	Email	Phone
Tina Aubut	Research Integrity	tina.aubut@maine.edu	

+

Type in part of the name, click the magnifying glass symbol, then the plus sign next to the name you want. A green check will confirm selection. 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.

Faculty Led Student Classroom Projects also asks for CITI and CV for the Faculty Principal Investigator, as well as the course syllabus.

The screenshot shows the 'Initial - USM' form with a 'Preview Only' label. The left sidebar lists sections: Sections, Getting Started, Project Personnel, Basic Information, and Attachments. The main content area has three sections:

- * 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.
If No or Student Classroom Project, choose "Request for Determination of Human Subject Research" under Basic Information.
Radio buttons: ☒ Yes, ☐ No, ☐ Faculty Led Student Classroom Project.
- * Study Personnel Training Documentation**
Upload documentation of any required training (e.g., CITI training) for each member of study personnel.
ATTACH button.
- * 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 button.

A 'DOCUMENTS' pop-up window is shown at the bottom, with a red circle around the '+' button and another around the 'APPLY' button. The pop-up contains the text: 'Click the plus button to upload files or add links.' and buttons for 'CANCEL' and 'APPLY'.

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.

[< SUBMISSION DETAILS](#)

IRB NUMBER: IRB-2024-109
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**

Sections

Getting Started

Project Personnel

Basic Information

Attachments

Collaboration Information

Please note external collaborators must ensure their institution will accept USM's review of this study.

* Has or will another ethics committee (or IRB) review this protocol?

☒ Yes
☐ No

Ethics Committee

Name of ethics committee

Name of ethics committee's institution

Ethics committee's point of contact

Name, title, email, phone, etc

Study Products

International Resea...

Participant Protect...

HIPAA

* 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.

Sections

Getting Started

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* Project Type

What type of project is this submission for?

☒ Research Study
☐ Request for Determination of Human Subject Research

Select this option if any are true:

- You are not sure if your project requires IRB oversight.
- You need a formal IRB determination on whether the project requires IRB oversight.
- Faculty-Led Student Classroom Project

☐ Determination of Future Research (only select this option if you have previously consulted with ORIO)
☐ Clinical Trial (only select this option if you have previously consulted with ORIO)
☐ Clinical use of a humanitarian use device (HUD) for treatment or diagnosis consistent with approved labeling. (only select this option if you have previously consulted with ORIO)
☐ Emergency or Compassionate Use of Investigational Drug or Device (only select this option if you have previously consulted with ORIO)
☐ Emergency Use of a Humanitarian Use Device (HUD) in a life-threatening or severely debilitating situation in which no standard acceptable treatment is available and in which there is **not sufficient time to obtain IRB approval.** (only select this option if you have previously consulted with ORIO)

Getting Started ✓
Project Personnel
Basic Information
Attachments ✓

Maine Department of Health and Human Services

* Does this activity involve the Maine Department of Health and Human Services (DHHS) or its programs, services, offices, divisions, or data?

☒ Yes
☐ No

Check all that apply:

☐ Direct funding by Maine DHHS
☐ Any data from Maine DHHS
☐ Maine DHHS employees
☒ Other

Describe other:

If obtaining data from Maine DHHS, please attach proof of permission to access the data.

ATTACH

Getting Started ✓
Project Personnel
Basic Information
Attachments ✓

U.S. Department of Education

* Will the research occur within a school district or K-12 school that receives funding from the U.S. Department of Education?

This includes all public schools and most private schools.

☒ Yes
☐ No

Please provide a letter of support or other documentation from each school supporting the conduct of the research and its compliance with The Protection of Pupil Rights Amendment (PPRA).

ATTACH

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.

Sections <
Getting Started ✓
Project Personnel
Basic Information
Study Selection
Study Design
Study Procedures
Participant Protection
Attachments ✓

* Institutional Review Board

☐ Social/Behavioral IRB
☐ Biomedical IRB

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

- Exempt categories do not apply to research involving prisoners and are not likely to apply to research involving children.
- Expedited: 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

SUBMISSION DETAILS
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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 must not exceed the lesser of 50 ml or 3% of total body blood volume 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

You must choose **Other** in Find Sponsors as well as typing in funding entity.

* Funding

* Name the Funder(s):

FIND SPONSORS

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

Sections

Getting Started ✓

Project Personnel

Basic Information

Attachments ✓

* Title of Grant (If different from protocol title):

* Period of funding:

* Amount of funding:

* 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.

ATTACH

Attachments ✓

If applicable, USM Research Service Center Award Notification Number(s):

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

-Word or pdf copies are best. Links, such as Google or SharePoint, cannot be accessed by external reviewers.

ATTACH

End of Basic Information Section