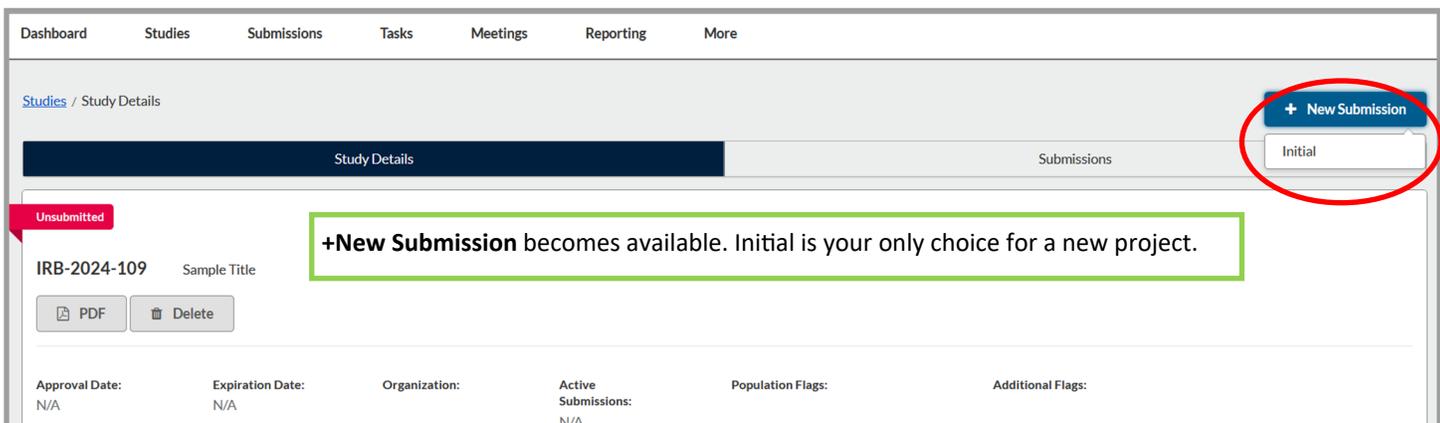
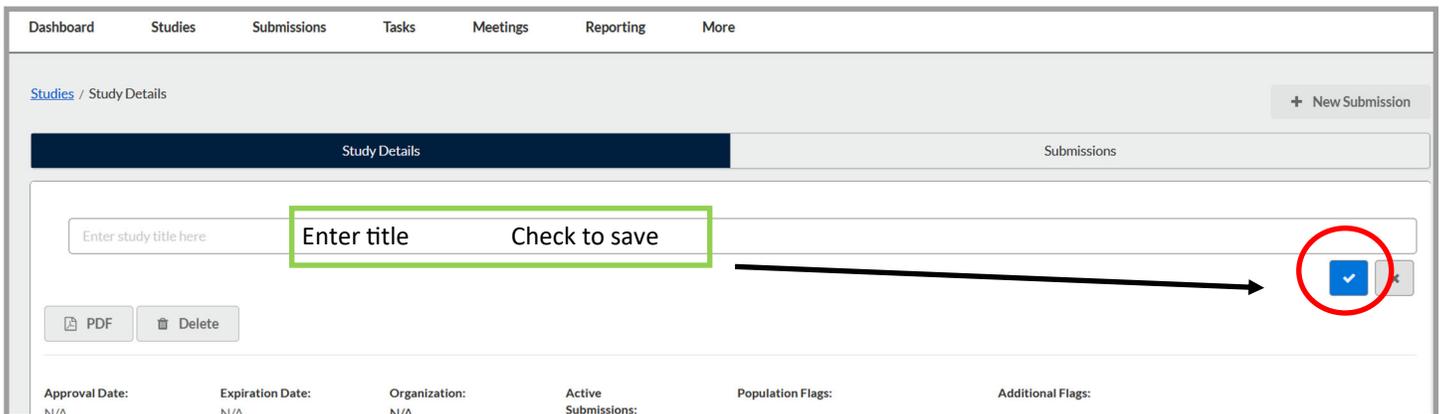
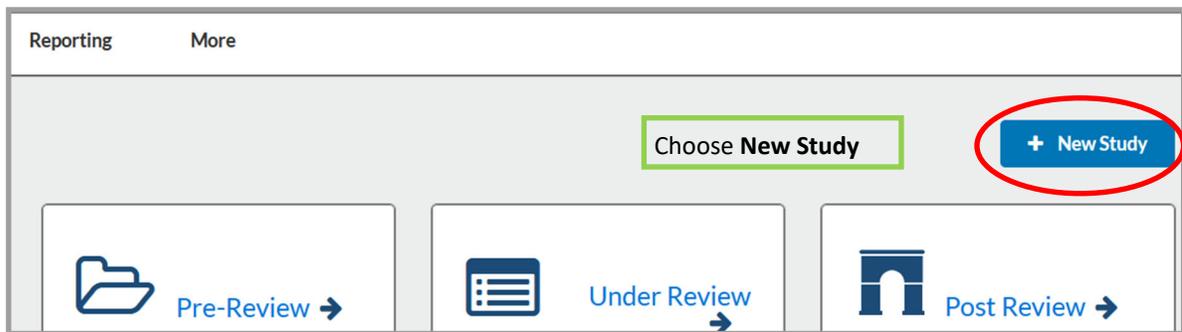
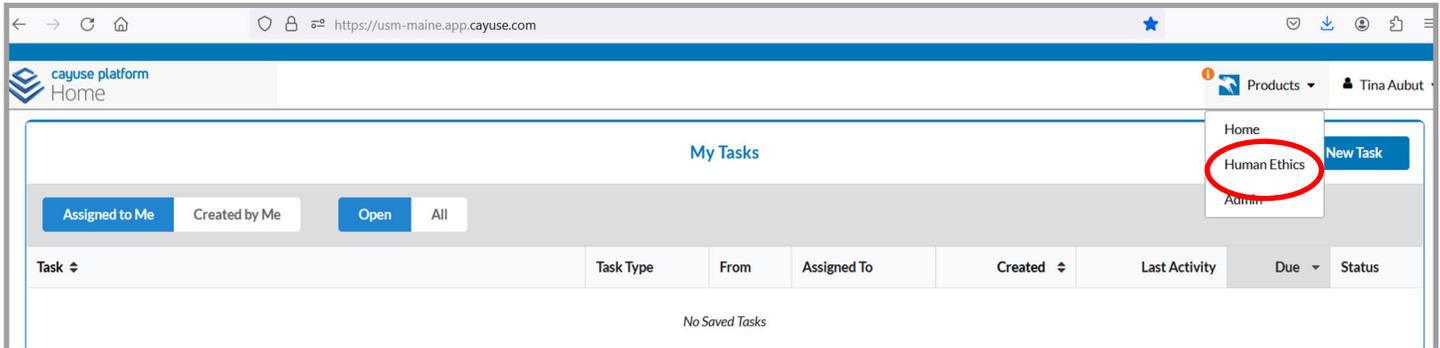


Starting a New Human Subject Research Study

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



Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / 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

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:
N/A N/A N/A Post-2018 Rule **Assign PI**
Review Type: Review Board: Meeting Date: Assign PI
N/A N/A N/A Complete Submission

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

Getting Started

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 Sou
IRB 11534, U of Sou

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

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

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-2024-109

Sample Title - Initial

Sections Getting Started Project Personnel Basic Information Attachments

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- Consent Forms
- Assent Forms/Parental Permission
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- 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>

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... can create follow-on sub... required to certify submi

FIND PEOPLE

Co-Principal Investigator

Any person listed as Co-P... after Initial approval, and before they are sent to th

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.

Dashboard Studies Submissions Tasks Meetings Reporting More

Initial - USM Preview Only

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.
If No or Student Classroom Project, choose "Request for Determination of Human Subject Research" under Basic Information.

Yes
 No
 Faculty Led Student Classroom Project

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.

+
Add Link
Add File

CANCEL 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.

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

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

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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 ✓

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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 | IRB NUMBER: IRB-2024-109

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 3% of total body weight. For pediatric subjects, the amount drawn may not exceed 50 ml or 3% of total body weight.

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

* End Date

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):

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

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

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.

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.

End of Basic Information Section