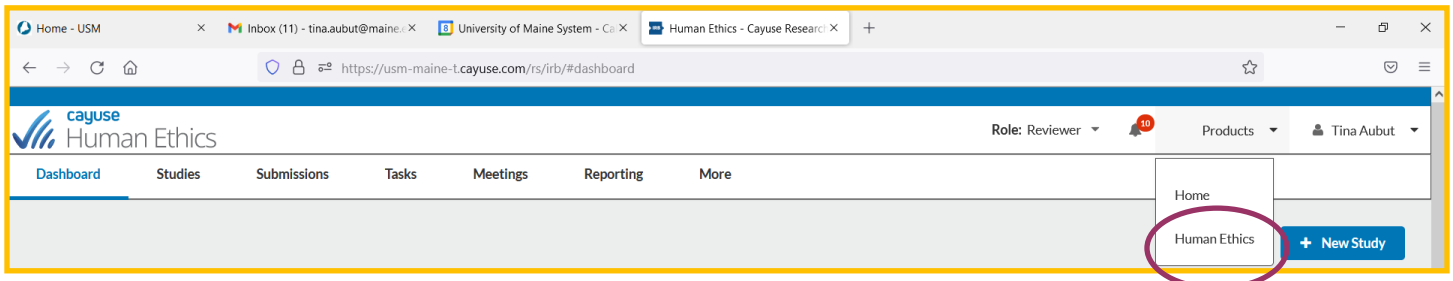
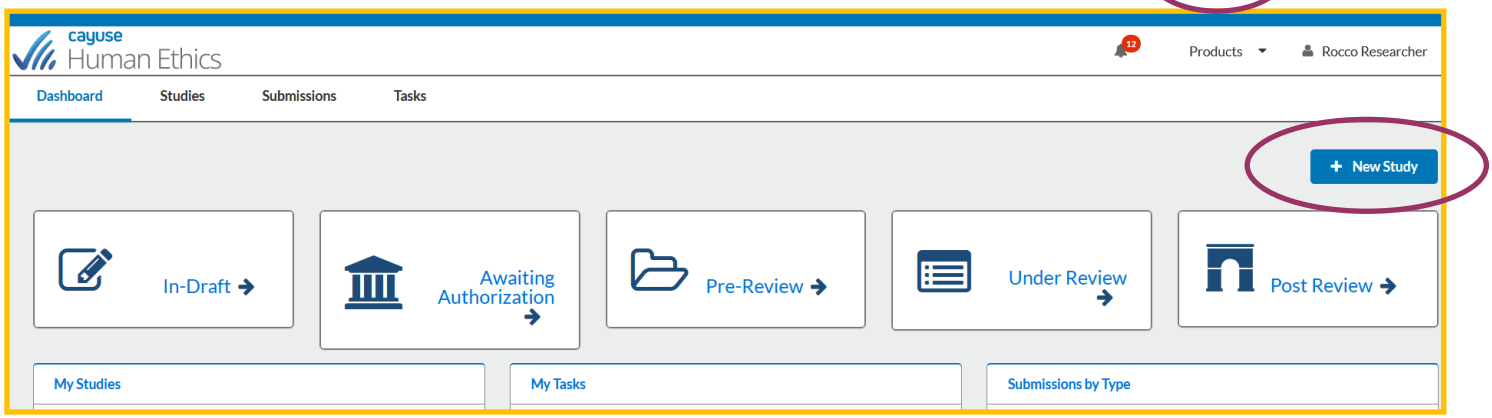
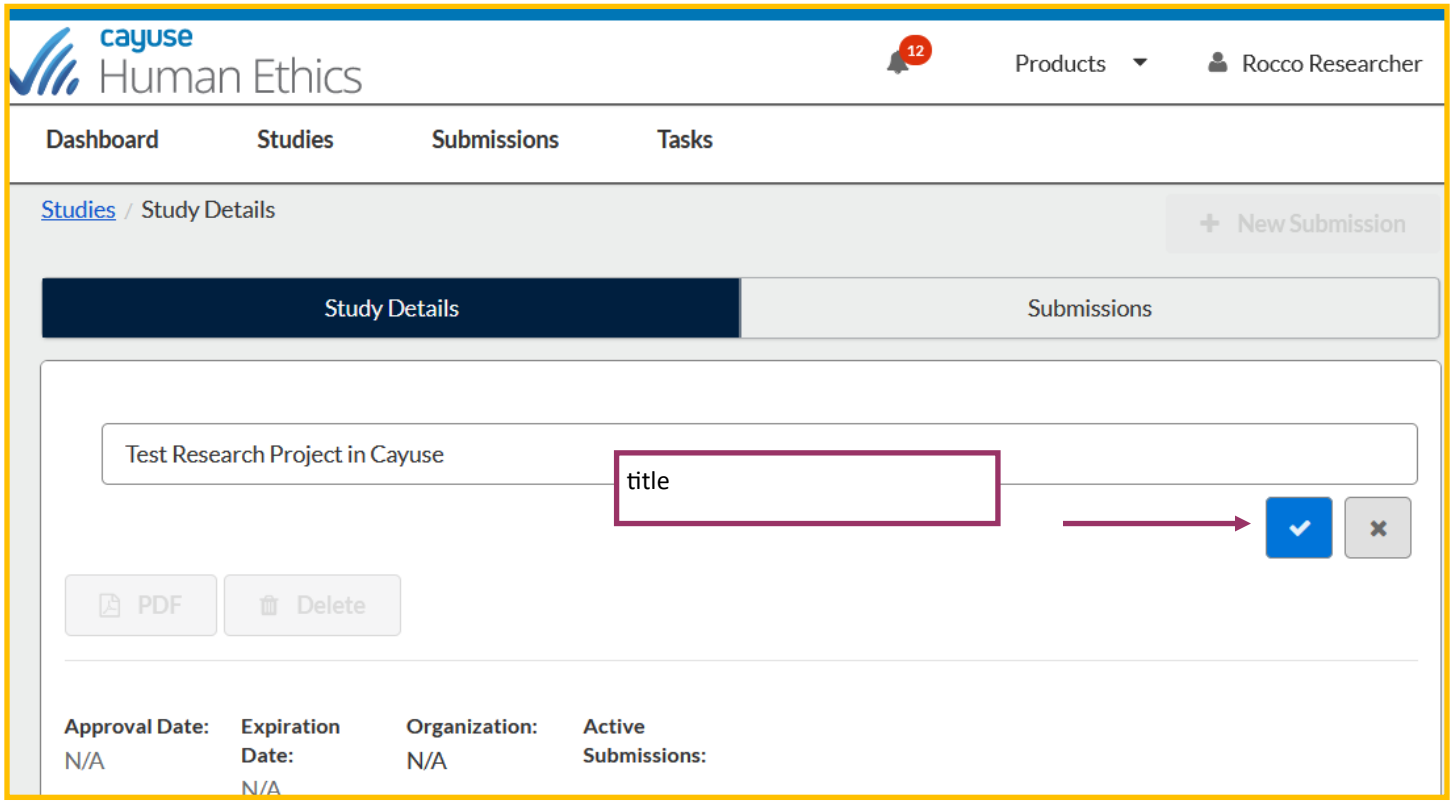
Request for Determination of Human Subject Research

After logging in, select **Human Ethics** from the Products drop-down.
Click the New Study button. Enter a title, click the green checkmark to save.

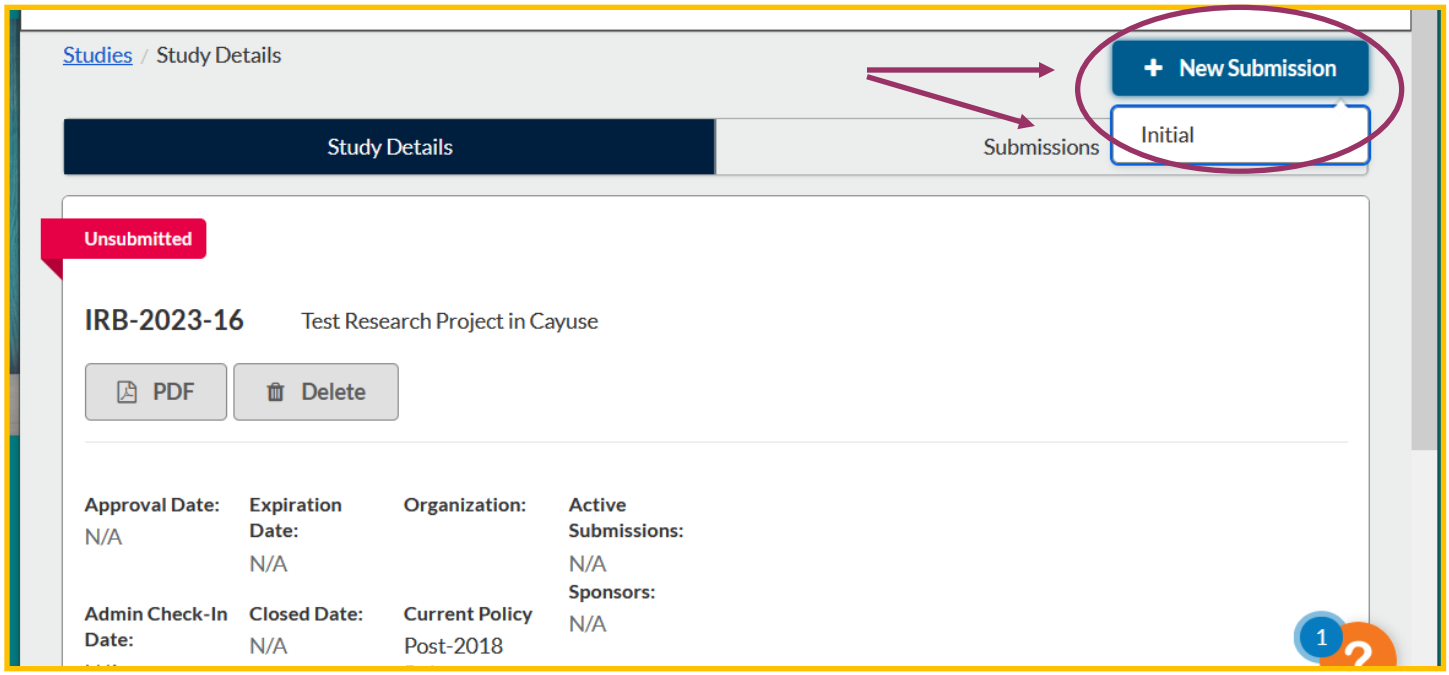




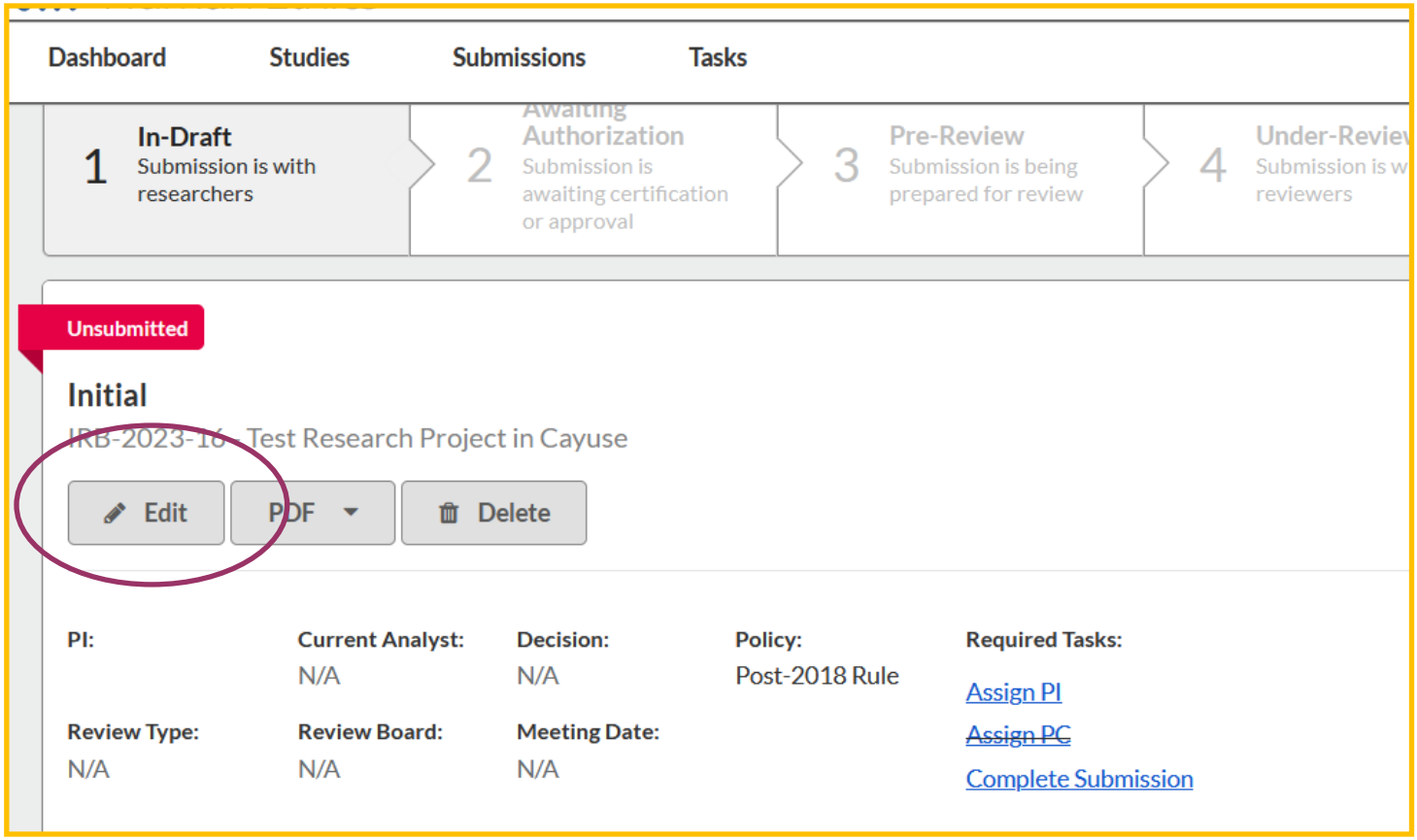


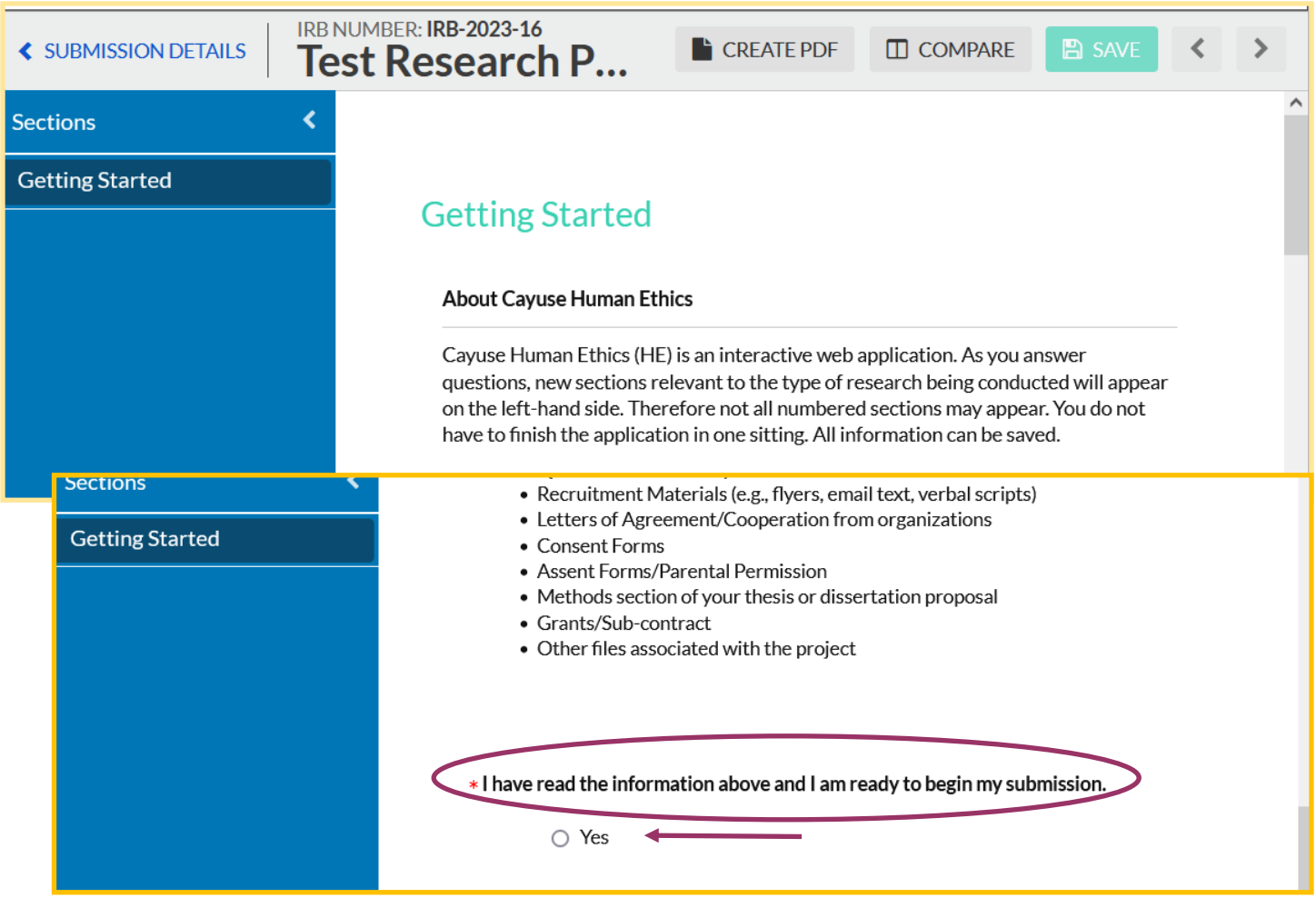
Click the New Submission button, Initial in the dropdown.

Click on Edit.



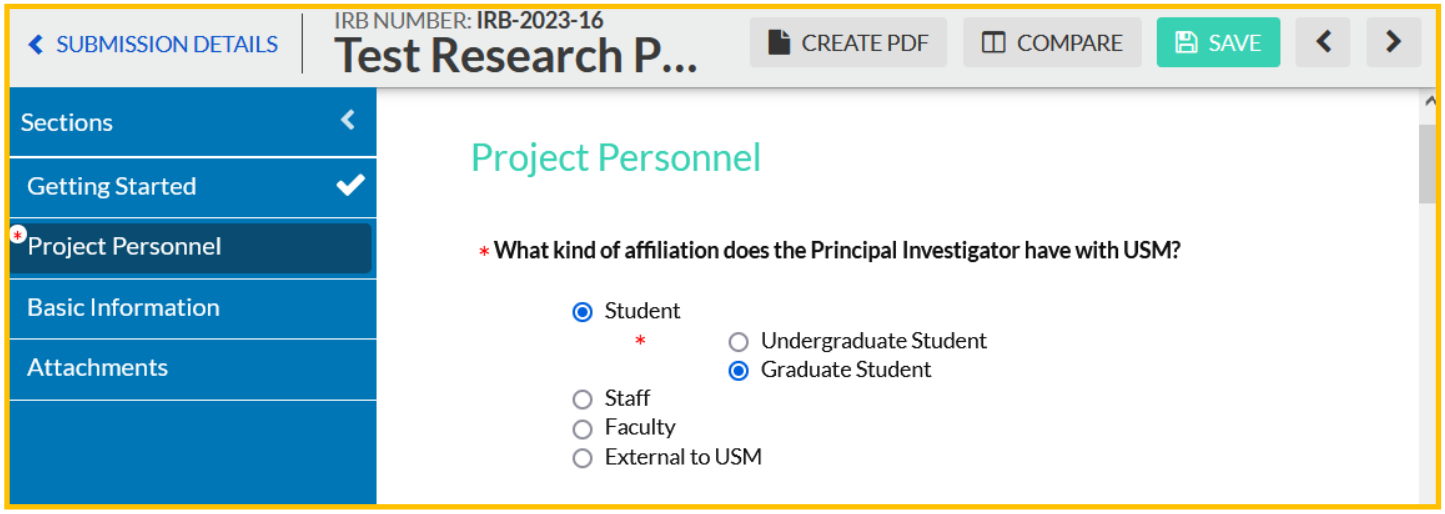
The person creating the submission is automatically the Primary Contact (PC); however, that can be changed under Personnel. Click on Assign PI (or Edit button).





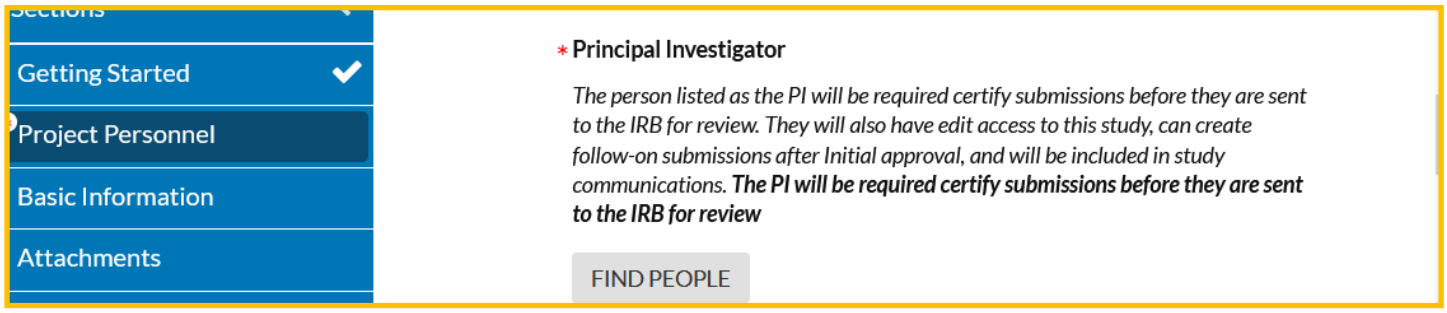
Other sections now appear below Getting Started. As a smart form, sections will be added based on your responses.

In the scenario below, checking off Student triggers adding a Faculty "sponsor", mentor, advisor for this research project. Which behind the scene is a Co-Principal Investigator (PI).

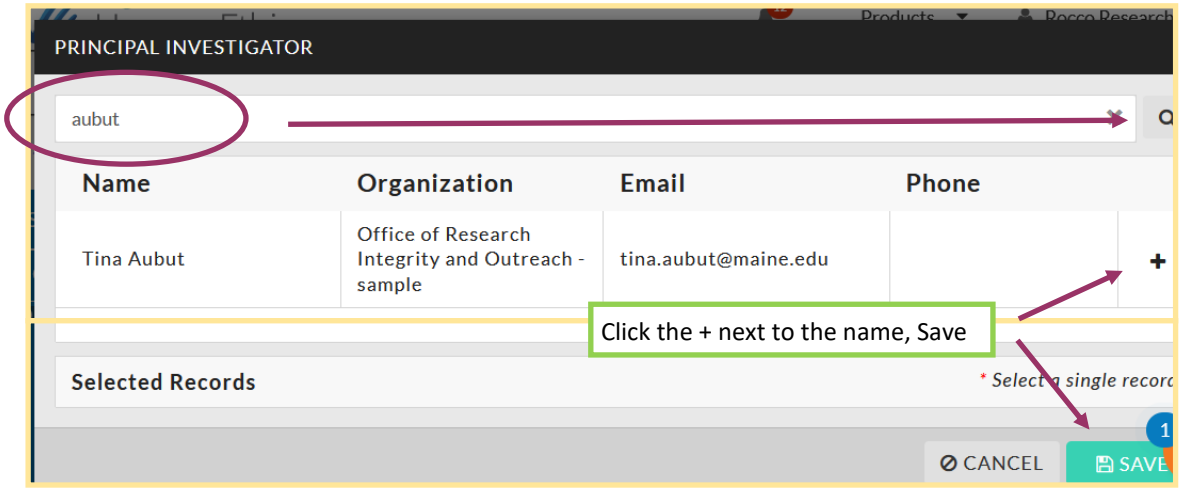


Click “Find People” to add the **Principal Investigator.** POP–UP: type in part of a name, click find icon.

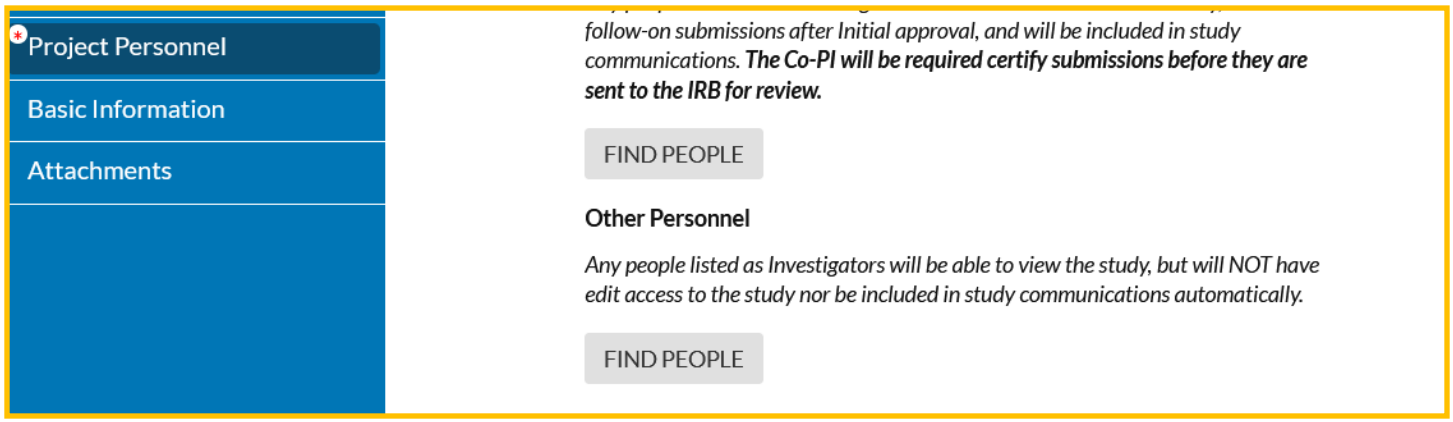
If you are not finding someone, they may not have had a profile set up. Cayuse User ID Request: https://forms.gle/SUUNkEmL2EE3AKEW7



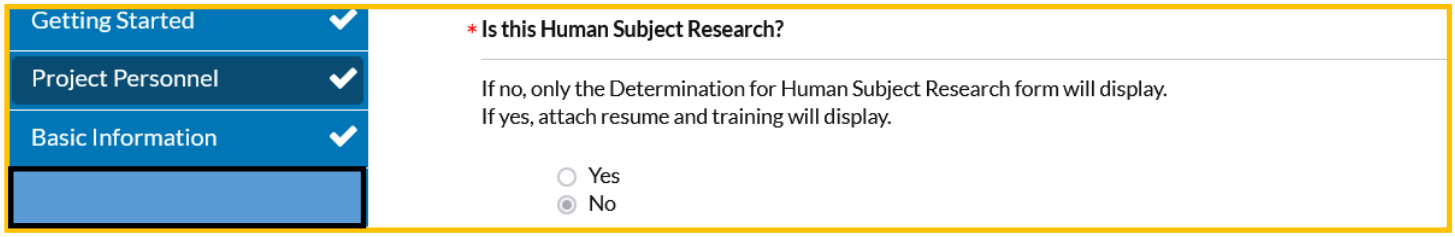
In the pop-up type part of the persons name, click the magnifying glass at the end of the line for a list of potential people. Click the + next to the name you want, then click Save.



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.

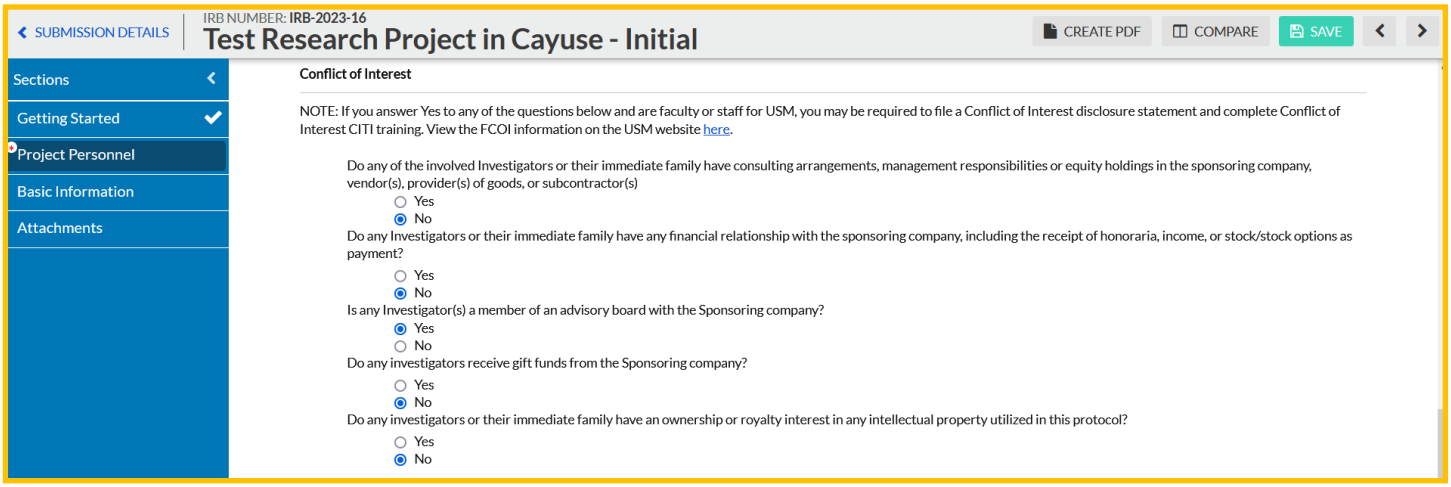


Is this Human Subject Research? By checking NO you will NOT be required to upload Human Subject Research CITI training report (or equivalent).



You may add multiple documents within attachments. A pop-up will appear. Note: **we do not accept links to Google docs**. Some of our reviewers are not able to access them. Please make sure anyone can access links to online surveys, etc.

For University of Maine System Faculty, Staff, or Students with a conflict of interest may require a separate reporting and training. FMI: https://usm.maine.edu/orio/financial-conflicts-of-interest-fcoi/



If there are any “yes” answers, then Find People will appear.

Here is where things get interesting!

This is a "smart form." The form will adapt to your responses.

Let's continue as if this were a **Request for Determination of Human Subject Research…..**

Getting Started
Project Personnel
Basic Information

Basic Information

* **Study Site(s)**

List all sites/locations involved with this project.

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* **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

* **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

* **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.

The screenshot below shows the additional questions, compared to the above screenshot.

Sections
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* **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

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.

- ○ No

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.

B I U S

Checking YES to External Sites will prompt the additional questions, example above.

If YES is selected for International Sites, International Research Section appears.

The start date should be when you expect to start collecting data, after IRB approval. For a determination, about 2 weeks from submission.

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Study Dates

Please provide the intended study start and end dates.

* Start Date

MM-DD-YYYY

* End Date

MM-DD-YYYY

* Is this research funded?

- Yes
- No

* Primary source of funding:

Does this project have external or internal funding source(s). Is this project have funding or another type of in-kind support) e.g., provision of drugs/study products, internal support, etc.)?

- Industry Sponsored
- International/Non US
- Internal/None/In Kind
- Other External Funding
- US Government

These questions do not show if you select NO to funded project.

* Funding

Name the Funder(s):

FIND SPONSORS

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

Updated 2/2024

Sections
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NR NHSR Not Research or Not Human Subject Research

Request for Human Subject Research Determination

* What is the purpose of the activity?

Project Personnel
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* What are the activities being conducted?

Getting Started ✓
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NR NHSR Not Research o...
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* **Who are the intended subjects/participants?**

-If your project includes a specific group or population, please elaborate in narrative.

B I U S

Getting Started ✓
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* **Who is the intended audience?**

-How will the results be shared, with whom, and in what form?

B I U S

Sections
Getting Started ✓
Project Personnel
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NR NHSR Not Research o...
Attachments ✓

* **If there is a Business Associate Agreement (BAA), with which healthcare provider?**

* **Are you using Maine Integrated Youth Health Survey (MIYHS) data?**

- ○ Yes
- ○ No

* **Has this been reviewed by another IRB?**

- ○ Yes
- ○ No

* **Are you requesting a determination in order to fulfill W-9 form requirements?**

Incentive/payment to UMS employees.

- (●) Yes
- ( ) No

If yes, the following questions will appear.

* **W-9**

Who will be responsible for obtaining, securing, and disbursing compensation?

If participants were required to complete a W-9 form, how would it negatively impact your study?

How will you be compensating your study participants?

What is the total amount of compensation per participant?

On how many separate occasions throughout the study will a participant receive compensation?

How will you ensure a participant does not obtain more than $600 in a calendar year resulting from participation?

How will compensation to participants be distributed?

Where will compensation be stored until it is dispersed?

What security provisions will be in place to prevent theft?

* **Is the Activity Non-research?**

§46.102 (l) (1-4)

* **Is the activity scholarly or journalistic?**

-Examples include oral history, journalism, biography, literary criticism, legal research, and historical scholarship.

○ Yes
○ No

* **Is the activity a public health surveillance activity?**

-These activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

○ Yes
○ No

* **Is the activity a collection and analysis of information for a criminal justice agency?**

-Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

○ Yes
○ No

* **Is this Non-Research?**

- Did you answer yes to any of the 3 previous questions?

○ Yes
○ No

* **Is the Activity Non-research?**

§46.102 (l) (1-3)

* **Is the activity scholarly or journalistic?**

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

○ Yes
○ No

* **Is the activity a public health surveillance activity?**

-Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

○ Yes
○ No

* **Is the activity a collection and analysis of information for a criminal justice agency?**

-Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

○ Yes
○ No

* **Is this Non-Research?**

- Did you answer yes to any of the 3 previous questions?

○ Yes
○ No

* **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 an investigation?**

-Investigation means a searching inquiry for ascertaining facts or a detailed or careful examination.

○ Yes
○ No

* **Is the activity systematic?**

-Systematic means having or involving a system, method, or plan. (including the selection of subjects, decisions about what observations to record, and an interview process)

○ Yes
○ No

* **Is the activity designed to develop or contribute to knowledge?**

-Designed means done with purpose or intent. Develop means to elaborate or expand in detail. Contribute means to be an important factor in. Knowledge means truth, facts, or information.

○ Yes
○ No

* **Is the knowledge generalizable?**

-Generalizable means relevant beyond the population or program from which it was collected, or universally applied/accepted, to other contexts or situations.

○ Yes
○ No

Is this Research?

- Did you answer yes to any of the 4 previous questions?

○ Yes
○ No

As defined by 45 CFR 46, a human subject is "*a living individual, about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*"

* **Does the research involve obtaining information (or biospecimens) about a living individual?**

-About means the information concerns the individual whose information is collected; the focus of the investigation is the opinions, characteristics, or behavior of the individual.
-Biospecimen means material such as urine, blood, tissues, cells, DNA, RNA, and proteins.

- ○ Yes
- ○ No

* **Does the project involve interaction with individuals?**

-Interaction includes communication or interpersonal contact between investigator and participant.

- ○ Yes
- ○ No

* **Does the research involve intervention with individuals?**

Intervention includes both physical procedures by which information or biospecimens are gathered and manipulation of the participant or the participant's environment that are performed for research purposes (for example, having participant listen to music and then having them perform memory tasks in order to investigate the effect of music on memory).

- ○ Yes
- ○ No

* **Does the project involve obtaining, using, studying, analyzing, or generating private information?**

Private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
***Consider**: If the project only involves data and/or specimens that were pre-existing, or collected for some purpose other than this project, consider the original source of the data/specimens, how they are provided to investigators, if the data/specimens are identifiable in any way to investigators, etc.*

- ○ Yes
- ○ No

* **Does the research involve obtaining, using, studying, analyzing, or generating identifiable biospecimens?**

Identifiable biospecimens means the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

- ○ Yes
- ○ No

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HIPAA

HIPAA

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule applies to projects where Protected Health Information (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, 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

* **Does this project involve obtaining, using, or releasing/disclosing identifiable PHI by a Covered Entity?**

- ◉ Yes
- ○ No

Getting Started ✓
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Please include any additional information you would like to provide.

B I U S

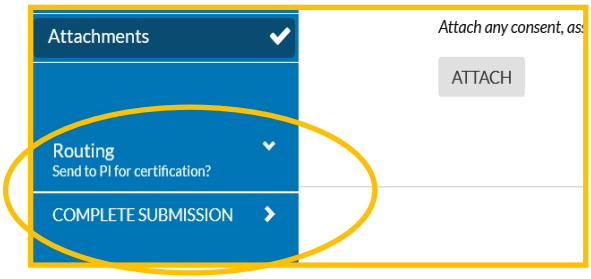
Attachments

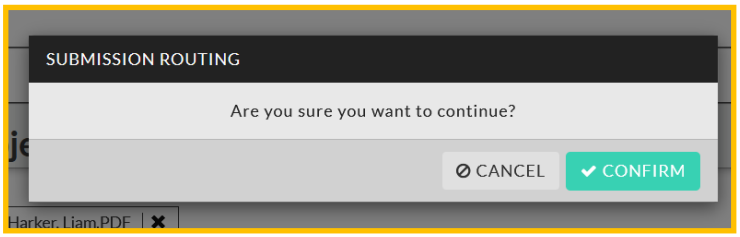
Attach recruitment material(s), questionnaires or surveys, and consent language document(s), etc.

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

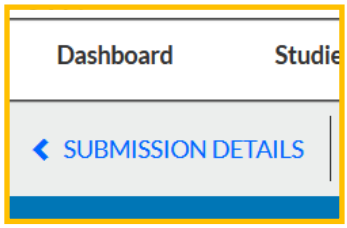
ATTACH

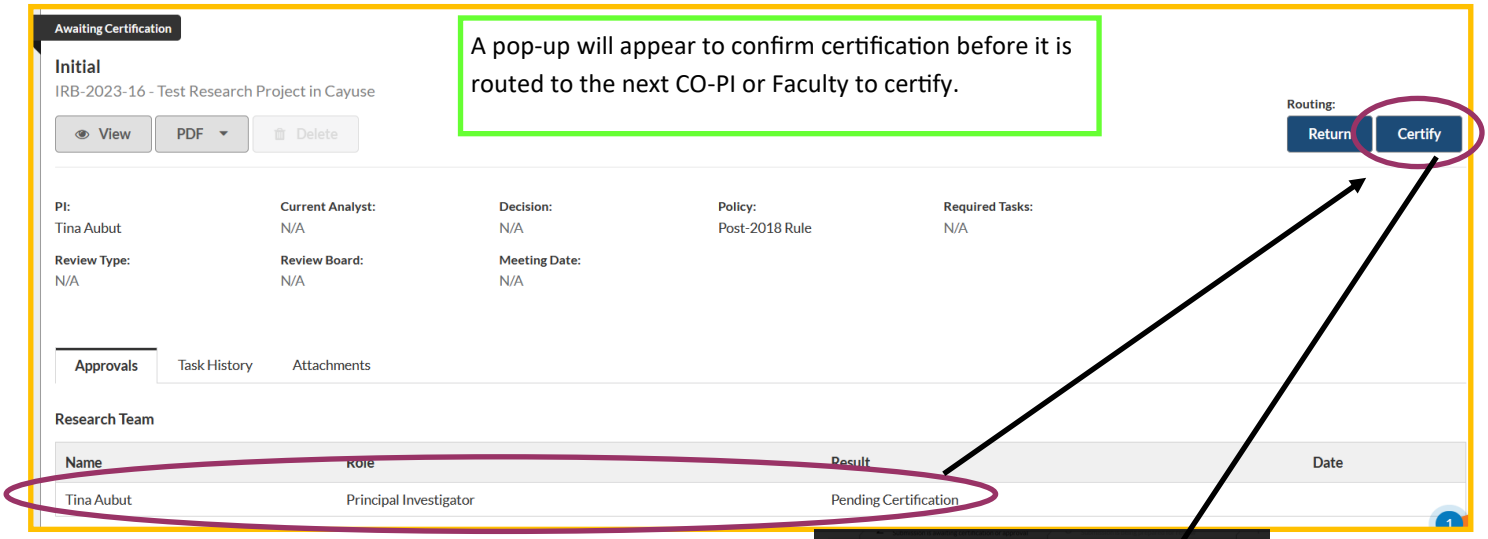
Once each section has a checkmark, the COMPLETE SUBMSISION will appear. Click on COMPLETE SUBMISSION.



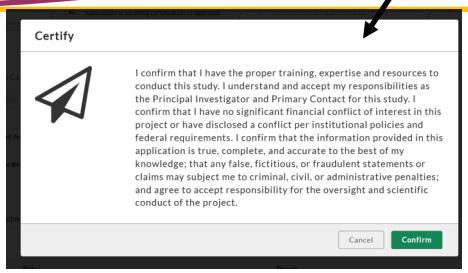


Clicking on **Submission Details** in the upper left corner of the page will get you back to the certification page.





A pop-up will appear to confirm certification before it is routed to the next CO-PI or Faculty to certify.



When all certification routing is done, it goes into the que of an ORIO analyst for next steps.