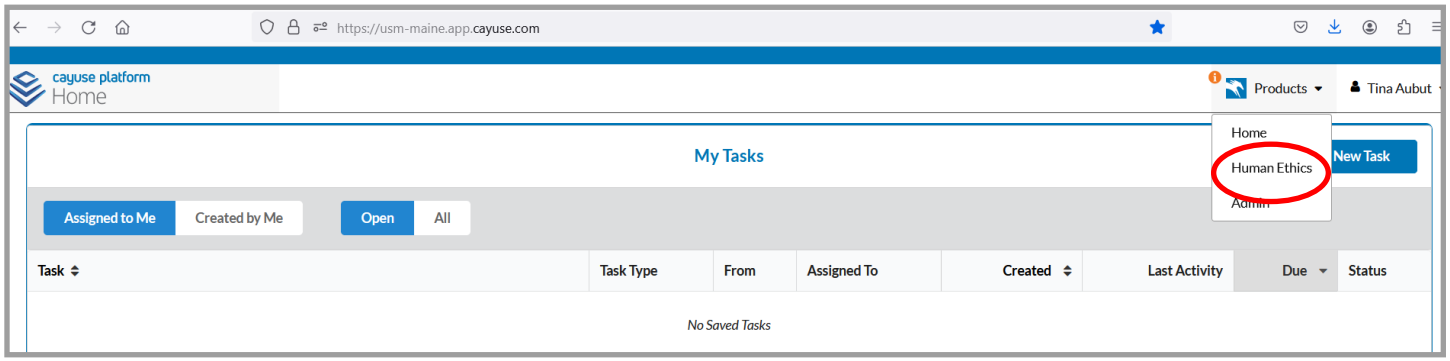
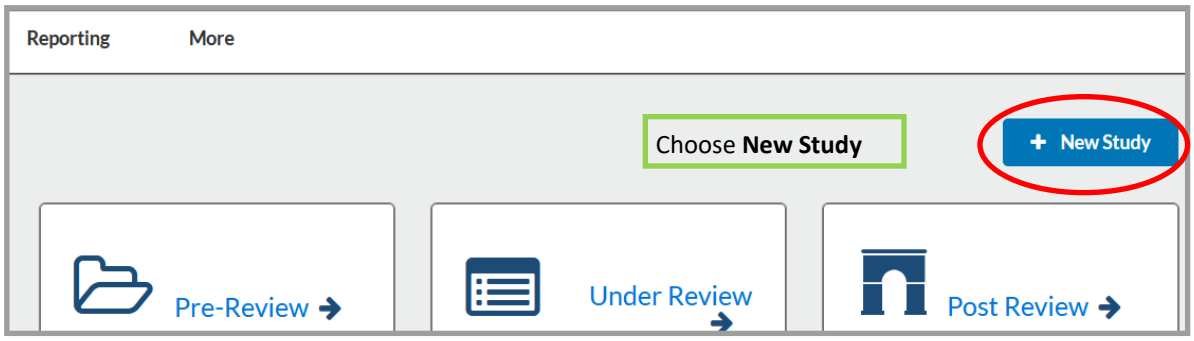
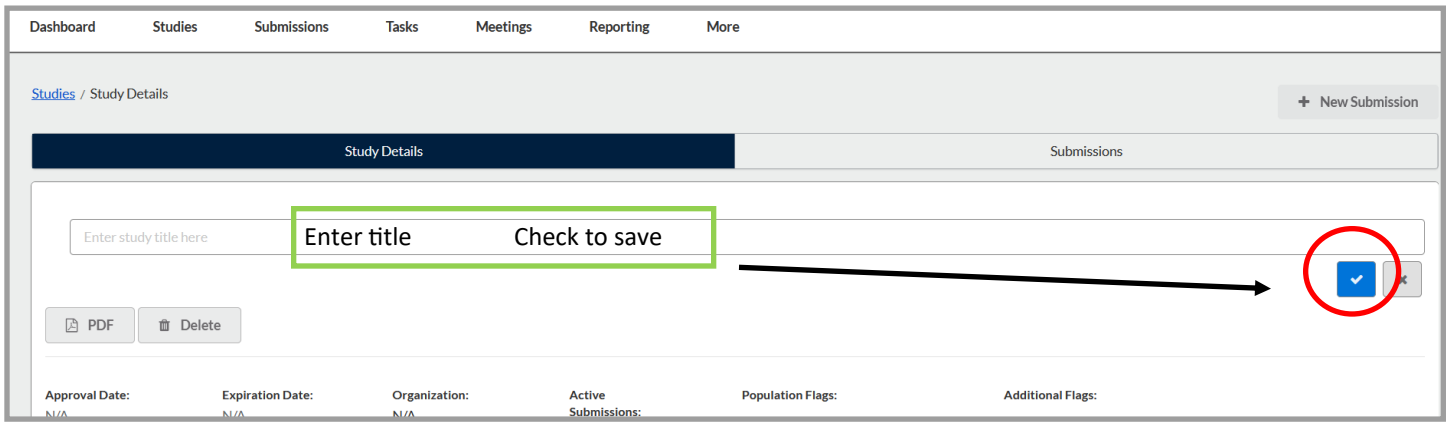
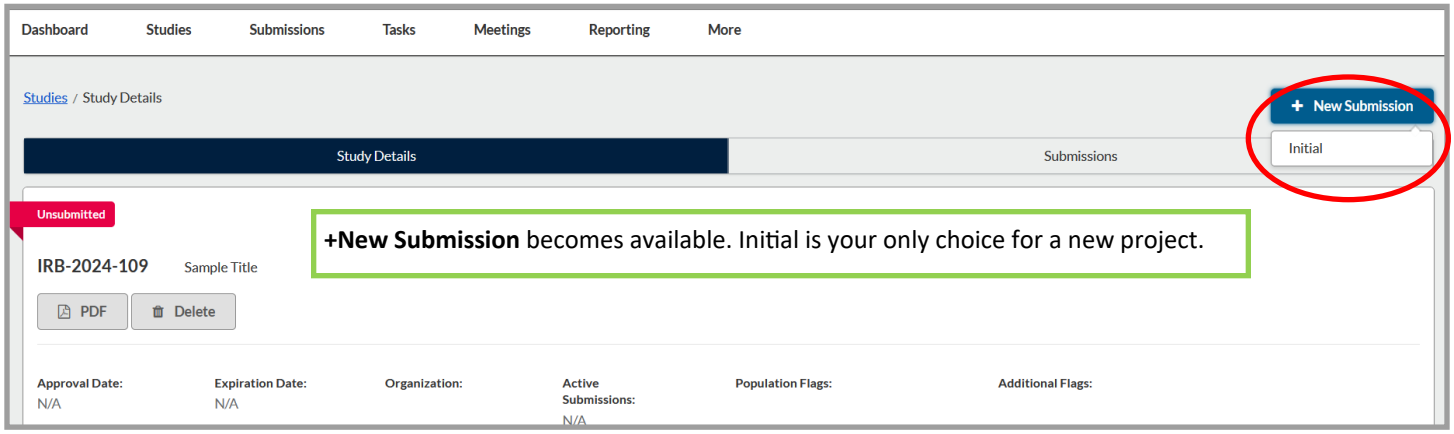
Request for Determination of Human Subject Research

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

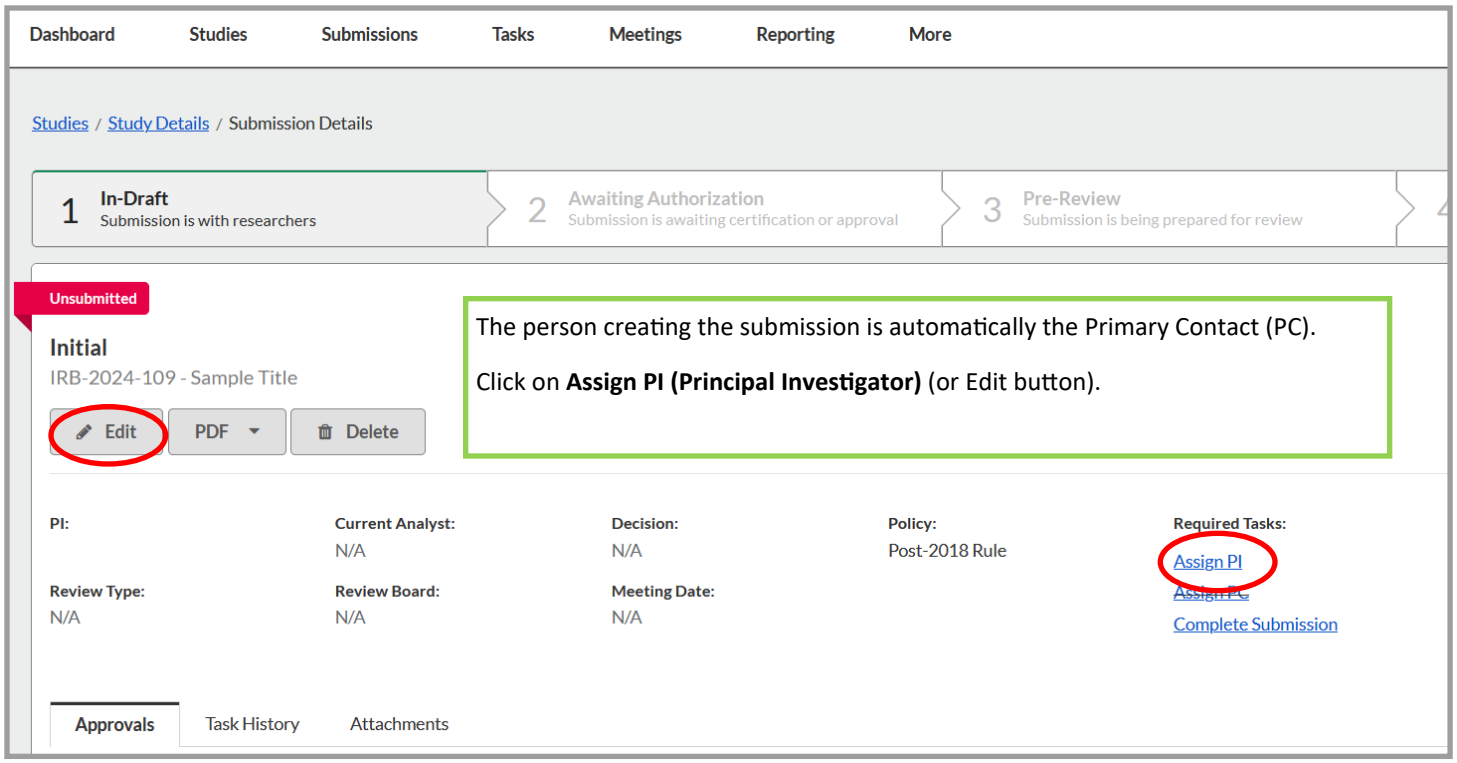








Update 5.2024


Dashboard
Studies
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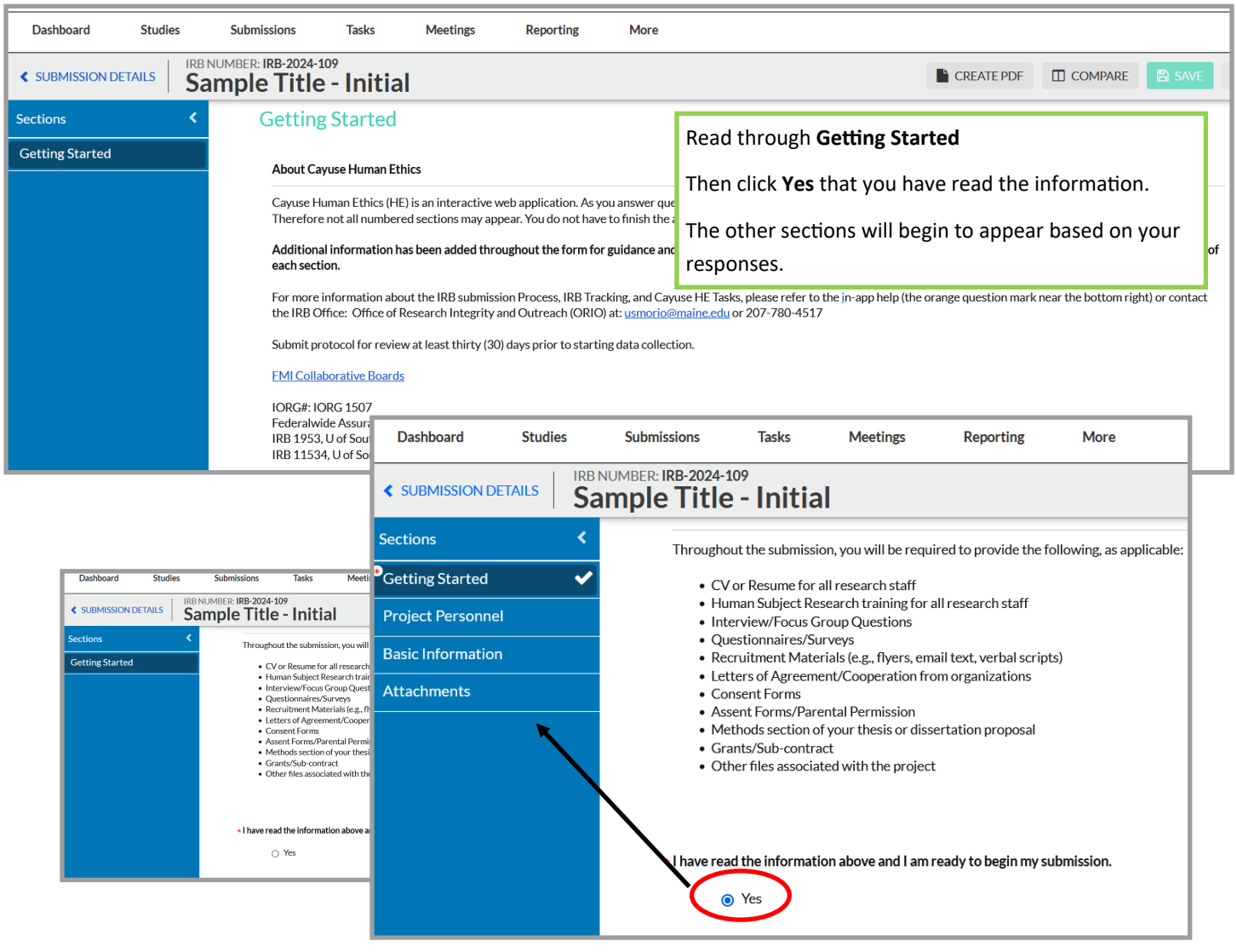
Studies / Study Details / Submission Details
1 In-Draft
Submission is with researchers
2 Awaiting Authorization
Submission is awaiting certification or approval
3 Pre-Review
Submission is being prepared for review
Unsubmitted
Initial
IRB-2024-109 - Sample Title
Edit
PDF
Delete
The person creating the submission is automatically the Primary Contact (PC).
Click on Assign PI (Principal Investigator) (or Edit button).
PI:
Current Analyst:
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
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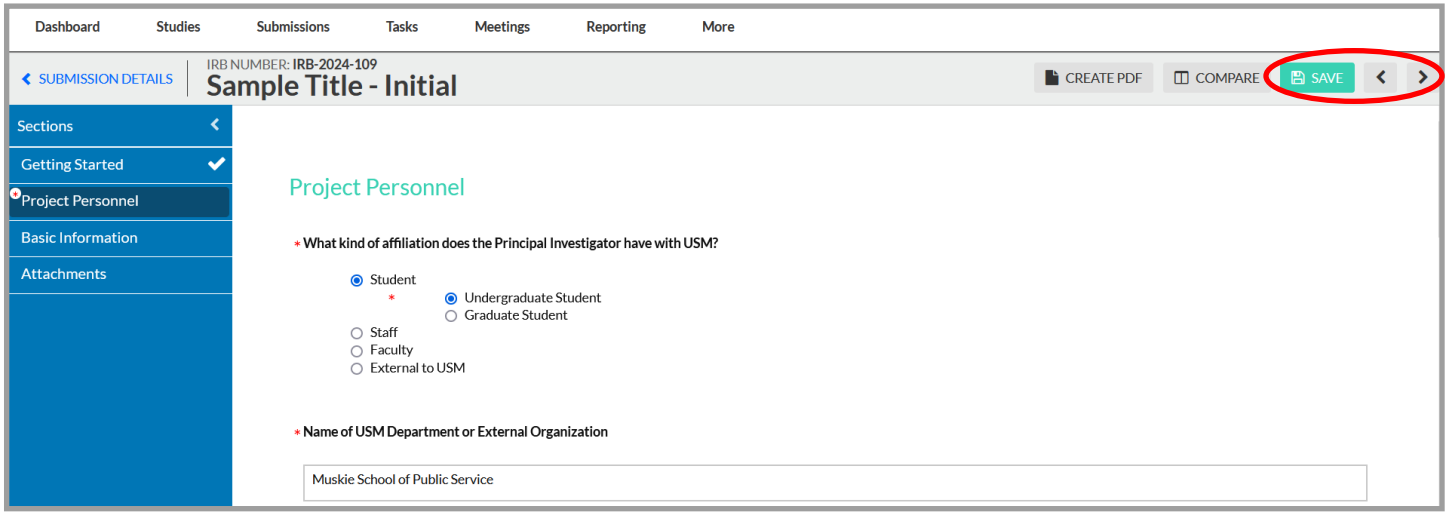
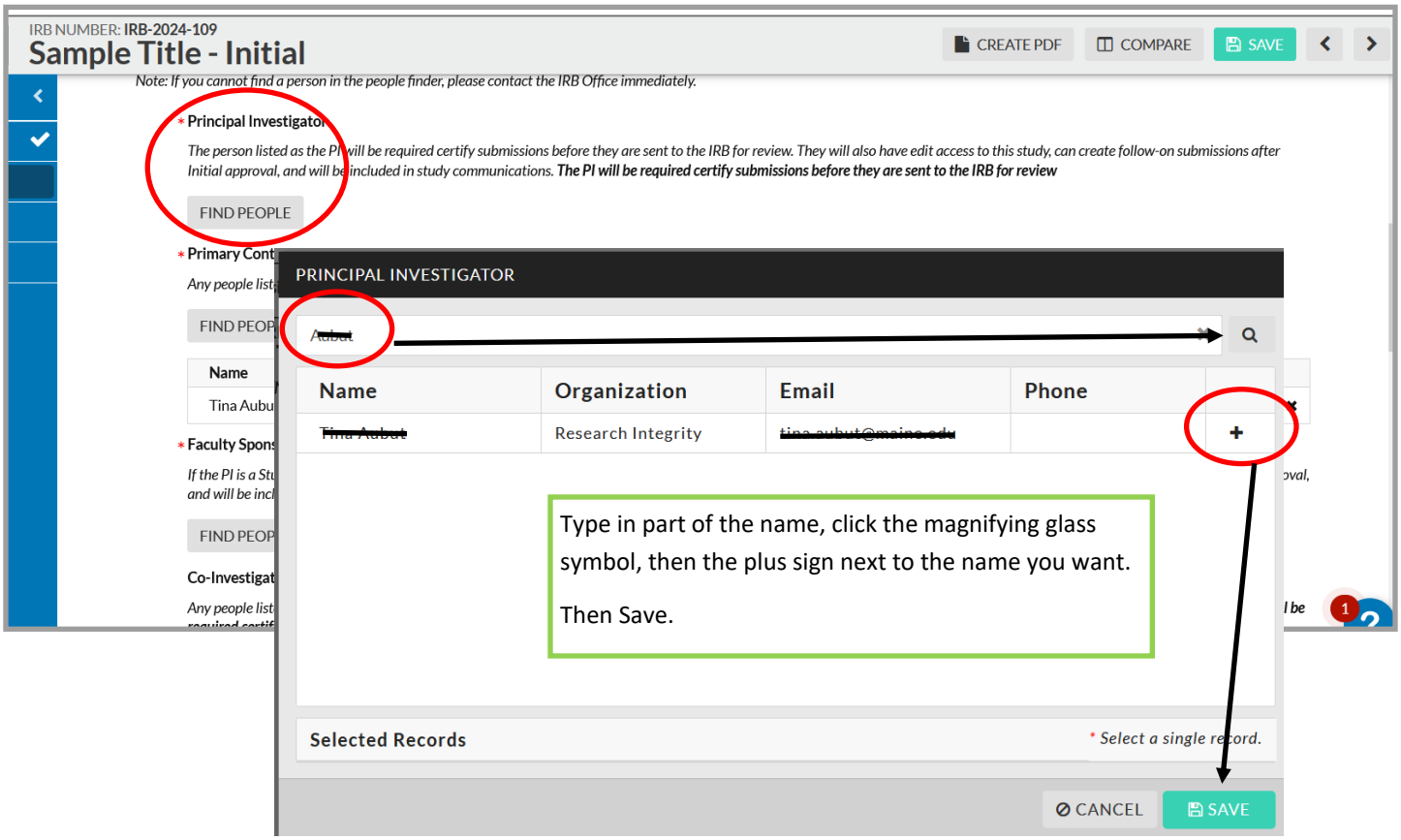
SUBMISSION DETAILS
IRB NUMBER: IRB-2024-109
Sample Title - Initial
CREATE PDF
COMPARE
SAVE
Sections
Getting Started
Getting Started
About Cayuse Human Ethics
Cayuse Human Ethics (HE) is an interactive web application. As you answer que
Therefore not all numbered sections may appear. You do not have to finish the
Additional information has been added throughout the form for guidance and
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.
FMI Collaborative Boards
IORG#: IORG 1507
Federalwide Assura
IRB 1953, U of Sout
IRB 11534, U of So
Read through Getting Started
Then click Yes that you have read the information.
The other sections will begin to appear based on your responses.
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.



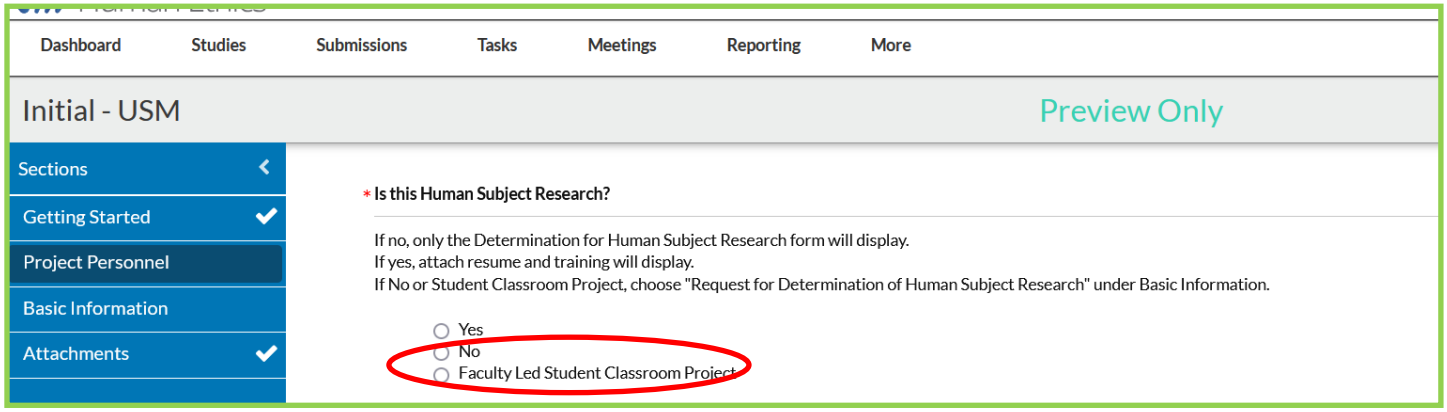
Click "Find People" to add the **Principal Investigator.** POP–UP: type in part of a name, click find icon.

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



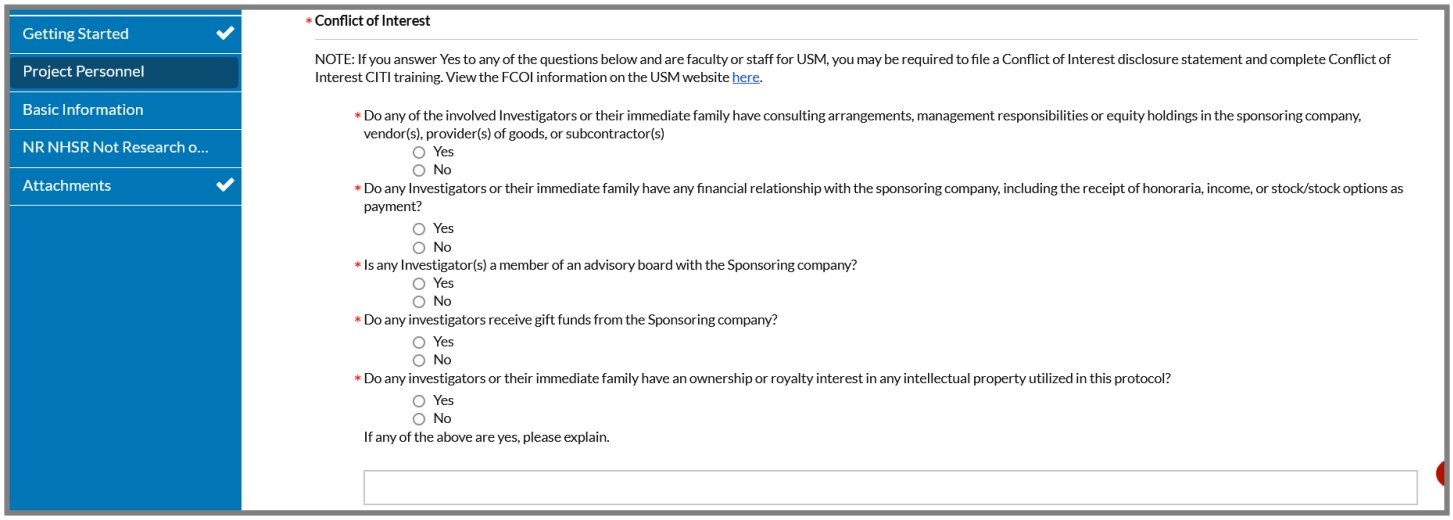
You may add more than one Co-PI. However, all the Co-PI(s) and Faculty Advisor are also ***required to certify submissions before they are sent to the IRB for review.*** As the protocol goes through a review, it may be sent back with questions. Each PI will need to certify each time it is returned to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

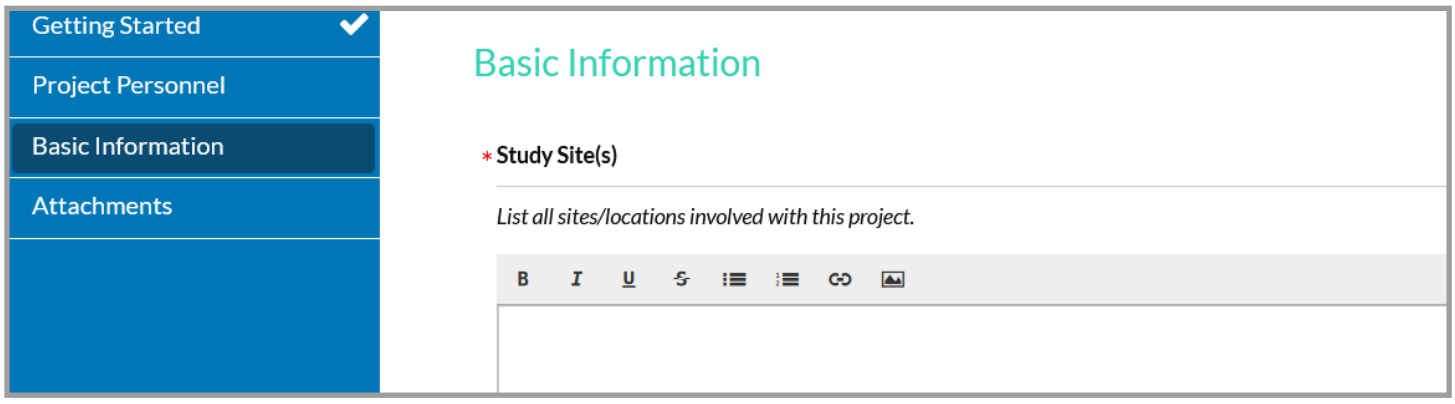
This guide shows the process for a **request for human subject research** projects. It is recommended that the student notify their Faculty Advisor when a draft is complete **BEFORE** Complete Submission and Certify the submission.

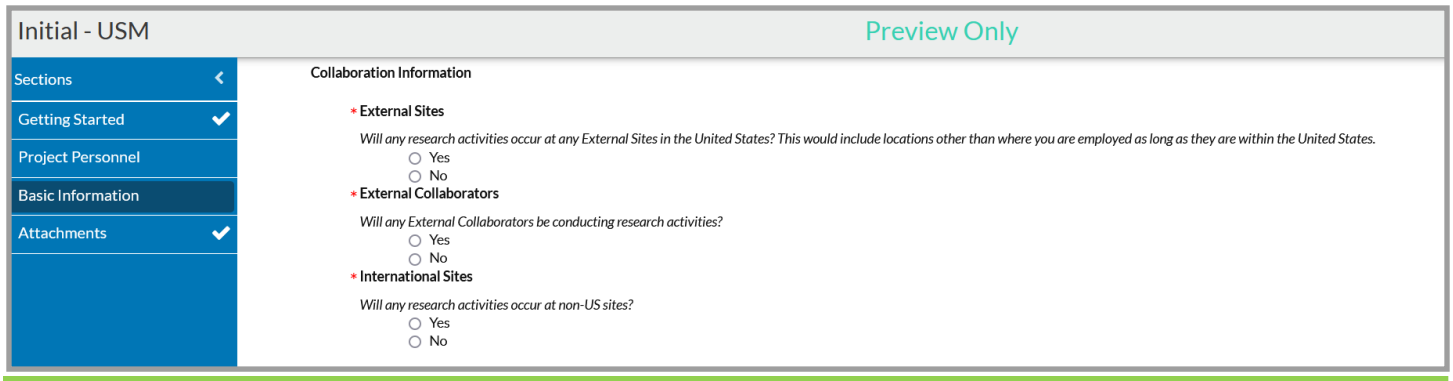


Faculty Led Student Classroom Project will ask to upload the Faculty Principal Investigator's CITI training, CV, and Course Syllabus.

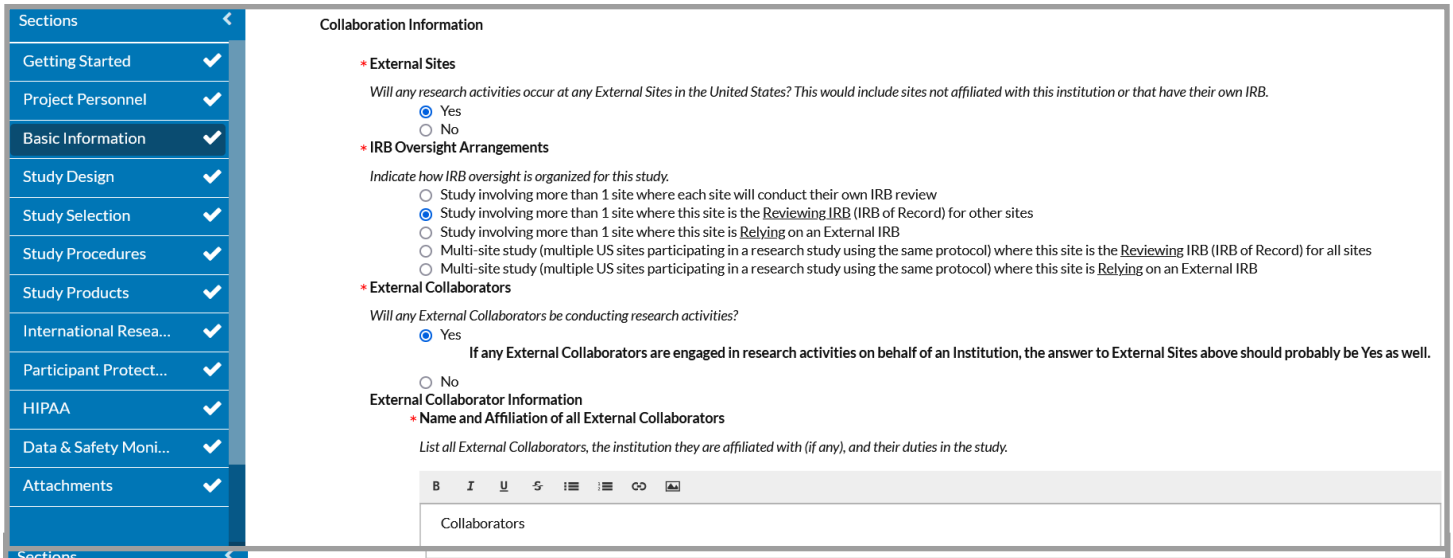
Conflict of Interest. If any are marked as Yes it will ask to explain and to pick a name of the person with the conflict.

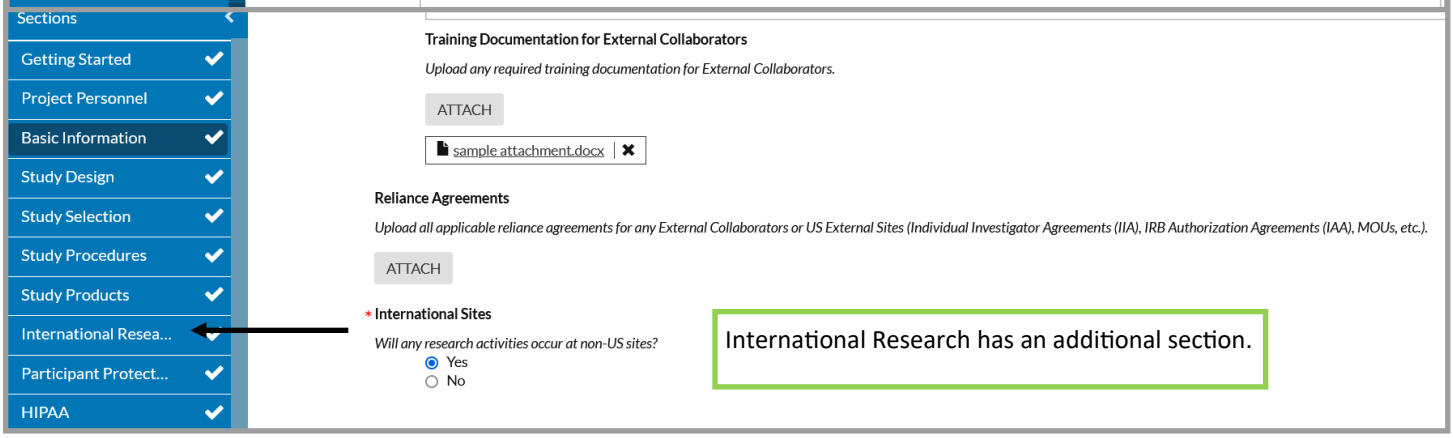




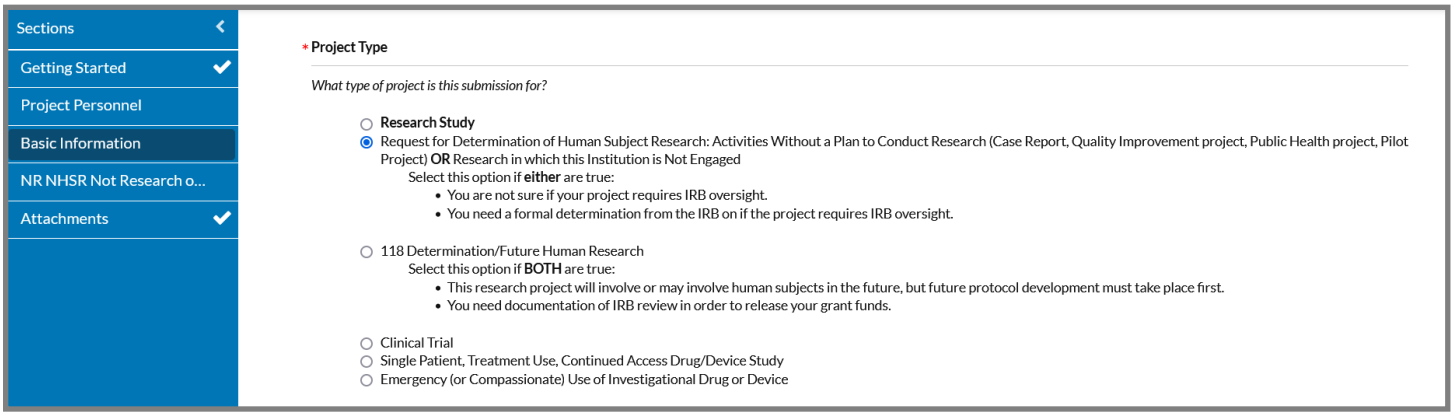


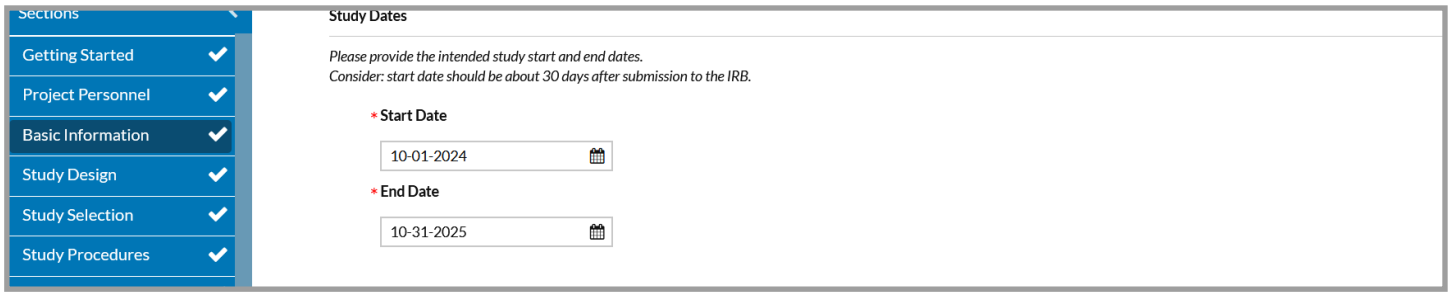
Depending on your answers to Collaborative Information, additional questions may appear. Example on next images.

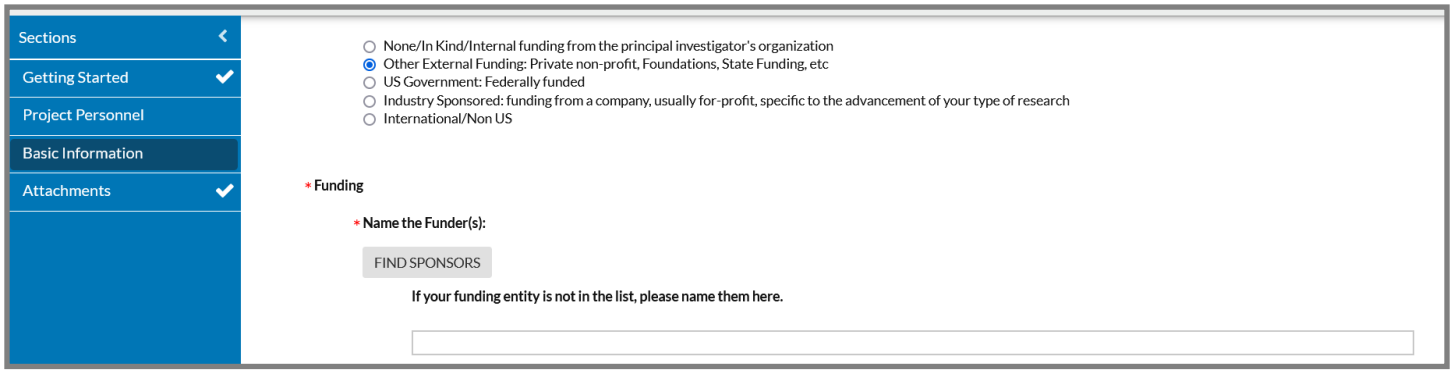


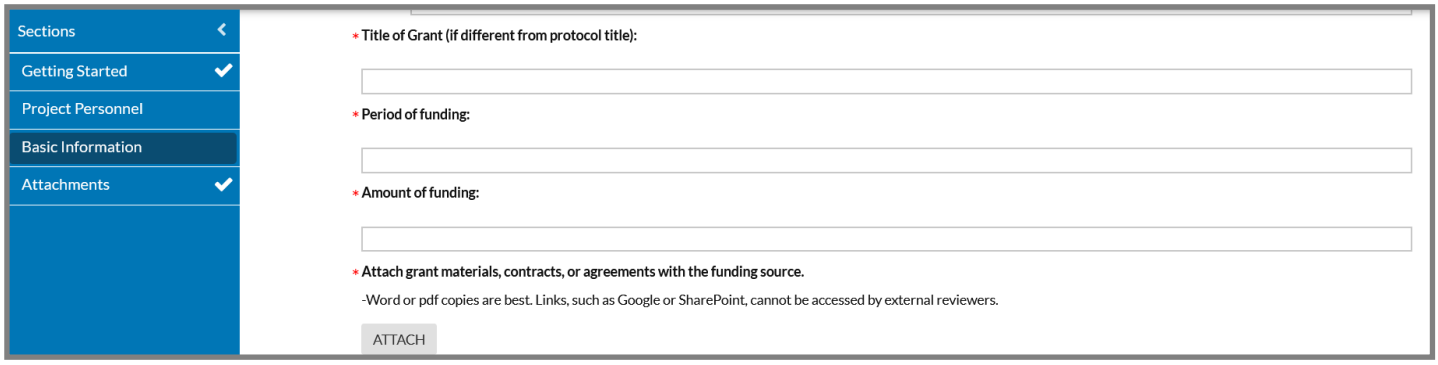


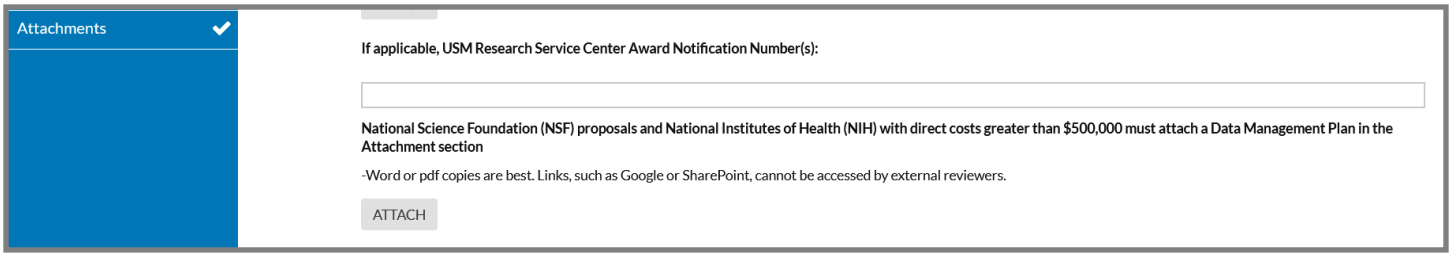
Once a Yes/No is chosen above, the type of project will appear. For this example, Research Study.



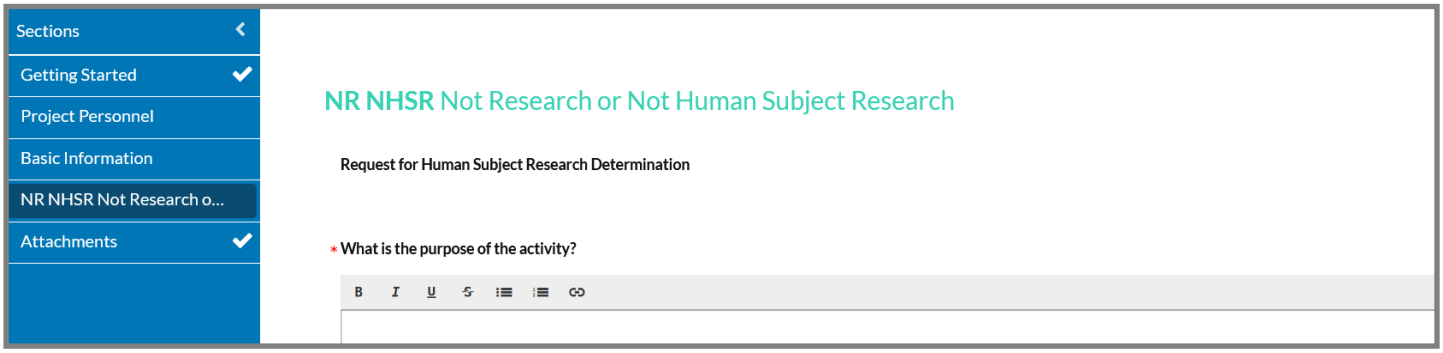


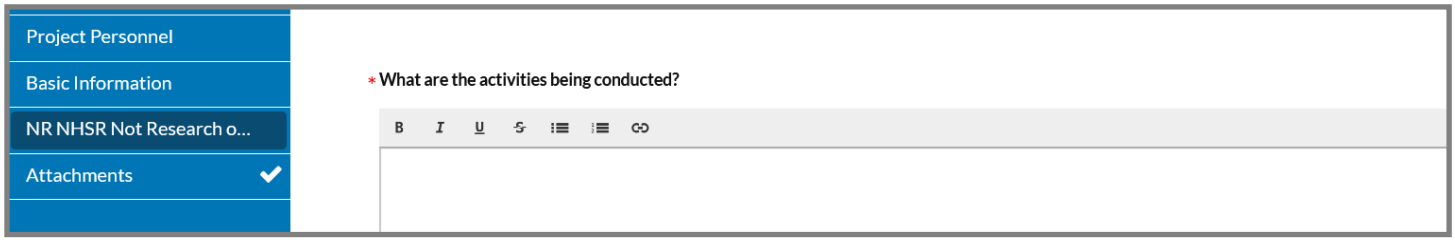


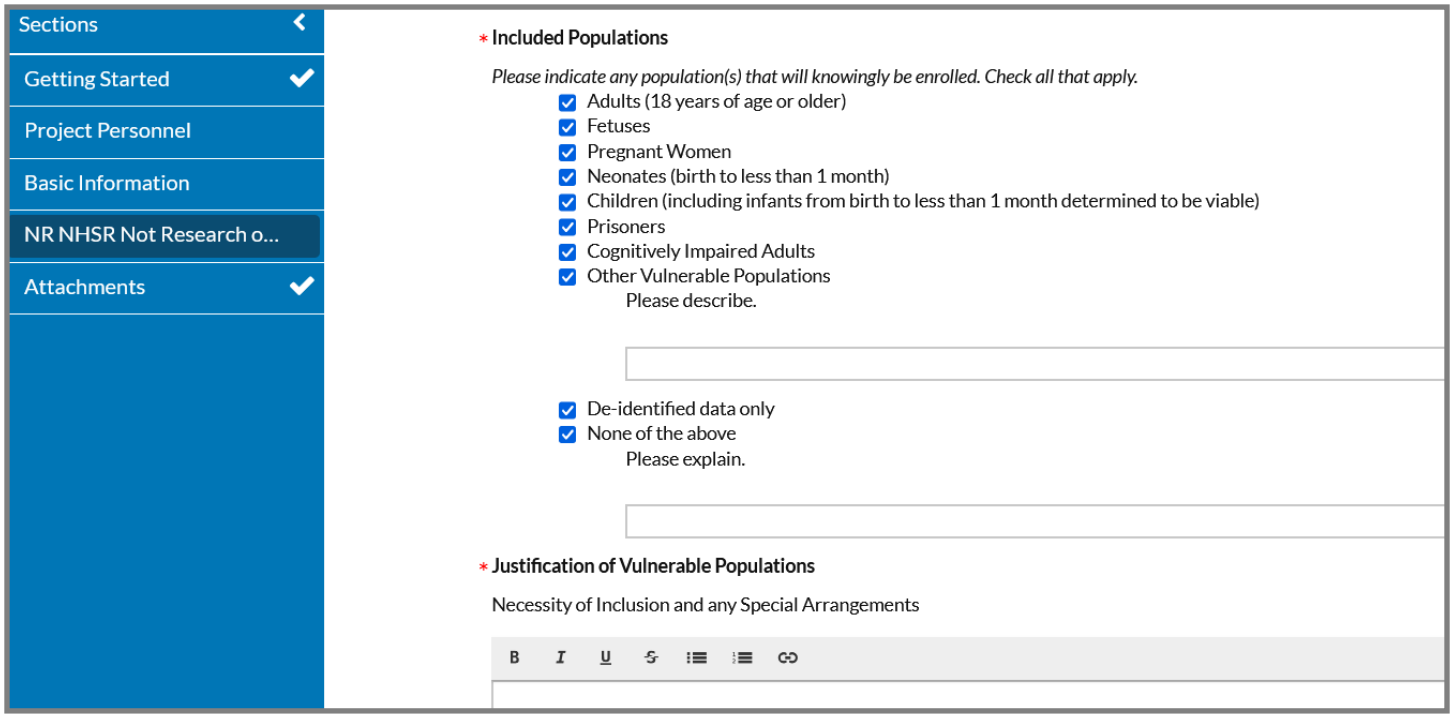


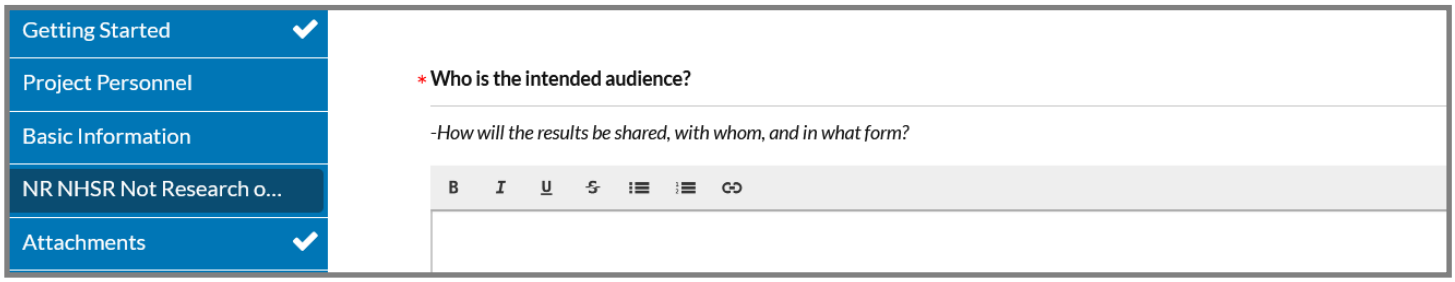


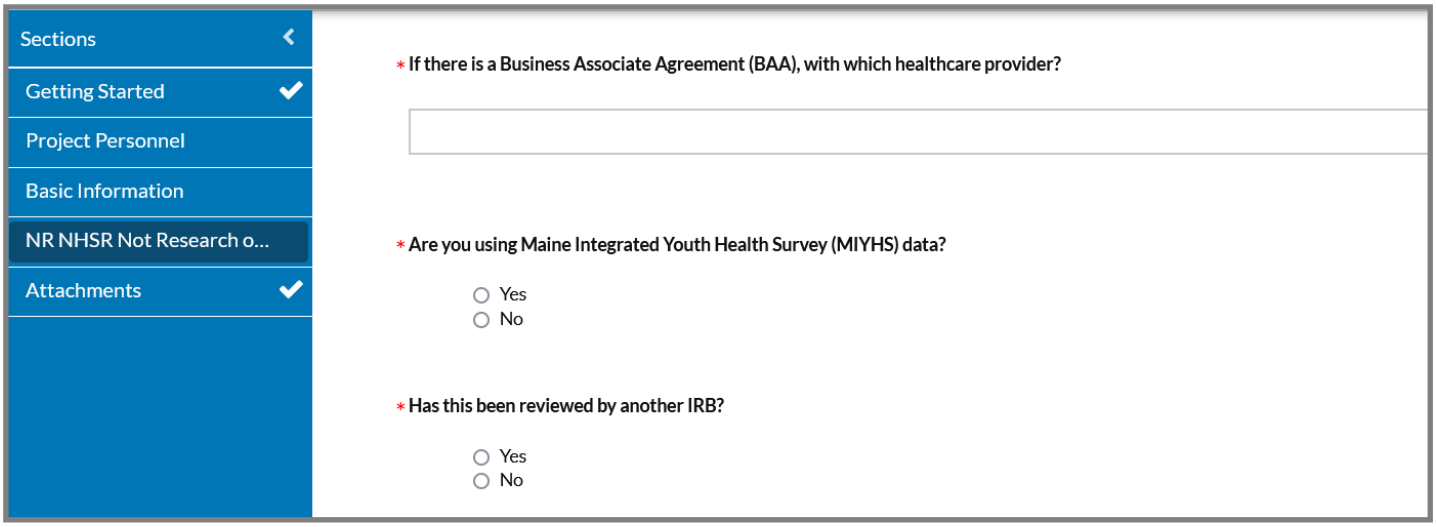
End of Basic Information Section

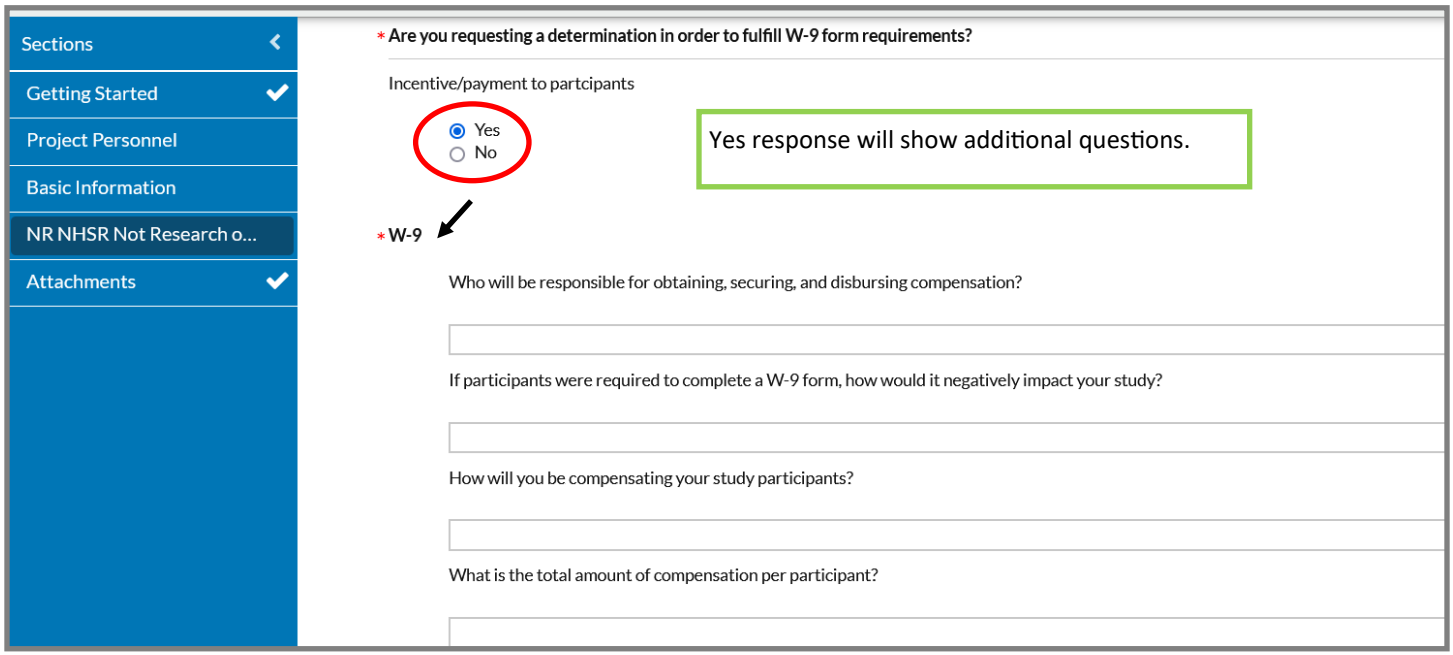

Sections
Getting Started
Project Personnel
Basic Information
NR NHSR Not Research o...
Attachments
NR NHSR Not Research or Not Human Subject Research
Request for Human Subject Research Determination
* What is the purpose of the activity?


Project Personnel
Basic Information
NR NHSR Not Research o...
Attachments
* What are the activities being conducted?


Sections
Getting Started
Project Personnel
Basic Information
NR NHSR Not Research o...
Attachments
* Included Populations
Please indicate any population(s) that will knowingly be enrolled. Check all that apply.
Adults (18 years of age or older)
Fetuses
Pregnant Women
Neonates (birth to less than 1 month)
Children (including infants from birth to less than 1 month determined to be viable)
Prisoners
Cognitively Impaired Adults
Other Vulnerable Populations
Please describe.
De-identified data only
None of the above
Please explain.
* Justification of Vulnerable Populations
Necessity of Inclusion and any Special Arrangements


Getting Started
Project Personnel
Basic Information
NR NHSR Not Research o...
Attachments
* Who is the intended audience?
-How will the results be shared, with whom, and in what form?


Sections
Getting Started
Project Personnel
Basic Information
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


Sections
Getting Started
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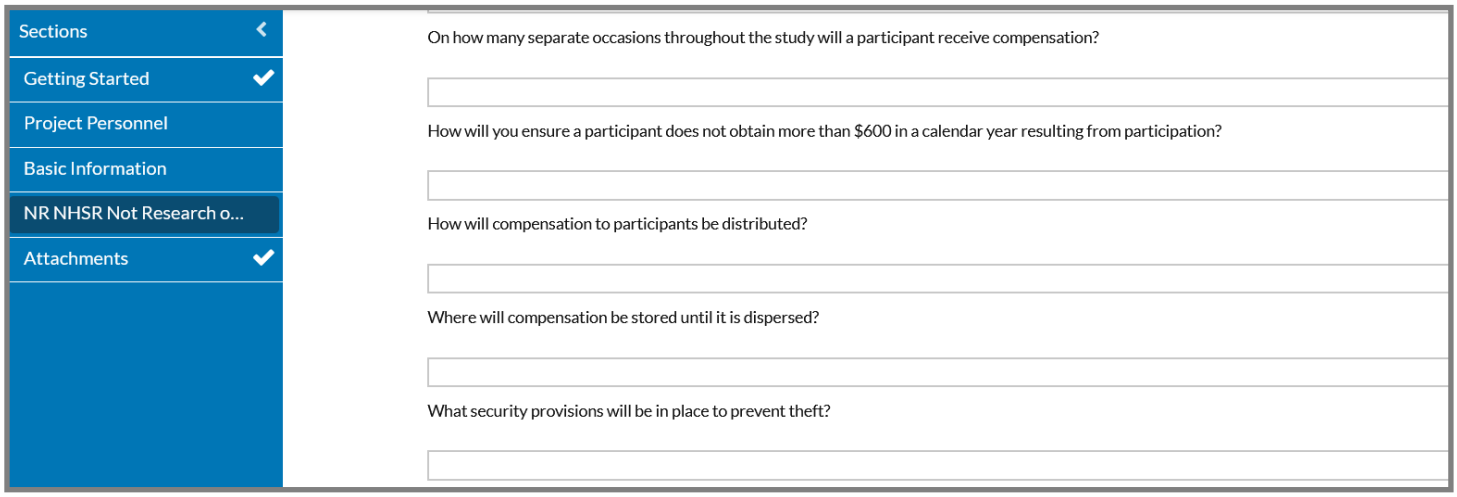
Basic Information
NR NHSR Not Research o...
Attachments
* Are you requesting a determination in order to fulfill W-9 form requirements?
Incentive/payment to partcipants
Yes
No
Yes response will show additional questions.
* W-9
Who will be responsible for obtaining, securing, and disbursing compensation?
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?


Sections
Getting Started
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NR NHSR Not Research o...
Attachments
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?

Sections

- Getting Started ✓
- Project Personnel
- Basic Information
- NR NHSR Not Research o...
- Attachments ✓

* **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

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

* **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

Sections

- Getting Started ✓
- Project Personnel
- Basic Information
- NR NHSR Not Research o...
- Attachments ✓

* **If the project is research, does it meet the definition of "Human Subject" research?**

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 or intervention with individuals?**

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

NR NHSR Not Research o...
Attachments ✓

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

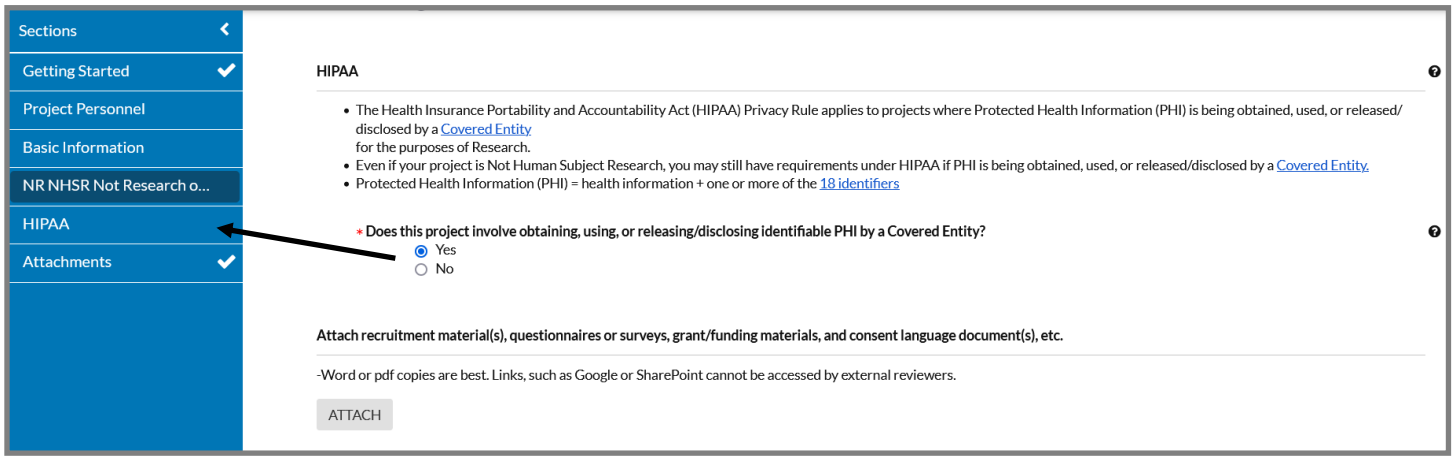
Private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will 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.*

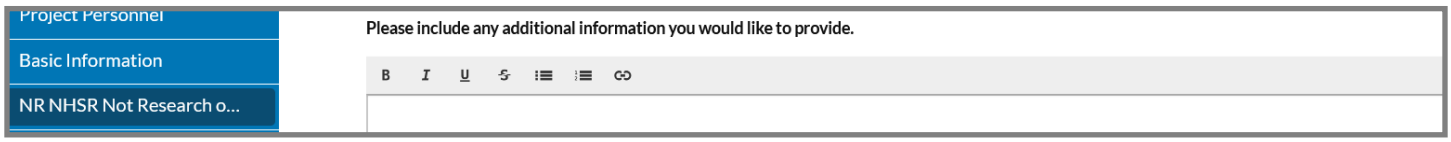
- ○ Yes
- ○ No

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

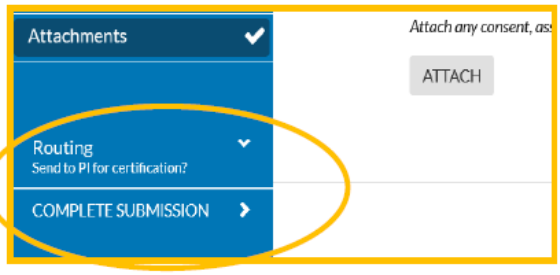
Identifiable biospecimens means the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

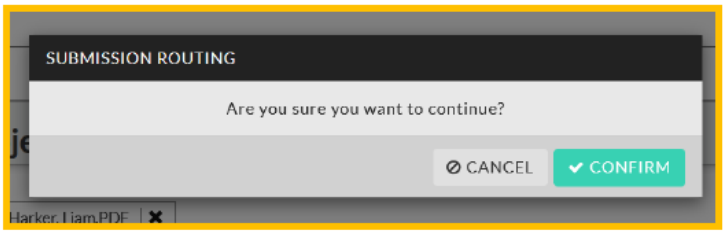
- ○ Yes
- ○ No



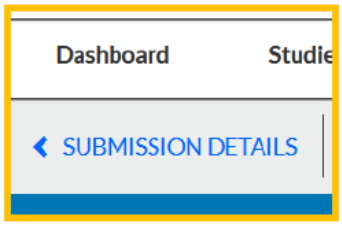


Once each section has a checkmark, the COMPLETE SUBMSISION will appear. Click on COMPLETE SUBMISSION.





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



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