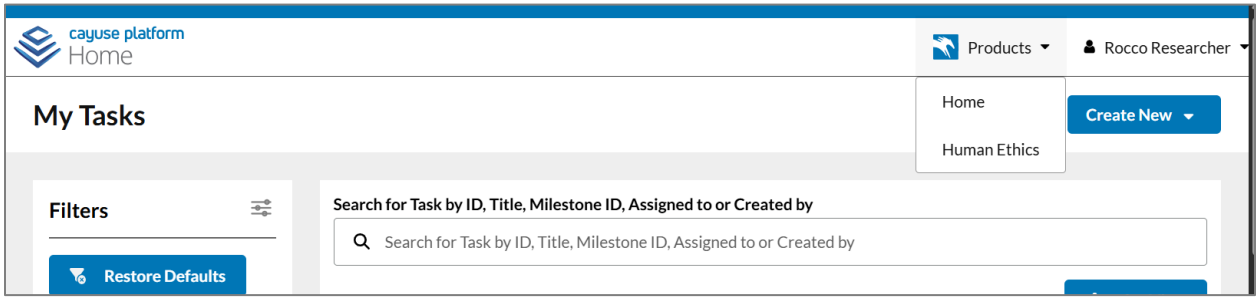
Request for Determination of Human Subject Research

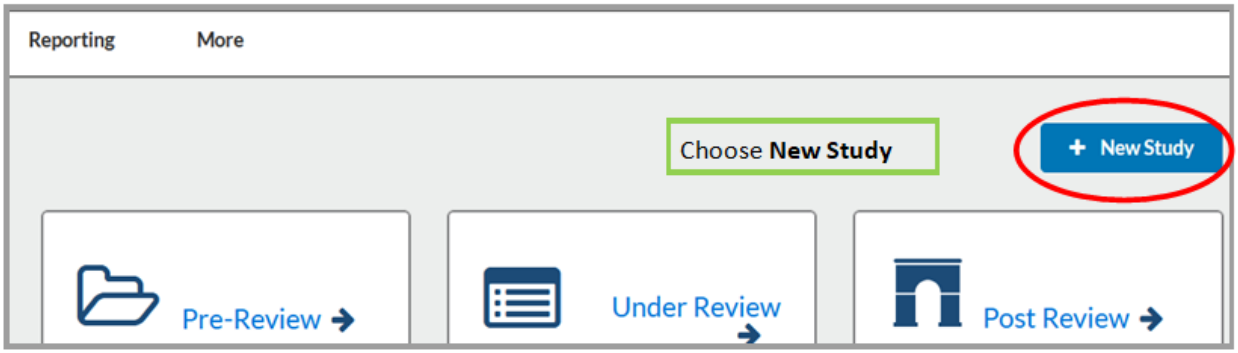
Faculty Led Student Classroom Project

Dashboard

After logging in to Cayuse, select “Human Ethics” from the Products drop-down on the landing page to get to your Dashboard.

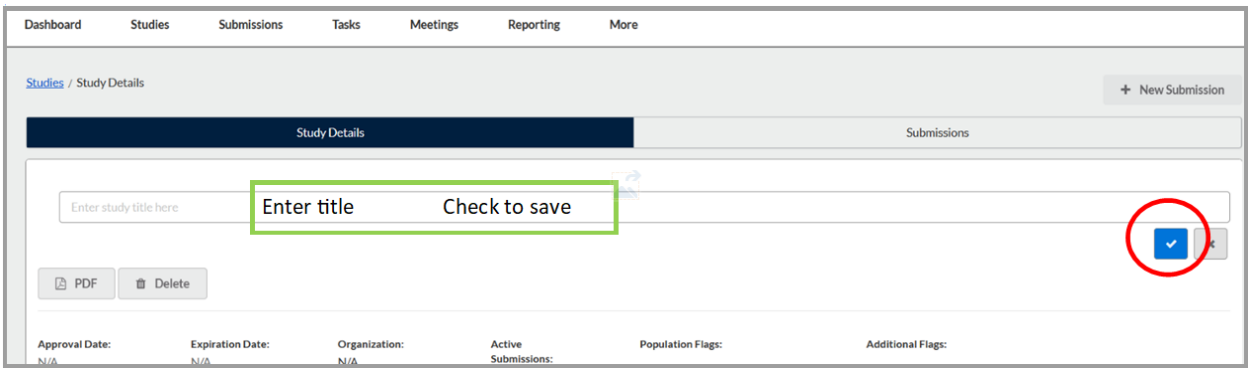


On your Dashboard click on the New Study button on the upper right of the page to start a new study.

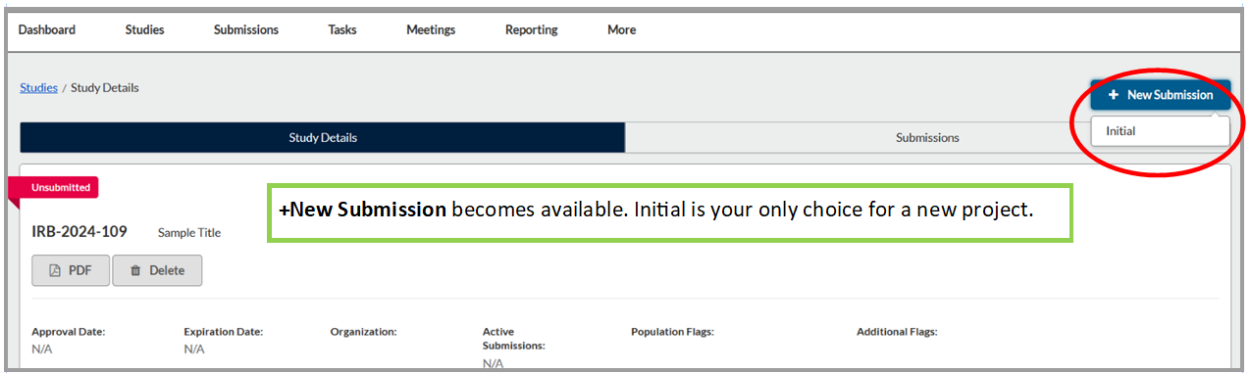


Study Details

The new study defaults to Study Details where there is a text box to enter the project's title. Click on the check mark to save the title.



After setting the title, the New Submission button is available. Click on the button on the button to choose Initial from the drop-down menu.



Submission Details

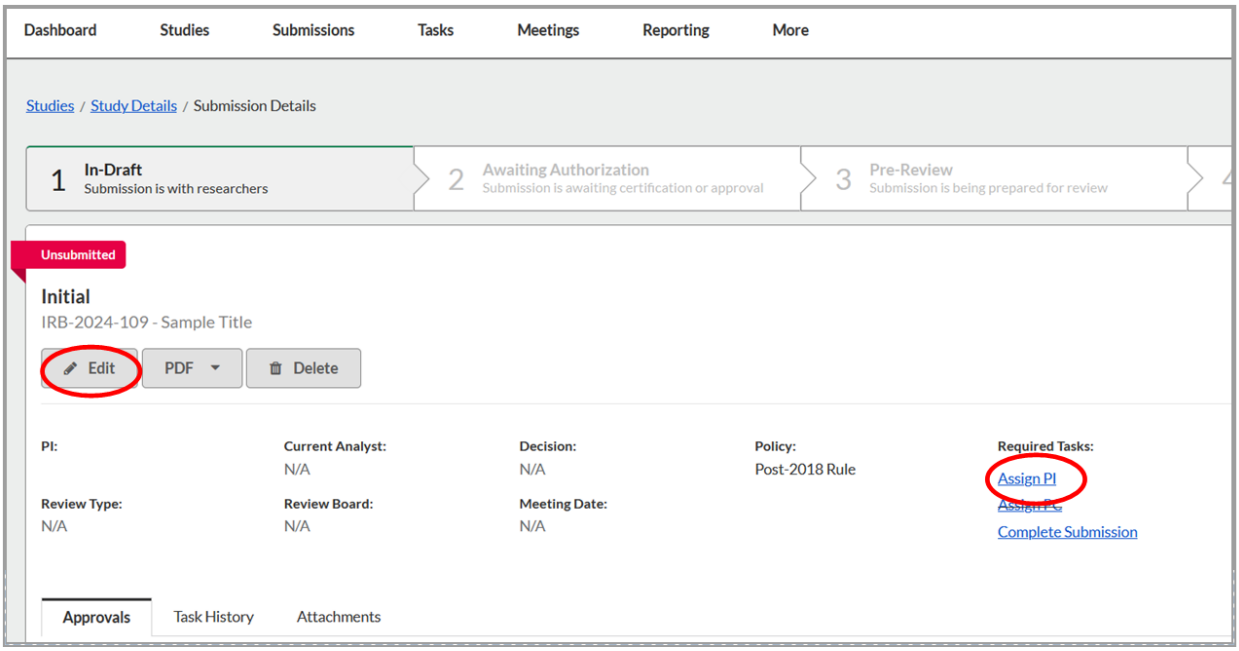
Cayuse automatically provides a protocol number for the initial submission.

To the right is a list under Required Tasks that are highlighted as links. Assign PI, Assign PC, and Complete Submission.

PI stands for Principal Investigator, PC stands for Primary Contact.

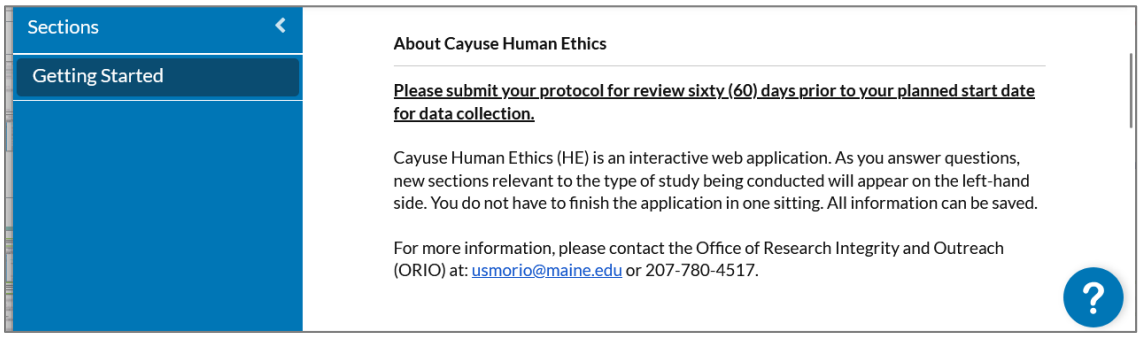
The person filling out the submission automatically a Primary Contact so Assign PC is crossed off the list. Additional Primary Contacts can be added within the form.

Click on either Edit button or Assign PI link, either will take you into the protocol form.

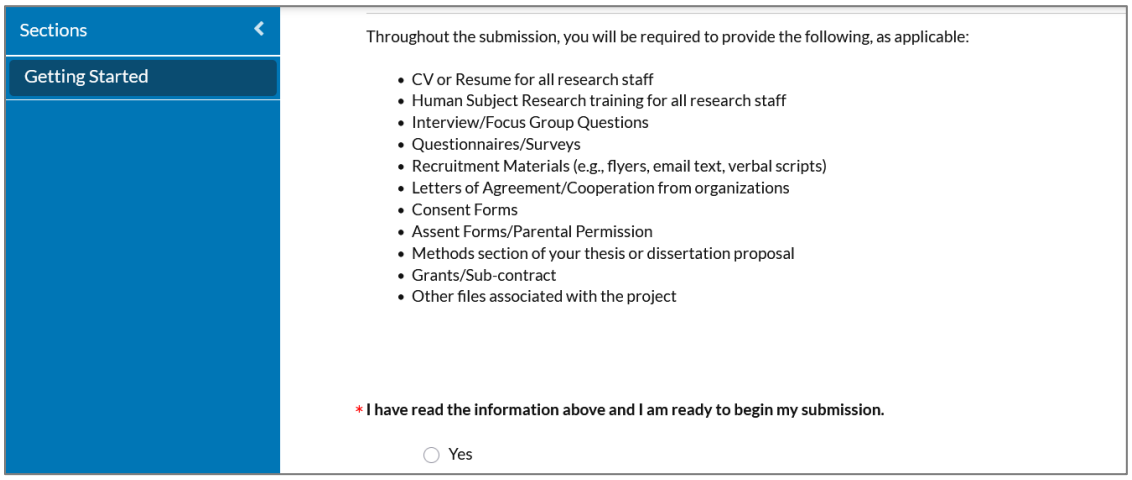


Getting Started

Once in the form, the navigation bar on the left will show each section completed and show a checkmark. Getting started shows a list of possible documents you will need to attach. **Please submit your protocol for review sixty (60) days prior to your planned start date for data collection.** Click Yes that you have reviewed them to continue.

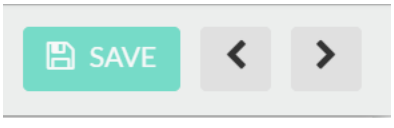


"Getting Started" listing required documents and materials for submission, including CV, human subject research training, interview questions, surveys, recruitment materials, consent forms, and grant proposals. A confirmation statement with a red asterisk asks users to acknowledge readiness to begin submission, followed by a "Yes" radio



Any question with a red asterisk requires a response.

Use the Save button in the upper right of the page frequently. Use the previous page and next page navigation buttons instead of the browser navigation.

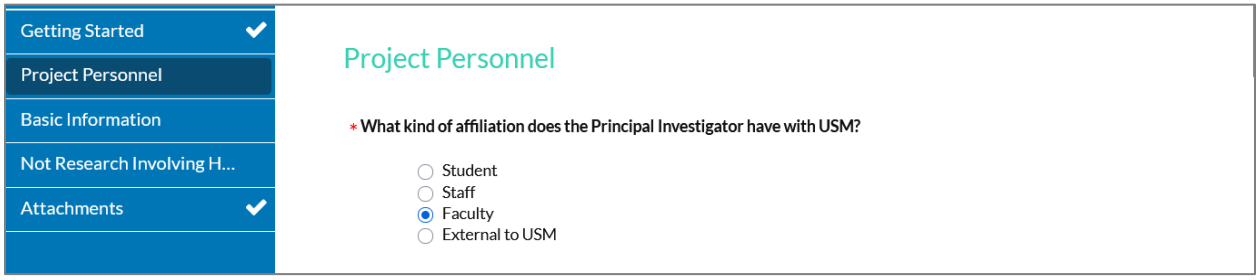


Save as you go along to not lose your work.

Project Personnel

Check the Principal Investigator's role in the context of the research submission from Student, Staff, Faculty, or External to USM.

Enter the name of the USM Department or External Organization in the context of the project in the text box.



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 (PI) and Co-Principal Investigator (Co-PI)

The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable USM policies and procedures and federal, state, and local laws and regulations. The person listed as the PI will 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 to certify submissions before they are sent to the IRB for review.**

Co-Principal Investigator

Any person listed as Co-Principal Investigator (Co-PI) will have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications. The Co-PI will be required to certify submissions before they are sent to the IRB for review.

Primary Contact

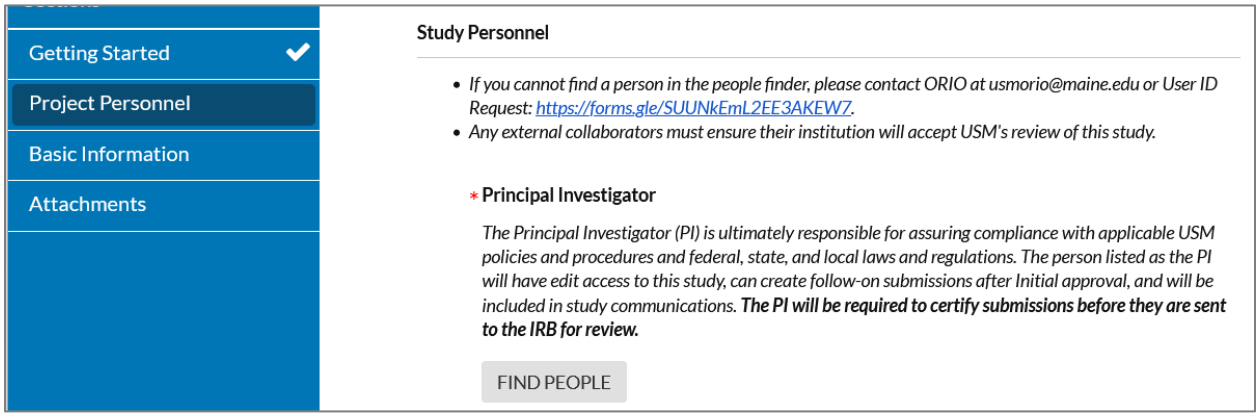
Any person listed as a PC will have edit access to this study, can create follow-on submissions after Initial approval, and will be included in study communications.

Investigators

Any person listed as Investigators will be able to view the study, but will NOT have edit access to the study nor be included in study communications automatically.

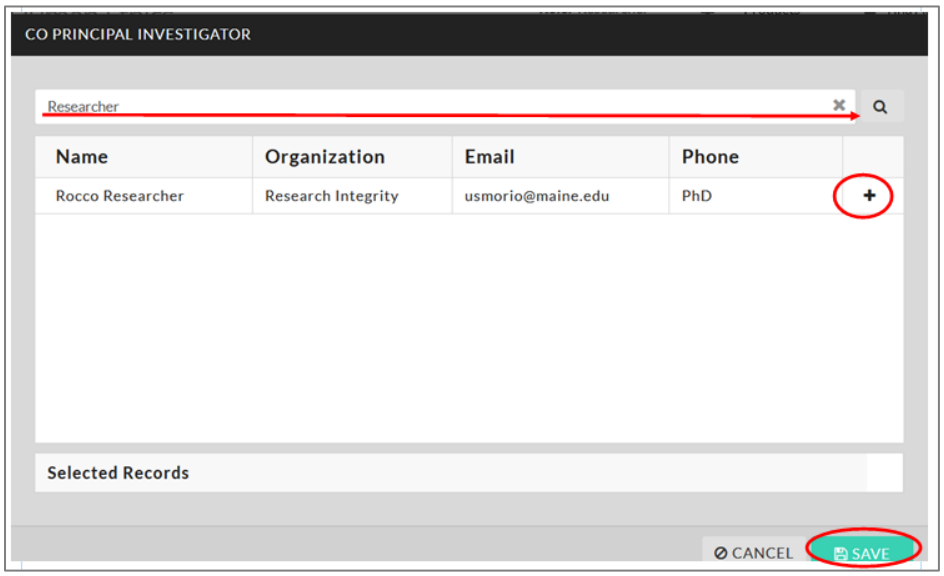
Other Research Team Members

Any person listed as Other Research Team Members will be NOT able to view the study, edit, nor be included in study communications automatically.



Add a Person to a Role

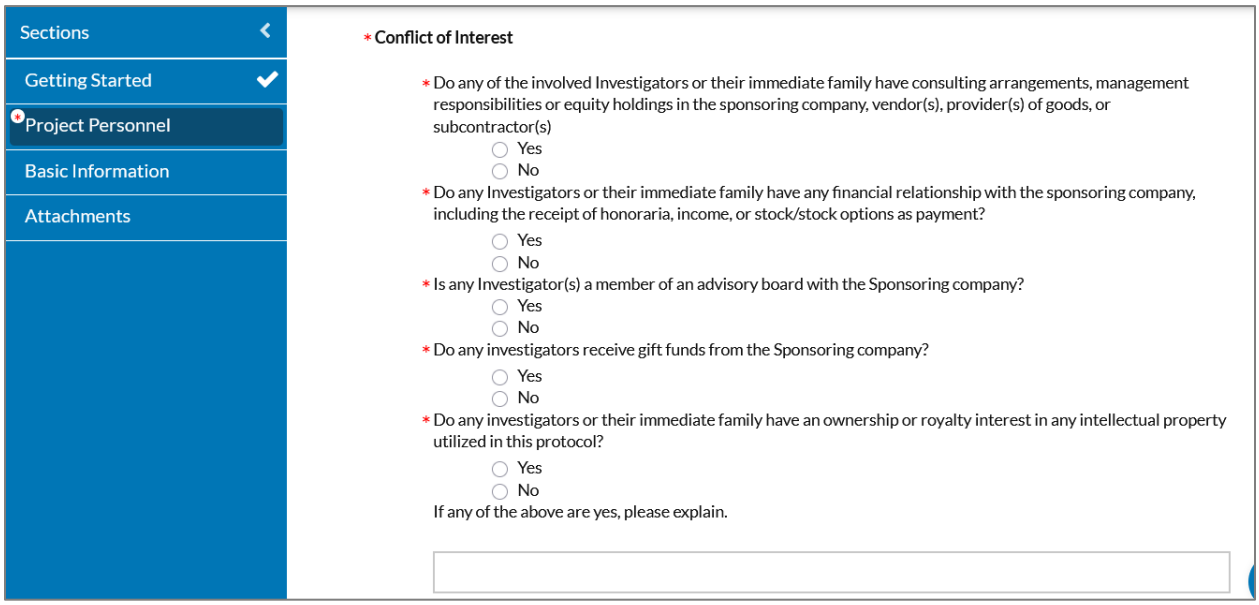
To add a person to a role, click on the Find People for that role. A pop-up window will appear. In the text area, type in part of their name, click the magnifying glass to the right to find. Click the plus sign to the right of their name and Save.



Conflicts of Interest

These questions are asked in the context of the study ie the site, funding, etc

- 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)
- 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?
- Is any Investigator(s) a member of an advisory board with the Sponsoring company?
- Do any investigators receive gift funds from the Sponsoring company?
- Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?
- If any of the above are yes, please explain.

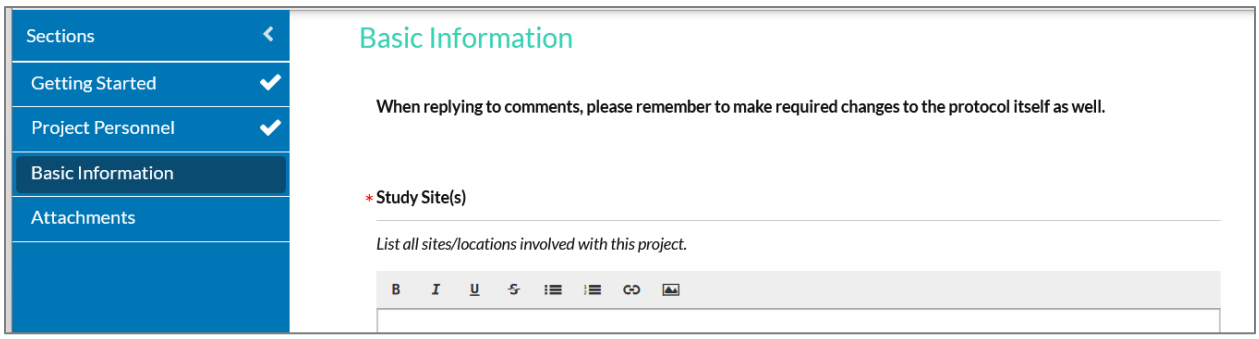


Basic Information

When replying to comments, please remember to make required changes to the protocol itself as well.

Study Site(s)

List all sites/locations involved with this project.

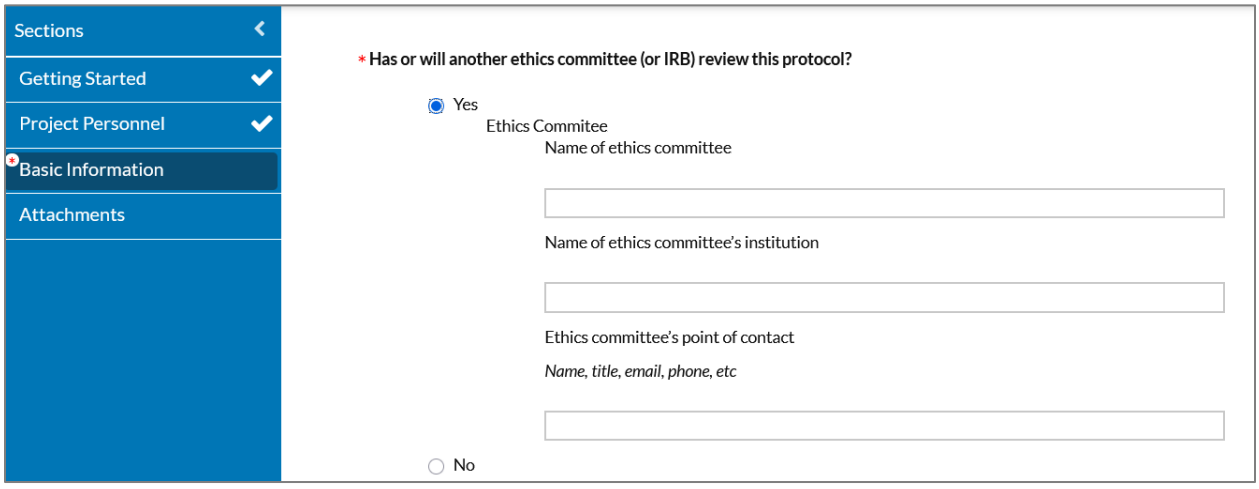


Personnel now has a checkmark. That means the section is complete.

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

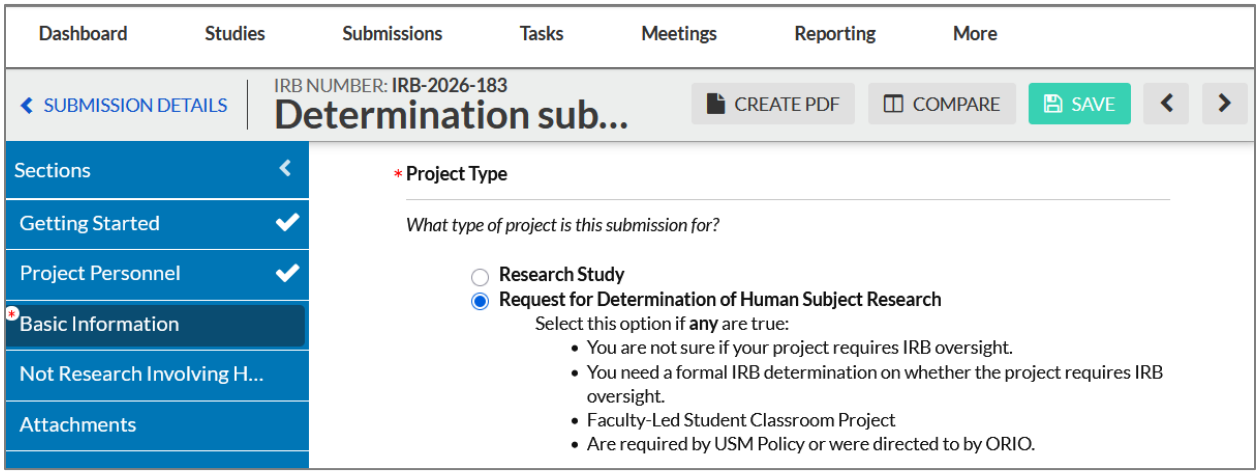
Yes/No, If yes text boxes for:

- Name of Ethics Committee
- Name of ethics committee's institution
- Ethics Committee's point of contact: Name, title, email, phone, etc



Project Type

Once you check **Request for Determination of Human Subject Research** other sections will appear in the left navigation.

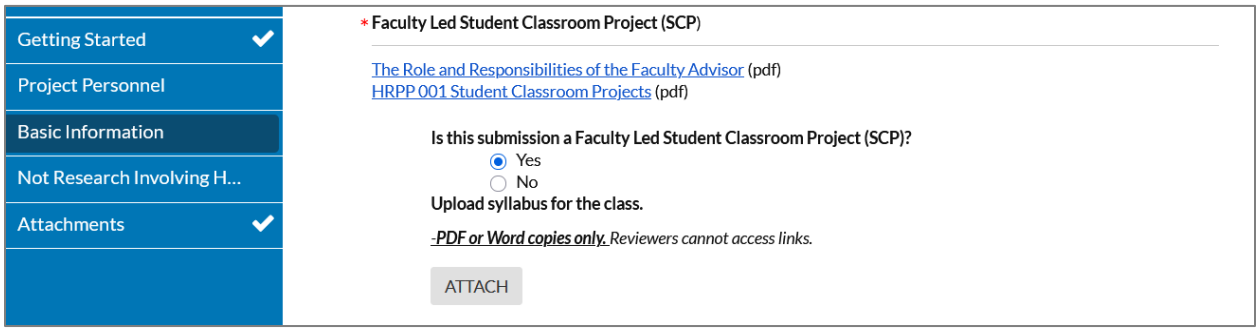


Faculty Led Student Classroom Project (SCP)

This section will appear when **Faculty** is checked under the question "What type of affiliation does the PI have with USM?"

Is this submission a Faculty Led Student Classroom Project (SCP)?

Yes/No, if yes upload syllabus for this class. PDF or Word copies only.

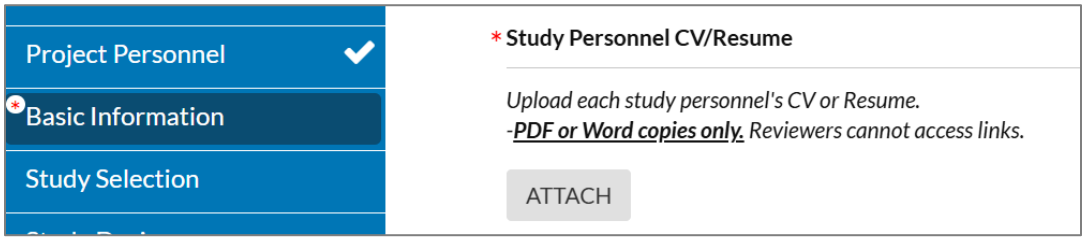


Study Personnel CV/Resume

Upload each study personnel's CV or Resume.
-PDF or Word format only. Reviewers cannot access links.

ATTACH button

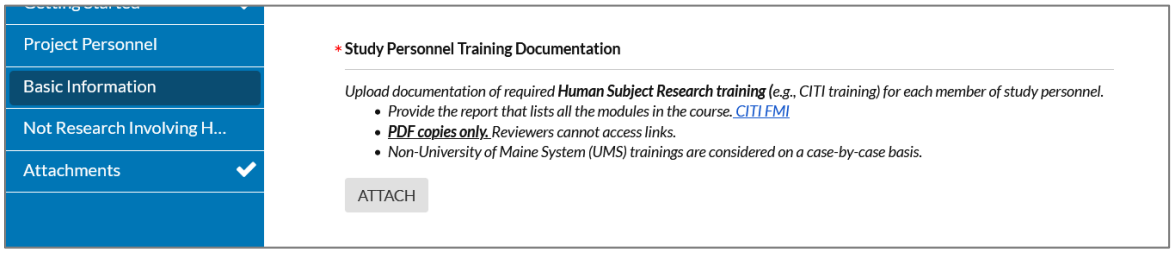
Study Personnel are considered to be persons who 1) obtain or view data about living individuals for research purposes through intervention or interaction with them; 2) obtain individually identifiable private information for research purposes; and/or 3) obtain informed consent of human research participants.



Study Personnel Training Documentation

SCP is the exception to providing proof of human subject research CITI training for a determination of research. Faculty are expected to have completed the course.

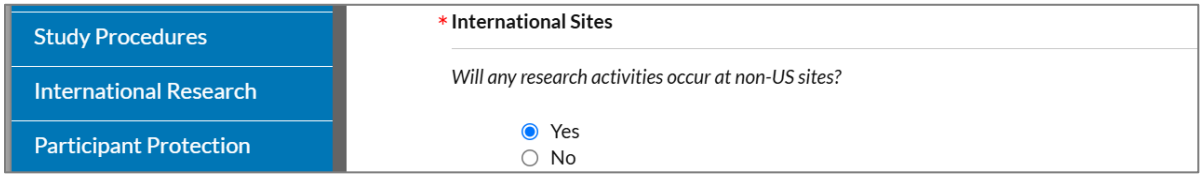
ATTACH Button for pdf copy of CITI completion report



International Research Sites

Will any research activities occur at non-US sites?

Yes/No, If yes, the International Research section will appear in the left navigation bar.

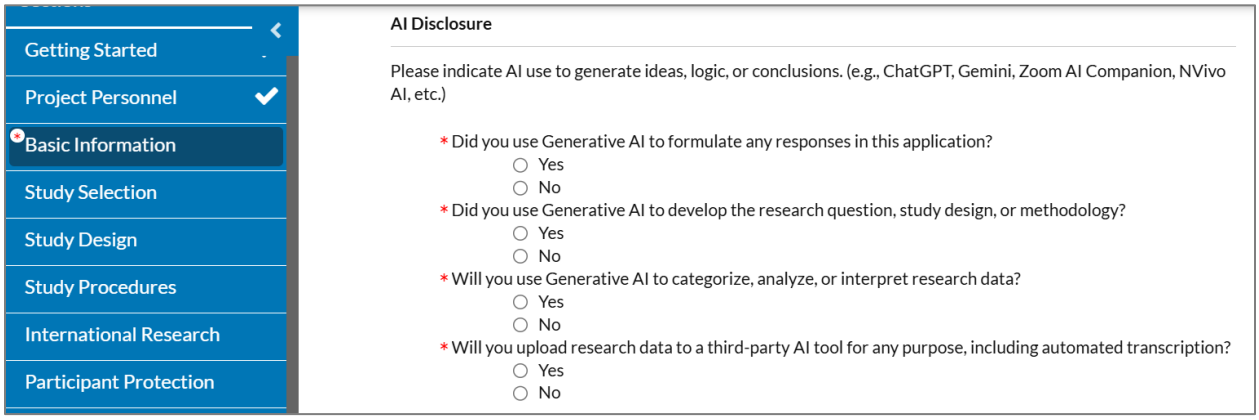


Artificial Intelligence (AI)

Please indicate AI use to generate ideas, logic, or conclusions.

- 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)

- 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?
- Is any Investigator(s) a member of an advisory board with the Sponsoring company?
- Do any investigators receive gift funds from the Sponsoring company?
- Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?
- If any of the above are yes, please explain.

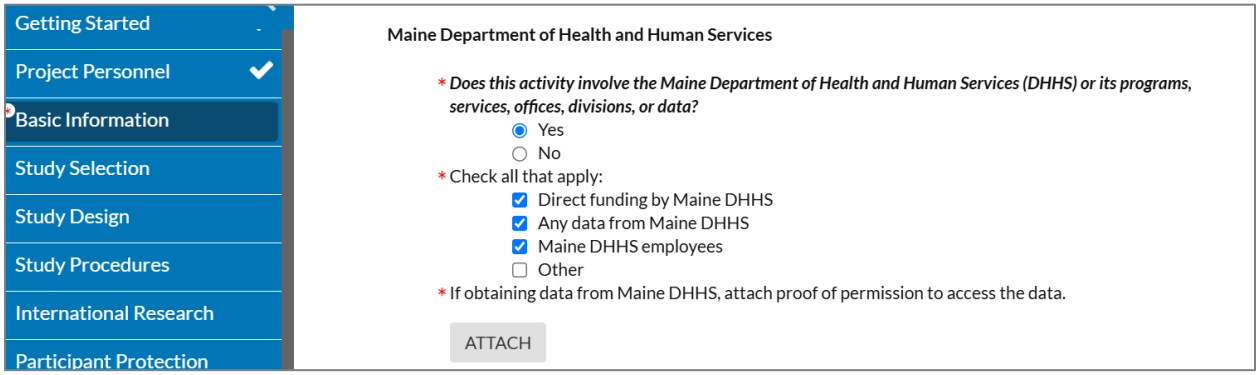


Maine Department of Health and Human Services

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

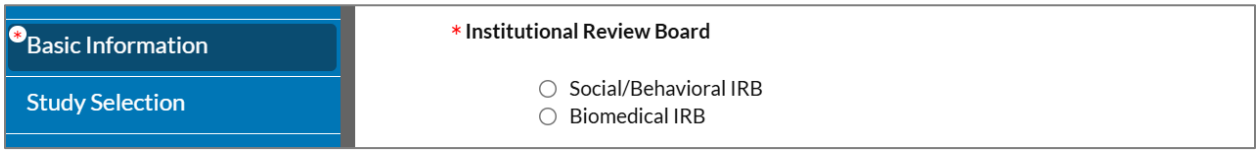
Yes/No, If yes check all that apply:

- Direct funding by Maine DHHS
- Any data from Maine DHHS
- Maine DHHS employees
- Other: Describe other: Text box



Institutional Review Board

- Social and Behavioral
- Biomedical IRB



Study Dates

Please provide the intended study start and end dates.

- State Date: Start date to collect data should be about **60 days** after submission to the IRB.
- End Date: Date picker

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.)?

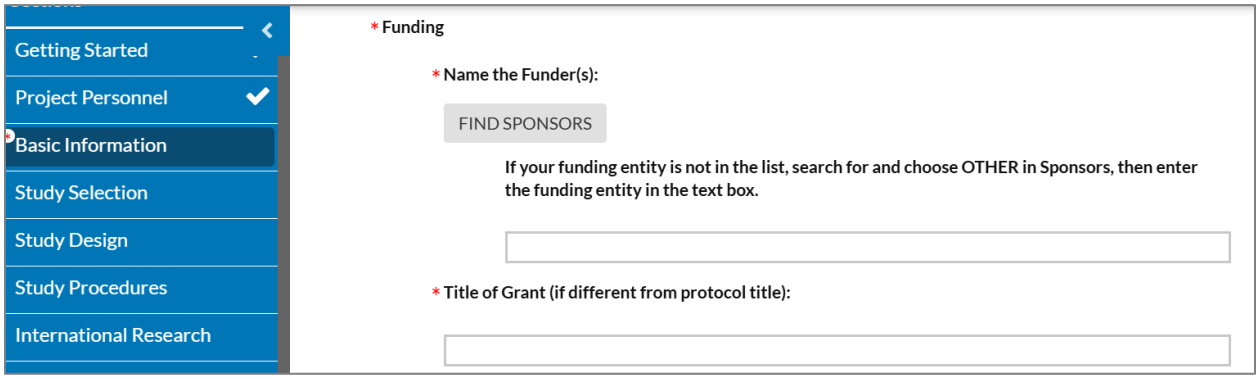
- ☐ None/In Kind/Internal funding from the principal investigator's organization
- ☐ Other External Funding: Private non-profit, Foundations, State Funding, etc
- ☐ US Government: Federally funded
- ☐ Industry Sponsored: funding from a company, usually for-profit, specific to the advancement of your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

If any response is other than None/Inkind/Internal funding, additional questions will be asked. See next.

Find Sponsors

Click the **Funding Sponsors** button for the funding source. If your funding entity is not in the list, search for and choose OTHER in Sponsors, then enter the funding entity in the text box.

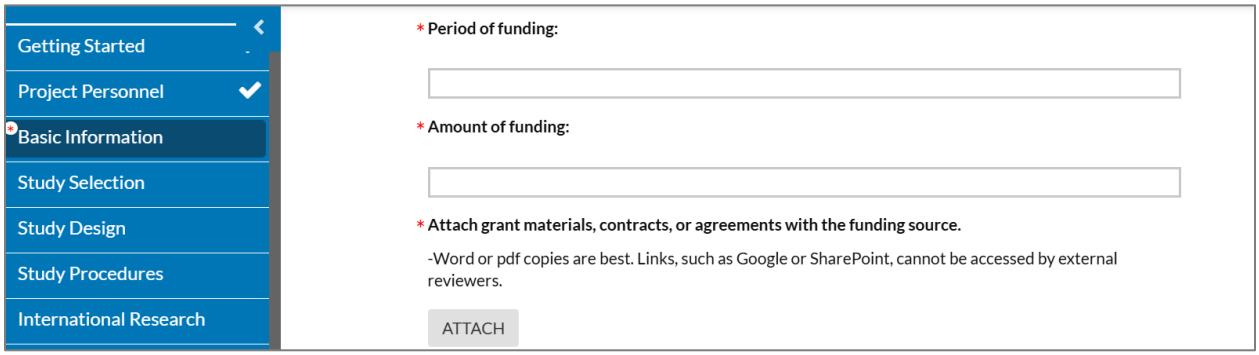
Title of Grant (if different from protocol title): text box



Period of funding: Text box

Amount of Funding: Text box

Attach grant materials, contracts, or agreements with the funding source. ATTACH button



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

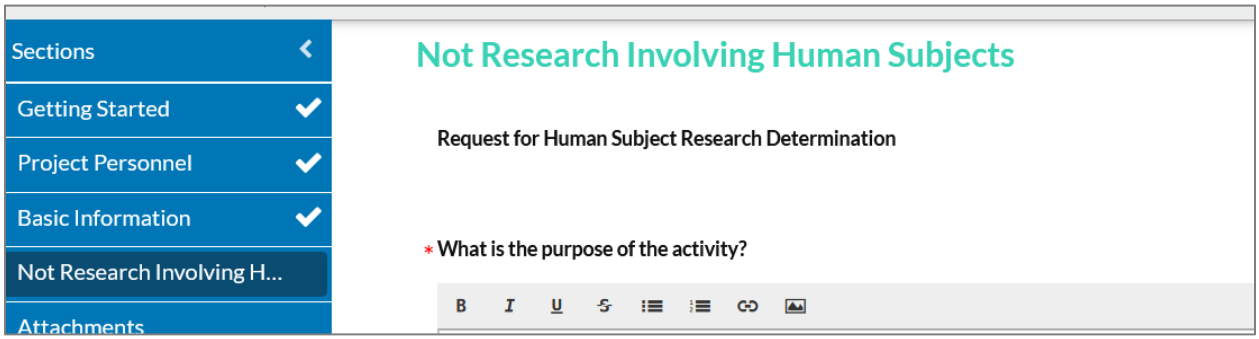
Text box

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.

ATTACH button

Not Research Involving Human Subjects

What is the purpose of the activity? Text box



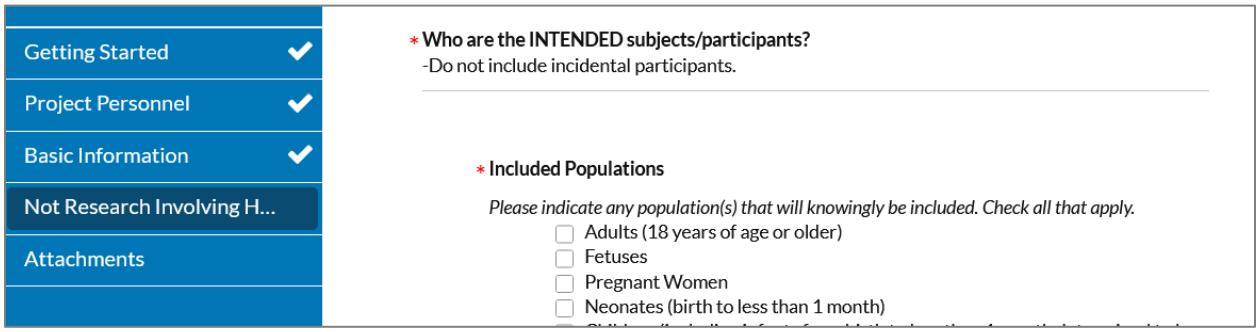
What are the activities being conducted? Text box

Who are the INTENDED subjects/participants?
-Do not include incidental participants.

Included Populations

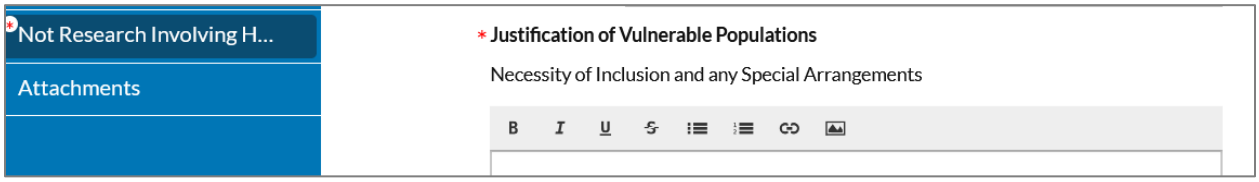
Please indicate any population(s) that will knowingly be included. **Check all that apply**.

- ☐ 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)
- ☐ Students - any grade (including pre-school to post-graduate)
  Prisoners
- ☐ Cognitively Impaired Adults
- ☐ Other Vulnerable Populations: Please describe Text box
- ☐ De-identified data only
- ☐ None of the above: Please explain Text box



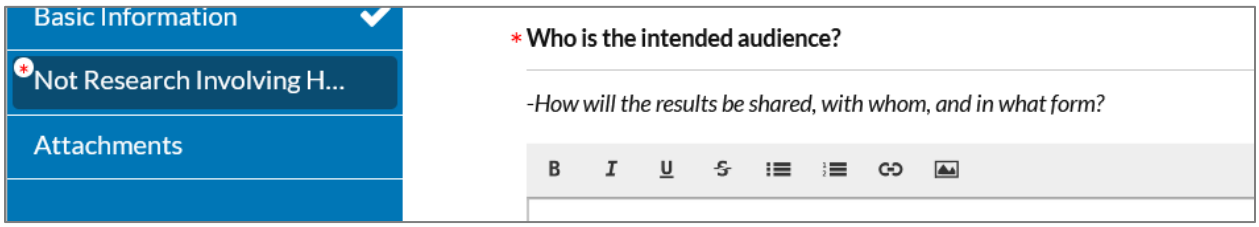
Justification of Vulnerable Populations

Necessity of Inclusion and any Special Arrangements. Text box



Who is the intended audience?

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



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

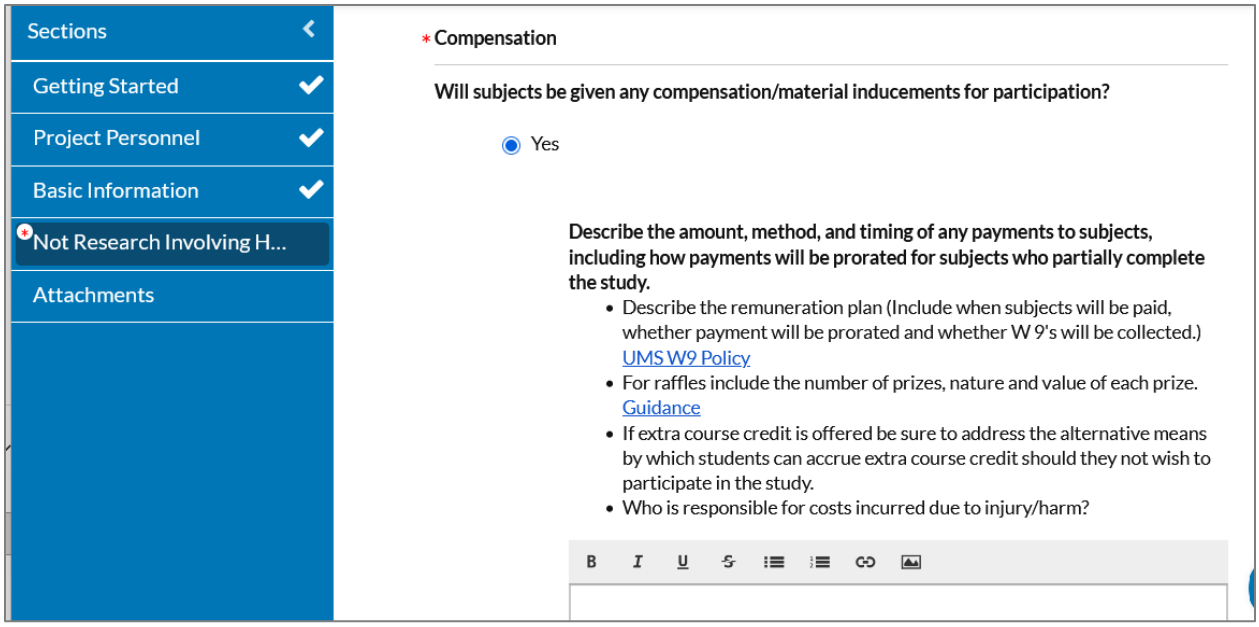
Yes/No, If yes, Remember to check Yes to Maine Department of Health and Human Services under Basic Information.

Compensation

Will subjects be given any compensation/material inducements for participation?

Yes/No, if Yes: Describe the amount, method, and timing of any payments to subjects, including how payments will be prorated for subjects who partially complete the study. Text box

- Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether W 9's will be collected.) UMS W9 Policy
- For raffles include the number of prizes, nature and value of each prize. Guidance
- If extra course credit is offered be sure to address the alternative means by which students can accrue extra course credit should they not wish to participate in the study.
- Who is responsible for costs incurred due to injury/harm?



Is the Activity Non-research?

The following activities are deemed not to be research.

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

Does the project meet definition of "Research”?

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

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

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

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

If yes, Is the private information identifiable?

-Identifiable means the identity of the participant is or may readily be ascertained by the investigator or associated with the information.

Text Box

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.

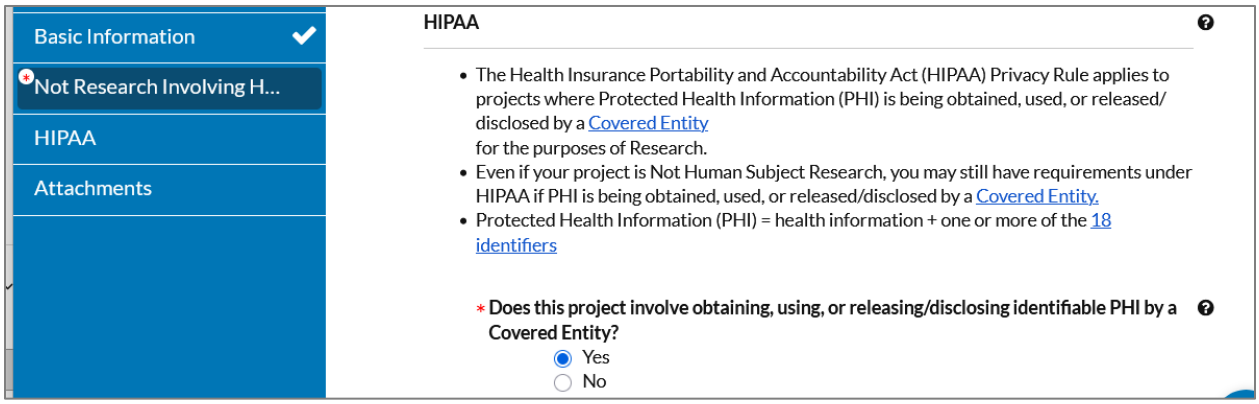
Yes/No

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



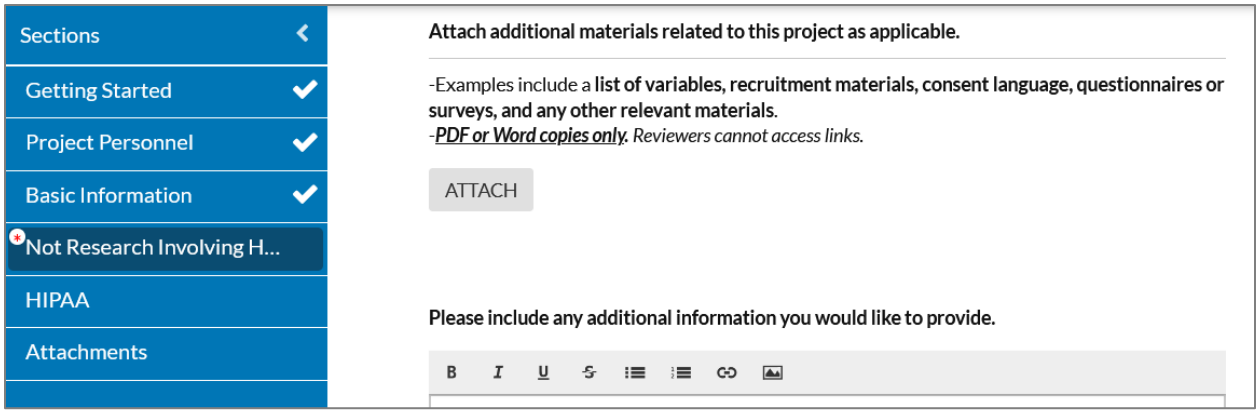
Attach additional materials related to this project as applicable.

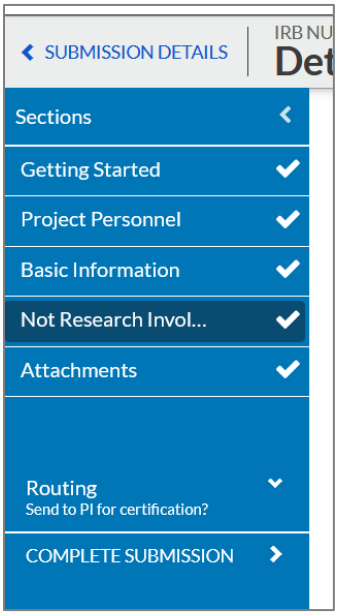
-Examples include a list of variables, recruitment materials, consent language, questionnaires or surveys, and any other relevant materials.

ATTACH button

Please include any additional information you would like to provide.

Text box





Don't forget to save your work.

When all sections of the submission have a check in the left navigation bar, the "Routing: Send to PI for Certification?" will appear at the bottom of the left blue navigation bar. You may have to scroll down to see it.

Click on COMPLETE SUBMISSION just below the Routing.

A pop-up message will ask for a confirmation. Click the Confirm button.

Then, in the upper left of the navigation bar click on SUBMISSION DETAILS to go back to the details page and click on the Certify button on the right side of the page.

A pop-up will ask to confirm certification. Click on the Confirm button.



It is recommended that students notify their Faculty Advisor when a draft is complete and routing it to them. ORIO staff can send it back before it is assigned a reviewer if needed.