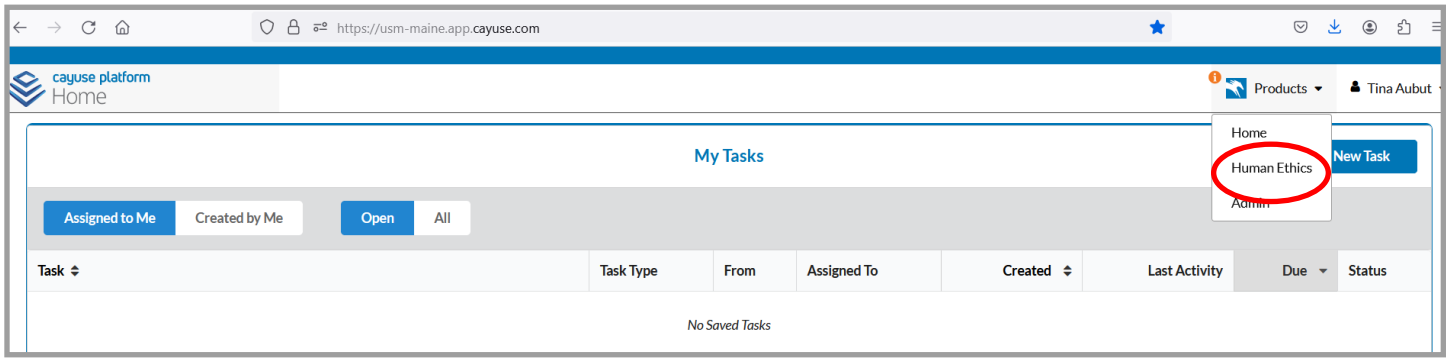
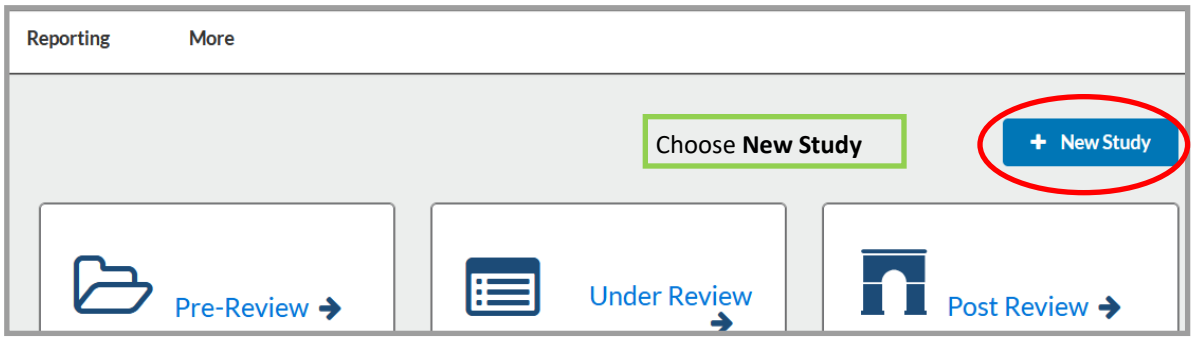
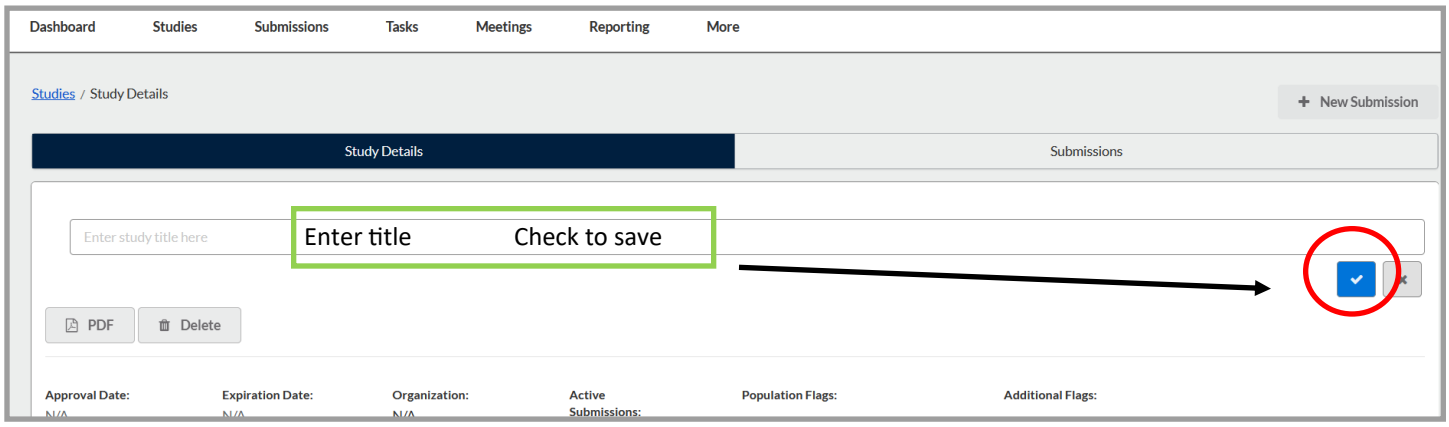
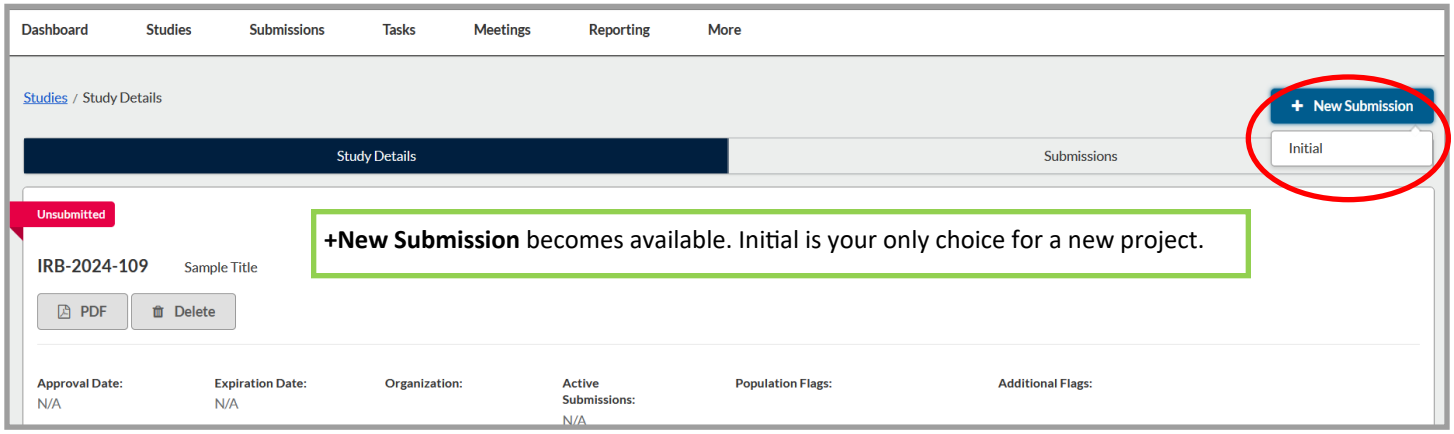
Starting a New Human Subject Research Study

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

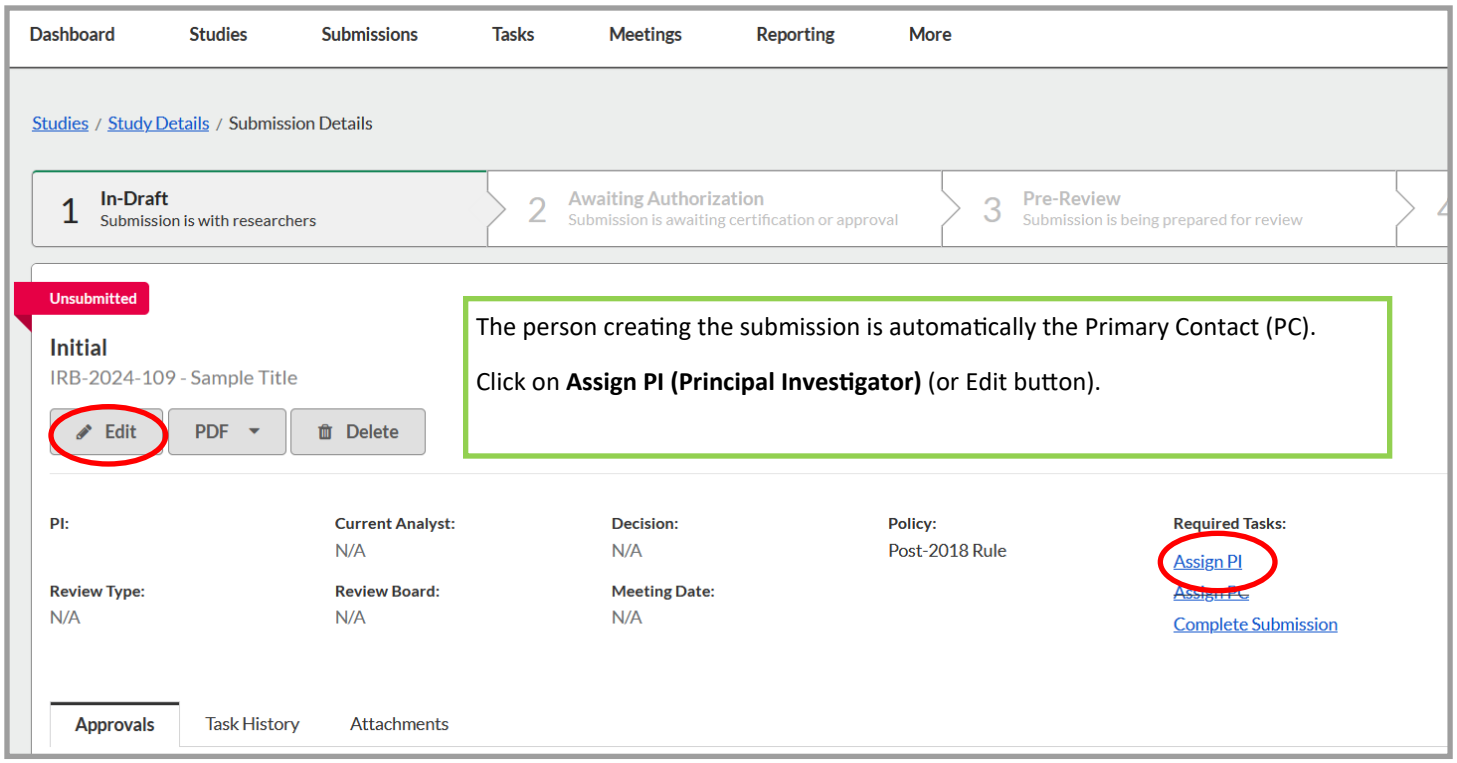


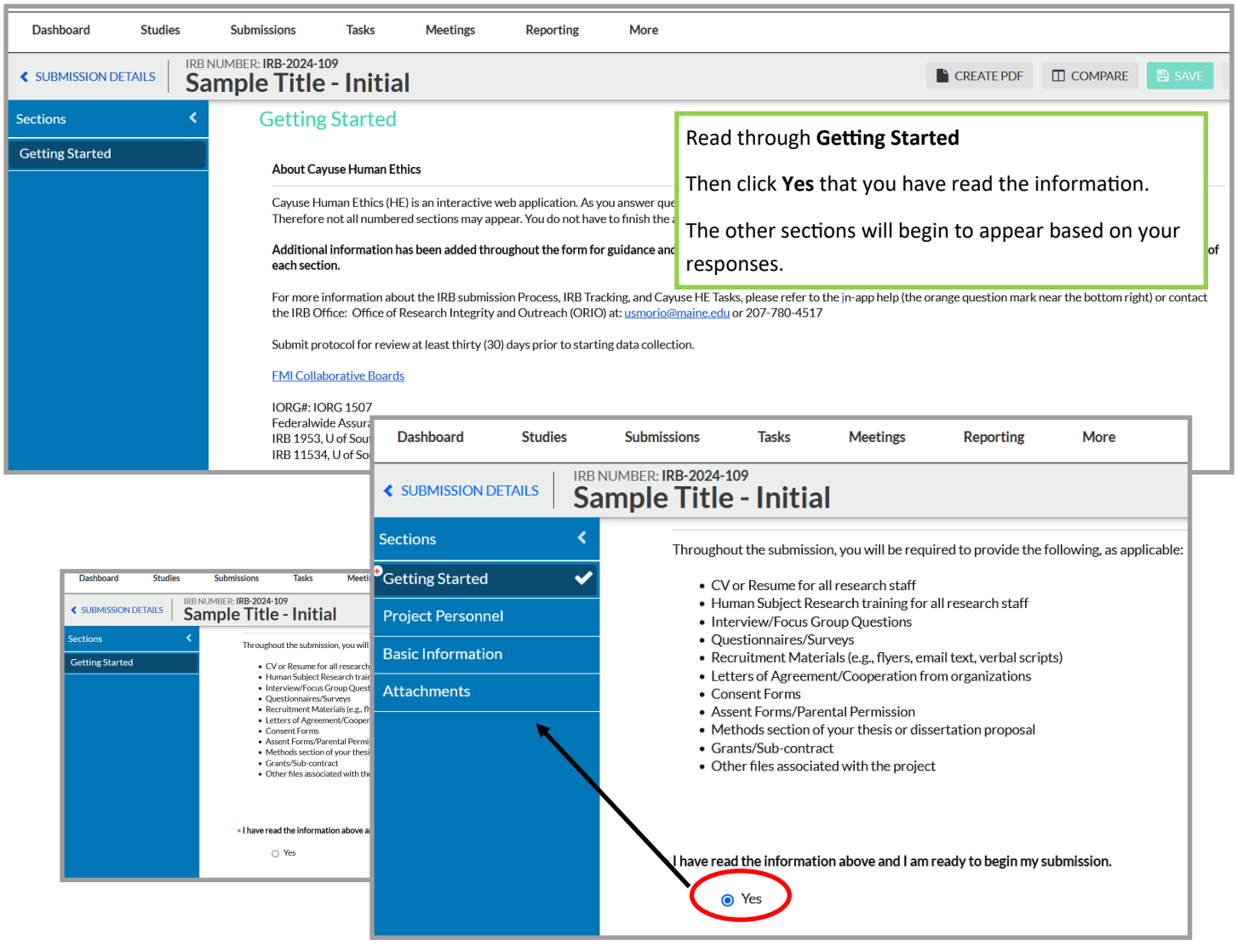






Update 5.2024


Dashboard
Studies
Submissions
Tasks
Meetings
Reporting
More
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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Tasks
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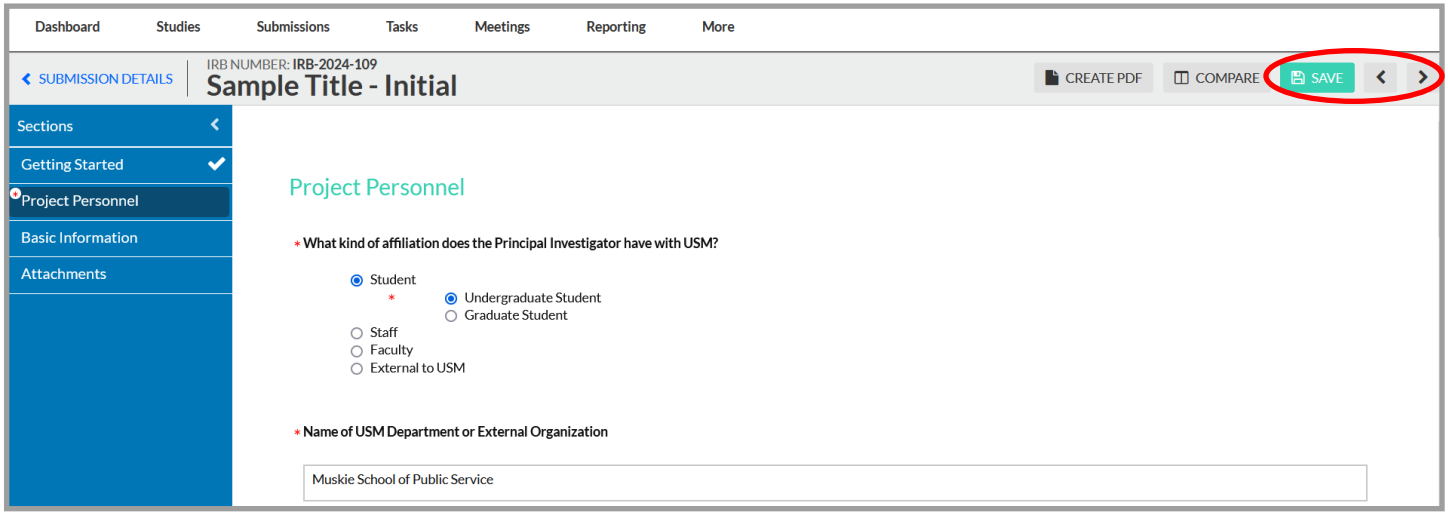
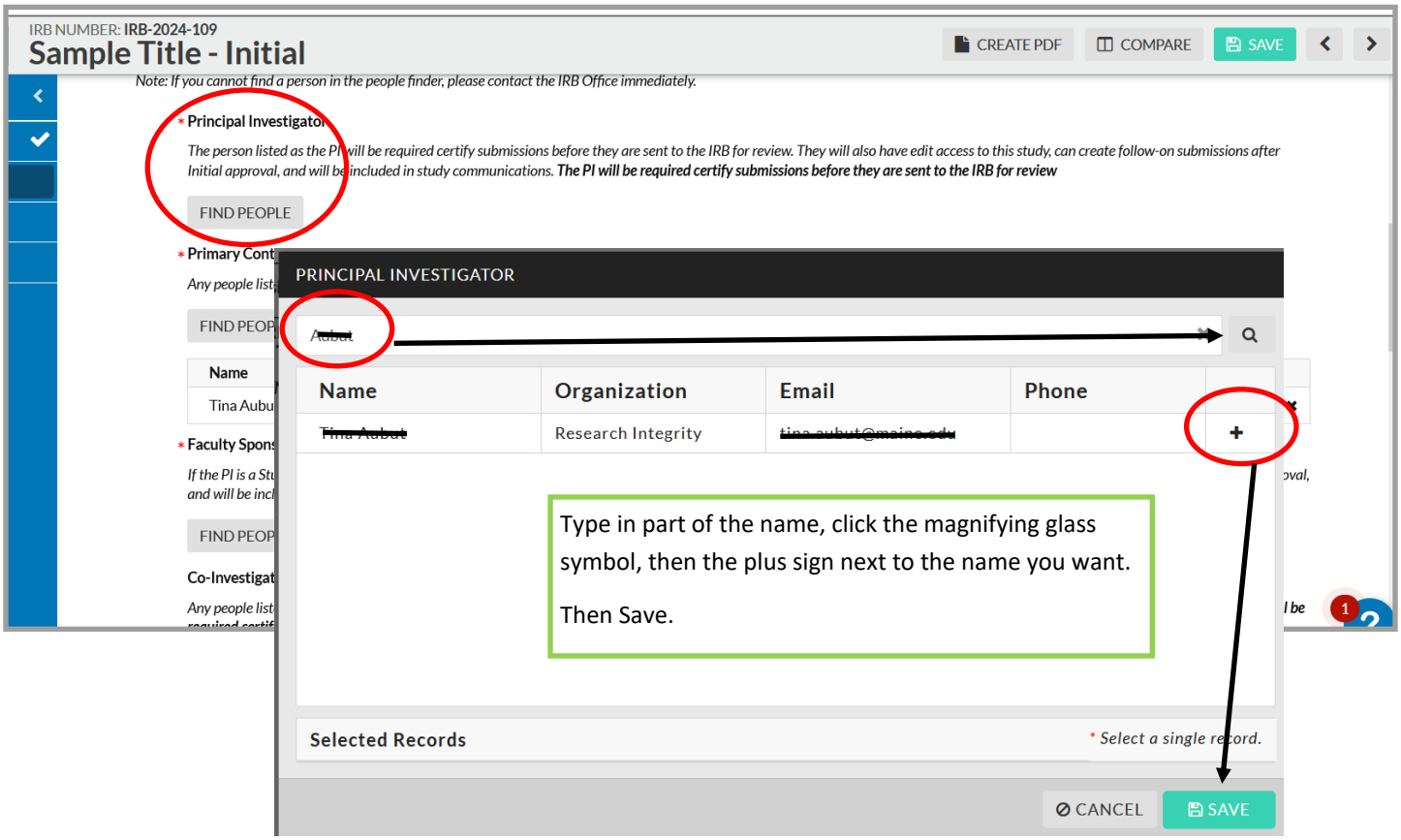
Reporting
More
SUBMISSION DETAILS
IRB NUMBER: IRB-2024-109
Sample Title - Initial
CREATE PDF
COMPARE
SAVE
Sections
Getting Started
Getting Started
About Cayuse Human Ethics
Cayuse Human Ethics (HE) is an interactive web application. As you answer que
Therefore not all numbered sections may appear. You 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.



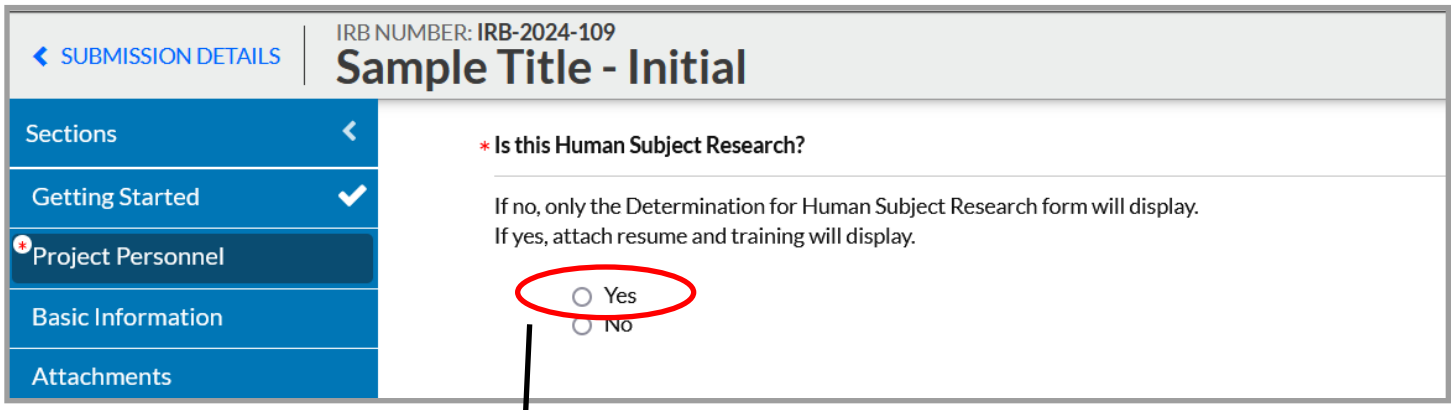
Click "Find People" to add the **Principal Investigator.** POP–UP: type in part of a name, click find icon.

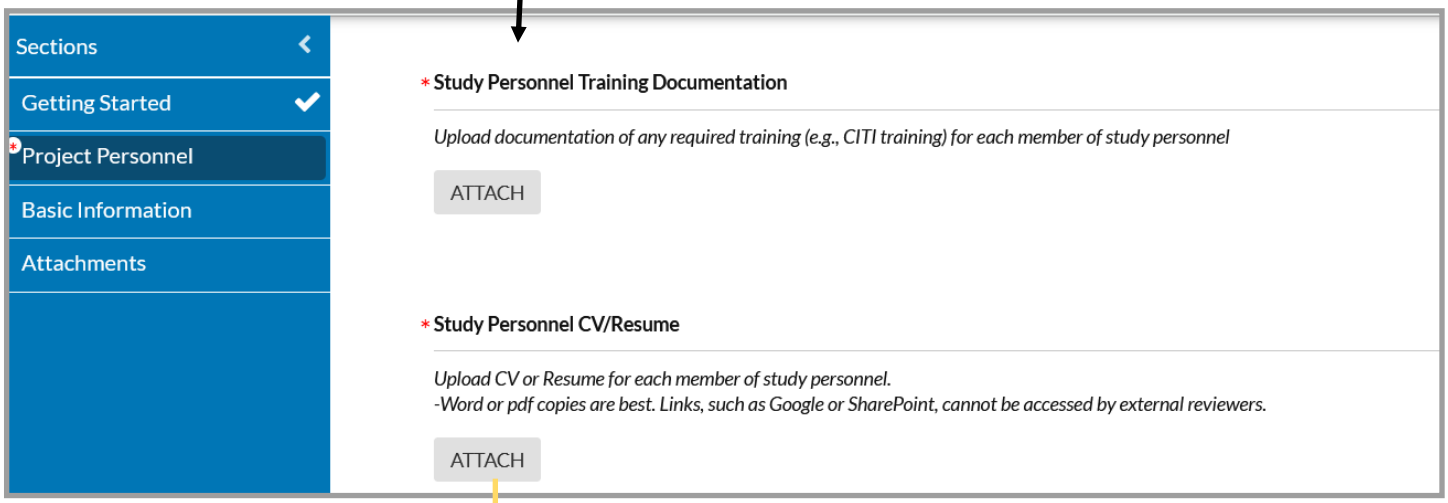
If you are not finding someone, they may not have had a profile set up.
Cayuse User ID Request: https://forms.gle/SUUNkEmL2EE3AKEW7

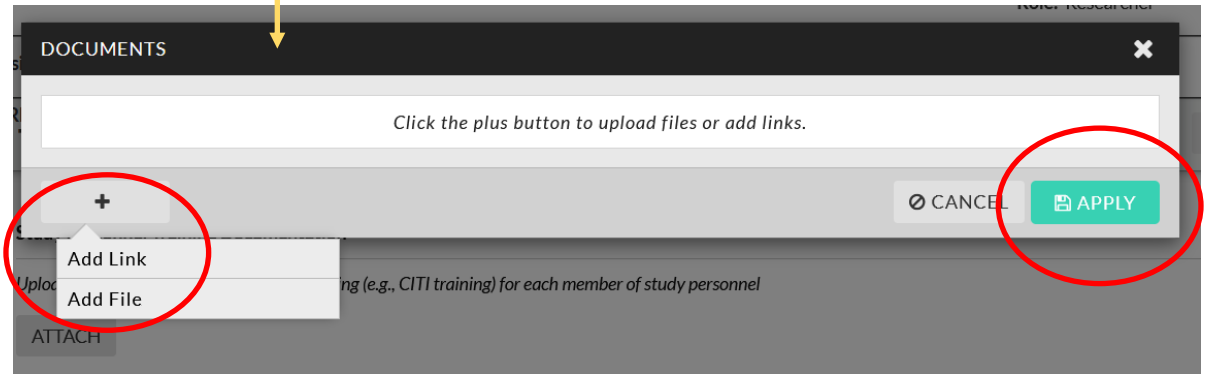


You may add more than one Co-PI. However, all the Co-PI(s) and Faculty Advisor are also ***required to certify submissions before they are sent to the IRB for review.*** As the protocol goes through a review, it may be sent back with questions. Each PI will need to certify each time it is returned to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

This guide shows the process for **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.



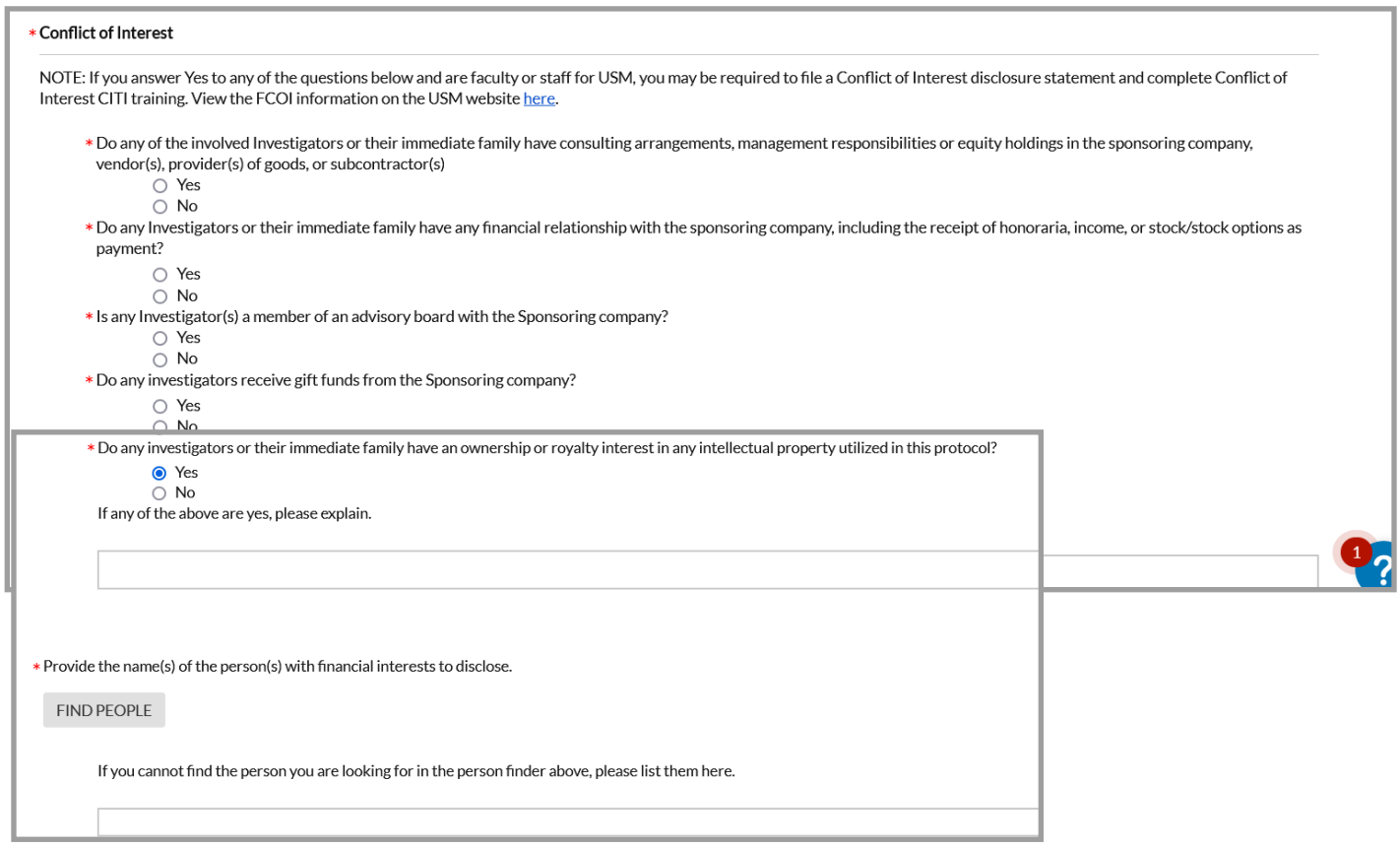




You may add multiple documents within attachments. A pop-up will appear. Note: **we do not accept links to Google docs or SharePoint**. Some of our reviewers are not able to access them. Word or PDF documents work best.

Please make sure anyone can access links to online surveys, etc.

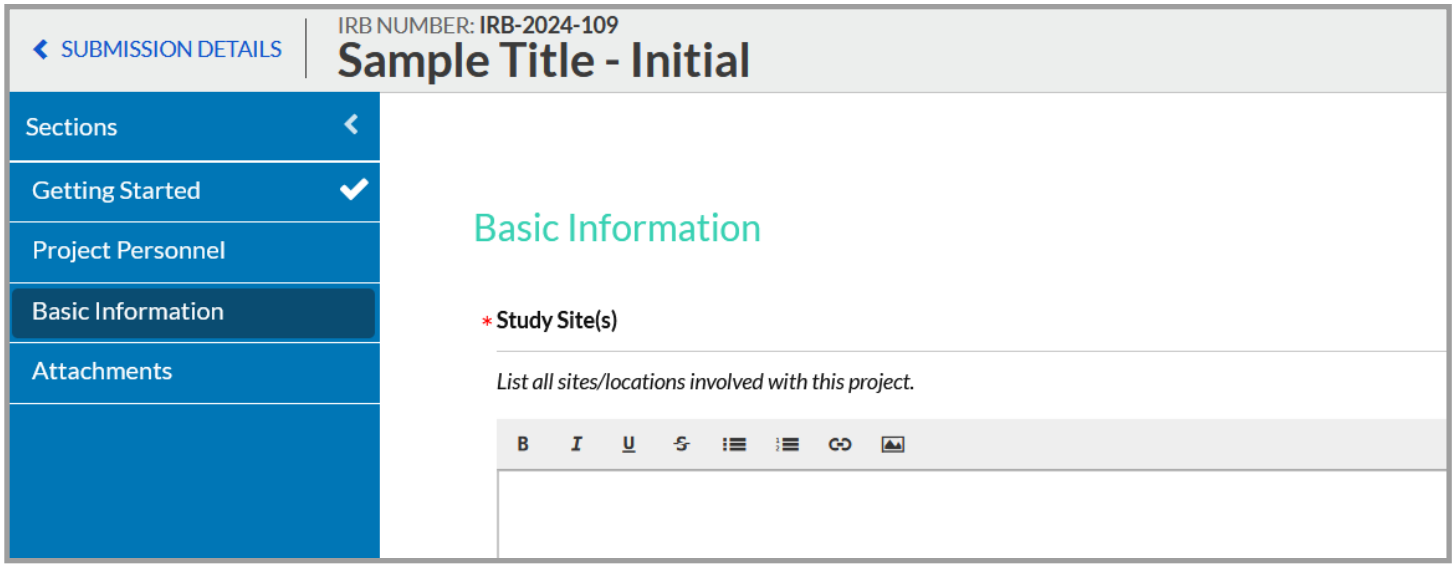
Conflict of Interest. If any are marked as Yes it will ask to explain and to pick a name of the person with the conflict.

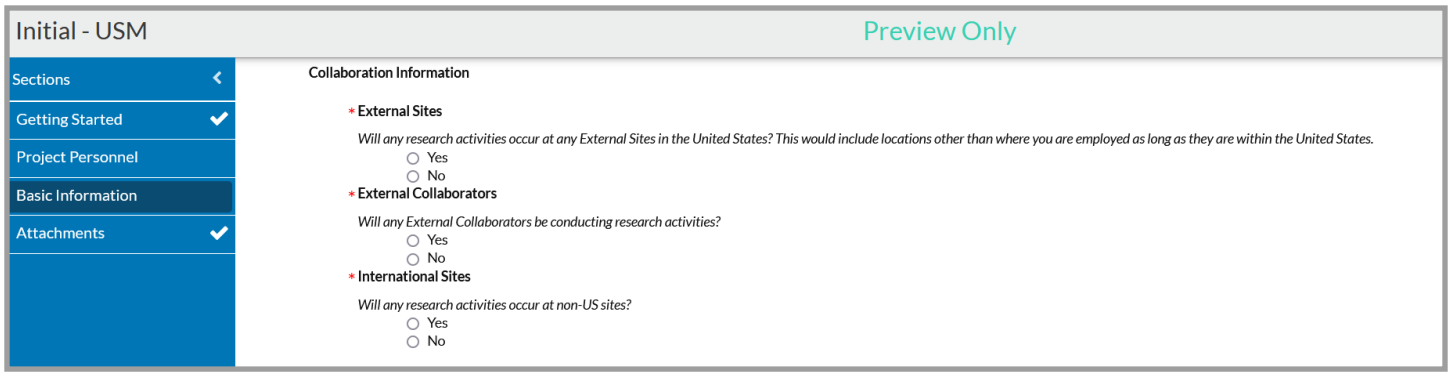


Students and Faculty Advisors (FA) and/or Co-PIs

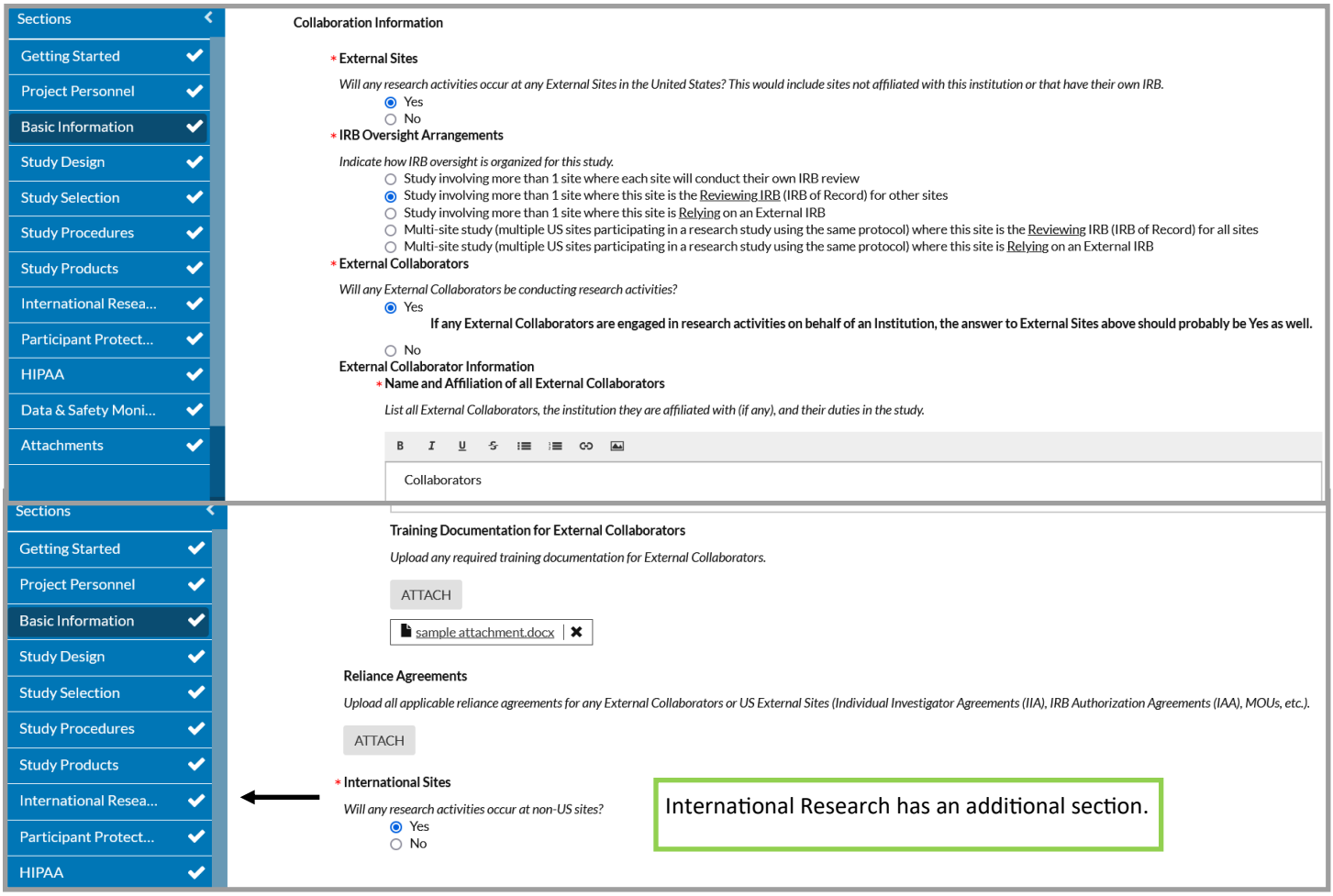
It is recommended that the student notify their Faculty Advisor when a draft is complete **BEFORE** Complete Submission and Certify the submission. Once certified, the Faculty Advisor cannot review and make any edits. ORIO staff can send it back; however, that is an extra step and takes time.

Faculty Advisor reviews first before either Complete and Certify the submission at the end.

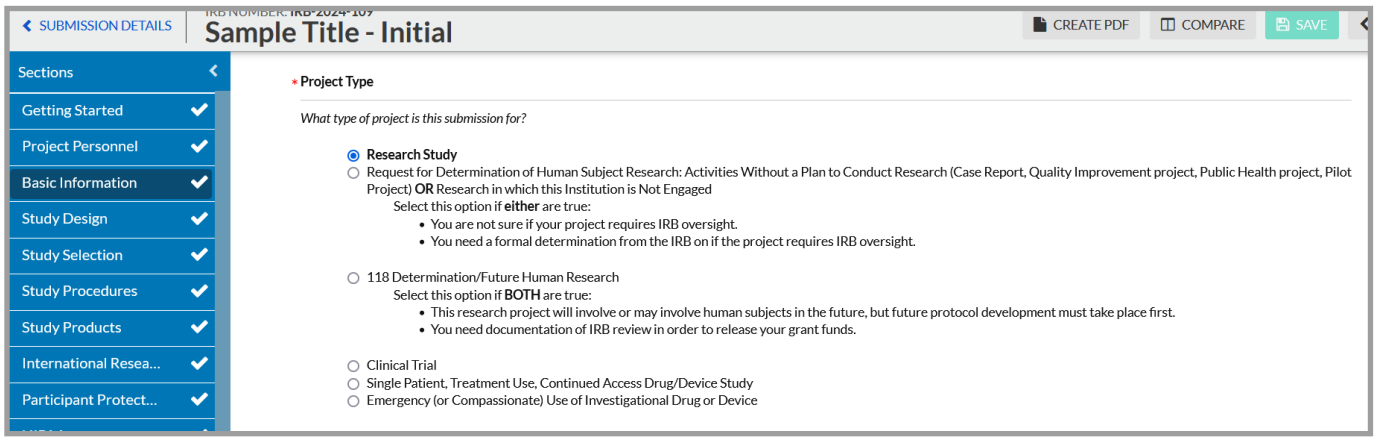




Depending on your answers to Collaborative Information, additional questions may appear. Example on next image.



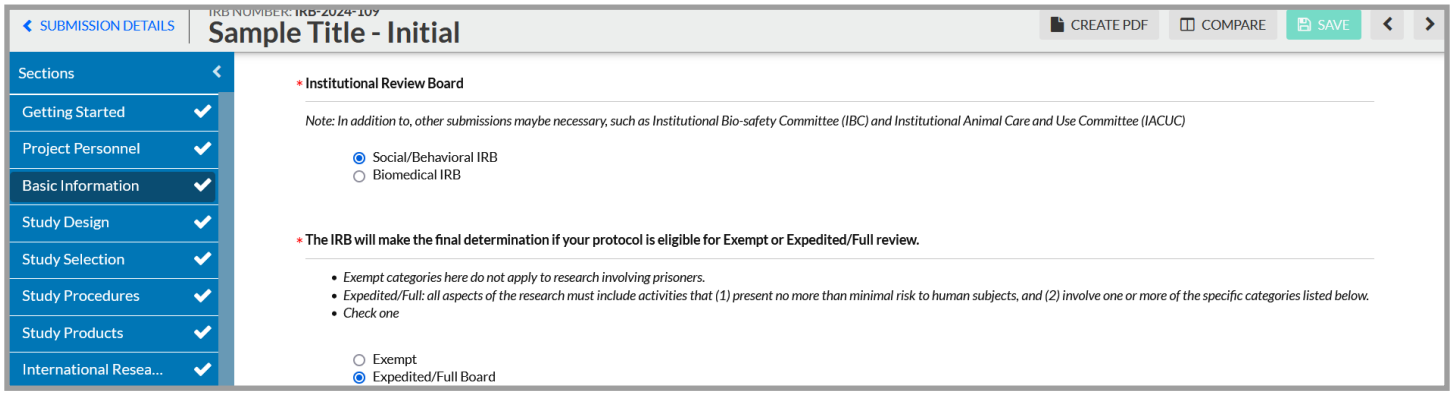
Once a Yes/No is chosen above, the type of project will appear. For this example, Research Study.

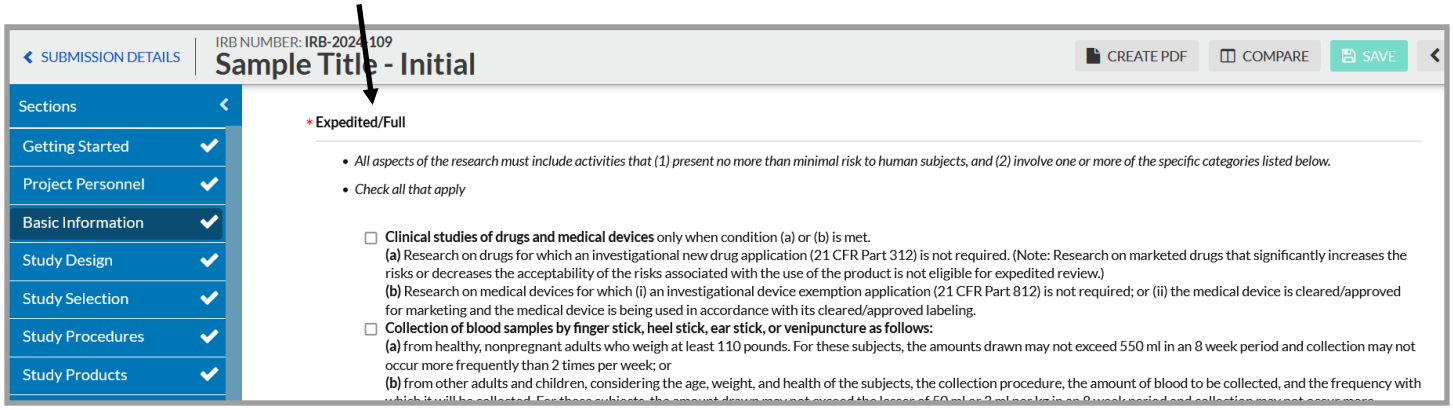


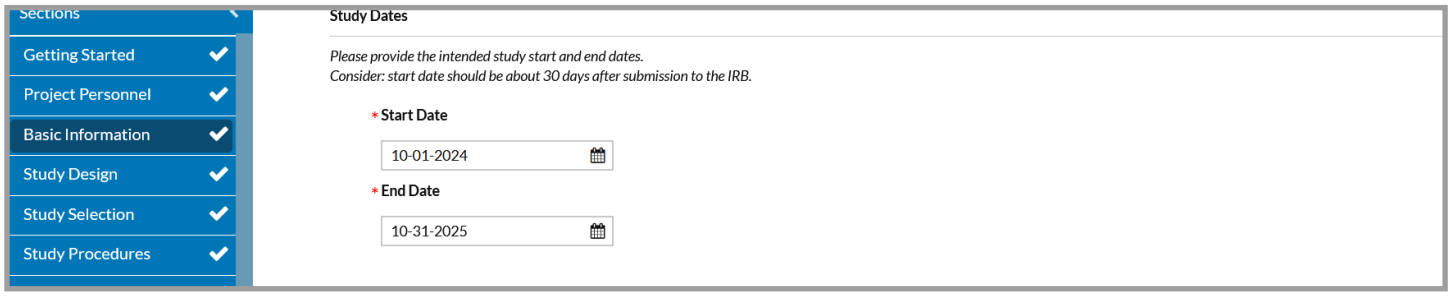
Choose the most appropriate board for your project. Then Exempt or Expedited.

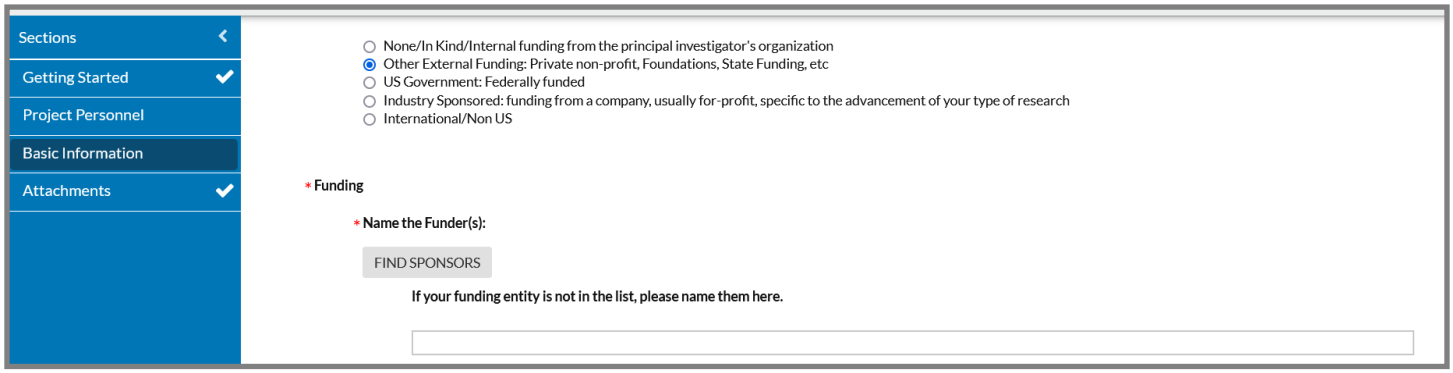
Exempt Categories: https://usm.maine.edu/orio/wp-content/uploads/sites/361/2022/08/IRB-Exempt-categories.pdf
Expedited Categories: https://usm.maine.edu/orio/wp-content/uploads/sites/361/2022/08/IRB-Expedited-categories-1.pdf

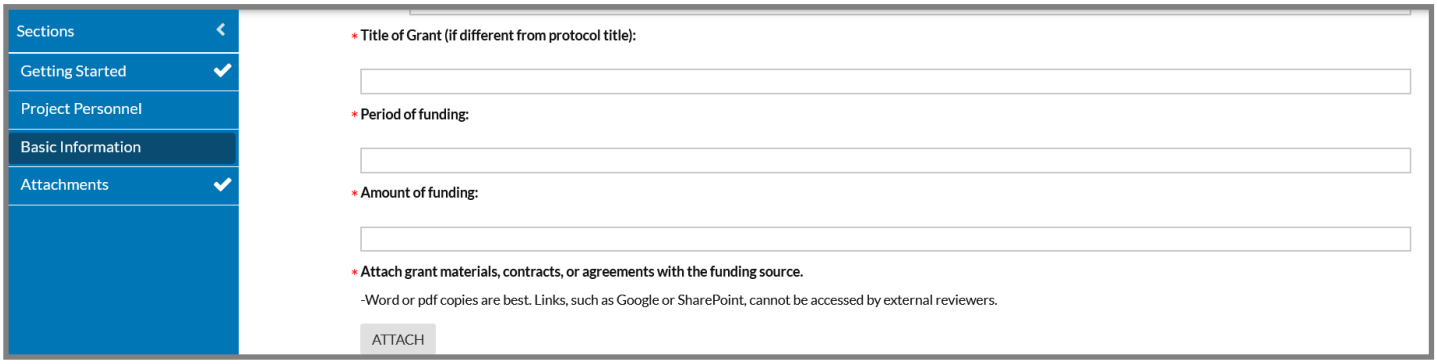
Categories for that type of review will appear. Choose all that apply to the best of your knowledge.

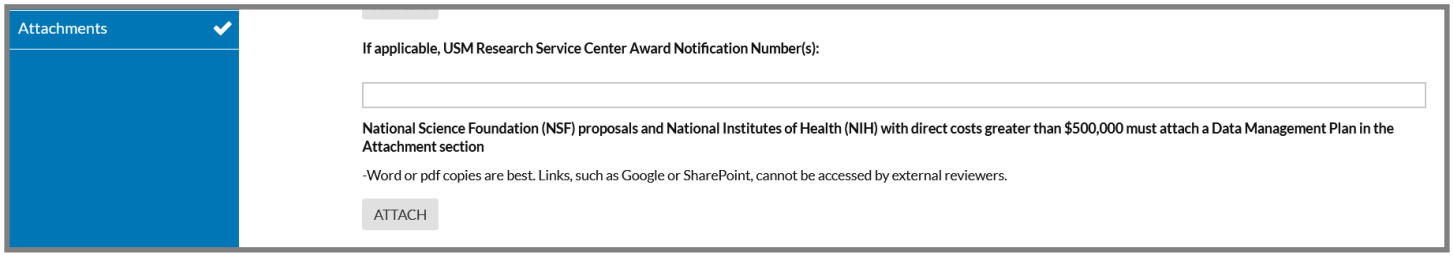












End of Basic Information Section