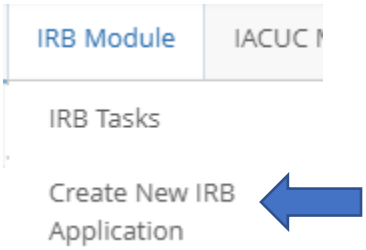
Creating an IRB Protocol Application

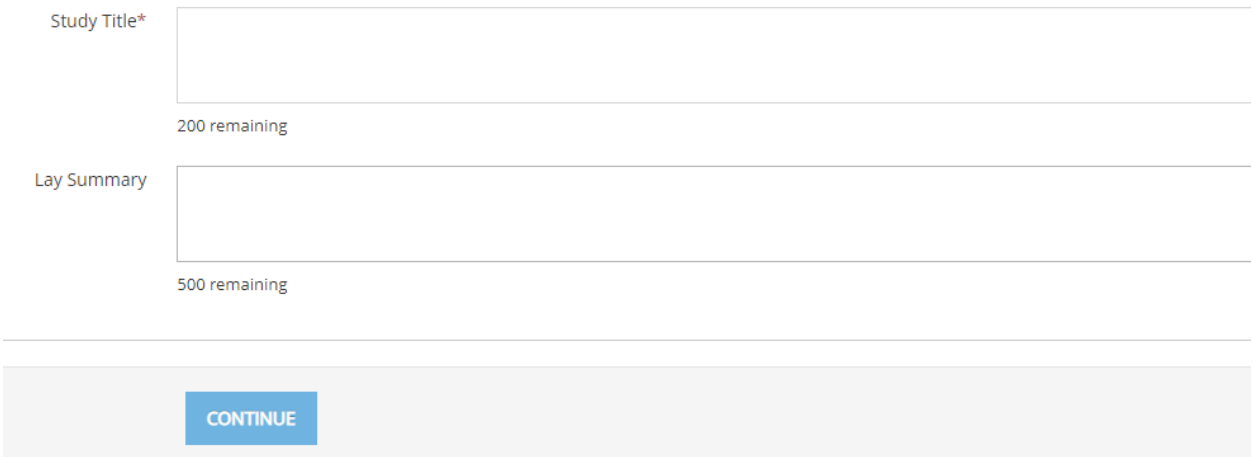
From the IRB Module menu, select Create IRB New Application.



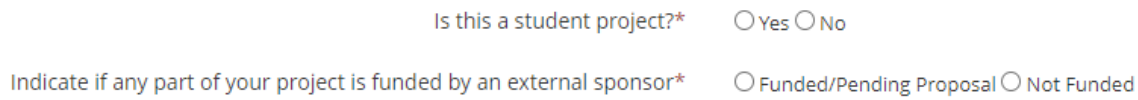
Starting your application – The Primary Info Panel:

1. If you are not the Principal Investigator, you may select the PI from the drop-down list by typing in a few letters of their name, the person creating the application will automatically be added to the research team.

2. Enter the Study Title, and a short summary of the protocol, and click "Continue."



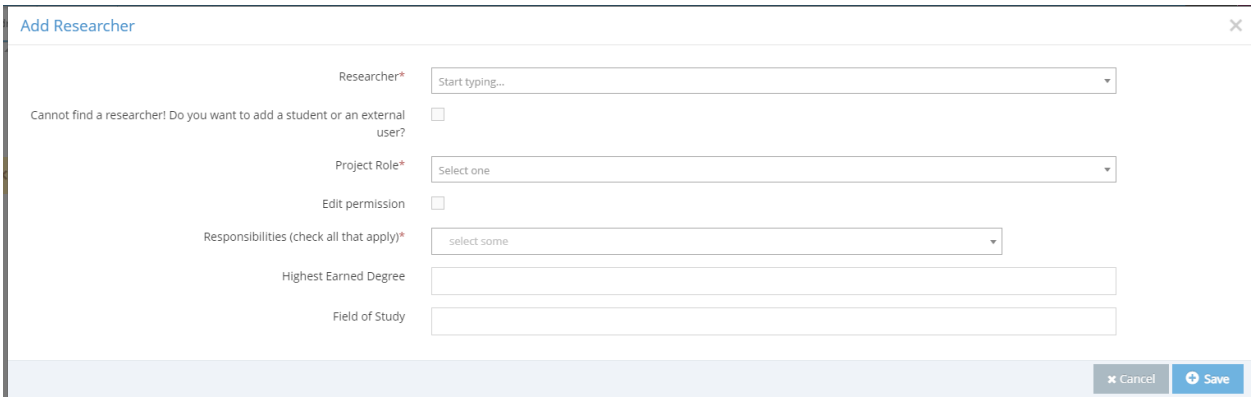
3. Any questions containing a red * are required and must be completed in order to submit the application.



Research Team Panel:

1. Additional Research team members can be added by clicking the Add Researcher Button.

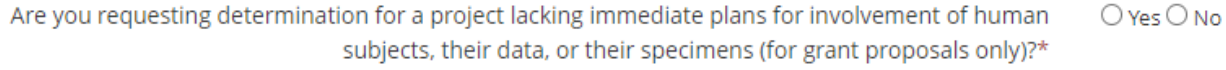
2. A modal will pop up allowing you to enter the research team member, select their role on the protocol as well as their responsibilities. You can grant edit access to the protocol by checking the "Edit Permission" check box.



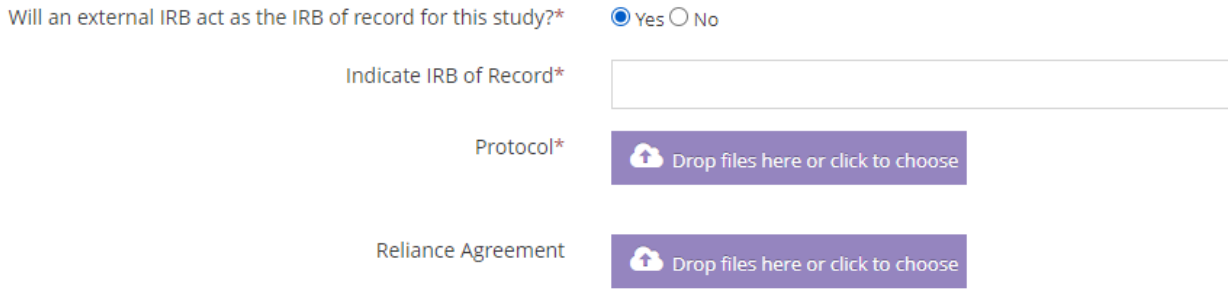
The Review Type Determination panel:

1. The Review type determination panel is used to determine the appropriate review type for the study.

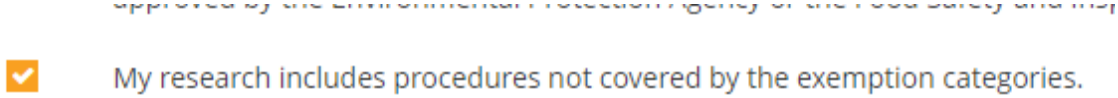
2. Projects seeking pre-approval (for release of funds for projects lacking definite plans for the involvement of human subjects should answer yes to:



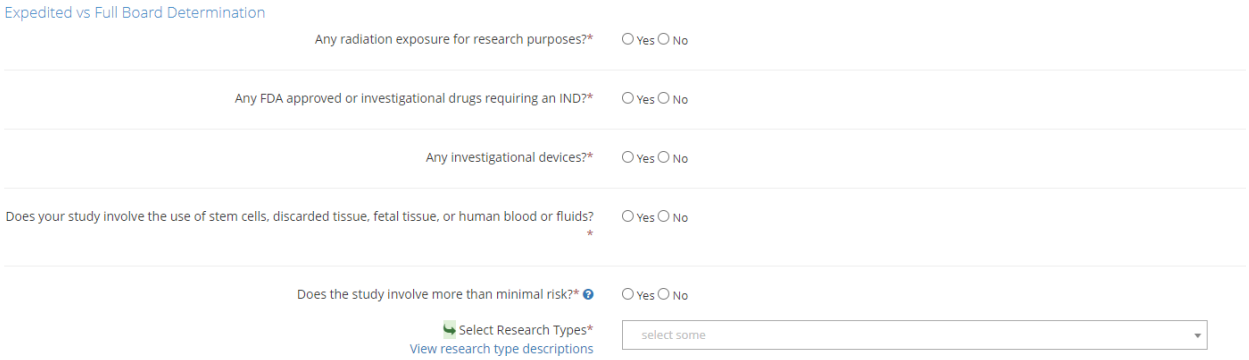
3. If an external IRB will serve as the reviewing IRB for the study (aka a Reliance or IRB Authorization Agreement), answer yes, and upload relevant materials for review.



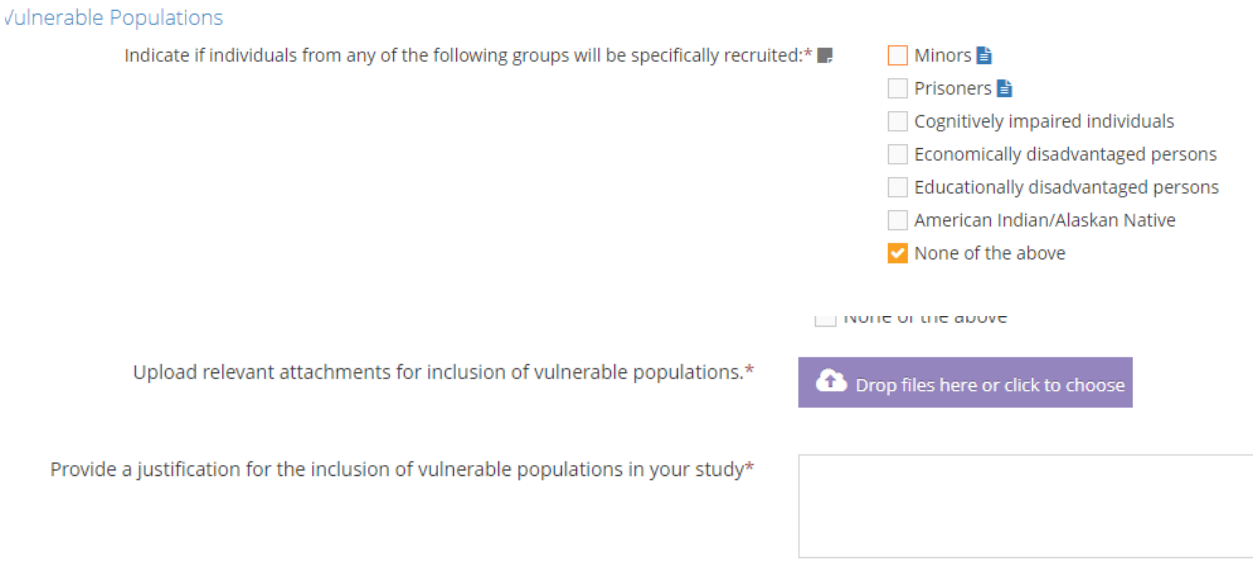
4. If you believe your study is exempt, and it does not involve: Prisoners or other institutionalized individuals, the collection of biological specimens, or conducting of biomedical procedures, you will be able to select the appropriate Exemption category(ies) from a list. If your study falls outside of the exemption categories, you'll mark:



5. When applicable (e.g. if the study is not exempt), the Expedited vs Full Board determination panel will show to assist you in determining if the study will qualify for expedited review, or if review by the convened board is required.



6. If there are Vulnerable Groups involved in your study, indicate as such by checking the populations from which you will recruit. If there is a blue document icon next to the selection (e.g. for Minors or Prisoners) you will need to download the attachment by clicking on the Blue document icon, completing the form, and uploading it to the relevant section.



Remaining Application Sections:

1. Once the Review Type Determination Panel is complete, the application should be populated with the correct questions for the type of research you are proposing. Complete any questions which contain a red asterisk and/or upload required documents (such as recruitment materials, consent forms, questionnaires, etc.) into the appropriate areas of the protocol application.

2. Be sure to "Save" the document periodically as the program does not auto-save.
3. You may check the completeness of the application at any time by clicking "Check Validations."
4. Once the application is complete, you will "Submit for Approval."

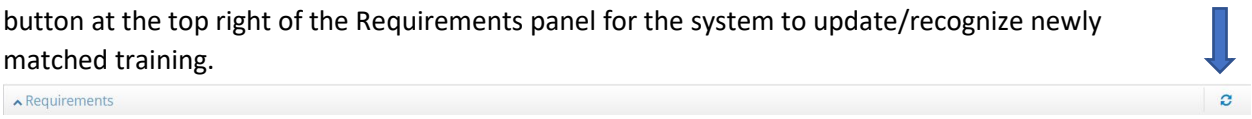
The Requirements Panel and Automatic Routing/Notifications:

1. Once the study has been submitted, you can view the "next steps" in the review process via the Requirements Panel

Status	Requirement	Completion State
Draft Submission Pending	Submit protocol	✔Completed
PI Certification Pending	Certify protocol (PI)	✔Completed
Pre-submission Requirements	Approval by VP: Jane Marie Schuh	Ready
	Complete Human Subjects training on Citi: Kristy Marie Shirley	✔Completed
IRB Review Pending	IRB Admin Processing	Not ready

2. Training for all members of the research team must be completed before the study can be reviewed. You can see the status of Team members training in the Requirements panel. If the panel states "Completed" in the Completion State column, the training is current/complete. If it states "Ready" the individual has not completed the training requirement OR the training could not be matched because two different email addresses are used in the Novelution and the CITI training systems. To correct this individual may either:
    a. Add their "CITI email address" to their Novelution profile, or
    b. Change their Primary email address in CITI (citiprogram.org) to match their Novelution email.

3. NOTE: The system updates training records every 24 hours. If training records were not current, you will need to wait 24 hours for the records to update and then click the refresh button at the top right of the Requirements panel for the system to update/recognize newly matched training.



4. The Department Chair/Head, Dean or VP is automatically notified that a study needs their approval. Once approved, and the protocol is ready for review, the IRB Review Pending requirement will show as "Ready."

IRB Review Pending	IRB Admin Processing	Ready