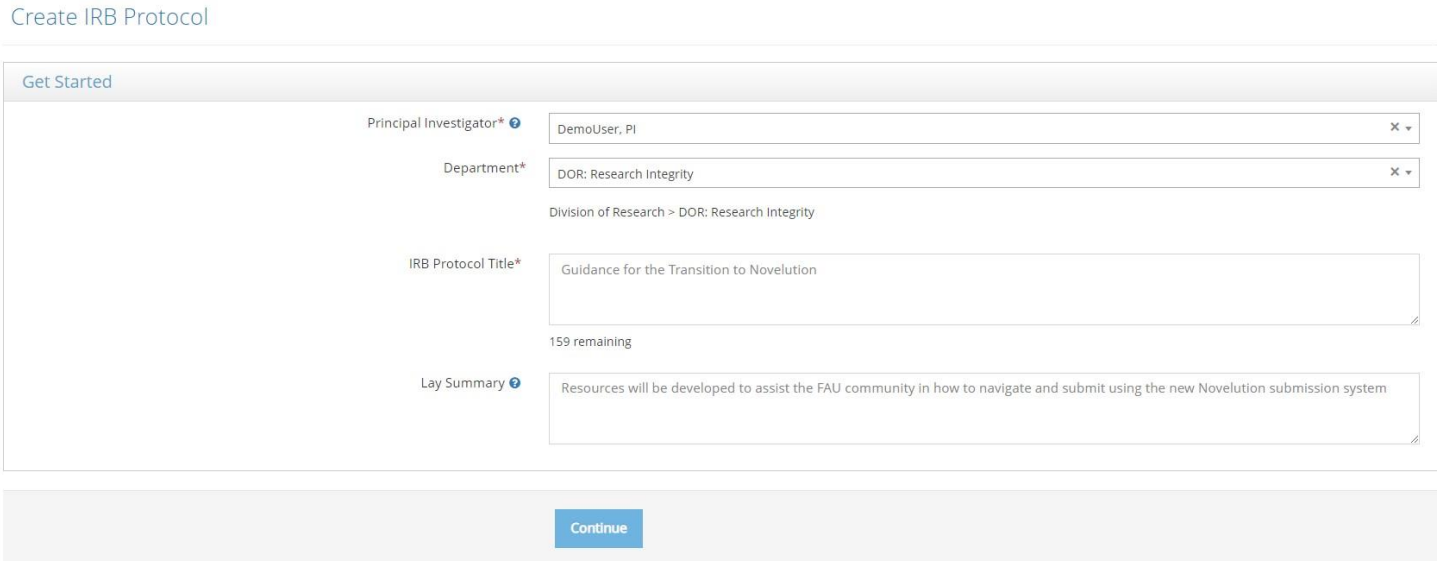
FAU IRB NOVELUTION

Creating a New Project

Hover over the IRB Tab

Click “Create IRB Protocol”



If you are an eligible Principal Investigator (PI), your name and Department will be populated in the first two fields.

If your department is missing, contact the IRB Office to administratively update this for you.

If you are the student completing this project for your degree, you cannot also be the PI.

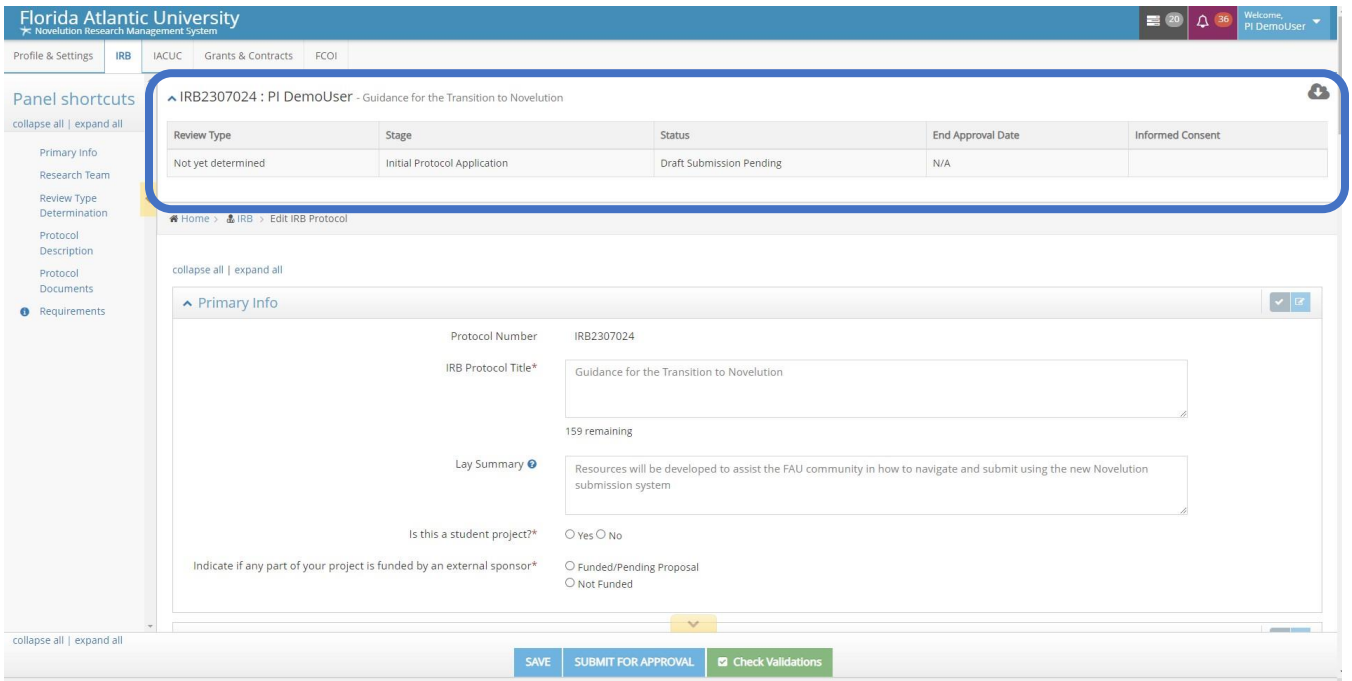
If you are a student or otherwise do not have PI eligibility, type the name of your PI in the Principal Investigator field to continue.

Add your title and lay summary

Click continue

Answer questions and follow-up questions as they pertain to your study

This is your new project page. Up at the top you'll see the Project Details box which will contain an overview look at your project.



The Project Details box includes information such as:

- Review Type: Exempt, Expedited, Full Board Review
- Stage: Initial Protocol Submission, Amendment, etc
- Status: Draft Submission Pending, Pre-Review, etc
- End Approval Date: Upon approval decision the date will be listed here
- Informed Consent: Any approved, stamped consent documents will be linked here for easy access

Of note, is the status letting you know where your project is in the workflow, in the example below the project is in a Draft Status where the Submission is Pending.

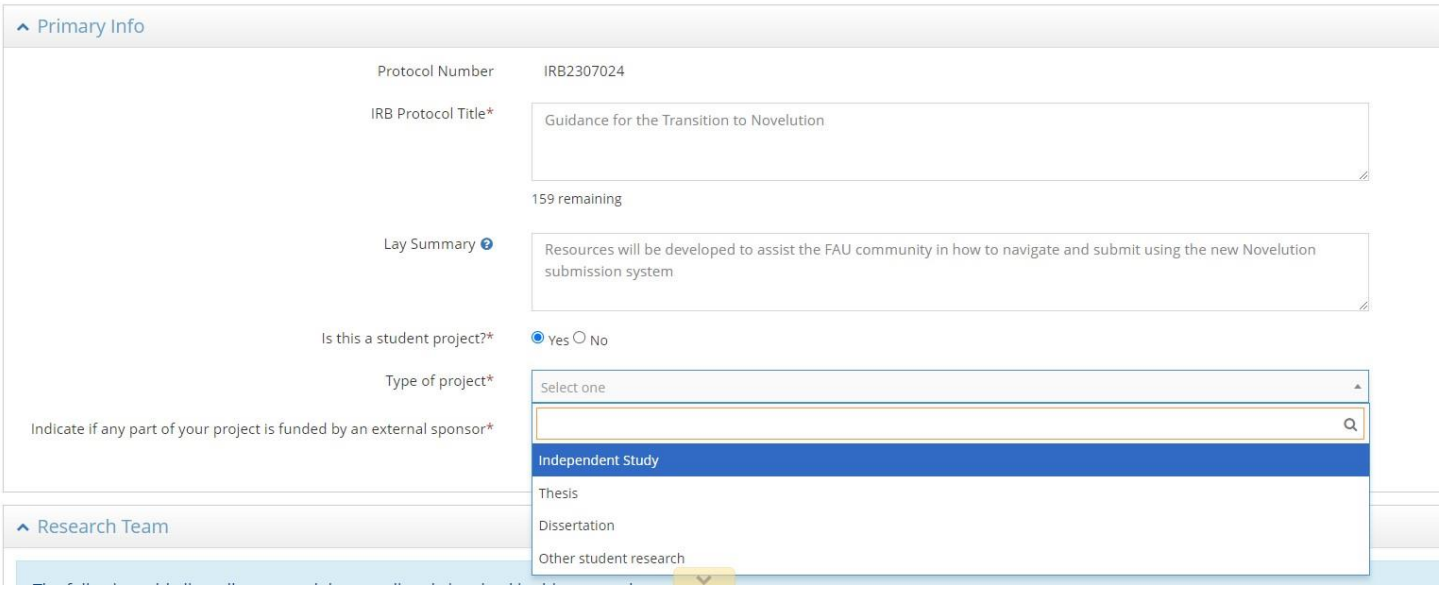
On the left-hand side are the Panel shortcuts which will allow you to skip to different sections in your submission

- It is recommended to scroll through as you complete your submission to avoid skipping sections
- Additional Panel shortcuts will appear as your answers may prompt new panels

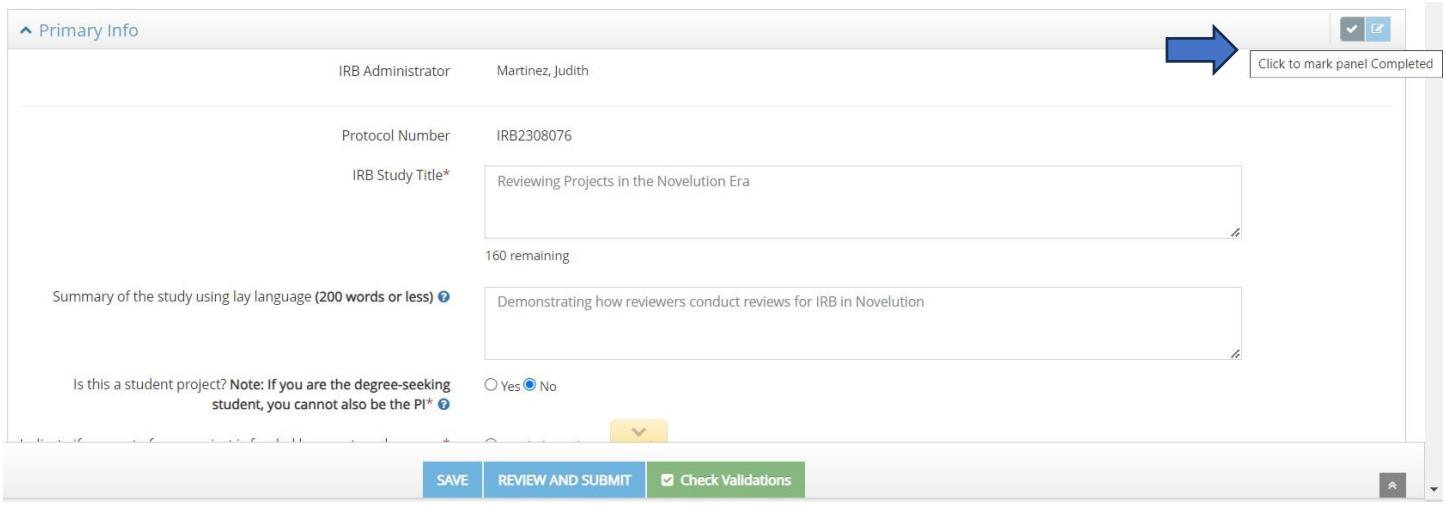
Primary Info

Your submission will begin with the Primary Info panel which will auto-populate the Title and Lay Summary fields from the first Create an IRB protocol page you completed.

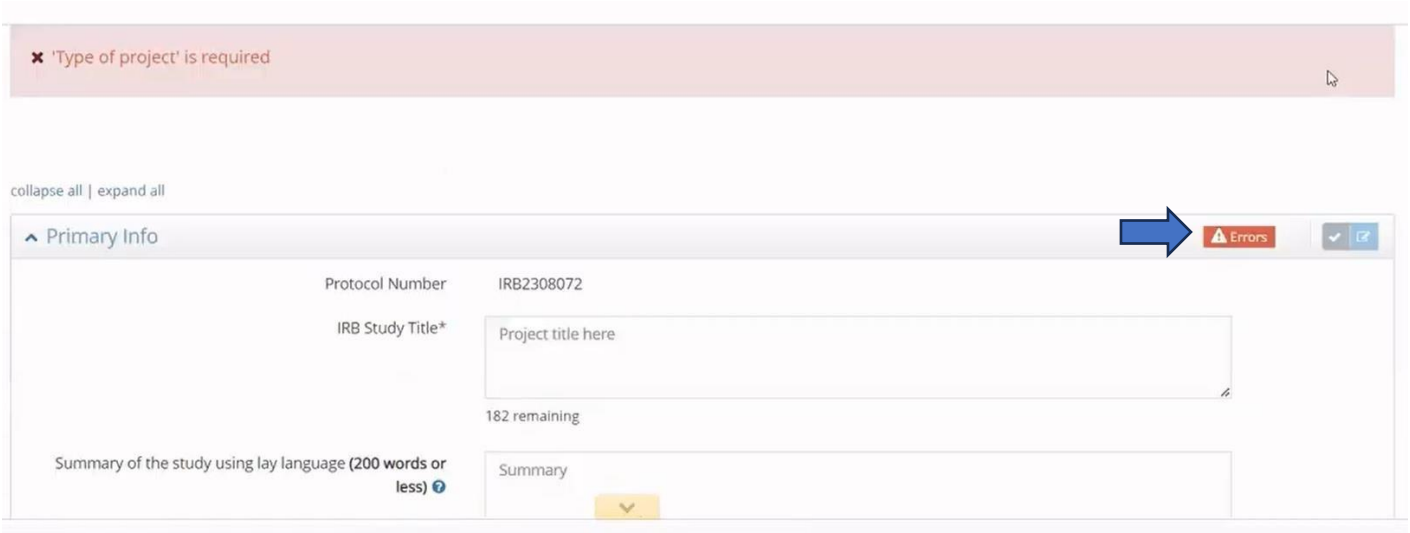
Questions follow smart logic and will produce additional follow-up questions depending on certain selections. In this example, selecting Yes to the question “Is this a student project?” will show a new “Type of project” drop down list to select the specific student project.



Be sure to answer all follow-up questions. You can see if all the required fields in a panel have been completed by clicking the checkmark at the top corner of the panel box.

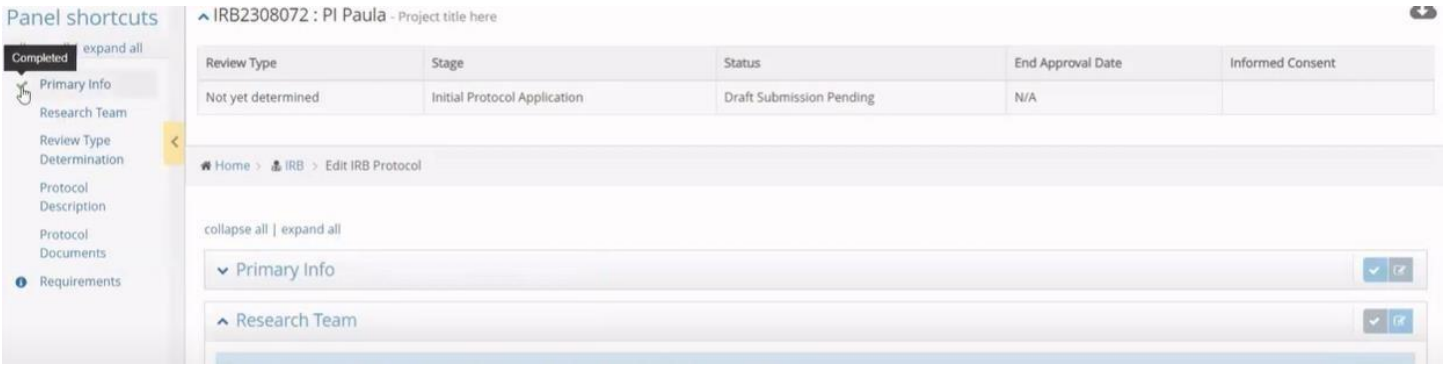


If any required fields are missing, you'll see an "Errors" box appears in the panel header and a red box appears up at the top listing the required field that is missing. You can click that link to be taken directly to the field to fill in your response(s).



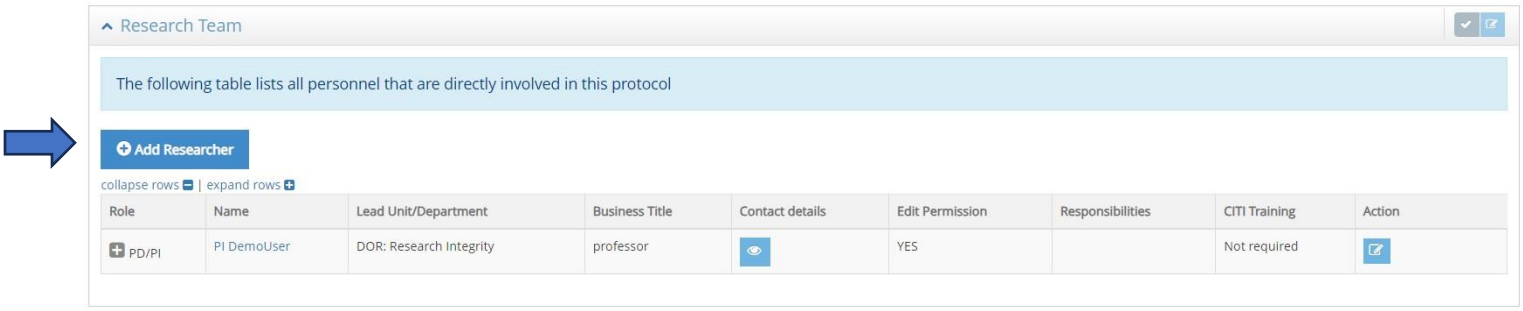
Fill out any missing required fields then click the checkmark again to see the panel is now Completed, indicated with a Checkmark in the Panel Shortcuts.

Tip: Using the check mark after completing a field is also a good way to Save your progress along the way



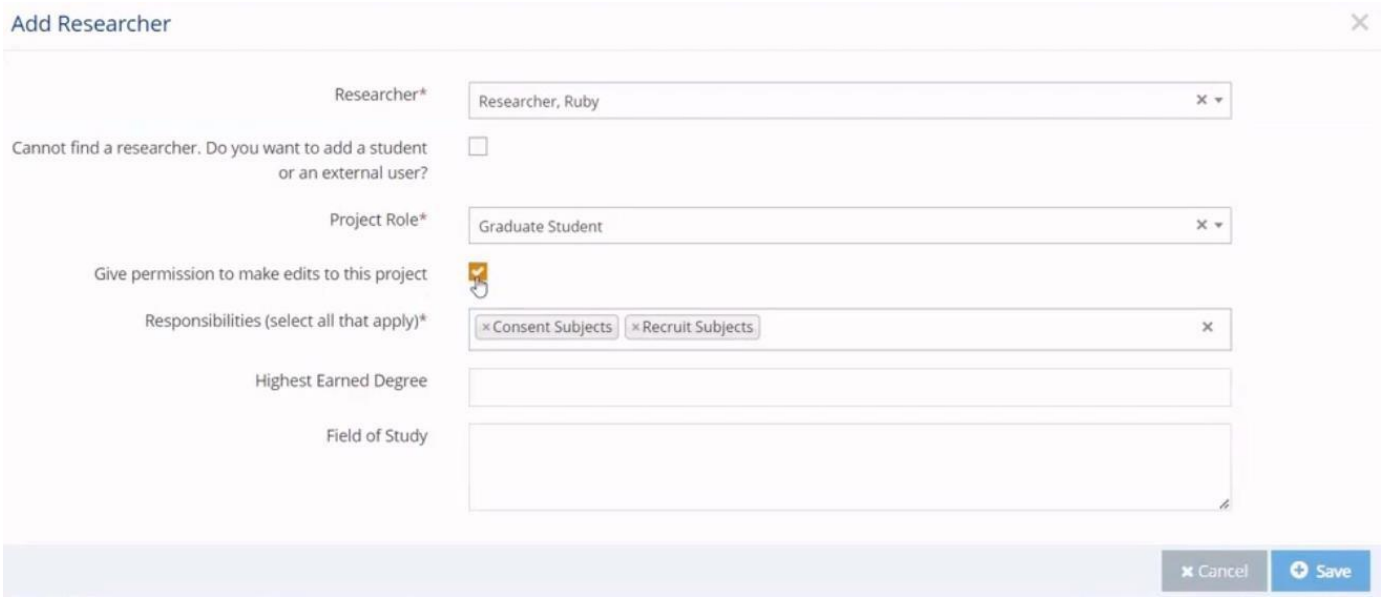
Research Team

Click the button to Add Researcher. You can add as many researchers as needed.



Begin by searching for the researcher's name in the "Researcher" field. Then select the person's project role from the drop-down list, as well as their responsibilities. If there are additional responsibilities which are not listed here, click other which will provide a "Please describe" field to enter those details.

Note: If this is a person that should have the ability to make edits to the project be sure to check the box for "Give permission to make edits to this project" if it has not automatically populated.

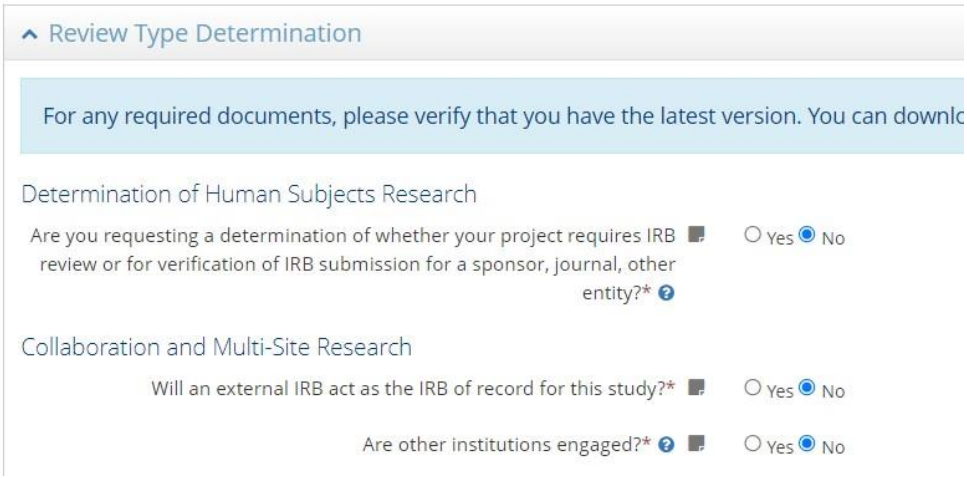


Once a researcher has been added, click to save. Repeat the process to add other researchers to the team personnel.

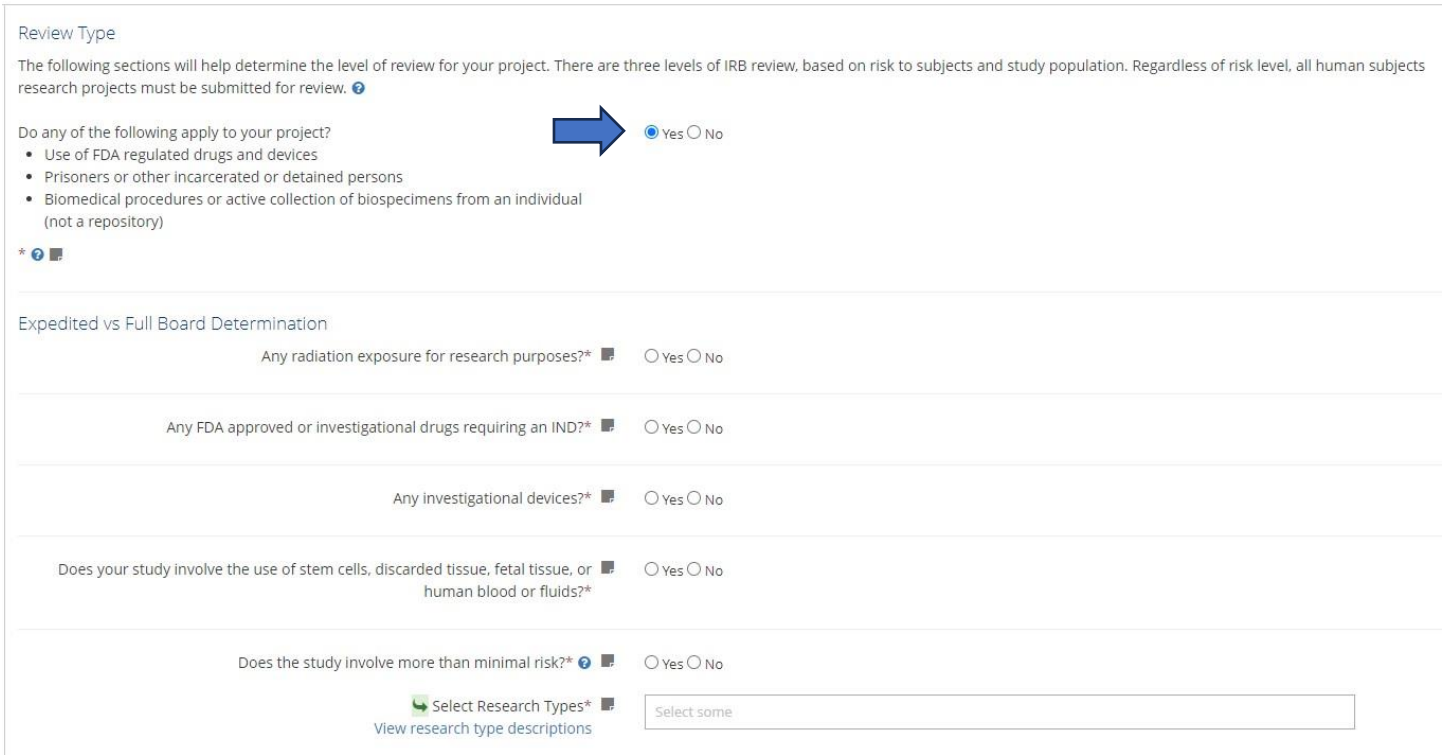
Review Type Determination

In this panel, you'll be asked a series of questions to identify the review type of your project such as Exempt, Expedited, or Full Board.

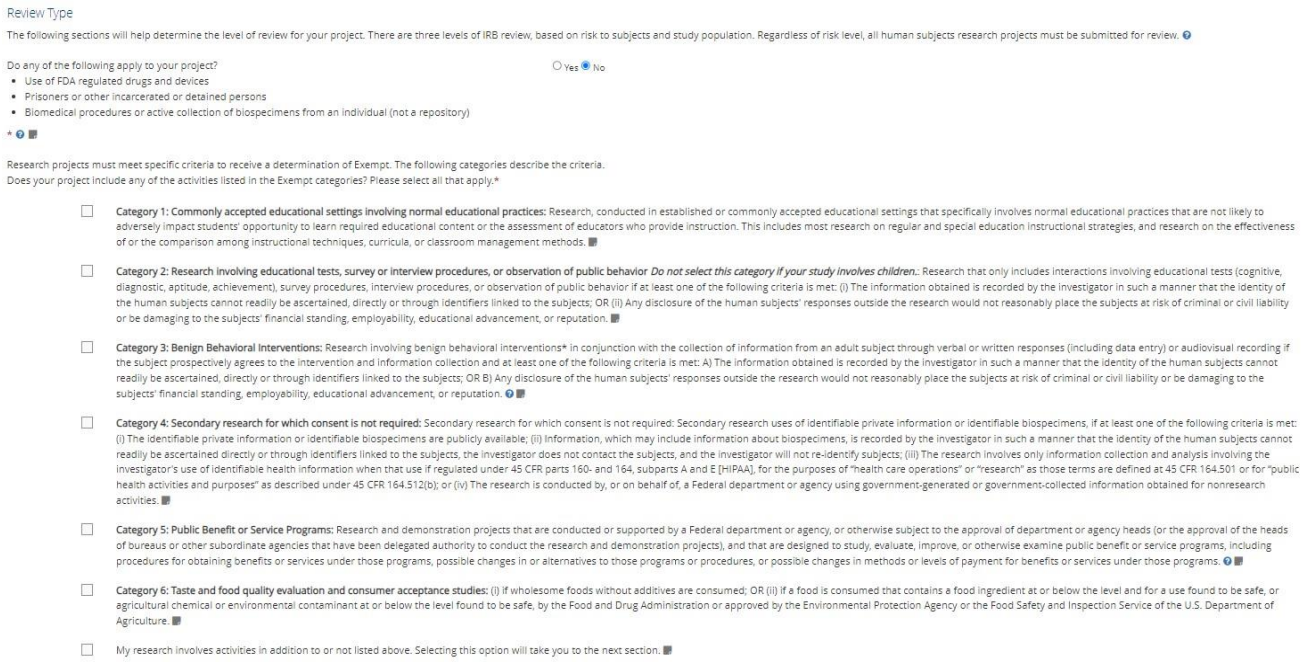
Selecting no to the first few questions regarding Determination of Human Subjects Research and Collaboration and Multi-Site Research will lead you to the Review Type section.



Selecting yes to the question "Do any of the following apply to your project?" will lead you to an Expedited vs. Full Board determination review



Selecting no will reveal the Exempt Review Categories



Review Type

The following sections will help determine the level of review for your project. There are three levels of IRB review, based on risk to subjects and study population. Regardless of risk level, all human subjects research projects must be submitted for review.

Do any of the following apply to your project? ○ Yes ◉ No

- Use of FDA regulated drugs and devices
- Prisoners or other incarcerated or detained persons
- Biomedical procedures or active collection of biospecimens from an individual (not a repository)

*

Research projects must meet specific criteria to receive a determination of Exempt. The following categories describe the criteria.
Does your project include any of the activities listed in the Exempt categories? Please select all that apply.*

☐ **Category 1: Commonly accepted educational settings involving normal educational practices:** Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2: Research involving educational tests, survey or interview procedures, or observation of public behavior** ***Do not select this category if your study involves children.:*** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; OR (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

☐ **Category 3: Benign Behavioral Interventions:** Research involving benign behavioral interventions* in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; OR B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

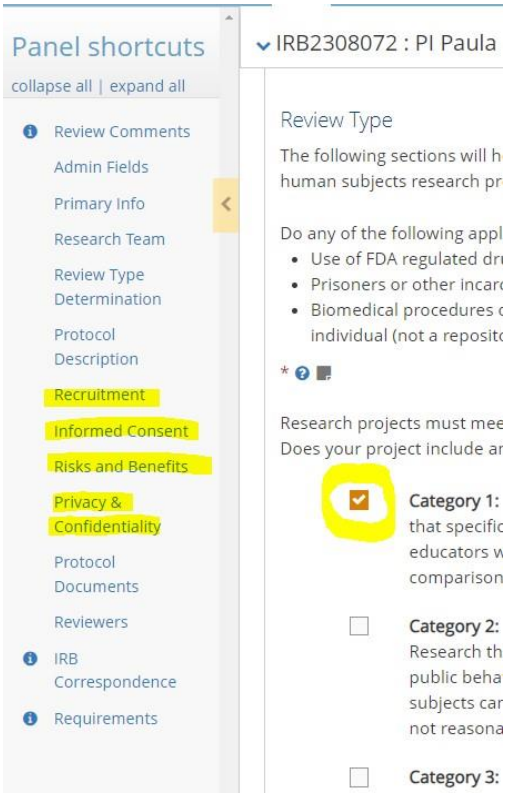
☐ **Category 4: Secondary research for which consent is not required:** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use if regulated under 45 CFR parts 160- and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities.

☐ **Category 5: Public Benefit or Service Programs:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

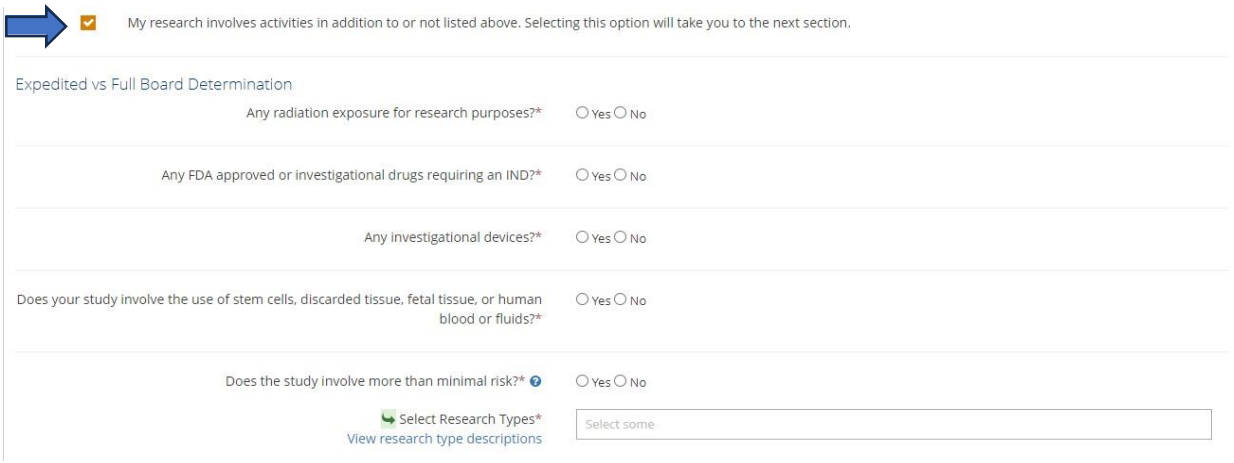
☐ **Category 6: Taste and food quality evaluation and consumer acceptance studies:** (i) if wholesome foods without additives are consumed; OR (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ My research involves activities in addition to or not listed above. Selecting this option will take you to the next section.

Read through the Exempt Categories and select those that apply to your research. You can check more than one category as applicable.
When you check an Exempt Category, new panels will appear in the Panel Shortcuts including the Recruitment, Informed Consent, Risks & Benefits, and Privacy & Confidentiality panels

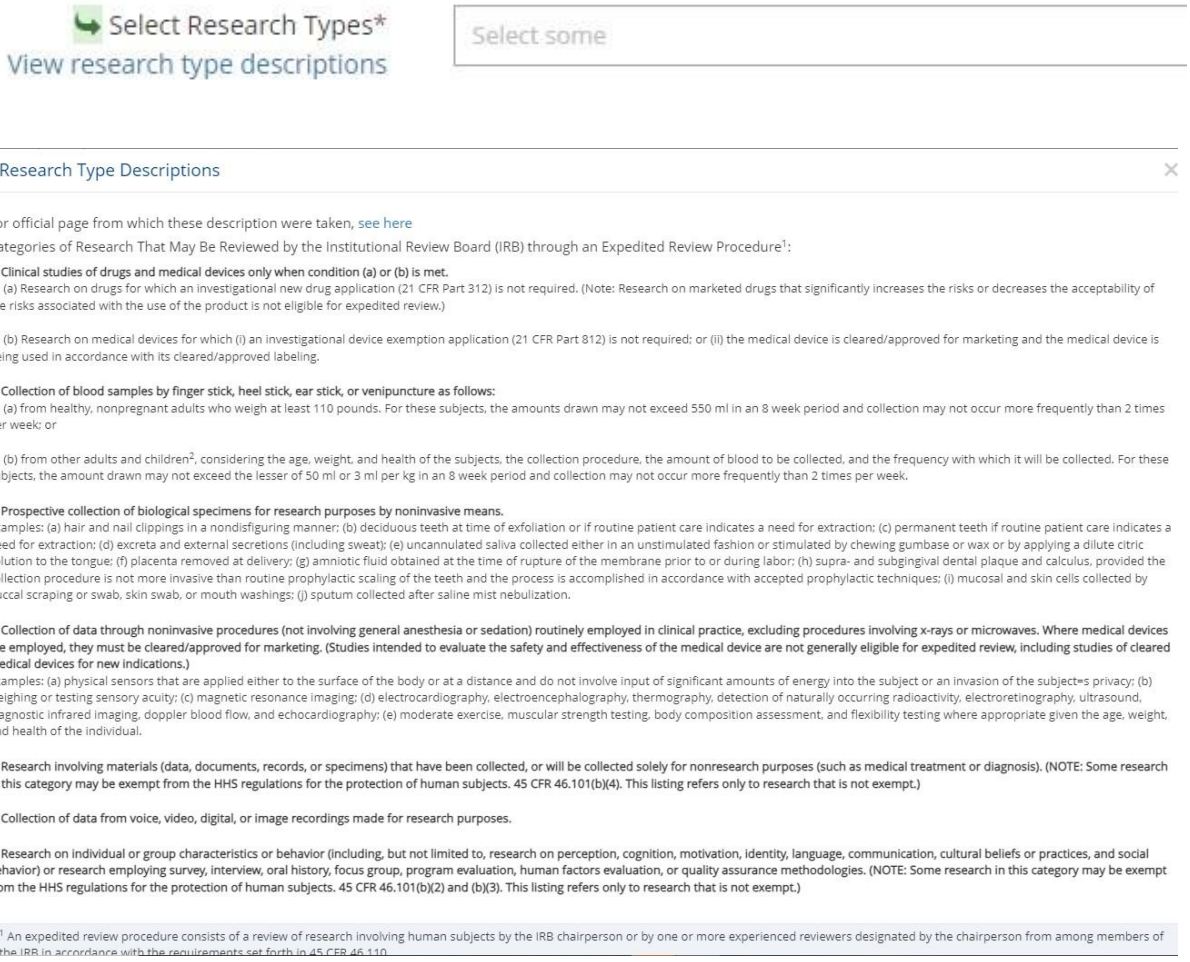


If you select the last box below the Exempt Review Categories, it will uncheck any Exempt Categories you previously selected, and hide the panels that had appeared.



Your project has been moved to an Expedited vs Full Board Determination review and you'll receive new questions to answer.

Click "view research type descriptions" to see the list of Expedited Review categories

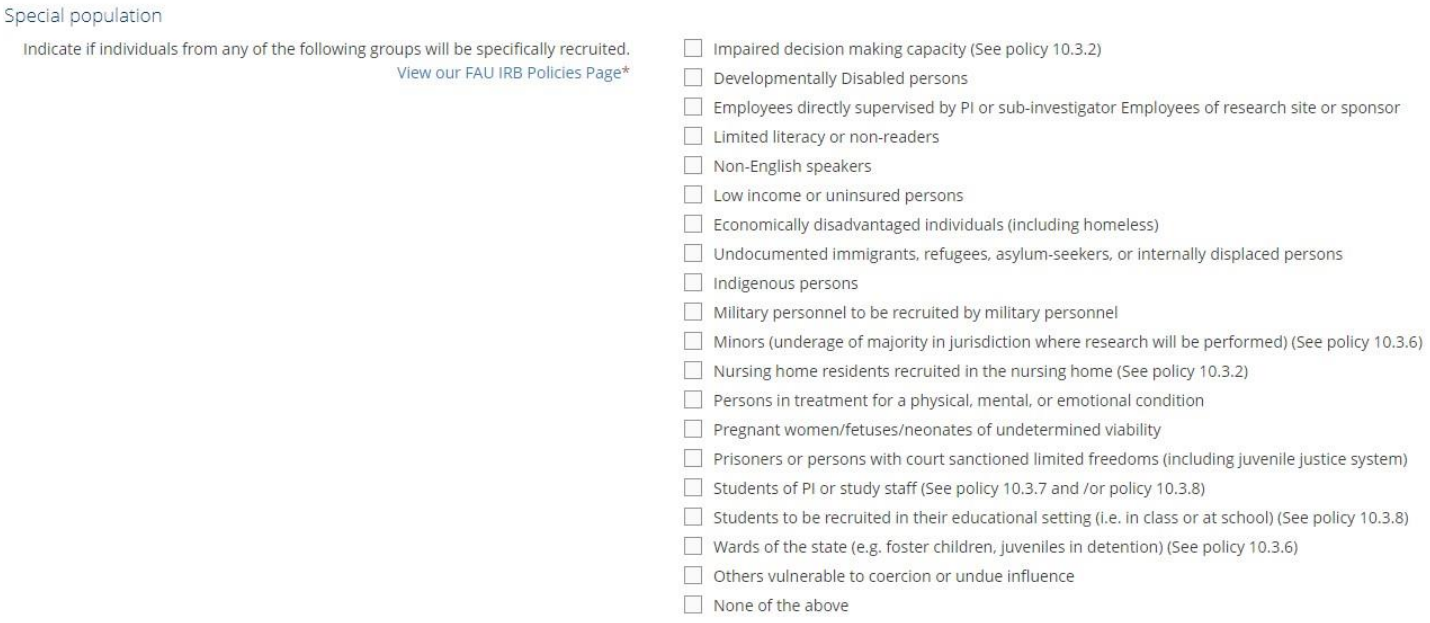


Then, return to the “Select Research Types” field and select all Expedited Categories that apply by selecting them from the drop-down menu

In this How to Guide, we’ll act as if the project is an Exempt Category.

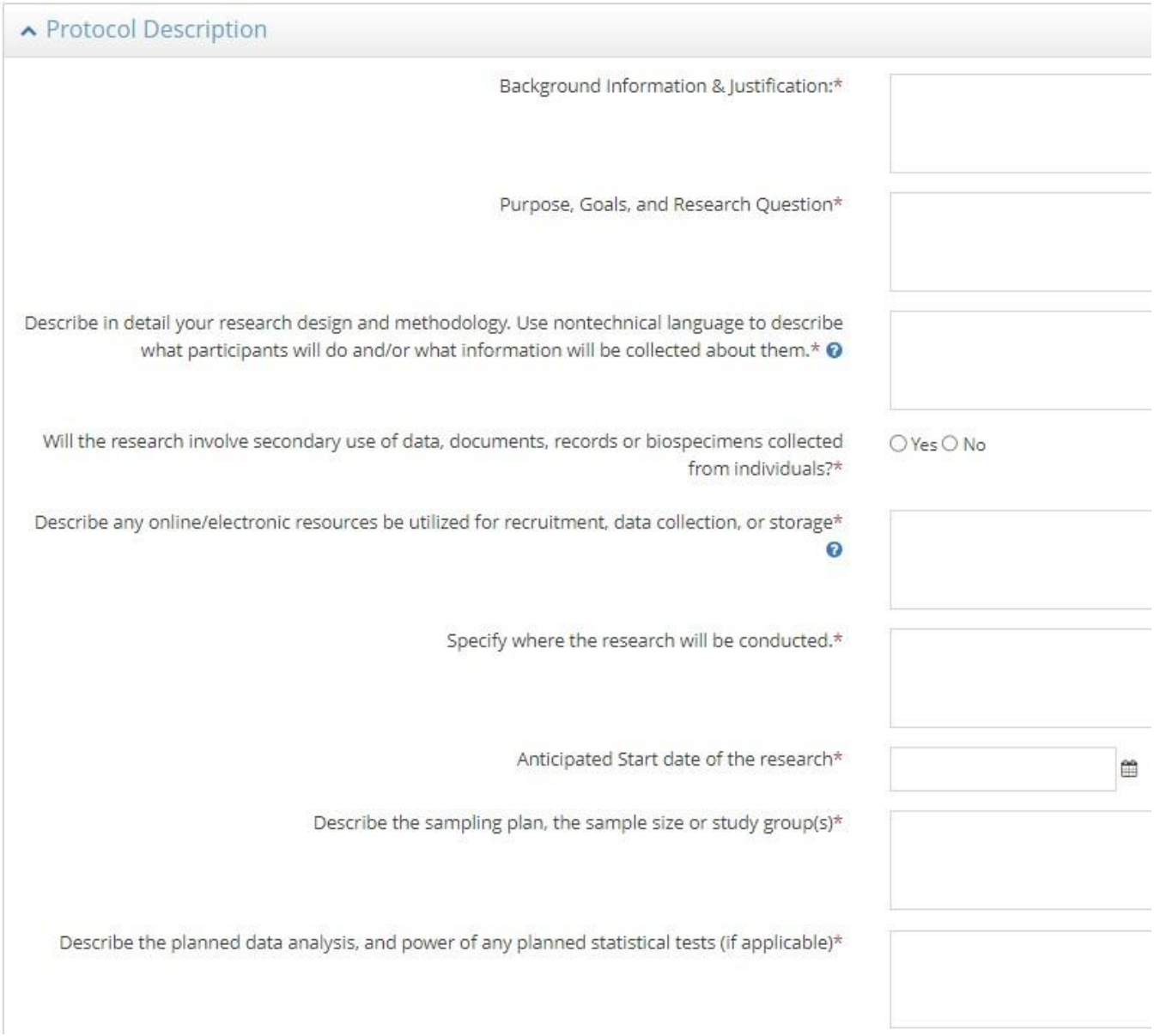
Following the Exempt Categories is the Special Population Section.

Select those options that apply or click “None of the above”. Use the link to our FAU IRB Policies Page for information on the policies that apply to certain populations.



Protocol Description

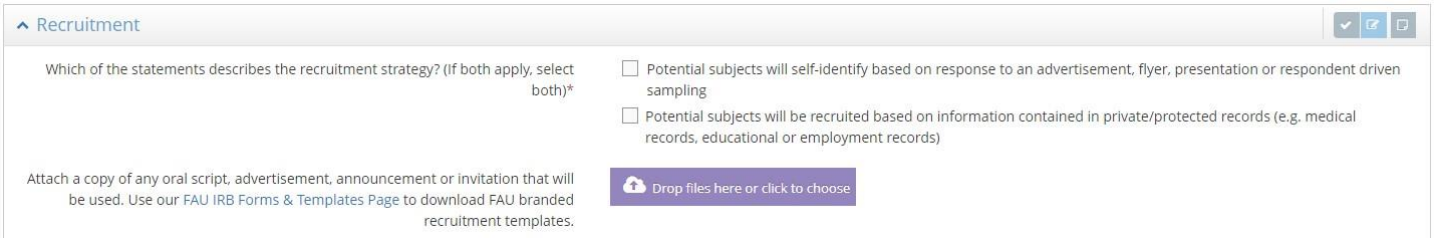
This is where you'll enter your protocol details. You can type into the fields directly, or copy and paste text from a separate document, making sure to save as you go along



Recruitment

This is where you will describe your recruitment strategy and is one of three panels that will give you the option to upload documents such as recruitment email scripts, flyers, etc.

Use the new FAU IRB Forms & Templates Page link to download template flyers, make changes to it according to your project specifications, then save and upload in the purple button in this recruitment panel.

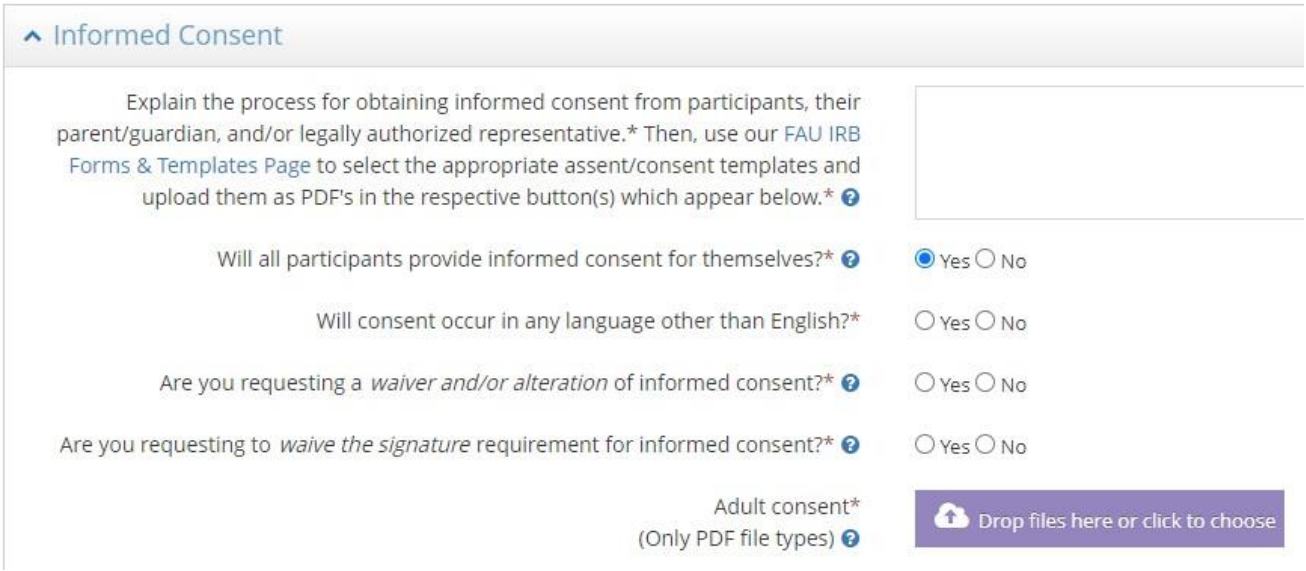


Informed Consent

This is where you'll explain the process for obtaining informed consent for participants (informed consent, assent, parental permission, and so on).

It is the second panel where you have the option to upload documents. Here too use the FAU IRB Forms & Templates page linked in the panel to visit our new forms page and download the necessary templates to modify to your project specifications, save to your computer, and return to upload in the purple button in the informed consent panel.

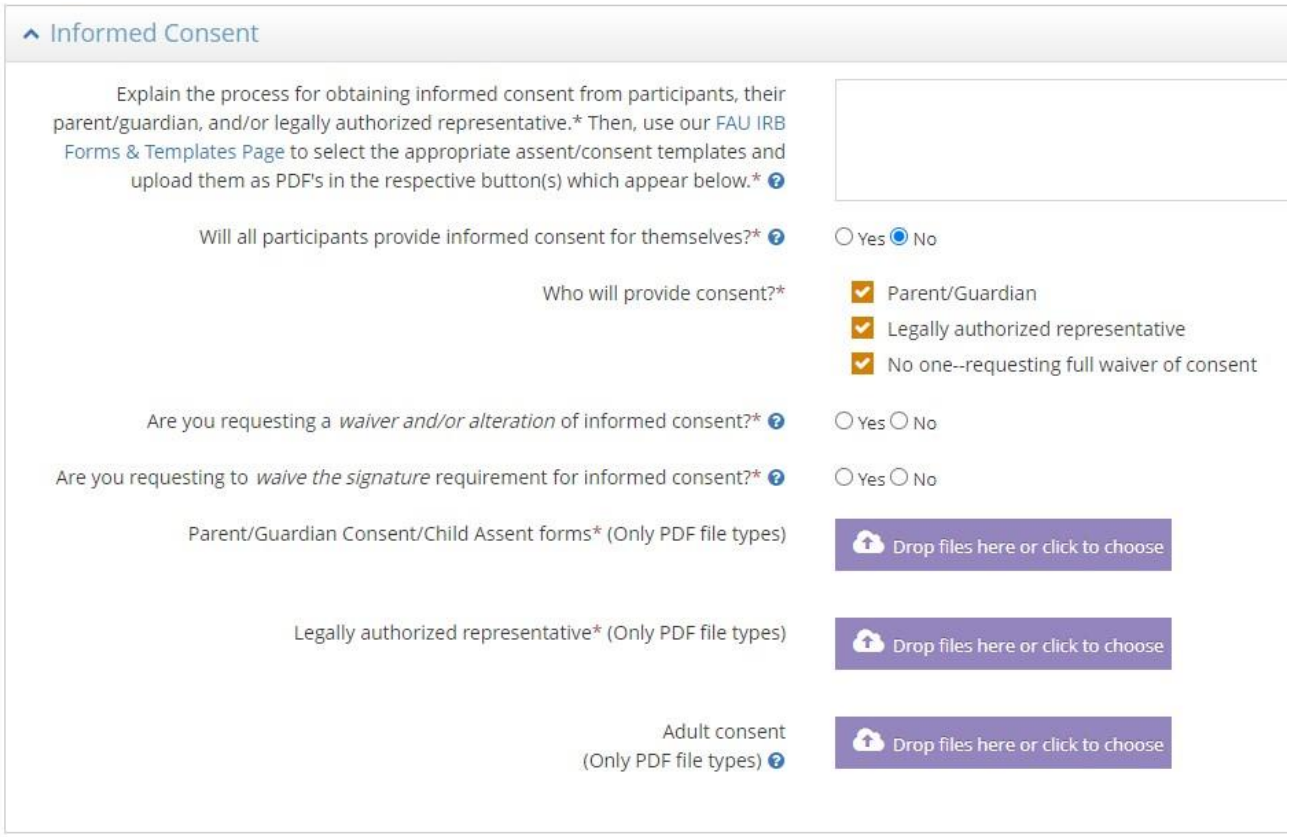
If you answer yes to the question "Will all participants provide informed consent for themselves?" the Adult consent upload button will become a required field.



Unlike the recruitment panel, only PDF files can be uploaded in the Informed Consent panel for administrative stamping purposes. If you'd like to keep a Word version of your Informed Consent with this project for future use, upload it using the "IRB Submission Records" button use the Protocol Documents panel . More information on this will be provided below.

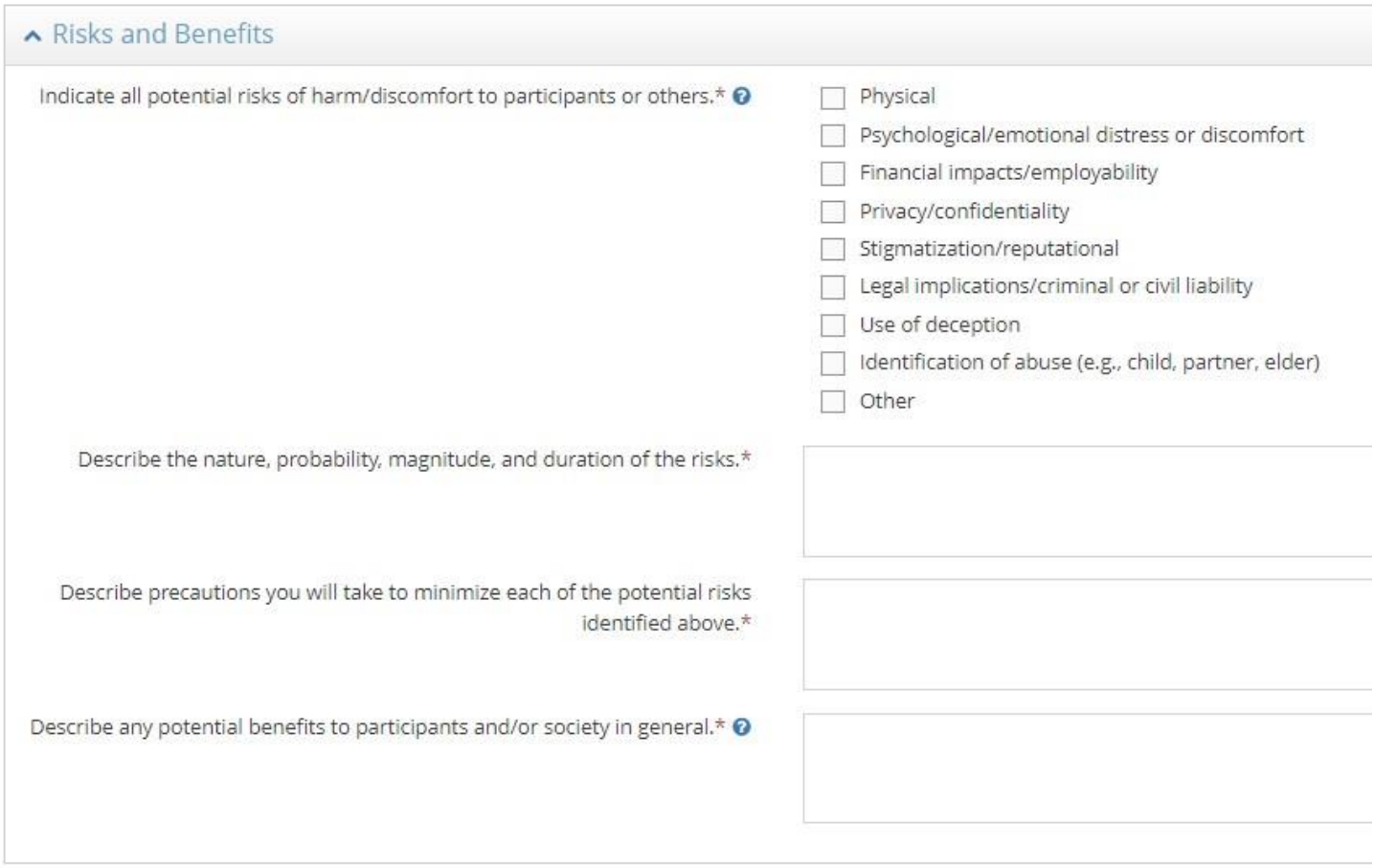
If you answer no to the question "Will all participants provide informed consent for themselves?", you will be asked "Who will provide consent?" and a separate required upload button will appear for each type.

For instance, checking "Parent/Guardian" will produce a required upload button for "Parent/Guardian Consent/Child Assent forms"



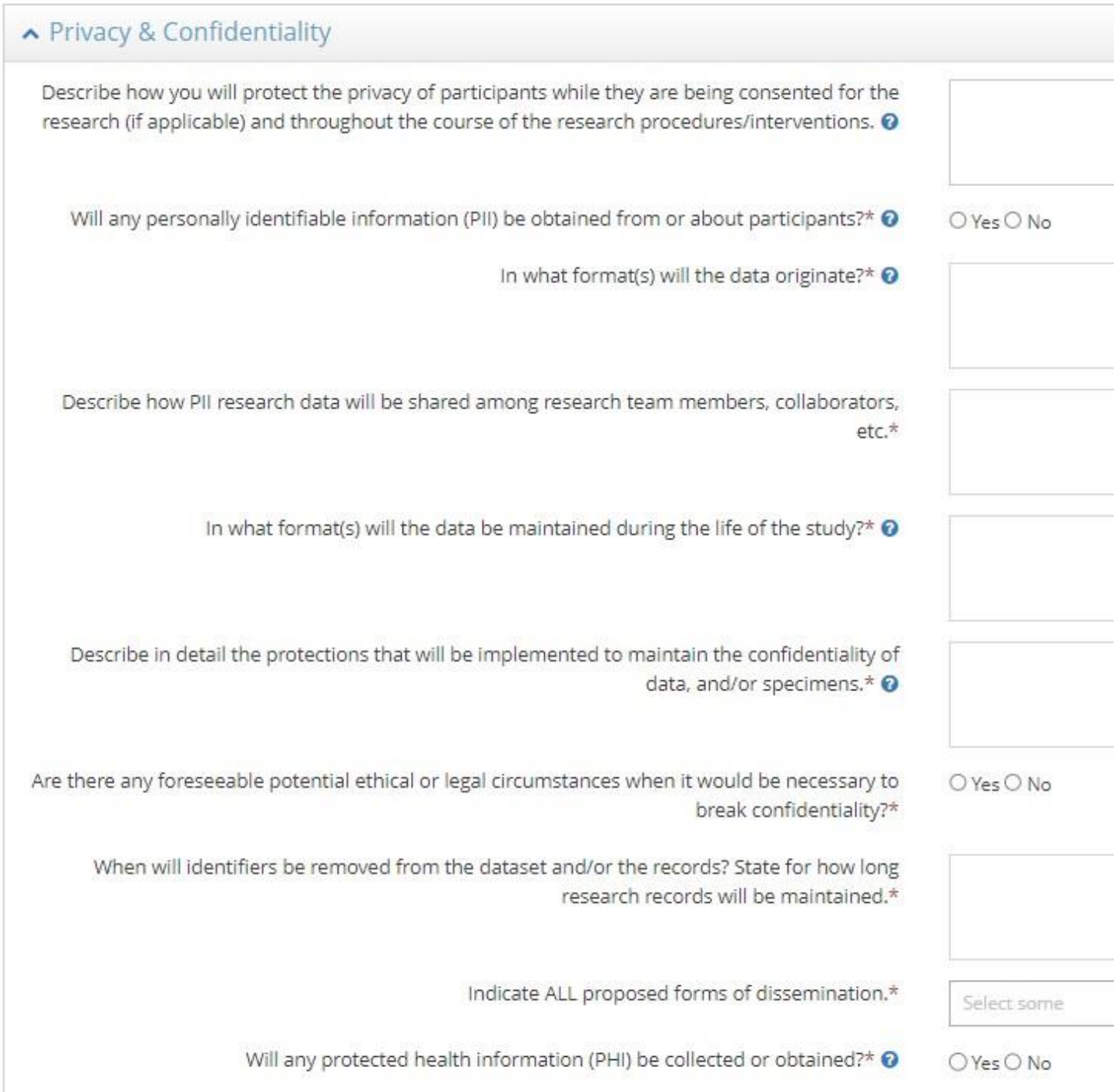
Risks & Benefits

Complete all fields in this section describing the risks and benefits of your research.



Privacy & Confidentiality

The Privacy & Confidentiality panel will ask detailed questions about the type of data you are collecting and will include several smart logic questions with a series of follow ups depending on your answers.



Protocol Documents

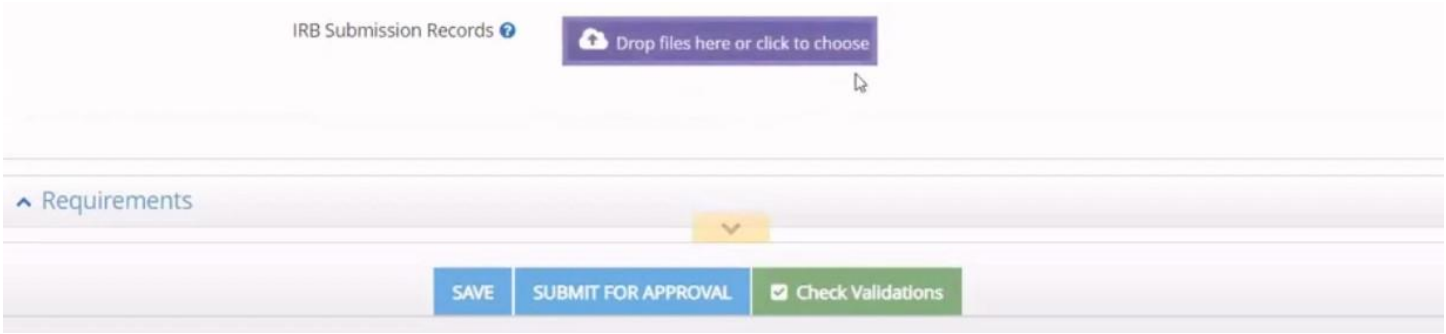
This is the third panel with optional uploads, however there is a required upload for “Data Collection Tools”. This can include your questionnaires, interview materials, and so on.

If you have any other documents that you’d like to upload that are not required, use the Other Documents button for those files

Likewise for Data Use Agreements, upload it in the “Data Use Agreement” upload button when applicable

The IRB Submission Records, as mentioned above, are any of those documents such as consent forms in Word format so that you can keep them with the project

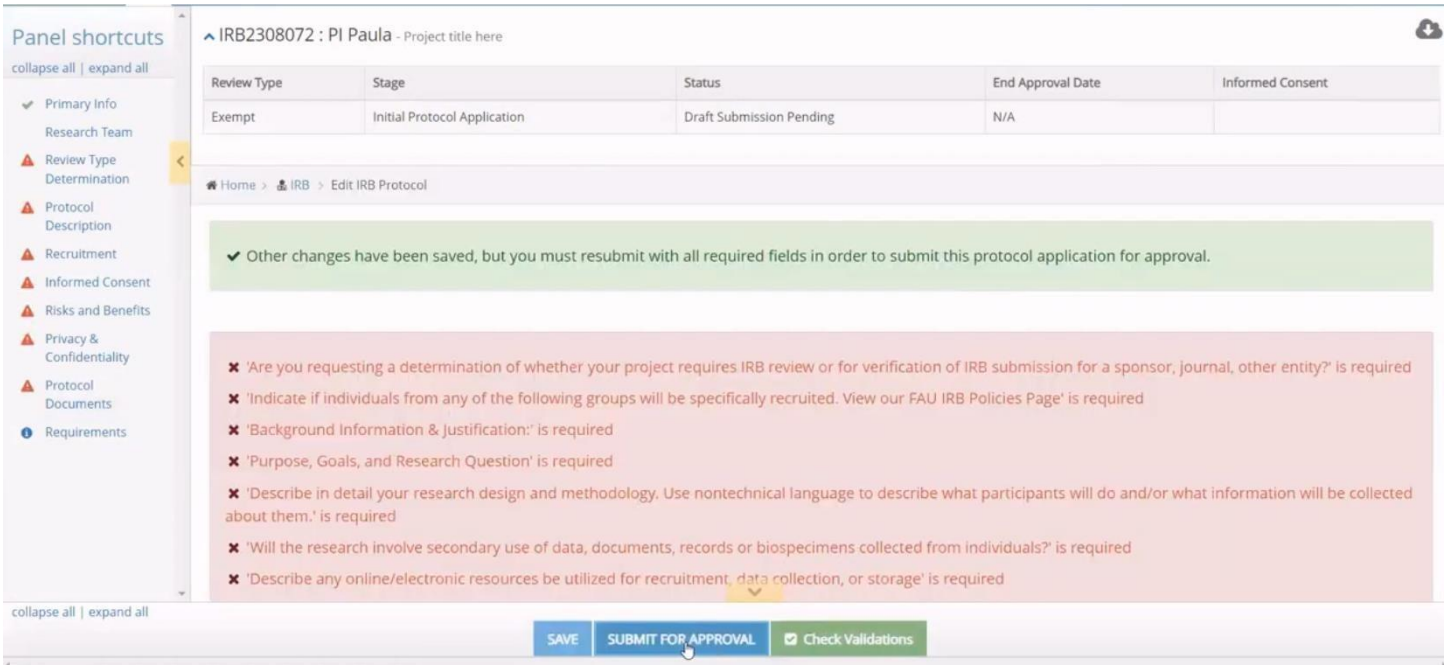
Once you have completed your IRB Application, click to Submit for Approval



Check Validations (Incomplete Required Fields)

Any required fields that were not completed will show up in a red box and will be noted as errors in the Panel Shortcuts.

Click the links in the red box to be taken directly to the incomplete required field to provide your response.



Once you have addressed all required fields, click again to Submit for Approval. When your submission has been successful, you'll see a green bar confirming your submission. You'll also see the project's Status has changed to the next step which is in this case PI Certification Pending