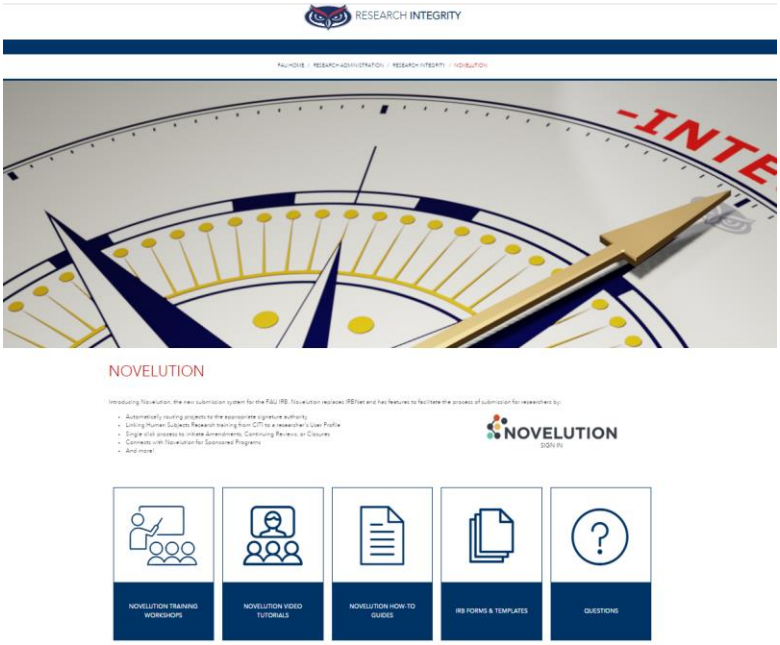
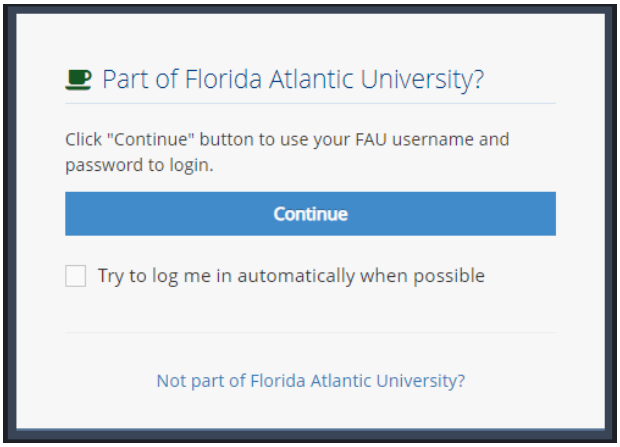
FAU IRB NOVELUTION

Overview

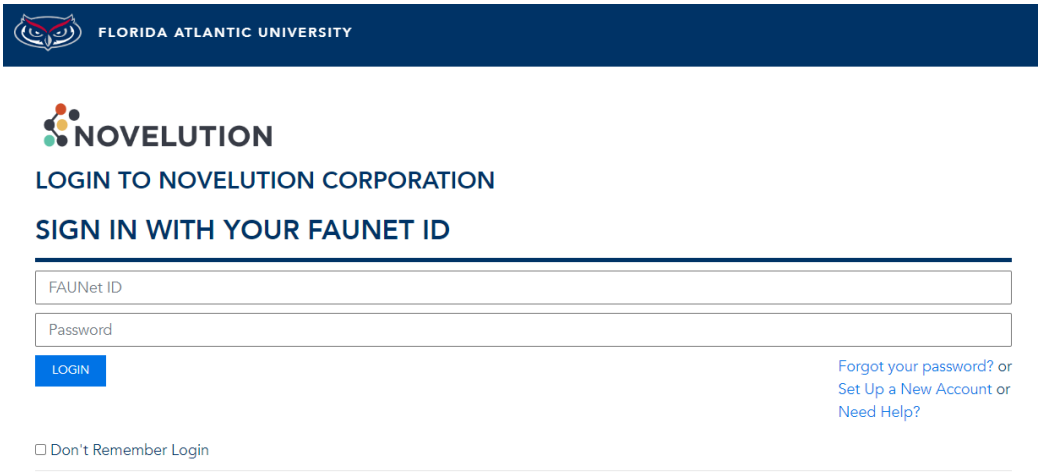


You can access Novelution from the new Novelution page by clicking the sign in button or by searching https://fau.novelution.com/login

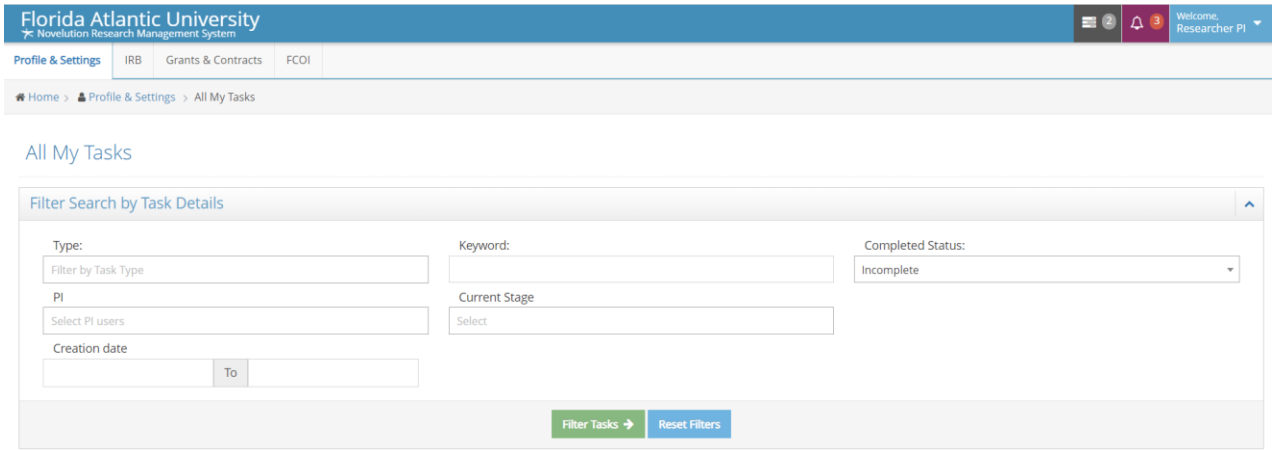
Click to Continue



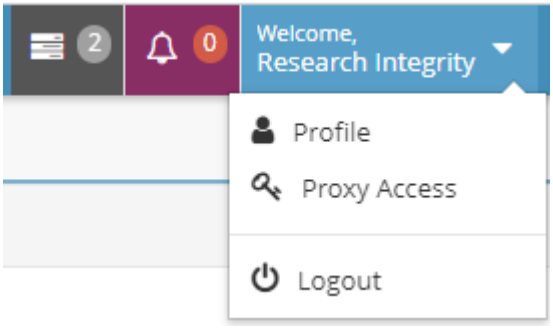
Enter your FAU Credentials to log in



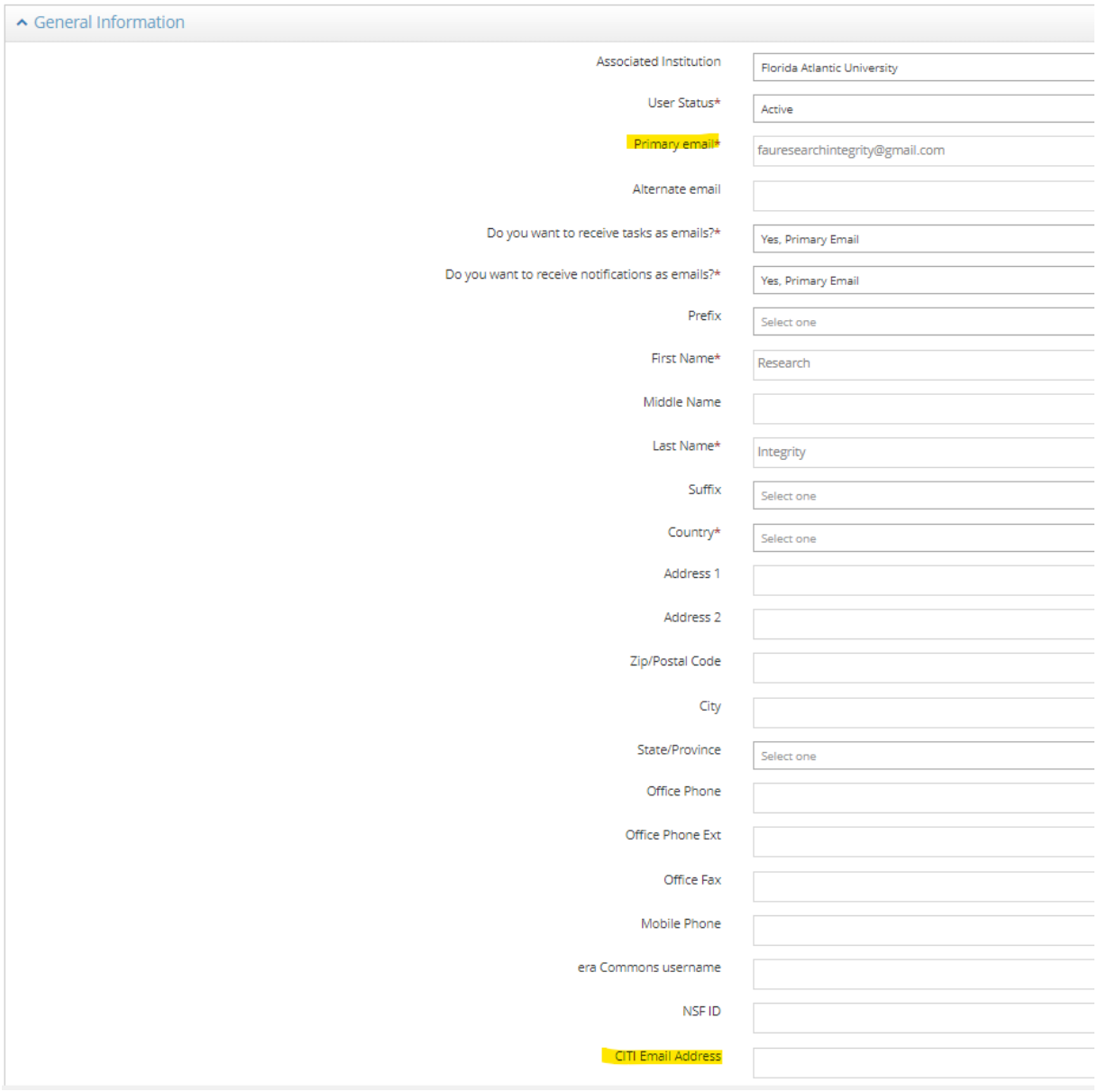
Welcome to the new Novelution system. This will be the landing page once you've logged in. You'll notice you have the IRB tab now and several buttons up at the top.



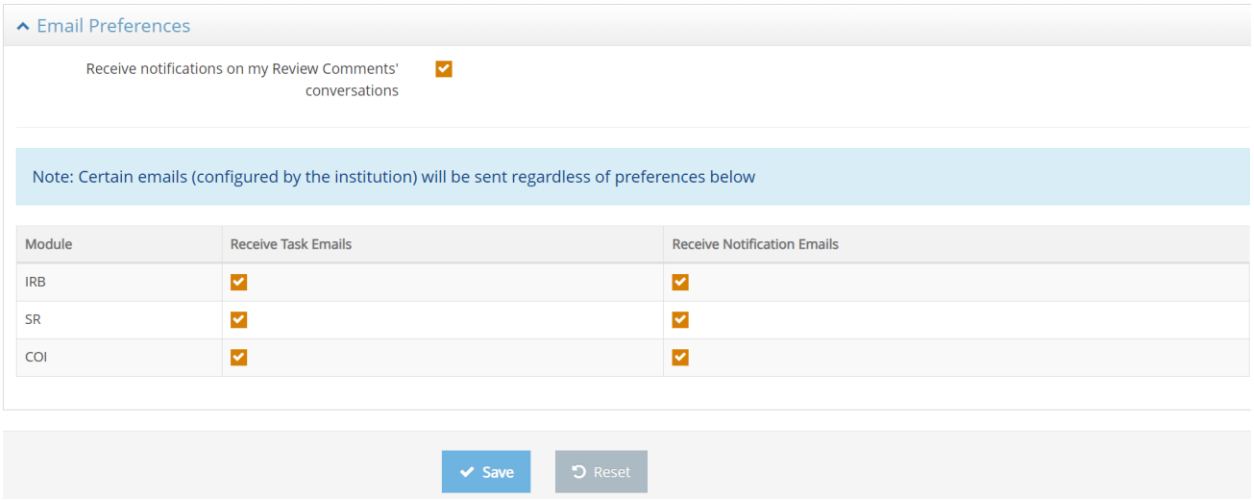
Access your Profile page from the Welcome (blue box)



Review your User Profile information. If your Primary email is different from the email you have listed for CITI, scroll to the bottom, and add your CITI email in the CITI Email Address field. This will allow Novelution to be able to pull your training records directly from CITI into your account and auto-populate your training records on all your IRB submissions or submissions where you are listed as research team personnel.

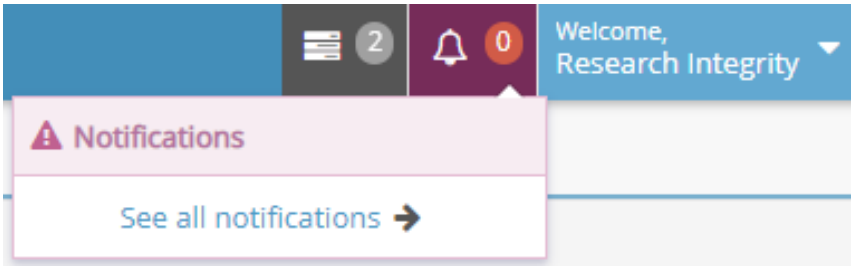


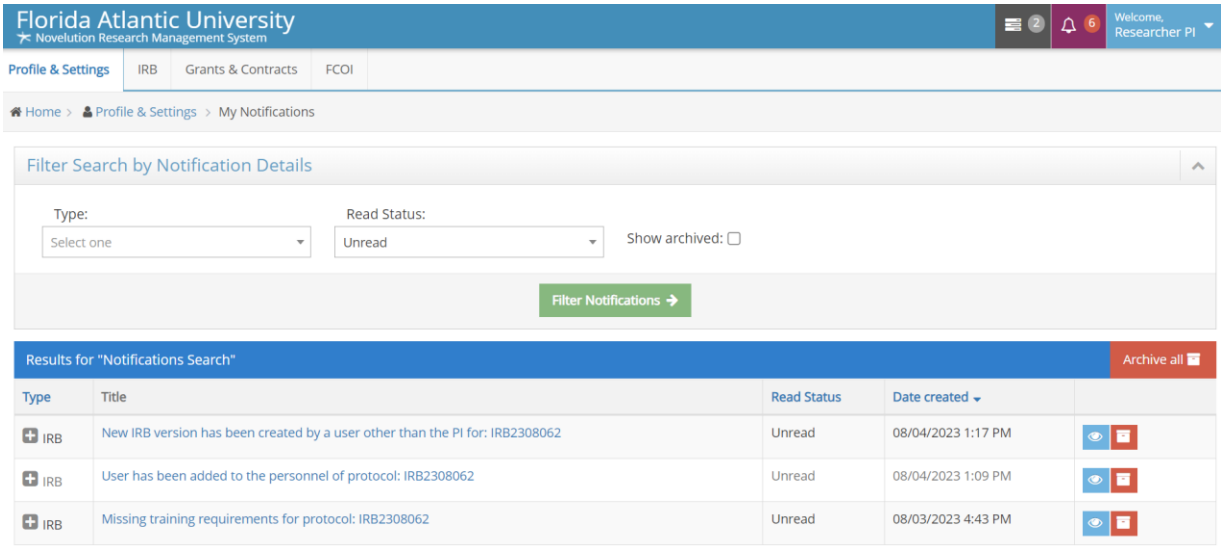
Scroll to the bottom to Email Preferences and make sure the “Receive notifications on my Review Comments’ conversations” box is checked off so that you will receive email notifications.



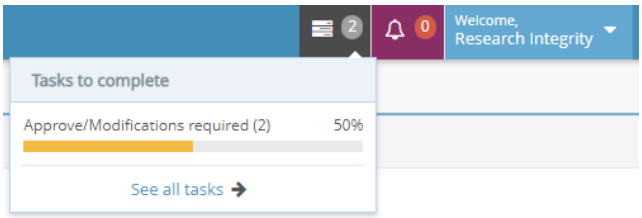
Click to save!

Notifications (purple box) do not require an action step from you but serve to keep you informed on the status of your project such as when another user on the research team creates a new version of the project, or have added personnel, or are missing training requirements.

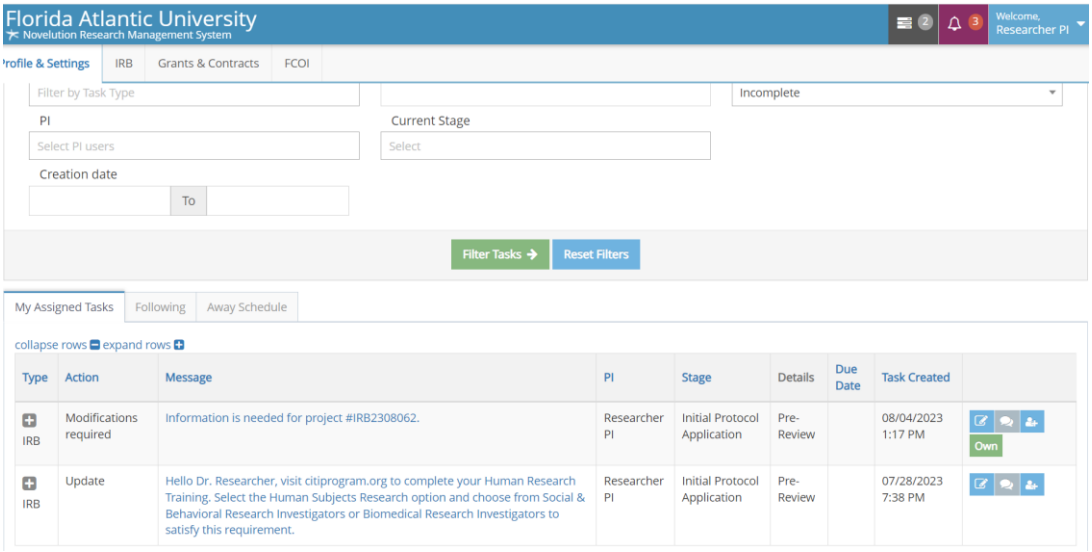




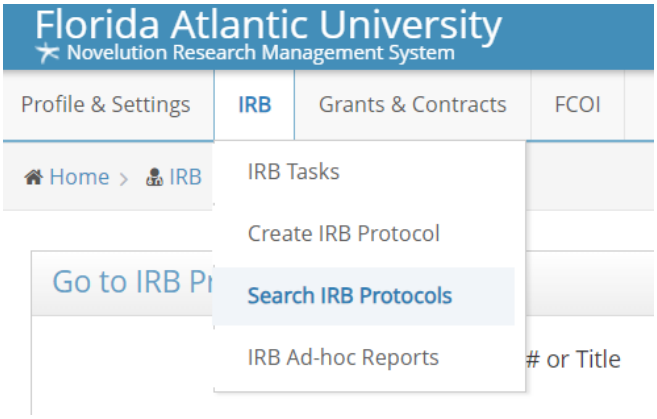
Tasks to complete (gray box) will show you the items that require an action from you such as signing as PI if someone has submitted a project on your behalf, responding to required changes from the IRB, etc.



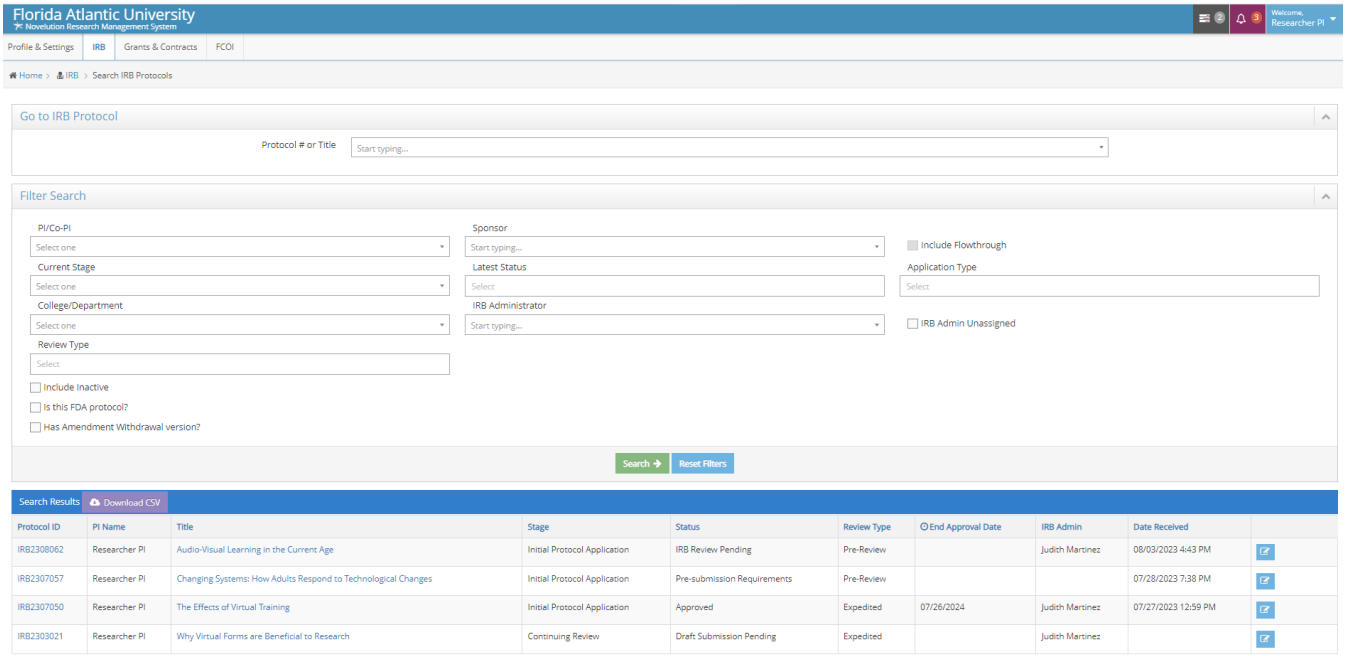
Clicking on a task link (listed in the Message column) will lead you straight to the project requiring your attention.



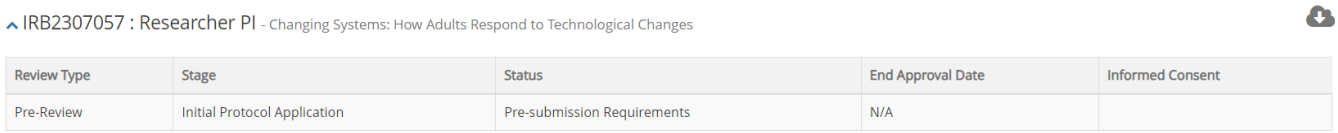
You can also search for your IRB projects by hovering over the IRB tab and clicking “Search IRB Protocols”



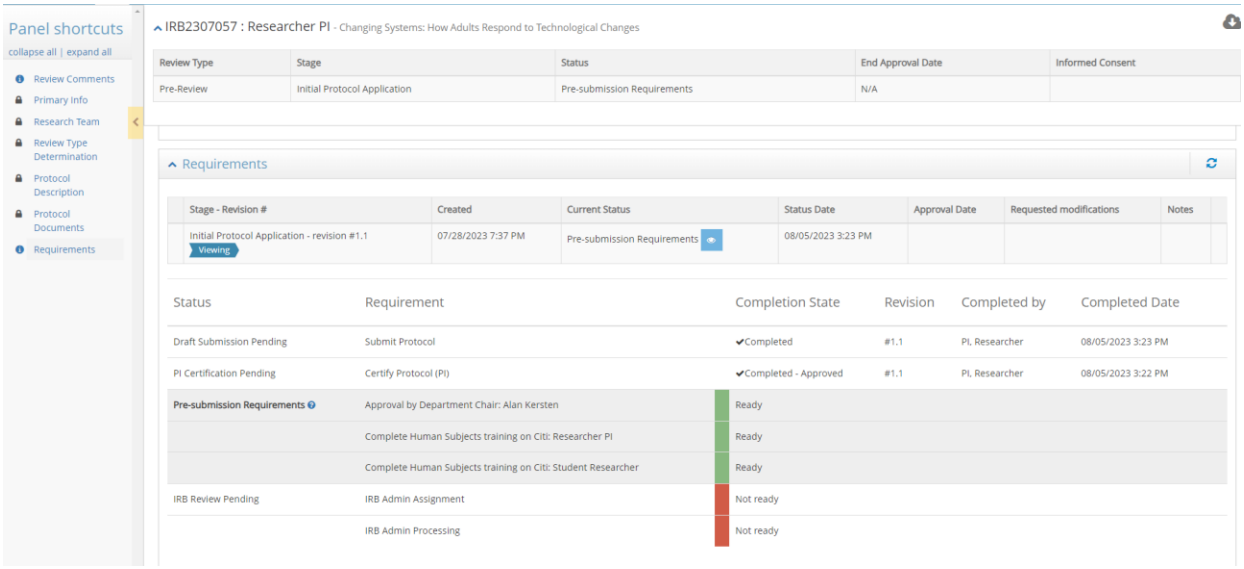
Scroll to the bottom to view the list of your research projects. You can click into the project by using the link in the Protocol ID column, Title column, or the pencil icon at the end.



The Project Details Panel will provide summary information about your project



For more information click on the Requirements link in the Panel Shortcuts to be taken to the Requirements panel which will provide a step-by-step listing of the stages of your project workflow



In the example above, the requirements to Submit the Protocol and for the PI to Certify the Protocol have been completed and now the project is ready for the Approval by the Department Chair and for CITI training to be complete.

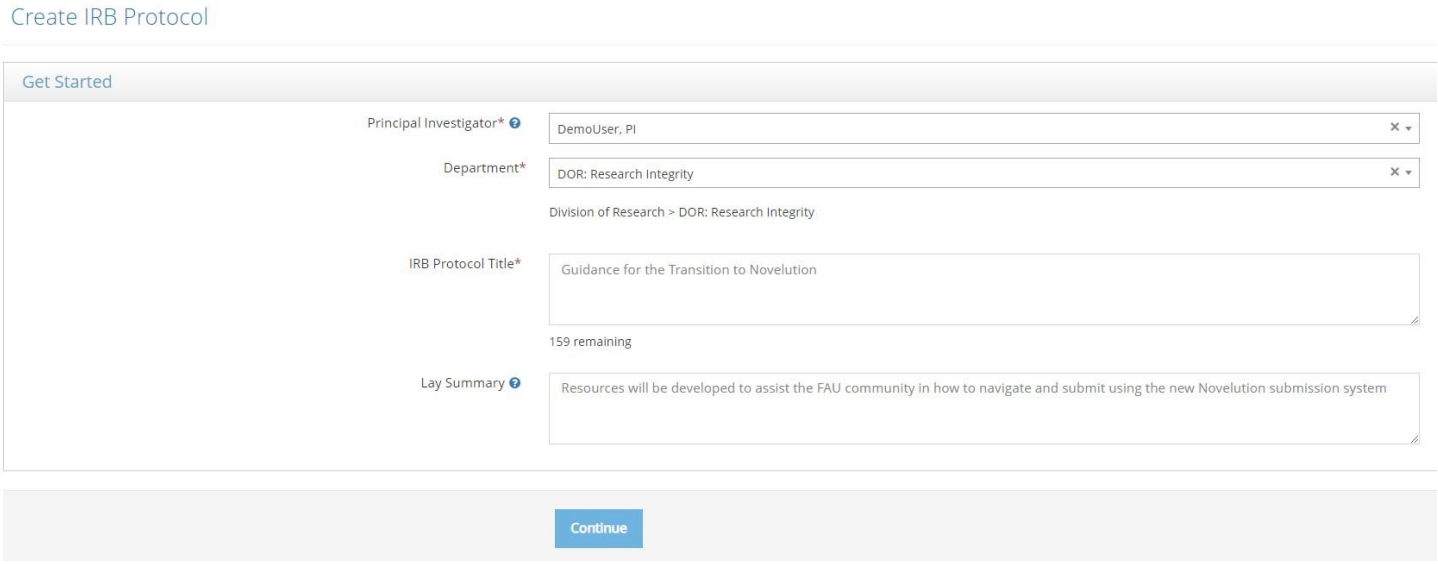
It is however not ready for the IRB Office to process this submission. The IRB will not receive a notification of your project submission until all the preceding steps are complete.

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.

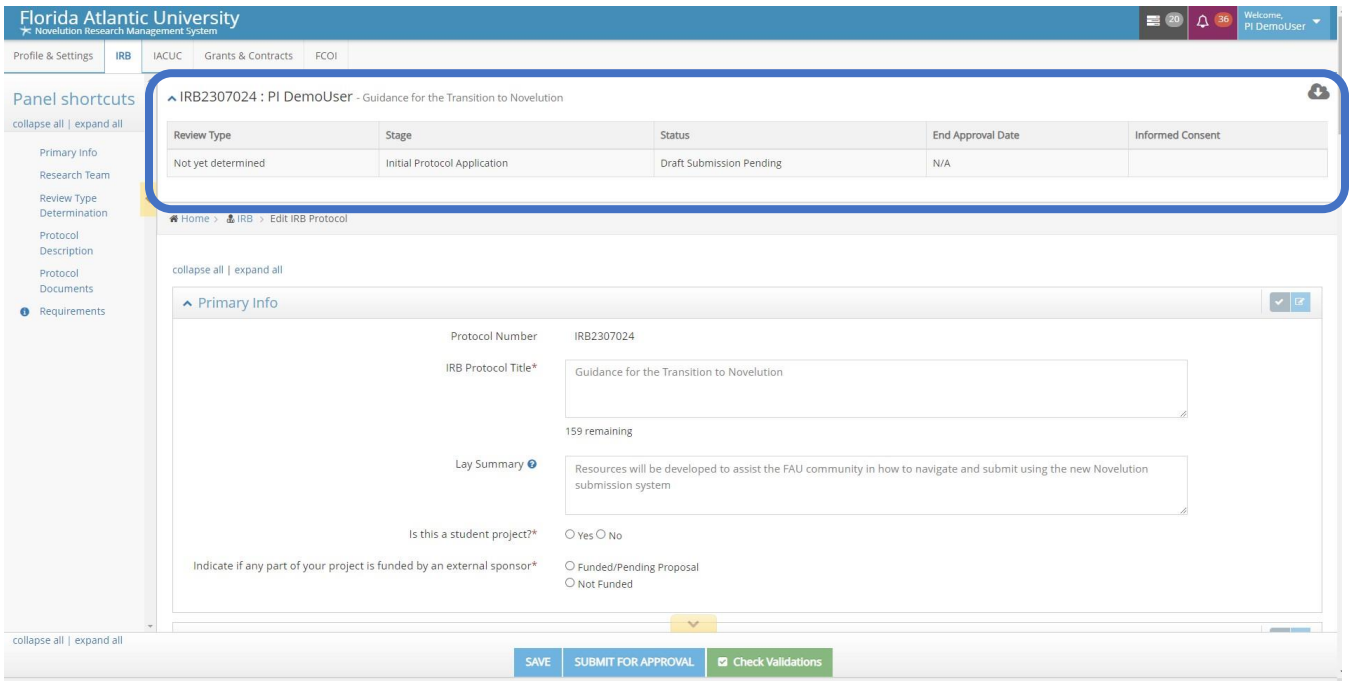
If you are a student or otherwise do not have PI eligibility, type the name of your PI in the Principal Investigator field to continue.

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.

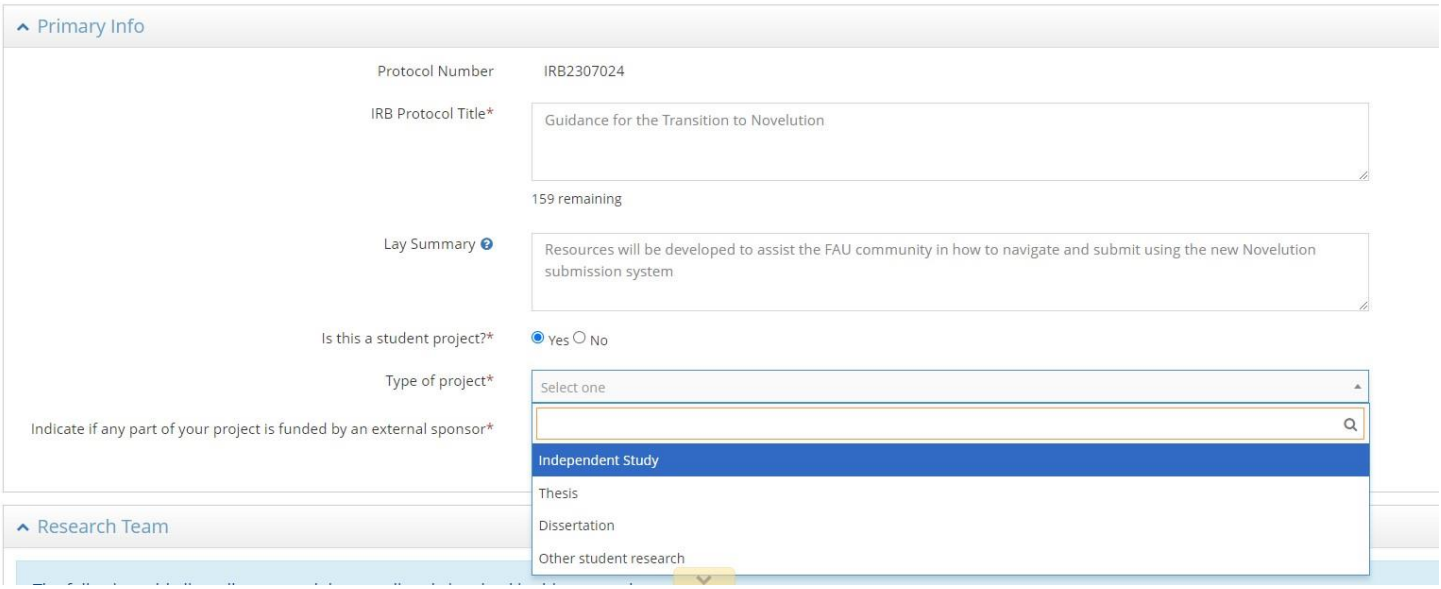
On the left-hand side are the Panel shortcuts which will allow you to skip to different sections in your submission

- 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

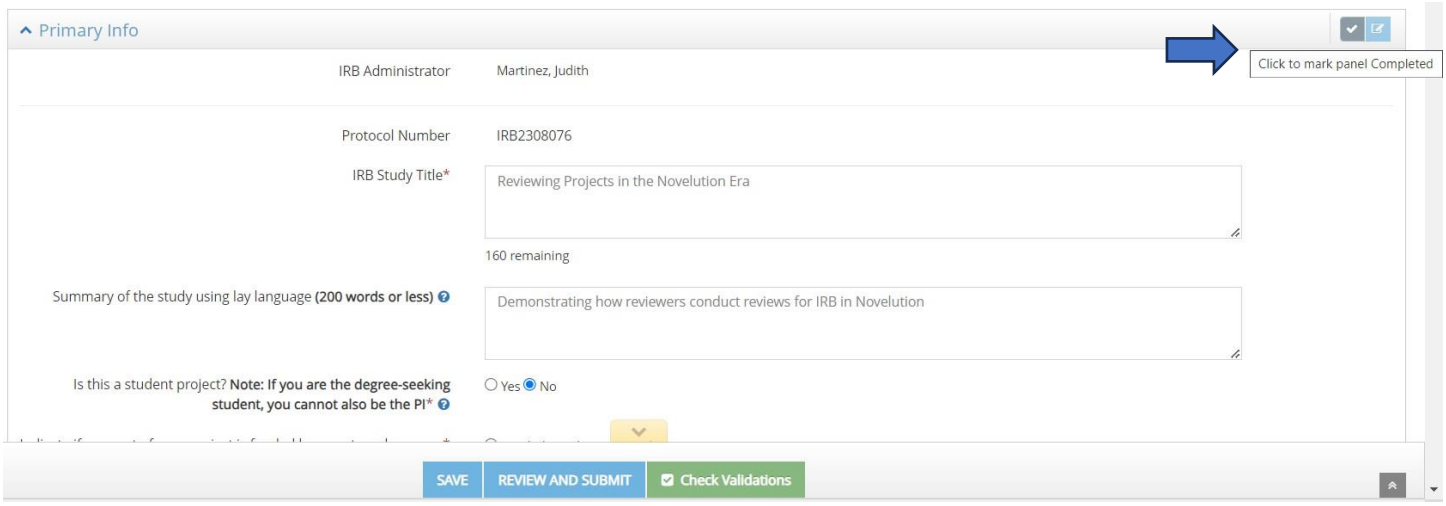
Primary Info

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.

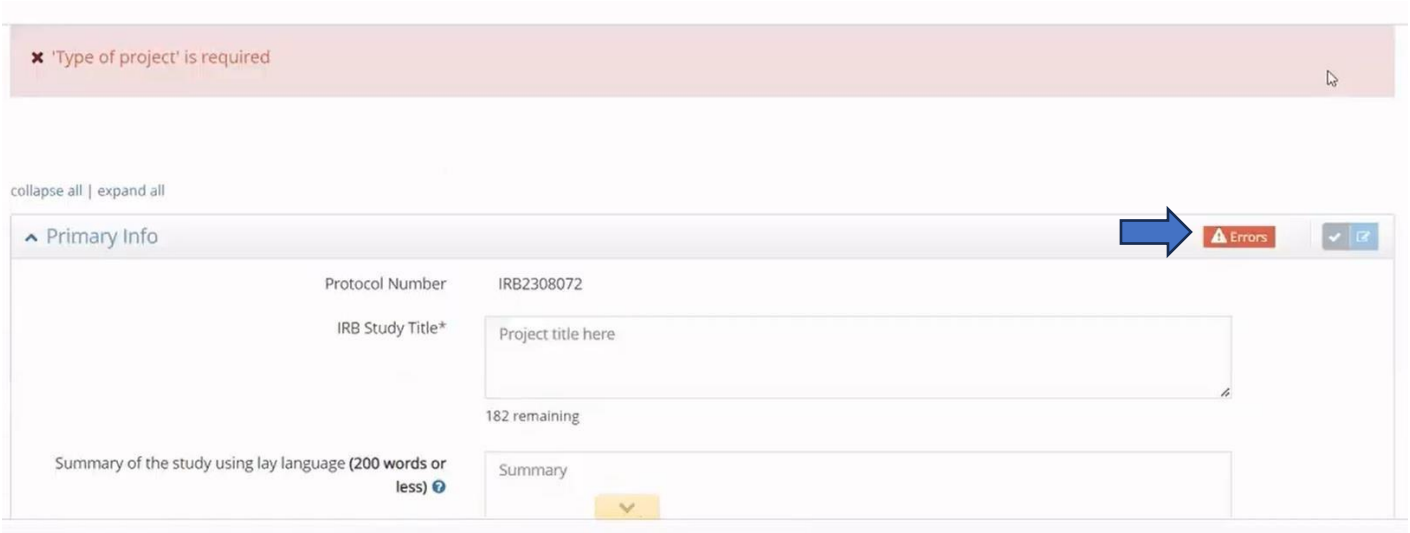
Questions follow smart logic and will produce additional follow-up questions depending on certain selections. In this example, selecting Yes to the question “Is this a student project?” will show a new “Type of project” drop down list to select the specific student project.



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.

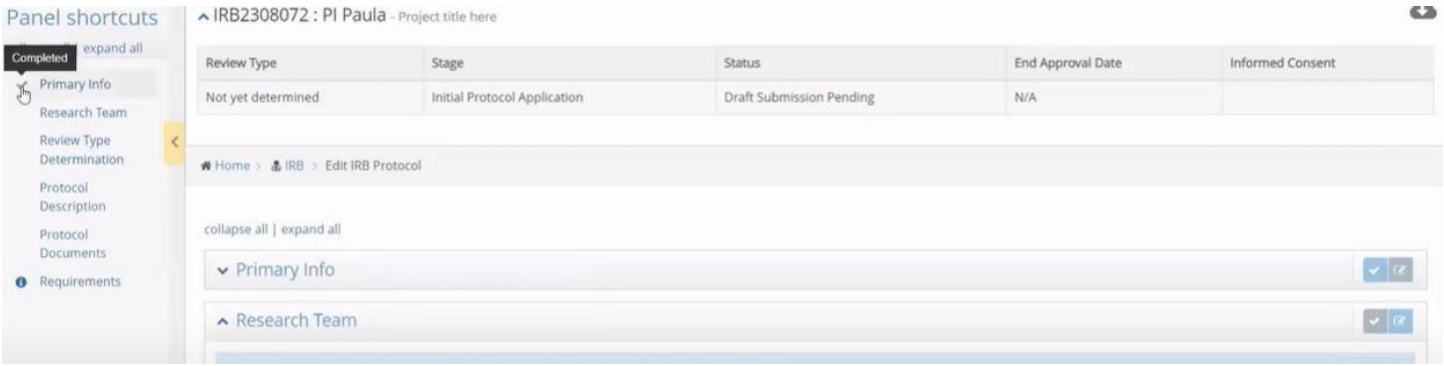


If any required fields are missing, you'll see an "Errors" box appears in the panel header and a red box appears up at the top listing the required field that is missing. You can click that link to be taken directly to the field to fill in your response(s).



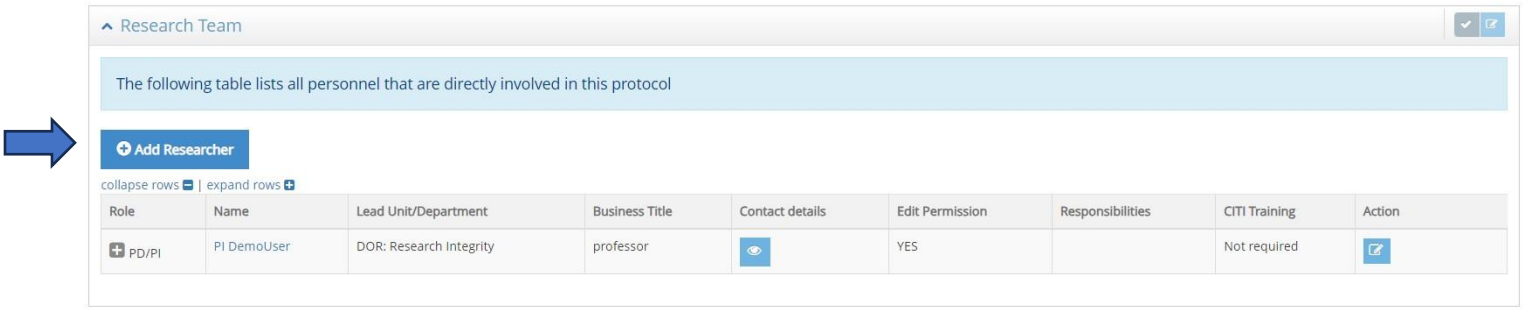
Fill out any missing required fields then click the checkmark again to see the panel is now Completed, indicated with a Checkmark in the Panel Shortcuts.

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



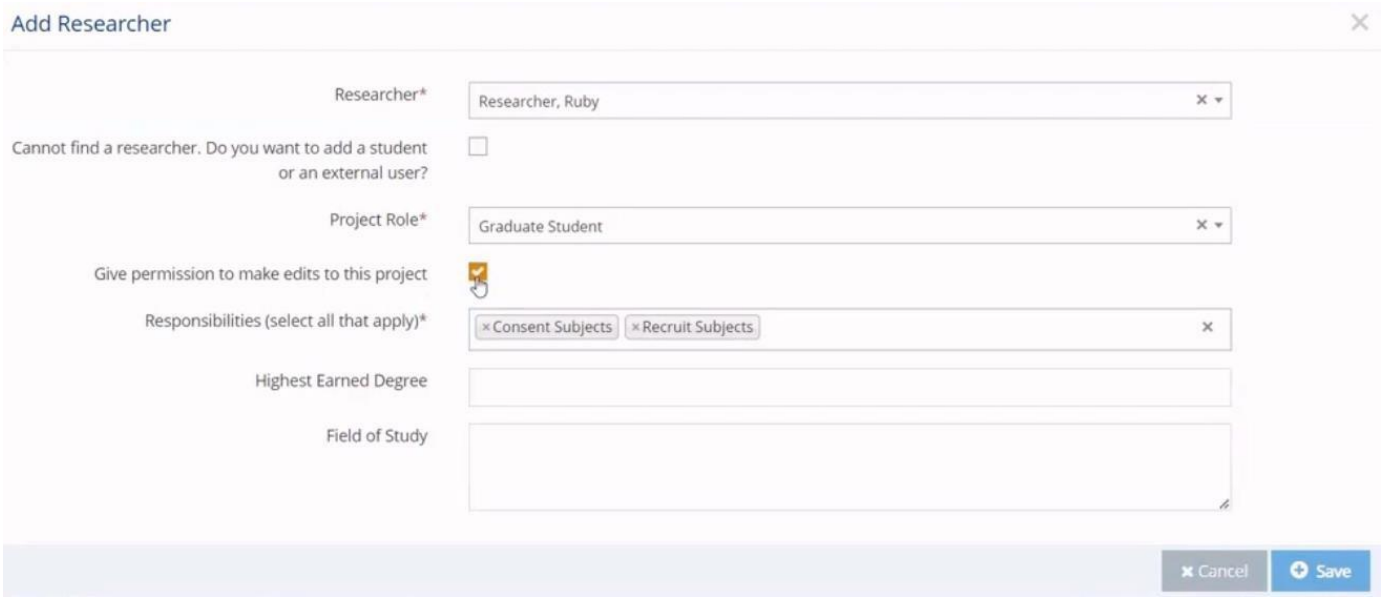
Research Team

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.

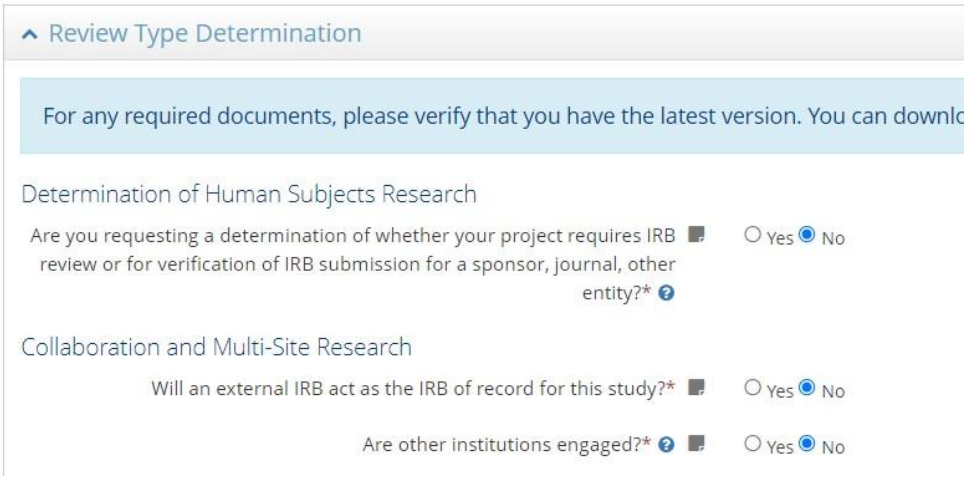


Once a researcher has been added, click to save. Repeat the process to add other researchers to the team personnel.

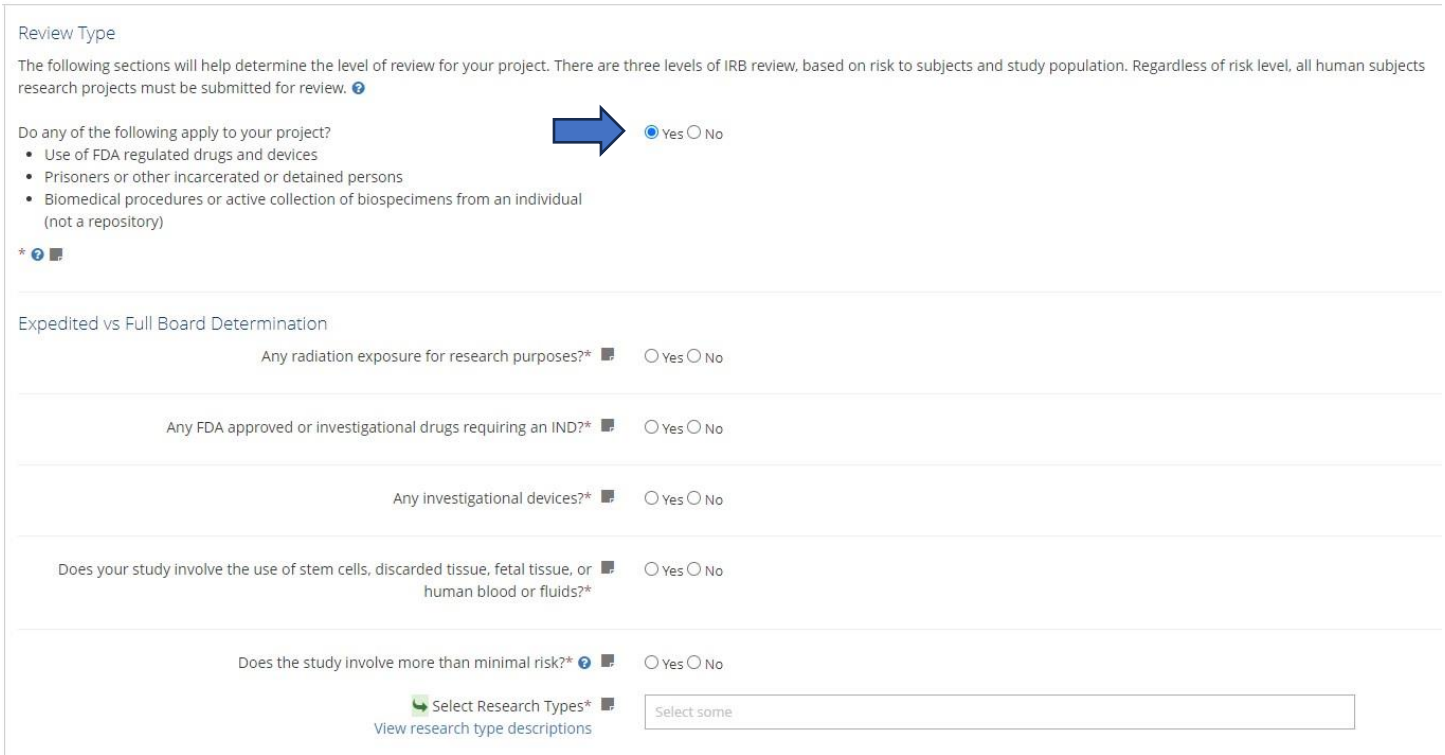
Review Type Determination

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.

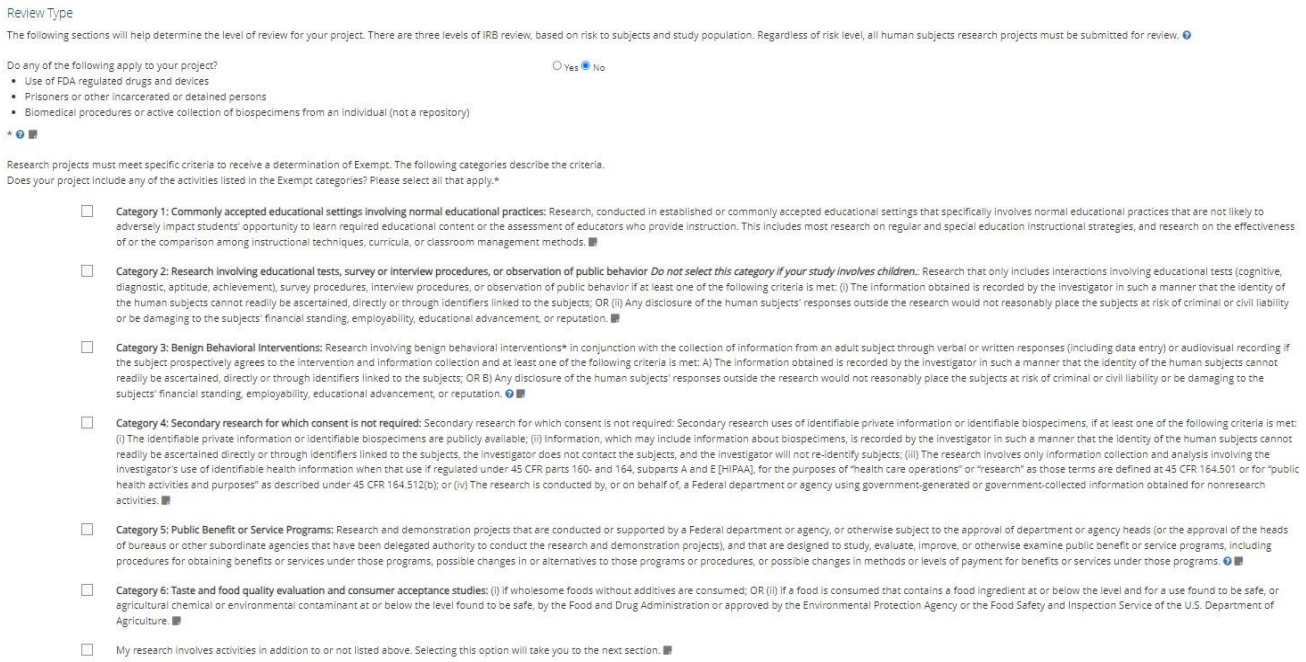
Selecting no to the first few questions regarding Determination of Human Subjects Research and Collaboration and Multi-Site Research will lead you to the Review Type section.



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.

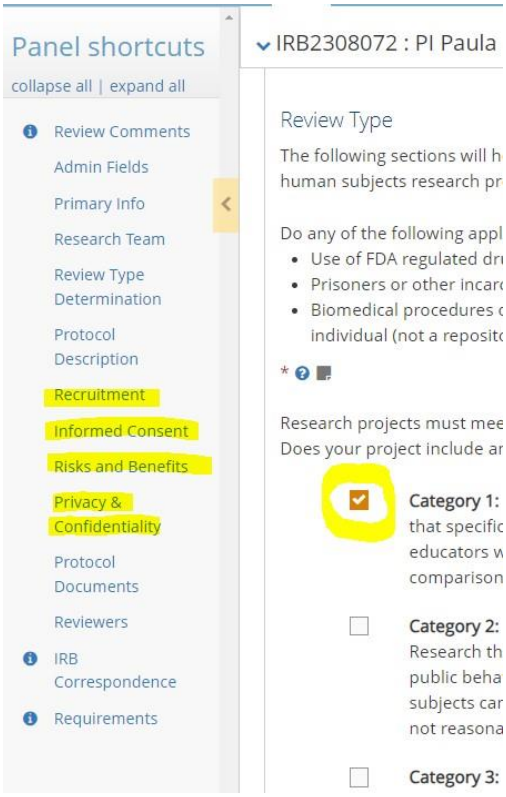
☐ **Category 4: Secondary research for which consent is not required:** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information 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.

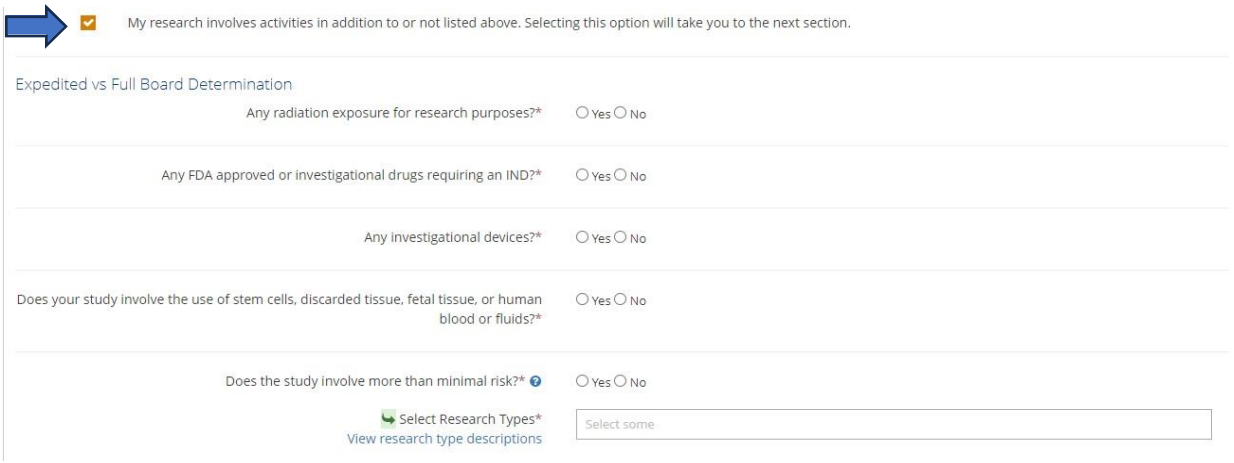
☐ **Category 6: Taste and food quality evaluation and consumer acceptance studies:** (i) if wholesome foods without additives are consumed; OR (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant 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

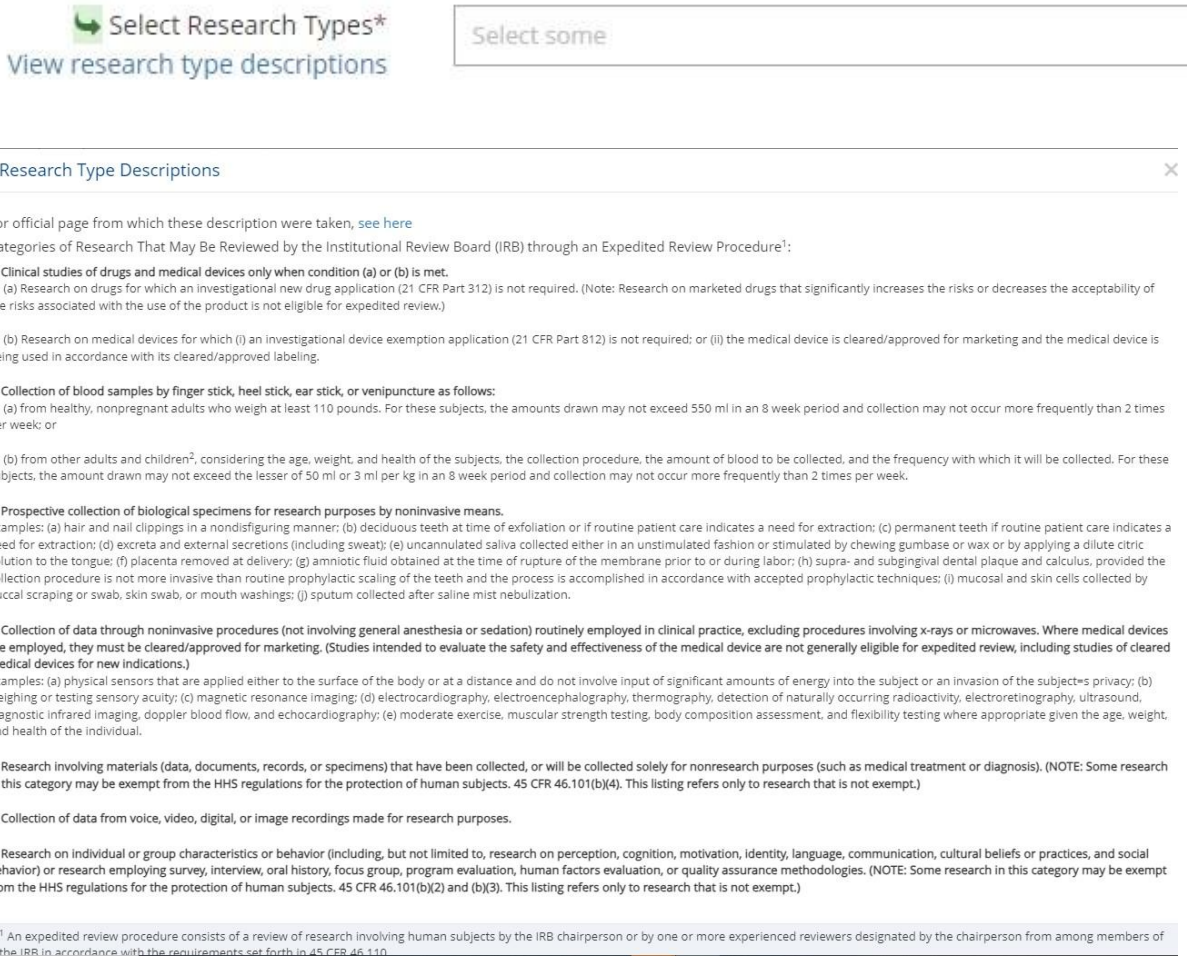


If you select the last box below the Exempt Review Categories, it will uncheck any Exempt Categories you previously selected, and hide the panels that had appeared.



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

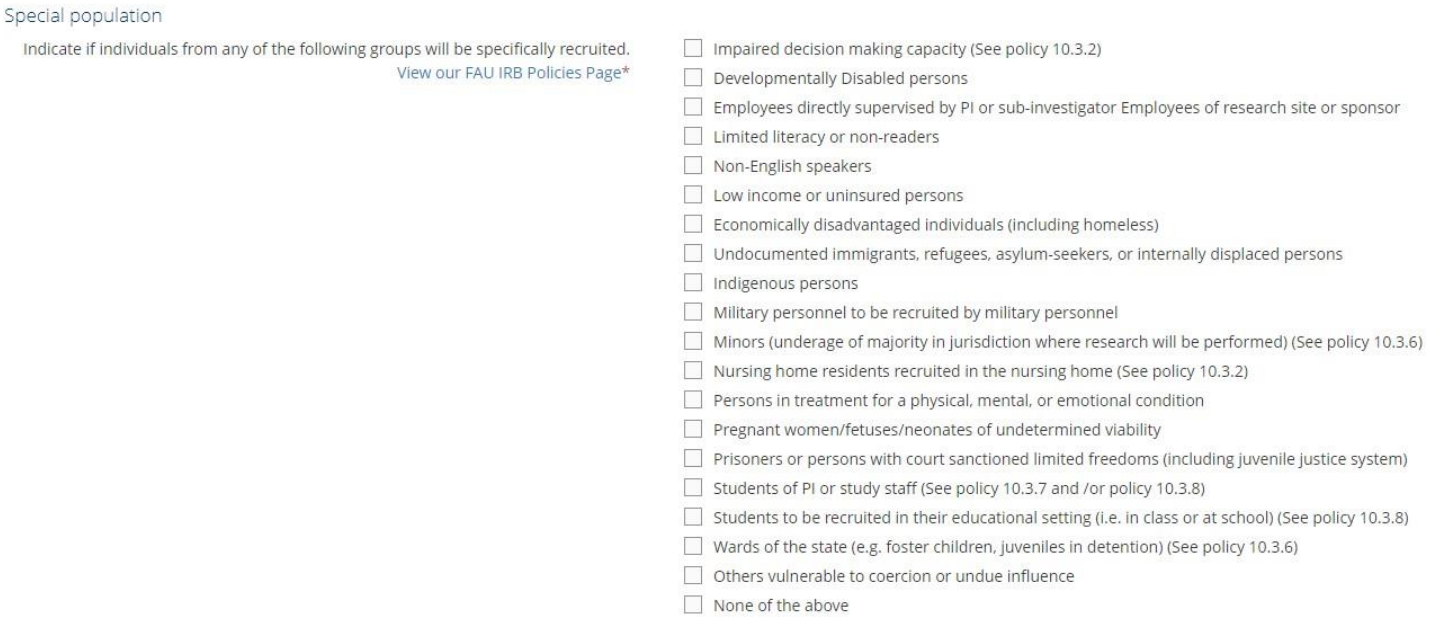


Then, return to the “Select Research Types” field and select all Expedited Categories that apply by selecting them from the drop-down menu

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

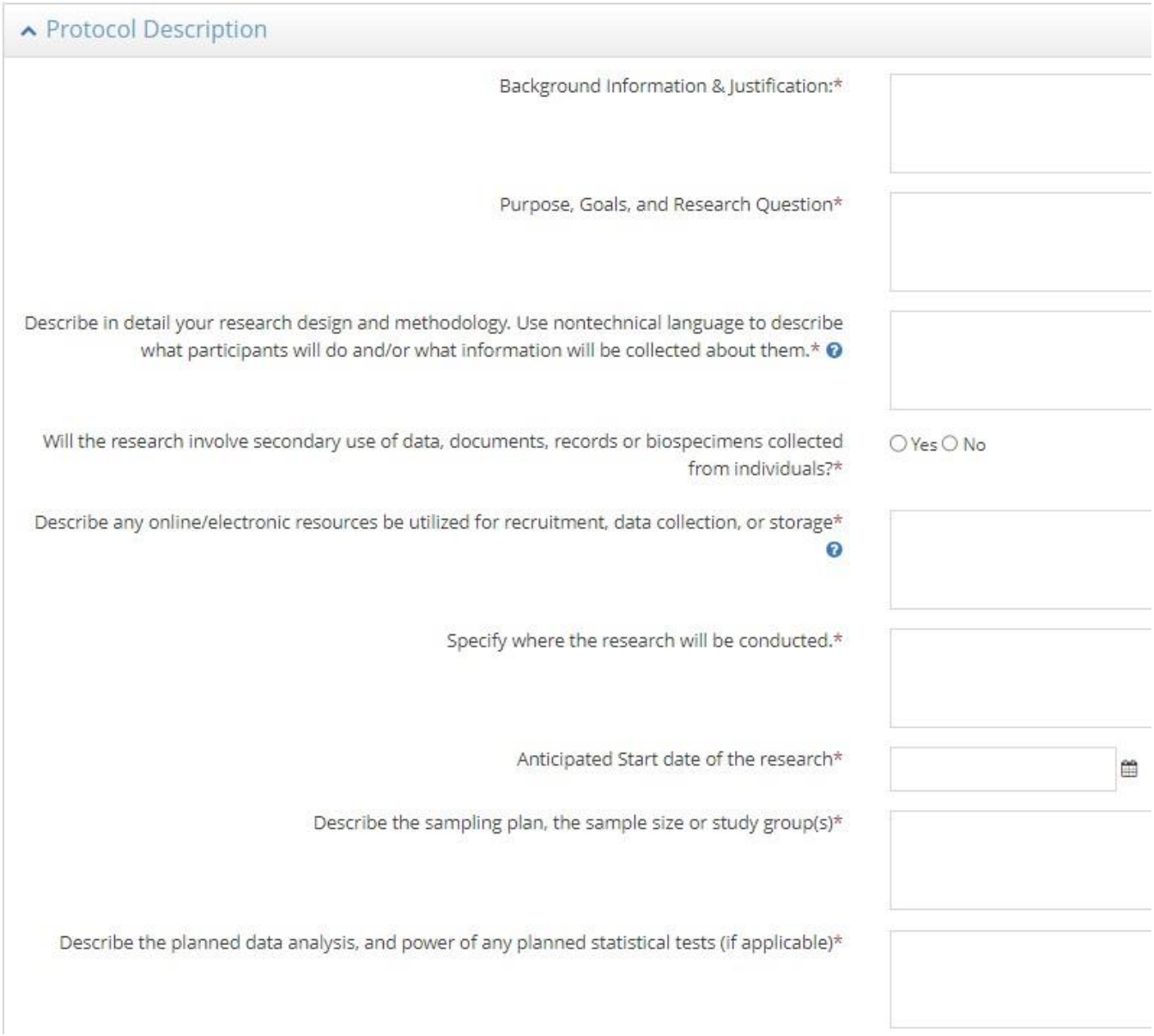
Following the Exempt Categories is the Special Population Section.

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

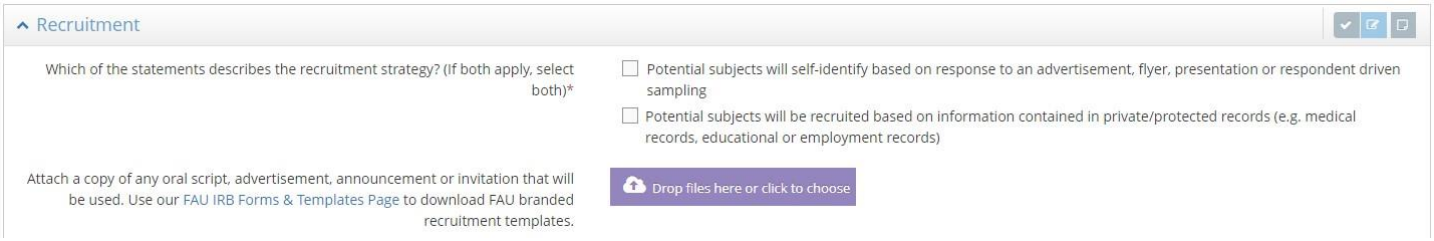
This is where you'll enter your protocol details. You can type into the fields directly, or copy and paste text from a separate document, making sure to save as you go along



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.

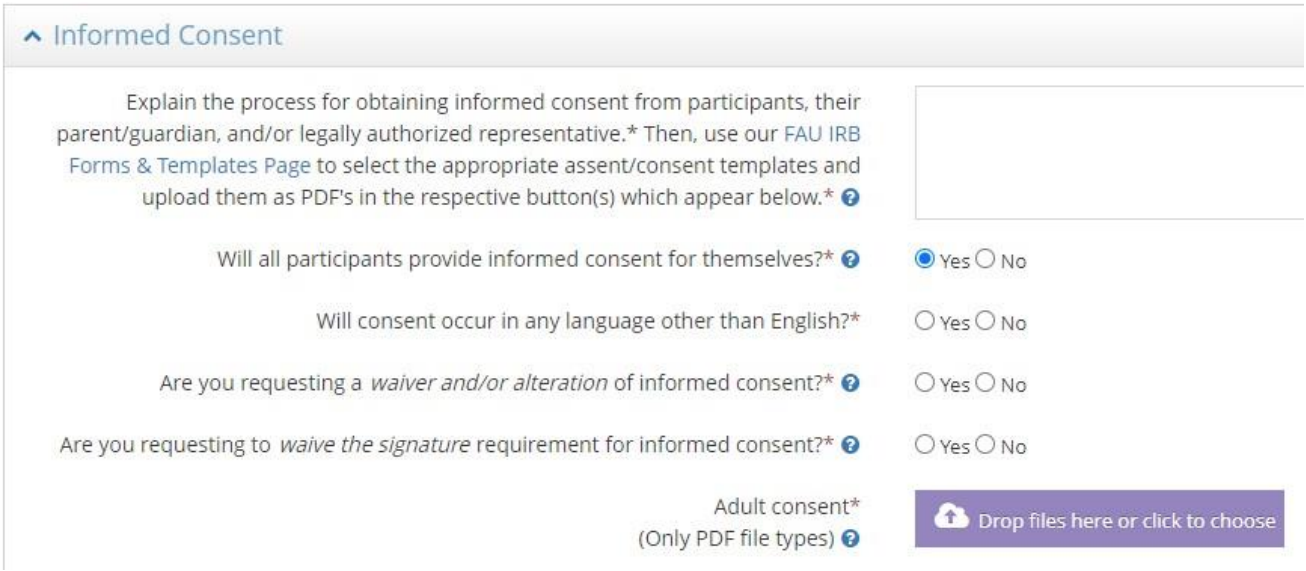


Informed Consent

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.

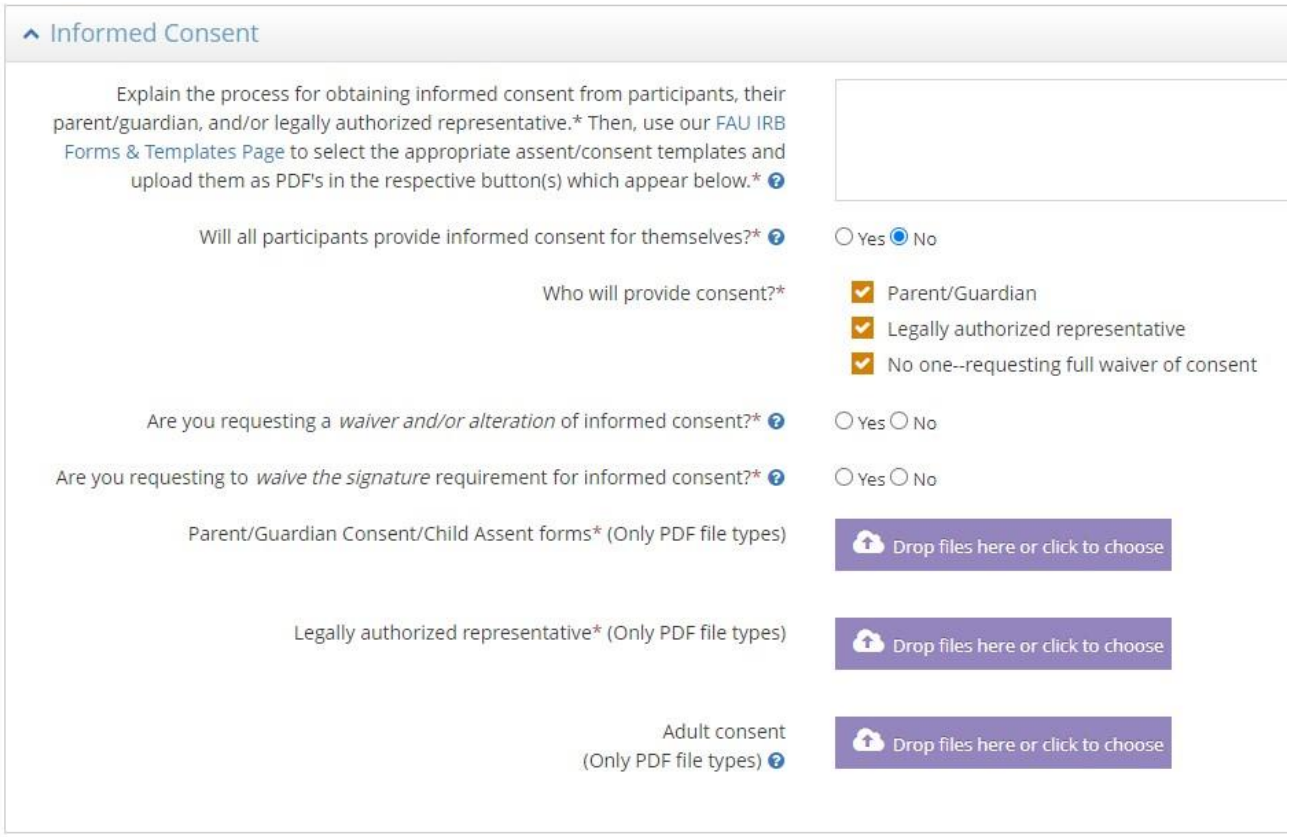
If you answer yes to the question "Will all participants provide informed consent for themselves?" the Adult consent upload button will become a required field.



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.

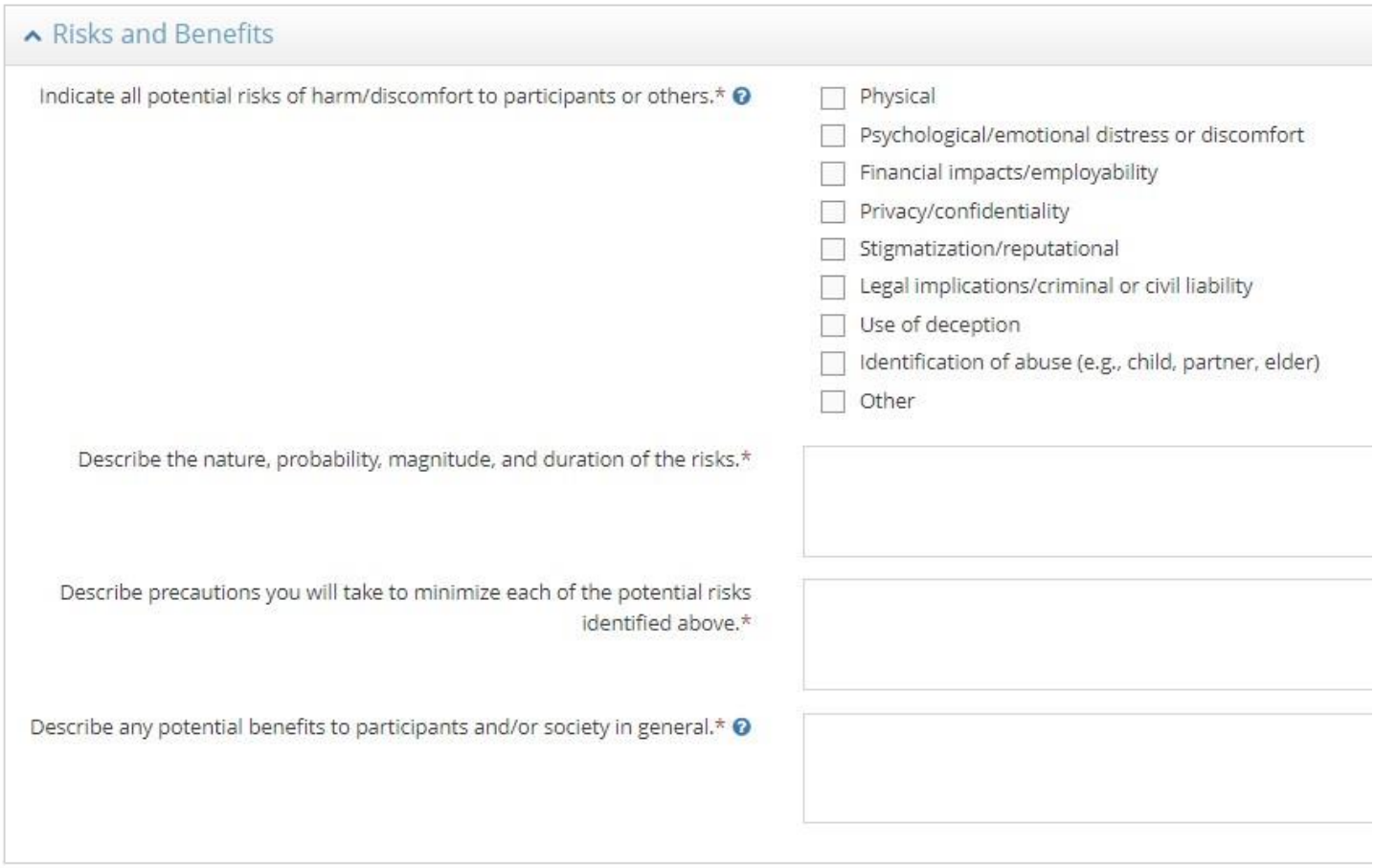
If you answer no to the question "Will all participants provide informed consent for themselves?", you will be asked "Who will provide consent?" and a separate required upload button will appear for each type.

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



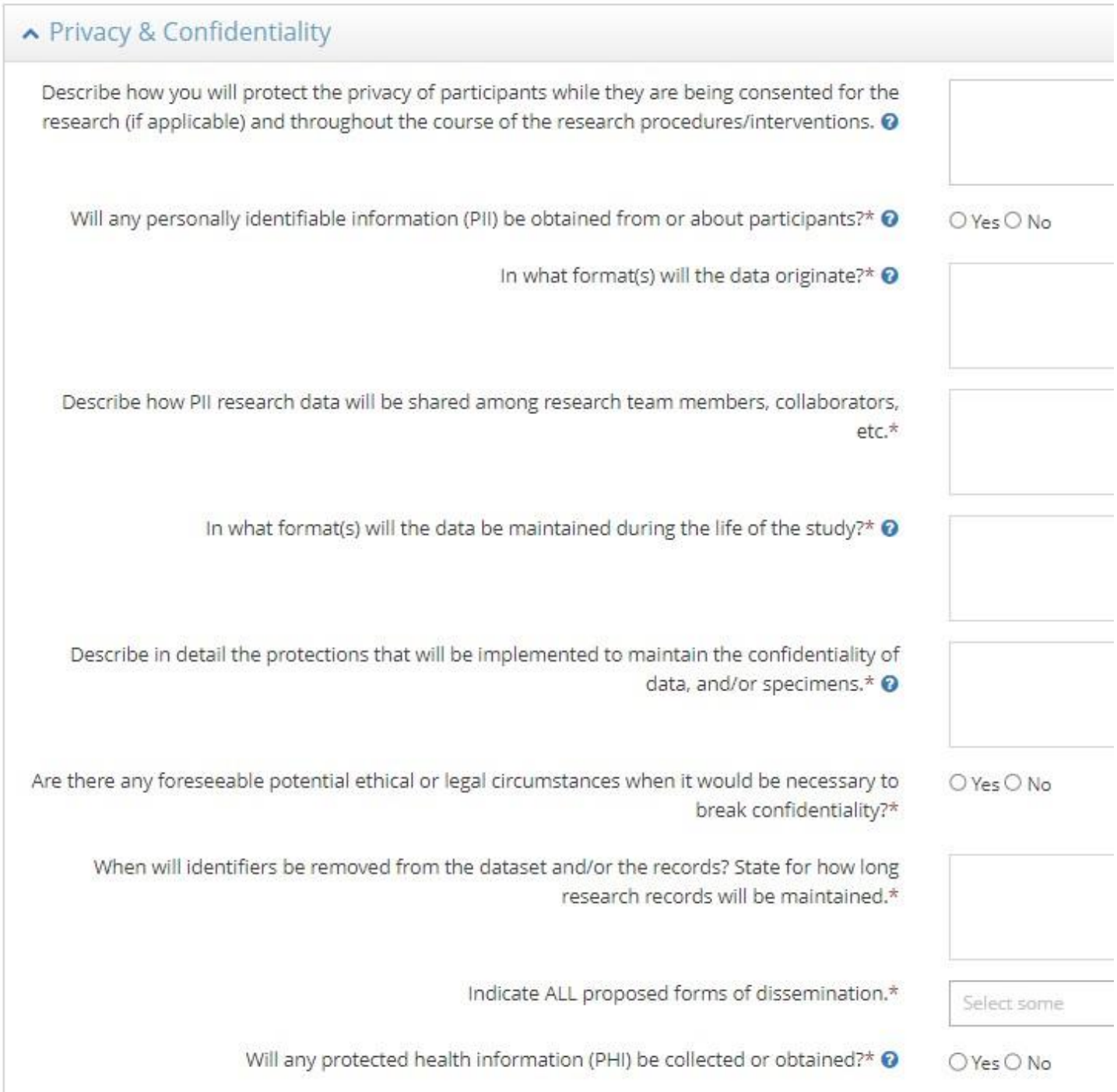
Risks & Benefits

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

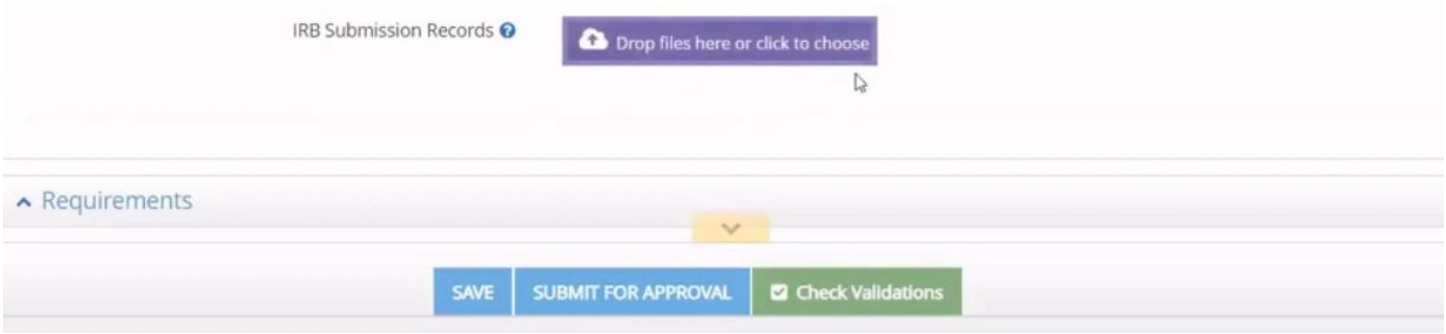
This is the third panel with optional uploads, however there is a required upload for “Data Collection Tools”. This can include your questionnaires, interview materials, and so on.

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

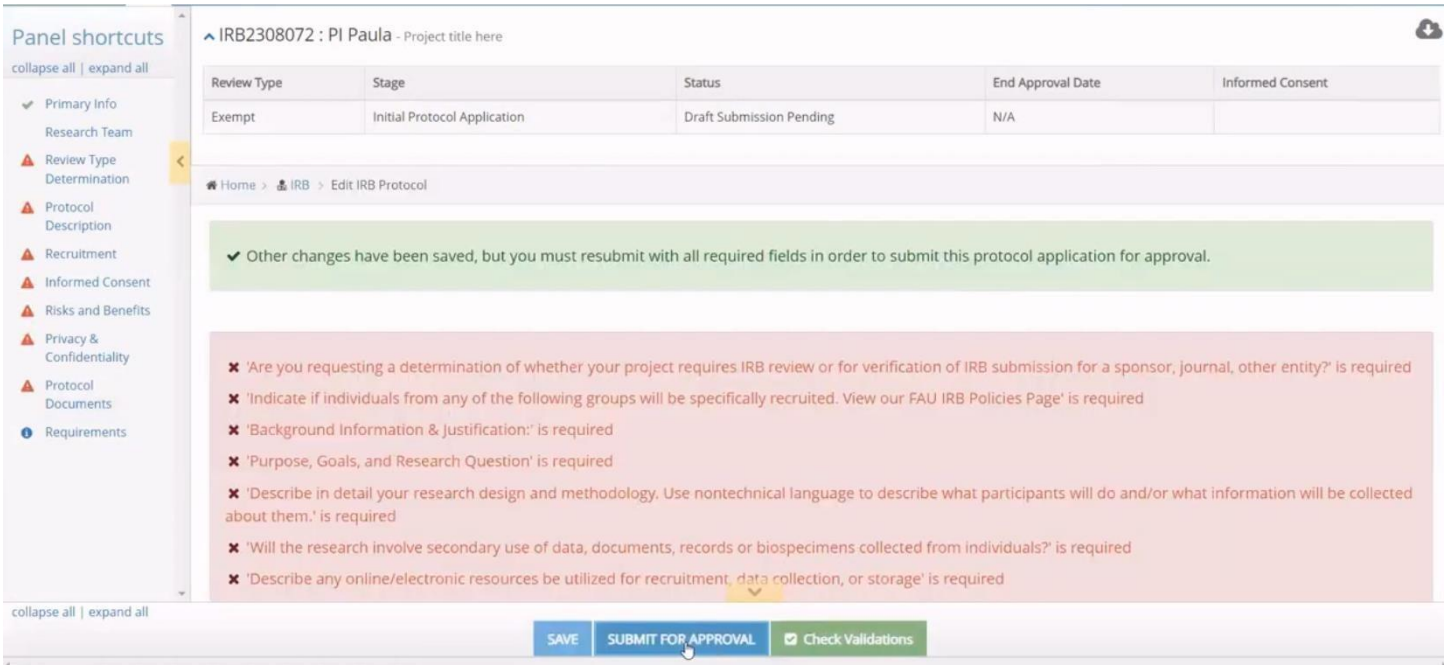
Once you have completed your IRB Application, click to Submit for Approval



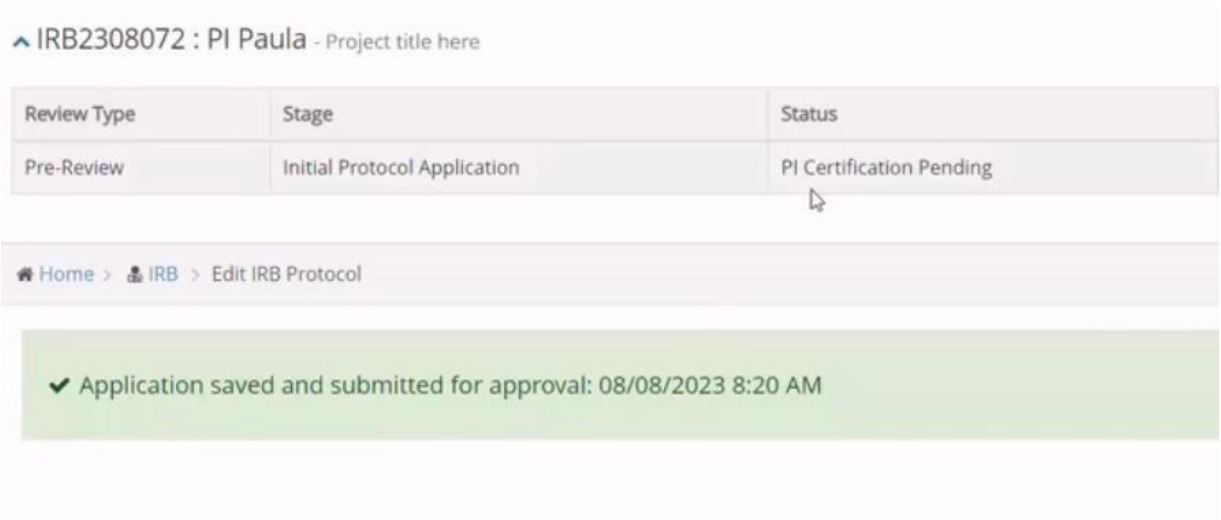
Check Validations (Incomplete Required Fields)

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



FAU IRB NOVELUTION

Submission Workflow & Statuses

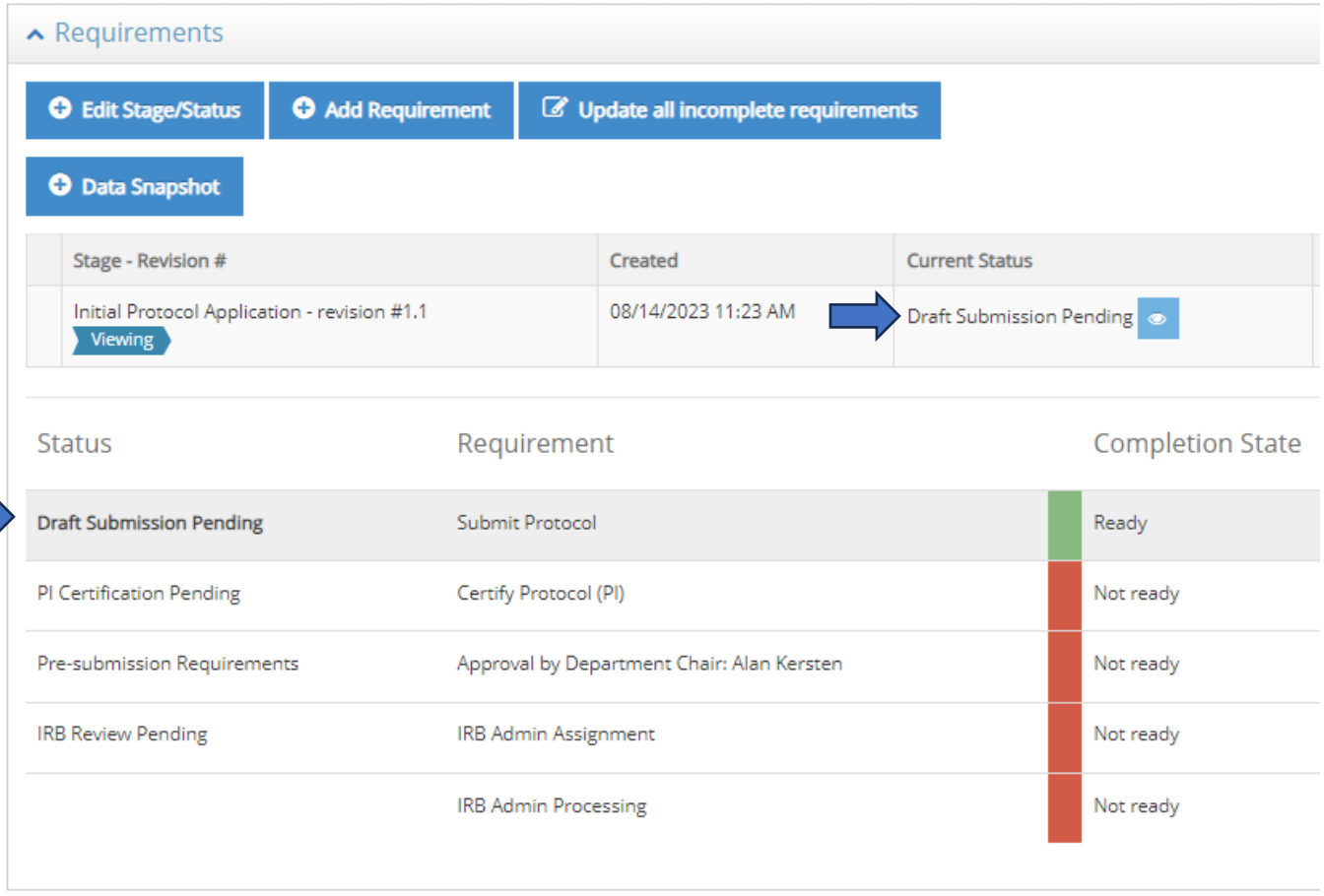
When you create a new project in Novelution, you'll be able to see the project status in the workflow in two different places.

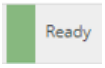
The first is up at the top in the project details panel. You'll see in the status column that the status is "Draft, Submission Pending"

Review Type	Stage	Status	End Approval Date	Informed Consent
Not yet determined	Initial Protocol Application	Draft Submission Pending	N/A	

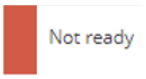
The second place is using the Requirements link from the Panel Shortcuts to the requirements panel which provides a detailed view of the entire IRB workflow process.

The status you're currently in will be noted in bold.





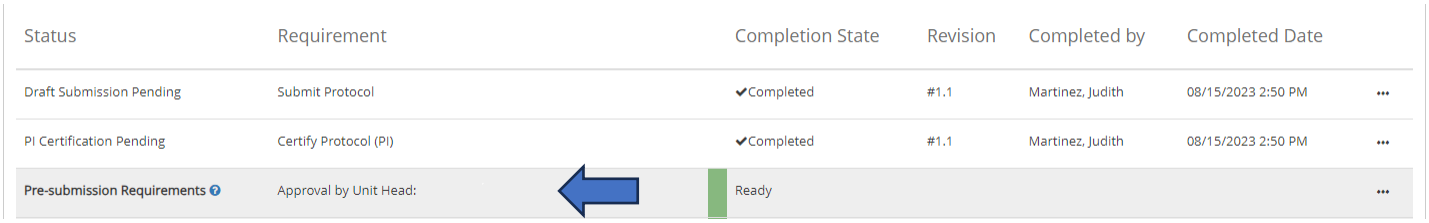
A green “Ready bar” means that it’s possible to complete this action.
For instance, in the example above, the system is ready for the project to be submitted and a submission can be made at any time once all submission requirements are met.



A red “Not Ready” bar means these are actions that cannot be taken.
Since the workflow follows a sequence, items are Not Ready when those items that precede it have not been completed. For instance, the PI cannot certify a project that has not yet been submitted.

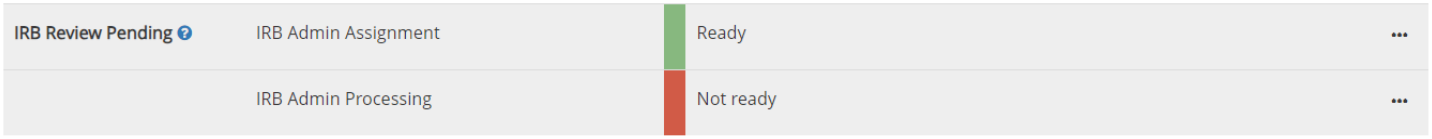
All members of the research team, including the PI, will receive a task email informing them of the actions they must take for the project to continue to move forward.

Note: there should be a name listed for the Approval by Unit Head or Department Chair. If no name is listed, contact the IRB Office to address this issue.



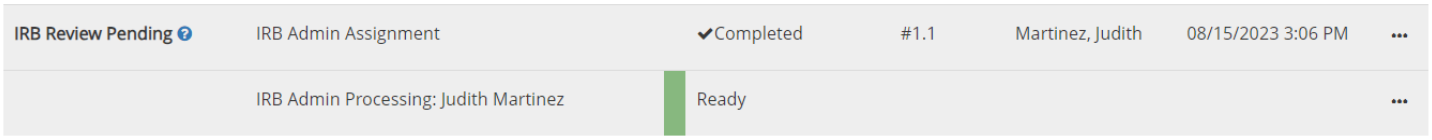
Status	Requirement	Completion State	Revision	Completed by	Completed Date	
Draft Submission Pending	Submit Protocol	✔Completed	#1.1	Martinez, Judith	08/15/2023 2:50 PM	•••
PI Certification Pending	Certify Protocol (PI)	✔Completed	#1.1	Martinez, Judith	08/15/2023 2:50 PM	•••
Pre-submission Requirements	Approval by Unit Head:	Ready				•••

The IRB Office will not receive your submission until all of the actions before it have been completed. You’ll know your submission has reached the IRB Office when the Status is “IRB Review Pending”



IRB Review Pending	IRB Admin Assignment	Ready	•••
	IRB Admin Processing	Not ready	•••

You’ll also see when an IRB Admin has been assigned to your project. This will be the point of contact between you and the IRB Reviewers as applicable for the workflow of your project.



IRB Review Pending	IRB Admin Assignment	✔Completed	#1.1	Martinez, Judith	08/15/2023 3:06 PM	•••
	IRB Admin Processing: Judith Martinez	Ready				•••

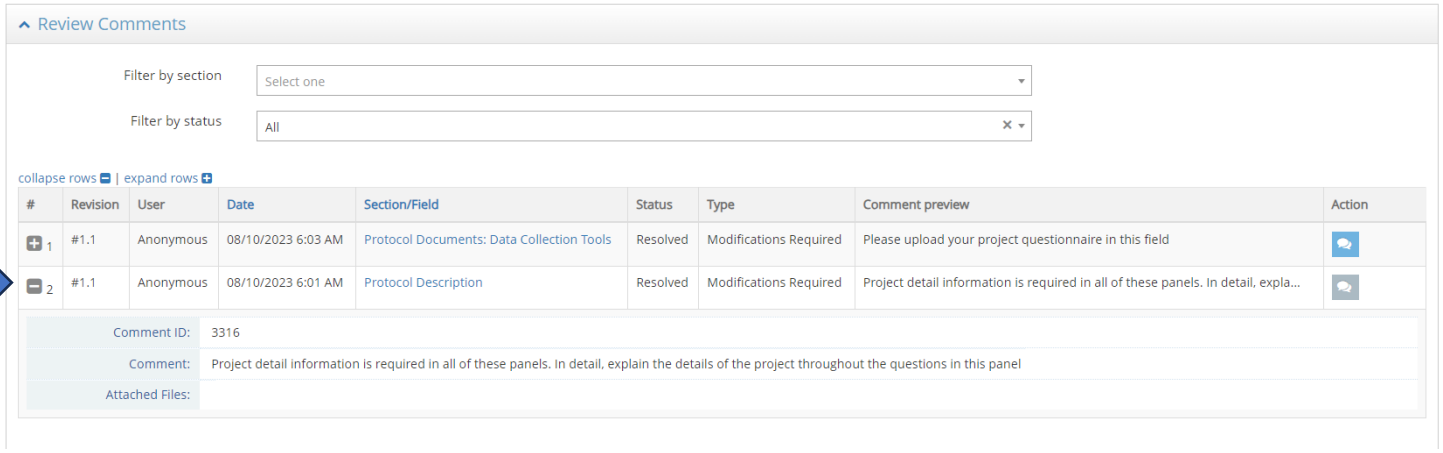
The status “IRB Admin Processing” covers the entire review process including assigning to IRB members or to a full board meeting as applicable. In other words, though the status is “IRB Admin Processing” it is possible that your project is out for review by a reviewer during this stage.

FAU IRB NOVELUTION

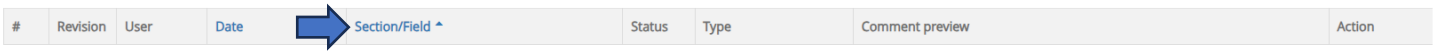
Responding to Modifications Required

Modifications Required can be found in the Review Comments panel, which is the first panel that will appear at this stage of the project.

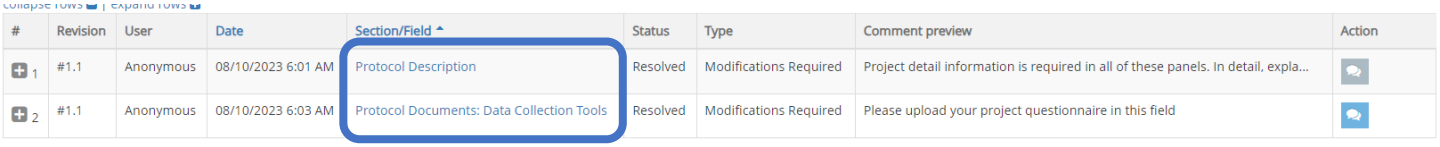
Each comment represents a modification required and you can click the plus sign or anywhere in the comment row to have the field expand so you can read the whole comment.



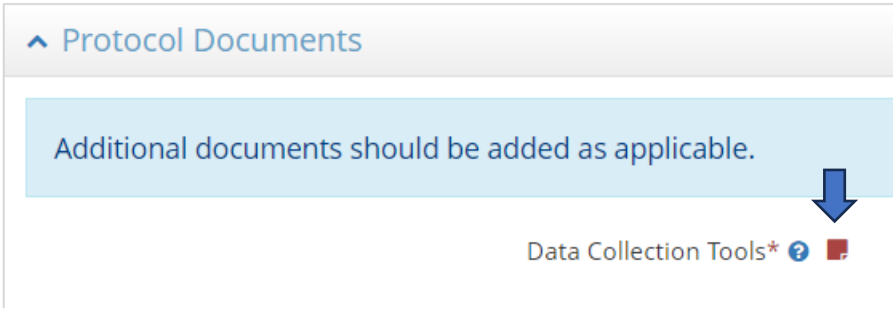
Using the Section/Field column you can click to sort the comments to see them in order from top to bottom of the submission. Use the Panel Shortcuts to see that order.



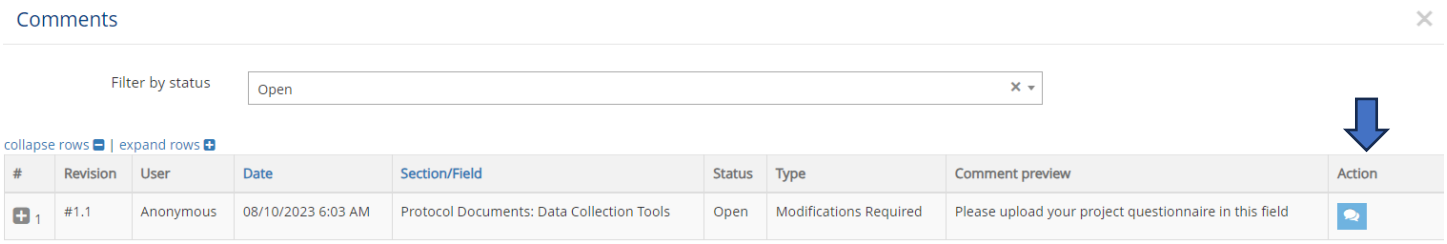
Comments can be addressed in any order as you will be led straight to the part of the project that needs modifications by clicking on the comment link.



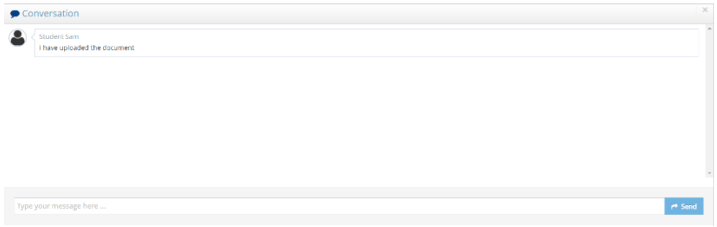
In this case the comment has been made on a field or in other words: a specific question. Fields with modifications required will have a red paper icon noted next to it such as in this example of Data Collection Tools.



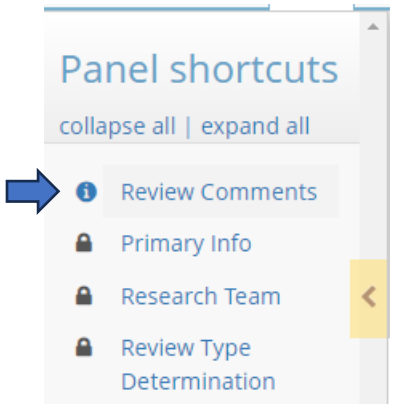
Click the red paper icon to view the comment again as needed.



You can also use the chat bubble in the action column to respond to the comment directly. The IRB Admin and/or IRB Reviewer will be notified that you have made a response. They can also respond to your comment directly, and this chat will stay with your project for future reference.

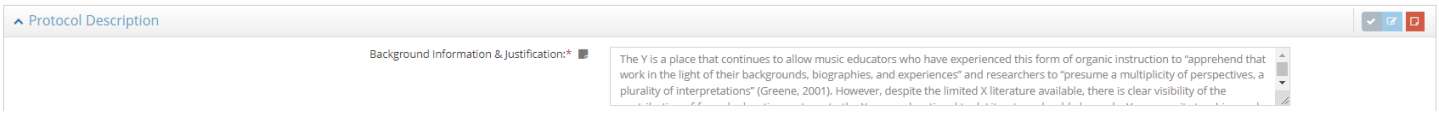


To view the additional modifications required, you can use the Panel Shortcuts to click back to the Review Comments panel, then click on the next comment.



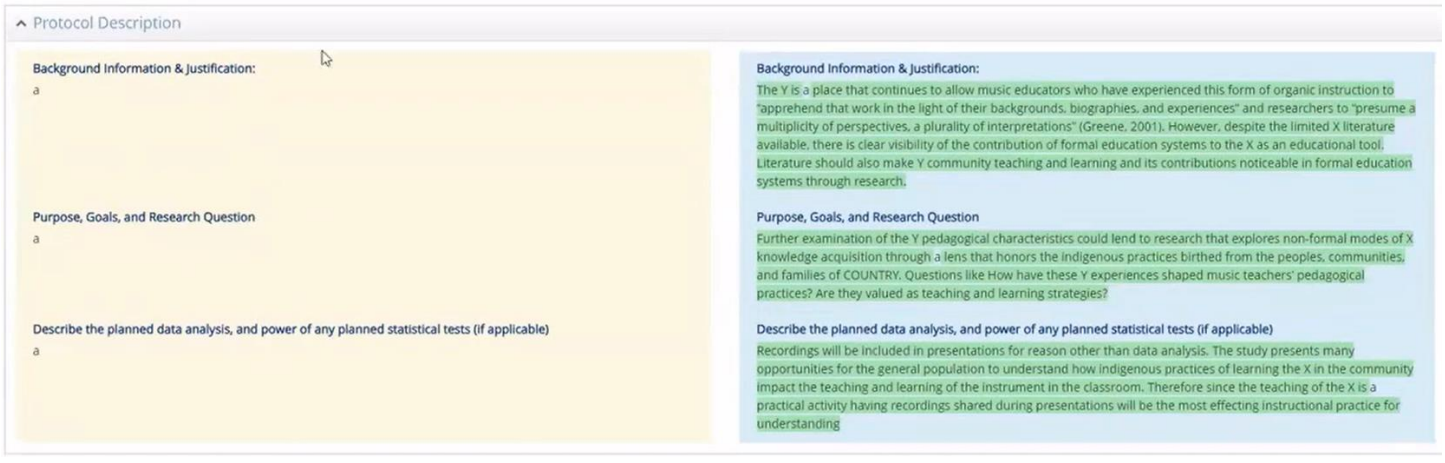
When a whole section has modifications required, the red paper icon will appear at the top right-hand corner of the panel name such as in this example for Protocol Description.

Here too, click the red paper icon to view the comment as needed, and click the table to expand the comment to view the full details.



Complete the modifications as indicated in the comments by clicking directly into the fields and entering responses. Once you have completed your responses, click to review, and submit.

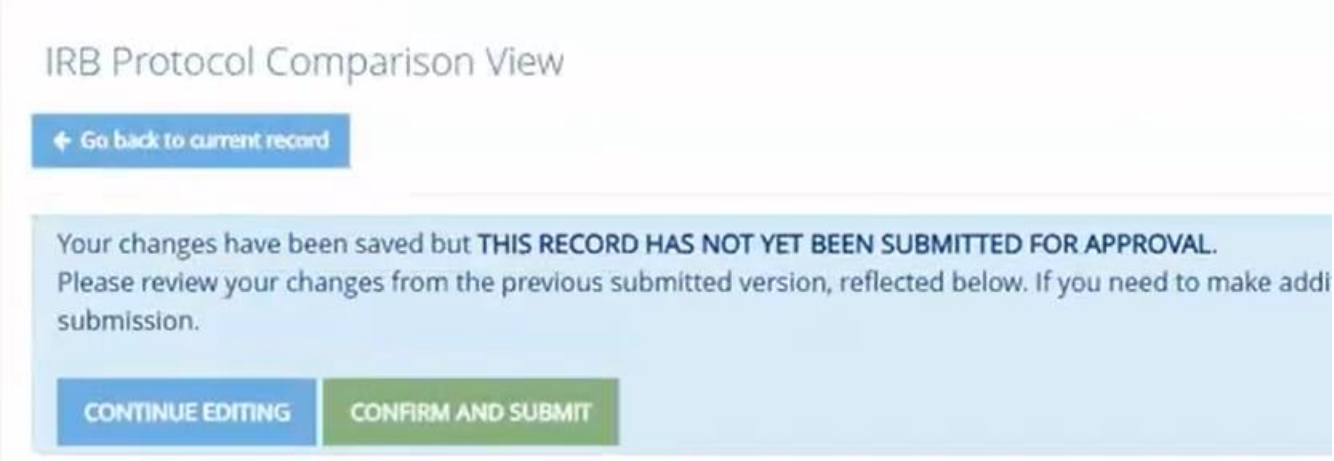
On the IRB Protocol Comparison page, you will be able to see a side by side comparison of the changes you have made to the document. On the left side in the yellow box you will see the original submission, and on the right side in the blue box, you will see revisions made.



In the text fields for instance, you will see that new text is highlighted in green.

You will also see a link to download any document that has been added.

Once you have reviewed your changes, scroll back up to the top and either click to Confirm and Submit if finished or Continue Editing to make additional changes.



Once you Confirm and Submit, the project returns to the IRB Admin for processing.

You'll see the confirmation screen that the application has been saved and submitted for approval. This lets you know you have successfully submitted your project back to the IRB for review.

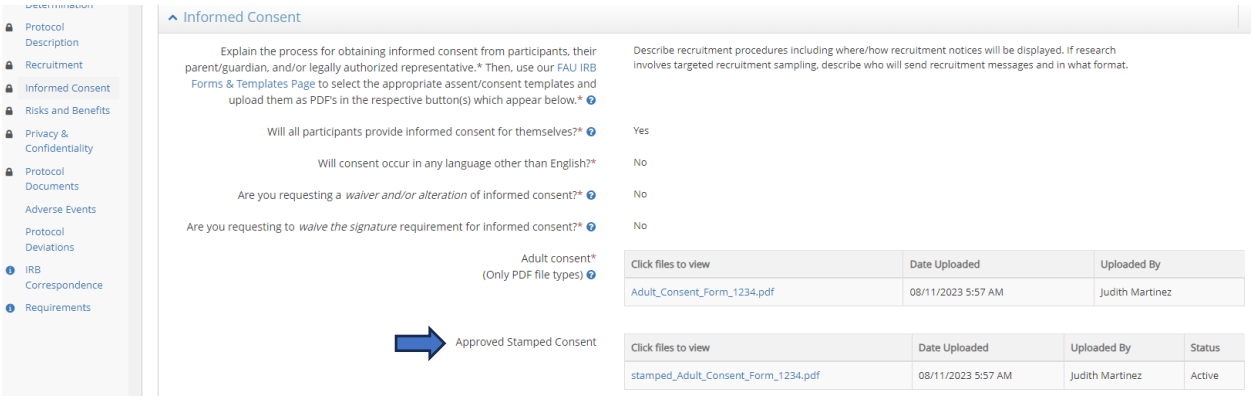
FAU IRB NOVELUTION

Board Documents

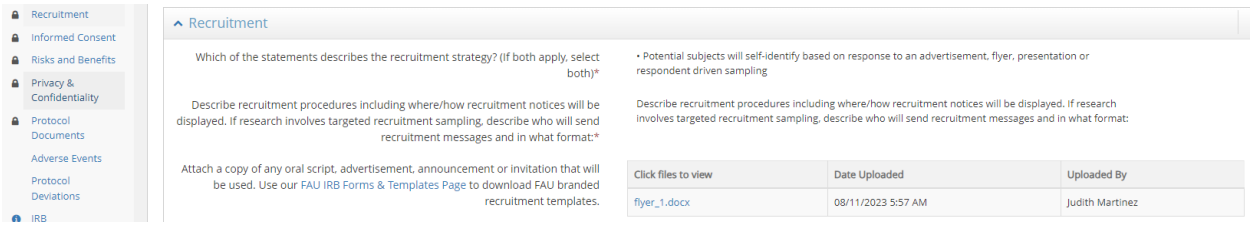
You can check the details of the IRB Decision beginning with the Project Details panel which will state the Review Type, Stage of the project, Status which will list the decision, End Approval Date when it applies, and any stamped consent materials

Review Type	Stage	Status	End Approval Date	Informed Consent
Expedited	Initial Protocol Application	Approved	08/13/2024	Adult_Consent_Form_1234.pdf

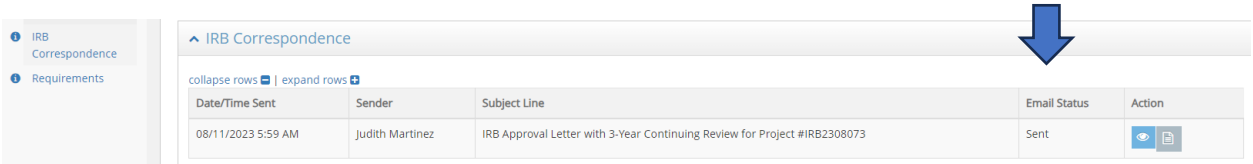
Stamped Consent materials are also located in the Informed Consent Panel in a new “Approved Stamped Consent” section



Any Recruitment or Protocol Documents will remain in the respective panels they were uploaded to

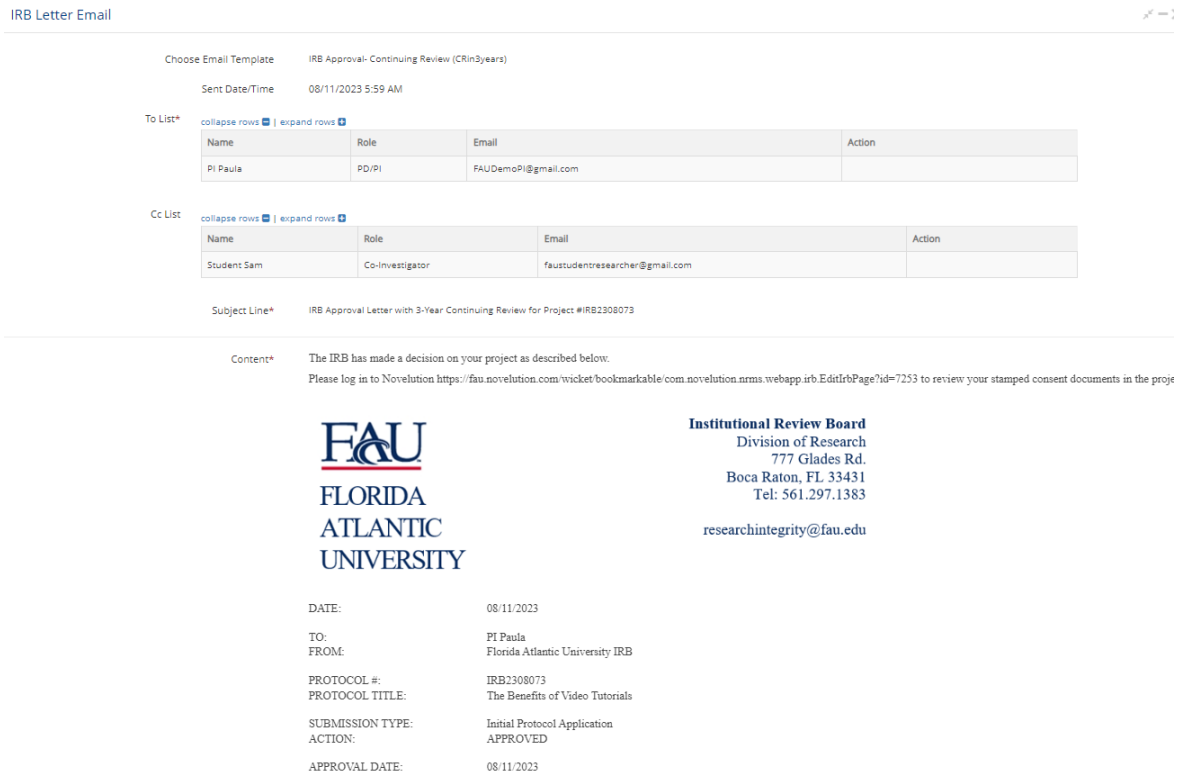


In the Panel Shortcuts, you’ll see there is now an IRB Correspondence link. Click here to view the IRB Decision letter. The Research Team will also receive an email with the IRB decision and attached letter.

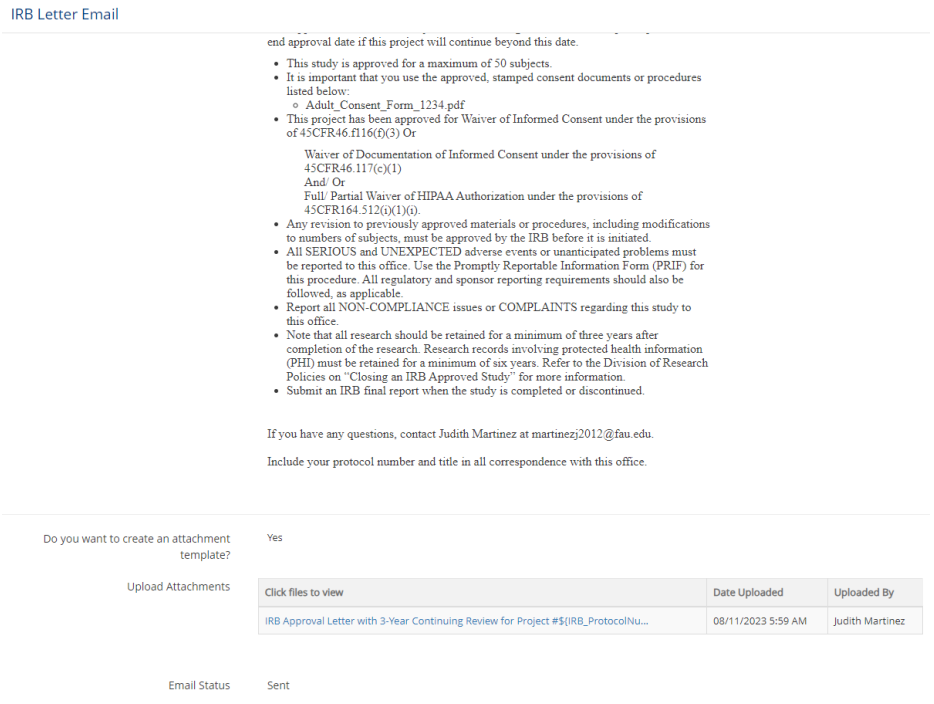


Click on the eye icon to view the letter in the system or click the paper icon to download the form.

A view of the decision email within the system:

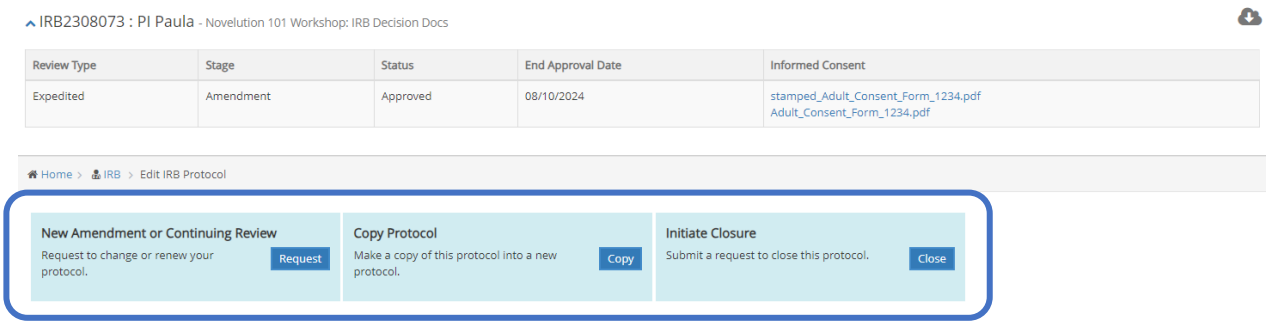


You can also click to download the letter from the bottom of the email view.



Download your Protocol by using the Cloud icon at the top of your project page

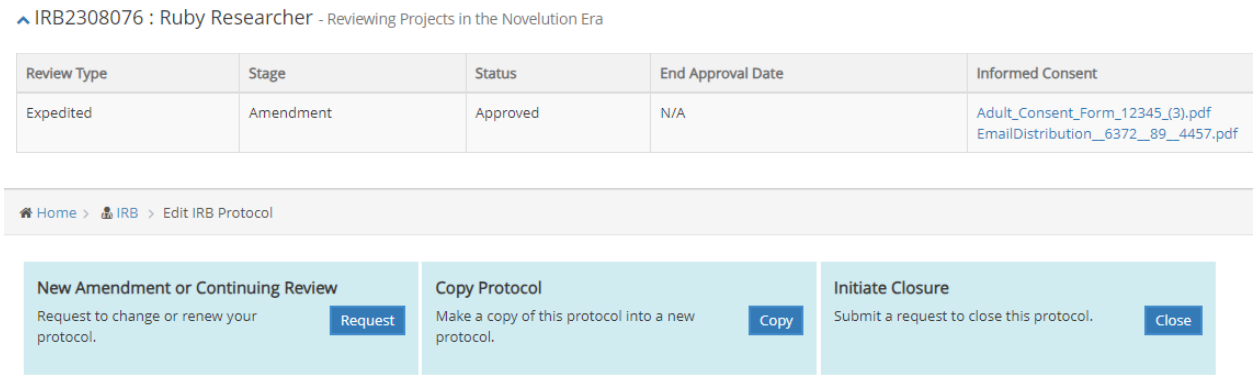
Right below the Project Details panel you will now see several buttons which will allow you to take different actions on your project such as create a New Amendment or Continuing Review, copy your protocol or initiate closure. Click any of these when a new action needs to be made to your project



FAU IRB NOVELUTION

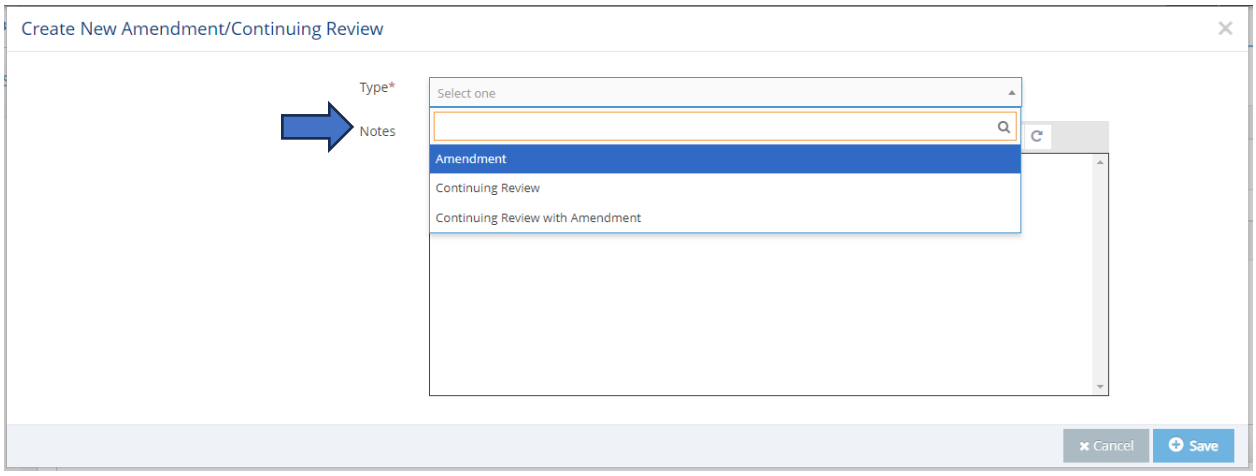
Creating an Amendment

When an Amendment needs to be made to a project, click into that project to view the action options up at the top. If you don't see these options on your project, contact the IRB office.

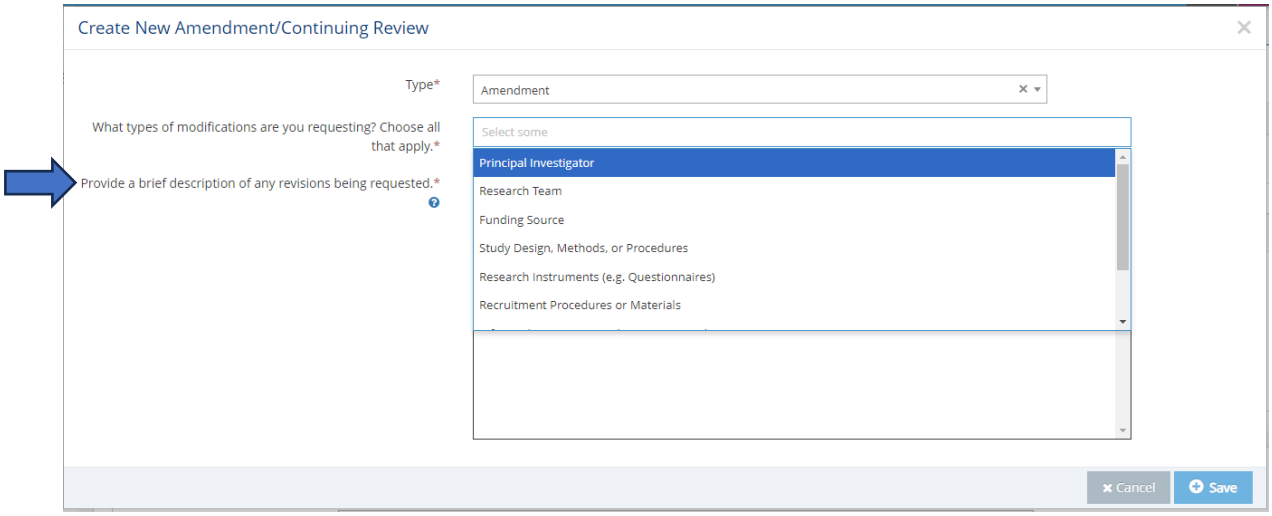


In the New Amendment or Continuing Review box, click the Request button to begin

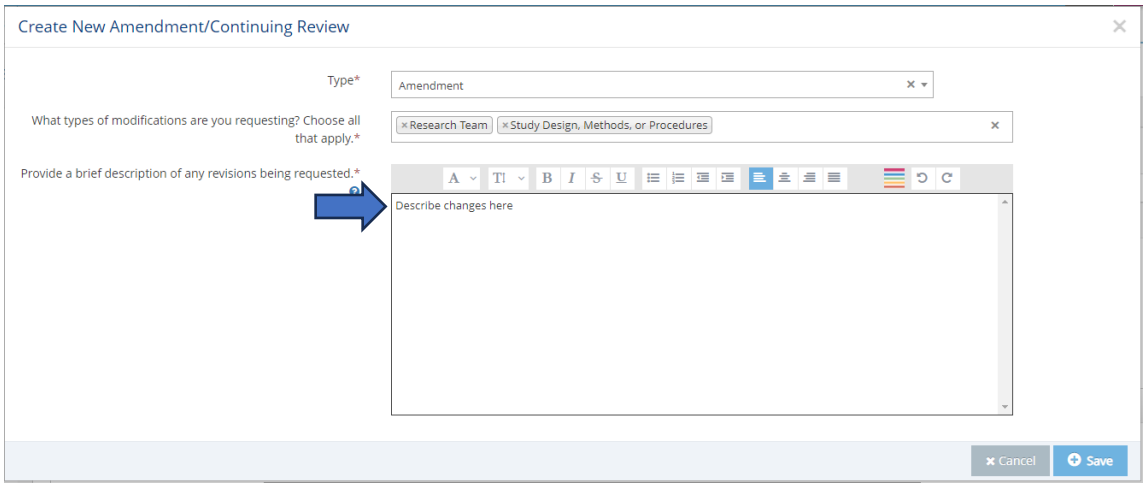
Select Amendment as the Type



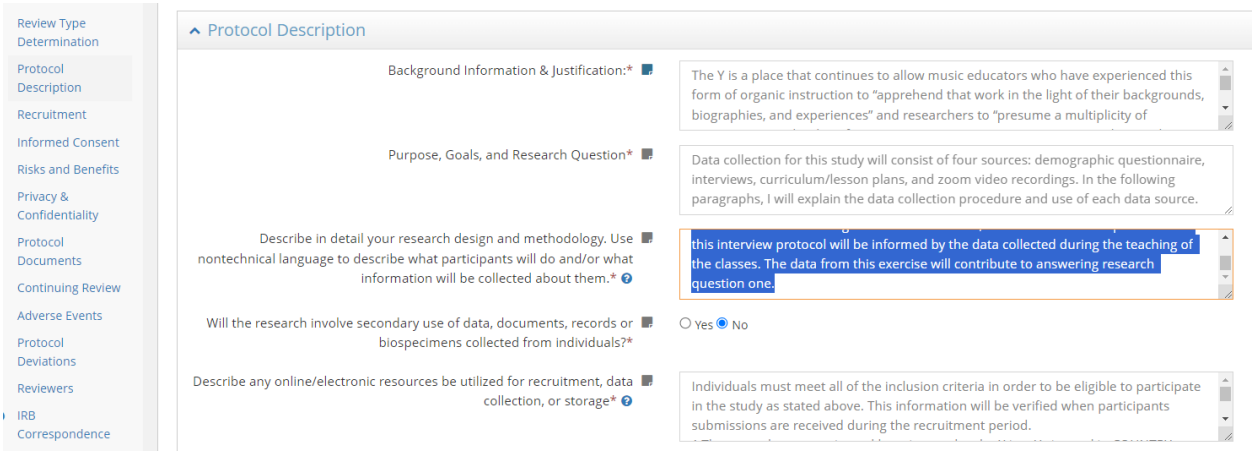
In the "What types of modifications are you requesting? Choose all that apply" field, select those items that you are looking to amend in this project. You can select as many as needed. And if what you're looking to amend is not listed in these options, you can select "Other Changes" and specify the changes in the field that will appear beneath it.



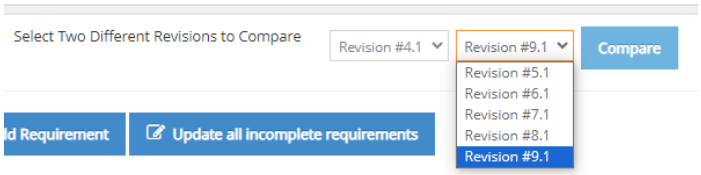
Then, describe the changes you're making to the project in the field below and click to save.



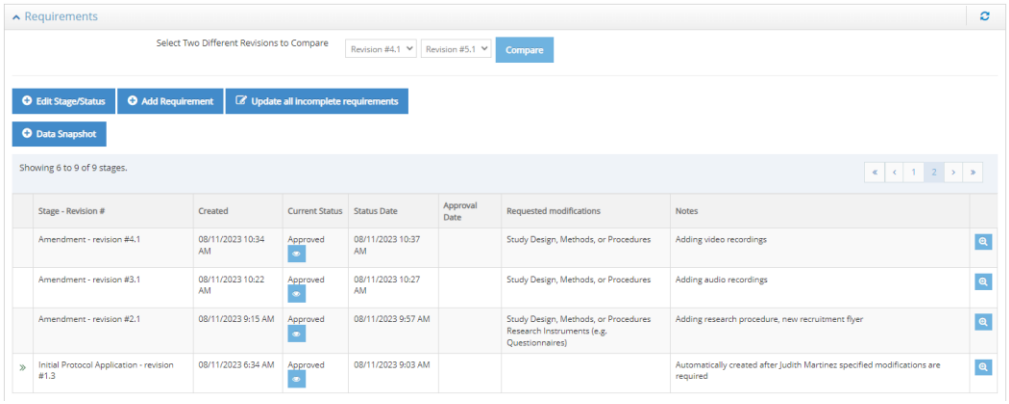
To make changes in Novelution you will go directly into the panel or field where the changes need to be made and re-enter that information as if you were filling it out for the first time. You can type in your changes directly to the field or copy and paste from another document.



Each revision you create will be accessible from the Requirements panel which you can click to view at any time.

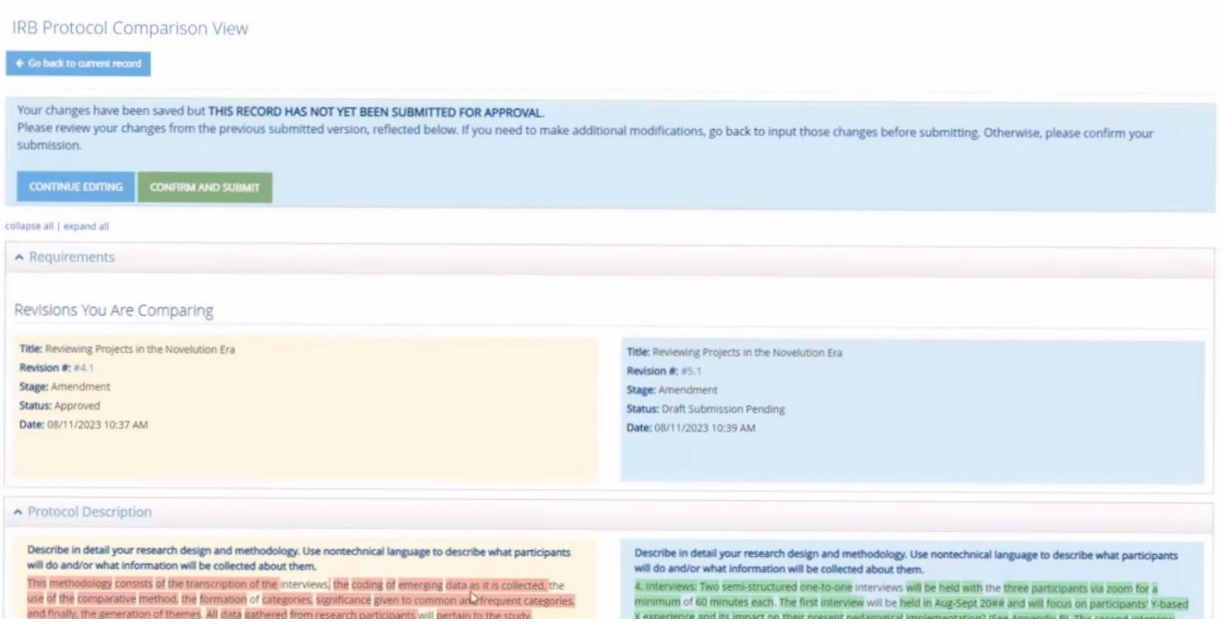


You can also see previous amendments you have submitted.



Once you have finished making the necessary amendments to your project, click to Review and Submit your changes

Then in the IRB Comparison page, review your changes which will be listed in the right blue box.



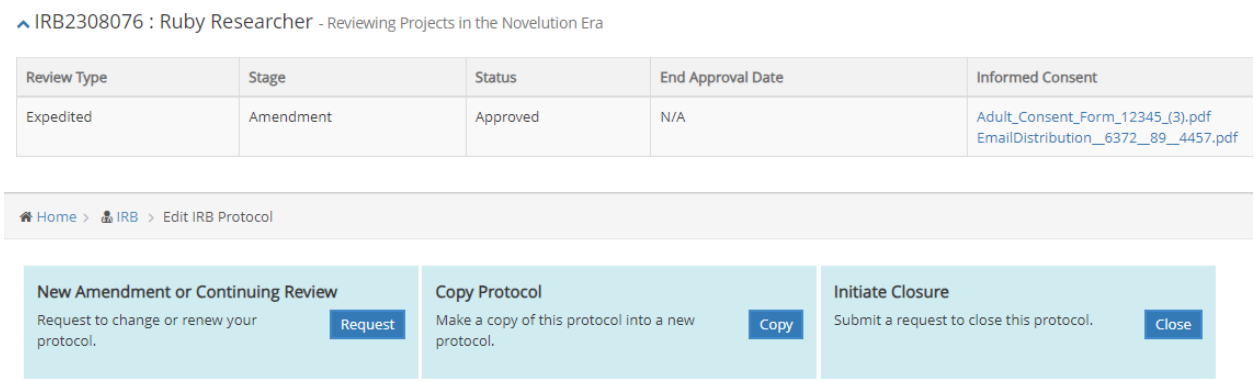
Click to Confirm and Submit

NOTE: If you no longer need to make an Amendment, contact the IRB Office to cancel this process administratively

FAU IRB NOVELUTION

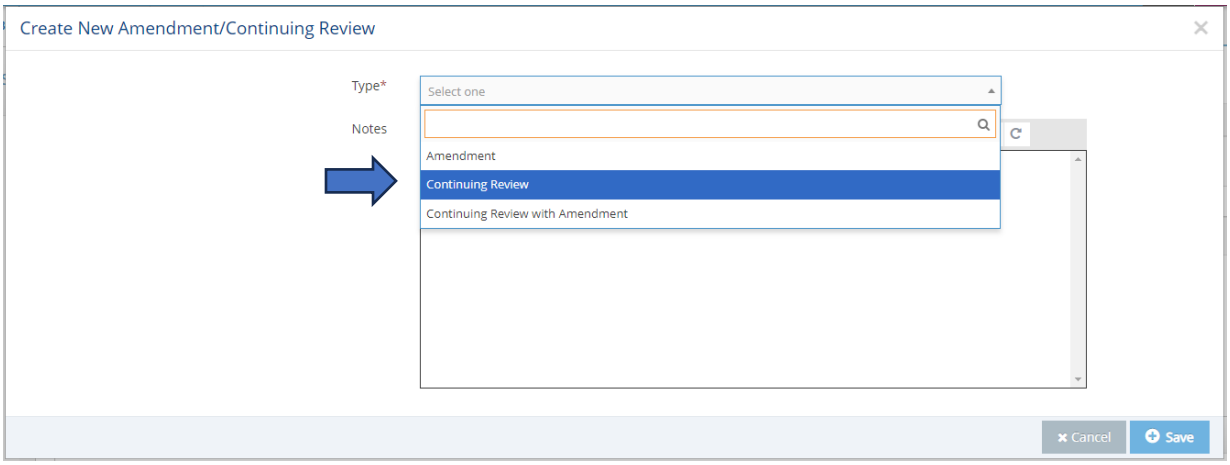
Creating a Continuing Review

When a Continuing Review is needed to extend a project approval, click into that project to view the action options up at the top. If you don't see these options on your project, contact the IRB office.

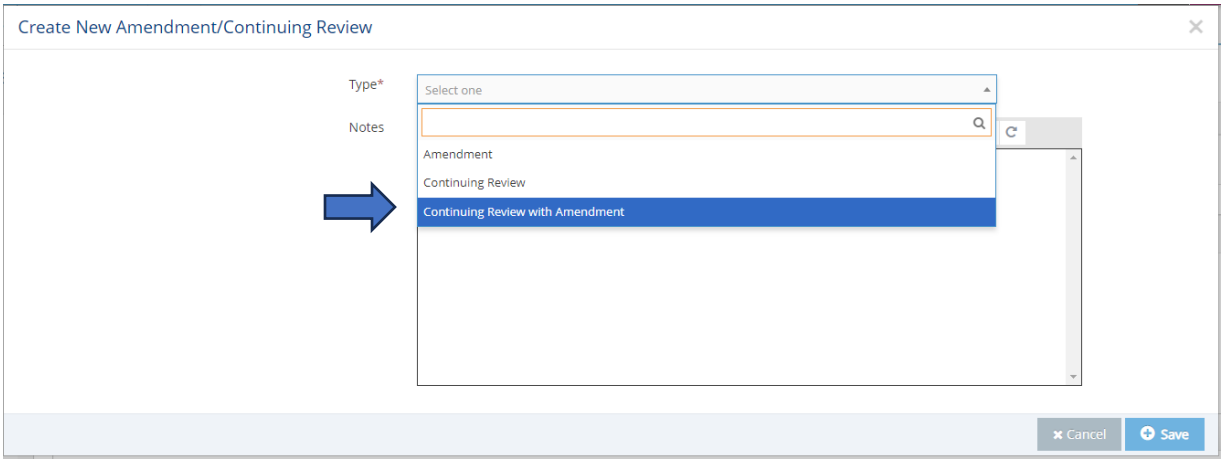


In the New Amendment or Continuing Review box, click the Request button to begin

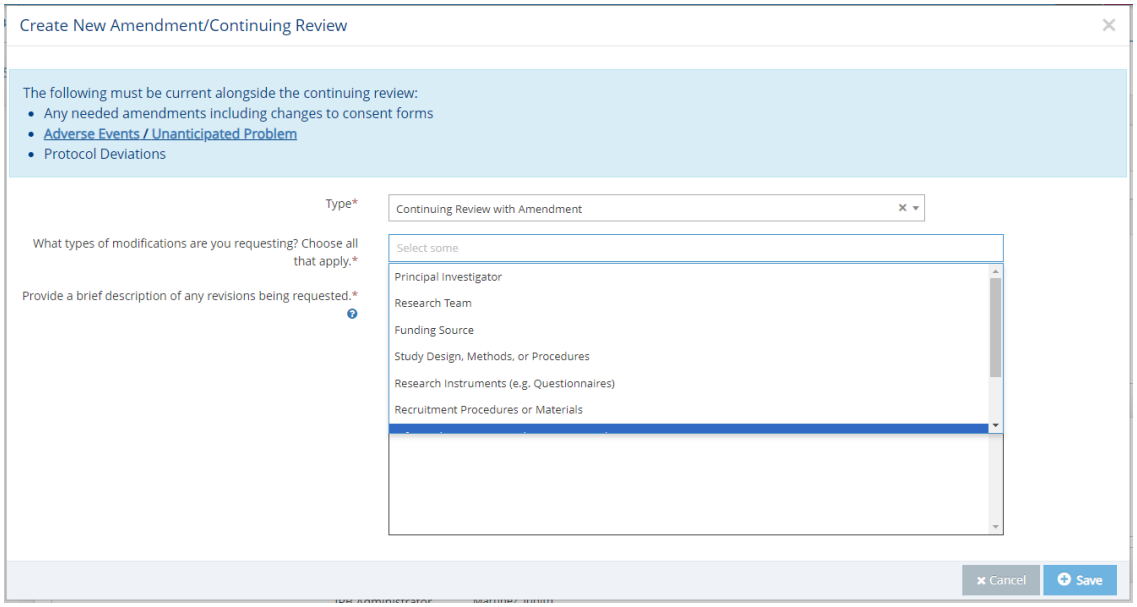
Select Continuing Review if you are not making any changes to your project at this time, then enter any notes you have about the project and click to save.



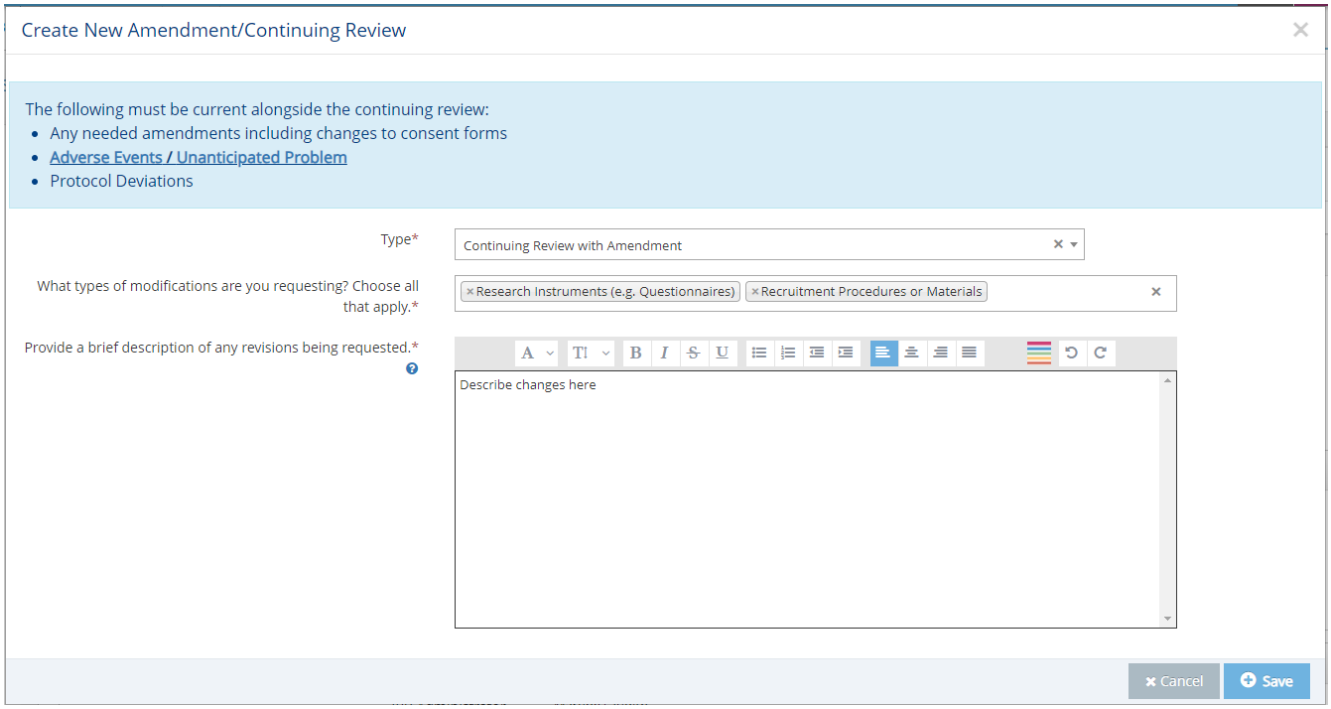
If you *are* making changes to your project along with this Continuing Review, select Continuing Review with Amendment as the Type.



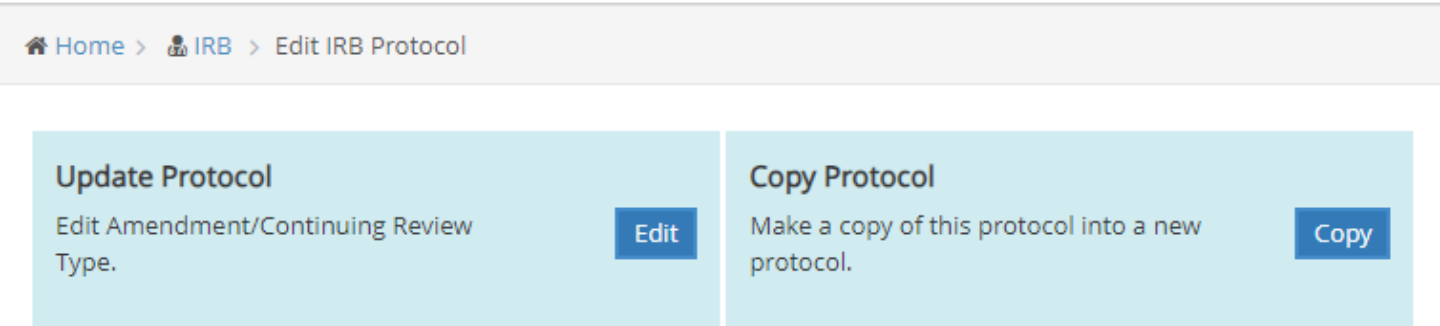
In the “What types of modifications are you requesting? Choose all that apply” field, select those items that you are looking to amend in this project. You can select as many as needed. And if what you’re looking to amend is not listed in these options, you can select “Other Changes” and specify the changes in the field that will appear beneath it.



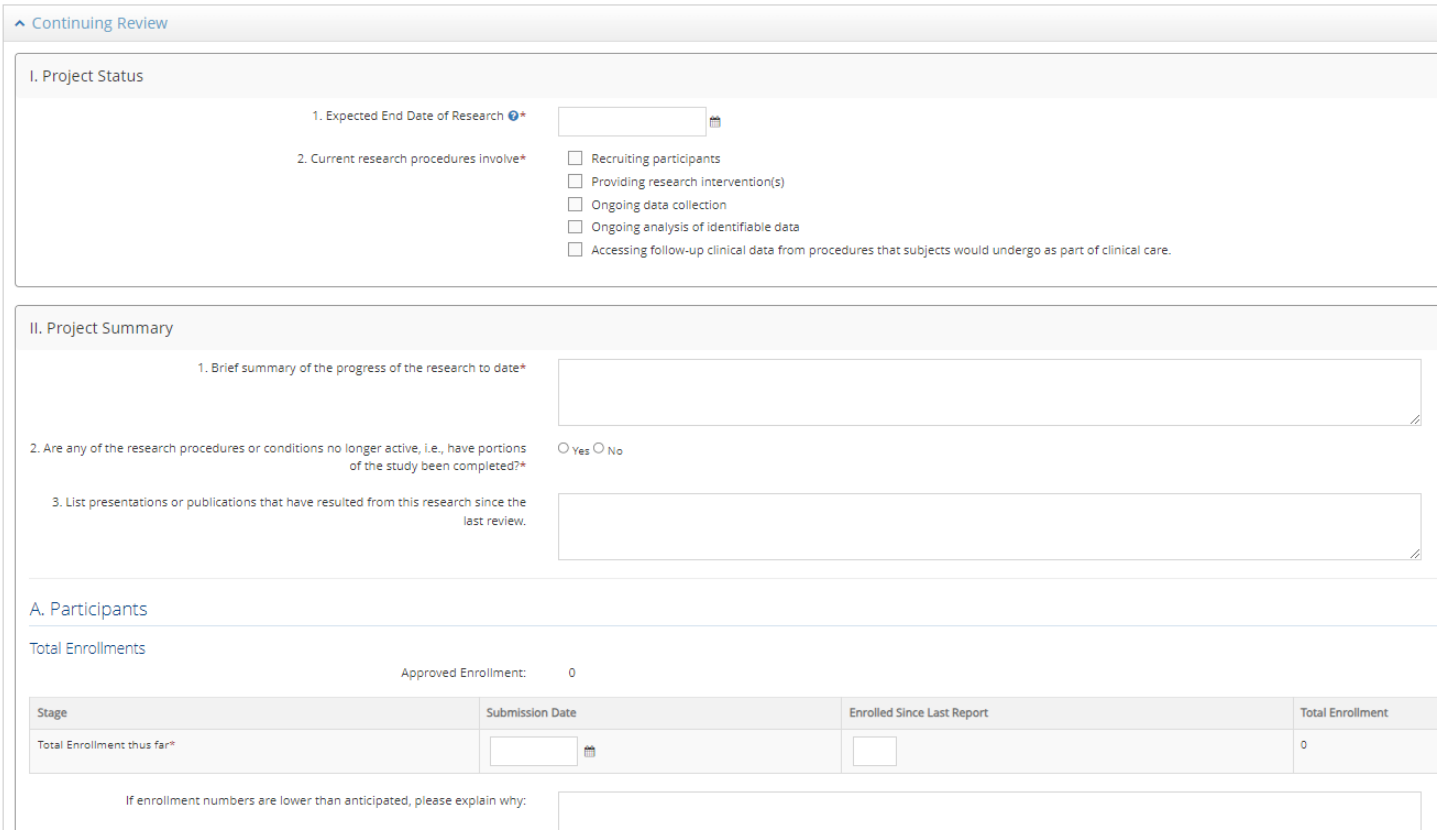
Then, describe the changes you’re making to the project in the field below and click to save.



Note: If you select Continuing Review and need to change the type to Continuing Review with Amendment or vice versa, return to the action buttons at the top which will now read "Update Protocol" and click "Edit" to change the Amendment or Continuing Review Type

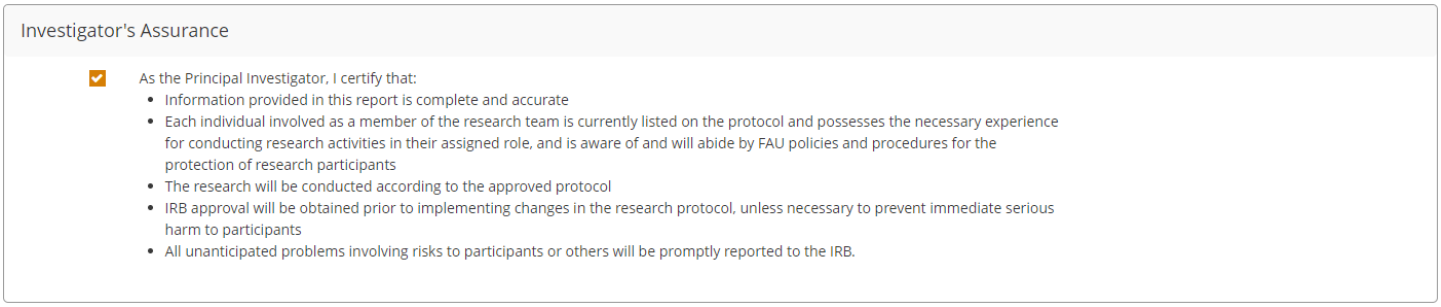


A new Continuing Review panel will open for you within your project submission.



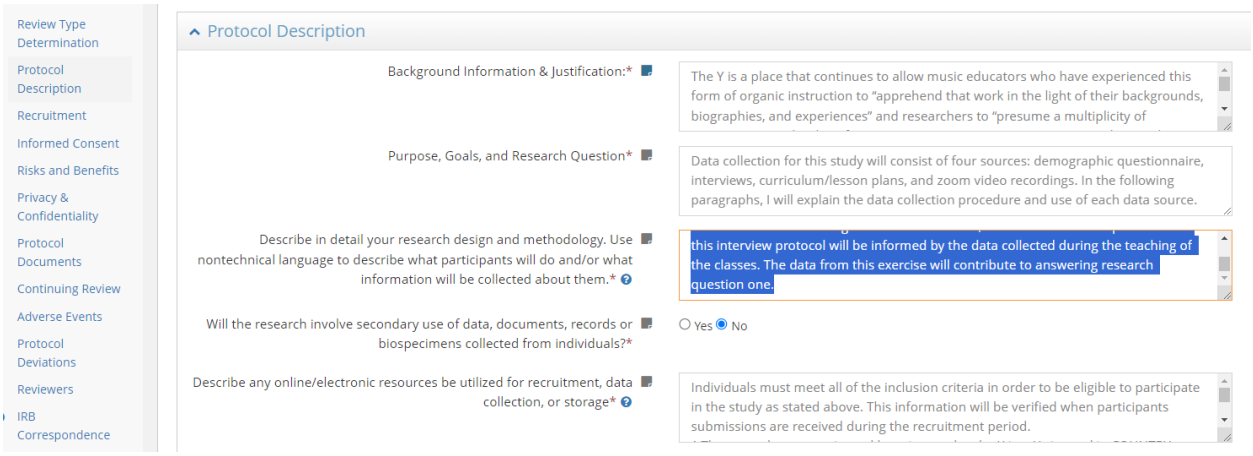
Fill in your responses into the Continuing Review panel including what the current research procedures involve, enrollment numbers, and so on.

Review and check the box to certify to the Investigator's Assurance of your duties as a PI.

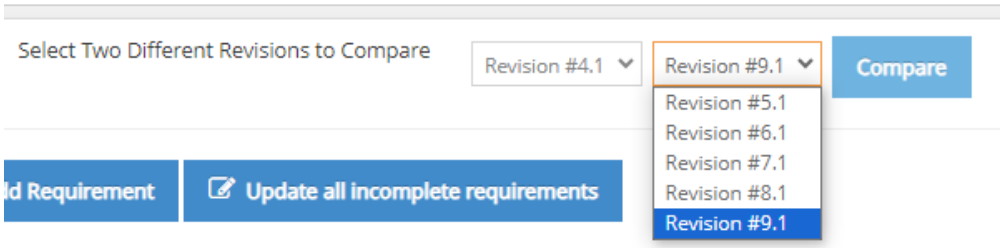


Once all questions have been answered, click Review and Submit to continue

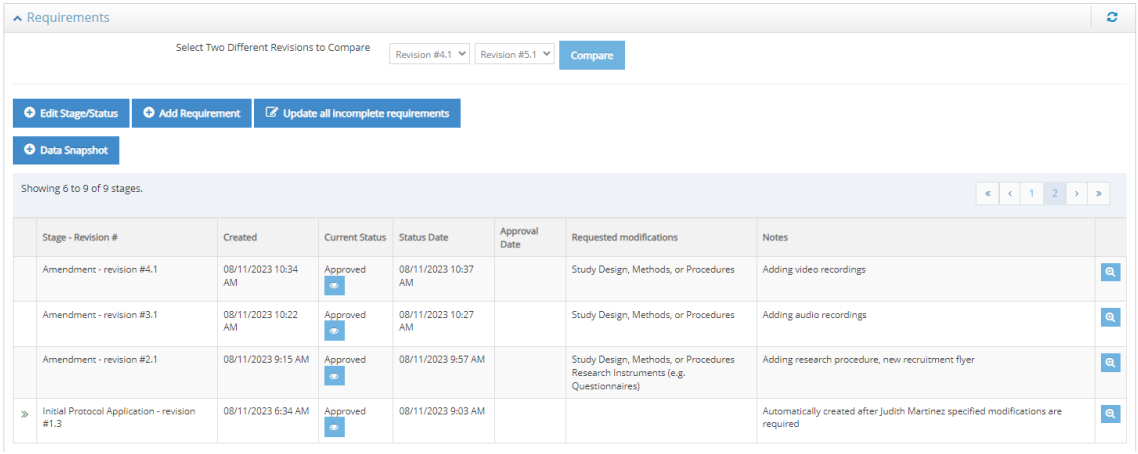
For the amendment component, you will go directly into the panel or field where the changes need to be made and re-enter that information as if you were filling it out for the first time.



Each revision you create will be accessible from the Requirements panel which you can click to view at any time.

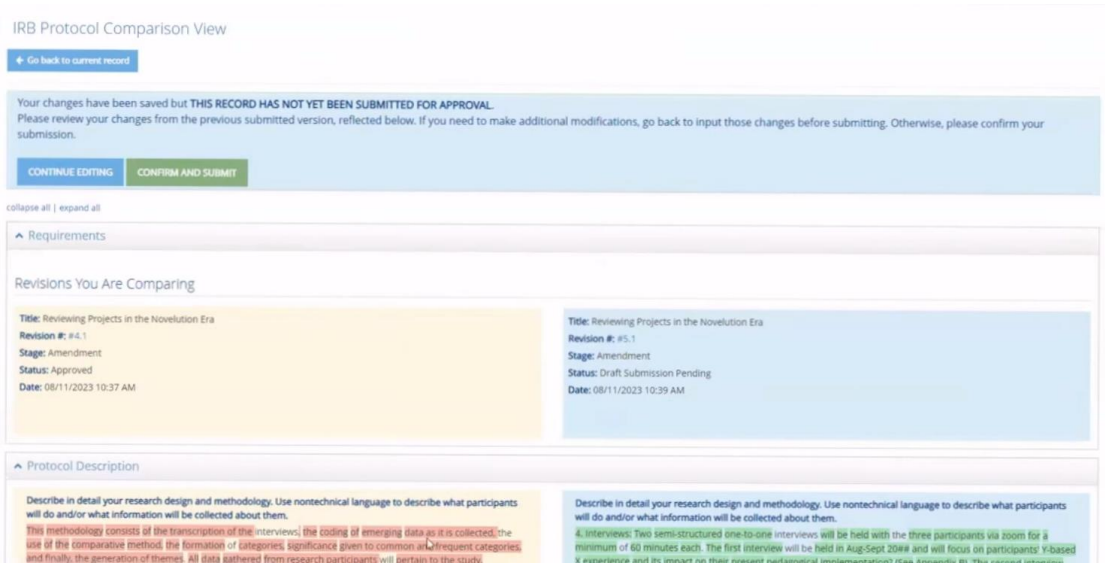


You can also see previous submissions you have made.



Once you have finished making the necessary amendments to your project, click to Review and Submit your changes

Then in the IRB Comparison page, review your changes which will be listed in the right blue box.



Click to Confirm and Submit

Note: If you no longer need to make a Continuing Review or an Amendment, contact the IRB Office to cancel this process administratively

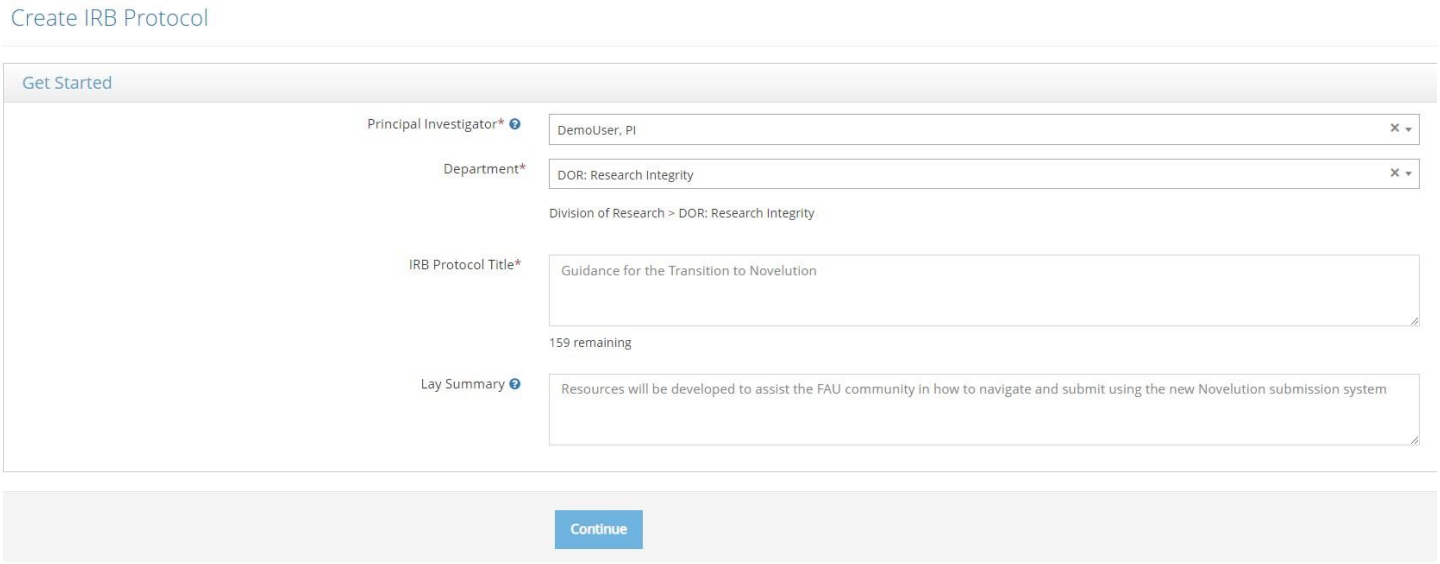
Note: The next time you need to fill out a Continuing Review, your information from the previous submission will be auto-populated in the panel.

FAU IRB NOVELUTION

Requesting a Determination of Human Subjects Research

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.

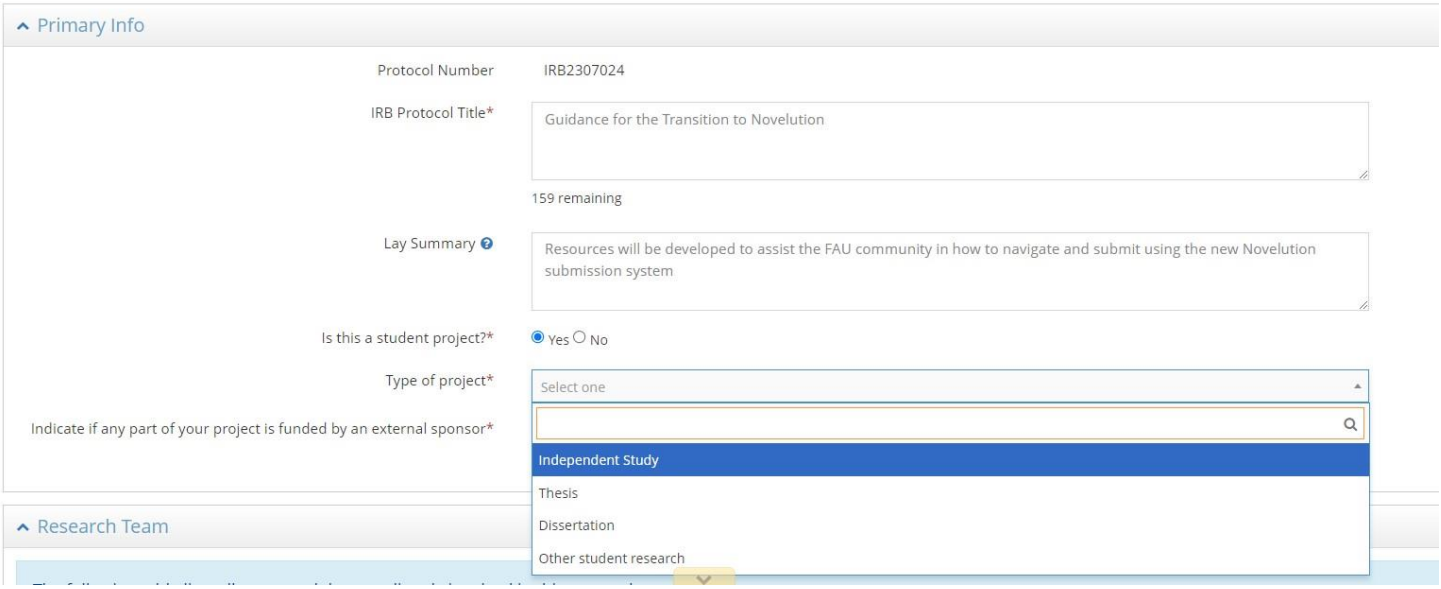
If you are the student completing this project for your degree, you cannot also be the PI.

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.

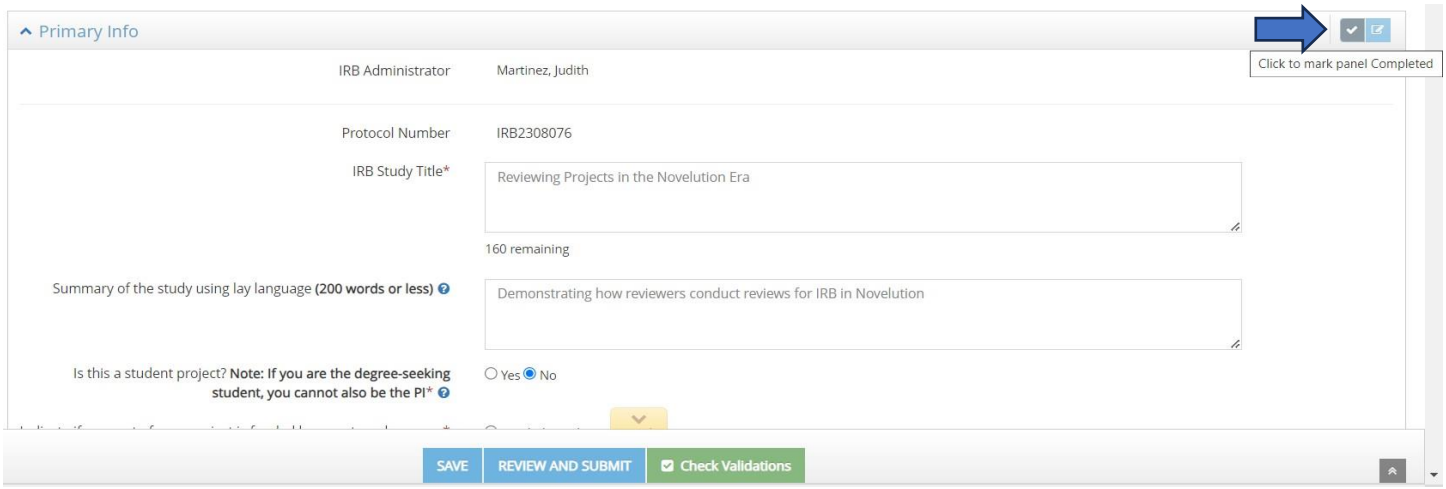
Add your title and lay summary, then click continue

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.

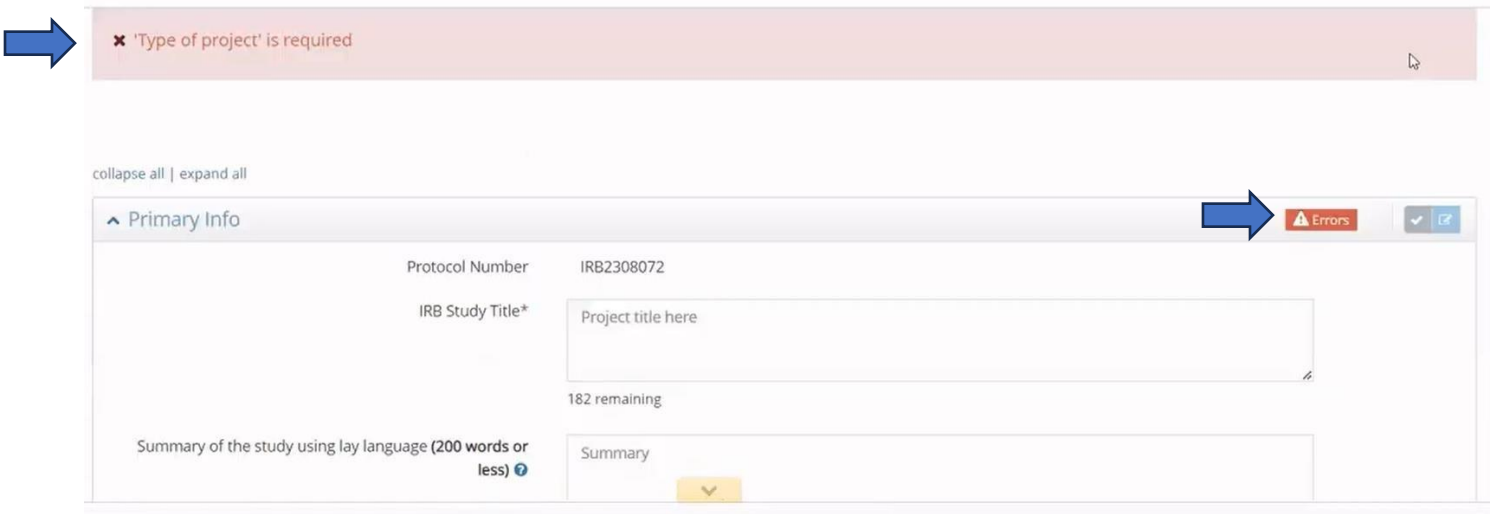
Questions follow smart logic and will produce additional follow-up questions depending on certain selections. In this example, selecting Yes to the question “Is this a student project?” will show a new “Type of project” drop down list to select the specific student project.



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.

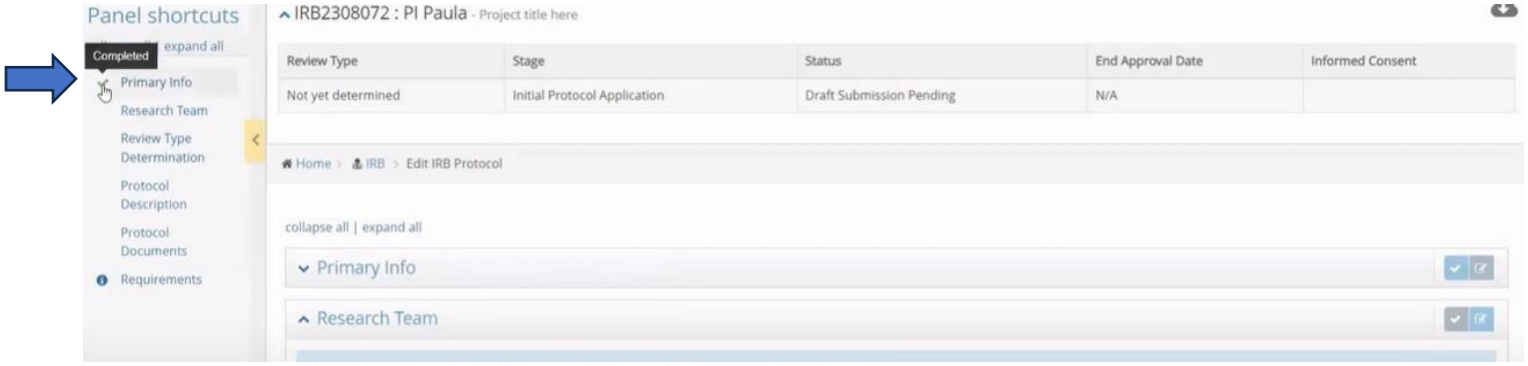


If any required fields are missing, you'll see an "Errors" box appears in the panel header and a red box appears up at the top listing the required field that is missing. You can click that link to be taken directly to the field to fill in your response(s).

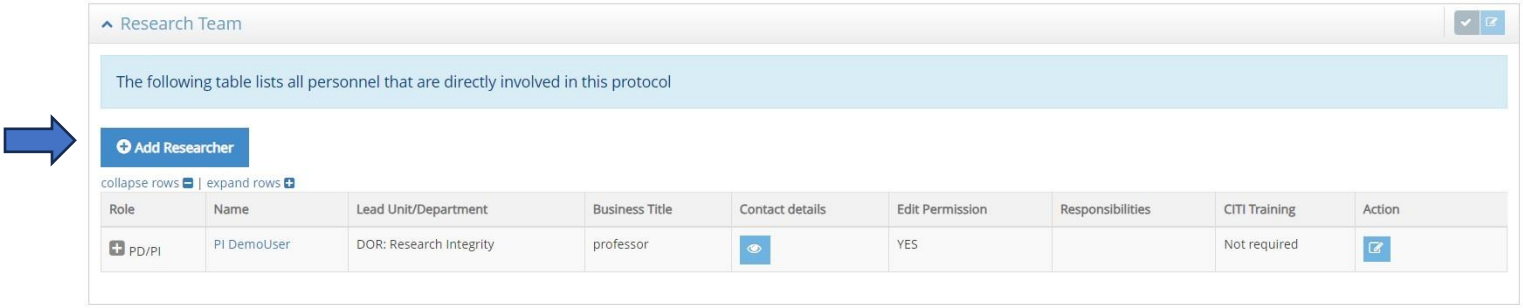


Fill out any missing required fields then click the checkmark again to see the panel is now Completed, indicated with a Checkmark in the Panel Shortcuts.

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

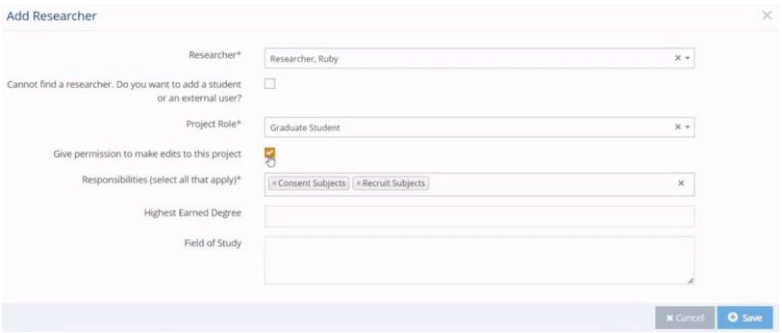


Next, in the Research Team panel, click the button to Add Researcher. You can add as many researchers as needed.



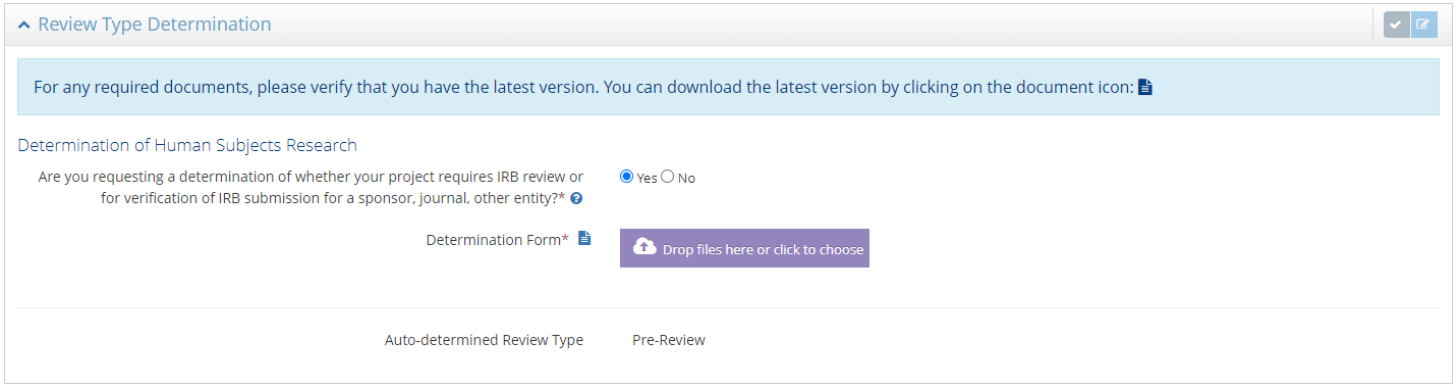
Begin by searching for the researcher's name in the "Researcher" field. Then select the person's project role from the drop-down list, as well as their responsibilities. If there are additional responsibilities which are not listed here, click other which will provide a "Please describe" field to enter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

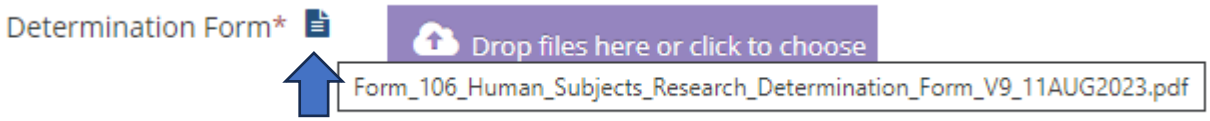


Once a researcher has been added, click to save. Repeat the process to add other researchers to the team personnel.

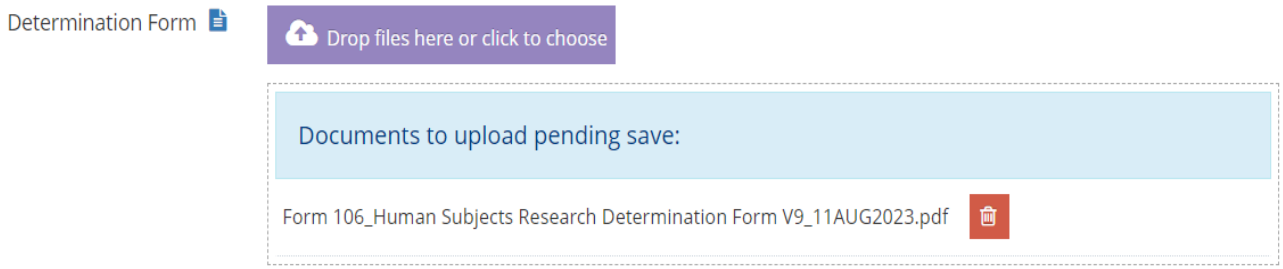
In the Review Type Determination panel select yes to the question “Are you requesting a determination of whether your project requires IRB review or for verification of IRB submission for a sponsor, journal, or other entity?”



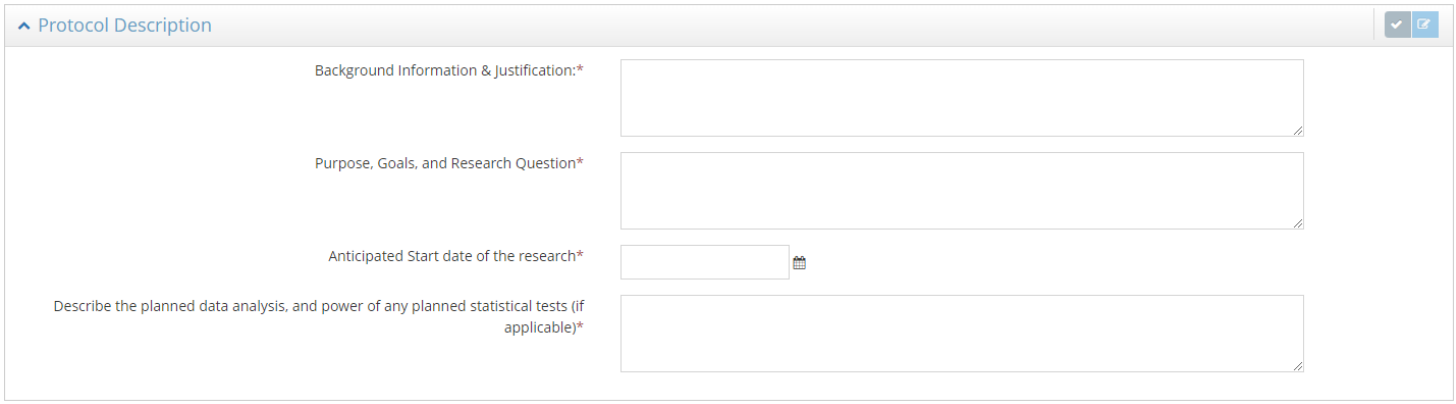
Click to download and complete Form 106 by clicking the document icon 



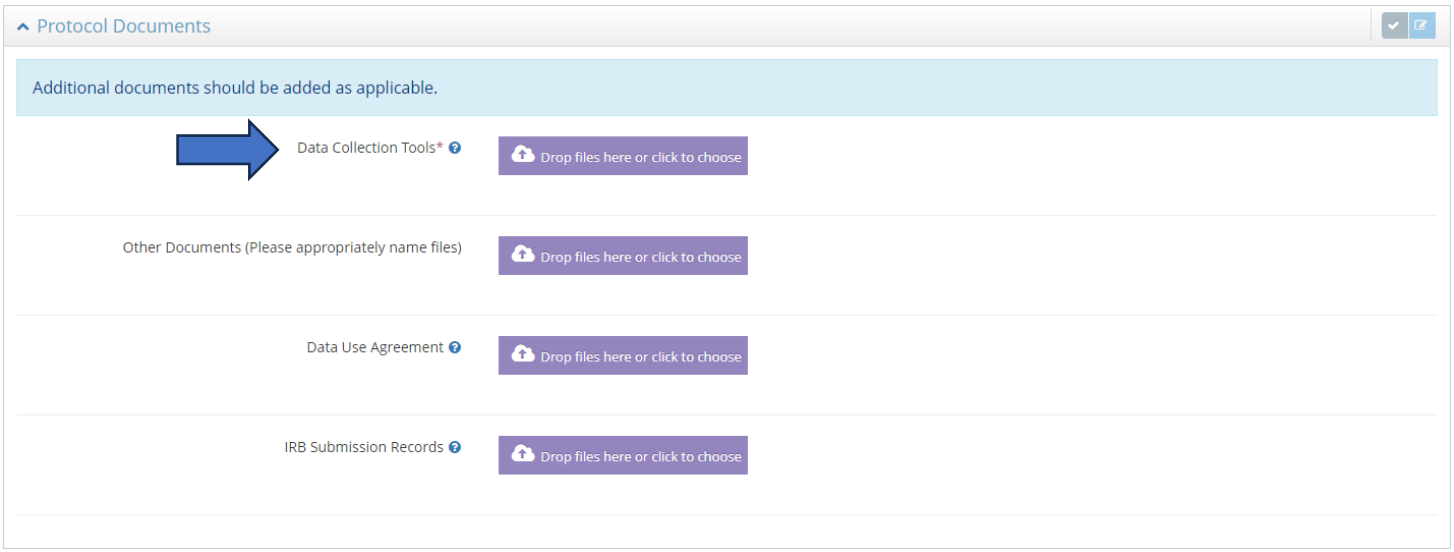
Fill out Form 106 and save the form to your computer, then return to Novelution to upload your completed form in Novelution using the button



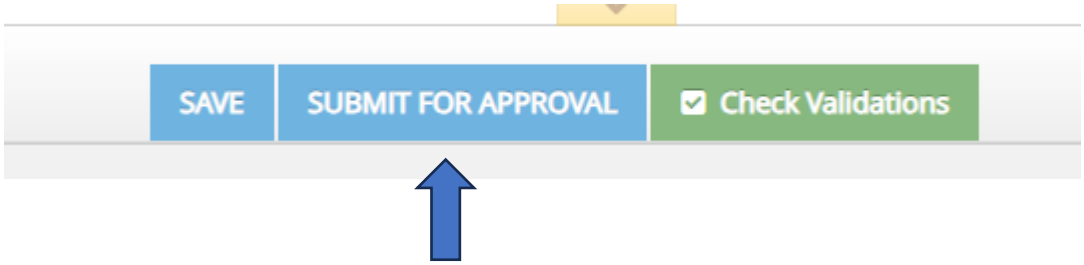
Complete the fields in the Protocol Description panel



Then add your data collection tools in the Protocol Documents panel in the “Data Collection Tools” upload button



Once you have completed these steps, click the button to submit for approval



You’ll receive a confirmation bar when you have successfully submitted your project