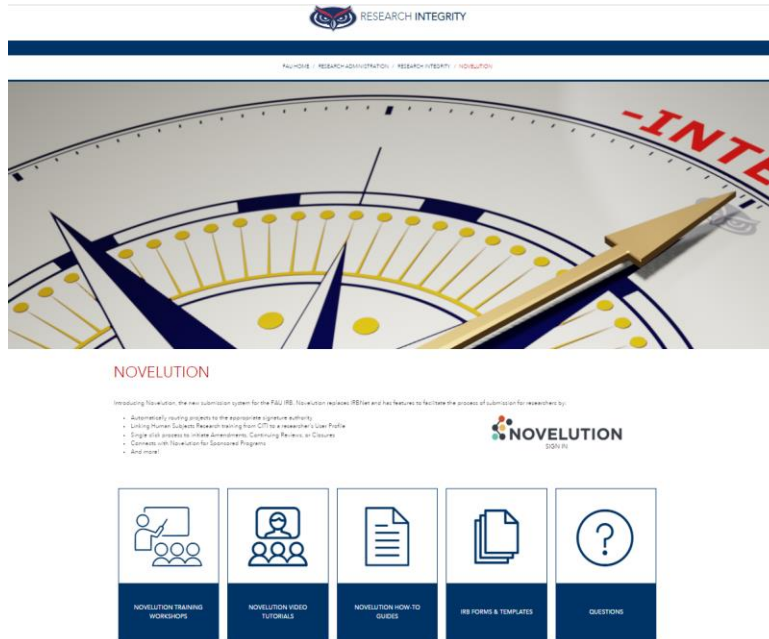



FAU IRB NOVELUTION

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

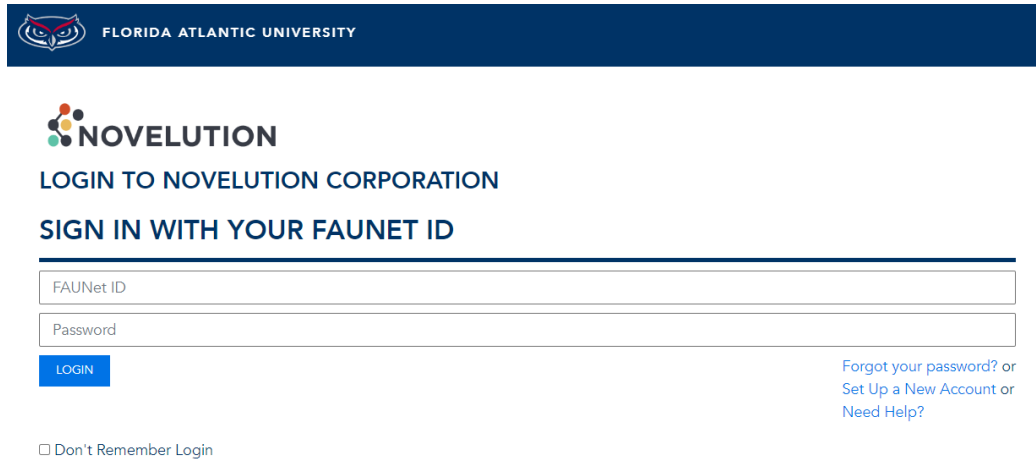
 Part of Florida Atlantic University?

Click "Continue" button to use your FAU username and password to login.

Try to log me in automatically when possible

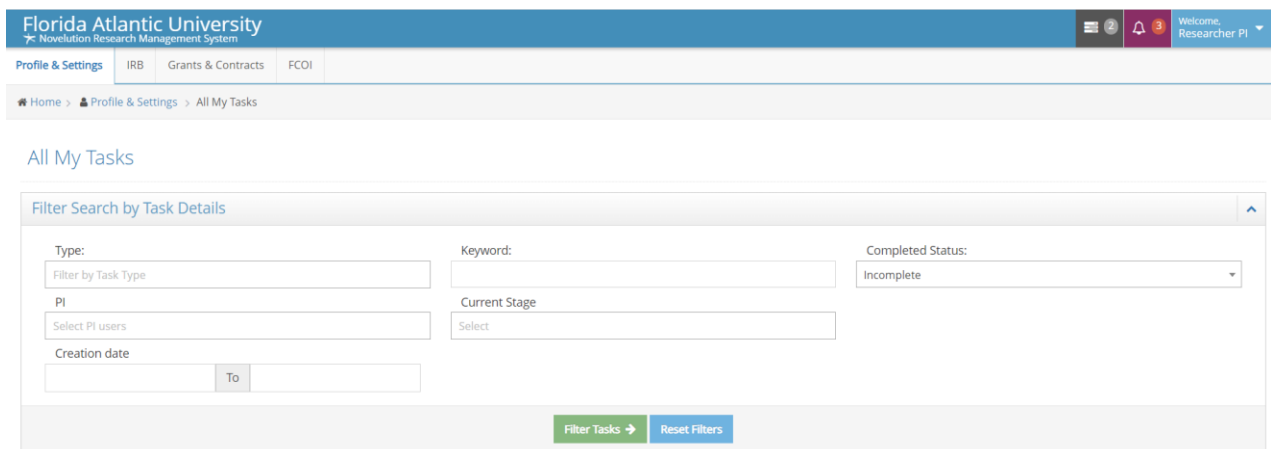
[Not part of Florida Atlantic University?](#)

Enter your FAU Credentials to log in



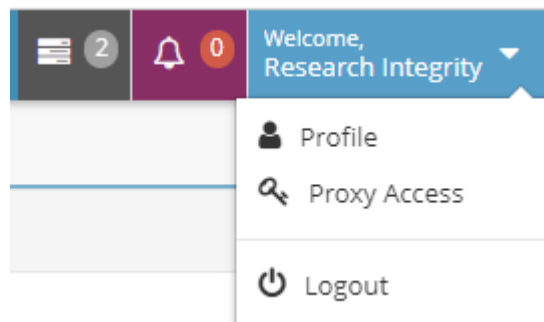
The image shows the login page for the Novelution system. At the top, there is a dark blue header with the Florida Atlantic University logo and name. Below this, the Novelution logo is displayed, followed by the text "LOGIN TO NOVELUTION CORPORATION" and "SIGN IN WITH YOUR FAUNET ID". There are two input fields: "FAUNet ID" and "Password". A blue "LOGIN" button is positioned below the password field. To the right of the login button, there is a link that says "Forgot your password? or Set Up a New Account or Need Help?". At the bottom left, there is a checkbox labeled "Don't Remember Login".

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.



The image shows the dashboard of the Novelution system. At the top, there is a blue header with the Florida Atlantic University logo and name. Below this, there is a navigation bar with tabs for "Profile & Settings", "IRB", "Grants & Contracts", and "FCOI". The "IRB" tab is currently selected. Below the navigation bar, there is a breadcrumb trail: "Home > Profile & Settings > All My Tasks". The main content area is titled "All My Tasks" and contains a "Filter Search by Task Details" section. This section has several input fields: "Type:" (with a dropdown menu), "Keyword:" (text input), "Completed Status:" (dropdown menu), "PI" (with a dropdown menu), "Current Stage" (with a dropdown menu), and "Creation date" (with two text inputs and a "To" button). At the bottom of the filter section, there are two buttons: "Filter Tasks" and "Reset Filters".

Access your Profile page from the Welcome (blue box)



The image shows a close-up of the user profile dropdown menu. The menu is open, showing three options: "Profile", "Proxy Access", and "Logout". The "Profile" option is highlighted. The menu is positioned over a blue box that says "Welcome, Research Integrity".

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 Novolution 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.

General Information

Associated Institution	Florida Atlantic University
User Status*	Active
Primary email*	fauresearchintegrity@gmail.com
Alternate email	
Do you want to receive tasks as emails?*	Yes, Primary Email
Do you want to receive notifications as emails?*	Yes, Primary Email
Prefix	Select one
First Name*	Research
Middle Name	
Last Name*	Integrity
Suffix	Select one
Country*	Select one
Address 1	
Address 2	
Zip/Postal Code	
City	
State/Province	Select one
Office Phone	
Office Phone Ext	
Office Fax	
Mobile Phone	
era Commons username	
NSF ID	
CITI Email Address	

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.

^ Email Preferences

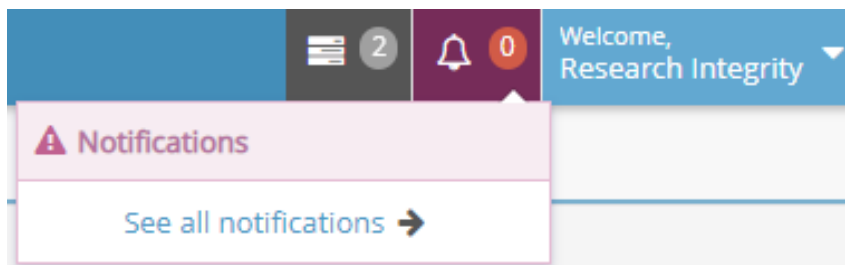
Receive notifications on my Review Comments' conversations

Note: Certain emails (configured by the institution) will be sent regardless of preferences below

Module	Receive Task Emails	Receive Notification Emails
IRB	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
SR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
COI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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.



Florida Atlantic University
Novelation Research Management System

Profile & Settings | IRB | Grants & Contracts | FCOI

Home > Profile & Settings > My Notifications

Filter Search by Notification Details

Type: Read Status: Show archived:

[Filter Notifications](#)

Results for "Notifications Search" [Archive all](#)

Type	Title	Read Status	Date created	
+ IRB	New IRB version has been created by a user other than the PI for: IRB2308062	Unread	08/04/2023 1:17 PM	
+ IRB	User has been added to the personnel of protocol: IRB2308062	Unread	08/04/2023 1:09 PM	
+ IRB	Missing training requirements for protocol: IRB2308062	Unread	08/03/2023 4:43 PM	

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.

Tasks to complete

Approve/Modifications required (2) 50%

[See all tasks](#)

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

Florida Atlantic University
Novelation Research Management System

Profile & Settings | IRB | Grants & Contracts | FCOI

Filter by Task Type Current Stage

PI Current Stage

Creation date To

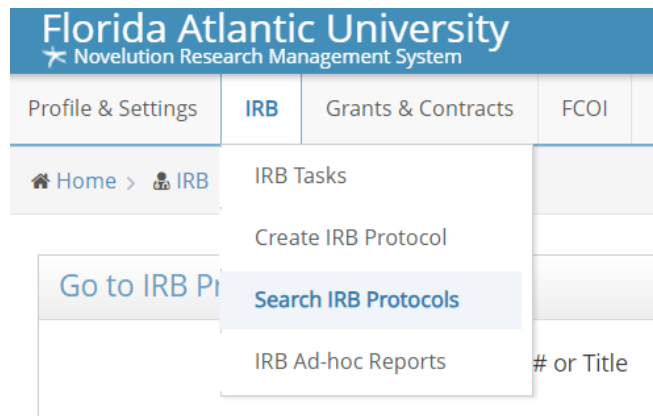
[Filter Tasks](#) [Reset Filters](#)

My Assigned Tasks | Following | Away Schedule

collapse rows expand rows

Type	Action	Message	PI	Stage	Details	Due Date	Task Created	
+ IRB	Modifications required	Information is needed for project #IRB2308062.	Researcher PI	Initial Protocol Application	Pre-Review		08/04/2023 1:17 PM	
+ IRB	Update	Hello Dr. Researcher, visit citiprogram.org to complete your Human Research Training. Select the Human Subjects Research option and choose from Social & Behavioral Research Investigators or Biomedical Research Investigators to satisfy this requirement.	Researcher PI	Initial Protocol Application	Pre-Review		07/28/2023 7:38 PM	

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 screenshot shows the search results page for IRB protocols. The top navigation bar includes the university name and system title. Below the navigation bar, there is a search filter section with various dropdown menus and checkboxes. The search results are displayed in a table with columns for Protocol ID, PI Name, Title, Stage, Status, Review Type, End Approval Date, IRB Admin, Date Received, and a link icon.

Protocol ID	PI Name	Title	Stage	Status	Review Type	End Approval Date	IRB Admin	Date Received	
IRB2308062	Researcher PI	Audio-Visual Learning in the Current Age	Initial Protocol Application	IRB Review Pending	Pre-Review		Judith Martinez	08/03/2023 4:43 PM	🔗
IRB2307057	Researcher PI	Changing Systems: How Adults Respond to Technological Changes	Initial Protocol Application	Pre-submission Requirements	Pre-Review			07/28/2023 7:38 PM	🔗
IRB2307050	Researcher PI	The Effects of Virtual Training	Initial Protocol Application	Approved	Expedited	07/26/2024	Judith Martinez	07/27/2023 12:59 PM	🔗
IRB2303021	Researcher PI	Why Virtual Forms are Beneficial to Research	Continuing Review	Draft Submission Pending	Expedited		Judith Martinez		🔗

The Project Details Panel will provide summary information about your project

IRB2307057 : Researcher PI - Changing Systems: How Adults Respond to Technological Changes



Review Type	Stage	Status	End Approval Date	Informed Consent
Pre-Review	Initial Protocol Application	Pre-submission Requirements	N/A	

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

Panel shortcuts

collapse all | expand all

- Review Comments
- Primary Info
- Research Team
- Review Type Determination
- Protocol Description
- Protocol Documents
- Requirements

IRB2307057 : Researcher PI - Changing Systems: How Adults Respond to Technological Changes

Review Type	Stage	Status	End Approval Date	Informed Consent
Pre-Review	Initial Protocol Application	Pre-submission Requirements	N/A	

Requirements

Stage - Revision #	Created	Current Status	Status Date	Approval Date	Requested modifications	Notes
Initial Protocol Application - revision #1.1	07/28/2023 7:37 PM	Pre-submission Requirements	08/05/2023 3:23 PM			

Status	Requirement	Completion State	Revision	Completed by	Completed Date
Draft Submission Pending	Submit Protocol	✓Completed	#1.1	PI, Researcher	08/05/2023 3:23 PM
PI Certification Pending	Certify Protocol (PI)	✓Completed - Approved	#1.1	PI, Researcher	08/05/2023 3:22 PM
Pre-submission Requirements	Approval by Department Chair: Alan Kersten	Ready			
	Complete Human Subjects training on CITI: Researcher PI	Ready			
	Complete Human Subjects training on CITI: Student Researcher	Ready			
IRB Review Pending	IRB Admin Assignment	Not ready			
	IRB Admin Processing	Not ready			

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”



Create IRB Protocol

Get Started

Principal Investigator*	<input type="text" value="DemoUser, PI"/>
Department*	<input type="text" value="DOR: Research Integrity"/>
Division of Research > DOR: Research Integrity	
IRB Protocol Title*	<input type="text" value="Guidance for the Transition to Novelution"/>
159 remaining	
Lay Summary	<input type="text" value="Resources will be developed to assist the FAU community in how to navigate and submit using the new Novelution submission system"/>

[Continue](#)

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 screenshot displays the Florida Atlantic University Novolution Research Management System interface. At the top, there is a navigation bar with 'Profile & Settings', 'IRB', 'IACUC', 'Grants & Contracts', and 'FCOI'. A 'Panel shortcuts' sidebar on the left lists various options like 'Primary Info', 'Research Team', and 'Requirements'. The main content area features a 'Project Details' box for protocol IRB2307024, titled 'PI DemoUser - Guidance for the Transition to Novolution'. This box contains a table with the following data:

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

Below the table, the 'Primary Info' section includes fields for 'Protocol Number' (IRB2307024), 'IRB Protocol Title*' (Guidance for the Transition to Novolution), 'Lay Summary*' (Resources will be developed to assist the FAU community in how to navigate and submit using the new Novolution submission system), and two questions: 'Is this a student project?*' (Yes/No) and 'Indicate if any part of your project is funded by an external sponsor*' (Funded/Pending Proposal/Not Funded). At the bottom, there are buttons for 'SAVE', 'SUBMIT FOR APPROVAL', and 'Check Validations'.

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.

Primary Info

Protocol Number IRB2307024

IRB Protocol Title*
Guidance for the Transition to Novelution
159 remaining

Lay Summary*
Resources will be developed to assist the FAU community in how to navigate and submit using the new Novelution submission system

Is this a student project?* Yes No

Type of project*
Select one
Independent Study
Thesis
Dissertation
Other student research

Indicate if any part of your project is funded by an external sponsor*

Research Team

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.

Primary Info

IRB Administrator Martinez, Judith

Protocol Number IRB2308076

IRB Study Title*
Reviewing Projects in the Novelution Era
160 remaining

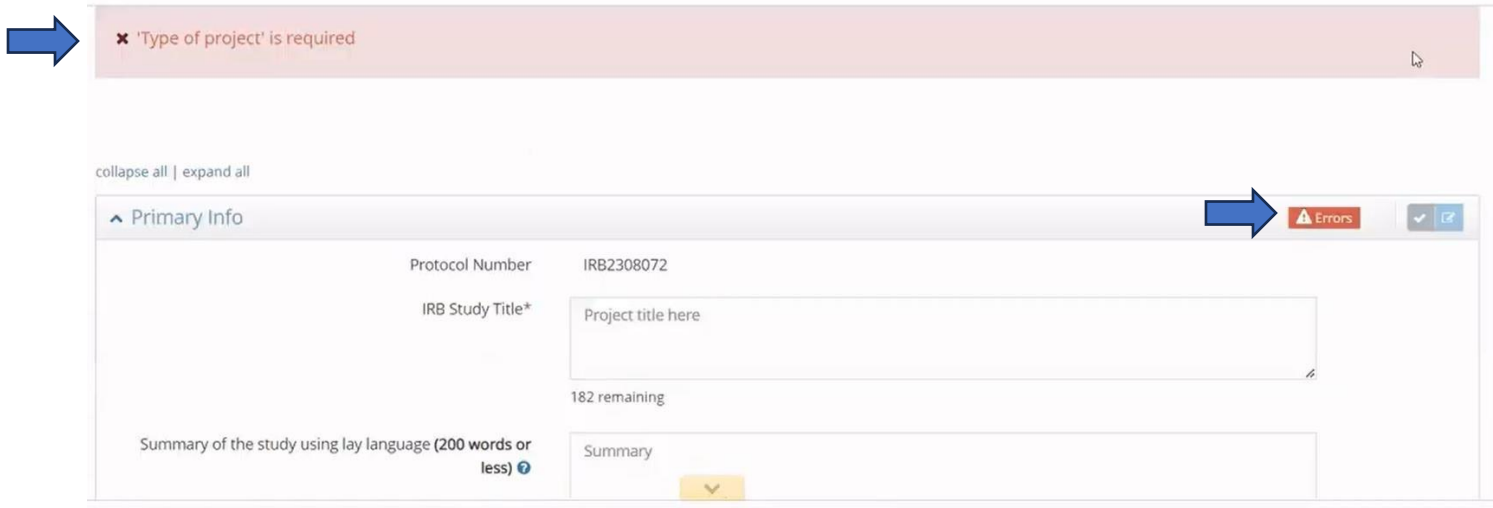
Summary of the study using lay language (200 words or less)*
Demonstrating how reviewers conduct reviews for IRB in Novelution

Is this a student project? Note: If you are the degree-seeking student, you cannot also be the PI* Yes No

Click to mark panel Completed

SAVE REVIEW AND SUBMIT Check Validations

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).



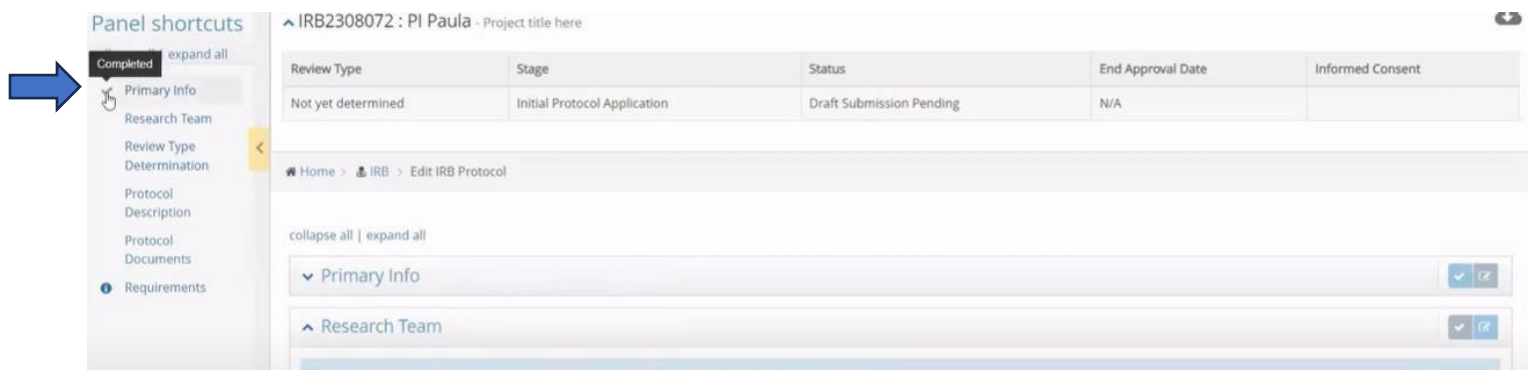
A blue arrow points to a red error banner at the top of the page that reads: "x 'Type of project' is required". Below this is a form panel titled "Primary Info" with a "collapse all | expand all" link. The panel contains the following fields:

- Protocol Number: IRB2308072
- IRB Study Title*: Project title here (with a character count of 182 remaining)
- Summary of the study using lay language (200 words or less): Summary

In the top right corner of the "Primary Info" panel, there is a red "Errors" button with a checkmark icon next to it. A blue arrow points to this "Errors" button.

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



A blue arrow points to the "Completed" status in the "Panel shortcuts" sidebar. The sidebar lists various sections: Primary Info, Research Team, Review Type Determination, Protocol Description, Protocol Documents, and Requirements. The "Completed" status is highlighted with a checkmark icon.


The main content area shows a table for "IRB2308072 : PI Paula - Project title here":

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

Below the table, there is a breadcrumb trail: "Home > IRB > Edit IRB Protocol". At the bottom, there are two expandable panels: "Primary Info" (collapsed) and "Research Team" (expanded). Both panels have a checkmark icon in their top right corner, indicating they are completed.

Research Team

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



Role	Name	Lead Unit/Department	Business Title	Contact details	Edit Permission	Responsibilities	CITI Training	Action
PD/PI	PI DemoUser	DOR: Research Integrity	professor		YES		Not required	

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.

Add Researcher ✕

Researcher* ✕

Cannot find a researcher. Do you want to add a student or an external user?

Project Role* ✕

Give permission to make edits to this project

Responsibilities (select all that apply)* ✕

Highest Earned Degree

Field of Study

✕ Cancel ➕ Save

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.

Review Type Determination

For any required documents, please verify that you have the latest version. You can download the latest version here.

Determination of Human Subjects Research

Are you requesting a determination of whether your project requires IRB review or for verification of IRB submission for a sponsor, journal, other entity?*

Yes No

Collaboration and Multi-Site Research

Will an external IRB act as the IRB of record for this study?*

Yes No

Are other institutions engaged?*

Yes No

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

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)

*

Expedited vs Full Board Determination

Any radiation exposure for research purposes?*

Yes No

Any FDA approved or investigational drugs requiring an IND?*

Yes No

Any investigational devices?*

Yes No

Does your study involve the use of stem cells, discarded tissue, fetal tissue, or human blood or fluids?*

Yes No

Does the study involve more than minimal risk?*

Yes No

Select Research Types*

[View research type descriptions](#)

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 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 is 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

The screenshot shows the IRB review interface for project IRB2308072 : PI Paula. On the left is a 'Panel shortcuts' sidebar with a list of sections: Review Comments, Admin Fields, Primary Info, Research Team, Review Type, Determination, Protocol Description, Recruitment, Informed Consent, Risks and Benefits, Privacy & Confidentiality, Protocol Documents, Reviewers, IRB Correspondence, and Requirements. The 'Recruitment', 'Informed Consent', 'Risks and Benefits', and 'Privacy & Confidentiality' sections are highlighted in yellow. The main content area is titled 'Review Type' and contains the same text and questions as the top image. A yellow box highlights the 'Category 1' checkbox, which is checked, indicating that the project falls under this category.

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.

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

Expedited vs Full Board Determination

Any radiation exposure for research purposes?* Yes No

Any FDA approved or investigational drugs requiring an IND?*

Yes No

Any investigational devices?*


Yes No

Does your study involve the use of stem cells, discarded tissue, fetal tissue, or human blood or fluids?*

Yes No

Does the study involve more than minimal risk?*

Yes No

 **Select Research Types***
View research type descriptions

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

 **Select Research Types***
View research type descriptions

Research Type Descriptions ✕

For official page from which these description were taken, [see here](#)

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure¹:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

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

Select Research Types*
View research type descriptions

Select some

- 1 - No IND or IDE involved
- 2 - Minimal blood collection by finger stick, heel stick, venipuncture
- 3 - Non-invasive biological collection e.g. hair/nail clippings
- 4 - Non-invasive data collection excluding X-ray
- 5 - Data/specimen collection for non-research purposes
- 6 - Collection of data from voice, video, image, recorded for research

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.

Special population

Indicate if individuals from any of the following groups will be specifically recruited.
[View our FAU IRB Policies Page*](#)

- Impaired decision making capacity (See policy 10.3.2)
- Developmentally Disabled persons
- Employees directly supervised by PI or sub-investigator Employees of research site or sponsor
- Limited literacy or non-readers
- Non-English speakers
- Low income or uninsured persons
- Economically disadvantaged individuals (including homeless)
- Undocumented immigrants, refugees, asylum-seekers, or internally displaced persons
- Indigenous persons
- Military personnel to be recruited by military personnel
- Minors (underage of majority in jurisdiction where research will be performed) (See policy 10.3.6)
- Nursing home residents recruited in the nursing home (See policy 10.3.2)
- Persons in treatment for a physical, mental, or emotional condition
- Pregnant women/fetuses/neonates of undetermined viability
- Prisoners or persons with court sanctioned limited freedoms (including juvenile justice system)
- Students of PI or study staff (See policy 10.3.7 and /or policy 10.3.8)
- Students to be recruited in their educational setting (i.e. in class or at school) (See policy 10.3.8)
- Wards of the state (e.g. foster children, juveniles in detention) (See policy 10.3.6)
- Others vulnerable to coercion or undue influence
- None of the above

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

^ Protocol Description

Background Information & Justification:*

Purpose, Goals, and Research Question*

Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.* ?

Will the research involve secondary use of data, documents, records or biospecimens collected from individuals?*

Describe any online/electronic resources be utilized for recruitment, data collection, or storage* ?

Specify where the research will be conducted.*

Anticipated Start date of the research*

Describe the sampling plan, the sample size or study group(s)*

Describe the planned data analysis, and power of any planned statistical tests (if applicable)*

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.

Recruitment

Which of the statements describes the recruitment strategy? (If both apply, select both)*

Potential subjects will self-identify based on response to an advertisement, flyer, presentation or respondent driven sampling

Potential subjects will be recruited based on information contained in private/protected records (e.g. medical records, educational or employment records)

Attach a copy of any oral script, advertisement, announcement or invitation that will be used. Use our FAU IRB Forms & Templates Page to download FAU branded recruitment templates.

Drop files here or click to choose

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.

Informed Consent

Explain the process for obtaining informed consent from participants, their parent/guardian, and/or legally authorized representative.* Then, use our [FAU IRB Forms & Templates Page](#) to select the appropriate assent/consent templates and upload them as PDF's in the respective button(s) which appear below.*

Will all participants provide informed consent for themselves?* Yes No

Will consent occur in any language other than English?* Yes No

Are you requesting a *waiver and/or alteration* of informed consent?* Yes No

Are you requesting to *waive the signature* requirement for informed consent?* Yes No

Adult consent*
(Only PDF file types)

Drop files here or click to choose

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"

^ Informed Consent

Explain the process for obtaining informed consent from participants, their parent/guardian, and/or legally authorized representative.* Then, use our [FAU IRB Forms & Templates Page](#) to select the appropriate assent/consent templates and upload them as PDF's in the respective button(s) which appear below.*

Will all participants provide informed consent for themselves?*

Yes No

Who will provide consent?*

Parent/Guardian

Legally authorized representative

No one--requesting full waiver of consent

Are you requesting a *waiver and/or alteration* of informed consent?*

Yes No

Are you requesting to *waive the signature* requirement for informed consent?*

Yes No

Parent/Guardian Consent/Child Assent forms* (Only PDF file types)

Drop files here or click to choose

Legally authorized representative* (Only PDF file types)

Drop files here or click to choose


Adult consent
(Only PDF file types)

Drop files here or click to choose

Risks & Benefits

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


^ Risks and Benefits

Indicate all potential risks of harm/discomfort to participants or others.* 

- Physical
- Psychological/emotional distress or discomfort
- Financial impacts/employability
- Privacy/confidentiality
- Stigmatization/reputational
- Legal implications/criminal or civil liability
- Use of deception
- Identification of abuse (e.g., child, partner, elder)
- Other

Describe the nature, probability, magnitude, and duration of the risks.*

Describe precautions you will take to minimize each of the potential risks identified above.*

Describe any potential benefits to participants and/or society in general.* 

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.

^ Privacy & Confidentiality

Describe how you will protect the privacy of participants while they are being consented for the research (if applicable) and throughout the course of the research procedures/interventions. [?](#)

Will any personally identifiable information (PII) be obtained from or about participants?*

Yes No

In what format(s) will the data originate?*

Describe how PII research data will be shared among research team members, collaborators, etc.*

In what format(s) will the data be maintained during the life of the study?*

Describe in detail the protections that will be implemented to maintain the confidentiality of data, and/or specimens.* [?](#)

Are there any foreseeable potential ethical or legal circumstances when it would be necessary to break confidentiality?*

Yes No

When will identifiers be removed from the dataset and/or the records? State for how long research records will be maintained.*

Indicate ALL proposed forms of dissemination.*

Select some

Will any protected health information (PHI) be collected or obtained?*

Yes No

Protocol Documents

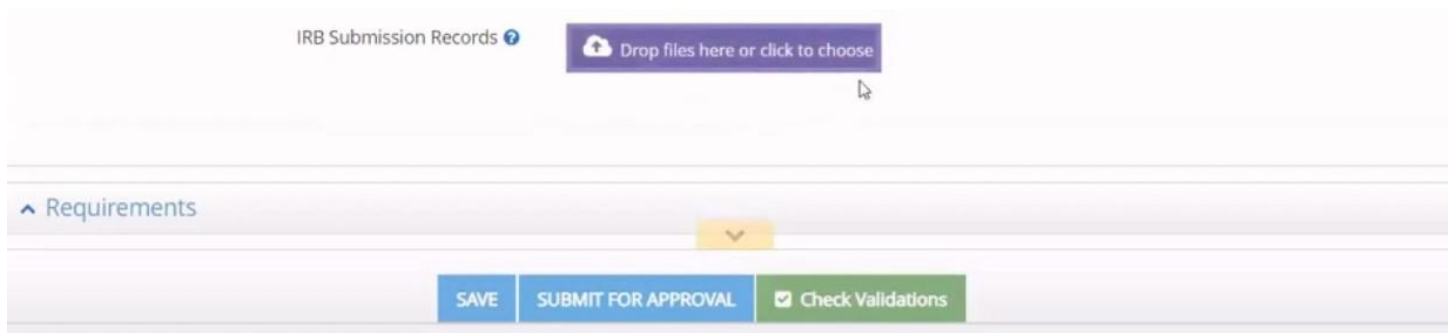
This is the third panel with optional uploads, however there is a required upload for “Data Collection Tools”. This can include your questionnaires, interview materials, and so on.

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



The screenshot shows a web interface for uploading IRB Submission Records. At the top, there is a section labeled "IRB Submission Records" with a blue circular icon containing a question mark. Below this label is a purple rectangular button with a white cloud icon and the text "Drop files here or click to choose". A mouse cursor is positioned over the bottom right corner of this button. Below the upload area is a horizontal separator line. Underneath, there is a section labeled "Requirements" with a blue upward-pointing arrow to its left and a yellow downward-pointing arrow centered below the text. At the bottom of the interface, there are three buttons: a blue "SAVE" button, a blue "SUBMIT FOR APPROVAL" button, and a green "Check Validations" button with a white checkmark icon.

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.

The screenshot shows the IRB system interface for project IRB2308072. On the left is a 'Panel shortcuts' sidebar with a list of sections: Primary Info, Research Team, Review Type Determination, Protocol Description, Recruitment, Informed Consent, Risks and Benefits, Privacy & Confidentiality, Protocol Documents, and Requirements. The main content area displays a table with the following data:

Review Type	Stage	Status	End Approval Date	Informed Consent
Exempt	Initial Protocol Application	Draft Submission Pending	N/A	

Below the table is a breadcrumb trail: Home > IRB > Edit IRB Protocol. A green notification bar states: 'Other changes have been saved, but you must resubmit with all required fields in order to submit this protocol application for approval.' Below this is a red box containing a list of validation errors:

- × 'Are you requesting a determination of whether your project requires IRB review or for verification of IRB submission for a sponsor, journal, other entity?' is required
- × 'Indicate if individuals from any of the following groups will be specifically recruited. View our FAU IRB Policies Page' is required
- × 'Background Information & Justification:' is required
- × 'Purpose, Goals, and Research Question' is required
- × 'Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.' is required
- × 'Will the research involve secondary use of data, documents, records or biospecimens collected from individuals?' is required
- × 'Describe any online/electronic resources be utilized for recruitment, data collection, or storage' is required

At the bottom of the interface are three buttons: 'SAVE', 'SUBMIT FOR APPROVAL', and 'Check Validations'.

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

The screenshot shows the IRB system interface after a successful submission. The table now displays:

Review Type	Stage	Status
Pre-Review	Initial Protocol Application	PI Certification Pending

The breadcrumb trail remains: Home > IRB > Edit IRB Protocol. A green notification bar at the bottom states: 'Application saved and submitted for approval: 08/08/2023 8:20 AM'.

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.

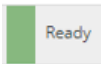
Requirements

[+ Edit Stage/Status](#) [+ Add Requirement](#) [Update all incomplete requirements](#)

[+ Data Snapshot](#)

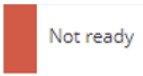
Stage - Revision #	Created	Current Status
Initial Protocol Application - revision #1.1 Viewing	08/14/2023 11:23 AM	Draft Submission Pending

Status	Requirement	Completion State
Draft Submission Pending	Submit Protocol	Ready
PI Certification Pending	Certify Protocol (PI)	Not ready
Pre-submission Requirements	Approval by Department Chair: Alan Kersten	Not ready
IRB Review Pending	IRB Admin Assignment	Not ready
	IRB Admin Processing	Not ready



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				...

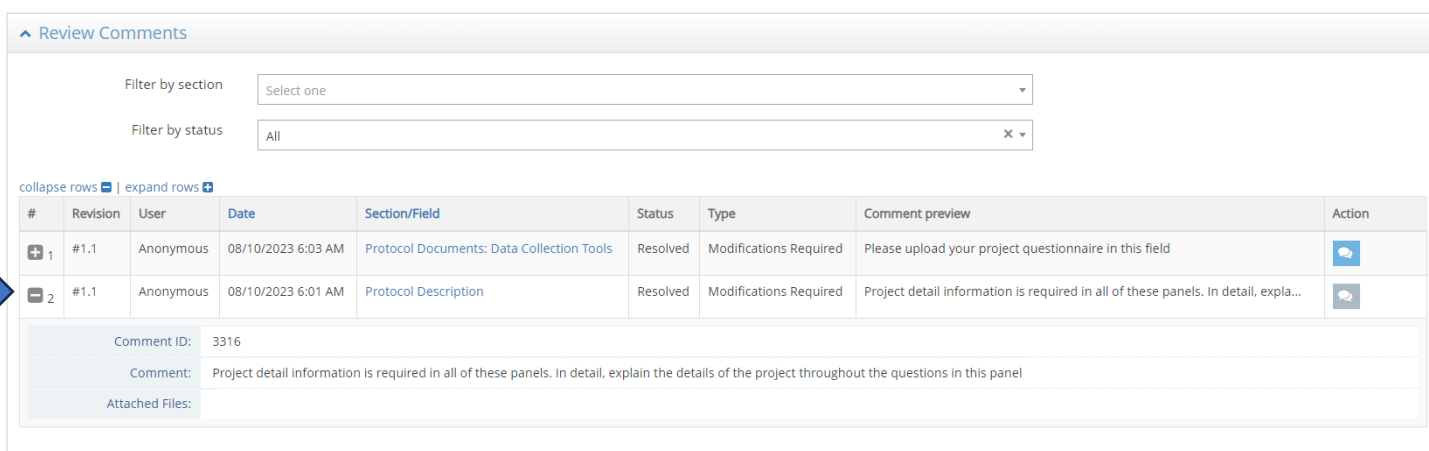
The status “IRB Admin Processing” covers the entire review process including assigning to IRB members or to a full board meeting as applicable. In other words, though the status is “IRB Admin Processing” it is possible that your project is out for review by a reviewer during this stage.

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.



Review Comments

Filter by section: Select one

Filter by status: All

collapse rows | expand rows

#	Revision	User	Date	Section/Field	Status	Type	Comment preview	Action
+	#1.1	Anonymous	08/10/2023 6:03 AM	Protocol Documents: Data Collection Tools	Resolved	Modifications Required	Please upload your project questionnaire in this field	
+	#1.1	Anonymous	08/10/2023 6:01 AM	Protocol Description	Resolved	Modifications Required	Project detail information is required in all of these panels. In detail, expla...	

Comment ID: 3316

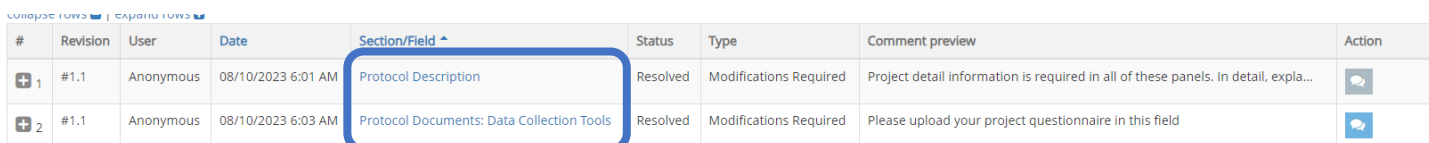
Comment: Project detail information is required in all of these panels. In detail, explain the details of the project throughout the questions in this panel

Attached Files:

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.

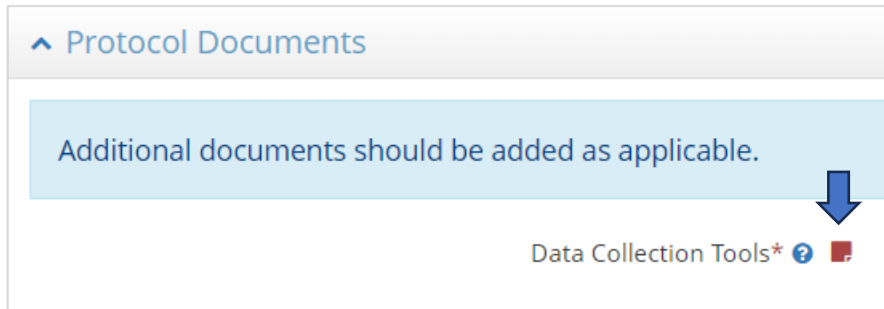
#	Revision	User	Date	Section/Field	Status	Type	Comment preview	Action
---	----------	------	------	---------------	--------	------	-----------------	--------

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.



#	Revision	User	Date	Section/Field	Status	Type	Comment preview	Action
+	#1.1	Anonymous	08/10/2023 6:01 AM	Protocol Description	Resolved	Modifications Required	Project detail information is required in all of these panels. In detail, expla...	
+	#1.1	Anonymous	08/10/2023 6:03 AM	Protocol Documents: Data Collection Tools	Resolved	Modifications Required	Please upload your project questionnaire in this field	

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.

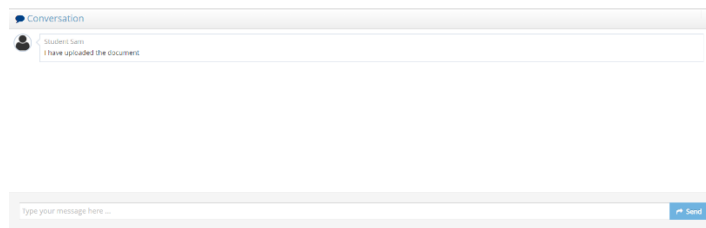
Comments ×

Filter by status ×

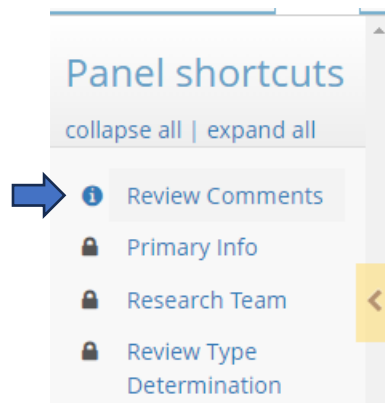
collapse rows | expand rows

#	Revision	User	Date	Section/Field	Status	Type	Comment preview	Action
1	#1.1	Anonymous	08/10/2023 6:03 AM	Protocol Documents: Data Collection Tools	Open	Modifications Required	Please upload your project questionnaire in this field	

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.

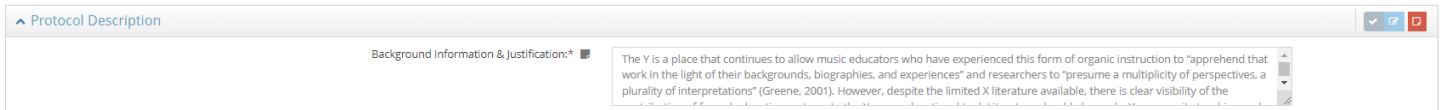


To view the additional modifications required, you can use the Panel Shortcuts to click back to the Review Comments panel, then click on the next comment.

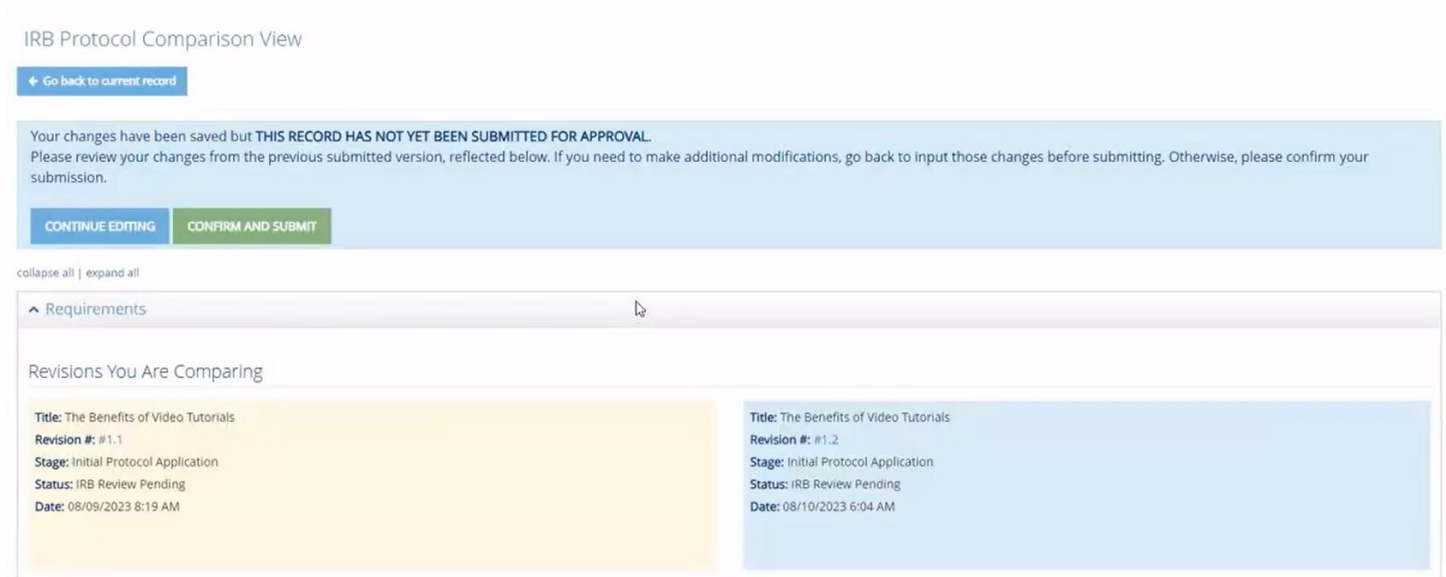


When a whole section has modifications required, the red paper icon will appear at the top right-hand corner of the panel name such as in this example for Protocol Description.

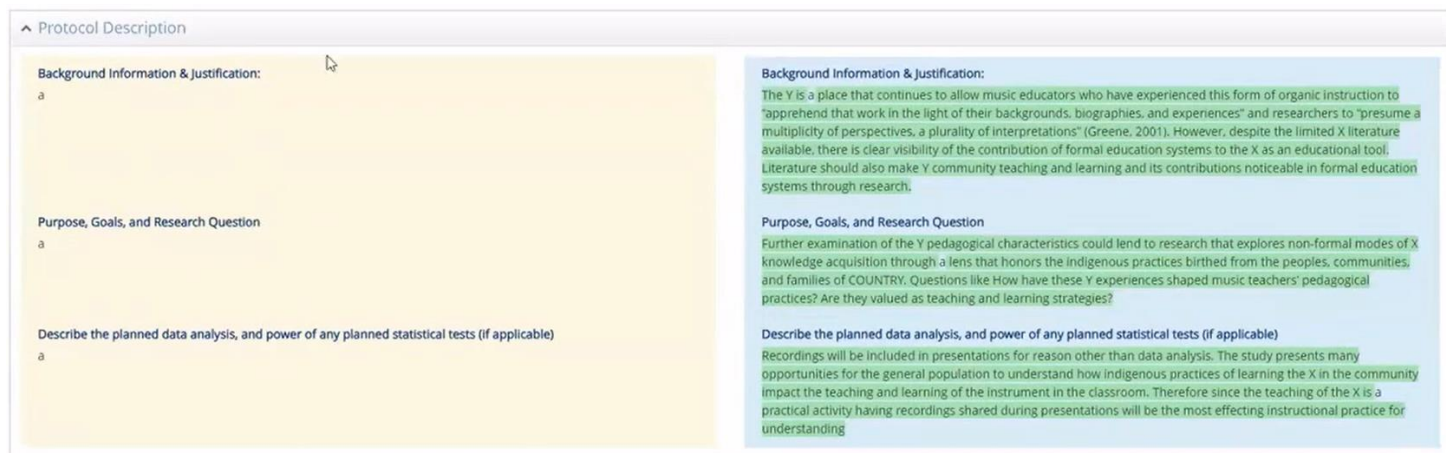
Here too, click the red paper icon to view the comment as needed, and click the table to expand the comment to view the full details.



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.

The screenshot shows the 'IRB Protocol Comparison View' interface. At the top left, there is a blue button with a left-pointing arrow and the text 'Go back to current record'. Below this is a light blue notification box containing the text: 'Your changes have been saved but **THIS RECORD HAS NOT YET BEEN SUBMITTED FOR APPROVAL.** Please review your changes from the previous submitted version, reflected below. If you need to make additional submission.' At the bottom of this notification box are two buttons: a blue button labeled 'CONTINUE EDITING' and a green button labeled 'CONFIRM AND SUBMIT'.

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.

- ✓ Application saved and submitted for approval: 08/10/2023 7:05 AM
- ✓ This task has already been completed



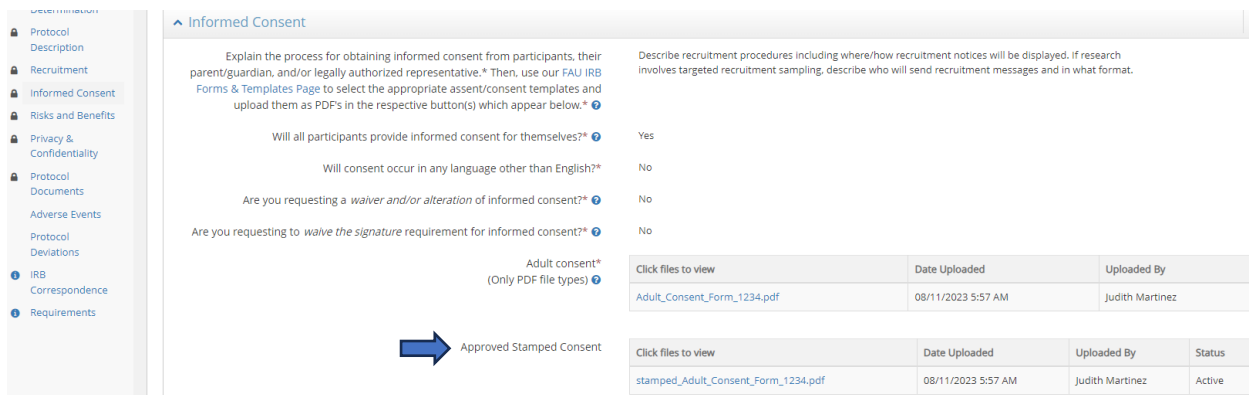
FAU IRB NOVELUTION

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



The screenshot shows the 'Informed Consent' panel with a sidebar on the left containing navigation links: Protocol Description, Recruitment, Informed Consent, Risks and Benefits, Privacy & Confidentiality, Protocol Documents, Adverse Events, Protocol Deviations, IRB Correspondence, and Requirements. The main content area includes instructions for obtaining informed consent and a form with the following questions and answers:

- Will all participants provide informed consent for themselves?* Yes
- Will consent occur in any language other than English?* No
- Are you requesting a *waiver and/or alteration* of informed consent?* No
- Are you requesting to *waive the signature* requirement for informed consent?* No

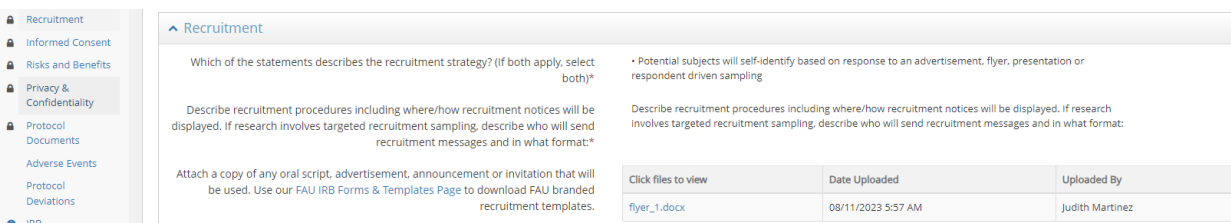
Below the form is the 'Adult consent* (Only PDF file types)' section, which contains two tables:

Click files to view	Date Uploaded	Uploaded By
Adult_Consent_Form_1234.pdf	08/11/2023 5:57 AM	Judith Martinez

Click files to view	Date Uploaded	Uploaded By	Status
stamped_Adult_Consent_Form_1234.pdf	08/11/2023 5:57 AM	Judith Martinez	Active

A blue arrow points from the text 'Approved Stamped Consent' to the second table.

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



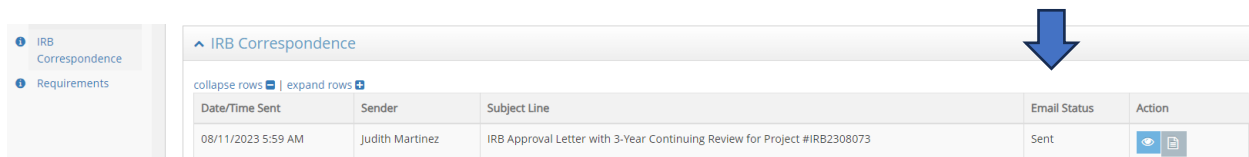
The screenshot shows the 'Recruitment' panel with a sidebar on the left containing navigation links: Recruitment, Informed Consent, Risks and Benefits, Privacy & Confidentiality, Protocol Documents, Adverse Events, Protocol Deviations, IRB, and Requirements. The main content area includes instructions for recruitment strategy and a form with the following questions and answers:

- Which of the statements describes the recruitment strategy? (if both apply, select both)*
 - Potential subjects will self-identify based on response to an advertisement, flyer, presentation or respondent driven sampling
- Describe recruitment procedures including where/how recruitment notices will be displayed. If research involves targeted recruitment sampling, describe who will send recruitment messages and in what format.*
 - Describe recruitment procedures including where/how recruitment notices will be displayed. If research involves targeted recruitment sampling, describe who will send recruitment messages and in what format.



Below the form is a table of uploaded files:

Click files to view	Date Uploaded	Uploaded By
flyer_1.docx	08/11/2023 5:57 AM	Judith Martinez

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.



The screenshot shows the 'IRB Correspondence' panel with a sidebar on the left containing navigation links: IRB Correspondence and Requirements. The main content area includes a table of correspondence items:

Date/Time Sent	Sender	Subject Line	Email Status	Action
08/11/2023 5:59 AM	Judith Martinez	IRB Approval Letter with 3-Year Continuing Review for Project #IRB2308073	Sent	 

A blue arrow points down to the 'Action' column of the table.

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:

IRB Letter Email

Choose Email Template: IRB Approval- Continuing Review (CRin3years)

Sent Date/Time: 08/11/2023 5:59 AM

To List*

Name	Role	Email	Action
PI Paula	PD/PI	FAUDemoPI@gmail.com	

Cc List*

Name	Role	Email	Action
Student Sam	Co-Investigator	faustudentresearcher@gmail.com	

Subject Line* IRB Approval Letter with 3-Year Continuing Review for Project #IRB2308073

Content* The IRB has made a decision on your project as described below.
Please log in to NoVelution <https://fau.novelution.com/wicket/bookmarkable/com.novelution.nrms.webapp.irb.EditIrBPage?id=7253> to review your stamped consent documents in the project.



Institutional Review Board
Division of Research
777 Glades Rd.
Boca Raton, FL 33431
Tel: 561.297.1383
researchintegrity@fau.edu

DATE: 08/11/2023
TO: PI Paula
FROM: Florida Atlantic University IRB
PROTOCOL #: IRB2308073
PROTOCOL TITLE: The Benefits of Video Tutorials
SUBMISSION TYPE: Initial Protocol Application
ACTION: APPROVED
APPROVAL DATE: 08/11/2023

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

IRB Letter Email

end approval date if this project will continue beyond this date.

- This study is approved for a maximum of 50 subjects.
- It is important that you use the approved, stamped consent documents or procedures listed below:
 - Adult_Consent_Form_1234.pdf
- This project has been approved for Waiver of Informed Consent under the provisions of 45CFR46.116(f)(3) Or
 - Waiver of Documentation of Informed Consent under the provisions of 45CFR46.117(c)(1) And/ Or
 - Full/ Partial Waiver of HIPAA Authorization under the provisions of 45CFR164.512(g)(1)(i).
- Any revision to previously approved materials or procedures, including modifications to numbers of subjects, must be approved by the IRB before it is initiated.
- All SERIOUS and UNEXPECTED adverse events or unanticipated problems must be reported to this office. Use the Promptly Reportable Information Form (PRIF) for this procedure. All regulatory and sponsor reporting requirements should also be followed, as applicable.
- Report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.
- Note that all research should be retained for a minimum of three years after completion of the research. Research records involving protected health information (PHI) must be retained for a minimum of six years. Refer to the Division of Research Policies on "Closing an IRB Approved Study" for more information.
- Submit an IRB final report when the study is completed or discontinued.

If you have any questions, contact Judith Martinez at martinezj2012@fau.edu.
Include your protocol number and title in all correspondence with this office.

Do you want to create an attachment template? Yes

Upload Attachments

Click files to view	Date Uploaded	Uploaded By
IRB Approval Letter with 3-Year Continuing Review for Project #\$(IRB_ProtocolNu...	08/11/2023 5:59 AM	Judith Martinez

Email Status Sent

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

IRB2308073 : PI Paula - Novelution 101 Workshop: IRB Decision Docs



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

IRB2308073 : PI Paula - Novelution 101 Workshop: IRB Decision Docs



Review Type	Stage	Status	End Approval Date	Informed Consent
Expedited	Amendment	Approved	08/10/2024	stamped_Adult_Consent_Form_1234.pdf Adult_Consent_Form_1234.pdf

Home > IRB > Edit IRB Protocol

New Amendment or Continuing Review

Request to change or renew your protocol.

[Request](#)

Copy Protocol

Make a copy of this protocol into a new protocol.

[Copy](#)

Initiate Closure

Submit a request to close this protocol.

[Close](#)

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.

IRB2308076 : Ruby Researcher - Reviewing Projects in the Novelution Era

Review Type	Stage	Status	End Approval Date	Informed Consent
Expedited	Amendment	Approved	N/A	Adult_Consent_Form_12345_(3).pdf EmailDistribution_6372_89_4457.pdf

[Home](#) > [IRB](#) > Edit IRB Protocol

New Amendment or Continuing Review

Request to change or renew your protocol.

[Request](#)

Copy Protocol

Make a copy of this protocol into a new protocol.

[Copy](#)

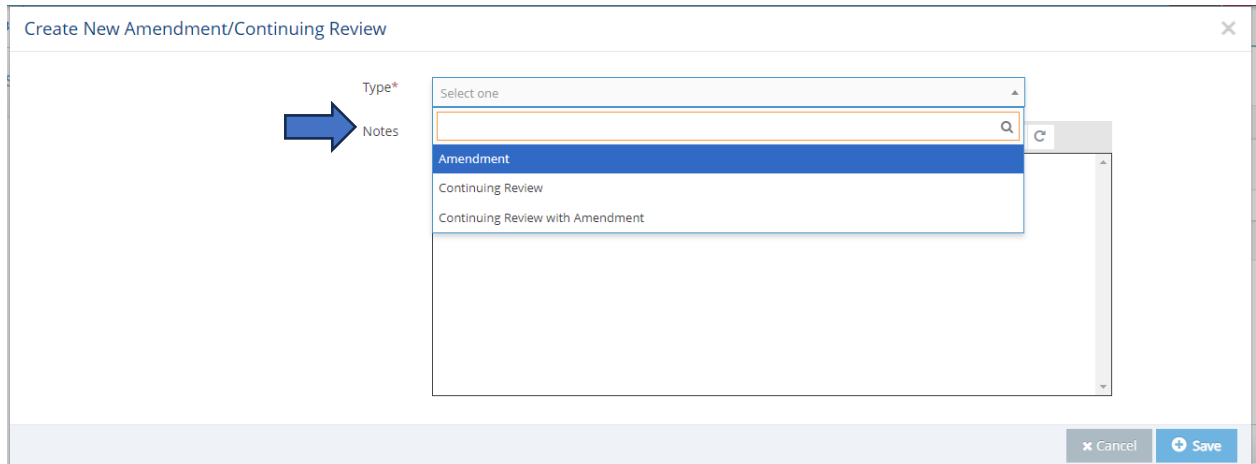
Initiate Closure

Submit a request to close this protocol.

[Close](#)

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

Select Amendment as the Type



Create New Amendment/Continuing Review

Type*

Notes

- Amendment
- Continuing Review
- Continuing Review with Amendment

[Cancel](#) [Save](#)

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.

Create New Amendment/Continuing Review

Type*

What types of modifications are you requesting? Choose all that apply.*

Provide a brief description of any revisions being requested.*

- Principal Investigator
- Research Team
- Funding Source
- Study Design, Methods, or Procedures
- Research Instruments (e.g. Questionnaires)
- Recruitment Procedures or Materials

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

Create New Amendment/Continuing Review

Type*

What types of modifications are you requesting? Choose all that apply.*

Research Team Study Design, Methods, or Procedures

Provide a brief description of any revisions being requested.*

Describe changes here

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.

Review Type Determination

Protocol Description

Recruitment

Informed Consent

Risks and Benefits

Privacy & Confidentiality

Protocol Documents

Continuing Review

Adverse Events

Protocol Deviations

Reviewers

IRB

Correspondence

Protocol Description

Background Information & Justification:*

Purpose, Goals, and Research Question*
 Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.*

Will the research involve secondary use of data, documents, records or biospecimens collected from individuals? Yes No

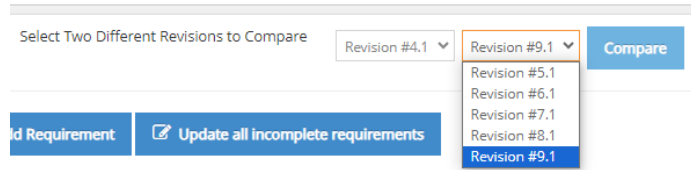
Describe any online/electronic resources be utilized for recruitment, data collection, or storage*
 Individuals must meet all of the inclusion criteria in order to be eligible to participate in the study as stated above. This information will be verified when participants submissions are received during the recruitment period.

The Y is a place that continues to allow music educators who have experienced this form of organic instruction to "apprehend that work in the light of their backgrounds, biographies, and experiences" and researchers to "presume a multiplicity of

Data collection for this study will consist of four sources: demographic questionnaire, interviews, curriculum/lesson plans, and zoom video recordings. In the following paragraphs, I will explain the data collection procedure and use of each data source.

this interview protocol will be informed by the data collected during the teaching of the classes. The data from this exercise will contribute to answering research question one.

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.

Requirements

Select Two Different Revisions to Compare: Revision #4.1, Revision #5.1, Compare

[Edit Stage/Status](#)
[Add Requirement](#)
[Update all incomplete requirements](#)

[Data Snapshot](#)

Showing 6 to 9 of 9 stages.

Stage - Revision #	Created	Current Status	Status Date	Approval Date	Requested modifications	Notes
Amendment - revision #4.1	08/11/2023 10:34 AM	Approved	08/11/2023 10:37 AM		Study Design, Methods, or Procedures	Adding video recordings
Amendment - revision #3.1	08/11/2023 10:22 AM	Approved	08/11/2023 10:27 AM		Study Design, Methods, or Procedures	Adding audio recordings
Amendment - revision #2.1	08/11/2023 9:15 AM	Approved	08/11/2023 9:57 AM		Study Design, Methods, or Procedures Research Instruments (e.g. Questionnaires)	Adding research procedure, new recruitment flyer
Initial Protocol Application - revision #1.3	08/11/2023 6:34 AM	Approved	08/11/2023 9:03 AM			Automatically created after Judith Martinez specified modifications are required

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.

IRB Protocol Comparison View

[Go back to current record](#)

Your changes have been saved but **THIS RECORD HAS NOT YET BEEN SUBMITTED FOR APPROVAL**. Please review your changes from the previous submitted version, reflected below. If you need to make additional modifications, go back to input those changes before submitting. Otherwise, please confirm your submission.

[CONTINUE EDITING](#)
[CONFIRM AND SUBMIT](#)

collapse all | expand all

Requirements

Revisions You Are Comparing

<p>Title: Reviewing Projects in the Novelation Era</p> <p>Revision #: #4.1</p> <p>Stage: Amendment</p> <p>Status: Approved</p> <p>Date: 08/11/2023 10:37 AM</p>	<p>Title: Reviewing Projects in the Novelation Era</p> <p>Revision #: #5.1</p> <p>Stage: Amendment</p> <p>Status: Draft Submission Pending</p> <p>Date: 08/11/2023 10:39 AM</p>
---	---

Protocol Description

<p>Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.</p> <p>This methodology consists of the transcription of the interviews, the coding of emerging data as it is collected, the use of the comparative method, the formation of categories, significance given to common and frequent categories, and finally, the generation of themes. All data gathered from research participants will pertain to the study.</p>	<p>Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.</p> <p>4. Interviews: Two semi-structured one-to-one interviews will be held with the three participants via zoom for a minimum of 60 minutes each. The first interview will be held in Aug-Sept 2024 and will focus on participants' Y-based experiences and the impact on their research participation. Participants may be asked to provide feedback on their research participation and the impact on their research participation.</p>
---	---

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.

IRB2308076 : Ruby Researcher - Reviewing Projects in the Novelution Era

Review Type	Stage	Status	End Approval Date	Informed Consent
Expedited	Amendment	Approved	N/A	Adult_Consent_Form_12345_(3).pdf EmailDistribution_6372_89_4457.pdf

[Home](#) > [IRB](#) > Edit IRB Protocol

New Amendment or Continuing Review

Request to change or renew your protocol.

[Request](#)

Copy Protocol

Make a copy of this protocol into a new protocol.

[Copy](#)

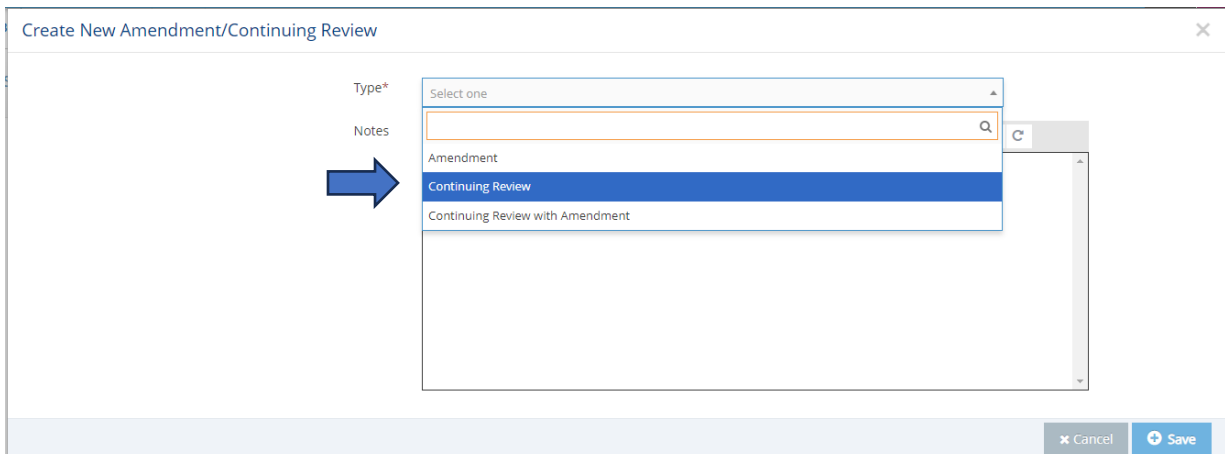
Initiate Closure

Submit a request to close this protocol.

[Close](#)

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.



Create New Amendment/Continuing Review

Type*

Notes

Amendment

Continuing Review

Continuing Review with Amendment

[Cancel](#) [Save](#)

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

The screenshot shows a web form titled "Create New Amendment/Continuing Review". The "Type*" field is a dropdown menu that is currently open, displaying three options: "Amendment", "Continuing Review", and "Continuing Review with Amendment". A blue arrow points to the "Continuing Review with Amendment" option, which is highlighted in blue. The "Notes" field is empty. At the bottom right, there are "Cancel" and "Save" buttons.

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.

The screenshot shows the same web form. The "Type*" dropdown is now set to "Continuing Review with Amendment". Below it, a light blue box contains the text "The following must be current alongside the continuing review:" followed by a bulleted list: "Any needed amendments including changes to consent forms", "[Adverse Events / Unanticipated Problem](#)", and "Protocol Deviations". The "What types of modifications are you requesting? Choose all that apply.*" dropdown is open, showing a list of options: "Principal Investigator", "Research Team", "Funding Source", "Study Design, Methods, or Procedures", "Research Instruments (e.g. Questionnaires)", and "Recruitment Procedures or Materials". The "Recruitment Procedures or Materials" option is highlighted in blue. The "Provide a brief description of any revisions being requested.*" field is empty. At the bottom right, there are "Cancel" and "Save" buttons.

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

Create New Amendment/Continuing Review ✕

The following must be current alongside the continuing review:

- Any needed amendments including changes to consent forms
- [Adverse Events / Unanticipated Problem](#)
- Protocol Deviations

Type*

What types of modifications are you requesting? Choose all that apply.*

Provide a brief description of any revisions being requested.*

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

[Home](#) > [IRB](#) > Edit IRB Protocol

<p>Update Protocol</p> <p>Edit Amendment/Continuing Review Type.</p> <p style="text-align: right;"><input type="button" value="Edit"/></p>	<p>Copy Protocol</p> <p>Make a copy of this protocol into a new protocol.</p> <p style="text-align: right;"><input type="button" value="Copy"/></p>
---	--

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

Continuing Review

I. Project Status

1. Expected End Date of Research

2. Current research procedures involve*

- Recruiting participants
- Providing research intervention(s)
- Ongoing data collection
- Ongoing analysis of identifiable data
- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

II. Project Summary

1. Brief summary of the progress of the research to date*

2. Are any of the research procedures or conditions no longer active, i.e., have portions of the study been completed?* Yes No

3. List presentations or publications that have resulted from this research since the last review.

A. Participants

Total Enrollments

Approved Enrollment: 0

Stage	Submission Date	Enrolled Since Last Report	Total Enrollment
Total Enrollment thus far*	<input type="text"/>	<input type="text"/>	0

If enrollment numbers are lower than anticipated, please explain why:

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.

Investigator's Assurance

As the Principal Investigator, I certify that:

- Information provided in this report is complete and accurate
- Each individual involved as a member of the research team is currently listed on the protocol and possesses the necessary experience for conducting research activities in their assigned role, and is aware of and will abide by FAU policies and procedures for the protection of research participants
- The research will be conducted according to the approved protocol
- IRB approval will be obtained prior to implementing changes in the research protocol, unless necessary to prevent immediate serious harm to participants
- All unanticipated problems involving risks to participants or others will be promptly reported to the IRB.

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.

Review Type Determination

- Protocol Description
- Recruitment
- Informed Consent
- Risks and Benefits
- Privacy & Confidentiality
- Protocol Documents
- Continuing Review
- Adverse Events
- Protocol Deviations
- Reviewers
- IRB Correspondence

Protocol Description

Background Information & Justification:*

Purpose, Goals, and Research Question*

Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.*

Will the research involve secondary use of data, documents, records or biospecimens collected from individuals?*

Describe any online/electronic resources be utilized for recruitment, data collection, or storage*

The Y is a place that continues to allow music educators who have experienced this form of organic instruction to "apprehend that work in the light of their backgrounds, biographies, and experiences" and researchers to "presume a multiplicity of

Data collection for this study will consist of four sources: demographic questionnaire, interviews, curriculum/lesson plans, and zoom video recordings. In the following paragraphs, I will explain the data collection procedure and use of each data source.

this interview protocol will be informed by the data collected during the teaching of the classes. The data from this exercise will contribute to answering research question one.

Yes No

Individuals must meet all of the inclusion criteria in order to be eligible to participate in the study as stated above. This information will be verified when participants submissions are received during the recruitment period.

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

Select Two Different Revisions to Compare

Revision #4.1 Revision #9.1

Revision #5.1
Revision #6.1
Revision #7.1
Revision #8.1
Revision #9.1

You can also see previous submissions you have made.

Requirements

Select Two Different Revisions to Compare

Revision #4.1 Revision #5.1

Showing 6 to 9 of 9 stages.

Stage - Revision #	Created	Current Status	Status Date	Approval Date	Requested modifications	Notes
Amendment - revision #4.1	08/11/2023 10:34 AM	Approved	08/11/2023 10:37 AM		Study Design, Methods, or Procedures	Adding video recordings
Amendment - revision #3.1	08/11/2023 10:22 AM	Approved	08/11/2023 10:27 AM		Study Design, Methods, or Procedures	Adding audio recordings
Amendment - revision #2.1	08/11/2023 9:15 AM	Approved	08/11/2023 9:57 AM		Study Design, Methods, or Procedures Research Instruments (e.g. Questionnaires)	Adding research procedure, new recruitment flyer
Initial Protocol Application - revision #1.3	08/11/2023 6:34 AM	Approved	08/11/2023 9:03 AM			Automatically created after Judith Martinez specified modifications are required

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.

IRB Protocol Comparison View

[Go back to current record](#)

Your changes have been saved but **THIS RECORD HAS NOT YET BEEN SUBMITTED FOR APPROVAL.**
Please review your changes from the previous submitted version, reflected below. If you need to make additional modifications, go back to input those changes before submitting. Otherwise, please confirm your submission.

[CONTINUE EDITING](#)

[CONFIRM AND SUBMIT](#)

collapse all | expand all

Requirements

Revisions You Are Comparing

Title: Reviewing Projects in the Novelation Era

Revision #: #4.1

Stage: Amendment

Status: Approved

Date: 08/11/2023 10:37 AM

Title: Reviewing Projects in the Novelation Era

Revision #: #5.1

Stage: Amendment

Status: Draft Submission Pending

Date: 08/11/2023 10:39 AM

Protocol Description

Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.

This methodology consists of the transcription of the interviews; the coding of emerging data as it is collected; the use of the comparative method; the formation of categories; significance given to common and frequent categories; and finally, the generation of themes. All data gathered from research participants will pertain to the study.

Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them.

4. Interviews: Two semi-structured one-to-one interviews will be held with the three participants via zoom for a minimum of 60 minutes each. The first interview will be held in Aug-Sept 2023 and will focus on participants' y-based experiences and the impact on their professional development from attending the conference.

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”




Create IRB Protocol

Get Started

Principal Investigator*  DemoUser, PI 

Department* DOR: Research Integrity 
Division of Research > DOR: Research Integrity

IRB Protocol Title* Guidance for the Transition to Novelution
159 remaining

Lay Summary  Resources will be developed to assist the FAU community in how to navigate and submit using the new Novelution submission system

[Continue](#)

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.

Primary Info

Protocol Number IRB2307024

IRB Protocol Title* Guidance for the Transition to Novelution

159 remaining

Lay Summary* Resources will be developed to assist the FAU community in how to navigate and submit using the new Novelution submission system

Is this a student project?* Yes No

Type of project* Select one

- Independent Study
- Thesis
- Dissertation
- Other student research

Indicate if any part of your project is funded by an external sponsor*

Research Team

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.

Primary Info

IRB Administrator: Martinez, Judith

Protocol Number: IRB2308076

IRB Study Title*: Reviewing Projects in the Novelution Era

160 remaining

Summary of the study using lay language (200 words or less): Demonstrating how reviewers conduct reviews for IRB in Novelution

Is this a student project? Note: If you are the degree-seeking student, you cannot also be the PI* Yes No

SAVE REVIEW AND SUBMIT Check Validations

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).

x 'Type of project' is required

collapse all | expand all

Primary Info

Protocol Number: IRB2308072

IRB Study Title*: Project title here

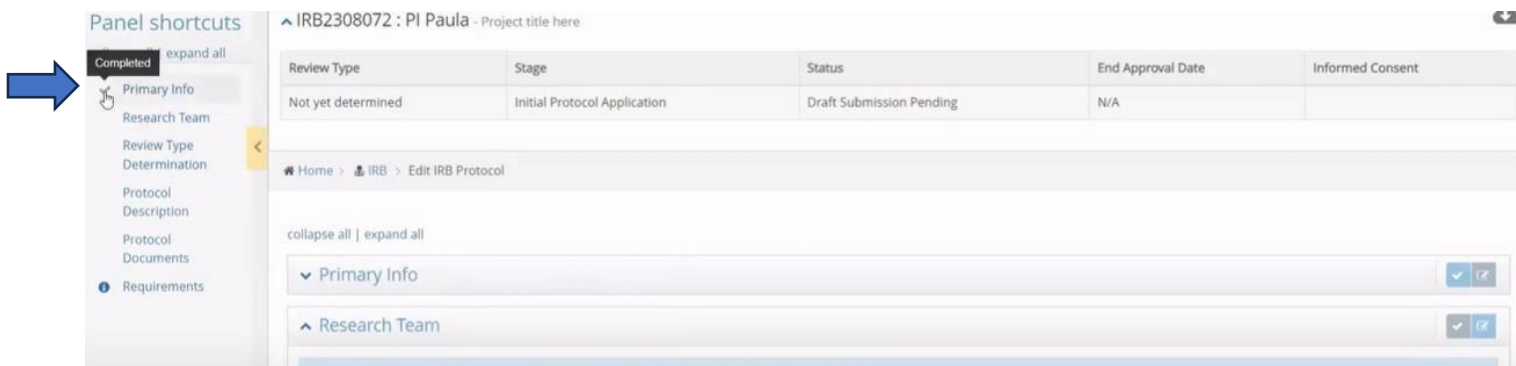
182 remaining

Summary of the study using lay language (200 words or less): Summary

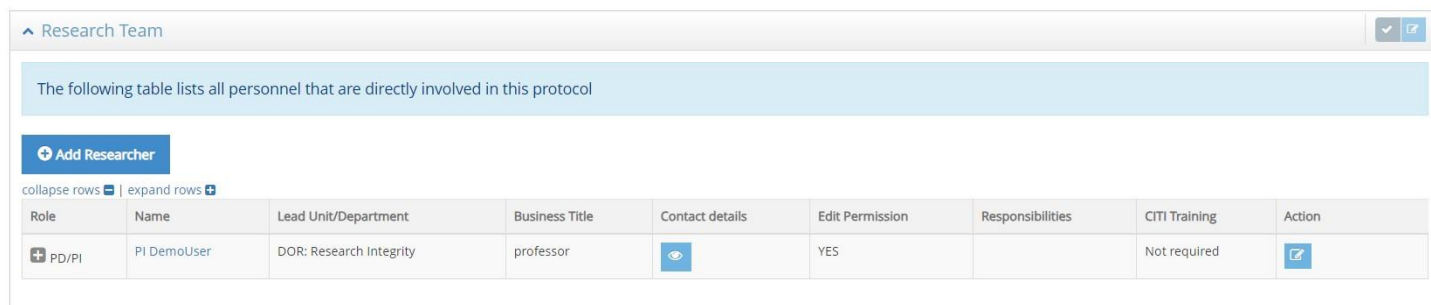
Errors

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.

Add Researcher

Researcher* Researcher, Ruby

Cannot find a researcher. Do you want to add a student or an external user?

Project Role* Graduate Student

Give permission to make edits to this project

Responsibilities (select all that apply)* Consent Subjects Recruit Subjects

Highest Earned Degree

Field of Study

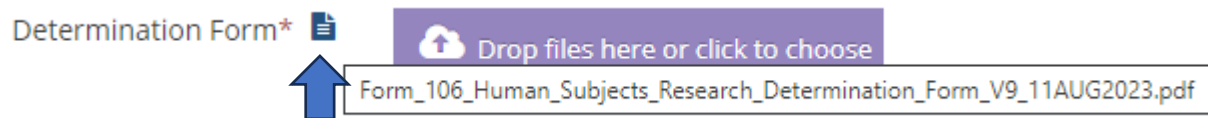
Cancel Save

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

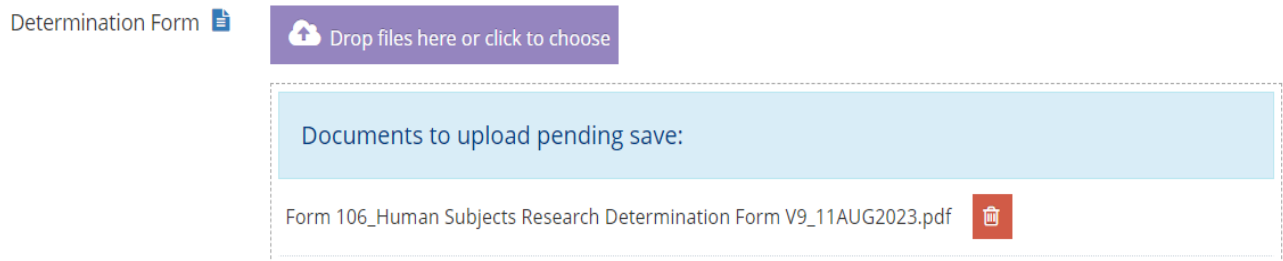
In the Review Type Determination panel select yes to the question “Are you requesting a determination of whether your project requires IRB review or for verification of IRB submission for a sponsor, journal, or other entity?”

The screenshot shows a panel titled "Review Type Determination". At the top, there is a light blue banner with the text: "For any required documents, please verify that you have the latest version. You can download the latest version by clicking on the document icon: [document icon]". Below this, the section is titled "Determination of Human Subjects Research". It contains a question: "Are you requesting a determination of whether your project requires IRB review or for verification of IRB submission for a sponsor, journal, other entity?*" with radio buttons for "Yes" (selected) and "No". Below the question is a label "Determination Form*" with a document icon and a purple button that says "Drop files here or click to choose". At the bottom of the panel, there are two options: "Auto-determined Review Type" and "Pre-Review".

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



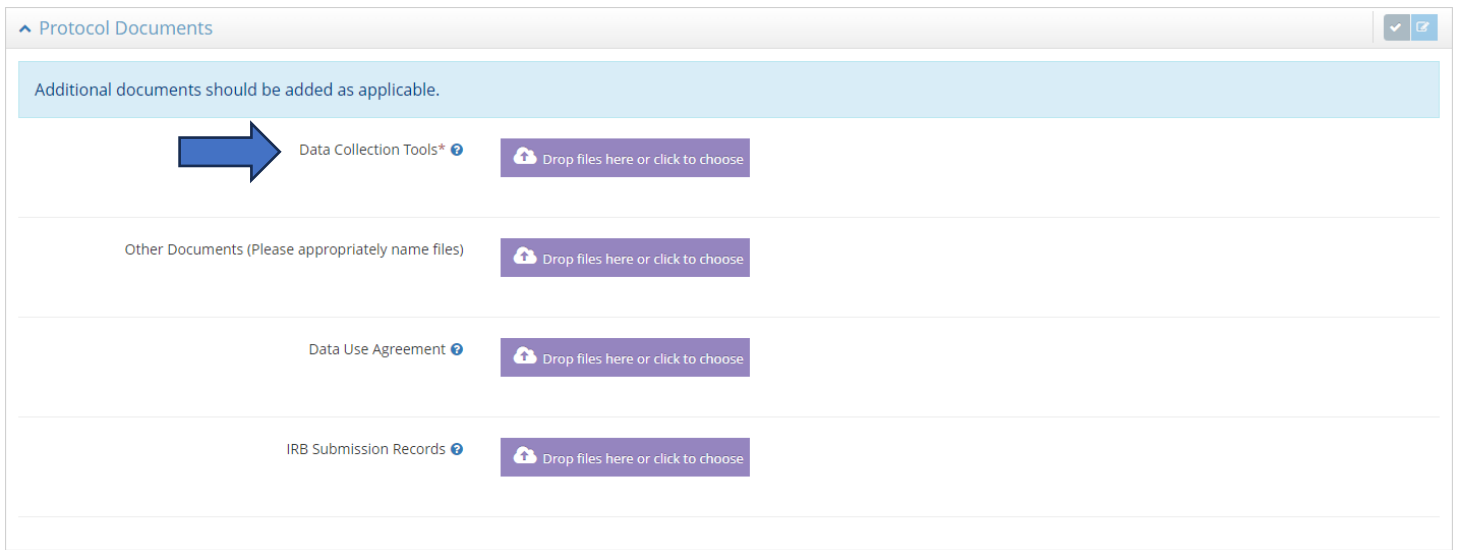
Fill out Form 106 and save the form to your computer, then return to Novelution to upload your completed form in Novelution using the button



Complete the fields in the Protocol Description panel


The screenshot shows a panel titled "Protocol Description". It contains four text input fields. The first is labeled "Background Information & Justification:*". The second is labeled "Purpose, Goals, and Research Question*". The third is labeled "Anticipated Start date of the research*" and includes a calendar icon. The fourth is labeled "Describe the planned data analysis, and power of any planned statistical tests (if applicable)*".


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





Protocol Documents

Additional documents should be added as applicable.

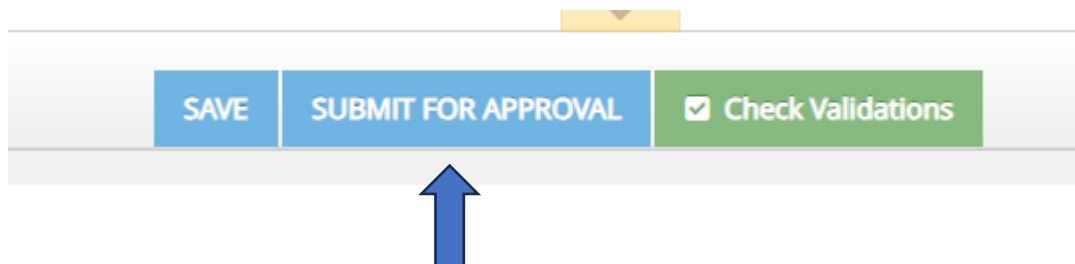
Data Collection Tools*  Drop files here or click to choose

Other Documents (Please appropriately name files)  Drop files here or click to choose

Data Use Agreement  Drop files here or click to choose

IRB Submission Records  Drop files here or click to choose

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



SAVE SUBMIT FOR APPROVAL Check Validations

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

