

FAU IRB NOVELUTION

Creating a New Project



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

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 tabs for Profile & Settings, IRB, IACUC, Grants & Contracts, and FCOI. A user notification area on the right shows 'Welcome, PI DemoUser'. Below the navigation bar, a 'Panel shortcuts' sidebar is visible on the left. The main content area features a 'Project Details' box at the top, which is highlighted with a blue border. 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 Project Details box, the 'Primary Info' section is visible, containing the following fields:

- Protocol Number: IRB2307024
- IRB Protocol Title*: Guidance for the Transition to Novelation (159 remaining)
- Lay Summary: Resources will be developed to assist the FAU community in how to navigate and submit using the new Novolution submission system
- Is this a student project?: Yes No
- Indicate if any part of your project is funded by an external sponsor*: Funded/Pending Proposal Not Funded

At the bottom of the form, there are three buttons: '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

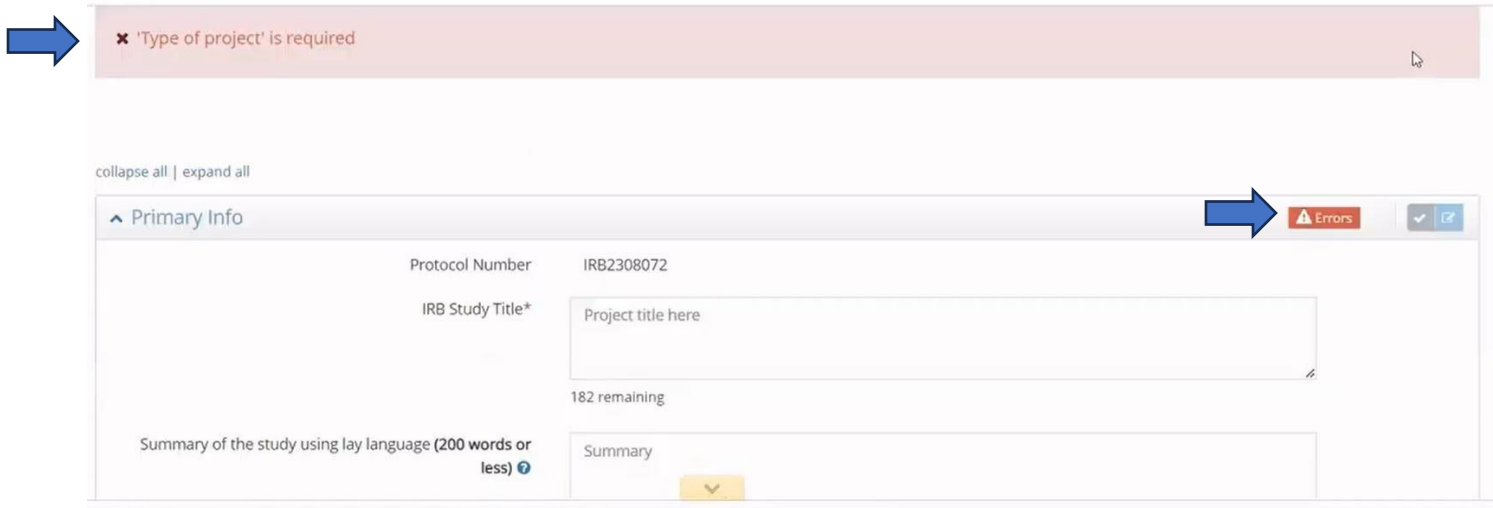
Summary of the study using lay language (200 words or less)*
Demonstrating how reviewers conduct reviews for IRB in Novelution

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

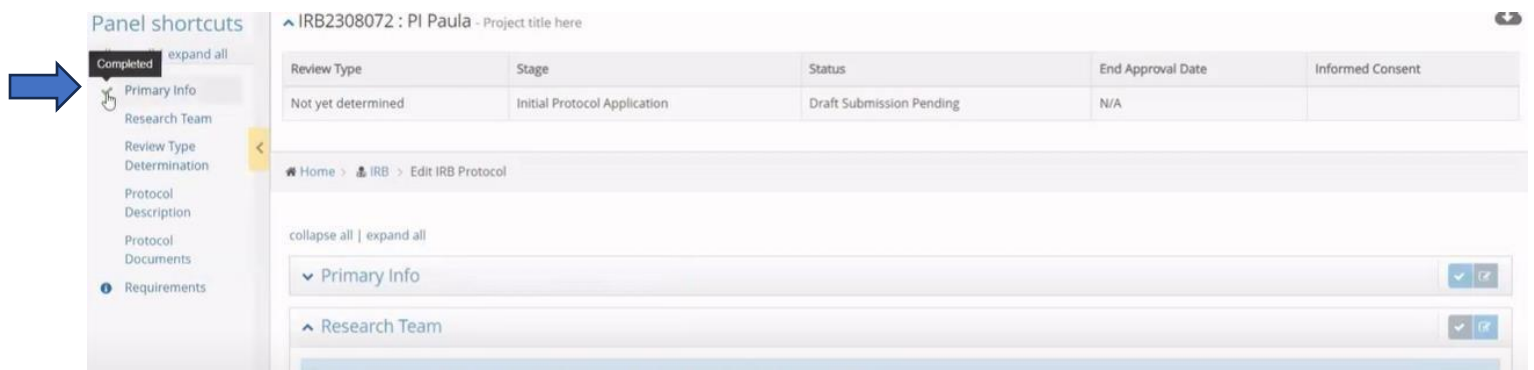
If any required fields are missing, you'll see an "Errors" box appears in the panel header and a red box appears up at the top listing the required field that is missing. You can click that link to be taken directly to the field to fill in your response(s).



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 fields for "Protocol Number" (IRB2308072), "IRB Study Title*" (with a placeholder "Project title here" and "182 remaining" characters), and "Summary of the study using lay language (200 words or less)". A blue arrow points to a red "Errors" button in the top right corner of the panel, which also contains a checkmark and a refresh icon.

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 main content area shows 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 is a breadcrumb trail: "Home > IRB > Edit IRB Protocol". At the bottom, there are two expandable panels: "Primary Info" (collapsed) and "Research Team" (expanded). A blue arrow points to a checkmark icon in the top right corner of the "Primary Info" panel header.

Research Team

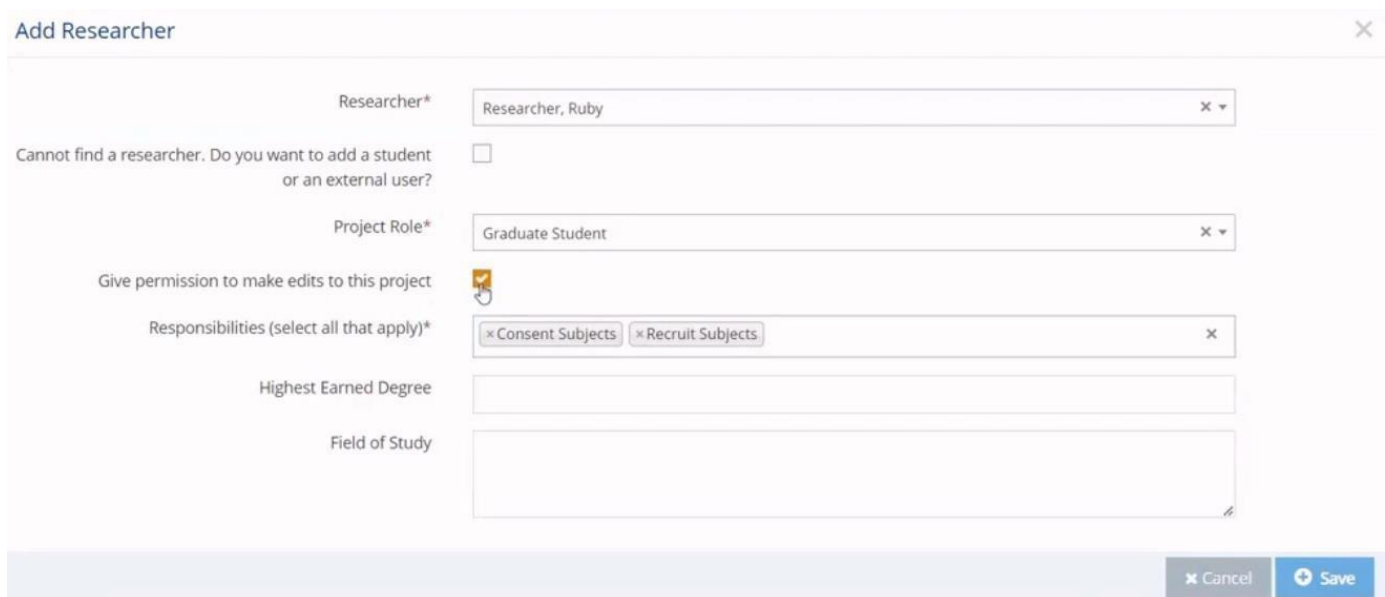
Click the button to Add Researcher. You can add as many researchers as needed.



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

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 as the top image, including the question 'Do any of the following apply to your project?' and the list of categories. The 'Category 1' checkbox is checked, and a yellow circle highlights it.

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 PDFs 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.*

Will any protected health information (PHI) be collected or obtained?* [?](#) Yes No

Protocol Documents

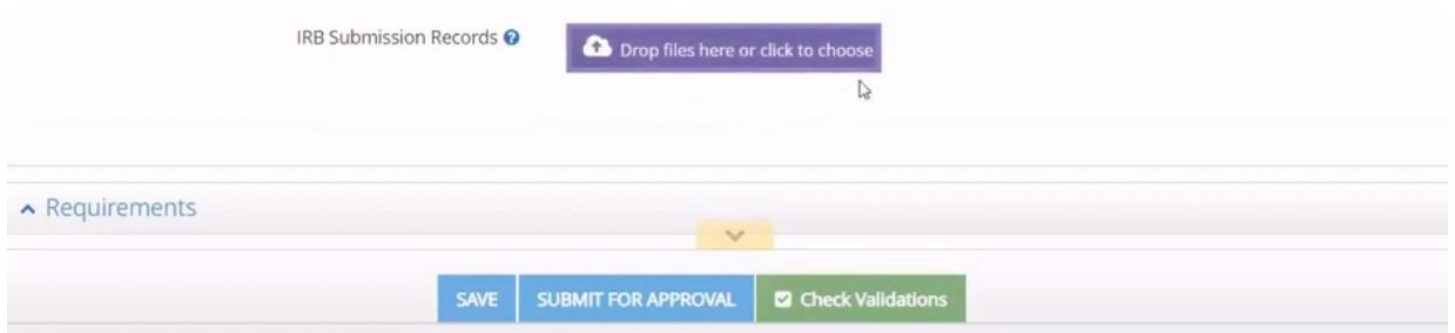
This is the third panel with optional uploads, however there is a required upload for “Data Collection Tools”. This can include your questionnaires, interview materials, and so on.

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 to its right. 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. A table at the top displays the current status: Review Type (Exempt), Stage (Initial Protocol Application), Status (Draft Submission Pending), End Approval Date (N/A), and Informed Consent. Below the table, 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." A red box contains 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, there are buttons for "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 at the top now displays: Review Type (Pre-Review), Stage (Initial Protocol Application), and Status (PI Certification Pending). Below the table, a green notification bar states: "Application saved and submitted for approval: 08/08/2023 8:20 AM".