

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](#)

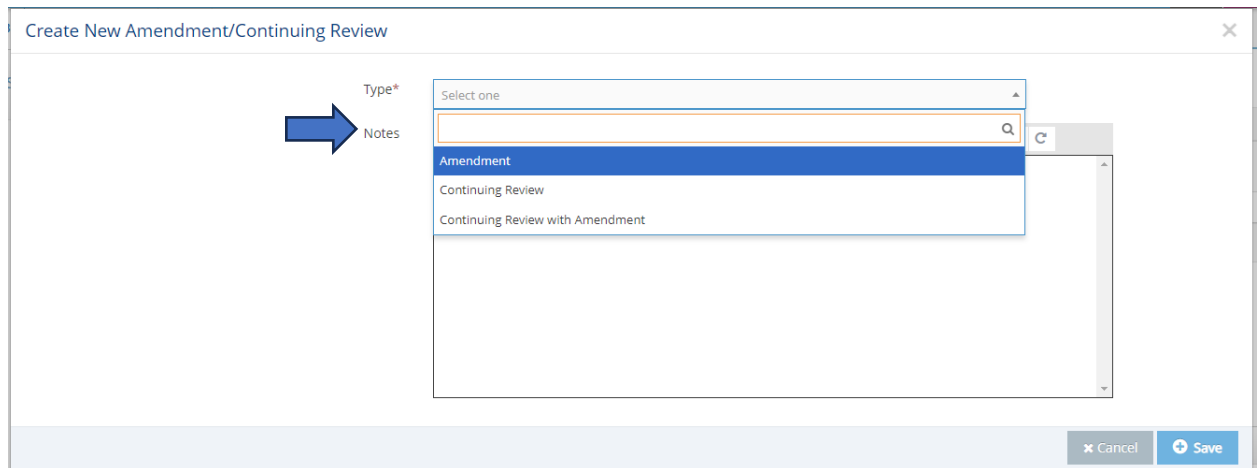
Initiate Closure

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* Amendment

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

Cancel Save

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

Create New Amendment/Continuing Review

Type* Amendment

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

Provide a brief description of any revisions being requested.*

Describe changes here

Cancel Save

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

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

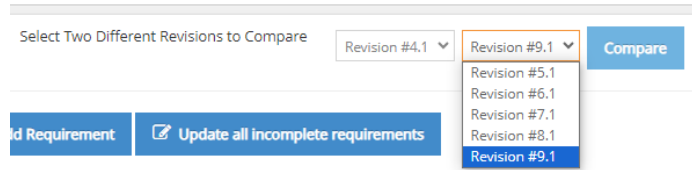
Background Information & Justification:*

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.

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

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 2024 and will focus on participants' y-based experiences and the impact on their research participation health outcomes. This research is...

Click to Confirm and Submit

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