Institutional Review Board
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UMD Kuali-IRB: Guide to Submitting an Amendment

Human Research Protection Office

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Purpose

The purpose of this guide is to provide instructions on how to submit an amendment for an IRB Protocol in Kuali-IRB.

The Structure of an IRB Application - IRB Protocol & Amendment

The Kuali-IRB platform includes multiple forms, each serving a different purpose. The IRB Application Form is specifically for submitting and amending IRB Protocols, requesting a human subjects research determination of a project, and requesting a 118 Letter.

IRB Application Versions

The first version of an IRB Protocol is similar to an initial application that would be submitted on IRBNet. Following the initial approval, the IRB Protocol can be amended to make changes. To submit an amendment to the IRB Protocol, researchers must create a new version of the IRB Application Form.

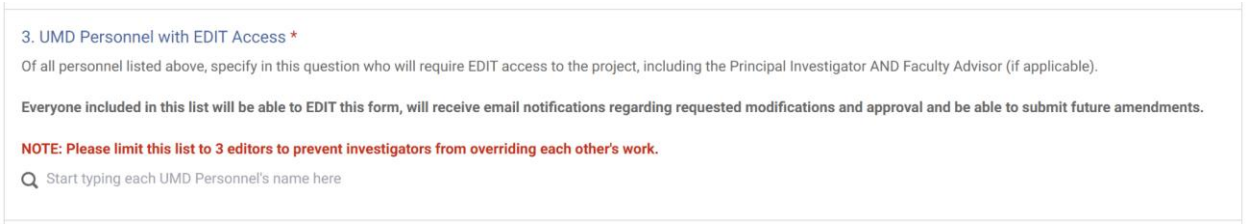
Who can create an Amendment?

Only those who are given 'Edit Access' can initiate an Amendment for the IRB Protocol. 'Edit Access' will have been shared with the Principal Investigator and Faculty Advisor (if applicable) during the initial submission of the IRB Protocol.

To check who has been given Edit Access, open the IRB Application via the Document List. Scroll down to the 'Key Personnel' section of the Form. Investigators listed in the '3. UMD Personnel with EDIT Access' field will have the ability to create an Amendment.

Who can work on the Amendment?

The Kuali-IRB platform allows for collaborative editing of the IRB Forms. Each IRB Form has a field where researchers can share 'Edit Access' to the form. Only users with 'Edit Access' to the IRB Form will be able to edit the form. The field looks like this:



!!Only those listed in this field will be able to edit the IRB Application while it is in Draft form and when the IRB Form is returned for researcher revisions.

When working on a draft, researchers can edit this field and click 'Save'. After saving, those in the updated Edit Access list can begin editing the form in Draft. They will be able to access the draft by visiting their "Document List" on Kuali.

!!It is crucial that only one person edits the IRB Form at any given time to prevent the risk of overriding each other's responses. Please coordinate with those who have edit access to manage and limit editing to one individual at a time.

The Amendment Application

To submit an amendment to an IRB-approved IRB Protocol, you must create a new version of the IRB Protocol and complete the Amendment Application that will open in the new version. The Amendment Application is a section within the IRB Protocol in which you can describe the changes and their purpose.

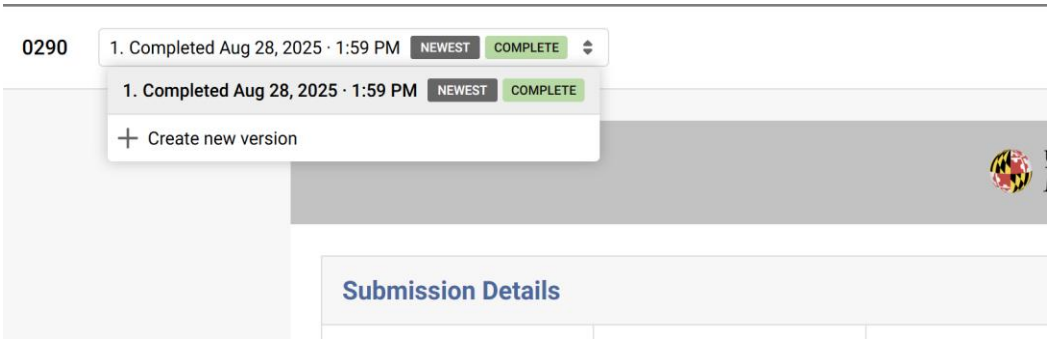
Questions in the Amendment Application

1. **Current Research Participant Enrollment Status** (Multiple Choice) - indicate whether the study is currently enrolling participants.
2. **Current Research Activity** (Multiple Choice) - indicate whether the research activities have begun
3. **Amendment Scope** (Checkbox) - indicate the type of changes being made to the IRB Protocol
4. **Describe and Provide Rationale for the Amendment Scope** (Text Box) - detail the changes being made and the purpose for them
5. **Will the Changes Require Re-Consent and Describe** (Multiple Choice + Text Box) - indicate whether the changes will require re-consent and describe why or why not
6. **Indicate Whether the Changes Impact Study Risks and Describe** (Multiple Choice + Text Box) - indicate whether there is an impact on study risks and if so, describe the impact.
7. **Indicate Whether the Changes Impact the Scientific Integrity of the Study and Describe** (Multiple Choice + Text Box) - indicate whether there is an impact on the scientific integrity of the study, and describe the impact (or lack thereof).

How to Create + Submit an Amendment

Link to Kuali-IRB: https://go.umd.edu/kuali-irb

Step 1: To create a new document version in Kuali, locate the IRB Application you wish to amend, open it, then find the Version Dropdown in the upper left-hand corner and select "+Create New Version".



> **Note:** A new version can only be created if the existing versions are "Complete". New versions cannot be created if there is a version marked as "In Progress" or "Draft".

After clicking "Create New Version," a new draft of the IRB Application will be created, including all the completed fields from the previous submission. In the new version, a new **Amendment Application** section will be included.

Step 2: Complete the Amendment Application as it applies to the changes being requested in this amendment.

Step 3: Once the Amendment Application is complete, continue to the following pages of the IRB Application and edit each section as needed.

> **!!Be sure that ALL changes made in the IRB Protocol are clearly detailed in the Amendment Application. Failure to do so will result in a delay in the IRB Review of the amendment.**

Step 4: Submit the IRB Application for review.

Step 5: If the submitter of the Amendment is not the Principal Investigator (PI) of the project, the PI will receive an email from Kuali requesting a review of the submission. The PI can make direct edits to the application. Once they are satisfied with the submission, they should click 'Approve' to move forward.

Step 6: The IRB Office will review the submission. If modifications are needed to the submission, the researchers given "Edit Access" will receive an email from Kuali IRB to make the necessary changes.

Step 7: Once the IRB Review is complete, researchers will receive a notification of the review outcome.

Scribe: [How to Submit an Amendment to the IRB Protocol]

Amending the IRB Protocol

The changes made to the IRB Protocol must be described in the Amendment Application. Failure to do so will result in a delay in IRB Review.

How to Update the IRB Protocol

Simply edit the contents of a text box or change the multiple-choice or checkbox selection. The IRB Protocol is a live form that you can update as needed.

How to Upload a New File

If the amendment involves updating an existing file or uploading a new file, find the appropriate IRB Protocol section to upload the file.

If you are revising a previously approved document, you must REPLACE any files that are being updated as part of the amendment. To do so, select the trash can icon within the file upload to delete the file and upload the new copy by clicking “+ Add Another Row”.

If you are only ADDING NEW DOCUMENTS, do not remove previously approved ones from the submission. Click "+ Add Another Row" to add a new document.

What Needs to be Changed in the Protocol & What Does NOT Need to be Changed

Change:

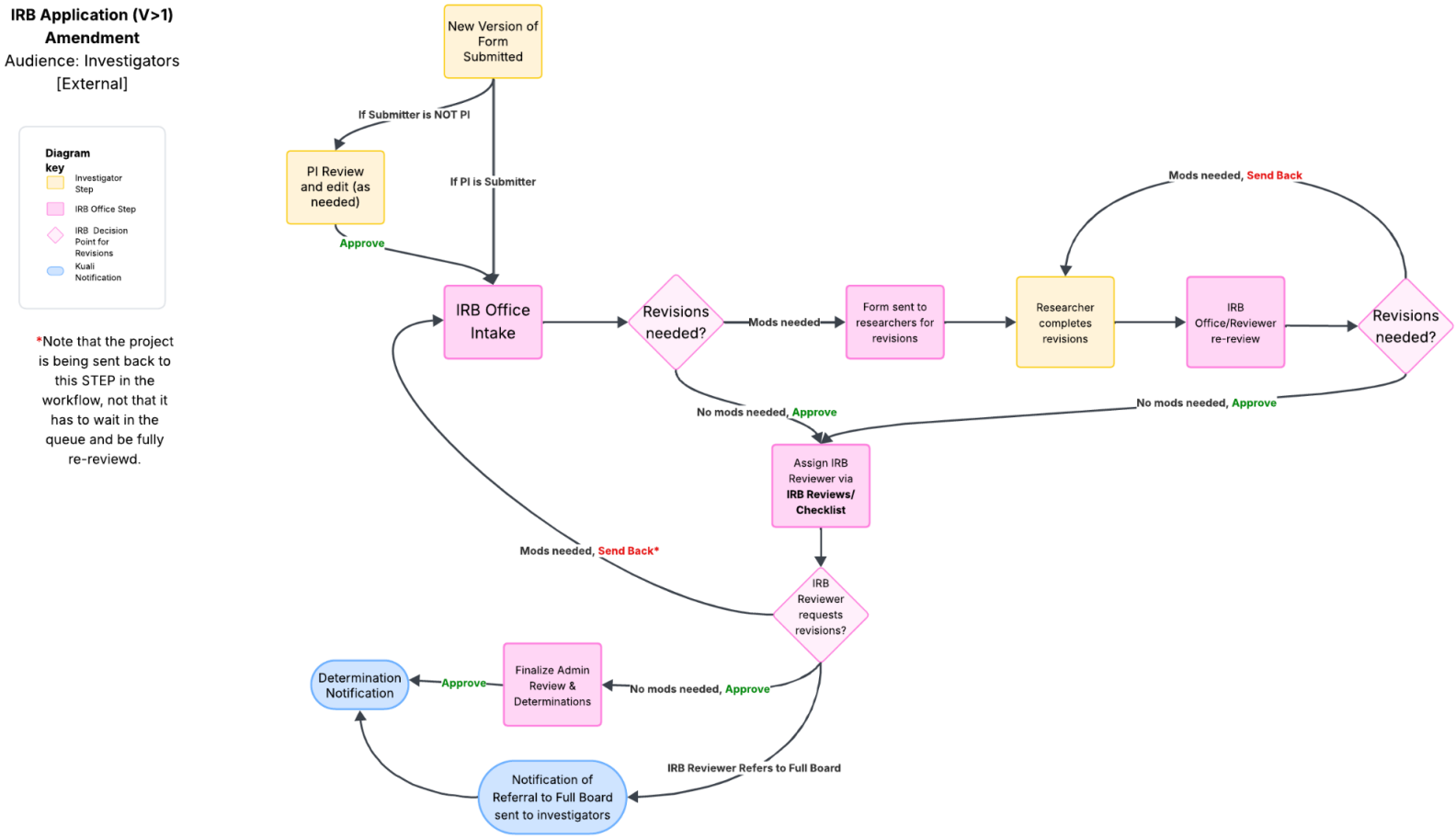
- Fields in the IRB Protocol that directly correspond to the changes described in the Amendment Application.
- If a new file is being uploaded for review that is replacing a file that was previously approved in a different version, delete the outdated file and upload the new file for review. (Ex. Updating the Consent Form)
    - If the consent form is being amended, be sure to update the Kuali-IRB number.

Do NOT Change:

- The application title to indicate this is an amendment.
- Any field in the IRB Protocol without describing the change in the Amendment Application first.
- The Submission Type from an IRB Protocol to a Human Subjects Research Determination or a 118 Letter Request.
    - If either of these submissions is needed for an IRB Protocol, please contact the IRB Office (irb@umd.edu) to discuss next steps.

Amendment Review Process

Once the Amendment has been submitted, the submission is sent to the IRB Office for review. The review time may vary depending on the timing of the semester and the current volume of submissions. Amendment submissions will follow the review process below:



IRB Application Amendment Visual Aid

Principal Investigator Review

If the submitter is not the Principal Investigator (PI) of the project, the PI will receive an email from Kuali requesting a review of the submission. The PI can make direct edits to the form. Once they are satisfied with the application, they should click 'Approve' to move forward.

IRB Office Review

The analyst conducting the review of the amendment will review the requested changes and ensure that the protocol has been appropriately edited in accordance with the request. If any

modifications are needed to secure IRB approval of the amendment, the analyst will list them in the “IRB Office Modifications” section.

Respond to Modifications

An email notification will be sent to the investigators with edit access that the submission requires modifications. The investigators with edit access can click on the “View Task” button in the email to open the submission and begin editing. Alternatively, this task will appear in the “Action List” of each of the investigators with edit access. Once the modifications are complete, click "Mark Complete" in the upper-right-hand corner. You will have the option to leave a comment for the reviewer there.

IRB Office Re-Review

The IRB Office will review the revisions. If additional modifications are needed, the submission will be returned to the investigators with edit access. If the amendment is ready for approval, the analyst will route the amendment for final approval.

Once the IRB Member has reviewed and approved the amendment, the analyst will process the corresponding letter. This could be an approval letter, an acknowledgement letter, or an exempt determination letter based on the scope of the amendment and the project review path. All users listed as needing edit access to the Kuali-IRB application will receive the letter via email.

Helpful Tips

How to Locate an Approval Letter

After the amendment has been approved, all investigators with Read and/or Edit access will be able to access the resulting letter on Kuali-IRB. Only investigators with Edit access will receive an email notification when the amendment is approved.

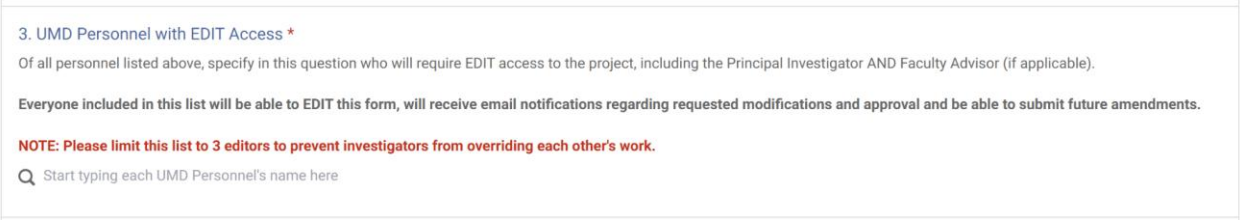
Here is a Scribe on how to find an Approval Letter for any of the Kuali-IRB Forms: https://scribehow.com/viewer/How_to_find_a_Kuali_IRB_Approval_Letter__wSUVSItLRcyy0__wRhRO1A

Collaborate with the Research Team

Edit Access

The Kuali-IRB platform allows for collaborative editing of the IRB Forms.

Each IRB Form has a field where researchers can share 'Edit Access' to the form. Only users with 'Edit Access' to the IRB Form will be able to edit the form. The field looks like this:



Only those listed in this field will be able to edit the IRB Application while it is in Draft form and when the IRB Form is returned for researcher revisions.

When working on a draft, researchers can edit this field and click 'Save'. After saving, those in the updated Edit Access list can begin editing the form in Draft. They will be able to access this draft by visiting their "Document List" on Kuali.

Note: It is crucial that only one person edits the IRB Form at any given time to prevent the risk of overriding each other's responses. Please coordinate with those who have edit access to manage and limit editing to one individual at a time.

Add/Remove Edit Access

If different investigators than those on the Edit Access list need to edit a version of the IRB Protocol, the Edit Access list can be updated. However, only those listed in the Edit Access field of the previous version can create a new version of the form. Once the new version is created, the Edit Access list can be updated by someone with editing privileges to the form. After saving, those in the updated Edit Access list can begin editing the form in Draft.

Read-Only Access

All investigators listed on the IRB Protocol will have read-only access to the form. The field in the IRB Protocol looks like this:

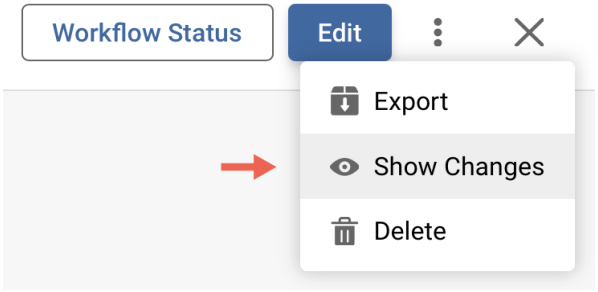
Everyone listed in this table will have read-only access to each version of the IRB Protocol. They will be able to view the form by visiting their "Document List" on Kuali while it is in a Draft, In-Progress, and Complete workflow status.

This list can be updated via an Amendment at any time by an individual with Edit Access to the IRB Protocol.

“Show Changes”

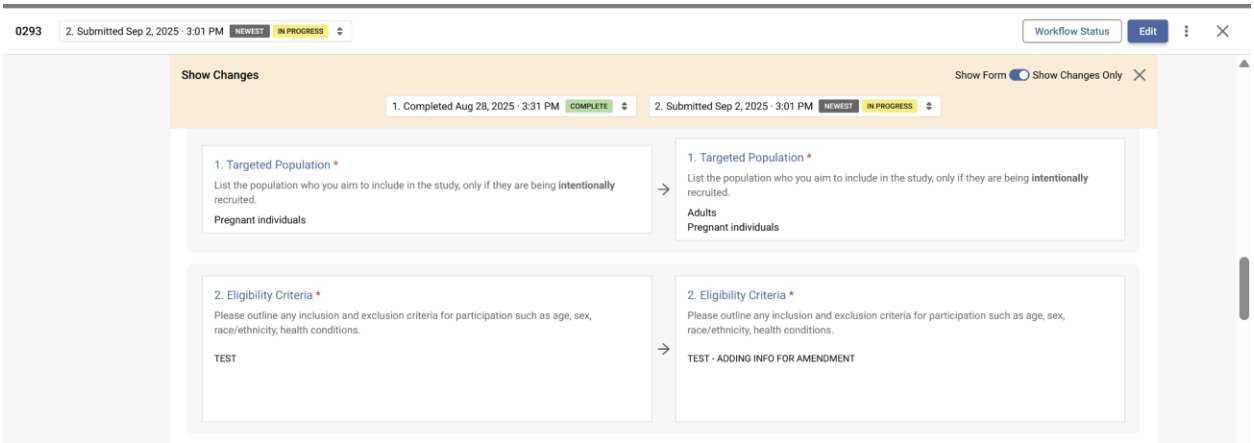
Kuali-IRB includes a feature that allows users to compare changes between versions. This can especially be helpful when teams are submitting an amendment and would like to review the exact changes to the IRB Protocol.

To enable the “Show Changes” feature, a user with Edit Access to the IRB Protocol must open the form via the Document List. The IRB Protocol must have at least 2 versions to use the feature. In the upper right-hand corner of the form, click on the three dots to find the “Show Changes" button.



Once enabled, it will open the Show Changes header where you can select the versions you want to compare, and it will show you added/removed data between the two documents:

You can also toggle the 'Show Changes Only' option in the top header to only show the form fields that have changed in the document:



You can get out of the 'Show Changes' view by selecting the 'Hide Changes' option in the document menu.

Note: Metadata Kuali fields such as the Version Number and Creation Date will automatically show as a “Change” as these fields update automatically with each version. These changes DO NOT need to be described in the Amendment Application.