Institutional Review Board
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UMD Kuali-IRB: Guide to a Reliance Agreement Request

Human Research Protection Office

Version 1.0
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Purpose

The purpose of this guide is to provide instructions on how to submit a reliance agreement request via Kuali IRB.

The Reliance Agreements Form

The Reliance Agreements (RA) Form in Kuali-IRB serves many functions. Researchers can receive the following outcomes from a submission:

- New Reliance Agreement - UMD is the Reviewing IRB
- New Reliance Agreement - UMD is the Relying IRB
- New Individual Investigator Agreement
- UMD Acceptance of External Exemption
- Agreement Closure (via Amendment ONLY)
- Agreement Updates (via Amendment ONLY)

The RA Form will replace email communication that was previously required to request an agreement for study collaborations and will help study teams keep track of these collaborations in one place.

The Link between IRB Application and the RA Form

For study collaborations where UMD is the Reviewing IRB, the RA Form will be linked to the IRB Application page. This allows researchers to save all study information - protocol and collaborations in one place. **For each Protocol, there should be only one RA Form.** If additional reliance agreements are needed, the initial RA Form can be amended to request additional agreements.

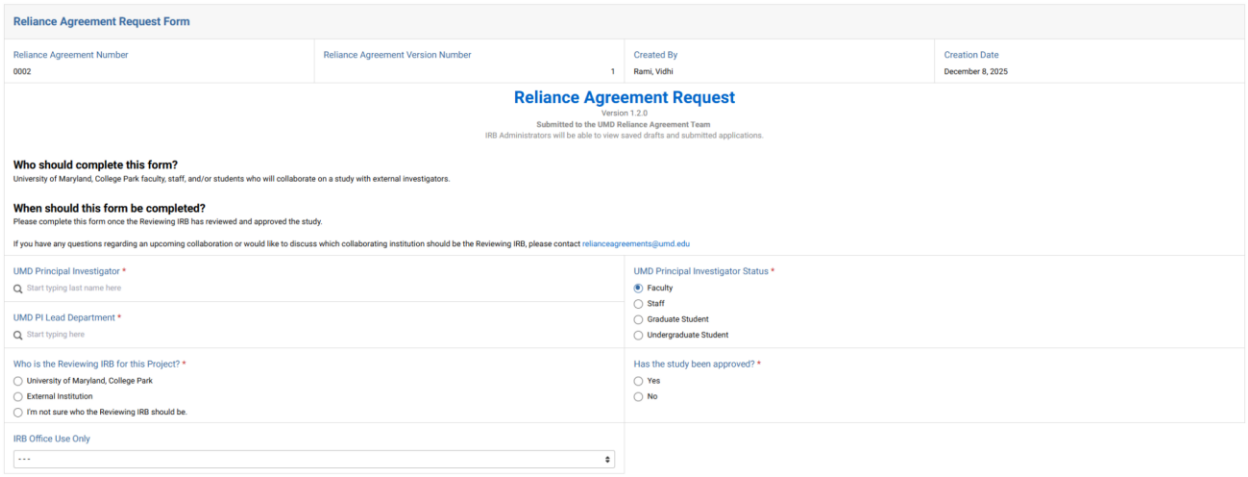
Complete the Reliance Agreement Form

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

Create a new Reliance Agreement Form on the Kuali IRB page. Find guidance based on the sections of the Form below:

Reliance Agreement Request Form

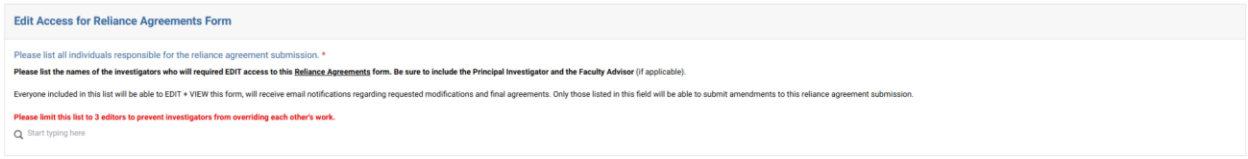
The first section on the reliance agreement form will collect administrative details regarding the study collaboration.



Complete the items as it applies to the study collaboration. Based on your response to the 'Who is the Reviewing IRB for this Project?' question, an additional section will be added to the form.

!!If the study has not yet been approved and you would like guidance on how to best organize your multi-site or collaborative study, please email relianceagreements@umd.edu.

Edit Access for Reliance Agreements Form



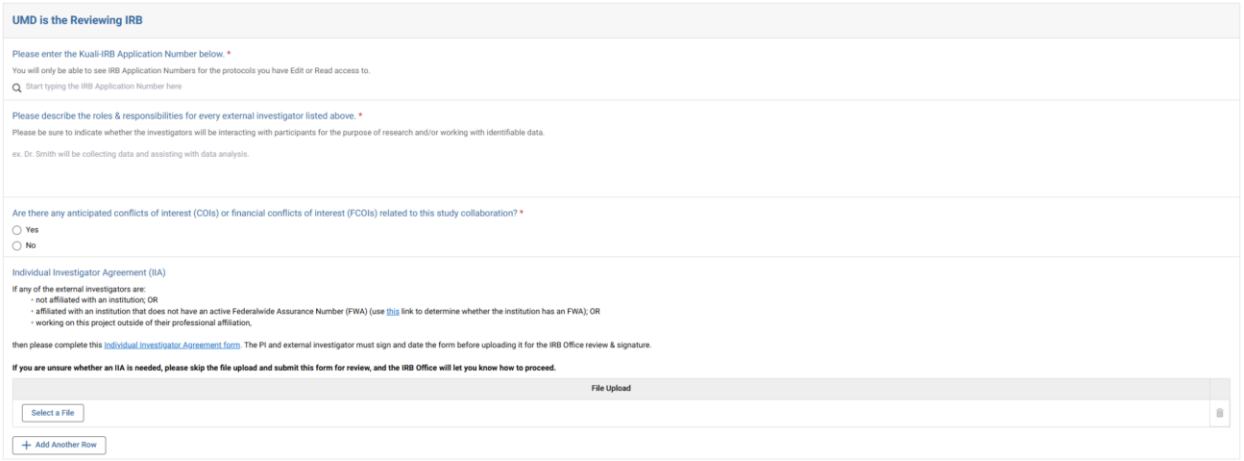
The next section on the form is the 'Edit Access for Reliance Agreements Form'. Only those included in this field will be able to edit the Form while it is in Draft form and when the Form is returned for researcher revisions.

When working on a draft, researchers can complete this field and click 'Save'. This will share edit access with the individuals listed in this field. They will be able to access this draft by visiting their "Document List" on Kuali.

!!It is crucial that only one person edits the 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.

UMD is the Reviewing IRB

If you selected 'University of Maryland, College Park' to the 'Who is the Reviewing IRB for this Project?' question, this section will appear. If an External Institution is the Reviewing IRB, please move on to the UMD is the Relying Institution section of this guide



Entering the Kuali-IRB Application Number

In this section, you must first enter the Kuali-IRB Application number of the IRB Protocol associated with this study collaboration. **If the study has not yet been approved, please 🛑STOP🛑 - only submit this form once the study has been approved.**

‼**This form only applies to studies that exist in Kuali-IRB.** If your project has not been transitioned to Kuali-IRB and is active in IRBNet, please email relianceagreements@umd.edu to request a reliance agreement.

‼**If you cannot find the K-IRB Application number in the dropdown, you may not have the right permissions to submit a reliance agreement form for the IRB Application.** Check your IRB Application Document List to find the IRB Application. If you can find the IRB Application in your Document List but not in the Reliance Agreement K-IRB Look Up Dropdown, please email irb@umd.edu.

IRB Protocol Details

Once you have entered the Kuali-IRB Application number for an approved protocol, a table will appear with relevant read-only protocol details such as the Protocol Title, Protocol Review Path, List of Funders, and List of External Investigators. This is pulled from the IRB Protocol and **cannot** be edited via the RA Form.

The IRB Office will reference the List of External Investigators section to understand the reliance agreements that are needed for this protocol. **If this table is not up-to-date, please STOP.** Submit an amendment to the IRB Protocol so that this table aligns with the external investigators involved in this project. Guidance on how to submit an amendment can be found here.

Roles and Responsibilities

The rest of the section collects information called the “Roles and Responsibilities” of the external investigators. In order for the IRB Office to determine whether a reliance agreement is suitable for a collaboration, it must know the activities the investigators will be involved in and whether there are any conflicts of interest involved.

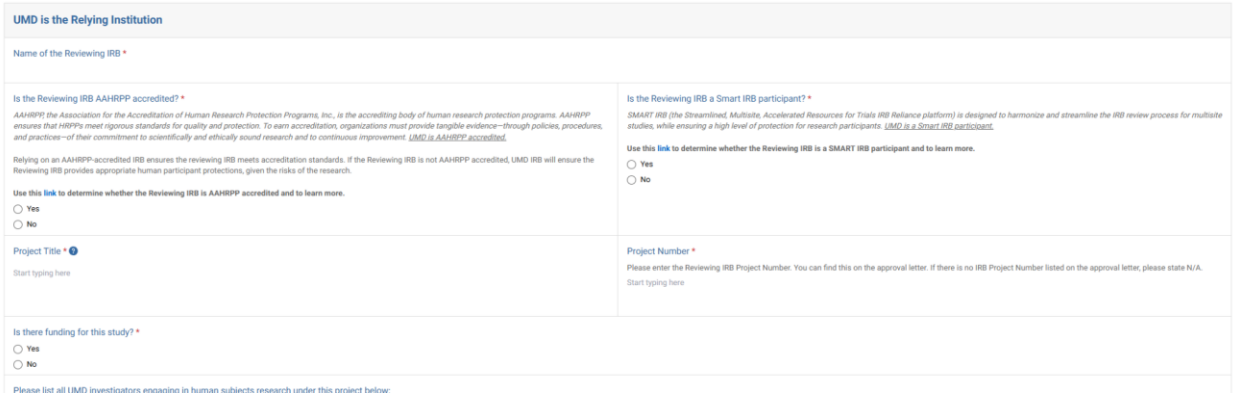
Individual Investigator Agreement (IIA)

An IIA is used for an external investigator who may not be affiliated with an institution or an investigator whose institution does not have a Federalwide Assurance (FWA) number. If you know that an IIA will be needed for one or more of the external investigators on your Protocol, please complete the linked IIA form (both the external investigator and the Principal Investigator must sign) and upload the partially completed agreement at the end of this section. The Reliance Agreement specialist will confirm an IIA is appropriate during their review of the submission.

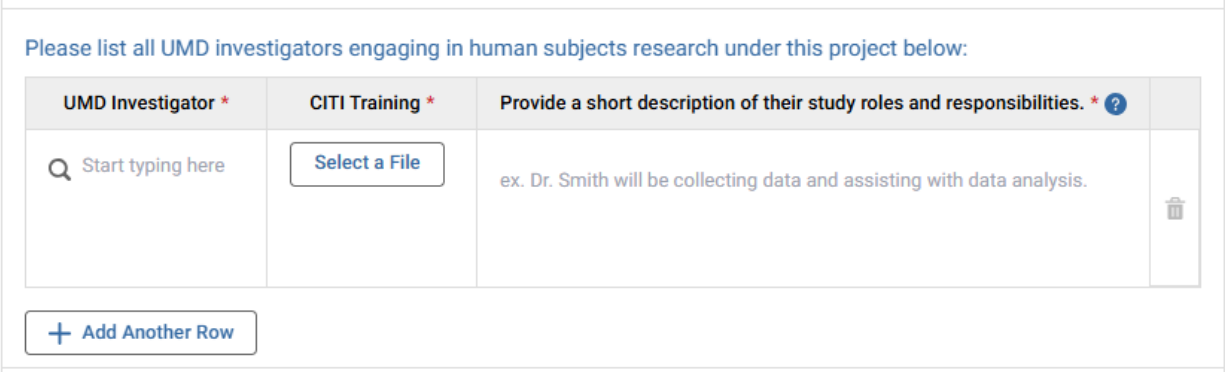
This is the end of the form for when UMD is the Reviewing IRB. Move forward to Submit the Reliance Agreement form.

UMD is the Relying Institution

If you selected ‘External Institution’ to the ‘Who is the Reviewing IRB for this Project?’ question, this section will appear. If UMD IRB is the Reviewing IRB, please change your answer to this question in the “Reliance Agreement Request Form” section and reference the UMD is the Reviewing IRB section in this guide.



Complete this section as it applies to your study collaboration. Use the description text to help answer the questions.



When completing this table, be sure to list EVERY UMD investigator involved in human subjects research under this project. If this list changes, you may submit an amendment to the Reliance Agreement form.

An investigator is considered to be engaged in human subjects research if they are interacting with participants and/or working with identifiable data. If you are unsure about someone's role in the project, use this Decision Tool by OHRP to guide you.

CITI Training is required for each UMD investigator engaged in human subjects research. Find more information here.

Uploading the Reviewing IRB Approval and Study Documents

Please upload all relevant study documents for UMD IRB's review and documentation. If the Reviewing IRB shared documents for UMD IRB's completion as part of the reliance agreement process, please upload those as well.

Examples of relevant documents include:

- External IRB Approval Letter (REQUIRED)
- Approved IRB Protocol
- Approved Consent Forms
- External IRB's Reliance Agreement Template (if this has been shared with you)
- External IRB's Local Context Form (if this has been shared with you)

If additional information is needed, the IRB Specialist will let you know at the time of their review.

Submit the Reliance Agreement Form

Click “Submit” in the top-right corner to submit this form to the IRB Office for review. Please note: You will not be able to edit this form unless a reviewer sends the form back to you with requested edits. Please ensure that this submission is accurate and complete before submitting.

Reliance Agreement Review Process

Once the RA Form has been submitted for IRB Review, it may be sent to the Principal Investigator (PI) and/or the Faculty Advisor for their review. This depends on who submitted the form and whether the PI is a student.

Research Team Review

Principal Investigator Review

If the submitter of the form is not the Principal Investigator (PI) of the project, the PI will receive an email from Kuali requesting a review of the application. The PI can open the RA Form for review via the email notification or by finding the RA Form notification in their Action List. If any edits are needed, the PI can make them directly on the application. Once they are satisfied, they should click ‘Approve’ to move forward.

!!**After the form has been submitted, researchers cannot edit a Form via the Document List. They must be assigned an action item to be able to make edits via the Action List or their email notification.**

In the Action List, the Workflow Step will be RA: PI Approval.

Faculty Advisor Review

If the Principal Investigator (PI) is an undergraduate or graduate student, the Faculty Advisor listed on the application will also receive an email from Kuali to review the application. This email will be sent at the same time as the notification to the PI (if applicable).

The Faculty Advisor will have access to the RA Form but will not be able to make direct edits to it. If the Faculty Advisor has any modifications to suggest, they should note them in a table within the “Advisor Modifications” Page.

If modifications are needed, the application will be returned to the investigators with edit access for revisions. Once the modifications are addressed, researchers should mark the form as complete and the application will be sent to the Advisor for re-review.

If no modifications are necessary and/or when the Advisor is satisfied with the modifications, the application will move forward for IRB Office Review.

IRB Office Administrative Review

Once the reviews by the PI and/or Faculty Advisor have been completed, the IRB Office will receive notification to begin its review. If any modifications are needed, the IRB Office will send the application to the investigators with edit access for revisions.

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. This task will also appear in their Kuali “Action List”. You can find the modifications in the “IRB Office Modifications” section. 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.

‼**You can only address modifications if the RA Form is opened via the Action List or the email notification.**

IRB Office Re-review/Notification

Should the IRB Analyst require additional modifications to the protocol, the form will be sent back to the investigators for edits. If no more modifications are needed, the IRB Office will notify the investigators with edit access which (if any) agreements are needed.

Reliance Agreement Processing

The next steps will vary depending on the agreement(s) that are needed. Review the notification you received from Kuali-IRB at this step and find the corresponding action to understand the next steps:

New Agreement Decision

This action indicates that a new reliance agreement or individual investigator agreement is needed. The UMD IRB Office will begin processing these agreements. The Reliance Agreements team will copy the UMD Lead Investigators on the email communications for their awareness on the progress.

This might take 2 business days or a few months, depending on the responsiveness of the collaborating institution. This part of the RA Form workflow will not be completed until all

required agreements have been executed. However, the form will be updated with the new agreements when they are complete.

When all the required agreements have been processed, the investigators with edit access will receive an email from Kuali IRB notifying them of the finalized agreements.

If UMD IRB is the Reviewing IRB in this situation, the IRB Office will update the “External Investigators” section of the IRB Protocol to document the processed agreements.

No Agreement Needed

If the IRB Office determines that no agreement is needed for the collaboration, the list of investigators with edit access will receive an email from Kuali. The notification will include the reason for this action. No further action is required from the investigators. If investigators have any questions, they can contact the reliance agreements team at relianceagreements@umd.edu.

Close an Agreement

If the IRB Office determines that an agreement needs to be closed, the list of investigators with edit access will receive an email from Kuali with a list of the agreements that will be closed. No further action is required from the investigators. If investigators have any questions, they can contact the reliance agreements team at relianceagreements@umd.edu.

If UMD IRB is the Reviewing IRB in this situation, the IRB Office will update the “External Investigators” section of the IRB Protocol to document the closed agreements.

Update an Agreement

If the IRB Office determines that one or more of the agreements need to be updated, the list of investigators with edit access will be notified that certain agreements need to be updated. The UMD IRB Office will begin processing these updates. The Reliance Agreements team will copy the UMD Lead Investigators on the email communications for their awareness on the progress.

This might take 2 business days or a few months, depending on the responsiveness of the collaborating institution. This part of the RA Form workflow will not be completed until all required agreements have been executed. However, the form will be updated with the new agreements when they are complete.

When all the required agreements have been processed, the investigators with edit access will receive an email from Kuali IRB notifying them of the finalized agreements.

If UMD IRB is the Reviewing IRB in this situation, the IRB Office will update the “External Investigators” section of the IRB Protocol to document the updated agreements.

UMD will accept an external exemption

If the IRB Office agrees to accept an external institution’s exemption, the list of investigators with edit access will receive an email to this effect. No further action is required from the investigators. If investigators have any questions, they can contact the reliance agreements team at relianceagreements@umd.edu.

UMD requires UMD IRB Submission

If the IRB Office reviews an exempt study collaboration and decides that a separate UMD IRB review is needed to proceed, the list of investigators with edit access will receive an email to this effect. Researchers must submit the project for UMD IRB review using the guidance found here. Be sure to only describe the roles of the UMD investigators, as opposed to the entire collaborative research team.

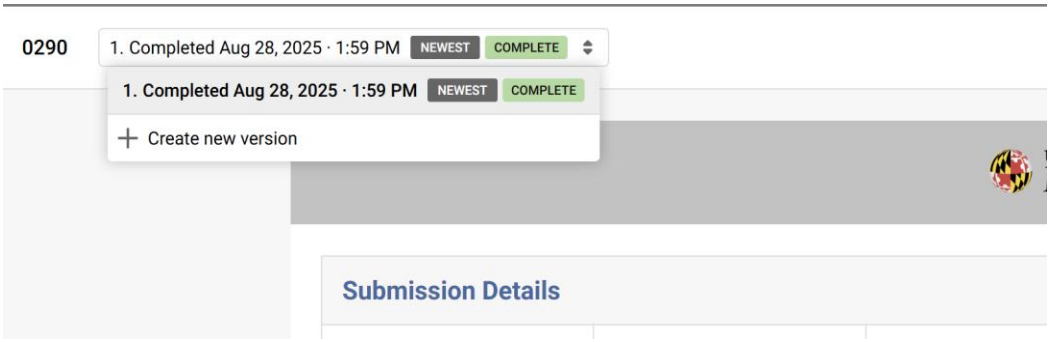
Submit an Amendment to an Existing RA Form

Researchers can amend the RA Form after the first version has been completed. For example, if a UMD Protocol initially involved one external study site but has since evolved to include an additional site, researchers can submit an amendment to request an additional agreement for the protocol.

!!Only investigators with edit access to the RA form in the previous version can create a new version of the form.

How to Create + Submit an Amendment

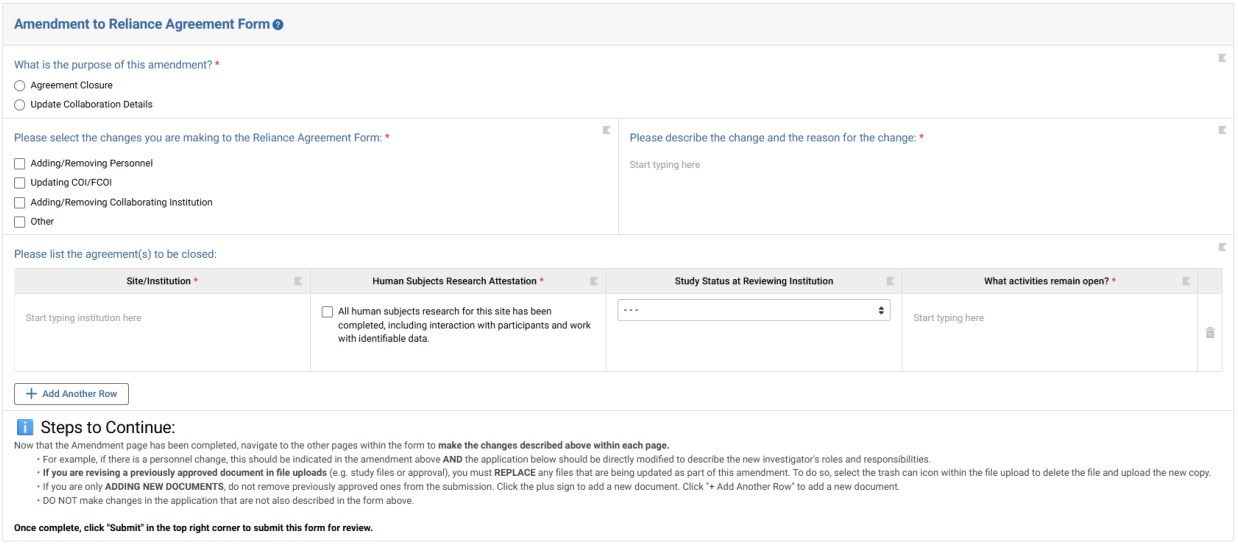
Step 1: To create a new document version in Kuali, locate the RA Form you wish to amend, open it, then find the Version Dropdown in the upper left-hand corner and select “+Create New Version”.



> **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 RA Form will be created, including all the completed fields from the previous submission. In the new version, a new **Amendment** section will be included.

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



Step 3: Once the Amendment Section is complete, continue to the following sections of the RA Form and edit each section as needed.

Step 4: Submit the RA Form for review.

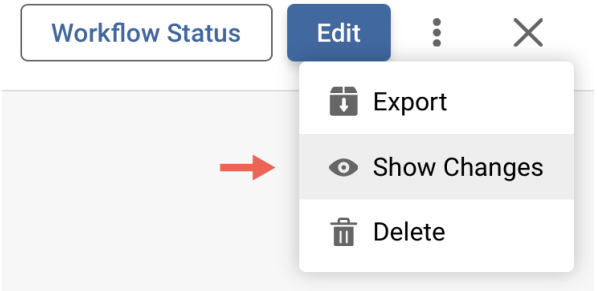
Follow the guidance in the Submit the Reliance Agreement Form Section and beyond to understand the Researcher and IRB Office Review Process that will be followed.

Tips

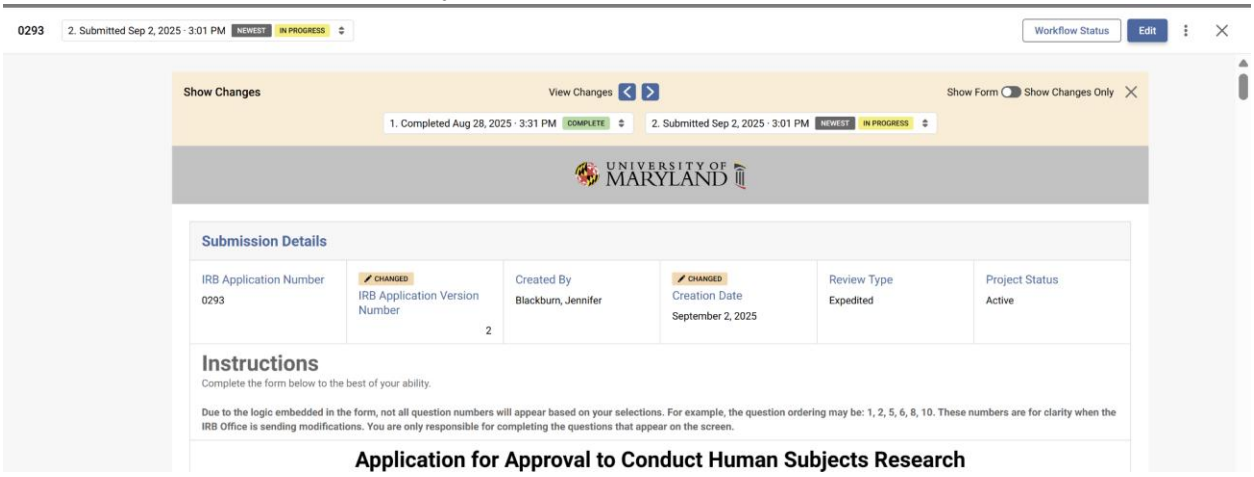
“Show Changes”

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 RA Form.

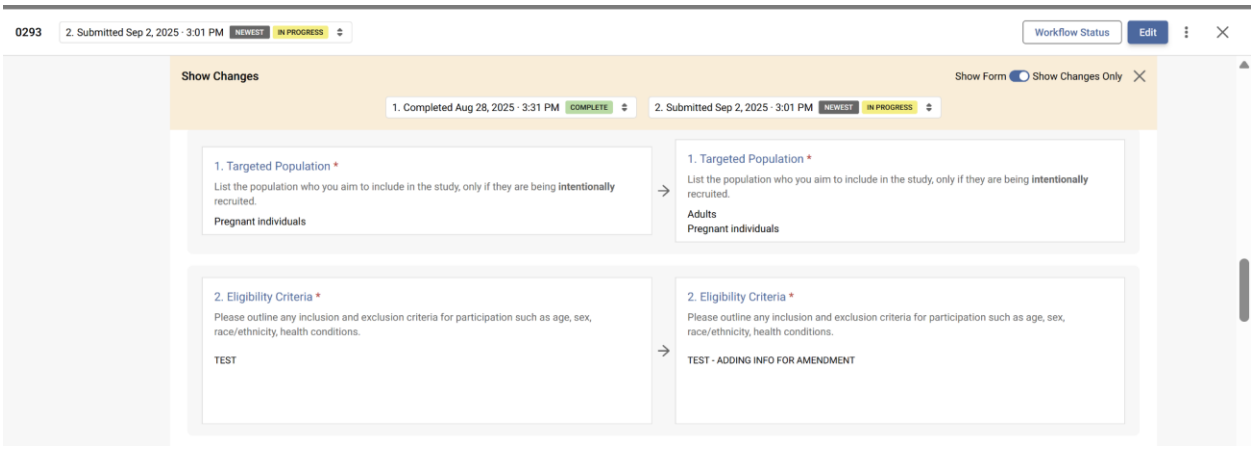
To enable the “Show Changes” feature, a user with Edit Access to the RA Form must open the form via the Document List. The RA Form must have at least 2 versions to use the feature. In the upper right-hand corner of the form, click on the three dots to find the “Show Changes" button.



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.