UMD Kuali-IRB: Guide to Submitting an IRB Protocol for Initial Review

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 an initial for an IRB Protocol in Kuali-IRB.

Introduction to Kuali-IRB

In January 2026, the UMD IRB will launch a new system to replace IRBNet. The rationale for the transition is that IRBNet does not offer the flexibility UMD investigators require. The new system will be called Kuali-IRB.

Overview of Kuali-IRB

[Kuali Build](#) is a no-code, cloud-based platform specifically designed for higher education institutions to create online forms and automate workflows. The IRB Office has spent the last year building and tailoring the UMD Kuali-IRB system to serve the research community.

Kuali-IRB is a module of Kuali Build, which is already being used by other entities on campus, such as the inTERP system for COI disclosures and ORA Gift Forms.

Intended Users of Kuali-IRB

Kuali-IRB will be used to draft and submit IRB applications for review. Principal Investigators and research team members will be able to create and amend IRB Forms, such as:

- IRB Protocols
- 118 Letter Requests
- Human Subjects Research Determinations

- Reliance Agreement Requests
- Continuing Reviews
- Reportable Events
- Closure Reports

The IRB Office will use the system to review IRB Form submissions and provide its determination to the researchers. The IRB Office will also document its monthly Full Board meeting on this platform with the IRB Committee.
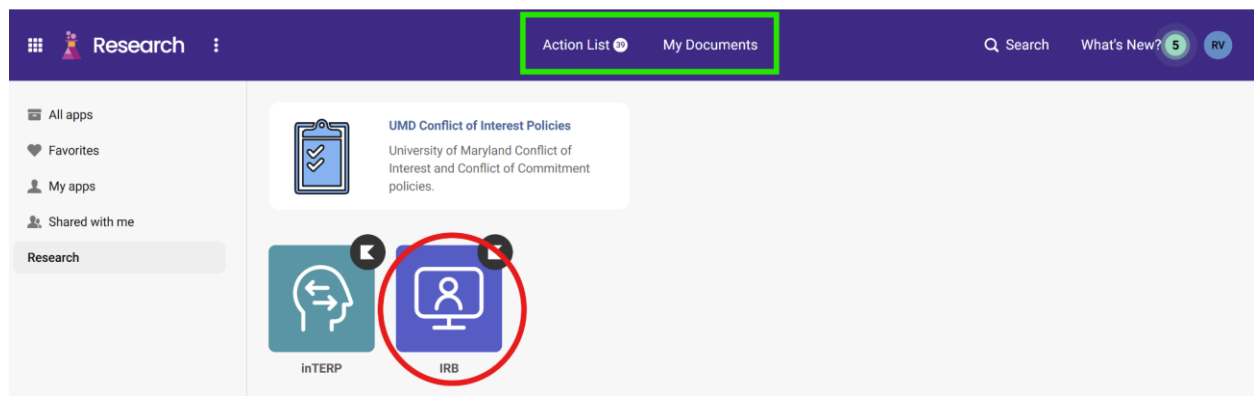
Navigating the Kuali-IRB Dashboard

How to Access the Kuali-IRB Platform

Kuali-IRB can be accessed via the following link: https://go.umd.edu/kuali-irb

Use your **UMD credentials + Duo Mobile** to log in. Select UMD - College Park, if prompted, NOT UMaryland Baltimore.

When you see this Main Page, click on "IRB" to access the Kuali-IRB Platform (red circle).

Additional items on this page include an "**Action List**" and "**My Documents**" at the top of the page (green rectangle).

> The "**Action List**" is similar to "My Reminders" on IRBNet. This list will include any form where your action is required (i.e., Action to address IRB Office Modifications).

> "**My Documents**" will list any form that is created in Kuali-IRB, including drafts, withdrawn forms, and "completed' forms. For example, your IRB Application will be saved in this list.

How Kuali-IRB Functions

IRB Forms
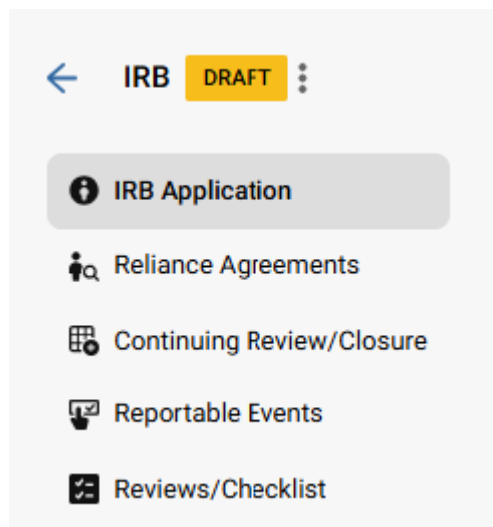
The snapshot below shows the IRB Forms available on Kuali-IRB.

IRB Application
- IRB Protocol (Initial AND Amendment)
- Human Subjects Research Determination
- 118 Letter Request

Reliance Agreements
- Request UMD to Serve as the Reviewing IRB
- Request for UMD to Rely on an External IRB
- Request UMD Review of Exempt Collaborations
- Request an Individual Investigator Agreement

Continuing Review/Closure
- Continuing Review Application
- Closure Report

Reportable Events
- Reportable Event Application

Reviews/Checklist, IRB Meetings, and IRB Dashboard are internal forms for IRB Administrator use only.

Form Numbering Mechanism

Each IRB Form is identified by a unique application number. For example, the Continuing Review associated with IRB Application #123456 will be CR #022. The Reportable Event Form associated with the IRB Application might be Reportable Event #4.

IRB Application Number: 123456
Continuing Review Number: 022 *for IRB Application #123456*
Reportable Event Number: 004 *for IRB Application #123456*

Each form also has version numbers - each time a new version of the form is submitted, it will have an updated version number. For example, each time an amendment to a Protocol is submitted, the version will increase. This is similar to how IRBNet Project Numbers were used:

IRBNet Project Number: 123456-78

<u>Kuali-IRB IRB Application Number:</u> IRB Application #123456, Version #78

> **IRB Application Number** - *this is the main identifier of an application*
> **Version Number** - *this indicates the latest submission of the application*

Linking IRB Forms

How do the Forms talk to each other?

Continuing Review/Closure and Reportable Event submissions will be linked to the associated IRB Application by entering the IRB Application number at the beginning of the form.

For example, the image below is of Continuing Review/Closure Report Form #0084, Version #1. The first field in this form is to enter the number of the IRB Protocol I am submitting a Continuing Review/Closure Report for. I entered IRB Application #0292, which populated the IRB Protocol Details.

Now, I can submit a Continuing Review or Closure Report for IRB Application #0292.

When you communicate with the IRB Office, the IRB Application number is the most important.

Pages

Each IRB Form has multiple pages. Think of the pages as application sections. To toggle between pages, you must scroll up to the top of the page. There is a reminder at the bottom of each page to this effect.

The pages will be different based on each application type. Below is the list of pages that will appear for an IRB Protocol involving primary data collection.

You can navigate between pages by clicking on its row within the list or by using the "Back" and "Next" buttons.

Submitting an IRB Protocol for Initial IRB Review

To submit a protocol for review in Kuali-IRB, investigators must complete a Kuali-IRB Application form and upload all active supporting documents (e.g., recruitment materials, consent forms).

How to Submit an IRB Protocol - Initial

Create a New Form

When you click on IRB on the Kuali Dashboard, you will see the screen below, which is called the **Document List**:
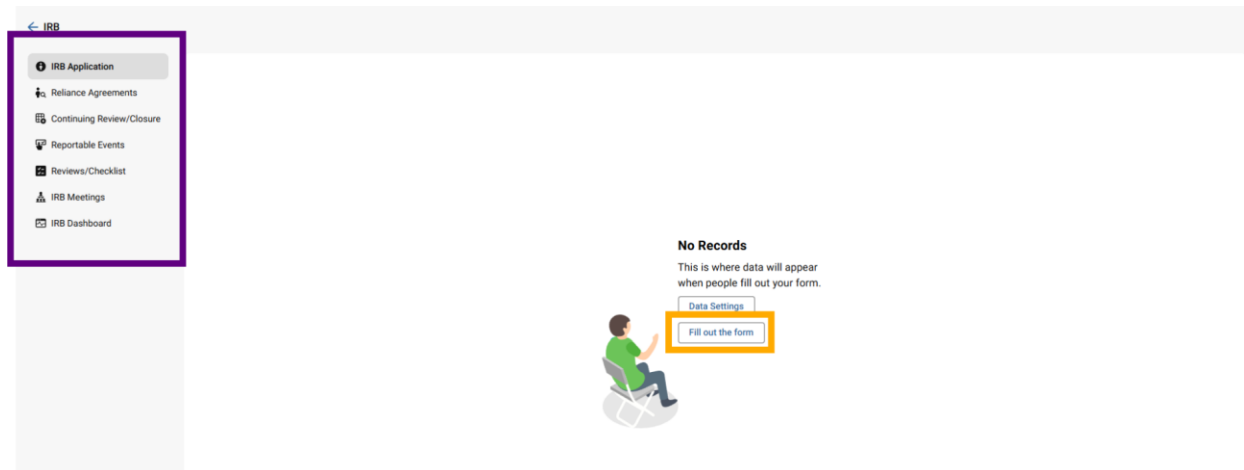
On the left-hand side (purple rectangle), you will see a list of the **IRB Forms**. Each form will open a View with a list of the Draft, In-Progress, and Complete submissions. **If this is your first submission, you will not see anything on this page.** To begin a new form, click "Fill out the form" (orange rectangle). This will open a new draft of the form.

Once you have drafted your first form, you will see a view similar to the one below. If you want to create a new form, the button to create a new form is in the top right-hand corner (green rectangle) "New".
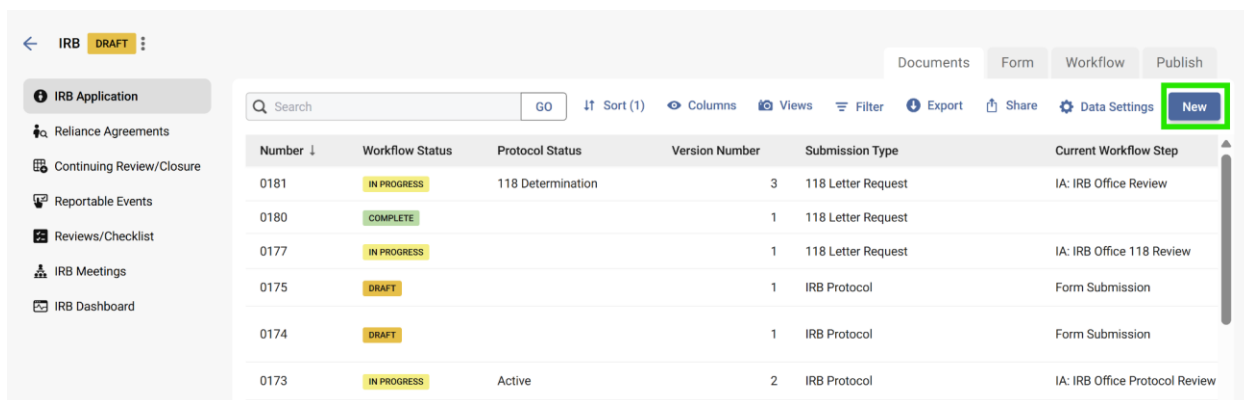
Complete the Form

Once the new IRB Application form is open, you must indicate this is an IRB Protocol submission (as opposed to a Human Subjects Research Determination or 118 Letter request) by answering the 'Submission Type' question on the first page with 'IRB Protocol'.

Answer the questions on the form as they apply to the project. Guidance is available as description text and will appear when hovering over the ❓ help text.

Share Edit/Read Access with Investigators

Edit Access
The Kuali-IRB platform allows for collaborative editing of the IRB Forms. Only users with 'Edit Access' to the IRB Form will be able to edit the form.

Each IRB Form has a field where researchers can share 'Edit Access' to the form. The field will look like this in the 'Key Personnel' Page:

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

When working on a draft, the creator of the form 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 and edit 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.

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 in the 'Key Personnel' Page:

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.

Submit the Form

When the form is complete and ready for submission, click "Submit" in the upper right corner.

Note: After submitting, the application will go through reviews by the Principal Investigator and/or Faculty Advisor and the Department Liaison (more information is below) before it is submitted to the IRB Office. The submission **will not** be returned to the investigators unless a reviewer requests modifications.

Visual Aid: [IRB Application Workflows - Investigator Workflow.pdf](#)

Research Team Review

Based on the Submitter of the form, the form must be reviewed by the Principal Investigator (PI) and/or the Faculty Advisor before the IRB Protocol is submitted to the IRB Office for 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 IRB Application for review via the email notification or by finding the 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 it 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.

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 IRB application 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 "Liaison/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, 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.

Department Liaison Review

Similar to the Faculty Advisor review, the Department Liaison(s) listed on the application will receive an email from Kuali to review the application. The Liaison(s) will be asked to review the application **after** the PI and Faculty Advisor have approved the application (if applicable).

If you listed two Liaisons in the field, only one liaison must approve the application to move forward. Department Liaisons have been provided with guidance on how to split the reviews. If you have any questions, please contact both liaisons if you are unsure who will conduct the review.

The Liaison will have access to the IRB application but will not be able to make direct edits to it. If the Liaison has any modifications to suggest, they should note them in a table within the "Liaison/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, mark the form as complete and the application will be sent to the Liaison for re-review. If no modifications are necessary and/or when the Liaison is satisfied with the modifications, the application will move forward.

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. This may take anywhere from 1-3 weeks depending on the current turnaround time. 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". 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.
NOTE: You cannot make edits to an application when it is opened via the Document List.

IRB Office Re-review/Approval

Should the IRB Analyst require additional modifications to the protocol, the form will be sent back to the investigators for edits. Once the IRB Analyst has accepted the revisions, the protocol will be sent to the final IRB Reviewer. If the Reviewer has additional modifications, the protocol will be sent back to the investigators for revision. Once the Reviewer approves the protocol, the IRB Analyst will process the approval/notification letter. All investigators with edit access to the Kuali-IRB application will receive the approval/notification letter.

How to Locate an Approval Letter

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

Here is a Scribe on how to find an Approval Letter for any of the Kuali-IRB Forms: Scribe - How to Find a Kuali IRB Approval Letter

Helpful Tips

Update the List of Investigators with Edit Access between Versions

If different individuals need the ability to edit each 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.