



Institutional Review Board

1204 Marie Mount Hall • 7814 Regents Drive • College Park, MD 20742 • 301-405-4212 • irb@umd.edu

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

Human Research Protection Office

VERSION 1.0

Last Updated 12/02/2025



Table of Contents

Purpose.....	3
Introduction to Kuali-IRB	3
Overview of Kuali-IRB	3
Intended Users of Kuali-IRB.....	3
Navigating the Kuali-IRB Dashboard	4
How to Access the Kuali-IRB Platform.....	4
How Kuali-IRB Functions	5
IRB Forms	5
IRB Application.....	5
Reliance Agreements	5
Continuing Review/Closure	5
Reportable Events.....	5
Form Numbering Mechanism.....	5
Linking IRB Forms.....	6
Pages	6
Submitting an IRB Protocol for Initial IRB Review	7
How to Submit an IRB Protocol - Initial	7
Create a New Form	7
Complete the Form	8
Share Edit/Read Access with Investigators	9
Edit Access.....	9
Read-Only Access.....	10
Submit the Form.....	10
Visual Aid: IRB Application Workflows - Investigator Workflow.pdf	10
Research Team Review.....	10
Principal Investigator Review	10
Faculty Advisor Review	11
Department Liaison Review	11
IRB Office Administrative Review	11
Respond to Modifications	12
IRB Office Re-review/Approval	12
How to Locate an Approval Letter.....	12
Helpful Tips	12
Update the List of Investigators with Edit Access between Versions	12



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
- Reliance Agreement Requests
- 118 Letter Requests
- Continuing Reviews
- Human Subjects Research Determinations
- 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.

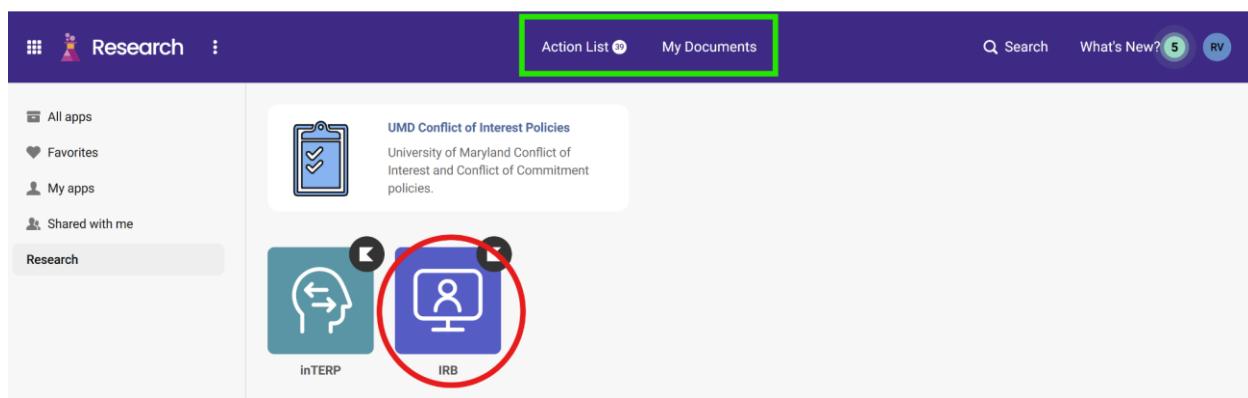


Navigating the Kuali-IRB Dashboard

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 screenshot shows the Kuali-IRB interface with the following menu structure:

- Left sidebar: Back arrow, IRB (highlighted in yellow), DRAFT, three dots.
- Top navigation: IRB Application, Reliance Agreements, Continuing Review/Closure, Reportable Events, Reviews/Checklist.
- Right panel:
 - 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** (disabled)

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



Guide to Submitting an IRB Protocol (Initial) - VERSION 1.0

Kuali-IRB IRB Application Number: 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.

Continuing Review/Closure Report Details			
Continuing Review/Closure Number 0084	Continuing Review/Closure Version Number 1	Created By Blackburn, Jennifer	Creation Date August 28, 2025

Associated IRB Protocol	
IRB Application Number *	0292

IRB Protocol Details	
Principal Investigator Blackburn, Jennifer (jdesl@um.edu)	Protocol Title TEST
Principal Investigator Status Staff	Lead Department 1420101 - CC011073 - VPR - VP Research

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.

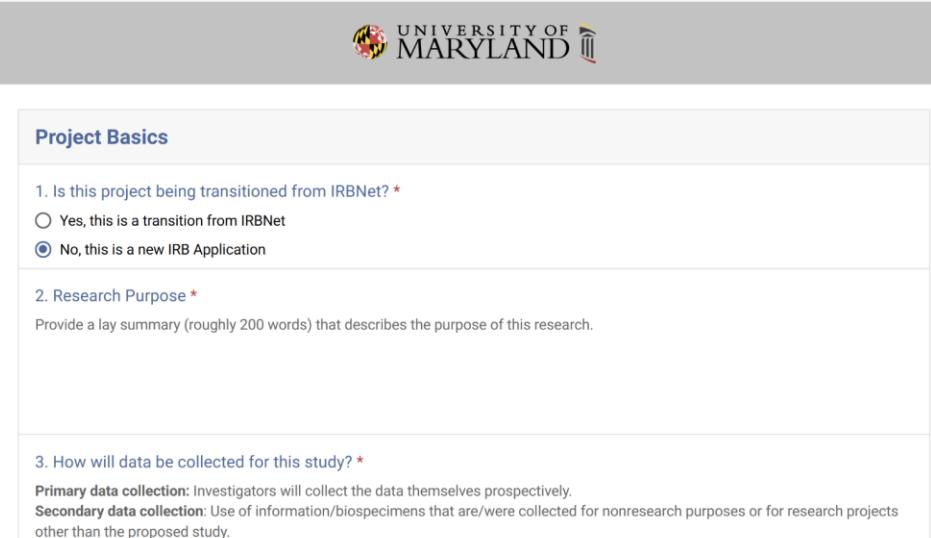
Pages

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.



Guide to Submitting an IRB Protocol (Initial) - VERSION 1.0

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.



The screenshot shows a navigation sidebar on the left with a list of sections: Submission Details (checked), Key Personnel (unchecked), Project Basics (checked), Recruitment (unchecked), Procedures (unchecked), Risks and Benefits (unchecked), Confidentiality (unchecked), Consent Process (unchecked), and Final Check & Next ... (unchecked). Below the sidebar are two buttons: "Back" and "Next". The main content area is titled "Project Basics" and contains three numbered questions. Question 1 asks if the project is transitioning from IRBNet, with two radio button options: "Yes, this is a transition from IRBNet" (unchecked) and "No, this is a new IRB Application" (checked). Question 2 asks for the research purpose, with a text input field for a lay summary. Question 3 asks how data will be collected, with a note explaining the difference between primary and secondary data collection.

Pages

Submission Details

Key Personnel

Project Basics

Recruitment

Procedures

Risks and Benefits

Confidentiality

Consent Process

Final Check & Next ...

Back **Next**

Project Basics

1. Is this project being transitioned from IRBNet? *

Yes, this is a transition from IRBNet

No, this is a new IRB Application

2. Research Purpose *

Provide a lay summary (roughly 200 words) that describes the purpose of this research.

3. How will data be collected for this study? *

Primary data collection: Investigators will collect the data themselves prospectively.

Secondary data collection: Use of information/biospecimens that are/were collected for nonresearch purposes or for research projects other than the proposed study.

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**:



Guide to Submitting an IRB Protocol (Initial) - VERSION 1.0

The screenshot shows the 'IRB Application' section of the software. On the left, a sidebar lists various forms: IRB Application, Reliance Agreements, Continuing Review/Closure, Reportable Events, Reviews/Checklist, IRB Meetings, and IRB Dashboard. The 'IRB Application' item is highlighted with a purple rectangle. The main area displays a 'No Records' message with a small illustration of a person sitting at a desk and a button labeled 'Fill out the form' which is highlighted with an orange rectangle.

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”.

The screenshot shows the 'IRB Application' section with a 'DRAFT' tab selected. The left sidebar is identical to the previous screenshot. The main area displays a table of submissions with the following data:

Number	Workflow Status	Protocol Status	Version Number	Submission Type	Current Workflow Step
0181	IN PROGRESS	118 Determination	3	118 Letter Request	IA: IRB Office Review
0180	COMPLETE		1	118 Letter Request	
0177	IN PROGRESS		1	118 Letter Request	IA: IRB Office 118 Review
0175	DRAFT		1	IRB Protocol	Form Submission
0174	DRAFT		1	IRB Protocol	Form Submission
0173	IN PROGRESS	Active	2	IRB Protocol	IA: IRB Office Protocol Review

A green rectangle highlights the 'New' button in the top right corner of the table header.

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’.



Guide to Submitting an IRB Protocol (Initial) - VERSION 1.0

Lead Department * ?

Type the department name here.

Submission Type * ?

IRB Protocol

Human Subjects Research Determination

118 Letter Request

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:

3. UMD Personnel with EDIT Access *

Of all personnel listed above, specify in this question who will require EDIT access to the project, including the Principal Investigator AND Faculty Advisor (if applicable).

Everyone included in this list will be able to EDIT this form, will receive email notifications regarding requested modifications and approval and be able to submit future amendments.

NOTE: Please limit this list to 3 editors to prevent investigators from overriding each other's work.

Start typing each UMD Personnel's name here

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:



Guide to Submitting an IRB Protocol (Initial) - VERSION 1.0

2. ALL UMD Investigators/Personnel

List all UMD Investigators in the table below, **INCLUDING** the Principal Investigator and Faculty Advisor (if applicable).

Everyone included in this list will have READ-ONLY access to the project (except for the investigators also listed in Item #3 below, who will have READ + EDIT access).

2a. Person *	2b. Project Role *	2c. Home Department *	2d. Engaged in Human Subjects Research? *	2e. CITI Training (File Upload) *
Blackburn, Jennifer (jdesi@umd.edu)	Principal Investigator	1420101 - CC011073 - VPR - VP Research	Yes	TEST.docx (13.3 kB)

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.



Guide to Submitting an IRB Protocol (Initial) - VERSION 1.0

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.