



Institutional Review Board

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UMD Kuali-IRB: Guide to Submitting an HSRD Request

Human Research Protection Office

VERSION 1.0

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Purpose

The purpose of this guide is to support investigators in submitting a Human Subjects Research Determination Request 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

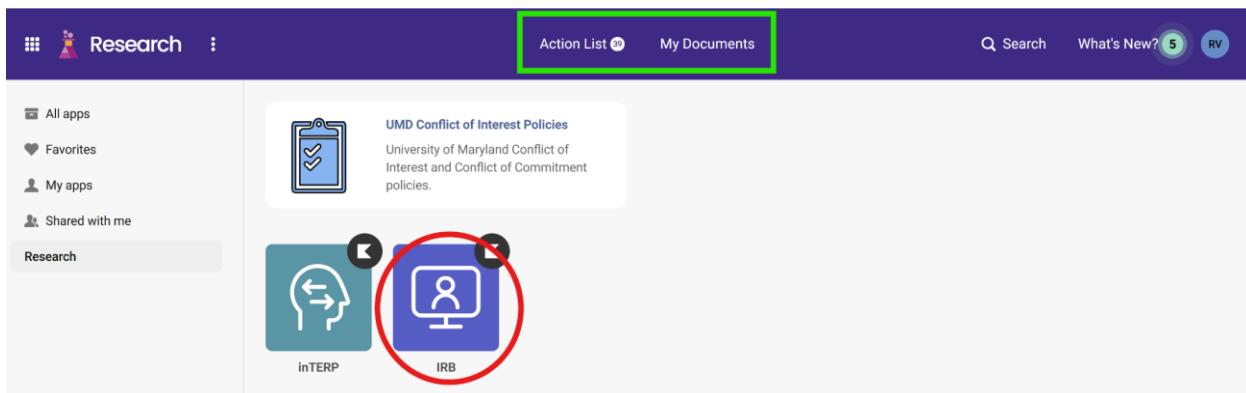
How to Access the Kuali-IRB Platform

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



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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



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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.

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 HSRD Request.

A screenshot of a web-based application interface for an IRB submission. On the left, a sidebar titled 'Pages' lists several sections: 'Submission Details' (with a checked radio button), 'Key Personnel', 'Human Subject Res...', and 'Final Check & Next ...'. The main content area shows the 'Submission Details' page. At the top is the University of Maryland logo. Below it is a table with four columns: 'IRB Application Number' (0001), 'IRB Application Version Number' (DATA NOT AVAILABLE), 'Created By' (Rami, Vidhi), and 'Creation Date' (December 12, 2025). Below the table is the title 'Application for Approval to Conduct Human Subjects Research' in blue, followed by 'Version 1.2.0' and 'Submitted to the IRB Office'. A note states 'IRB Administrators will be able to view saved drafts and submitted applications.' At the bottom, there is an 'Instructions:' section with a note: 'Complete the form below to the best of your ability. Due to the logic embedded in the form, not all question numbers will appear based on your selections. For example, the question'.

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



How to Submit an HSRD Request

Create a New Form

When you click on IRB, you will see the screen below, which is called the **Document List**:

No Records
This is where data will appear when people fill out your form.
Data Settings
Fill out the form

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”.

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

Indicate your Submission as an HSRD Request

In the “Submission Details” Page, answer the ‘Submission Type’ question with **Human Subjects Research Determination**. Complete all questions to the best of your ability.



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.

Q 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.

!! 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 in this field will have read-only access to the form. The field looks like this in the 'Key Personnel' Page:

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

Everyone listed in this table will have read-only access to the HSRD Submission. 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.

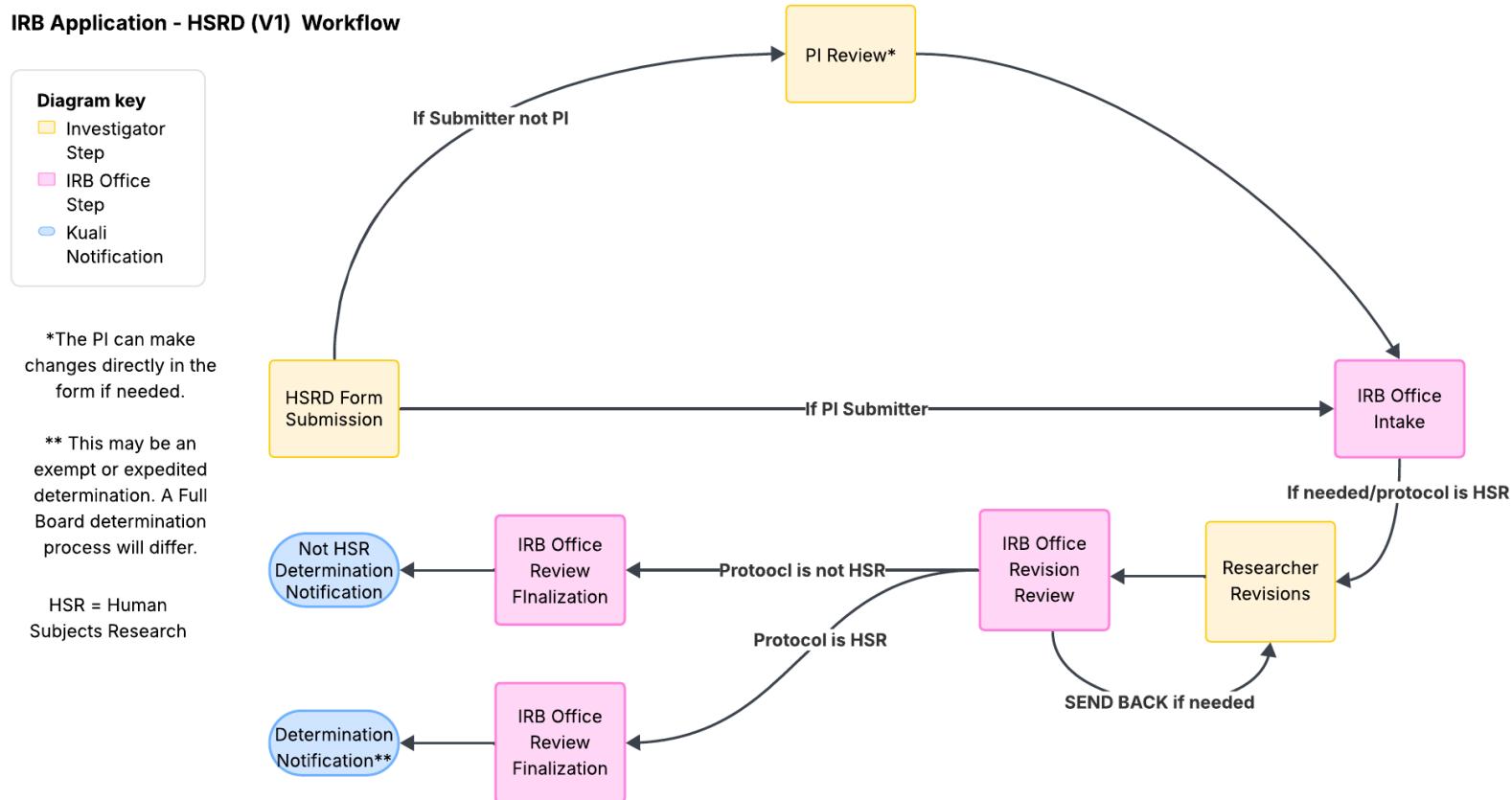


Submit the Form

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.

HSRD Review Process

Once the IRB Application has been submitted for IRB Review, the IRB Office will be able to distinguish an IRB Initial Application from a Transition via the multiple-choice question regarding the transition status. For projects that are being transitioned from IRBNet to Kuali-IRB, they will follow the review process below:



HSRD Review Process Visual Aid

Research Team Review

Based on the Submitter of the Application, the Application will be reviewed by the Principal Investigator (PI) before the IRB Application is submitted to the IRB Office for review.



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 application. The PI can make direct edits to the application from the Action List. Once they are satisfied with the application, they should click 'Approve' to move forward.

IRB Office Review

Once the required reviews by the PI are complete, the IRB Office will receive notification to begin its review. The IRB Office will review each submission and determine whether it meets the criteria for human subjects research.

!!If the IRB Reviewer determines that the project is human subjects research, they may send a modification to the researchers to update their submission to an IRB Protocol.

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.

IRB Office Re-Review/Approval

Once the IRB Reviewer has reviewed and confirmed the requested modifications, they will process the final determination.

Researchers who have Edit access to the form will receive the determination letter via email.

How to Locate a Determination Letter

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

Here is a Scribe on how to find a Determination Letter for any of the Kuali-IRB Forms:
https://scribehow.com/viewer/How_to_find_a_Kuali_IRB_Approval_Letter_wSUVSlLRcyy0wRhRO1A



Amending an HSRD

Contact the IRB Office at irb@umd.edu if you wish to make changes to an HSRD that has a Workflow Status of Complete. Do not submit version 2 of an HSRD without discussing it with the IRB Office first.