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 a Reportable Event

Human Research Protection Office

VERSION 1.0
Last Updated 11/14/2025

Table of Contents

Purpose

The purpose of this guide is to provide instructions on how to submit a Reportable Event in Kuali-IRB.

Kuali-IRB Reportable Events Form

The Kuali-IRB platform includes multiple forms, each serving a different purpose. The Reportable Events form allows researchers to submit a reportable event for a project to the IRB.

Reportable events include adverse events, unanticipated problems, and protocol deviations. For more information on what is considered a reportable event, see the Reportable Events and Non-Compliance page.

The Link between the IRB Protocol and Reportable Events Form

The first field in the Reportable Events form requires the IRB Application number of the project the submission applies to. This will link the Reportable Events form to the IRB Application and pull in pertinent IRB Protocol information into the Reportable Events form.

There should only be one Reportable Event form associated with each IRB Protocol. For subsequent Reportable Event submissions, researchers can create a new version of the form. More information on subsequent submissions is below.

One-to-One Format

The Reportable Events form is structured to ensure there is only one form for each IRB Protocol. For each new reportable event, you will submit it by creating a new version of the existing Reportable Event form.

Form Access

Who can create a Reportable Event submission?

First Reportable Event Submission: Only those who are given 'Edit Access' to the IRB Protocol can create the first Reportable Event submission for the IRB Protocol. At minimum, 'Edit Access' will have been shared with the Principal Investigator and Faculty Advisor (if applicable) during the initial submission of the IRB Protocol.

For subsequent Reportable Event Submissions: Only those with 'Edit Access' to the previous Reportable Event submission can create another version of the form to submit. At minimum, 'Edit Access' will have been shared with the Principal Investigator and Faculty Advisor (if applicable) during the initial submission of the Reportable Event.

To check who has been given Edit Access, open the IRB Form via the Document List.

> **IRB Protocol:** 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 a Reportable Events form.

> **Reportable Event:** Scroll down to the 'Edit Access for Reportable Events Submission' section of the Form. Investigators listed in the 'List of Investigators with EDIT Access to the Reportable Events form' field will have the ability to create a new version of the Reportable Events form.

Who can work on a Reportable Event submission?

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

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.

Note: It is crucial that only one person edits an 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.

Who can view a Reportable Event submission?

All investigators listed on the IRB Protocol will have read-only access to the Reportable Events form. The field in the IRB Protocol is titled "2. ALL UMD Investigators/Personnel" in the Key Personnel section.

Everyone listed in the table will have read-only access to the Reportable Events form for the project. 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 to the IRB Protocol at any time by an individual with Edit Access to the IRB Protocol.

Reportable Event Review Process

The review time may vary depending on the time of the semester and the current volume of submissions. Reportable Event submissions will follow the review process below:
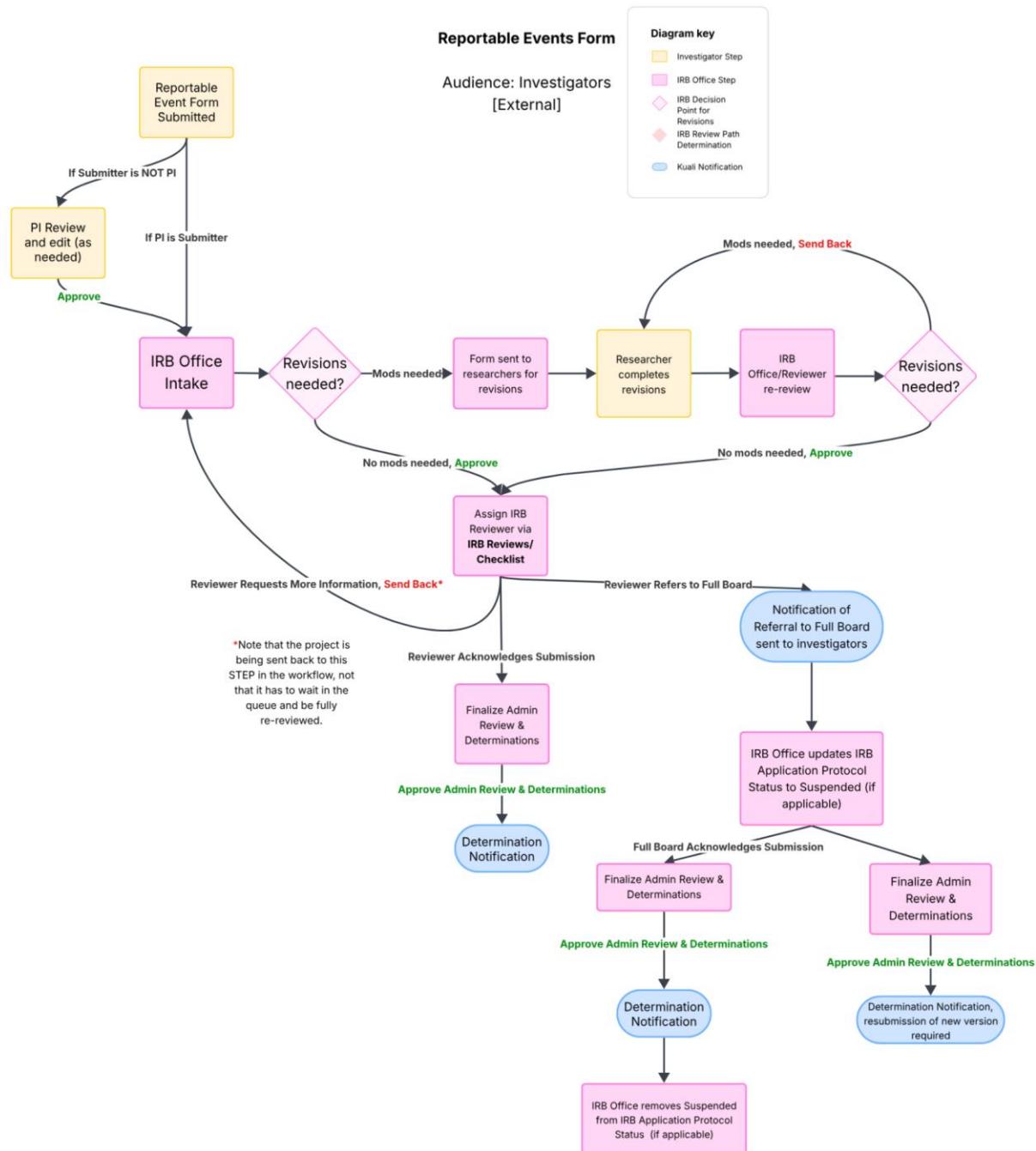
Reportable Event Visual Aid

How to Create + Submit a Reportable Event

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

Step 1: To initiate a Reportable Event form, navigate to the Reportable Events IRB Form.

> **First Reportable Event:** If this is the first reportable event for this IRB Protocol, click "New" or "Fill out the form" to start a new form.
>
> **Any Subsequent Reportable Event:** If this is not the first reportable event for this IRB Protocol, find the previous Reportable Event Submission for the IRB Protocol in the Document List. Open the RE Submission, then find the Version Dropdown in the upper left-hand corner and select "+Create New Version".
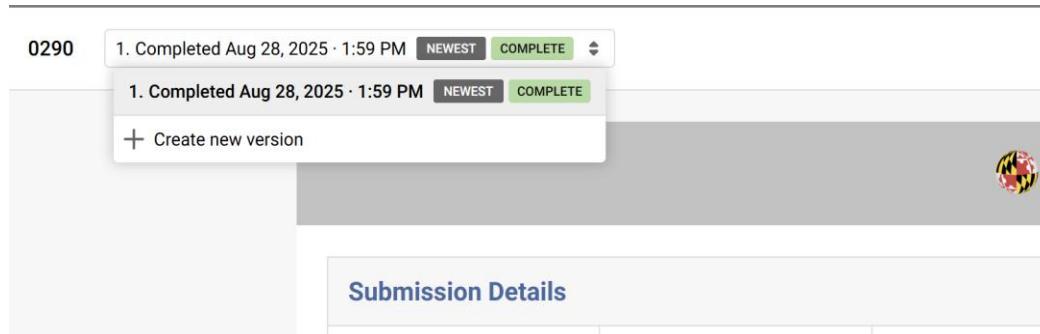
> **Note:** A new version can only be created if the existing versions are "Complete". New versions cannot be created if there is a version marked as "In Progress" or "Draft".

Step 2: Complete the Reportable Event form. Click "Submit."

Step 3: 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 application. Once they are satisfied with the submission, they should click 'Approve' to move forward.

Step 4: 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 5: Once the IRB Review is complete, researchers will receive a notification of the review outcome.