



Institutional Review Board

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UMD Quali-IRB: Guide to Submitting a Continuing 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 a continuing review via Quali IRB.

The Continuing Review/Closure Form

The Quali-IRB platform includes multiple forms, each serving a different purpose. The Continuing Review/Closure Report Form in Quali-IRB allows researchers to submit a Continuing Review for projects with an expiration date and a Closure Report for completed projects.

The Link between IRB Application and the Continuing Review/Closure Form

The first field in the Continuing Review/Closure (CR/C) form requires the IRB Application number of the project the submission applies to. This will link the CR/C form to the IRB Application and pull in pertinent IRB Protocol information into the CR/C form.

One-to-One Format

The Continuing Review/Closure form is structured to ensure there is only one form for each IRB Protocol. For subsequent CR/C submissions (ex. Multiple Continuing Reviews or Closure Report following a CR), researchers can create a new version of the form. More information on subsequent submissions is below.

Form Access

Who can create a Continuing Review submission?

First Continuing Review/Closure Submission: Only those who are given 'Edit Access' to the IRB Protocol can create the first Continuing Review 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 Continuing Review/Closure Submissions: Only those with 'Edit Access' to the previous Continuing Review 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 Continuing Review.

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 Continuing Review/Closure form.



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Continuing Review: Scroll down to the 'Edit Access for Continuing Review/Closure Report' section of the Form. Investigators listed in the 'List of Investigators with Edit Access to the Continuing Review/Closure Form' field will have the ability to create a new version of the Continuing Review/Closure form.

!!NOTE: Only the creator of the form can submit it for IRB Review. Please be mindful of study roles when creating the form.

Who can work on a Continuing Review submission?

The KualI-IRB platform allows for collaborative editing of the IRB Forms. Only users with 'Edit Access' to the Continuing Review/Closure form will be able to make edits.

Edit Access for Continuing Review/Closure Report

List of Investigators with Edit Access to the Continuing Review/Closure Form *

Please list the names of the investigators who will required EDIT access to this Continuing Review/Closure Report form. Be sure to include the Principal Investigator and the Faculty Advisor (if applicable).

Everyone included in this list will be able to EDIT + VIEW this form, will receive email notifications regarding requested modifications and approval. Only those listed in this field will be able to submit subsequent Continuing Reviews or Closure Reports.

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

Q Start typing each UMD Personnel's last name here

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 Continuing Review submission?

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



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Everyone listed in that table will have read-only access to the Continuing Review form for the project. They will be able to view the form by visiting their “Document List” on Quali 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.

Continuing Review Submission Review Process

The review time may vary depending on the time of the semester and the current volume of submissions. Continuing Review submissions will follow the review process below:



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Continuing Review Visual Aid



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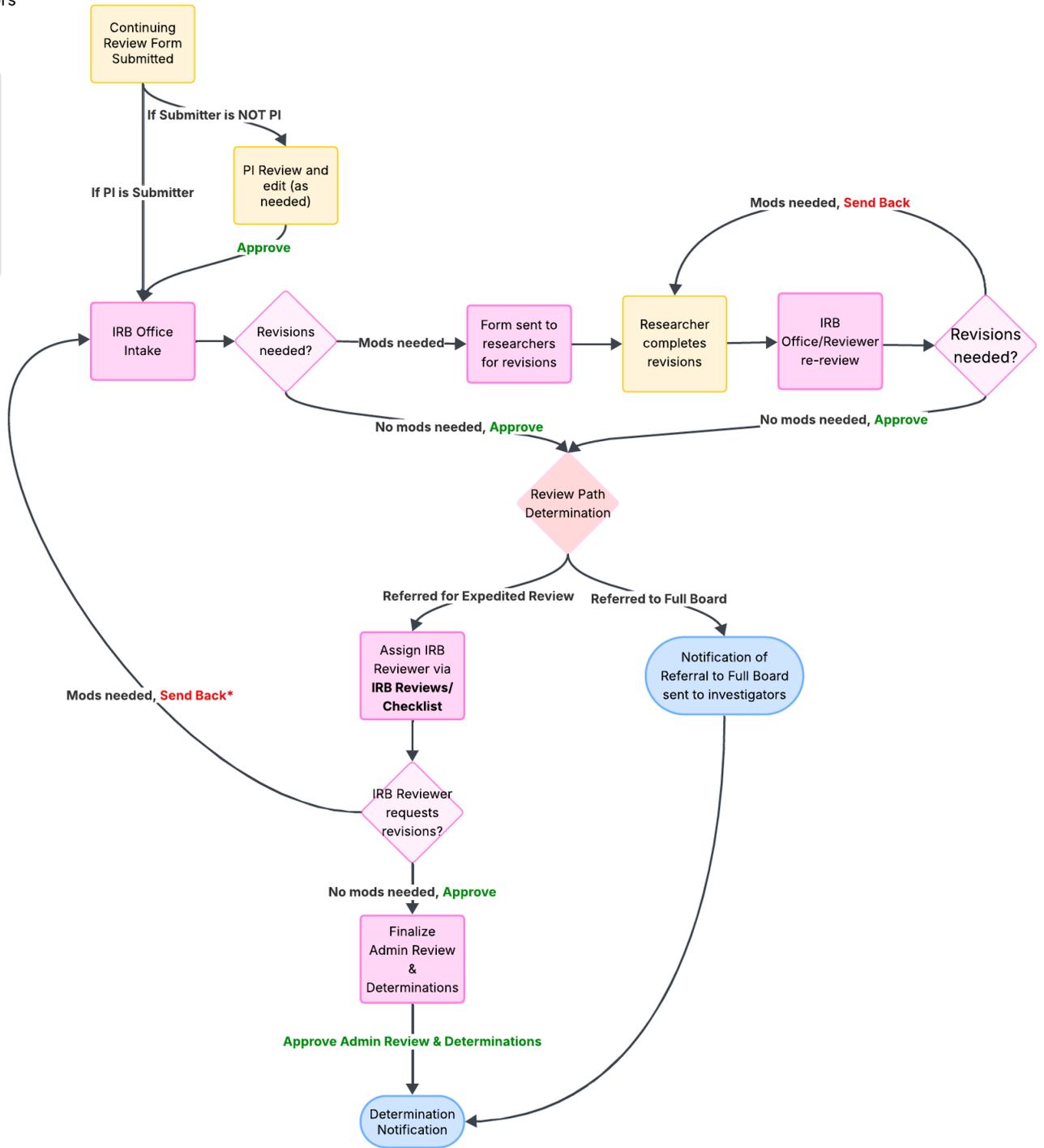
Continuing Review Form

Audience: Investigators
[External]

Diagram key

- Investigator Step
- IRB Office Step
- IRB Decision Point for Revisions
- IRB Review Path Determination
- Kualiti Notification

*Note that the project is being sent back to this STEP in the workflow, not that it has to wait in the queue and be fully re-reviewed.





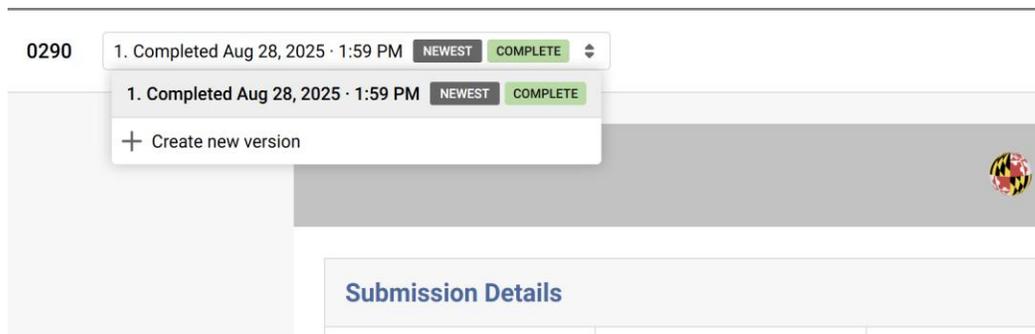
How to Create + Submit a Continuing Review

Link to KualI-IRB: <https://go.umd.edu/kuali-irb>

Step 1: To initiate a Continuing Review form, navigate to the Continuing Review/Closure IRB Form.

First Continuing Review: If this is the first continuing review submission for this IRB Protocol, click “New” or “Fill out the form” to start a new form.

Any Subsequent Continuing Review: If this is not the first Continuing Review for this IRB Protocol, find the previous Continuing Review Submission for the IRB Protocol in the Document List. Open the 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 Continuing Review form. Click “Submit.”

!!NOTE: Only the **creator** of the form can submit it. Scroll to the top of the Continuing Review form to confirm the creator of the form. Only the creator will have access to the “Submit” button.

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.



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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 Quali IRB to make the necessary changes.

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