

Kuali Protocols: IRB/HRPP Investigator User Guide

Institutional Review Board/Human Research Protections Program

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Kuali Protocols Overview

Kuali Protocols is the electronic research administration tool selected by the [Human Research Protections Program](#) to manage protocol submissions and review. This guide is designed to help system users with protocol submission and approval of activities subject to HRPP oversight.

NOTE: Only PSU-affiliated individuals with an Odin ID have access to Kuali Protocols.

How to navigate Kuali Protocols:

- Click the link to access Kuali Protocols: <https://pdx.kuali.co/protocols/>
- Click on **Manage Protocols** to see protocols
- After clicking into a protocol, use the following:
 - Navigation Menu (left side): Use this menu to jump between sections of the protocol.
 - Action Menu (right side): Use this menu to complete specific actions on the protocol.
 - Tabs (top): Use the tabs at the top to view the **Activity Log**, to view/submit **Reportable Events**, and to view **Permissions** for the protocol.
 - To navigate between different protocol versions, choose the “Selected Version” drop down to change to the most current version (the version number will be different - some actions will not be available if not in the most current submission).

Notifications:

- Kualii Protocols utilizes automatic email notifications to track the status of all protocols. These notifications are sent at time of submission, request for revisions, protocol approval, protocol amendment, and protocol expiration, etc. These notifications will include direct links to the protocol.

New Protocol Submission

To create a new application, login to Kualii using SSO. The application will autosave as the fields are completed. The application may be completed over multiple sessions.

- Click **Protocols**
- Click **New Protocol** and select **IRB**
- Complete **General Information**
 - **NOTE:** PSU policy requires that a faculty member **must** be identified as Principal Investigator (PI). All student-initiated research must list their faculty advisor as the PI.
- Identify the type of review request (one of the following):
 - Future Human Subjects approval: *Is this a request for Future Human Subjects approval?*
 - Select Yes only if you have a project that is funded or pending funding and is subject to documentation of human subjects approval and you are not yet prepared to submit a complete HRPP application for review due to the project being in design and development. Approval is for no more than one year.
 - Cede review: *Will an external site will serve as the IRB of Record*
 - Select Yes only when you have a non-exempt collaborative research project and an external collaborator's institution will serve as the IRB of Record (PSU will cede IRB review to the collaborating institution). This option does not apply to Exempt research.
 - Not Human Subjects Research: *Is this a request to determine if this project requires IRB review?*
 - Select Yes if you require a "Not Human Subjects Research" determination for your records. This process is optional, typically used for grants and publications, when IRB/HRPP oversight is not required.
 - Exempt review: *Is this a request for exempt review?*
 - Research can qualify for an exemption if it is no more than minimal risk and all research procedures fit within one or more of the exemption categories in the federal IRB regulations. Studies that qualify for exemption must be submitted to the HRPP for review and formal determination before starting the research.
 - Data analysis only research: *Will the activities be limited to data analysis?*

- Select No if the research will involve any interaction or intervention with participants (e.g., online surveys, interviews, behavioral interventions, etc.).
- Expedited/Full review
 - Research that does not qualify for exemption will qualify for expedited review unless it is deemed by an IRB member or HRPP staff to require Full Board Review.
- Click **Next**
- Complete the **Research/Human Subjects Determination and Risk**
- Click **Next** - the application that appears will be based on the answers to the previous questions.
- Continue on to complete the form, using in-form instructions for each applicable section.
- If any PSU-affiliated personnel are not able to be added to the Personnel section after searching by their Odin ID, please submit a [Kuali System User Access Request](#).
- Once completed click **Submit**
 - Note: If the protocol creator is not the listed Principal Investigator, the protocol creator will need to click **Notify PI to Submit** and the Principal Investigator must review the submission and click **Submit** for formal submission for review.

Kuali Review & Approval Process

Once a protocol is submitted, the HRPP staff will review each submission and determine if review by an IRB member is required. The following actions are available in the system:

- **Return to Researcher:**
 - The protocol will be returned to the investigator if the materials are determined to be incomplete, or there are questions or clarifications needed before the protocol can be formally reviewed.
- **Revisions:**
 - Once the protocol is formally reviewed by the HRPP/IRB, revisions or clarifications may be required before approval. The protocol will be sent to the investigator to address the specific questions or issues, which will be identified in the Action Items.
- **Approval:**
 - Once the protocol is approved, the approval letter may be viewed in the Activity Log tab. Following approval, all changes to the study need to be submitted via an Amendment request.

Training

CITI training is required for all study personnel.

- CITI Training:
 - CITI training requirements are detailed on our [Training Page](#)

- All CITI trainings need to be accessed using the PSU SSO in order to automatically populate in Kuali. Please ensure access to CITI for all personnel is through SSO if their training is not showing up in the Personnel table.
- CITI Training & Kuali Integration
 - **PSU faculty or employees:** Kuali Protocols connects to the required CITI training records through PSU's single-sign on (SSO). In order for Kuali to reflect training for PSU-affiliated researchers, ensure the CITI account is linked using these CITI SSO instructions, under the Human Subjects Research Training section.
 - **PSU students:** CITI training records are not connected to Kuali at this time. Please upload completion certificates in the Personnel table for each student.

Amendment Submission

All protocol changes must be approved prior to implementation. To request approval for proposed amendments, login to Kuali using SSO.

- Open the current protocol and click **Amend**
 - For Migrated Records:
 - For the first amendment on a migrated record, the system will notify the investigator of a protocol form template change.
 - Click **Edit Protocol**
 - Due to the template change, there will be new sections of the protocol form that will appear. These sections will need to be completed in order to finalize the amendment for submission (even if these sections are not impacted by the amendment as a complete application is required in order to submit for review).
 - For all other Kuali protocols:
 - Use the **Amend** action to make a change to the protocol outside of annual/continuing review.
- The Amendment form will display; click all checkboxes applicable to the proposed changes and provide details on the changes proposed.
- Apply all changes described in the amendment in each applicable section of the protocol form.
- Once complete, click **Submit**

Renew (annual or continuing review) Submission

Submit a **Renew** request during annual check-in. An email notification will be sent to remind investigators about upcoming annual renewal requirements.

- Open the protocol and click **Renew**
 - If there are any changes to the protocol, **Abandon** the renewal and select **Renew and Amend**
- Complete all applicable sections.

- Once complete, click **Submit**

Renew and Amend Submission

Use the **Renew and Amend** action to submit an annual review with an amendment to the protocol

- Open the protocol and click **Renew and Amend**
- Complete all applicable sections.
- Once complete, click **Submit**

Reportable Event Submission

To submit a reportable event:

- Open the protocol and click the tab at the top titled: **Reportable Events**
 - Any current and past events associated with the protocol may be viewed here, unless the study was migrated into Kuali (migrated event reports will be included in the original protocol attachments).
- Click on **Report an Event** in the top right to open up a new reportable event form
 - Complete the form and all required fields. If needed, click **Save** to come back to the submission at a later time.
 - If the reportable event requires an amendment, the form will prompt to begin an amendment, however the form can be submitted without an amendment.
- Once complete, click **Submit for Review**

Request to Close

To close a protocol:

- Open protocol and click **Request to Close**
- Fill out the Closeout Request form and submit when complete.
- Once submitted, HRPP staff will be notified. If necessary, HRPP staff may follow-up and/or formally process the protocol for closure.
- Once closure is confirmed by HRPP staff, the protocol status will be updated to Closed
 - The Kuali system will automatically generate an email notification once the protocol is closed. Closed protocols may not be reopened, but may be duplicated as a new submission.

Protocol Expiration

Protocols that are subject to an expiration date require Continuing Review. Protocol personnel will receive an email notification for approaching expiration dates. The renewal must be submitted before the expiration date in order to remain active. Once the protocol formally expires in Kuali, a brand new submission will be required for approval and no further actions may be taken on an expired protocol.

System Help

To request specific help with navigating the system or for assistance with which action type to select, please reach out to psuirb@pdx.edu. Additionally, our program has developed a [Kuali Feedback Form](#) for faculty and students to provide details related to any issues encountered while developing a submission. These identified issues will be taken under consideration while performing routine updates to the system.