

Kuali Protocols: IACUC Investigator User Guide

Animal Care & Use Program

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Kuali Protocols Overview

Kuali Protocols is the electronic research administration tool selected by the [PSU Animal Care & Use Program](#) to manage protocol submissions and review. This guide is designed to help system users with protocol submission and approval of activities subject to animal care and use 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.

Notifications:

- Kuali 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 protocol or request an exemption determination for a proposed animal activity, login to Kuali using SSO.

- Click **Protocols**
- Click **New Protocol** and select **IACUC**
- Complete **General Information** and click **Next**
- Select **Activity Type**
 - Faculty-led
 - Student-led
 - Class/lab
- If requesting an IACUC Exemption Determination (field observation only with no impact to wildlife) select Yes
 - Complete subsequent exemption questions and submit for formal determination
- If requesting regular review, select NO and select **Next**
- Continue on to complete the form, using in-form instructions for each applicable section.
- 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**

Kuali Review & Approval Process

Once a protocol is submitted, the Animal Care & Use Program will review each submission. 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 IACUC, revisions or clarifications may be required before approval. The protocol will be returned to the investigator to address the specific questions or issues, using the Action Items.
- **Approval:**
 - Once the protocol is approved the approval letter may be viewed in the Activity Log tab. Approval is typically for three years. Once the protocol is approved, all changes to the study need to be submitted via an Amendment request.

Training and Animal Contact Clearance

CITI training and Animal Contact Clearance are required for all personnel with animal contact.

- CITI Training:
 - CITI training requirements are detailed on our [Training Page](#)
 - All CITI trainings need to be accessed using SSO in order to automatically populate in Kuali. Please ensure access to CITI for all personnel is through SSO
- Animal Contact Clearance:
 - All personnel with animal contact will be enrolled in the PSU Occupational Health & Safety Program for Animal Contact Clearance by the IACUC Administrator. A separate email outside of Kuali will be sent to initiate that process

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 submission (even if these sections are not impacted by the amendment)
 - For all other Kuali protocols:
 - Use the **Amend** action to make a change to the protocol outside of annual review or the three-year renewal process
- The Amendment form will display; click all the 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 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 (de novo review) Submission

Use the **Renew and Amend** action to (1) submit an annual review with a major or minor amendment to the protocol, or (2) request a three-year de novo renewal of an expiring 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
- Click the tab at the top titled: **Reportable Events**
 - Any current and past events associated with the protocol may be viewed here
- 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, the IACUC Administrator will be notified. If necessary, the IACUC Administrator will follow-up and/or formally process the protocol for closure
- Once closure is confirmed by the IACUC Administrator, the protocol status will be updated to Closed
 - The Kualu system will automatically generate an email notification once the protocol is closed

Protocol Expiration

Protocols expire at the end of the three year approval period. To request approval beyond the three year period, a *de novo request* must be submitted prior to expiration. Once the protocol formally expires in Kualu, a brand new submission will be required for approval and no further actions may be taken on the expired protocol.

- The Kualu system will automatically send the investigator email notifications about upcoming protocol expirations

