

# Kuali Research

**California State University, Fresno**

**Institutional Animal Care and Use Committee (IACUC)**

**Guide for Creating, Reviewing, and Managing IACUC Protocols**

Last update: 16 March 2021

## **Table of Contents:**

- Logging In (page 2)
- Creating a New Protocol (page 3)
- Searching for Protocols (page 4)
- Completing Requested Revisions as the Researcher (page 5)
- Submitting a Post Approval Action – Protocol Amendment, Renewal, or Closure (pages 6–7)
- Reviewing Protocols (pages 8–9)
- Ancillary Review (page 10)

## Logging In

Step No.	Instructions
----------	--------------

- |   |  |
|---|--|
| 1 | Navigate to: <a href="https://csufresno.kuali.co/protocols/new?protocolType=IACUC">https://csufresno.kuali.co/protocols/new?protocolType=IACUC</a> |
|---|--|
- 

Enter your Fresno State email credentials.

- |   |  |
|---|--|
| 2 | <b>Username:</b> <enter your username> |
|   | <b>Password:</b> <enter your password> |
-

## Creating a New Protocol

Step No.	Instructions
----------	--------------

- |   |  |
|---|--|
| 1 | <p>From the <b>Manage Protocols</b> screen:</p> <ul style="list-style-type: none"><li>Click the <b>+ New Protocol</b> button and select <b>IACUC</b> from the dropdown menu.</li></ul> |
|---|--|

- 
- |   |   |
|---|---|
| 2 | <p>The Kuali Research <b>Protocol</b> document will open. Complete the information as indicated below:</p> <ul style="list-style-type: none"><li><b>Principal Investigator:</b> Name of the lead faculty researcher or faculty advisor</li><li><b>Lead Unit:</b> The home department or unit housing the principle investigator</li><li><b>Title:</b> Your protocol title</li></ul> <p>Click the <b>Next</b> button in the upper right-hand corner of the screen.</p> |
|---|---|


- 
- |   |  |
|---|--|
| 3 | <p>The <b>General Questionnaire</b> will open.</p> <ul style="list-style-type: none"><li>Select responses to each question. Your responses will determine what information is requested by the online form.</li><li>These responses can be adjusted any time prior to protocol submission if needed.</li></ul> <p>Click the <b>Next</b> button in the upper right-hand corner of the screen.</p> |
|---|--|

- 
- |   |   |
|---|---|
| 4 | <p>The full protocol will open. Complete the fields with data that is appropriate to your protocol and press the <b>Submit</b> button.</p> <ul style="list-style-type: none"><li>Clear any errors that display through your protocol form. Any errors will be highlighted in red.</li><li>Press the <b>Submit</b> button again and confirm that the protocol screen goes into a Read Only mode and the status updates to <b>Submitted for Review</b>.</li></ul> |
|---|---|

## Searching for Protocols

### Step No. Instructions

From the **Home** screen:

- 1
  - Click the **Manage Protocols** button on the left-hand menu. Near the top of the page, click the **Advanced Filter**  button.
  - Select **No Filter** in the **Saved Filters** dropdown.

---

Click **Advanced Filter** followed by **Add Rule** and enter the following details.

- 2
  - **First Dropdown: Type**
  - **Second Dropdown: is equal to**
  - **Third Dropdown: IACUC**
  - Click in the grey area.

---

In the displayed search results:





- 3
  - Click the **Title** of one of the protocols to open it.

- 
- 4 Navigate through the protocol and review the information in the document.
-

## Completing Requested Revisions as the Researcher

### Step No. Instructions

From the **Manage Protocols** screen:

- 1
  - Click on the title of your protocol, which should display **Revisions In Progress** in the status column.
  - To view a summary with all comments and requested revisions, Click  **Action Items Summary** from the right-hand menu.
  - Sections with action items that need to be addressed are designated with a  symbol in the navigation menus on the left and right side of the screen. The number displayed is the number of action items in that section.
  - To view and respond to specific action items, click the  **Action Items:** button associated with each  symbol.

---

Address each reviewer comment (i.e. action item)

- 2
  - Navigate to the protocol section that requires revision and make necessary changes.
  - From within each action item, click **Reply** and type in a response.
  - Click **Post** at the bottom of the reply when your response is complete.
  - Repeat these steps for all fields with an Action Item.

---

Complete revisions.

- 3
    - Scroll through your protocol and review the changes you have made to the fields.
    - Make any additional changes that are needed.
    - Press the **Resubmit** button on the right-hand action bar.
-

## Submitting a Post Approval Action – Protocol Amendment, Renewal, or Closure

### Step No. Instructions

- 1 From the **Manage Protocols** tab search for and open your protocol.

To submit a **protocol amendment**:

- 2
  - Click the **Amend** button in the upper right-hand corner of the protocol screen.
  - Enter a summary of proposed changes and rationale for those changes in the text field that appears.
  - Edit the appropriate sections of the protocol. All sections of the protocol can be edited.
  - Press the **Submit** button.
  - Click on **Activity Log** and confirm that there are entries for the amendment.

Note: If you select **Amend** or **Renew and Amend**, you will be able to make changes to your protocol details. If you select **Renew** or **Request Close**, you will only be able to fill out the supplemental information form that appears at the top of your application.

To **renew** your protocol:

- 3
  - Click the **Renew** button in the upper right-hand corner of the screen.
  - Provide requested information about the number of animals used.
  - Review all sections of your previously submitted protocol to ensure no amendments are necessary.
  - Press the **Submit** button.

To **renew and amend** your protocol:

- Click the **Renew & Amend** button in the upper right-hand corner of the screen.
- Provide requested information about the number of animal's used.
- Enter a **Summary of Proposed Changes** and rationale for those changes in the text field that appears.
- Edit the appropriate sections of the protocol. All sections of the protocol can be edited.
- Press the **Submit** button.
- Click on **Activity Log** and confirm that there are entries for the amendment.

---

To **close** your study protocol:

- 4
    - Click the **Request Close** button in the upper right-hand corner of the screen.
    - Provide requested information about the number of animals used.
    - Press the **Submit** button.
-

## Reviewing Protocols (for IACUC members only)

### Step No. Instructions

Access protocols assigned for your review

- 1
  - From the **Home screen**, click the **Protocols Assigned to Me** button on the left-hand menu.
  - All protocols assigned for your review should show up in your list.



- 2 Find and click on the title of the protocol in need of review. This will open the protocol.

If the protocol is a new submission, proceed to **Step 4**


If the protocol is a resubmission or an amendment:

- 3
  - Make sure  **Compare Versions** at the top of the page is checked. This will highlight all changes from the previous version of the protocol.
  - View researcher responses to prior action items. If responses and revisions pertaining to the action items are satisfactory, check the  **Mark as resolved** button at the bottom of the action item's dialogue box. When checked, this will now appear as  **Resolved**.



Scroll through the protocol. View and read all components.

- 4
  - Be sure to review all tabular entries. Full information is not visible by default and you will need to expand table entries to view all details. Information in tabular form includes, Personnel, Species, Procedures, Consideration of Alternatives, Euthanasia/Disposition, etc.
  - To view all information for a specific table entry, click the  button within the table:
  - To adjust the fields visible in the table, click the  button above the table and select the items to view.

Add **Action Items** to communicate issues or concerns.

- 5
  - For comments that apply to the **entire proposal**.
    - Click  **General Action Items** from the right-hand menu.




- 
- Click  **Action Item** from the pop-out menu.
  - Add your comment to the text field.
  - Select who the comment should be visible to. Options include **Assigned Reviewers** which will allow other reviews to view the comment, **Researchers** which will allow the protocol PI and researchers approved by the PI to view the comment, and **Meeting** will allow all committee members to view during full committee meetings. Only the individuals that you select and the IACUC administrator can view. You may select more than one group of individuals to view the comment.
- **Line items**
    - Click the  **Action Item** button associated with the line item for which you would like to comment.
    - Add your comment to the text field.
    - Select who the comment should be visible to. Options include **Assigned Reviewers** which will allow other reviews to view the comment, **Researchers** which will allow the protocol PI and researchers approved by the PI to view the comment, and **Meeting** will allow all committee members to view during full committee meetings. Only the individuals that you select and the IACUC administrator can view. You may select more than one group of individuals to view the comment.

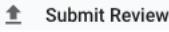
*NOTE: DO NOT ADD ACTION ITEMS WITHIN THE DETAILED ENTRIES FOR A TABLE.* These action items will not be viewable to the researchers or committee members.

---

#### Complete **Reviewer Checklist** (skip if a resubmission)

- 6
- This should be the final component of the review
  - Click the **MY CHECKLIST** tab at the top of the protocol page.
  - Answer each yes/no question.
  - If a dialogue box appears, provide an explanation for your answer.
  - When you are done, click the  button on the right-hand menu.
  - Navigate back to the protocol by selecting the **PROTOCOL** tab at the top of the page.
- 


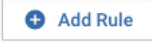

#### **Submit Review**

- 7
- When you are done with your review, click the  button in the right-hand menu. This will send the protocol to the IACUC administrator for next steps.
-

## Ancillary IACUC Review (for EHS and Attending Veterinarian Only)



### Step No. Instructions

#### Identify Protocols Awaiting Ancillary Review

- 1
  - From the **Home screen**, click the **Protocols Assigned to Me** button on the left-hand menu.
  - Filter protocols for those awaiting Ancillary Review.
    - Click  at the top of the page to open filter options.
    - Click .
    - From the **first** drop down, select **Ancillary Review Status** (bottom of the list).
    - From the **second** drop down, select **is equal to**.
    - From the **third** drop down, select **Pending**.
    - Type a name for this filter in the grey field and click . In future, you can simply select the saved filter.
    - All protocols now displayed are awaiting your Ancillary Review
  - Click on the title of a protocol awaiting Ancillary Review to open the protocol.


---

#### Review the protocol for specific EHS or Veterinary concerns (as appropriate)

- 2
  - To view all information for a specific table entry, click the  button within the table:
  - To adjust the fields visible in a table, click the  button above the table and select the items to view.
  - *Note:* Ancillary Reviewers may not add action items.

---

#### Update Ancillary Review Status

- 3
  - Click the **ANCILLARY REVIEW** tab at the top of the protocol page
    - It will have an orange dot next to it when Ancillary Reviews are pending. This turns green upon approval.
  - To add comments, click the  button next to your reviewer title, click **Add Comment** and add text to the text field. Alternatively, you can click **Add Attachment** to upload a document or other media.
  - From the drop down, select **Approved** or **Not Approved Yet** to change the Ancillary Review Status
  - Use the **Back** button at the top of the page to exit the protocol.